Products Liability NEWSLETTER

OSB Products Liability Section

A section newsletter of the Oregon State Bar

Fall 2008 Volume XVII, Number 3

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Notes from the Chair

By Bruce Hamlin, Lane Powell PC

The Section's annual CLE on Mistakes Made by Plaintiff and Defense Counsel was well-done, and well-received. A panel consisting of Bill Crow, Jeff Foote, John Barker and Mark Bocci, and moderated by Circuit Court Judge Janice Wilson, was "engaging," just as promised. I kept thinking that there would be a lull, but it never happened. Three hours of very solid content! Our thanks go to John Knottnerus, Scott Kocher, Deanna Wray (and her assistant Heather Coffey), and to the panel, for planning and execution.

As 2008 and my term as Chair come to a close, I also want to thank the members of the Executive Committee who pitched in on a variety of projects important to the work of the Section. Volunteerism like that makes the Section more productive, and the work easier.

Toxic Plastics?

By Heather J. Van Meter, Williams Kastner, Portland, Oregon

In April 2008, Health Canada, the Canadian health service, issued a new report concluding that bisphenol A, or BPA, a chemical found in numerous plastic products, was potentially toxic to humans, especially infants. Health Canada also took steps to ban certain baby bottles from the marketplace. Canada became the first country in the world to place limits on bisphenol A-containing products. The same month, the U.S. Food and Drug Administration (FDA) decided to conduct further studies on bisphenol A. On August 15, 2008, the FDA issued a draft report finding that the chemical is safe at normal exposure levels. These events may mark a dramatic change in official categorization and treatment of the chemical after decades of scientific and public debate. These events also are spawning new litigation across the country.

This article discusses the chemical bisphenol A, then outlines the positions of the plastics industry, government regulatory bodies and consumers groups on use of bisphenol A.

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What is Bisphenol A?

Bisphenol A is an industrial chemical formed by an acidic reaction between acetone and phenol. It is a polycarbonate plastic that is easily molded, temperature resistant, impact resistant, and highly transparent. These properties make it a top choice in the plastics world, including use in injection molding and extrusions. It is also used in epoxy resins. Global production of this chemical was estimated to be three billion kilograms in 2003 alone, including approximately one billion kilograms in the United States.

Bisphenol A is found in a range of consumer products, including baby bottles, water bottles, food storage containers, plastic tableware, plastic toys, iPods and Mac computers, eyeglasses, CDs and DVDs, hockey helmets and other sports equipment, car headlights and bumpers. It is also used as a protective coating in metal food and beverage containers, including infant formula containers. Medical applications include dental sealants, blood oxygenators, incubators and respirators.

Bisphenol A has been found in groundwater, surface water, wastewater, sewage and other open environments despite rapid degradation in oxygenated environments, suggesting that the chemical is so widespread as to create a constant environmental presence. It is acutely toxic to aquatic organisms.

The primary human concern presented by bisphenol A is not from direct contact, but from leaching. Bisphenol A may leach from food and beverage containers and other consumer products into food, which is then ingested. For instance, babies drinking infant formula from baby bottles may be exposed to bisphenol A after it leaches into the formula from the original container, as well as leaching from the baby bottle into the formula as the baby is being fed. The chemical leaching may be promoted by hot liquids in the baby bottle, or by heating the baby bottle itself. Although dietary intake is the main source of exposure, other human exposures may arise from ambient air, drinking water, soil and dust.

Bisphenol A has been in the news for the past several years, ever since molecular biologist Patricia Hunt of Case Western Reserve University performed a study on mice entirely unrelated to plastics or bisphenol A. In her study, the control group mice cells showed a huge spike in chromosomal abnormalities. The abnormalities were traced to degrading plastic in the mice cages after the cages were cleaned and replaced with fresh material (*Current Biology*, April 2003). Professor Frederick vom Saal of the University of Missouri at Columbia has since performed extensive research on the chemical, determining that low doses of exposure to bisphenol A during egg cell or fetal development, or in early life, can have profound physical impacts. Bisphenol A is now considered by some scientists to be an endocrine disrupter, potentially interfering with human hormone functions including egg cell production, reproductive organ processes and fat cell development. The U.S. National Toxicology Program issued a statement in April 2008 expressing "some concern" regarding bisphenol A's effects on the mammary gland, prostate gland and its possible acceleration of female puberty.

On September 16, 2008, the Journal of the American Medical Association published a new study titled "Association of Urinary Bisphenol A Concentration with Medical Disorders and Laboratory Abnormalities in Adults," led by author Iain Lang, Ph.D., of the United Kingdom. This study of 1455 adults conducted in 2003 and 2004 found statistically significant associations between high urinary bisphenol A concentrations and adult heart disease and diabetes. Release of the study coincided with an FDA scientific advisory committee hearing during which FDA senior scientist Laura Tarantino testified that the current allowable exposures are sufficient to protect adults, children and infants based on mice and rat studies previously conducted.

For the legal community, bisphenol A has already resulted in significant

litigation. Cases are pending in at least seven states, not yet including Oregon, against manufacturers and retailers of plastic baby bottles and water bottles. A motion for centralization to the Judicial Panel on Multidistrict Litigation was heard on July 31, 2008. *See* MDL No. 1967, *In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation*. The panel granted the motion for centralization, and now all federal litigation involving bisphenol A is consolidated in the Western District of Missouri. Separately, the California legislature is considering a law limiting bisphenol A to trace amounts in products for children under age three.

The issue has also reached mass media. NBC's Today Show aired a consumer alert on April 9, 2008, warning against plastics and bisphenol A. On April 22, 2008, *USA Today* ran an editorial entitled "'Everywhere chemical' warrants more scrutiny," calling for more government study and regulation of bisphenol A.

There are at least three distinct perspectives on bisphenol A, from government regulators, the plastics and chemical industries, and consumer advocates.

Government Perspectives

On November 29, 2006, the European Food Safety Authority (EFSA) adopted an opinion on bisphenol A, finding that the No Observable Adverse Effect Level (NOAEL) for bisphenol A was 5,000 micrograms per kilogram of bodyweight per day (µg/kg bw/day). However, it also increased the Tolerable Daily Intake from 10 µg/kg bw/day, adopted in 2003, to 50 µg/kg bw/day. The five-fold increase in the Tolerable Daily Intake was based on additional repeated-dose toxicity studies in rodents as well as new comparisons of toxicokinetics in primates and humans versus rodents. In other words, the EFSA obtained more data on toxicity and also obtained data suggesting that humans process more and retain less bisphenol A than rodents. The EFSA estimated that the conservative average bisphenol A dietary exposure for a three-month old infant consuming formula in a bisphenol A bottle is 11 µg/kg bw/day. Infant exposure peaks at 13 µg/kg bw/day for a six-month old infant consuming formula from a bisphenol A bottle and commercial food and beverages. A one and a half year old consuming two kilograms of commercial food and beverages is exposed to 5.3 µg/kg bw/day of bisphenol A, while an adult consuming three kilos of commercial food and beverages is exposed to 1.5 µg/kg bw/day. Based on the EFSA findings, infant exposure exceeded the 2003 Tolerable Daily Intake, but reaches just 26% of the updated Tolerable Daily Intake.

Health Canada's investigation and conclusions were significantly different than the EFSA. In Health Canada's April 18, 2008 report, it found that bisphenol A was a danger to human life and health, and specifically infants. The draft screening assessment stated that the chemical "causes concern for human fertility based on sufficient evidence of reproductive toxicity in experimental animals." Additionally, the draft assessment stated that "[limited] studies provide evidence that exposure to bisphenol A during gestation and early postnatal life may be affecting neural development and some aspects of behaviour in rodents." Human exposure estimates range from 0.08 to 4.30 µg/kg bw/day, including average newborn (0-1 month) exposure estimated at 0.50 µg/kg bw/day with a maximum exposure of 4.30, and infant (12-18 month old) exposure estimated at 0.27 µg/kg bw/day with a maximum exposure of 1.75. Based on these exposure rates, Health Canada recommended that plastic baby bottles containing the chemical be removed from the marketplace and that infant caregivers cease using them. Health Canada also began working with the manufacturers of infant formula to eliminate the chemical from all formula containers. The review was conducted as part of Health Canada's 2006 Chemicals Management Plan, a priority review of approximately 200 chemicals and additional reviews on many more chemicals used in industrial and consumer applications. Bisphenol A was one of the first chemicals for which Health Canada took steps to limit human exposure.

In the United States, the National Toxicology Program, a part of the National Institutes of Health, issued a draft brief on April 14, 2008, declaring that "FDA-regulated products containing BPA currently on the market are safe and that exposure levels to BPA from food contact materials, including for infants and children, are below those that may cause health effects." This conclusion was based on findings of the EFSA's Scientific Panel on Food Additives and the Japanese National Institute of Advanced Industrial Science and Technology. At this same time, the FDA formed a task force to study bisphenol A in all FDA-regulated products. This was done in response to the National Toxicology Program's draft brief and the contradictory Health Canada draft screening assessment. In June 2008, the FDA set up a subcommittee of its Science Board to assess bisphenol A. The subcommittee is currently holding meetings, reviewing the task force's report, delivered preliminary findings, but has not yet released a final report.

Notably, the National Toxicology Program's draft brief found that bisphenol A may possibly affect human reproduction and early development, stating "[a]lthough there is no direct evidence that exposure of people to bisphenol A adversely affects reproduction or development, studies with laboratory rodents show that exposure to high dose levels of bisphenol A during pregnancy and/or lactation can reduce survival, birth weight and growth of offspring early in life, and delay the

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onset of puberty in males and females." The NTP went on to state, "[i]n addition to effects on survival and growth seen at high dose levels of bisphenol A, a variety of effects related to neural and behavior alterations, precancerous lesions in the prostate and mammary glands, altered prostate gland and urinary tract development, and early onset of puberty in females have been reported in laboratory rodents exposed during development to much lower doses of bisphenol A that are more similar to human exposures." The NTP found that the limited human studies supported a finding of hormonal effects due to bisphenol A. It estimated human exposure to bisphenol A is 0.0008-1.5 µg/kg bw/day in adults, 0.043-14.7 µg/kg bw/day in toddlers and children up to 6 years old, 1.65-13 µg/kg bw/day in infants age 6-12 months, and 1-11 µg/kg bw/day in formula-fed infants age 0 to 6 months.

In 2004, the Centers for Disease Control and Prevention's biomonitoring study found that 95% of Americans had bisphenol A in their urine.

Industry Position

The plastics industry, specifically the Polycarbonate/BPA Global Group, consisting of the American Chemistry Council (ACC), PlasticsEurope and the Japan Chemical Industry Association, finds Bisphenol A perfectly safe for humans.

One of the American Chemistry Council's websites, www.bisphenol-A.org, states:

> "For decades, polycarbonate plastic has been safely used to make baby bottles and reusable water bottles. The safety of these products has been supported by numerous science-based safety evaluations of bisphenol A that have been conducted by independent government and scientific bodies worldwide… In spite of this strong scientific support, numerous myths, misinformation and scare stories about polycarbonate bottles continue to circulate."

The American Chemistry Council points to several studies which support its position. First is a 1982 study conducted by the NTP. This study, which involved feeding rats and mice a diet of various levels of the chemical, concluded that bisphenol A increased the incidence of leukemias, lymphomas, interstitial-cell tumors of the testes, but not to a statistically significant level after adjusting for survival differences amongst the rodents and known high incidence rates of some of these conditions. The industry group's website does not address the April 14, 2008 NTP's draft brief, discussed above.

Another study cited is from the Harvard Center for Risk Analysis, and was published in 2004 in *Human and Ecological Risk Assessment*. This study was a "study of studies" conducted before 2002 on low-dose exposure to bisphenol A, and concluded that "at this time, effects at very low oral doses have not been reliably established in multiple strains or species." The study was based on bisphenol A exposures at well *below* the Lowest Observed Adverse Effect Level of 50 µg/kg bw/day previously determined by the U.S. Environmental Protection Agency.

Still another study cited is from Japan's National Institute of Health Sciences and was published in 2002, in *Reproductive Toxicology*. This was another low-dose study, this time a two-generational study on reproductive systems, based on rat exposures of 0.2, 2, 20 and 200 µg/kg bw/day. The authors concluded that the only observable effects of bisphenol A exposure on rats at these levels were anogenital distance per cube root of body weight ratio changes in males and females. The changes, however, were not statistically significant.

The only pharmacokinetics study cited on the website was sponsored and conducted by Dow Europe, Dow Chemical Company and Shell Chemical Company, and published in 2000 in *Toxicological Sciences*. Additionally, the website cites two studies performed by GE Plastics supporting safety in human reproductive health.

On a separate website, the American Chemistry Council takes a different approach to supporting bisphenol A. On the website www.factsonplastic.com, the ACC responds to each news publication, study or government report relating to bisphenol A, and refutes all negative information about the chemical. The ACC's activity includes a letter response to the Today Show's consumer alert; blogs in response to *USA Today*'s editorial; letters to the FDA; and a declaration that NTP's April 14, 2008 draft brief found "no serious or high level concerns for adverse effects of bisphenol A on human reproduction and development."

Separately, the American Plastics Council's Polycarbonate Business Unit points to industry-funded studies to support its position that bisphenol A is safe. The Council specifically cites a July 2002 study, funded by the Society of the Plastics Industry and published in *Toxicological Sciences*, which concluded that a three-generation, low-dose rat study found no effect on reproduction or development.

Consumer Perspective

In *National Geographic*'s The Green Guide, it states:

> "[I]f you consume canned soups, beans and soft drinks …, you also may be swallowing residues of a controversial chemical called bisphenol A (BPA) that can leak out of the can linings into your food. … Depending on whom you talk to, BPA is either perfectly safe or a dangerous health risk. The plastics industry says it is harmless, but a growing number of scientists are concluding, from some animal tests, that exposure to BPA in the womb raises the risk of certain cancers, hampers fertility and could

contribute to childhood behavioral problems such as hyperactivity."

The Center for Health, Environment & Justice has an active campaign against bisphenol A, calling for an immediate moratorium on the use of bisphenol A in plastic baby bottles and other food and beverage containers. The group cites vom Saal's findings to support their position.

The Environmental Working Group has actively opposed bisphenol A at state and national levels. The group's March 5, 2007 report found that, "[o]f all the foods tested, chicken soup, infant formula and ravioli had BPA levels of highest concern. Just one to three servings of foods with these concentrations could expose a woman or child to BPA at levels that caused serious adverse effects in animal tests."

Healthy Child Healthy World published a five-step program for healthy children. Step five recommended being wise with plastics. It stated "[s]ome petroleum-based plastics leach harmful chemical into foods and drinks, especially when plastic comes in contact with oily or fatty foods, during heating or microwaving, as a result of harsh cleaners, and when exposed to excessive moisture." The organization stated there are studies linking bisphenol A and other plastics to harmful effects in children.

Conclusion – or Lack Thereof

Everyone agrees that humans are exposed to bisphenol A by consuming commercial food and beverages. The effects and risks of bisphenol A remain in dispute. Consumer groups and some governmental agencies regard the chemical as potentially toxic to at least some humans, particularly infants. Industry groups and other governmental agencies conclude that infants and adults are exposed to levels of bisphenol A that do not pose a risk to human health. Most agree that more research is needed. Those concerned with human and reproductive health and development are waiting for a definitive answer. Meanwhile, more litigation is inevitable.

In response to the growing discussion and concern, many consumer product manufacturers are voluntarily eliminating the chemical from their products. Nalgene reusable water bottles and Camelbak water bags for backpacks are being offered in bisphenol A free versions. Glass baby bottles are now advertised as the preferred choice compared to bisphenol A-containing plastic bottles. Bisphenol-A-free sippy cups, teethers, and food storage containers are advertised on several eco-mom websites such as Cool Mom Picks and SafeMama. The marketplace is catching on to bisphenol A as a marketing tool. In this respect, the state of the science may not matter if public and consumer opinion turns against the chemical.

The Statute of Ultimate Repose: Still Viable at 40?

By Meagan Flynn, Preston Bunnell & Flynn LLP

While many Oregonians continue to use products, such as vehicles, appliances or machinery, that were purchased more than a decade ago, Oregon law has long barred individuals injured by a defect in these older products from bringing a civil action against the manufacturer or seller, so-called statutes of ultimate repose. First, the 1967 legislature adopted ORS 12.115(1), a ten-year statute of repose[1] for "any action for negligent injury to person or property," which the Supreme Court construed as extending to actions based on strict product liability as well as negligence. Or Laws 1967, c. 406, § 2; *Johnson v. Star Machinery Co.*, 270 Or 694, 709, 530 P2d 53 (1974). Then, the 1977 legislature expressly barred actions for harm from a defective product when the product is more than eight years old at the time of the harm. ORS 30.905(1).[2] As the Supreme Court has explained, there are important policy concerns often cited as justifying statutes of repose, including "the lack of reliability and availability of evidence after a lapse of long periods of time" and "allowing people, after the lapse of a reasonable time, to plan their affairs with a degree of certainty, free from the disruptive burden of protracted and unknown potential liability." *Johnson v. Star Machinery*, 270 Or at 700-701. But policy concerns are not generally a matter for the courts; the question for the courts is whether such statutes are consistent with the protections guaranteed by the Oregon Constitution.

After four decades of statutes of repose, a lawyer encountering a case of harm from an older product might assume that all questions of constitutional validity were long ago resolved. And a search of the existing case law would, indeed, reveal that the Oregon Supreme Court repeatedly sustained the statutes of repose against constitutional challenges. But there is reason to doubt that the answer would be the same today. In *Smothers v. Gresham*

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