BPA, Phthalates And The Law

Charles H. Moellenberg, Jr. and Mark Andreini

JONES DAY

Charles H. Moellenberg, Jr.

Mark Andreini

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, childcare items, medical devices, personal care items, and household items. BPA and phthalates have practically become household names due to media attention given to the concerns of some scientists about the potential health effects of low-level exposure to BPA and phthalates.

The argument for more regulation and outright bans on the use of BPA and certain phthalates has gained considerable momentum. The regulation of chemicals in the U.S. is starting to shift toward the European precautionary approach. This approach would shift the burden to the manufacturer to prove that a product is safe before it can be marketed, rather than demonstrating that it is not unsafe. 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 certain phthalates at levels resulting in an effective ban.

Bisphenol A

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

Scientific Studies. Despite the fact that the potential health risk of BPA has been studied for years, the science remains unsettled. Interest in BPA stems in part because BPA is used in many children's products and 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 via leaching from polycarbonate bottles and from the liners of metal food and drink cans into food and liquids. Once in the body, BPA can bind to estrogen receptors, although its binding affinity is orders of magnitude lower than that of endogenous estrogen.

BPA's low estrogenic potency, combined with the low level of human exposure, has traditionally been interpreted to indicate that it has little to no risk of human health effects. Recent reviews of risks associated with low-level exposure to BPA by the U.S. Food and Drug Administration ("FDA") (2008) and experts at the Harvard Center for Risk Analysis (2004) found no consistent evidence for BPA-related health effects.

But, in 2008, the National Toxicology Program ("NTP") issued a report on BPA. The NTP report concluded that there was "some concern" that BPA exposure in fetuses and infants could possibly affect brain and prostate health. For every other aspect of human BPA exposure, the NTP concluded that there was only "minimal" or "negligible concern." A NTP finding of "some concern" indicates the need for more research to better understand implications for human health. 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, bowing to 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." However, the FDA report noted that there was no evidence that BPA was unsafe.

Regulation. The CPSC does not currently regulate BPA. However, government regulators and legislators are now being pressured to reevaluate the potential low-dose effects of BPA. Congress has before it four bills banning or severely limiting the use of BPA. The most restrictive of the proposed bills would prohibit the use of BPA in all food and beverage containers manufactured, distributed, or offered for sale in the United States. At the state level, Minnesota and Connecticut have enacted anti-BPA legislation that becomes fully effective in 2011. Almost 20 other states have anti-BPA legislation pending or under consideration.

Litigation. A class action was recently filed 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 seek economic and punitive damages but have not alleged any health effects. The case is currently proceeding through discovery.

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 concluded that the complaints did not "allege that any particular person sustained any specific injury as a result of the use of Avent's products, nor do they pray for damages for personal injury." While this particular decision may prompt some insurers to argue that similar claims are not covered under the typical CGL policies, the *Medmarc* opinion is open to criticism and is at odds with analogous cases. The *Medmarc* court quoted, but failed to appreciate, that the relevant insurance policies provide coverage for claims seeking damages "because of bodily injury" rather than "for bodily injury." Because the gist of the underlying plaintiff's case was the allegation that BPA causes bodily injury, the insurer should defend *Medmarc*.

Phthalates

Phthalates are a group of chemicals called "plasticizers" that are used to make plastics, like polyvinyl chloride, softer and more flexible and durable. Phthalates are used in a wide variety of products, from children's toys to medical devices and cosmetics.

Scientific Studies. Phthalates are a group of chemicals with similar chemical structures but each with its own unique chemical and toxicological profile. The potential health effects of phthalates are the subject of numerous reviews. The NTP published extensive reports on the reproductive and developmental effects of seven phthalates. The NTP found that only one, Bis(2-ethylhexyl) phthalate (DEHP), presented a serious concern to human reproduction or development under one very specific condition—the exposure of male infants to intravenous tubing. The remaining phthalates studied typically were determined to be only of "some concern" or "negligible concern" for routine exposure. The NTP reports also found that the mouthing of toys containing phthalates did not expose children to sufficiently high levels to warrant toxicity warnings.

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 and subsequent regulation. The 2008 CPSIA regulates the use of six phthalates. 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. More than 20 states are in the process of enacting laws that closely track the CPSIA, and several phthalates have made California's Proposition 65 list.

Litigation. To date, the only reported federal litigation involving phthalates is *National Resource Defense Council v. CPSC*, 597 F. Supp. 2d 370 (S.D.N.Y. 2009). In finding for the NRDC, the court ruled that the plain language of the CPSIA did not create an exception for existing inventory.

At the state level, litigation over phthalates has been filed pursuant to California's Proposition 65 warnings law. Proposition 65 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. It demonstrated differences in the biological mechanisms underlying the metabolism in rats.

Given the media attention and the recent CPSIA requirements, phthalate litigation involving violation of the new standards, bodily injury, and warnings seems likely to be heating up.

Practical Guidance. In confronting concerns over BPA and phthalates, manufacturers need to consider proactive steps to neutralize or minimize their product-liability risk. A comprehensive action plan 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, consulting with experts to understand the scientific and legal terrain is essential. Scientific experts can provide data and analysis to assess any purported causal link between BPA or phthalate exposure and human injury. Scientific experts can provide a balanced and well-reasoned discussion of the safety of BPA and phthalates for affected companies, policymakers, and regulators. Monitoring of 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 is recommended. Expert commentary can play a crucial role in shaping the scope and ultimate impact of a final regulation.

Post-Legislative Regulatory Compliance. Companies should build an action plan to comply with relevant statutes and regulations. Consideration should be given to preexisting inventory, timetables for compliance, and necessary changes in product design, manufacturing, labeling, and quality control. Tracking product inventory and distribution is critical. Companies also need to consider securities disclosure obligations.

Preparedness for a Voluntary Product Recall. 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. Advance planning, including crisis communications management and employee training, is prudent.

Anticipating Possible Litigation. To deal most effectively with BPA or phthalate product liability claims, companies should consider centralizing control of the claims management process by engaging outside counsel with a significant geographic and jurisdictional footprint. A centralized approach allows for the development of a strong and consistent scientific defense. Also, consideration to contract terms, warnings, indemnities, and insurance should be given.

In this ever-changing area of science and federal and state law, the best recommendation is to be vigilant and prepared.

Charles H. Moellenberg, Jr. *is a Partner in the Pittsburgh office and* ***Mark Andreini*** *is a Partner in the Cleveland office of global law firm Jones Day.* *The authors acknowledge and thank their colleagues* ***Cynthia Driscoll***, ***Martin Harvey***, ***Jack Montgomery***, *and* ***Robert Walker*** *for their significant contributions to this article.*

Please email the author at chmoellenberg@jonesday.com or mjandreini@jonesday.com with questions about this article.