International Association of Defense Counsel

Product Liability Committee Newsletter

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Alleged Endocrine Disruptors: An Update on Legislation, Science, and Litigation Concerning Bisphenol-A and Phthalate

BY BRUCE J. BERGER

In the March 2008 IADC Product Liability Committee Newsletter, we wrote about "endocrine disruptors" ["EDs"], widely used chemicals that some believe can disrupt the hormone system and cause health effects. [1] We now briefly examine recent legislation, regulation, science, and litigation regarding two alleged EDs, bisphenol-A ["BPA"] and phthalate, chemicals that some say are potentially harmful to human health, e.g., allegedly causing prostate and breast cancer, early puberty, and lowered sperm count.[2]

Legislative and Regulatory Activities

In April, the Canadian legislature has brought BPA back into the public spotlight by adding BPA to the toxic substances list of the Canadian Environmental Protection Act ["CEPA"].[3] The addition of BPA to CEPA's toxic substances list will exclude the chemical from use in infant bottles, and the ban will take about a year to go in effect.[4]

The United States Food and Drug Administration ["FDA"] has not helped quell concerns. Although an FDA scientist reportedly told Congress that "exposure levels to BPA . . . are below those that may cause health effects,"[5] weeks later FDA "formed an agency-wide BPA . . . task force to facilitate cross-agency review of current research and new information on BPA for all FDA regulated products."[6] After forming this task force, FDA again said BPA products are safe.[7]

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[1] Berger, B. & Junk, M., *Endocrine Disruptors – An Update*, IADC Committee Newsletter, Products Liability, (March 2008).
[2] *Baby's Toxic Bottle: Bisphenol A Leaching From Popular Baby Bottles*, 7; www.babystoxicbottle.org (last visited June 23, 2008).
[3] Canadian Environmental Protection Act, 1999 S.C., ch. 33, part 5 (1999); *see also* http://www.ec.gc.ca/CEPARegistry/subs_list/Toxicupdate.cfm (listing substances categorized as toxic under CEPA, last updated December 27, 2006) (substance number 30 is Bis(2-ethylhexyl)phthalate) (last visited June 30, 2008).
[4] http://www.nytimes.com/2008/04/19/business/worldbusiness/19plastic.html (last visited June 30, 2008).
[5] http://blogs.wsj.com/health/2008/05/15/fda-bisphenol-a-in-plastic-bottles-is-safe/?mod=WSJBlog (last visited June 30, 2008).
[6] http://www.fda.gov/bbs/topics/NEWS/2008/NEW01847.html (last visited June 30, 2008).
[7] http://health.usnews.com/articles/health/healthday/ 2008/06/11/health-highlights-june-11--2008.html (last visited June 30, 2008).

Canada's legislation may have also sparked federal legislative activities in the United States. New York Senator Charles Schumer, on April 29, 2008, introduced the BPA-Free Kids Act ["BFKA"] which mandates a blanket ban of BPA use in products "designed for or intended for use by, or care of, a child 7 years of age or younger that is introduced into the interstate stream of commerce."[8] The BFKA has been referred to the Committee on Commerce, Science, and Transportation. On June 10, 2008, Massachusetts Representative Edward Markey introduced the Ban Poisonous Additives Act of 2008 ["BPAA"].[9] The BPAA would "ban the use of bisphenol A in food and beverage containers" and has been referred to the House Committee on Energy and Commerce.[10]

Two federal bills have been introduced in an attempt to ban phthalate use in children's products. The Children's Chemical Risk Reduction Act, introduced by Oregon representative Darlene Hooley, seeks to place phthalate under the Federal Hazardous Substances Act[11] and limit phthalate concentration to 0.1 percent in, for example, toys and products for feeding and sucking.[12] And California Senator Dianne Feinstein is pursuing a ban on the "manufacture, sale, or distribution in commerce of certain children's products and child care articles that contain specified phthalates."[13]

A number of state legislatures have also seen the introduction of bills attempting to ban BPA and/or phthalate after California broke the ice by banning phthalate from children's products in 2007.[14] In Minnesota, for instance, House Bill 2100 would prohibit the sale in "this state [of] a children's product that contains bisphenol-A" or the sale of a children's product containing more than 0.1 percent of phthalate.[15] Similarly, New York's

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[8] BPA-Free Kids Act, S. 2928, 110th Cong., 2d Session, § 2 (2008).
[9] Ban Poisonous Additives Act of 2008, H.R. 6228. 110th Cong., 2d Session, § 2 (2008).
[10] *Id.*
[11] 15 U.S.C. 1261 et seq.
[12] Children's Chemical Risk Reduction Act, H.R. 4030, 110th Cong., 1st Session, § 2 (2007-2008).
[13] Children's Chemical Risk Reduction Act of 2007, S. 2275, 110th Cong., 1st Session, § 2 (2007-2008).
[14] *See* Phthalates in Products for Young Children, A.B. 1108, 2007-2008 Sess. (Cal. 2007) (commencing January 1, 2009 and prohibiting children's products with phthalates in concentrations exceeding 1/10 of 1%); s*ee also* S.B. 83, 1st Special Sess. 2008 (Ala. 2008) (pending committee action); S.B. 1713, 2007-2008 Sess. (Cal. 2008) (introduced February 22, 2008) (will pass but first re-referred to Committee on Health); An Act Banning Children's Products Containing Lead, Phthalates or Bisphenol-A, H.B. 5601, 2008 Sess. (Conn. 2008) (tabled); Bisphenol A Products Act, H.B. 4744, 95th Gen Assem. Sess. (Ill. 2007) (re-referred to Rules Committee March 14, 2008); H.F. 2100, 85th Leg. Sess. (Minn. 2007) (introduced March 19, 2007) (referred by Chair to Housing Policy and Finance and Public Health Finance Division); Toxic-free Beverages Containers Act, S.B. 1859, 213th Leg., 2008-2009 Sess. (N.J. 2008) (referred to state Commerce Committee); A. 11277, 2007-2008 Reg. Sess. (N.Y. 2008) (ordered to third reading June 19, 2008 and banning BPA from children's products); A. 333, 2007-2008 Reg. Sess. (N.Y. 2008) (ordered to third reading June 19, 2008 and limiting phthalate concentration to 0.1 percent in children's products); South Carolina Child Safe Product Act, H. 5044, Gen. Assem., 117th Sess. (S.C. 2008) (referred to Committee on Judiciary); Banning the Retail Sale of Products that Contain the Chemical Bisphenol A, H. 0858, Gen. Assem., 2007-2008 Sess. (Vt. 2008) (in the house February 5, 2008); H.B. 4084, 78th Leg., 2d Sess. (W. Va. 2008) (referred to House Judiciary).
[15] H.F. 2100, 85th Leg. Sess. (Minn. 2007) (introduced March 19, 2007) (referred by Chair to Housing Policy and Finance and Public Health Finance Division).

Assembly Bill 6829 would impose a civil fine of $10,000 per day for making, selling, or producing child care products with BPA.[16] Legislators in New Jersey have proposed that "no person shall sell, distribute, or manufacture any hard plastic beverage container containing bisphenol-A."[17] The Illinois legislature has referred to its House Committee on Rules an extensive BPA ban as to any children's products, e.g., clothing, furniture, and jewelry.[18]

But concerns about alleged adverse health effects of BPA and phthalate have not induced all state legislatures to enact similar laws. Maryland withdrew from consideration a ban on BPA and phthalate.[19] Rhode Island has also recommended further study on the effects of BPA and phthalate before moving forward.[20] Other legislatures are asking states to monitor the ongoing debate about the potentially harmful effects of BPA and phthalate.[21]

Potential legislative action is not limited to children's products. California representative Rosa DeLauro wants the FDA's BPA task force to investigate the possibility of harmful effects from BPA use in medical devices.[22]

ABOUT THE COMMITTEE

The IADC's **Product Liability Committee** serves all members who defend manufacturers, product sellers, and product designers. Members publish newsletters and *Journal* articles and present educational seminars for the IADC membership at large and mini-seminars for the committee membership. Opportunities for networking and business referral are plentiful. With one broadcast e-mail, a member can obtain information on experts from the entire Committee membership.

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[16] A. 6829, 2008 Leg. Sess. (N.Y. 2008).
[17] Toxic-free Beverages Containers Act, S.B. 1859, 213th Leg., 2008-2009 Sess. (N.J. 2008) (referred to state Commerce Committee).
[18] Bisphenol A Products Act, H.B. 4744, 95th Gen Assem. Sess. (Ill. 2007) (re-referred to Rules Committee March 14, 2008).
[19] Phthalates and Bisphenol-A - Prohibitions - Toys and Child Care Articles, H.B. 56, Gen. Assem., 425th Sess. (Md. 2008) (withdrawn March 22, 2008).
[20] Children's Product Safety Act, S. 2685, 2008 Sess. (R.I. 2008) (held for further study March 19, 2008).
[21] S.C.R. 132, 24th Leg., 2008 Sess. (Haw. 2008) (requesting Department of Health to monitor research on risks of BPA and phthalate).
[22] *DeLauro Presses FDA to Include Medical Devices in BPA Investigation*, FDA Week, Vol. 14, Iss. 25, 2008 WLNR 11658573 (June 20, 2008).

Science

Two recent studies address the potential human health effects of BPA. In May, Tyl et al. released a study finding BPA "is not a selective reproductive or developmental toxicant" in mice.[23] The study was consistent with previous three-generation studies in rats. The study was part of the European Union ["EU"] Risk Assessment and cooperated with the oversight of an EU BPA steering group.[24] Polycarbonate/BPA Global Group, Arlington, VA funded the project.[25]

Unlike previously criticized rodent studies,[26] Tyl et al. addressed reliability concerns by employing "very low to very high dietary doses, an effective positive control, appropriate statistical analyses, an OECD Guideline protocol . . . and [it] used the CD-1 (Swiss) mouse."[27] In the July 2006 IADC Newsletter, we criticized a vom Saal et al. study for using sensitive mice because other less sensitive rodents may not have shown the same effects.[28] The Tyl et al. study, in using sensitive CD-1 mice[29] and finding no toxic effects, underscores the scientific uncertainty about the effects of BPA. Now it is clear that even studies using sensitive rodents produced inconsistent results.

We also previously noted the lack of consistency among studies and argued "that a toxic tort plaintiff must offer more than mere criticism of a defendant's or an industry's studies in order to carry his or her burden of proof."[30] Today, defense counsel has an even stronger foundation to question whether plaintiffs can prove causation when studies such as Tyl et al. avoid weaknesses of past studies and find BPA not to have toxic effects at anticipated levels of exposure. In fact, six current BPA class action complaints fail to refer to Tyl

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[23] Tyl et al., Two-Generation Reproductive Toxicity Study of Dietary Bisphenol A (BPA) in CD-1® (Swiss) Mice, Toxicol. Sci. (May 6, 2008).

[24] *Id*. at 5.

[25] *Id*. at 34.

[26] *See* vom Saal, F.S., corresponding author, *Chapel Hill bisphenol A Expert Panel Consensus Statement: Integration of Mechanisms, Effects in Animals and Potential to Impact Health at Current Levels of Exposure,* Reprod. Toxicol. 24 (2007); vom Saal, F.S. & Hughes, C., *An Extensive New Literature Concerning Low-Dose Effects of bisphenol A Shows Need for a New Risk Assessment*, Environ. Health Perspect. 113(8) (2005); Long et al., *Strain Differences in Vaginal Responses to the Xenoestrogen bisphenol A,* Environ. Health Perspect. 108(8) (2000).

[27] Tyl et al. administered 99.7% pure BPA through Purina Certified Ground Rodent Diet® and exposed mice to ~0.003-600 mg/kg/day of BPA. Tyl et al. at 5. Non-occupational exposure in humans of all ages ranges from 0.000008-0.0147 mg/kg bw/day. National Toxicology Program, *Draft NTP Brief on Bisphenol A,* Cas. No. 80-05-7, 6-7 (April 14, 2008) (peer review date June 11, 2008).

[28] Berger, B., *Endocrine Disruptor Studies Can Be Challenged as Lacking Proper "Fit" with the Human Question*, IADC Newsletter, Product Liability, 2, No. 11 (July 2006) (observing problems with vom Saal et al. because "the results of testing on the supremely responsive . . . CD-1 mice do not predict what happens when similar exposures occur in . . . the rat").

[29] *Id*. (citing vom Saal et al., *Large Effects from Small Exposures. II. The Importance of Positive Controls in Low-Dose Research on Bisphenol A,* Environ. Research 100, 52 (2006)) (noting CD-1 mice are sensitive to estrogenic chemicals when exposed during critical developmental periods).

[30] Berger, B. & Junk, M., E*ndocrine Disruptors: The Potential Cloud of Manufacturer Toxic Tort Liability*, Defense Counsel J., 116-17 (April 2007) (responding to vom Saal et al. criticism "that industry purposely designed poor studies that were destined not to show any adverse effects of endocrine disruptors").

et al., but do rely on criticized studies like those of vom Saal et al.[31] Plaintiffs must explain, rather than ignore, studies showing BPA causes negligible harm.[32]

The other recent and important scientific release is by the National Toxicology Program ["NTP"], part of the U.S. Department of Health and Human Services. NTP has prepared a draft brief on BPA designed as a resource to help interpret the 400-plus BPA-related articles that have been reported between February 2007 and April 2008.[33] The goal of the brief is to provide "conclusions regarding the potential for the chemical to adversely affect human reproductive health or children's development."[34]

NTP found insufficient evidence to say that BPA causes adverse developmental or reproductive effects in humans,[35] noting that only a few studies have looked at the alleged relationship between BPA exposure and reproductive or developmental effects in humans.[36] Though some studies suggest an association between BPA and health problems, the studies are problematic in NTP's view. The problems include inconsistent variables such as sample sizes, exposure routes, and lack of adjustments for potential confounders.[37] NTP ultimately found "there is currently insufficient evidence to determine if [BPA] causes or does not cause reproductive toxicity in exposed adults."[38] Simply put, insufficient human evidence exists "to determine if [BPA] does or does not cause developmental toxicity when exposure occurs prenatally or during infancy and childhood."[39]

For example, NTP cannot label BPA as a breast cancer health concern to humans even though animal study evidence suggests perinatal subcutaneous exposure at 0.0025 to 1 mg/kg bw/day causes tissue lesions that may lead to mammary gland tumors later in life[40] because "the lack of supporting pharmacokinetic information limits the ability to make

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[31] *Ganjei v. Ralphs,* No. BC367422, 2007 WL 843806 (Sup. Ct. Cal. 2007); F*elix-Lozano v. Nalge Nunc Int'l Corp.,* No. 08-CV-00854, 2008 WL 1923502 (E.D. CA 2008) (filed April 22, 2008); *Sullivan v. Avent Am. Inc.,* No. 08-309-CV-W-RED, 2008 WL 2035159 (W.D. Mo. 2008) (filed April 30, 2008); B*anse v. Avent Am. Inc.*, No. 08-CV-2604 (N.D. Ill. 2008) (filed May 6, 2008); *Raggio v. Gerber Products Co.*, No. 4-08-CV-0403 (E.D. Ark. 2008) (filed May 7, 2008); C*ampbell v. Playtext Products, Inc.,* No. 08-CV-00763, 2008 WL 2242329 (D. Conn. 2008) (filed May 19, 2008).

[32] *See, e.g., Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) (opinions of plaintiff's expert are viewed with suspicion when a leading medical treatise states opposite toxicological opinion).

[33] National Toxicology Program, *Draft NTP Brief on Bisphenol A*, Cas. No. 80-05-7, 2 (April 14, 2008) (peer review date June 11, 2008).

[34] *Id*.

[35] *Id*. at 16.

[36] *Id*. at 15. One human study concluded male exposure to BPA through inhalation and other routes at job sites may lower levels of a follicle-stimulating hormone. But occupational males may be exposed to up to 100 times the amount of BPA as the average person. I*d.* at 15-16.

[37] *Id*. at 15.

[38] *Id*. at 16.

[39] *Id*.

[40] *Id*. at 20 (citing Durando et al., *Prenatal Bisphenol A Exposure Induces Preneoplastic Lesions in the Mammary Gland in Wistar Rats*, Environ. Health Perspect., 11580-11586 (2007); Murray et al., *Induction of Mammary Gland Ductal Hyperplasias and Carcinoma in Situ Following Fetal Bisphenol A Exposure*, Reprod. Toxicol., 23(3): 383-390 (2007)).

comparisons to human exposures."[41] Nor can BPA be labeled a prostate cancer hazard in humans despite "evidence that perinatal exposure to [BPA] in rodents may alter prostate and urinary tract development and predispose the prostate to develop hormonally-induced preneoplastic lesions later in life."[42] NTP opined that follow-up studies are needed to understand the "significance of the structural and cellular effects observed in fetuses," "clarify the relevance of prostate intraepithelial neoplastic lesions," and produce "a more detailed histopathological evaluation of the prostate."[43] Likewise, accelerated puberty in human beings cannot be linked to low dose BPA exposure in rodent studies without further research, which among other things would need to elucidate why two rodent species – mice and rats – respond differently to BPA exposure.[44] Thus, although NTP reviewed many animal studies, it concluded that such studies simply cannot "be easily interpreted for biological or experimental consistency or for relevance to human health."

We have previously argued that when animal studies are not corroborated in human beings experts "cannot effectively connect the animal study to the human health event in issue."[45] NTP similarly concludes that insufficient evidence from animal studies exists to find BPA causes developmental and reproductive effects in humans.[46] Although high dose rodent studies suggest BPA causes reproductive and developmental problems, these effects emerge from dose levels "more than 3,500-times higher then 'worst case' daily intakes of [BPA] in infants and children less than 6 years of age ($\geq$ 50 mg/kg bw/day versus 0.008 – 0.0147 mg/kg bw/day)."[47] Some high dose study

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[41] *Id.* at 23.
[42] *Id.*
[43] *Id.* at 24.
[44] *Id.* at 27.
[45] Berger, B., *Endocrine Disruptor Studies Can Be Challenged as Lacking Proper "Fit" with the Human Question*, IADC Newsletter, Product Liability, 3, No. 11 (July 2006) (arguing that "until science sufficiently develops to establish that ultra-low levels of chemicals like BPA . . . cause human disease, the animal study basis for opinions from likely plaintiffs' experts is shaky at best") (emphasis in original).
[46] *NTP* at 39.
[47] *Id.* at 35.

intake levels are 160,000 times the daily intake of BPA for children 6-11 and adult women.[48] Thus, high dose animal studies cannot provide the basis for reliable scientific evidence because they rely upon data inapplicable to the average plaintiff.

As we stated in 2006, plaintiffs' experts will also struggle to rely upon low dose rodent studies as a basis for general causation opinions.[49] Although these studies rely on exposure levels that fall within the spectrum of average human exposure, they have flaws rendering them useless for establishing general causation opinions relevant to human beings. In particular, the studies do not account for the likelihood of highly increased sensitivity of certain rodents as compared to human beings.[50] The NTP draft will cut against causation in any future personal injury suits.

Litigation

The Ohio Court of Appeals recently excluded expert testimony about the harmful effects of BPA, among other chemicals, and granted summary judgment for lack of medical causation.[51] Plaintiff, having given birth to a mentally handicapped child with extensive birth defects, sued alleging she had been exposed to genotoxic chemicals at work.[52] Plaintiff's experts, however, relied on "nebulous methodology," could not rule out other causes, reached conclusions based upon speculation, and used incorrect measurements.[53]

The gap between speculation and legal causation has not thwarted massive consumer protection class action suits. As predicted,[54] five major class actions against manufacturers of products containing BPA have been filed since April 22, 2008.[55] Another, filed in March 2007, makes similar allegations.[56] The suits do not allege personal injury, but rather claim that the industry knew more about the potential dangers of BPA than it told consumers. Thus, according to the complaints, the industry's purported fraud, concealment, and

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[48] *Id*. (citing LaKind, JS. & Naiman, DQ., *Bisphenol A (BPA) Daily Intakes in the United States: Estimates from the 2003-2004 NHANES Urinary BPA Data*, J. of Exposure Sci. and Environ. Epidemiology (2008)).

[49] Berger, B., *Endocrine Disruptor Studies Can Be Challenged as Lacking Proper "Fit" with the Human Question*, Defense Counsel J., Newsletter, Product Liability, 3, No. 11 (July 2006).

[50] *NTP* at 39. (emphasis in original).

[51] *See Kerns v. Hobart Brothers Co.*, 2008 Ohio 2242, *13 (Ohio Ct. App. 2008) (excluding experts' testimony as unreliable where they were going to testify about the harmful effects on humans of various chemicals, including BPA).

[52] *Id*. at *1.

[53] *Id*. at *5-11.

[54] Berger, B. & Junk, M., *Endocrine Disruptors – An Update*, IADC Committee Newsletter, Product Liability, 3, (March 2008) (predicting that legislation would be "the catalyst for judicial action").

[55] *Felix-Lozano v. Nalge Nunc Int'l Corp.*, No. 08-CV-00854, 2008 WL 1923502 (E.D. CA 2008) (filed April 22, 2008); *Sullivan v. Avent Am. Inc.*, No. 08-309-CV-W-RED, 2008 WL 2035159 (W.D. Mo. 2008) (filed April 30, 2008); *Banse v. Avent Am. Inc.*, No. 08-CV-2604 (N.D. Ill. 2008) (filed May 6, 2008); *Raggio v. Gerber Products Co.*, No. 4-08-CV-0403 (E.D. Ark. 2008) (filed May 7, 2008); *Campbell v. Playtext Products, Inc.*, No. 08-CV-00763, 2008 WL 2242329 (D. Conn. 2008) (filed May 19, 2008).

[56] *Ganjei v.Ralphs*, No. BC367422, 2007 WL 843806 (Super. Ct. Cal. 2007).

misrepresentation allegedly caused plaintiffs to be exposed to potentially harmful chemicals without plaintiffs' knowledge and/or consent. Plaintiffs allege intentional misrepresentation, negligent misrepresentation, violation of state consumer protection laws, defect in design or manufacture, failure to warn, breach of implied warranty, and unjust enrichment.

While these actions focus on polycarbonate baby products and other re-usable polycarbonate products, the suits may soon cast a wider net. Manufacturers use BPA and phthalate in numerous products, *i.e.*, BPA in soup cans and gas station receipts, and phthalate in shower curtains and pizza boxes.[57] We will continue to monitor developments and report as necessary.

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[57] *See, e.g.,* http://www.chej.org/showercurtainreport/documents/VV%20national%20final.pdf (discussing that the new shower curtain smell caused by the presence of, among other things, phthalate could be toxic) (last visited June 30, 2008).

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