



## BPA, PHTHALATES, AND THE LAW

American manufacturers produce and use millions of pounds of Bisphenol A (“BPA”) and phthalates annually. These versatile organic compounds are used in a broad range of industries and products, including food and beverage containers, children’s toys, child-care items, medical devices, personal care items, and household items.

BPA and phthalates have received much attention in recent years and have practically become household names. This “celebrity” has occurred in large part due to media attention given to the concerns of environmentalists about the potential health effects of low-level exposure to BPA and phthalates. The story makes good headlines: High production volume chemicals, used in children’s products and throughout the food industry, are found in measurable quantities in children and adults and have been associated statistically in population studies with adverse health effects.

Of course, the headline is not as black and white as the media makes it sound. Nonetheless, the

argument for more regulation, higher penalties, and outright bans on the use of BPA and certain phthalates has gained considerable momentum. Attention has focused on the use of phthalates in toys and other childcare products and the use of BPA in food packaging and baby bottles, despite the fact that these chemicals have been used for many years without any reports of actual harm to children. Yet, lawmakers at the federal, state, and local levels have embraced the opportunity to use legislative powers to address BPA and phthalates usage to keep our children “safe.” Adult exposure to low-level BPA and phthalate exposure has reportedly been linked to common diseases such as diabetes, cancer, and obesity, but support for these links has yet to gain traction. But, given the regulatory climate, industries other than those that focus on children’s products and food and beverage packaging may be more closely scrutinized in the near future.

Some have called for the regulation of chemicals in the U.S. to shift toward the European precautionary

approach.<sup>1</sup> Current U.S. law typically requires manufacturers to perform “reasonable testing” of products, such as children’s beverage containers, before releasing them into the stream of commerce. A reasonable testing program is a set of procedures that are employed to provide reasonable certainty that products are in compliance with all applicable rules, bans, and standards that have been established to maintain consumer safety under reasonable use conditions, even when the products may contain chemicals that, under some other circumstances, may present a potential health risk. The precautionary approach, as epitomized by the Precautionary Principle, goes much further by dictating action whenever there *may* be a threat to human health, even if a causal relationship has not been scientifically established.<sup>2</sup> In other words, the burden shifts to prove that a chemical product is safe and not unsafe before it can be marketed, rather than withholding a product when it has been shown to be unsafe.

The Precautionary Principle presents a considerable challenge to responsible industries and policymakers alike, since most chemicals may pose a threat to human health under certain circumstances and that risk might not appear for some considerable time. Given that most chemicals do not have a demonstrated causal relationship with human injury, the question of what chemicals to regulate (and at what concentration and in what products) should be answered in the context of risk assessment and basic toxicological principles, such as bioavailability, dose, exposure duration, and species differences. But, even when these concepts are considered, there is no guarantee that the political and regulatory answer will be evidence-based.

This was apparently the case when Congress recently took a precautionary approach to the regulation of certain phthalates in the 2008 Consumer Product Safety

Improvement Act (“CPSIA”), which authorized the Consumer Product Safety Commission (“CPSC”) to regulate phthalates. As discussed below, the CPSC chose to regulate six phthalates, five of which were previously determined to be safe at current levels. Similarly, the Food and Drug Administration (“FDA”), having regulatory authority for some products currently in the crossfire, has been charged to review, yet again, its determination issued in 2008 that BPA is safe at current levels.

As more regulatory standards are established, manufacturers are at greater risk of running afoul of a concentration limit or a duty to warn for those products that continue to include the regulated substances. Close attention to good manufacturing standards and increased diligence in quality control will help to prevent violations. But, in the event that a standard is exceeded, having established procedures in place for promptly identifying and containing the noncompliant product, and recalling it if necessary, go far to minimize the potential damage from product liability suits that will likely be filed. In addition to product liability suits, other types of litigation could arise from a violation of a standard, including actions brought by the state attorneys general (“AGs”)<sup>3</sup> or pursuant to California’s Proposition 65 (“Prop 65”) (the Safe Drinking Water and Toxic Enforcement Act of 1986), a law that requires warning labels if products contain a listed chemical. Careful consideration and formulation of a plan before a violation occurs provides important damage control for all these types of actions.

Another key to successfully meeting litigation challenges that can occur in the wake of a recall involves understanding the potential impact of exceeding a standard. Contrary to what the plaintiffs’ bar will allege, exceeding a standard does not mean that the product is a dangerous health hazard. Knowing how to assess the real risks posed, if any, can alleviate the burden of a noncompliant product and can

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1 The earliest application of what is now known as the “Precautionary Principle” is rooted in the environmental policies of the 1970s in Germany. Thereafter, it spread throughout Europe and was adopted in numerous international environmental policies, such as the Rio Declaration from the 1992 United Nations Conference on Environment and Development.

2 “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.” *Wingspread Statement, January 1998*.

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3 Some statutes, like the CPSIA, grant AGs the power to bring suits on behalf of their states when a violation of the statute is alleged. 15 U.S.C. § 2073(b) (“The attorney general of a State, or other authorized State officer, alleging a violation of [the CPSIA] that affects or may affect such State or its residents may bring an action on behalf of the residents of the State in any United States district court for the district in which the defendant is found or transacts business to obtain appropriate injunctive relief.”).

underscore the likely tenuous nature of individual plaintiff suits, class actions, and suits brought by AGs or under Prop 65. And, of course, there is no substitute for taking action before a potential recall event occurs or a product liability suit is filed; companies should review and, if necessary, renegotiate their insurance coverage to ensure that a potential recall scenario or products claim would be covered.

An overview of some of the current relevant scientific, regulatory, and litigation issues regarding BPA and phthalates follows.

## BISPHENOL A

BPA is a primary component in polycarbonate plastic used to make the plastic harder and more resilient. Polycarbonate plastics are used for a host of consumer products, including plastic beverage containers, water bottles, baby bottles, food storage, sippy cups, sports equipment, DVDs, CDs, and eyeglass lenses. BPA is also found in epoxy resins that line the inside of metallic cans used for storing food and liquids, including baby formula.

**BPA—Scientific Studies.** The health effects of BPA have been studied extensively for years. Interest in BPA stems in part because BPA is used in many children's products. Interest in BPA is also keen because it has been characterized as an endocrine disruptor, meaning that it may interfere with normal development of the reproductive system and other hormonally mediated systems.

BPA ingestion occurs primarily through oral exposure. Polycarbonate bottles can leach small amounts of BPA into the liquid they contain. And, BPA can leach from the liner of metal food and drink cans into food and liquids. All U.S. manufacturers of canned baby formula also use BPA-based linings that can leach BPA into the formula. Microwaving plastic containers to heat food is another possible exposure pathway, although it is generally recognized that the levels of BPA that could leach from hard plastics is low. Nonetheless, consumer groups recommend avoiding the use of plastic containers to heat food, especially for young children. Recent evidence from the National Health and Nutrition Examination Survey ("NHANES III") conducted by the

Centers for Disease Control and Prevention ("CDC") found detectable levels of BPA in most people six years and older who were tested.

Once in the body, BPA can bind to estrogen receptors, although its binding affinity is orders of magnitude lower than that of endogenous estrogen. Controversy arises because evidence that a compound can have a certain effect in the body under certain circumstances is a far cry from establishing that the compound does affect the body at levels likely to be encountered from the typical low-level oral or dermal ingestion that occurs, for example, through leaching. Basic toxicological principles of dose, duration, and species extrapolation lie at the heart of the debate.

BPA's low estrogenic potency, combined with the low level of human exposure, has traditionally been interpreted to indicate little to no risk of human health effects from BPA exposure. Recent reviews of risks associated with low-level exposure to BPA by the FDA (2008) and experts at the Harvard Center for Risk Analysis (2004) found no consistent evidence for BPA-related health effects, supporting the safety of current low levels of human exposure to BPA. But, in 2008, the National Toxicology Program ("NTP") at the National Institutes of Health ("NIH") evaluated BPA and concluded that there was a basis for concern.

NTP reports are not quantitative assessments but instead evaluate the adverse effects and toxicity of a substance according to five "levels of concern." These levels range from "serious concern" (the substance causes reproductive/developmental effects in humans or in laboratory animals under typical human exposure conditions) to "negligible concern" (there is good evidence that the substance under evaluation is not a reproductive or developmental toxicant). The NTP report concluded that there was "some concern" that BPA exposure in fetuses and infants could possibly affect brain and prostate health. But, for every other aspect of human BPA exposure, the NTP concluded that there was only "minimal" or "negligible concern." An NTP finding of "some concern" indicates the need for more research (and indeed, the studies reviewed by NTP provide only limited evidence for adverse effects on development), and more research is needed to better understand implications for

human health.<sup>4</sup> Nonetheless, media characterization of the NTP report led to public concern and a flood of regulatory and litigation activity.

On January 15, 2010, the FDA, under tremendous political pressure, issued an official update expressing “some concern about the potential effects of BPA on the brain, behavior and prostate gland of fetuses, infants and children.”<sup>5</sup> However, the FDA report noted that there was no evidence that BPA was unsafe. The Department of Health and Human Services—through the CDC, NIH, and the FDA—is investing more than \$30 million in new health studies in both animals and humans to better determine and evaluate the potential health effects of BPA exposure. These studies, involving rodents and nonhuman primates, will focus on the metabolic impact of oral versus intravenously administered BPA, the effect of oral BPA ingestion on the prostate and mammary glands, and at what, if any, dose point BPA may negatively affect behavioral and neuroanatomical development. The results of this new research are expected to be released in approximately two years.

When the FDA report of this research does become available, it is likely to evoke a media response similar to that prompted by the NTP report. In the meantime, those in favor of more stringent regulations of BPA will continue to point to anecdotal studies—for example, a recent *Consumer Reports* article advocating the avoidance of all canned foods due to the presence of leached BPA<sup>6</sup>—and dismiss studies that attest to the safety of low-level BPA exposure as the product of industry bias.

**BPA Regulation.** The FDA has never established an acceptable daily intake (“ADI”) for BPA exposure for use as a food

additive. In the 1980s, the FDA set a low-exposure safety threshold for BPA of 50 micrograms per kilogram of body weight per day (“µg/kg/day”). BPA opponents have recently challenged this threshold. They claim that even very low-level exposure to BPA poses a serious risk to human health, particularly if exposure occurs *in utero* or during the first 12 months of life. In 1993, the U.S. Environmental Protection Agency (“EPA”) published a reference dose (“RfD”) of 0.05 µg/kg/day for BPA, a dose considered safe for humans even with daily exposure over a lifetime. The CPSC does not currently regulate BPA. Even in the recently enacted CPSIA, the CPSC did not include regulation of BPA in toys or children’s products. (See discussion of phthalates below for more on the CPSIA.) However, government regulators and legislators are now being pressured to reevaluate the potential low-dose effects of BPA. In fact, efforts are underway to ban the use of BPA in a variety of products.

**Federal Regulation:** Four bills banning or severely limiting the use of BPA were recently considered by Congress. The most restrictive of the proposed bills, the Ban Poisonous Additives Act of 2009, would prohibit the use of BPA in all food and beverage containers manufactured, distributed, or offered for sale in the United States. Other proposed federal legislation would ban the use of BPA in all food and beverage containers designed for children three years of age or younger and require the Secretary of Health and Human Services to certify the safety of BPA or take action to ban its use.

**State and Local Regulation:** In 2009, Minnesota and Connecticut enacted anti-BPA legislation that becomes fully effective in 2011. The Minnesota law bans the use of BPA in beverage containers intended for use by children three years of age or younger. The Connecticut law prohibits the use of BPA in all infant formula containers or baby food jars and all reusable food and beverage containers. Both laws apply to manufacturers, wholesalers, and distributors.

As recently as January 25, 2010, the House in Washington State passed a bill (H.B. 1180) by a vote of 95–1 that would ban the manufacture and sale of BPA in sports water bottles and food and beverage containers used by children, such as baby bottles. Proposed penalties could be substantial. Manufacturers, retailers, or distributors who knowingly distribute products containing BPA would be subject to a civil

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4 For additional discussion of BPA science, see podcast, “Are Plastic Products Safe? An Overview of the Science,” <http://getbetterhealth.com/are-plastic-products-safe-an-overview-of-the-science/2009.12.01> and “Science Suppressed: How America Became Obsessed with BPA,” [http://stats.org/stories/2009/science\\_suppressed\\_BPA\\_intro\\_jun12\\_09.html](http://stats.org/stories/2009/science_suppressed_BPA_intro_jun12_09.html).

5 “Update on Bisphenol A for Use in Food Contact Applications,” U.S. Food and Drug Administration, January 2010, <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM197778.pdf>.

6 “Concern Over Canned Foods,” <http://www.consumerreports.org/cro/magazine-archive/december-2009/food/bpa/overview/bisphenol-a-ov.htm>.

penalty of \$5,000 for the first offense and \$10,000 for subsequent offenses. Other states, such as California, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Jersey, New York, and Vermont, all have anti-BPA legislation pending or under consideration. Even some local municipalities, such as the City of Chicago and Suffolk County, New York, have enacted BPA bans.

California's Prop 65 does not apply to BPA. However, on July 15, 2009, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment ("OEHHA") received a petition from the Natural Resources Defense Council ("NRDC") asking that OEHHA initiate the process for listing BPA as a reproductive toxicant under Prop 65. The OEHHA listing process takes time, and the outcome is uncertain. However, it would be wise for manufacturers potentially affected by a BPA listing to start to consider the potential implications now, if they have not done so already.

**Self-Regulation:** Toys R Us/Babies R Us and Wal-Mart have voluntarily removed infant and childcare products containing BPA from their shelves. Baby-product manufacturers Gerber, Evenflo, Avent America, Dr. Brown's, Disney First Years, Playtex Products, and bottle manufacturer Nunc Nalgene have stopped using BPA in their products.

**BPA Litigation.** In 2008, the American Association of Justice ("AAJ") formed a Bisphenol-A/Phthalates Proposed Litigation Group. With the AAJ's assistance, a class action was filed in a federal district court in Missouri against several baby bottle and infant formula manufacturers over the use of BPA in food and beverage containers and as a sealant component in canned infant formula.

In that class action, *In re: Bisphenol A (BPA) Polycarbonate*, 571 F. Supp. 2d 1374 (J.P.M.L. 2008), the plaintiff consumers argued that the use of BPA in various baby products constitutes a material fact that the defendant manufacturers failed to divulge in violation of various state consumer protection laws. The plaintiffs are not claiming any personal or bodily injury due to BPA exposure. Instead, plaintiffs are arguing that they have suffered an economic injury because they would not have purchased the products at issue had they known of the presence of BPA. Plaintiffs' claims for

fraudulent/negligent omissions, breach of implied warranties, and unjust enrichment against the bottle manufacturers have survived several motions to dismiss. The case is proceeding through discovery.

While *In re: Bisphenol A* involves failure to warn issues where the plaintiffs seek economic and punitive damages but have not yet alleged any health effects, presumably the litigation will involve the issue of BPA science and the difficulties involved in establishing general and specific causation. The widespread detection of BPA in the U.S. population and the ubiquitous nature of the diseases reportedly linked to BPA provide fertile ground to contrive a mass tort suit.

**BPA Liability and Insurance Coverage.** In *Medmarc v. Avent*, 653 F. Supp. 2d 879 (N.D. Ill. 2009), a federal district court found that Medmarc had no duty to defend its policy holder Avent, a defendant in *In re: Bisphenol A*. The court reasoned that because the plaintiffs in *In re: Bisphenol A* were not claiming any bodily injury for a specific use of Avent's products, the plaintiffs' claims were not covered under Avent's Comprehensive General Liability ("CGL") policy's insuring language.

In light of *Medmarc*, a recent post on [PlasticsNews.com](http://PlasticsNews.com) reported the likely refusal of insurers to cover litigation costs of manufacturers who use BPA in their products.<sup>7</sup> Insurers will argue that suits that fail to allege bodily injury, such as *In re: Bisphenol*, are simply not covered under the typical CGL policy.

## PHTHALATES

Phthalates are a group of chemicals called "plasticizers" that are used to make plastics, like polyvinyl chloride, softer and more flexible and durable. They also are widely used as adhesives and solvents. Phthalates are used in a wide variety of products: children's toys; modeling clay; medical devices, e.g., catheters and transfusion tubing; home products, e.g., shower curtains and hoses; food packaging; personal care products, e.g., nail polish, eye shadow,

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<sup>7</sup> "Surging Legal Action Over BPA Targets Manufacturers," <http://plasticsnews.com/headlines2.html?id=i7093>.

and hairspray; paints; adhesives; packaging materials; pharmaceuticals; and vinyl upholstery.

**Phthalates—Scientific Studies.** The media tends to treat all phthalates as if they were the same compound. In fact, phthalates are a group of chemicals with similar chemical structure but each with its own unique chemical and toxicological profile. Any discussion of potential health effects must distinguish between specific phthalates.

The potential health effects of phthalates have been well studied and are the subject of numerous reviews. The NTP published extensive reports on the reproductive and developmental effects of seven phthalates: Bis(2-ethylhexyl) phthalate (DEHP), Benzylbutyl phthalate (BBP), Dibutyl phthalate (DBP), Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and Di-n-octyl phthalate (DnOP). The NTP found that only one, DEHP, presented a serious concern to human reproduction or development under one very specific condition: possible adverse effects on the developing reproductive tract of male infants exposed to high concentrations through medical procedures using phthalate-containing equipment such as intravenous bags and tubing.

Aside from the isolated DEHP situation, the remaining phthalates studied typically were determined to be only of “some concern” or “negligible concern” for routine phthalate exposure. The NTP reports also found that the mouthing of toys containing phthalates did not expose children to sufficiently high levels of exposure to warrant toxicity warnings.<sup>8</sup>

Some phthalates have been found to interfere with normal sexual development in male rats at doses significantly higher than those typically experienced by humans. These reproductive and developmental effects, and others reported to be associated with phthalate exposure, have not been borne out in humans. The effects seen in laboratory animals may not be relevant given species differences in metabolism and other factors.

Phthalates are thought to enter the body primarily through ingestion. As plastics degrade, phthalates may be released.

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8 “Toy Tantrums—The Debate Over the Safety of Phthalates,” [http://www.stats.org/stories/toy\\_tantrums\\_jan30\\_06.htm](http://www.stats.org/stories/toy_tantrums_jan30_06.htm).

Oral exposure may occur, for example, if phthalates in packaging leach into food and liquids, or from mouthing plastic objects such as toys and ingestion of medications. Other less likely routes of exposure include dermal exposure, e.g., personal care products, and in medical settings, e.g., systemically from intravenous tubing.

The toxicity in animals and the widespread use of phthalates have raised concerns regarding potential human exposure. Within the last 10 years, NHANES and other studies have collected data to determine the concentration of phthalates in humans. These studies indicate relatively widespread human exposure to low levels of various phthalates. Some scientists and consumer groups have latched onto these data and sounded the alarm about exposure to even low levels of phthalates. The detection of phthalates in the body, however, is not synonymous with a human health effect.

Concern that even very low-level exposure can lead to developmental and reproductive toxicity in humans, as heralded in the media, is not supported by the predominance of the literature. The media, ever in search of a good story line, tends to cherry-pick those studies that purport to establish a causal link between phthalate exposure and harm to children. For example, in the so-called “Swan study,” Swan *et al.* claimed to show that *in utero* exposure to phthalates caused a shortening of the anogenital distance (“AGD”) in male infants, which is purportedly correlated with abnormal sexual development.<sup>9</sup> While trumpeted in the media, opposing scientists immediately attacked the Swan study in the very journal that published it.<sup>10</sup> Swan’s scientific critics noted that all male infants in the study appeared normal and that the use of AGD as a metric for sexual development is itself controversial. Swan’s critics also observed that the level of maternal phthalate exposure in the study was many magnitudes lower than the exposures at which phthalates have been found to interfere with sexual development in male rodents. They concluded: “It is biologically and

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9 “Decrease in Anogenital Distance among Male Infants with Prenatal Phthalate Exposure,” *Environmental Health Perspectives* (2005), <http://ehpnet1.niehs.nih.gov/members/2005/8100/8100.html>.

10 “Validity of Anogenital Distance as a Marker of *In Utero* Phthalate Exposure,” *Environmental Health Perspectives* (2006), <http://ehp.niehs.nih.gov/docs/2005/8688/letter.html#lett>.

toxicologically inconceivable that such low levels of human exposure would produce the significant structural differences claimed by Swan *et al.*<sup>11</sup> As in the case of BPA, the media unfortunately ignores the many studies showing the safety of phthalates even at exposure levels much higher than those encountered, for example, through the mouthing of toys.<sup>12</sup>

**Phthalate Regulation.** Despite the general lack of scientific support for low-level effects of phthalates, their widespread use, demonstrated exposure, and possible effects on children created a perfect storm for media attention. The spotlight the media placed on the presence of phthalates in toys, not unlike BPA in baby bottles, alarmed parents. Legislators quickly responded at both the federal and state levels. Ironically, most legislation only applies to toys and childcare products, a minimal route of exposure according to NTP reports. Yet, despite no reported case alleging harm, the current climate continues to reflect concerns about the potential health effects of phthalates, especially when used in children's products.

**Federal Regulation:** Although phthalates have been used in toys and baby care items for many years, the CPSC only recently enacted regulations governing the use of phthalates. The 2008 CPSIA regulates the use of six phthalates (BBP, DEHP, DBP, DINP, DIDP, and DnOP). As of February 10, 2009, it became unlawful to manufacture, sell, offer for sale, distribute in commerce, or import into the United States any "children's toy" or "childcare article" if the product contained any of the regulated phthalates at concentrations greater than 0.1 percent by weight. The Act defines "children's toy" as a product designed or intended by the manufacturer for use by a child 12 years of age or younger during play. A "childcare article" is a product designed or intended by the manufacturer for use by a child three years of age or younger to facilitate sleeping, eating, sucking, or teething.

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11 *Id.*

12 For example, a longitudinal study published the year before Swan *et al.* found no toxicological effects in adolescents who had been exposed to very high levels of DEHP as newborns via oxygenation tubing. See "Follow-up Study of Adolescents Exposed to di(2-Ethylhexyl) Phthalate (DEHP) as Neonates on Extracorporeal Membrane Oxygenation (ECMO) Support," *Environmental Health Perspectives* (2004), <http://ehpnet1.niehs.nih.gov/members/2004/6901/6901.html>.

The Act permanently regulates three phthalates (DEHP, DBP, BBP) and temporarily regulates three others (DINP, DIDP, DnOP) pending further study by a CPSC-appointed expert panel—the Chronic Hazard Advisory Panel ("CHAP"). CHAP is charged with reviewing the potential effects on children's health of all phthalates and phthalate alternatives for children's toys and childcare products. In doing so, CHAP will consider the cumulative effects of exposure to multiple phthalates from all sources, including personal care products. CHAP will then make a recommendation to the CPSC whether to continue the interim regulation and whether to increase regulation of these or other phthalates, or phthalate-alternatives. There is no deadline for the CHAP report.

The CPSIA preempts contrary state laws but does not prohibit state legislation in areas where the CPSIA remains silent. Enforcement may occur via the federal government or state AGs. Violations of the CPSIA can lead to fines of \$100,000 per occurrence and felony criminal sanctions.

**State Regulation:** More than 20 states are in the process of enacting laws that closely track the CPSIA. Some proposed state laws, such as New Jersey's, would extend the CPSIA's phthalate ban to include cosmetics and jewelry.

California's Prop 65 requires the state to list chemicals known to cause cancer or developmental/reproductive toxicity. Manufacturers of listed chemicals are required to place "reasonable warnings" on product packaging to alert purchasers. Several phthalates have made the Prop 65 list. DEHP was among the first to be listed; BBP, DBP, and Di-n-hexyl phthalate (DnHP) (a phthalate not regulated under the CPSIA) were added soon after the NTP reports were published, and DIDP was added in 2007.<sup>13</sup> To complicate the regulatory compliance issues, the Prop 65-listed phthalates overlap with, but are not identical to, those covered by the CPSIA. For example, DnHP is not a CPSIA-regulated chemical, and DnOP and DINP are not on the Prop 65 list.

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13 State of California, Environmental Protection Agency, Office of Environmental Health Hazard Assessment ("OEHHA"), "Chemicals Known to the State to Cause Cancer or Reproductive Toxicity," February 5, 2010, [http://www.oehha.ca.gov/prop65/prop65\\_list/files/P65single020510.pdf](http://www.oehha.ca.gov/prop65/prop65_list/files/P65single020510.pdf).



**Phthalate Litigation.** To date, the only reported federal litigation involving phthalates is *National Resource Defense Council v. U.S. Consumer Products Safety Commission*, 597 F. Supp. 2d 370 (S.D.N.Y. 2009). The NRDC sued the CPSC in federal district court in New York to challenge a Commission Advisory Opinion Letter stating that the CPSIA phthalate prohibition only applied to products entering commerce after February 10, 2009. In finding for the NRDC, the court ruled that the plain language of the CPSIA did not create an exception for existing inventory. Effective February 10, 2009, the CPSIA applied to all covered products.

At the state level, two California cases deserve mention. Prop 65 warning requirements can be avoided, but the manufacturer has the burden of proving that a listed chemical in its product does not pose a significant risk of cancer or reproductive toxicity to humans. For example, in *Baxter Healthcare Corp. v. Denton*, 15 Cal. Rptr. 3d 430 (Cal. Ct. App. 2004), Baxter, a medical device manufacturer, was able to avoid the warnings requirements by showing that DEHP did not pose a significant risk of cancer in humans due to differences in the biological mechanisms underlying the metabolism in rats. In *ExxonMobil Corp. v. Office of Environmental Health Assessment*, 87 Cal Rptr. 3d 580 (Cal. Ct. App. 2009), the opposite conclusion was reached for a different phthalate. ExxonMobil failed to show that the animal studies implicating DIDP were biologically inapplicable to human beings. The court subsequently upheld the state's imposition of phthalate-warning requirements on ExxonMobil.

Given the CPSIA requirements, any violation of the standard for new products could lead to litigation, particularly in the event of noncompliant levels of phthalates in regulated products. In such situations, even though it is unlikely that physical injury can be proven, the plaintiffs' bar may seek economic damages and medical monitoring, as was the case in some of the recent litigation over recalled toys. Failure to warn cases, like those in *In re: Bisphenol A*, are also possible.

**Phthalate Liability and Insurance Coverage.** There are currently no public legal disputes involving the refusal of insurers to defend or indemnify phthalate claims. As more regulatory standards are established for products that include regulated substances, manufacturers are at greater

risk of running afoul of a concentration limit or a duty to warn, which will increase the risk of product liability lawsuits. Manufacturers and distributors may also be sued for exposures occurring prior to the regulation of those substances. When these lawsuits are tendered to insurers, coverage disputes are inevitable. Key coverage issues will include whether the tort plaintiffs allege an injury that brings the claims within the scope of traditional CGL coverage, allocation of defense and indemnity costs, and the adequacy of the insured's disclosures to its insurers.

## PRACTICAL GUIDANCE

In confronting concerns over BPA/phthalates, manufacturers need to consider proactive steps to neutralize or minimize their product-liability risk. A comprehensive action plan to deal with potential BPA and phthalates liability should analyze four areas: pre-legislative awareness and educational efforts, post-legislative regulatory compliance, preparedness for a voluntary product recall, and anticipating possible BPA or phthalate litigation.

**Pre-Legislative Awareness and Educational Efforts.** At the pre-legislative stage, companies need to consult with experts to get an overview of the scientific and legal terrain. Scientific expertise is essential to understanding and addressing the data that BPA and phthalate opponents are bringing to bear in their proscriptive legislative efforts. Scientific experts can also provide data and analysis to assess any purported causal link between BPA/phthalate exposure and human injury. Scientific experts can also help to inform companies and to present a balanced and well-reasoned discussion of the safety of BPA and phthalates.

Companies may want to monitor ongoing legislative and regulatory efforts at both the federal and state levels to ban the use of BPA and phthalates in various types of manufactured goods. Awareness of state legislative and regulatory efforts is especially important. With BPA, the states themselves are taking the lead. In the case of phthalates, the CPSIA applies to the use of six specific phthalates in childcare products but allows states to go beyond the federal requirements. As noted above, New Jersey is considering a ban on several phthalates in cosmetics and jewelry products.



Once informed, companies, in conjunction with industry associations and trade groups, should be prepared, if advisable, to educate legislators and regulators about the scientifically established safety of BPA and phthalates. Educational efforts aimed at state senates and assemblies can prove particularly effective, as shown by recent events in Oregon. With a 15–15 tie vote, the Oregon State Senate failed to pass Senate Bill 1032, which would have banned BPA in baby bottles and sippy cups as a prelude to banning its use in canned-food sealants.<sup>14</sup> Concerns over the impact of such a ban on Oregon's local food-processing industry spurred several senators to oppose the bill.

**Post-Legislative Regulatory Compliance.** After the passage of legislation but prior to the adoption of final regulatory action, federal and state administrative agencies normally allow time for comment on proposed rules. At this stage, proper expert commentary can play a crucial role in shaping the scope and ultimate impact of a final regulation. Again, reliance on experts allows an informed company to present a fair and well-argued case for regulatory rules that are reasonable and practical in scope and application.

Companies subject to BPA and phthalate legislation also need to build an action plan to comply with relevant statutes and regulations. Pertinent issues include what to do with preexisting inventory, timetables for compliance, and changes needed in product design, manufacturing, labeling, and quality control. In addition, companies should consider the extent to which state regulations may exceed federal regulations and the possibility of industry-specific safe harbors. Companies need to be especially cognizant of any civil and criminal sanctions in the legislation and which federal and state authorities may enforce such sanctions.

A comprehensive BPA and phthalate action plan will also have to address the common law duties of when and how to warn and to test. Legislation is typically not found to

preempt these common law duties. Companies will thus need to take these duties into account as part of their post-legislative regulatory compliance plans.

**Preparedness for a Voluntary Product Recall.** If safety concerns arise about a product, then companies and retailers need to consider their reporting obligations to the CPSC. In instances of a substantiated product-hazard-causing injury, the CPSC may negotiate with the company to institute voluntary recalls. Given the intensive and highly critical media focus on BPA and phthalates, it is prudent for manufacturers to have a recall implementation plan in place should the safety of these substances for particular uses be called into question. In the case of a future voluntary recall, a well-devised plan should enable the affected company to determine the required scope of the recall, identify any affected products, notify the proper insurers and distributors, competently manage recall and replacement efforts, account for the cost of the recall, and institute claims processing procedures. Publicly traded companies will need to analyze reporting obligations under the securities laws and whether to suspend trading when a recall is announced.

In general, products manufacturers should draft a formal policy plan to implement a potential recall involving BPA- or phthalate-containing products. Companies further need to disseminate this policy to key officers and managers and assign a coordinator to guide any future recall efforts. Last, in the event of a recall, companies should consider whether they need to seek the assistance of product liability specialists. These experts can conduct hazard and defect analyses, submit regulatory reports, ensure compliance with the recall plan, manage contact with the media, assist in the preparation for legislative hearings, and carry the company through the voluntary recall process as smoothly as possible.

**Anticipating Possible BPA and Phthalate Litigation.** Possible BPA and phthalate litigation presents several challenges. Any such litigation would likely involve sympathetic plaintiffs, negative publicity, difficult discovery matters, sophisticated scientific questions with regard to toxicology and causation, and complex case management concerns involving multiple cases proceeding simultaneously through state and federal courts. To deal most effectively with such litigation, a company subject to a BPA or phthalate product liability

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14 "Oregon Senate shoots down ban of BPA in baby bottles, sippy cups," [http://www.oregonlive.com/politics/index.ssf/2010/02/oregon\\_senate\\_shoots\\_down\\_ban.html](http://www.oregonlive.com/politics/index.ssf/2010/02/oregon_senate_shoots_down_ban.html). Similarly, in September 2009, the California State Assembly voted down a bill that would have banned the use of BPA in products designed for children under three years of age. A new bill will be up for consideration in 2010. See "Effort to Ban BPA in California Fails," [http://www.sfgate.com/cgi-bin/blogs/sfmoms/detail?entry\\_id=47650](http://www.sfgate.com/cgi-bin/blogs/sfmoms/detail?entry_id=47650).

claim may want to centralize control of the claims management process. Engaging outside counsel with a significant geographic and jurisdictional footprint is normally the most efficient way to achieve centralization. The centralization of the claims management process allows for a consistent and uniform response to claims that greatly aids a host of litigation goals, from coordinating local counsel to “speaking with one voice” to the courts and the media.

Perhaps most importantly, centralizing the claims management process increases the likelihood of identifying and retaining qualified defense experts. The best avenue toward undermining potentially successful BPA/phthalate litigation is to attack plaintiffs’ claims on causation grounds—a strategy requiring well-prepared expert testimony that is consistent from case to case. In the case of a toxic tort claim, plaintiffs bear the burden of showing both general and specific causation. To show general causation, plaintiffs would need to prove that a particular disease or condition, for example cancer, can arise from a certain level of exposure

(dose) to BPA or phthalates. To show specific causation, the same plaintiffs would then have to prove that the level, duration, and proximity of BPA or phthalates to which they were exposed actually caused their alleged disease or condition. Here, qualified expert reports and testimony concerning the unsettled state of BPA and phthalate science would work to a defendant manufacturer’s favor to contest plaintiffs’ ability to establish general and specific causation.

Plaintiffs’ causation difficulties in the toxic tort arena would also work against them should they try to press medical monitoring claims. Success on a medical monitoring claim typically requires that plaintiffs show a causal link between their exposure to an allegedly toxic substance and a significantly increased risk of contracting a serious latent disease or injury, along with the benefits of early diagnosis and treatment. Again, defendant manufacturers could rely on qualified expert testimony and reports to cast serious doubt on the existence of such causal links.

## LAWYER CONTACTS

In this ever-changing area of science and federal and state law, the best recommendation is to be vigilant and prepared. Please contact the professionals listed below with any questions or concerns. General email messages may be sent using our “Contact Us” form, which can be found at [www.jonesday.com](http://www.jonesday.com).

### PRODUCT LIABILITY & TORT LITIGATION

#### **Paul M. Pohl**

Partner and Practice Leader  
Pittsburgh  
+1.412.394.7900  
[pmpohl@jonesday.com](mailto:pmpohl@jonesday.com)

#### **Charles H. Moellenberg, Jr.**

Partner  
Pittsburgh  
+1.412.394.7917  
[chmoellenberg@jonesday.com](mailto:chmoellenberg@jonesday.com)

#### **John Q. Lewis**

Partner  
Cleveland  
+1.216.586.1005  
[jqlewis@jonesday.com](mailto:jqlewis@jonesday.com)

### INSURANCE RECOVERY

#### **Steven E. Sigalow**

Partner and Practice Leader  
Cleveland  
+1.216.586.7105  
[sesigalow@jonesday.com](mailto:sesigalow@jonesday.com)

#### **J. W. Montgomery III**

Partner  
Pittsburgh  
+1.412.394.7913  
[jwmontgomery@jonesday.com](mailto:jwmontgomery@jonesday.com)

#### **Mark Andreini**

Partner  
Cleveland  
+1.216.586.7101  
[mjandreini@jonesday.com](mailto:mjandreini@jonesday.com)

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