The United States Food and Drug Administration Issues Update on Bisphenol A (BPA)

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The Food and Drug Administration ("FDA") recently updated its position on Bisphenol A ("BPA") citing certain studies as the basis for "some concern" about the potential effects of BPA on the brain, behavior, and prostate glands of fetuses, infants and young children. Prior to that announcement, the FDA had not publicly questioned the safety of BPA. Although BPA's permitted uses under FDA regulations have not changed, the FDA's subtle change in position will likely encourage more potential plaintiffs to join the growing litigation against manufacturers of BPA containing products. Manufacturers of any product that has ever contained BPA should be aware of the FDA's evolving position, as well as the status of BPA litigation to ensure they are prepared to defend any claims and to comply with the law.

BPA's approval by the FDA remains intact, despite ongoing studies regarding its safety

BPA is a chemical used to make hard, clear plastic known as polycarbonate, and is used for products such as baby bottles and sippy cups. BPA is also used in epoxy linings for metal-based food and beverage cans. The FDA first approved BPA's use as a "food additive" and "food contact substance" in the 1960's. Under the regulatory structure in place at that time, once BPA was approved for use, manufacturers could use BPA in accordance with the regulations without notifying the FDA of new formulations or uses. Since 2000, the FDA has regulated new food contact substances through the Food Contact Notification Program which provides more oversight than the prior system. The FDA is currently encouraging manufacturers of BPA-containing products to voluntarily comply with the Food Contact Notification Program and is supporting the industry's voluntary move away from using BPA.

The FDA's new position on BPA comes in response to public concern over potential effects of BPA on infants and children following studies from the mid-1990's to present. The FDA has referred to these studies as using "novel approaches" to assess the risk from BPA. Not surprisingly, assessment of the risk of harm in children from a given chemical is difficult as the absorption, metabolism and excretion of the chemical may be quite different than in adults. In an attempt to achieve closure on the debate, new
studies are underway at the FDA's National Center for Toxicological Research with results expected over the next few years.

Despite no FDA change in policy, legislation and litigation are underway

Although the FDA has not altered the approved uses of BPA, several states and local governments have already acted on public concern. Connecticut, Maryland, Minnesota, Washington, and Wisconsin have banned BPA from baby bottles and certain other children's beverage containers. The laws of Connecticut and Washington also ban BPA from sports water bottles. New York's Suffolk County passed a BPA ban, as has Chicago. Vermont's legislature is currently considering a ban, and an effort is underway in California to add BPA to its Proposition 65 list of toxic chemicals. Manufacturers of BPA-containing products, even if not children's beverage containers, should closely monitor the growing number of bans as the Maryland law also encompassed children's toys before a late amendment narrowed its focus. And with BPA bills having been introduced in both houses of Congress, a national ban is possible.

Even though there is no definitive scientific evidence that BPA causes harm, multidistrict litigation is underway in the Western District of Missouri (MDL 1967) and the Western District of Kentucky (MDL 2137). MDL 1967 involves class action suits against manufacturers of baby bottles and sippy cups. The claims include various counts for violation of state consumer protection statutes, fraud, breach of warranty, unjust enrichment, strict product liability, breach of contract and negligence. MDL 2137 involves suits against an aluminum bottle manufacturer claiming that the manufacturer marketed its product as an alternative to BPA containing plastic even though its metal bottles were lined with a BPA containing epoxy resin. Outside of the MDLs, a class action suit is ongoing in Colorado against another manufacturer of aluminum bottles involving claims similar to those in MDL 2137.

The future of BPA regulation and litigation is unclear

Changes to the FDA's regulation of BPA is a realistic possibility, either as a result of the ongoing scientific studies or continued public concern and political pressure. But even for manufacturers of products not within the FDA's purview, BPA use may become restricted or at least more regulated. The United States Environmental Protection Agency ("EPA") recently announced it is evaluating BPA issues within its authority and is considering steps to address the environmental effects of BPA and its release into the environment. EPA's potential actions include rulemaking under the Toxic Substances Control Act ("TSCA") to collect data and identify BPA on its Concern List, as well as conducting an assessment under EPA's Design For The Environment program to encourage reduction in BPA manufacturing and use.

At present it is unclear whether BPA will explode into the next asbestos type litigation. Whether the litigation expands to that level will depend in large part on the results of the ongoing studies, state legislative action, the amount of media attention, and manufacturers' counsels' ability to defeat the existing claims before they
become too widespread. If the current studies show even a tenuous link to injuries in children, an increased number of claims can be expected against a broader range of defendants. Even without the results of those studies, the plaintiffs' bar will likely continue its active pursuit of claims given BPA's status as a hot topic with the public.

John C. Babione, Daniel M. Long, or any other member of the Toxic Tort and Chemical Exposure Practice Group at Frost Brown Todd LLC are available to assist you with determining what actions you should take in response to regulatory requirements or in preparation for potential litigation arising from BPA or any other chemical.