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James Bothwell

Pacific McGeorge School of Law

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Toy Story: Timeout for Phthalates

James Bothwell

Code Sections Affected

Health and Safety Code §§ 108935, 108937, 108939 (new).
AB 1108 (Ma); 2007 STAT. Ch. 672.

I. INTRODUCTION

Wondering just what her children's toys were made of, Jackie Christensen, a mother of two small children, contacted McDonald's about the miniature Barbie dolls in her daughter's Happy Meals.¹ After receiving little information from McDonald's, the mother contacted Mattel, the company that manufactured the Barbie toy.² A customer service representative related "that all Barbies are made of a plastic called polyvinyl chloride, or PVC."³ Jackie knew that chemical plasticizers called "phthalates" were used to manufacture flexible PVC products and that phthalates have potentially adverse side-effects on people.⁴ Even more distressing, Jackie knew that "[p]hthalates are not chemically bound to PVC," which gives them the potential to leak out into the surrounding environment.⁵ Since her infant son had a habit of chewing on toys, the surrounding environment happened to be her son's mouth and digestive system.⁶

According to the U.S. Centers for Disease Control and Prevention, "phthalates are industrial chemicals that can act as plasticizers, which, when added to plastic, impart flexibility and resilience."⁷ Phthalates are used in consumer products such as vinyl flooring, adhesives, shampoo, soap, deodorant, fragrances, and nail polish.⁸ They are also widely employed in "inflatable recreational toys, blood-storage bags, intravenous medical tubing, and children's toys."⁹

Human exposure to phthalates generally occurs through direct contact with products containing the chemical, and the main route of exposure to phthalates is through the mouth.¹⁰ Normally, phthalates metabolize quickly and only

1. Jackie Hunt Christensen, *Toxic Toy Story*, MOTHERING, Sept. 1998, at 38, 38.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. CTNS. FOR DISEASE CONTROL & PREVENTION, THIRD NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS 253 (2005), http://www.cdc.gov/exposurereport/pdf/results_06.pdf [hereinafter THIRD NATIONAL REPORT] (on file with the *McGeorge Law Review*).

8. *Id.*

9. *Id.*

10. *Id.*

accumulate in the body in cases of overwhelming high exposure to the chemical.¹¹

Some scientific reports, however, demonstrate that exposure to certain phthalates causes detrimental health effects, such as testicular injury, liver injury, and liver cancer.¹² But these reports confirmed such side-effects primarily by testing rodents.¹³ While numerous studies researched the effects phthalates have on humans, research results have varied widely from one study to the next.¹⁴

Due to the discrepancies between rodent and human studies, debate exists regarding whether exposure to phthalates indeed causes detrimental health effects in humans.¹⁵ Although many foreign countries already err on the side of caution by banning the use of phthalates in children's toys, California recently became the first American jurisdiction to follow suit.¹⁶

11. *Id.*

12. *Id.*

13. *Id.*

14. *See infra* Part IV.B.1-2.

15. *See infra* Part IV.B-D.

16. *See* CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672) (banning the use of phthalates in children's toys and other child care items); Council Directive 2005/84/EC, 2005 O.J. (L 344) 40 (banning the presence of certain phthalates in children's toys); SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007) (listing countries that ban the use of certain phthalates in children's toys); Tom Chorneau, *A Nationwide Toxic Toy Ban Likely to Follow State Lead*, S.F. CHRON., Oct. 16, 2007, at A1 ("California became the first state in the nation to ban toys containing toxic plastic softeners . . .").

Bills similar to Chapter 672 have recently been proposed in a number of other jurisdictions. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007). In New York, Assembly Bill 6829 prohibits the manufacture, distribution, or sale of toys and childcare products intended for use by a child under three years of age containing phthalates or bisphenol-A. AB 6829, 2007 Leg., 2007-2008 Reg. Sess. (N.Y. 2007) (not enacted). Bisphenol-A is an "industrial chemical[] . . . used to make polycarbonate plastics" found in such products as "refillable beverage containers, protective linings in food cans, compact disks, [and] plastic dinnerware." CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: SPOTLIGHT ON BISPHENOL A AND 4-TERTIARY-OCTYLPHENOL 1 (2007), http://www.cdc.gov/exposurereport/pdf/factsheet_bisphenol.pdf (on file with the *McGeorge Law Review*). The first draft of Chapter 672 and the original San Francisco Ordinance banned bisphenol-A. AB 1108, 2007 Leg., 2007-2008 Sess. (Cal. 2007) (as introduced on Feb. 23, 2007, but not enacted); S.F., CAL., HEALTH CODE art. 34, § 34.1(c) (2006). However, both Chapter 672 and the San Francisco Ordinance were amended to remove bisphenol-A, due to inconclusive testing results and much opposition from manufacturers of consumer products. *See* 2007 Cal. Stat. ch. 672 (banning the use of the following phthalates: benzyl butyl, di-(2-ethylhexyl), dibutyl, diisononyl, diisodecyl, and di-n-octyl); S.F., CAL., HEALTH CODE art. 34, § 34.4(a)-(f) (2007) (same).

Assembly Bill 333, also introduced in New York, prohibits the sale of toys or other articles for use by children less than three years of age if such items contain phthalates. AB 333, 2007 Leg., 2007-2008 Reg. Sess. (N.Y. 2007) (not enacted). Moreover, New York City is considering an ordinance similar to the one adopted by San Francisco. Proposed Int. No. 0589-A, N.Y.C. (N.Y. 2007) (not enacted).

In Oregon, proposed Senate Bill 944 prohibits the sale of a toy or article intended for children less than five years of age if the toy contains "any measurable amount of phthalates." SB 944, 2007 Leg., 2007 Reg. Sess. (Ore. 2007) (not enacted). Further, the Oregon Senate Joint Memorial Committee proposed sending a message to the U.S. President and Congress on behalf of the Oregon Legislature urging comprehensive testing of phthalates, especially considering their frequent presence in cosmetics and children's toys. Senate Joint Memorial 8, 74th Leg., 2007 Reg. Sess. (Ore. 2007).

II. LEGAL BACKGROUND

A. Existing Federal Law

The Consumer Product Safety Act, passed by Congress in 1972, establishes and confers broad federal authority on the Consumer Product Safety Commission (CPSC).¹⁷ The CPSC “is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency’s jurisdiction.”¹⁸ The CPSC ensures the safety of consumer products that can injure children or “pose a fire, electrical, chemical, or mechanical hazard.”¹⁹

The CPSC has authority under the Consumer Product Safety Act to promulgate binding labeling or performance standards to protect the public from risks posed by consumer products.²⁰ Additionally, the CPSC is authorized to order appropriate corrective action for hazardous consumer products, such as product recalls or halting distribution.²¹

B. Existing State Law

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, requires the Governor to annually revise and publish a list of chemicals that are scientifically proven to cause cancer, birth defects, or reproductive harm.²² Under Proposition 65, businesses cannot “knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning.”²³ Such warning allows individuals “to make informed decisions about protecting themselves from exposure to [hazardous] chemicals.”²⁴

The Office of Environmental Health Hazard Assessment (OEHHA) is responsible for listing these chemicals and is the governor’s primary agency for

Additionally, legislators in Connecticut, Florida, Illinois, Maine, Maryland, Massachusetts, Texas, and Washington anticipate similar legislation in the coming months, and Senator Diane Feinstein is planning on introducing a replica of Chapter 672 at the national level. Chorneau, *supra*.

17. 15 U.S.C.A. §§ 2053(a), 2054(a)-(b) (West 1998).

18. U.S. Consumer Prod. Safety Comm’n, CPSC Overview, <http://www.cpsc.gov/about/about.html> (last visited Feb. 29, 2008) (on file with the *McGeorge Law Review*).

19. *Id.*

20. 15 U.S.C.A. § 2056(1)-(2) (West 1998).

21. *Id.* § 2064(c)-(d) (West 1998).

22. CAL. HEALTH & SAFETY CODE § 25249.5 historical and statutory note (West 2006); *id.* § 25249.8(a) (West 2006).

23. *Id.* § 25249.6 (West 2006).

24. Office of Env’tl. Health Hazard Assessment, Proposition 65 in Plain Language!, <http://www.oehha.ca.gov/prop65/background/p65plain.html> (last visited Feb. 29, 2008) [hereinafter Proposition 65] (on file with the *McGeorge Law Review*).

implementation.²⁵ Proposition 65 provides four principal bases for listing chemicals that are known to cause cancer or reproductive toxicity.²⁶

First, a chemical can be listed if the state or federal government requires it to be labeled as causing cancer, birth defects, or other reproductive harm.²⁷ Most of the chemicals listed on this basis are prescription drugs required by the U.S. Food and Drug Administration (FDA) to contain warning labels.²⁸

Second, a chemical can also be listed if either of two committees, the Carcinogen Identification Committee (CIC) or the Development and Reproductive Toxicant (DART) Identification Committee, after reviewing current scientific evidence, determines that the chemical causes cancer, birth defects, or other reproductive harm.²⁹ The CIC and the DART are both part of the OEHHA's Science Advisory Board.³⁰

The third basis for listing a chemical occurs when a body considered to be "authoritative" by the state's qualified experts (the CIC or the DART Identification Committee) formally identifies the chemical as causing cancer, birth defects, or reproductive harm.³¹ "Authoritative bodies" include "the U.S. Environmental Protection Agency, U.S. Food and Drug Administration (U.S. FDA), National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer."³²

Lastly, a chemical can be listed if it meets certain chemical criteria and is identified by the California Labor Code as causing cancer, birth defects, or other reproductive harm.³³ This basis was originally the sole means of listing toxic chemicals following voter approval of Proposition 65.³⁴

There are currently five phthalates identified by Proposition 65.³⁵ Di-(2-ethylhexyl) phthalate (DEHP) was listed as a carcinogen in 1988 and as a developmental and male reproductive toxin in 2003.³⁶ The OEHHA, in 2005, placed the phthalates butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and

25. CAL. HEALTH & SAFETY CODE § 25249.12(a) (West 2006); Proposition 65, *supra* note 24.

26. CAL. HEALTH & SAFETY CODE § 25249.8(a)-(c) (West 2006).

27. *Id.* § 25249.8(b) (West 2006).

28. Proposition 65, *supra* note 24.

29. CAL. HEALTH & SAFETY CODE § 25249.8(b); Proposition 65, *supra* note 24.

30. Proposition 65, *supra* note 24.

31. CAL. HEALTH & SAFETY CODE § 25249.8(b).

32. Proposition 65, *supra* note 24.

33. CAL. HEALTH & SAFETY CODE § 25249.8(a); Proposition 65, *supra* note 24. Such substances include those "listed as human or animal carcinogens by the International Agency for Research on Cancer" or "any substance within the scope of the federal Hazard Communication Standard." CAL. LABOR CODE § 6382(b)(1), (d) (West 2003).

34. Proposition 65, *supra* note 24.

35. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CAL. ENVTL. PROT. AGENCY, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY 3, 7 (2007), http://www.oehha.ca.gov/prop65/prop65_list/files/P65single092807.pdf [hereinafter CHEMICALS] (on file with the *McGeorge Law Review*).

36. *See id.* at 7 (listing DEHP as a toxic chemical).

di-n-hexyl phthalates (DnHP) on the list of toxic chemicals that require warnings.³⁷ More recently, the OEHHA determined that another phthalate, diisodecyl phthalate (DIDP), also met the criteria of Proposition 65 and added it to the list for causing adverse developmental reactions.³⁸

C. Existing Local Law

In July 2006, the City of San Francisco passed the Healthy Products, Healthy Children Ordinance.³⁹ The Ordinance bans child feeding products, child care products, and toys likely to be placed in children's mouths that contain specified phthalates in concentrations exceeding 0.1 percent.⁴⁰ Research demonstrating that phthalates cause genital defects, sperm damage, reduced testosterone production, and premature deliveries in humans prompted the City to enact the Ordinance.⁴¹

D. Foreign Nations

A number of foreign nations have banned the use of phthalates in products intended for use by children.⁴² In 2005, the European Parliament extended an earlier temporary ban on the use of phthalates in children's toys.⁴³ The directive permanently banned the phthalates DEHP, DBP, and BBP in all toys and childcare items and banned diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in toys capable of being placed in a child's mouth.⁴⁴ Similarly, fourteen other nations, including Argentina, Fiji, Mexico, and Japan, have banned the use of phthalates in toys and products intended for use by children.⁴⁵

III. CHAPTER 672

Chapter 672 prohibits, starting January 1, 2009, the manufacture, sale, or distribution of any toy⁴⁶ or child care article⁴⁷ that contains di-(2-ethylhexyl)

37. See *id.* at 3, 7 (listing BBP, DBP, and DnHP as toxic chemicals).

38. See *id.* at 7 (listing DIDP as a toxic chemical).

39. S.F., CAL., HEALTH CODE art. 34 (2007). As originally enacted, Article 34 was entitled "Sale of Toys and Child Care Articles Made with Bishenol-A." *Id.* The city subsequently amended the ordinance, re-titling it "Healthy Products, Healthy Children Ordinance." *Id.*

40. *Id.* § 34.4(a)-(f).

41. *Id.* § 34.1(c).

42. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007).

43. Council Directive 2005/84/EC, 2005 O.J. (L 344) 40.

44. *Id.*

45. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007); Chorneau, *supra* note 16.

46. A "toy" is defined as "all products designed or intended by the manufacturer to be used by children when they play." CAL. HEALTH & SAFETY CODE § 108935(a) (enacted by Chapter 672).

phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP) in concentrations exceeding 0.1 percent.⁴⁸ Chapter 672 further prohibits the manufacture, sale, or distribution of any toy or child care article intended for use by a child under three years of age if that product can be placed in the child's mouth and contains diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP) in concentrations exceeding 0.1 percent.⁴⁹

Chapter 672 mandates that when manufacturers replace phthalates in their products, they must use the least toxic alternative.⁵⁰ Accordingly, manufacturers cannot replace phthalates with A, B, or C carcinogens as rated by the EPA, substances listed as known, likely, or suggestive of being carcinogens by the "List of Chemicals Evaluated for Carcinogenic Potential," or substances known to the state to cause cancer as listed pursuant to Proposition 65.⁵¹ Manufacturers also cannot replace phthalates with reproductive toxicants that cause birth defects, reproductive harm, or developmental harm as identified by the EPA or listed pursuant to Proposition 65.⁵²

IV. ANALYSIS

A. Chapter 672 and Proposition 65

Proposition 65 requires manufacturers to warn consumers about the presence of known hazardous chemicals contained in a product.⁵³ Strictly speaking, manufacturers can, at their discretion, produce products with harmful chemicals so long as the consumer is warned about the presence of the chemicals.⁵⁴ Realizing this shortcoming, the California Legislature enacted Chapter 672.⁵⁵

Chapter 672 holds manufacturers to a higher standard and places a premium on children's safety by completely prohibiting concentrations of certain phthalates beyond 0.1 percent in children's toys.⁵⁶

47. A "child care article" is defined as "all products designed or intended by the manufacturer to facilitate sleep, relaxation, or the feeding of children, or to help children with sucking or teething." *Id.* § 108935(b) (enacted by Chapter 672).

48. *Id.* § 108937(a) (enacted by Chapter 672).

49. *Id.* § 108937(b) (enacted by Chapter 672).

50. *Id.* § 108939(a) (enacted by Chapter 672).

51. *Id.* § 108939(b) (enacted by Chapter 672).

52. *Id.* § 108939(c) (enacted by Chapter 672).

53. *Id.* § 20249.6 (West 2006).

54. *Id.*

55. See Telephone Interview with Assembly Member Fiona Ma, Cal. State Assembly, in Sacramento, Cal. (Dec. 21, 2007) [hereinafter Fiona Ma Interview] (on file with the *McGeorge Law Review*) ("[N]ot only is the routine of listing a chemical under Prop 65 very time-consuming, but we could not permit manufacturers to use measurable amounts of phthalates in their products, regardless of whether a warning label was attached, considering the harmful side-effects of the chemicals.").

56. CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672).

B. Scientific Studies of the Effects of Phthalates on Humans

1. Studies that Support the Ban on Phthalates

Various scientific studies have demonstrated that phthalate levels in humans are not only higher than once believed but also that phthalates have wide-ranging, adverse health effects on the human body.⁵⁷

In a 2000 study, the CDC found high levels of phthalates in all 289 adult Americans tested.⁵⁸ A subsequent independent study concluded that children had even higher levels of phthalates (especially DBP, BBP, and DEHP) in their systems than the average adult in the CDC study.⁵⁹ Another study conducted by the CDC in 2005 bolstered this conclusion by finding phthalates in virtually every person tested, with the highest levels among children, demonstrating the potential for adverse developmental effects on children and fetuses.⁶⁰ Similar to the prior independent study, children had the highest concentrations of the specific phthalates DEHP, BBP, and DINP in the 2005 CDC study.⁶¹

A high level of phthalates in the human body is especially worrisome considering the assorted adverse health effects purportedly linked to the chemicals.⁶² For example, DEHP exposure has been linked to premature breast development in girls.⁶³ A study of Puerto Rican girls concluded that girls suffering from premature breast development—girls with an average age of thirty-one months—had seven times as much DEHP in their system as the average infant girl.⁶⁴ Moreover, another study found that exposure to DEHP may cause pre-term birth, as higher levels of phthalates in newborn children correlated with higher incidences of premature delivery.⁶⁵

Phthalates have also been linked to sperm damage in men, as a study showed that men with higher phthalate levels, including DBP and DEHP, were more likely to experience low sperm count and impaired sperm quality.⁶⁶ Unfor-

57. See, e.g., Benjamin C. Blount et al., *Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population*, 108 ENVTL. HEALTH PERSP. 979, 979 (2000) [hereinafter Blount et al., *Levels of Urinary Phthalates*] (finding high levels of phthalates in every individual tested); Ivelisse Colón et al., *Identification of Phthalate Esters in the Serum of Young Puerto Rican Girls with Premature Breast Development*, 108 ENVTL. HEALTH PERSP. 895, 899 (2000) [hereinafter Colón et al., *Identification of Phthalate Esters*] (finding high levels of DEHP in female toddlers exhibiting premature breast development).

58. Blount et al., *Levels of Urinary Phthalates*, *supra* note 57.

59. J.W. Brock et al., *Phthalate Monoesters Levels in the Urine of Young Children*, 68 BULL. OF ENVTL. CONTAMINATION & TOXICOLOGY 309, 313 (2002).

60. THIRD NATIONAL REPORT, *supra* note 7, at 254.

61. *Id.* at 260, 262, 265, 269, 273, 275.

62. See, e.g., Colón et al., *Identification of Phthalate Esters*, *supra* note 57 (finding high levels of DEHP in female toddlers exhibiting premature breast development).

63. *Id.* at 895, 899.

64. *Id.* at 896, 898.

65. Giuseppe Latini et al., *In-Utero Exposure to Di-(2-ethylhexyl)phthalate and Duration of Human Pregnancy*, 111 ENVTL. HEALTH PERSP. 1783, 1784 (2003).

66. Susan M. Duty et al., *Phthalate Exposure and Human Semen Parameters*, 14 EPIDEMIOLOGY 269,

tunately, evidence suggests the typical American man has two to three times the phthalate levels of those who experienced sperm damage in the experiment.⁶⁷

Furthermore, a study of fetuses exposed to phthalates demonstrated two significant results.⁶⁸ First, the study demonstrated a strong correlation between phthalates and changes in the anatomy and size of genitalia in male babies.⁶⁹ Second, the study established that mothers with higher levels of phthalates in their urine who carried male fetuses were more likely to have babies with genital deformities.⁷⁰

Additionally, Dr. Earl Gray of the U.S. EPA reported that DEHP, BBP, and DINP disrupt sexual development in male rats, resulting in undescended testicles and reduced testosterone production.⁷¹ Based upon similarities between previous rat and human studies, it is believed that the health effects present in rats also occur in humans.⁷²

In 2000, the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services reviewed extensive scientific literature on seven of the most controversial phthalates, six of which are identified by Chapter 672 (BBP, DBP, DnOP, DIDP, DINP, and DEHP).⁷³ Although the NTP recommended that additional studies be conducted on the adverse effects of the phthalates, the NTP nonetheless reached a number of preliminary conclusions.⁷⁴

274 (2003) [hereinafter Duty et al., *Phthalate Exposure*]. However, another study by the same research group found no significant correlation between deformed sperm or sperm DNA damage and exposure to DBP, BBP, and DEHP. Susan M. Duty et al., *The Relationship Between Environmental Exposures to Phthalates and DNA Damage in Human Sperm Using the Neutral Comet Assay*, 111 ENVTL. HEALTH PERSP. 1164, 1168 (2003) [hereinafter Duty et al., *Relationship Between*] (finding a correlation between exposure to diethyl phthalate (DEP) and deformed sperm and sperm DNA damage).

67. Duty et al., *Phthalate Exposure*, *supra* note 66. Another study by the same research group discovered that deformed sperm and sperm DNA damage are more likely to be found in men with elevated levels of diethyl phthalate (DEP). Duty et al., *Relationship Between*, *supra* note 66.

68. Shanna S. Swan et al., *Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure*, 113 ENVTL. HEALTH PERSP. 1056, 1061 (2005).

69. *Id.*

70. *Id.*

71. L. Earl Gray Jr. et al., *Perinatal Exposure to the Phthalates DEHP, BBP, and DINP, but Not DEHP, DMT, or DOTP, Alters Sexual Differentiation of the Male Rat*, 58 TOXICOLOGICAL SCI. 350, 358 (2000).

72. *Id.* at 363.

73. Meeting Notice, 65 Fed. Reg. 33,343, 33,344 (May 23, 2000); CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672).

74. *See, e.g.*, CTR. FOR THE EVALUATION OF RISKS TO HUMAN REPROD., NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON BUTYL BENZYL PHTHALATE 32 (2000), <http://cerhr.niehs.nih.gov/chemicals/phthalates/bb-phthalate/BBP-final-inprog.PDF> [hereinafter EXPERT PANEL REPORT ON BBP] (on file with the *McGeorge Law Review*) (summarizing the conclusions for BBP).

With respect to BBP, an expert panel⁷⁵ of the NTP stated that “oral exposure to BBP can cause reproductive toxicity in adult rats and developmental toxicity in rats and mice. These data are assumed to be relevant to humans.”⁷⁶ The panel suggested that further studies were needed to establish the lowest doses of BBP that can alter the development of the male reproductive tract.⁷⁷

Similarly, the panel concluded that DBP can lead to developmental toxicity in both rats and mice,⁷⁸ and that studies on DnOP evidencing toxicity results in rats and mice provide a “reasonable basis for assuming relevance of these data for judging potential hazard to humans.”⁷⁹

The NTP’s expert panel also concluded that oral exposure to DIDP should be extensively examined in children and pregnant women after toxicology results showed adverse effects on the developing skeletal system in rats following oral exposure to DIDP.⁸⁰ The study ultimately found that small children and infants may be exposed to greater levels of DIDP because they “mouth toys and other objects that may contain DIDP which can migrate into saliva and be swallowed.”⁸¹ Likewise, the expert panel stated that while testing on DINP remains inconclusive, “[e]xposure of children to DINP through children’s products is a public concern” since children mouth toys that contain the potentially harmful phthalate.⁸²

In October 2005, a second expert panel of the NTP reaffirmed a 2000 finding by the first expert panel that DEHP poses a risk to human development and

75. The Center for the Evaluation of Risks to Human Reproduction (CERHR) impaneled a group of sixteen independent experts to review the evidence on phthalate exposure. Meeting Notice, 65 Fed. Reg. at 33,343-44. The NTP and the National Institute of Environmental Health Sciences (NIEHS) established the CERHR in order to “provide a strictly scientifically-based, uniform assessment of the evidence for reproductive and developmental toxicity of man-made or naturally occurring chemicals or chemical mixtures.” Meeting Notice, 63 Fed. Reg. 68,782, 68,782 (Dec. 14, 1998).

76. EXPERT PANEL REPORT ON BBP, *supra* note 74, at 31.

77. *Id.*

78. CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON DI *N* BUTYL PHTHALATE 36 (2000), <http://cerhr.niehs.nih.gov/chemicals/phthalates/dbp/dbp-final-inprog.PDF> (on file with the *McGeorge Law Review*).

79. CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON DI *N* OCTYL PHTHALATE 18 (2000), <http://cerhr.niehs.nih.gov/chemicals/phthalates/dnop/DnOP-final-inprog.PDF> (on file with the *McGeorge Law Review*).

80. CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON DI ISODECYL PHTHALATE 26 (2000), <http://cerhr.niehs.nih.gov/chemicals/phthalates/didp/DIDP-final-inprog.PDF> (on file with the *McGeorge Law Review*).

81. *Id.* at 25.

82. CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT’L TOXICOLOGY PROGRAM, U.S. DEP’T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON DI ISONONYL PHTHALATE 6, 31 (2000), <http://cerhr.niehs.nih.gov/chemicals/phthalates/dinp/DINP-final-inprog.PDF> (on file with the *McGeorge Law Review*).

fertility.⁸³ In the NTP's second review of DEHP in the last five years, the second expert panel concluded that DEHP causes reproductive and developmental damage in animal studies, which the panel deemed relevant to humans, especially infants, children, and pregnant and nursing women.⁸⁴ The panel concluded that further testing of children was "critical" because data suggests that infants and toddlers can be exposed to phthalates through the placenta while in utero, through breast milk (either directly or through phthalate-containing breast pumps), and by mouthing products containing phthalates.⁸⁵

2. Studies that Undermine the Ban on Phthalates

In 1998, the CPSC released the results of a comprehensive, five-year study of the health risks posed to children under three years of age by teethers, rattlers, and toys made from polyvinyl chloride (PVC) containing DINP.⁸⁶

The CPSC ultimately found that children were not at risk of liver or other organ toxicity from sucking on PVC toys that contain DINP.⁸⁷ The CPSC stated that the amount that children might ingest from teethers, rattlers, and toys was not significant enough to cause organ toxicity.⁸⁸

Yet, the CPSC report stated that significant uncertainties remain with respect to DINP, such as the cancer risk of DINP exposure, and that additional scientific studies were necessary to determine the full effects of DINP.⁸⁹ As a precaution, the CPSC requested that manufacturers remove phthalates from soft rattlers and teethers.⁹⁰ Additionally, the CPSC requested that manufacturers "find a substitute

83. Meeting Notice, 70 Fed. Reg. 69,567, 67,567 (Nov. 16, 2005); CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL REPORT ON DI(2-ETHYLHEXYL) PHTHALATE 99-100 (2000), <http://cerhr.niehs.nih.gov/chemicals/dehp/DEHP-final.pdf> (on file with the *McGeorge Law Review*) (finding that "there are sufficient data in rodents to conclude confidently that oral exposure to DEHP can cause reproductive and productive toxicity in rats and mice" and that "DEHP data from rats and mice are assumed relevant to judging hazard to human reproduction and development").

84. CTR. FOR EVALUATION OF RISKS TO HUMAN REPROD., NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., NTP-CERHR EXPERT PANEL UPDATE ON THE REPRODUCTIVE AND DEVELOPMENTAL TOXICITY OF DI(2-ETHYLHEXYL) PHTHALATE 171-73 (2005), http://cerhr.niehs.nih.gov/chemicals/dehp/DEHP_Report_final.pdf (on file with the *McGeorge Law Review*).

85. *Id.* at 169-171, 175.

86. U.S. CONSUMER PROD. SAFETY COMM'N, THE RISK OF CHRONIC TOXICITY ASSOCIATED WITH EXPOSURE TO DIISONONYL PHTHALATE (DINP) IN CHILDREN'S PRODUCTS: EXECUTIVE SUMMARY 1 (1998), <http://www.cpsc.gov/phth/execsum.pdf> [hereinafter DINP EXECUTIVE SUMMARY] (on file with the *McGeorge Law Review*).

87. *Id.* at 4.

88. *Id.*

89. *Id.* at 5 (recommending future research).

90. Press Release, U.S. Consumer Prod. Safety Comm'n, CPSC Releases Study on Phthalates in Teethers, Rattles and Other Children's Products (Dec. 2, 1998), <http://www.cpsc.gov/CPSC/PUB/PREREL/PRHTML99/99031.html> (on file with the *McGeorge Law Review*).

for phthalates in other products intended for children under [three] years old that are likely to be mouthed or chewed.”⁹¹

C. *The Debate Over Chapter 672*

Critics such as Louis W. Sullivan, former U.S. Secretary of Health and Human Services, contend that Chapter 672 “widely misses the mark on the most fundamental underpinning of all good public health policy—sound science.”⁹² Edward Manning of KP Public Affairs reiterated this sentiment, stating, “The bill seeks to substitute the judgment of objective science by government agencies with political considerations that are not well conceived. The bill bans chemicals not based on risk, but based on fear.”⁹³ As evidence for their claims, critics point to the CPSC study, which concluded that plastic toys containing DINP were not harmful to children—a conclusion reinforced by the European Union’s European Chemicals Bureau, the CDC, and various other scientific bodies.⁹⁴ The European Union’s European Chemicals Bureau also found that BBP and DBP do not pose adverse health effects in current consumer applications, such as toys and childcare articles, subsequent to the European Parliament’s legislative ban on the phthalates.⁹⁵

Further, critics assert that Chapter 672 is ambiguous and leaves much uncertainty for manufacturers.⁹⁶ For example, Chapter 672 requires manufacturers to replace phthalates with the “least toxic alternative,” but no guidance is given as to what “least toxic alternative” means.⁹⁷ In contrast, shortly after the European Parliament enacted its directive, the European Commission published a guidance document that provided examples and exceptions to the directive.⁹⁸ The guidance document granted clarity to manufacturers by giving

91. *Id.*

92. Letter from Louis W. Sullivan, President Emeritus, Morehouse Sch. of Med., to Governor Arnold Schwarzenegger, Cal. State Governor [hereinafter Sullivan Letter] (on file with the *McGeorge Law Review*).

93. Letter from Edward P. Manning, KP Pub. Affairs, to Assembly Member Fiona Ma, Cal. State Assembly (Mar. 23, 2007) (on file with the *McGeorge Law Review*).

94. Sullivan Letter, *supra* note 92.

95. Council Directive 2005/84/EC, 2005 O.J. (L 344) 40 (noting the European Parliament’s 1998 ban on “childcare articles and toys intended to be placed in the mouth . . . made of soft PVC containing certain phthalates”); EUROPEAN CHEMS. BUREAU, INST. FOR HEALTH & CONSUMER PROT., DIBUTYL PHTHALATE: SUMMARY RISK ASSESSMENT REPORT 19 (2004), http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/dibutylphthalatesum003.pdf (on file with the *McGeorge Law Review*); EUROPEAN CHEMS. BUREAU, 1,2-BENZENEDICARBOXYLIC ACID, DI-C8-10-BRANCHED ALKYL ESTERS, C-9 RICH AND DI-“ISONONYL” PHTHALATE (DINP): SUMMARY RISK ASSESSMENT REPORT 18 (2003), http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/dinpsum046.pdf (on file with the *McGeorge Law Review*).

96. Letter from Corinne Murat, Dir., Gov’t Affairs, Mattel, Inc., to Senator Alex Padilla, Cal. State Senate (July 13, 2007) [hereinafter Murat Letter] (on file with the *McGeorge Law Review*).

97. CAL. HEALTH & SAFETY CODE § 108939(a) (enacted by Chapter 672); Murat Letter, *supra* note 96.

98. European Comm’n, Guidance Document on the Interpretation of the Concept “Which Can be Placed in the Mouth” as Laid Down in the Annex to the 22nd Amendment of Council Directive 76/769/EEC,

examples of toys and childcare articles which can be “placed in the mouth.”⁹⁹ At this time, there is no indication that the Legislature intends to draft a similar document in California.¹⁰⁰

Critics also allege that, with the exception of DINP, the phthalates named in Chapter 672 are not widely used in components of child care articles accessible to children.¹⁰¹ For example, the phthalate DEHP is commonly used as fire resistant wire insulation that prevents access to circuits in electronic components.¹⁰² Yet Chapter 672 bans the presence of DEHP in childcare articles and toys despite the fact that the phthalate is used to “enhance the safety of the product and protect children from hazards” and is generally inaccessible within toys and childcare articles.¹⁰³

Moreover, critics allege that if manufacturers must replace DINP in childcare products with an alternative chemical, it will result in more brittle plastics that could break¹⁰⁴ and create serious choking hazards. By switching to less durable and untested alternate materials, critics believe that the California Legislature has needlessly abandoned scientifically-tested, safe, and durable plastics.¹⁰⁵

California Assembly Member Fiona Ma, author of Chapter 672, answers critics of the bill by stating that “the science is clearly in on phthalates; it has been proven in study after study that the six phthalates listed in Chapter 672 pose great risk to the human body.”¹⁰⁶ Proponents of the measure point to both the independent and the NTP studies, which show that phthalates likely present serious health risks to children.¹⁰⁷ Further, Assembly Member Ma pointed out that the number of CPSC employees has been cut in half, to approximately 400, since 1974, demonstrating a lack of priority for toy safety.¹⁰⁸ Assembly Member Ma stated that the findings of the CPSC cannot be regarded as entirely reliable, considering the CPSC’s budget is not sufficient to support oversight of consumer products, and many in Washington are calling for a large-scale reform of the CPSC.¹⁰⁹

http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&doc_id=165 (last visited Feb. 29, 2008) (on file with the *McGeorge Law Review*).

99. See *id.* (stating that an article can be placed in the mouth “[i]f an article or part of an article in one dimension is smaller than 5 [centimeters]”).

100. Murat Letter, *supra* note 96.

101. *Id.*

102. *Id.*

103. *Id.*

104. Letter from Tim Shestek, Am. Chemistry Council, to Cal. State Assembly (Oct. 25, 2006) (on file with the *McGeorge Law Review*).

105. Murat Letter, *supra* note 96.

106. Fiona Ma Interview, *supra* note 55.

107. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 2 (June 29, 2007).

108. Fiona Ma Interview, *supra* note 55.

109. *Id.*

D. Will Federal Law Have the Final Word?

In November of 2006, the Toy Industry Association, Ambassador Toys, the California Chamber of Commerce, and the American Chemistry Council brought suit challenging the San Francisco ordinance that banned phthalates.¹¹⁰ The suit maintained that the CPSC already reviewed the primary phthalate used in children's toys, diisononyl phthalate (DINP), and concluded that the phthalate was safe for children.¹¹¹ Thus, according to the plaintiffs, the City of San Francisco was precluded from banning DINP under the doctrine of preemption.¹¹² The lawsuit is still pending, but the outcome is particularly relevant since Chapter 672 also bans DINP in concentrations exceeding 0.1 percent.¹¹³

Preemption is "the principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation."¹¹⁴ Both federal statutes and regulations developed by federal agencies pursuant to a valid delegation of authority from Congress can preempt state laws.¹¹⁵ According to Professor Tribe, however, "the fact that . . . Congress created a regulatory agency . . . is not by itself determinative of the preemption inquiry."¹¹⁶ Critical to a preemption test is "[a]n analysis of the reasons why Congress created a particular regulatory agency, or of the policies pursued by that agency."¹¹⁷

The CPSC is a federal agency established and empowered by the Consumer Product Safety Act.¹¹⁸ Thus, any standards or regulations which it promulgates are considered federal law.¹¹⁹ The Consumer Product Safety Act was primarily enacted "to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations."¹²⁰ Section 26(a) of the

110. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007).

111. *Id.*

112. *Id.* The lawsuit was also based on the allegation that the San Francisco ordinance directly conflicted "with the California Hazardous Substances Act, which grants the state, not local jurisdictions, the authority to regulate 'hazardous substances' in consumer products such as toys or other articles intended for use by children." Press Release, Am. Chemistry Council, Lawsuit Asks Court to Overturn Flawed San Francisco Ban on Children's Products 2 (Oct. 25, 2006) (on file with the *McGeorge Law Review*). However, this point was rendered moot upon enactment of Chapter 672, which prohibits the same phthalates identified in the San Francisco ordinance. Compare CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672), with S.F., CAL., HEALTH CODE art. 34, § 34.4 (2007) (both laws prohibit certain uses of the same six phthalates—DEHP, DBP, BBP, DINP, DIDP, and DnOP).

113. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007).

114. BLACK'S LAW DICTIONARY 1216 (8th ed. 2004).

115. LAURENCE A. TRIBE, AMERICAN CONSTITUTIONAL LAW 1179 (3d ed. 2000).

116. *Id.* at 1212.

117. *Id.* at 1212-13.

118. 15 U.S.C.A. §§ 2053(a), 2054(a)-(b) (West 1998).

119. TRIBE, *supra* note 115, at 1179 ("Regulations duly promulgated by a federal agency, pursuant to a valid congressional delegation, have the same preemptive effect.")

120. 15 U.S.C.A. § 2051(b)(3) (West 1998).

Consumer Product Safety Act states:

Whenever a consumer product safety standard under this [Act] is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.¹²¹

Based solely upon section 26(a), Chapter 672 may be preempted by federal law, since Chapter 672 implements different safety standards for a consumer product: children's toys.¹²² However, the CPSC does not have the authority to preempt a state or local law, and preemption can only be raised as a defense to enforcement of a state or local regulation where a concurrent federal regulation is in place.¹²³ The final decision on any preemption issue thus lies with the courts, not with the CPSC.¹²⁴

Considering the current state of the CPSC, a court may be reluctant to strike down California's foray into consumer product safety standards.¹²⁵ Since July 2006, the CPSC has operated with only two of the three commissioners necessary for a quorum because President Bush and Congress have not been able to agree upon the next commissioner.¹²⁶ Congress granted the CPSC a "temporary quorum" to operate in the interim, but that grant expires in February 2008.¹²⁷ Unless the temporary quorum is extended, the CPSC can neither approve new regulations nor file suit against businesses that fail to recall hazardous products.¹²⁸

Further, the U.S. Senate refused to pass a House of Representatives bill which would have drastically enlarged the budget of the CPSC and "reform[ed]

121. 15 U.S.C.A. § 2075(a) (West 1998).

122. Compare DINP EXECUTIVE SUMMARY, *supra* note 86, at 4 (finding no DINP exposure health risks and, therefore, permitting manufacturers to use DINP in their products), with CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (prohibiting manufacturers from using DINP in certain children's products).

123. Section 26 of the Consumer Product Safety Act, Op. Consumer Prod. Safety Comm'n No. 281, at 1-2 (Mar. 23, 1981) (on file with the *McGeorge Law Review*).

124. *Id.*

125. See Fiona Ma Interview, *supra* note 55 ("Since the CPSC refuses to act, the states must step in to fill the void. I cannot foresee the courts looking down upon necessary state action."); Posting of Matt Madia to REG-WATCH Blog, *Politicking Between Democrats and Nord Threatens CPSC*, <http://www.ombwatch.org/article/blogs/entry/4173/20> (Oct. 30, 2007) (on file with the *McGeorge Law Review*) (discussing the challenges facing CPSC).

126. *Id.*

127. Anny Shin, *Congress Leaves Product Safety Overhaul in Limbo*, WASH. POST, Dec. 20, 2007, at D1.

128. *Id.*

the nation's consumer product safety system."¹²⁹ It thus seems highly unlikely that any major regulatory changes will affect children's toys sold during 2008.¹³⁰ In addition, the CPSC has lost fifteen percent of its workforce since 2004 and, according to one of its commissioners, is in the midst of a dramatic "downsizing and dismantling,"¹³¹ which gives the appearance that the CPSC is not meeting its congressional mandate. According to Ed Mierzwinski, the consumer program director for the U.S. PIRG, a federation of state Public Interest Research Groups, "[t]he Consumer Product Safety Commission is a little agency with a big job it simply cannot do."¹³²

The CPSC has also identified relatively few banned hazardous substances,¹³³ especially in comparison to California's Proposition 65,¹³⁴ and its list of banned toys and articles intended for use by children is paltry.¹³⁵ Rather, the CPSC has generally delineated safety standards for a narrow selection of consumer products, such as matchbooks, bicycle helmets, and swimming pool slides.¹³⁶ Although Congress established the CPSC in order to provide nationwide uniformity for consumer product safety regulations, the actions and policies of the CPSC do not seem extensive enough to promote the best interests of the children of our country. Despite the preemption provision of the Consumer Product Safety Act, Assembly Member Fiona Ma believes that courts will refuse to enforce the provision to override Chapter 672 because "the CPSC has simply failed to act, not only with regard to phthalates, but a host of other hazardous chemicals as well. Since the CPSC refuses to act, the states must step in to fill the void. I cannot foresee the courts looking down upon necessary state action."¹³⁷ Due to the CPSC's current state of flux and its lethargic identification of hazardous chemicals, it is unlikely that a court would find that Chapter 672 is preempted by the Consumer Product Safety Act.

129. *Id.*

130. *Id.*

131. *Bush OKs Tough Product Safety Rules*, CBS2CHICAGO.COM, Nov. 6, 2007, <http://cbs2chicago.com/politics/FDA.CPSC.import.2.489975.html> (on file with the *McGeorge Law Review*).

132. Hope Yen, *Toy Safety Warnings Issued*, BOSTON.COM, Nov. 20, 2007, http://www.boston.com/news/nation/washington/articles/2007/11/20/toy_safety_warnings_issued?mode=PF (on file with the *McGeorge Law Review*).

133. Products Requiring Special Labeling Under Section 3(b) of the Act, 16 C.F.R. § 1500.14 (2007); Banned Hazardous Substances, 16 C.F.R. § 1500.17 (2007).

134. CHEMICALS, *supra* note 35.

135. Banned Toys and Other Banned Articles Intended for Use by Children, 16 C.F.R. § 1500.18 (2007).

136. 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).

137. Fiona Ma Interview, *supra* note 55.

V. CONCLUSION

Even after the enactment of Chapter 672, debate rages on regarding the health effects of phthalates.¹³⁸ However, even with this debate, as many as ten other states are expected to introduce similar legislation within the coming months.¹³⁹ Although Congress established the CPSA in order to create a uniform system of consumer product safety regulations, preemption of Chapter 672 could prove detrimental to children's health.¹⁴⁰ While Chapter 672 does not guarantee the safety of all children's toys, it signals responsible action by the Legislature and sets an example for further regulation of children's toys.¹⁴¹ If Chapter 672 survives federal preemption, it will give parents like Jackie Christensen some comfort to know that their children's Happy Meal toys contain fewer potentially hazardous substances.

138. Compare Henry I. Miller, *Stop Scaring Us: Feinstein's Bill to Ban Some Chemicals in Toys Might Help Rats, But it's Bad for People*, L.A. TIMES, Dec. 18, 2007, at A27 (stating that the results of rodent studies should not be blindly analogized to humans, and that rigorous studies in the United States and Europe have shown that "human exposure to phthalates under ordinary circumstances is low and harmless"), with Al Meyerhoff, Dianne Feinstein & James T. Martin, *There's No Defense for Toxic Toys*, L.A. TIMES, Dec. 23, 2007, at M2 (pointing out that "[a]nimal testing to predict risks posed to humans by toxic substances is a well-established principle that provides the basis for the nation's fundamental cancer policy" and asserting that the dangers presented by phthalates are undeniable; each author answered Miller's piece with their own section).

139. Chorneau, *supra* note 16.

140. 15 U.S.C.A. § 2051(b)(3) (West 1998).

141. Chorneau, *supra* note 16; Shin, *supra* note 127.