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Volume 27, Number 6 • November/December 2010

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The Policy Journal of the Environmental Law Institute®

BPA: DOA?

How bisphenol A, a ubiquitous substance that is a key ingredient in many plastic products and metal containers, found itself in the regulatory crosshairs despite a clean bill of health from agencies in several countries

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"What criteria will be used to evaluate hazard and exposure pathways of BPA? Will it be based on 'weight of evidence' studies? Public opinion and legislative pressures? What scientific risks will be considered?" Lynn Bergeson, cofounder of the Washington law firm Bergeson & Campbell, P.C., and the lead attorney representing the North American Metal Packaging Alliance, Inc., can be excused for fretting about the tortuous political context of the public debate over the safety of bisphenol A, a common, useful, and in some cases irreplaceable product in commerce since the 1950s. Also known as BPA, the chemical is used to add strength and flexibility to plastic. It is the key ingredient in everything from CDs to dashboards, but most controversially food storage containers, polycarbonate water bottles, and sippy cups.

Fifteen companies produce approximately 7 billion pounds globally each year. At present, alternatives for many of its uses do not exist, such as in the plastic coating that prevents the corrosion of metal can liners, where it helps prevent bacterial contamination and extends shelf life without affecting taste. Nearly all 130 billion food and beverage cans made in the United States each year are lined with a BPA resin. That's why the food industry is concerned about the chemical's regulatory fate.

Critics of BPA have cited dozens of studies that suggest that under certain circumstances the chemical can modify endocrine function in animals, raising concerns about its impact on humans, infants in particular. But BPA is one of the most tested chemicals in the world — it has undergone more than 4,500 studies. In 1982, the National Cancer Institute and the National Toxicology Program (NPT) concluded that BPA is not a potential carcinogen. Reviews by the Environmental Protection Agency endorsed its safety for use in products handled by adults and children in 1988, 2008, and 2010. Ten other international regulatory bodies staffed and advised by internationally renowned scientists have reviewed the data — in Australia, New Zealand, Europe, and Canada and several countries in Asia — and none has determined it to be harmful. In what is considered the most comprehensive review, in 2006 the European Food Safety Authority (EFSA) certified BPA as safe for use in products handled by adults and infants and concluded that it does not pose serious harm. This finding is particularly striking because the EU evaluates chemicals using the precautionary principle, which holds that regulatory action can be taken based on suspicion of possible harm.

The precautionary principle has become the operative rule for chemicals in Europe and Canada. It is a hazard standard, and is gradually replacing the risk standard used in the United States. It posits that if any human activity raises a perceived threat of harm, regulatory and legal sanctions can be imposed even if no cause-effect relationship can be established. Some chemicals are held to be dangerous at any level, even absent definitive risk data.

It often doesn't matter whether the costs or unintended consequences of the regulation outweigh the potential benefits. The principle has been the basis for Europe's ban on genetically modified foods and many agricultural chemicals. But even under what amounts to this zero-risk guideline, the EU Risk Assessment Report updated in 2008 and again in 2010 concluded that polycarbonate plastic and epoxy resins, which both utilize BPA, are safe for consumers and the environment when used as intended.

BPA is nonetheless in the legislative and regulatory crosshairs. Two years ago Canada set aside the findings of Health Canada that BPA is safe as used and became the first country to ban the sale of infant bottles, feeding cups, and packaging for baby food containing the chemical, saying it had no choice to act under the country's strict precautionary standards. Denmark passed similar legislation and lawmakers in France overruled the recommendation of its Food Safety Authority and banned its use in baby bottles. There are bills before both the U.S. Senate and the House of Representatives to ban BPA or limit its use in children's products.

The Novel Hypothesis

The question about whether BPA exposure might pose dangers revolves around the murky issue of toxicity. As Paracelsus, the father of toxicology, observed, "All things are poison and nothing is without poison, only the dose permits something not to be poisonous." But some university scientists challenge this canon, citing more than 100 laboratory studies that suggest that low doses of BPA exposure might have more impact than high doses. Rodents exposed to BPA at low levels sometimes suffer from a variety of disorders, including developmental abnormalities, breast cancer, and male sexual dysfunction.

In the 1990s, BPA critics began branding the chemical as an endocrine disruptor, and that label has caught on. The "endocrine disruptor low-dose" hypothesis is the belief that BPA (and other chemicals) can seriously disrupt normal hormonal function at what traditional empirical science would suggest are insubstantial levels. The Food and Drug Administration has called this "a novel hypothesis."

The U.S. regulatory establishment has struggled to assess the importance of the research on the impact of chemicals on the endocrine system and infant development. Regulators and most scientists remain skeptical of the low-dose notion. Numerous natural substances also subtly alter the way the hormones in our endocrine system work, often operating at levels higher than BPA. The only significant science-based question is whether a particular sub-

stance is harmful at the trace level at which it is metabolized in the human body.

One of the most seemingly damning allegations against BPA — it shows up repeatedly in media reports — is that the Centers for Disease Control and Prevention has found the chemical in the urine of 95 percent of adults and 93 percent of children over six years old. Are those trace levels harmful? Advances in technology make it possible to detect even vanishingly low concentrations of almost anything looked for. In other words, such crude findings may be in themselves little more than artifacts of biomonitoring techniques that regularly find chemicals of all kinds in the human body. To put this in perspective, CDC tests have found dietary estrogens — known hormone disruptors that occur naturally in an array of substances such as nuts, seeds, clover, tofu, wheat, berries, bourbon, and beer — in the urine of more than 90 percent of people.

Repeated peer-reviewed studies have shown that neither BPA nor dietary estrogens bioaccumulate. Taken orally BPA is rapidly detoxified, first in the gastrointestinal tract and then in the liver, by enzymes that transform it into a water-soluble chemical known as BPA-glucuronide, which has a half-life of six hours. While some reports in which rodents were injected with BPA have shown some effects, studies in which rats receive the chemical orally have shown little or none. "In animal and human studies, bisphenol A is well absorbed orally," the CDC concluded. "Finding a measurable amount of bisphenol A in the urine does not mean that the levels of bisphenol A cause an adverse health effect."

Another potential problem with the novel hypothesis is that it is based almost entirely on administering BPA to rats by injection. Regulatory agencies do not put much stock in tests in which a substance is introduced to subjects in a different way than humans would come into contact with it. The EFSA, which uses the precautionary principle in its deliberations, as well as all international regulatory bodies that has systematically assessed the risks of BPA, either rejects studies of injected BPA or gives preference to studies in which it is ingested.

What about the slew of new studies that purport to show modifying effects of BPA on the endocrine system? Almost all of these studies are what are known as hypothesis research — small-scale investigations designed to alert scientists to potential concerns, which should lead to more robust guideline studies. Many of these smaller studies contradict each other — BPA shows an effect in one area, but not in another. That kind of noise happens all the time in hypothesis-driven studies, which is why regulators place far less weight on them than larger, guideline studies. These smaller tests for BPA toxicity have not been confirmed by larger studies, which is one reason why regulators have taken no action to restrict it.

The Role of Media and NGOs

In 2001, the NTP released an independent peer-reviewed analysis of the evidence for and against the novel hypothesis for BPA, concluding, "The subpanel is not persuaded that a low dose effect of BPA has been conclusively established as a general or reproducible finding," although it did recommend further research. Numerous reviews with similar conclusions followed, including by the Harvard Center for Risk Analysis. The findings and their authors were often attacked as being industry-manipulated by NGOs, reporters, and scientists devoted to the endocrine disruptor theory.

Frederick S. vom Saal, a neurobiologist at the University of Missouri, led a vocal group of scientists arguing that past reviews failed to take into account the "latest knowledge" in endocrinology, developmental biology, and estrogen-receptor research. In 2006, vom Saal coordinated a conference that brought together 38 scientists who advocated the low-dose endocrine-disruptor theory. What became known as the Chapel Hill Consensus declared that BPA is associated with changes in the prostate, breast, testes, mammary glands, body size, brain structure and chemistry, and behavior of laboratory animals. "The science is clear and the findings are not just scary, they are horrific," summarized vom Saal. "When you feed a baby out of a clear, hard plastic bottle, it's like giving the baby a birth control pill."

The consensus statement provided momentum for the emerging narrative against BPA aggressively advocated by environmental organizations, and adopted, often uncritically, by certain factions of the national media. Last year reports surfaced citing a study from China that BPA could cause male sexual dysfunction. The Environmental Working Group headlined its *Huffington Post* story: "BPA Wrecks Sex, Fouls Food — and Probably Worse." It generated similar scare stories in the *New York Times, Los Angeles Times, Milwaukee Journal Sentinel* (which has run more than 50 anti-BPA stories), and other outlets. But the study that prompted this news blizzard focused on Chinese workers who handled the chemical in bulk, not men exposed to BPA in plastics. The reports did not mention that the NTP has consistently reported "negligible concern" that men exposed at non-occupational capacities — workers exposed to BPA in plastic containers for example — would experience reproductive effects from encountering BPA in everyday use.

Similar urban legends around BPA, many promoted by activist websites presenting selective interpretations of complicated science, abound. One study

found BPA slightly increased the rate of breast cancer tumors in rats during lactation — but only after a secondary chemical fed to the animals induced tumors. In other reports, BPA pellets inserted into the uterus of mice led to abnormalities or were injected directly into organs or the blood stream. To regulators such research is not given much weight, but readers were never told that, in part because journalists are usually ill-trained to evaluate risk-based empirical studies. From this ambiguous animal research emerged a widely disseminated conclusion by *Consumer Reports* that linked BPA "to a wide array of health effects including reproductive abnormalities, heightened risk of breast and prostate cancers, diabetes, and heart disease" in humans — a conclusion no study or science-based regulatory body has found.

FDA Weighs in—Again

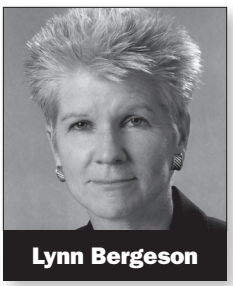
Reflecting this consensus by the regulatory community, in January the FDA released its second review of BPA in two years, again declaring it poses "negligible" or "minimal" concern for most adults and "is not proven to harm children or adults." The FDA also reiterated prior skepticism abut the novel hypothesis, stating that rodent studies suggesting some problems were not "experimentally consistent" — some showed no problems and many tests could not be replicated. "Studies . . . have supported the safety of current low levels of human exposure to BPA," the FDA concluded.

When asked if children faced health dangers, Joshua Sharfstein, M.D., the FDA's principal deputy commissioner, minced no words: "The FDA is not saying that it's unsafe to use a baby bottle with BPA. FDA does support the use of bottles with BPA because the benefit of nutrition outweighs the potential risk of BPA. If we thought it was unsafe, we would be taking strong regulatory action."

The FDA did introduce an ele-

Facts and Consequences

Jon Entine's case is compelling, and his article raises a fundamental question that has been largely lost in the bisphenol A debate. The question is how to balance the need to feed the world by maintaining a safe food supply system with the desire to be cautious in protecting human health from chemical exposures that may pose harm. As outside counsel to the North American Metal Packaging Alliance, Inc., I do not purport to be without strong views regarding the inherent safety of BPA-derived epoxy resins to make coatings for metal food and beverage packaging. My views are based on a review of the science, not a reflective allegiance to client interests.


Lynn Bergeson

The issue I find disturbing in the debate is the seemingly willful avoidance by BPA detractors to acknowledge the global adverse consequences of eliminating the use of BPA-derived epoxy resins in food and beverage containers. Metal packaging technology is a highly evolved science. Because metal packaging can be infinitely recycled, it is among the most sustainable packaging choices from a lifecycle perspective. In fact, the inherent value of metal packaging together with paper subsidizes the recycling of other materials and makes curbside collection of household materials possible.

The metal can itself is a resilient innovation. Now over 200 years old, the metal can is entirely tamper-resistant and thus a trusted form of food and beverage packaging. The unique value of BPA-derived epoxy coating is its unsurpassed ability to sustain the high temperature food packaging conditions required for sterilization, the process that guarantees that packed food is safe from microbiological contamination, which causes food poisoning.

The transition decades ago to epoxy resin technologies has enabled dramatic increases in the shelf-life of packed food products. This, in turn, has dramatically diminished food waste due to product expiration — no small accomplishment in a world challenged by food shortages that will only become more acute with the passage of time. Today's canned foods have shelf-lives of two years or more. Because metal packaging is the only container that is completely light-proof and oxygen-proof, the quality and nutritional value of the packed food remains unchanged over the shelf-life of the product.

BPA detractors claim alternatives exist. This is true, but only conditionally. What is seldom mentioned is that no other coating alternative offers the same level of food protection for as many food and beverage container applications, or protects packed food for as long as BPA-derived epoxy resins. The consequences that flow from this indisputable fact are many. They include, among others, the cost of a diminished shelf-life of canned goods, perhaps by as much as half; the potential for increased incidents of food poisoning; and the lifecycle burden occasioned by diminished use of metal packaging options.

The public's ability to make informed food packaging choices is no less important than the question of the safety of BPA-derived epoxy resin coatings. These unintended consequences of limiting uses of epoxy resins are important, and must be part of the debate.

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ment of confusion in reiterating a 2008 statement by the NTP that had expressed "some concern" about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children. It also recommended "certain ways of feeding babies to minimize exposure to BPA." Those qualifications were widely believed to be responses to political pressure. It gave the FDA leeway to endorse further studies, while reiterating it does not consider BPA harmful or worthy of formal labeling or warnings.

At the same time as it reaffirmed the safety of BPA, the FDA announced that it had authorized further research at a cost of $30 million. "Our safety assessment of BPA is ongoing," said FDA Commissioner Margaret Hamburg. "We will conduct studies on the safety of BPA over the next 18 to 24 months, which are intended to answer key questions and clarify uncertainties."

The first comprehensive FDA study of pharmacokinetics of BPA in primates was released in July. It again rejected the novel hypothesis. Among the findings of the University of Georgia researchers: BPA does not accumulate in the body; BPA is efficiently metabolized by adult monkeys after oral exposure; the capability of neonatal monkeys to metabolize BPA is equivalent to adult monkeys; primate results suggest that rates are likely over-predict health effects from BPA.

This spate of recent government-supported studies should have ended any reasonable debate over the merits of the low-dose, endocrine-disruptor hypothesis, but they have not.

The EPA Reviews the Evidence

In March, the Environmental Protection Agency was asked to weigh in on BPA. Under intense pressure, it issued an "action plan" designating BPA as a "chemical of concern" and limply proposed action in three areas:

- To rule or not to rule: whether it needs a course to limit risks to aquatic species;
- Building a better case: whether it needs additional data to evaluate if BPA poses an unreasonable risk to the environment, paying particular attention to sensitive species, as well as children and pregnant women; and
- Finding possible substitutes: what alternatives could replace common uses of the chemical.

While EPA could have decided to take broad action, it said it would only examine the chemical for possible pollution of the environment — which to this point has been shown to be negligible. It punted the food safety and health issue back to FDA. "This administration has been more mindful of jurisdictional limits," said Lynn Bergeson. "It clearly didn't want to pile into an area that another agency is already looking into."

The major concern by industry — and indeed by many scientists around the world — is that the weight-of-evidence deliberations that traditionally guide regulators will be usurped by precautionary politics.

Activists are targeting the 1976 Toxic Substances Control Act in particular, which they hope to evolve into the country's chemical oversight legislation. The battle over TSCA largely focuses on whether the United States will continue to embrace a risk-based view of chemicals, but modernized to reflect scientific data about non-carcinogenic effects, or will it gravitate to a precautionary model grounded in fear of unknown or suspected hazards.

TSCA provides EPA with the authority for data collection and risk assessment, risk management, and the prevention of "unnecessary economic barriers to technological innovation" for chemicals. Manufacturers must inform the agency of their intent to manufacture a new chemical and must present extensive evidence about its risks and potential benefits. Regulators must weigh the costs of restrictions against the economic benefits of keeping the chemical in commerce. If EPA finds an "unreasonable risk to human health or the environment," it may regulate the substance in a variety of ways, from limiting uses or production volume to an outright ban. The act does not require the agency to reassess the safety of thousands of chemicals that were previously evaluated and "grandfathered in" when the law was passed — a category that applies to BPA.

Other than screening new chemicals and regulating the five designated chemicals explicitly required in the law, the execution of TSCA's mandate is vague, partially because Congress failed to define what constitutes a reasonable risk of injury and how to evaluate that risk. One prominent TSCA critic and environmental advocate, Andy Igrejas, environmental-health campaign director for the Pew Charitable Trusts, maintains that the United States "has no real program to regulate industrial chemicals," as a result of TSCA's "deep flaws." The burden of proof is typically on regulators to show that synthetic molecules are dangerous. They need to show "substantial evidence" that a chemical is harmful, and must weigh the costs of restrictions against the economic benefits of keeping the chemical in commerce.

EPA Administrator Lisa Jackson moved reform of TSCA onto her list of top priorities when she assumed her position in 2009. Senator Frank Lautenberg (D-New Jersey) has proposed the Safe Chemicals Act of 2010, which would overhaul the whole system of regulating chemicals. It would require manufacturers to demonstrate safety in order to introduce new drugs or keep current ones on the market. A House draft of the bill would require EPA to maintain a list of 300 priority chemicals to investigate "based on available scientific evidence, consideration of their risk relative to other chemical substances and mixtures, presence in biological and environmental media, use, production volume, toxicity, persistence, bioaccumulation, or other properties indicating risk."

It's unclear from the House bill what criteria would be used to designate a chemical as dangerous. The recommendations are a hodgepodge of politics and precautionary-based science. For example, BPA is grouped in the same category as lead, asbestos, cadmium, and other known carcinogens, "which is absurd on its face," Bergeson and others believe. "Our concern is that the public bias against 'all things chemicals' will be incorporated in ill-conceived legislation that could undermine the long-standing regulatory commitment that relies on 'best available data.' "

To date, EPA has announced no plans to use TSCA to regulate BPA on the basis of the risks it poses to human health. However, with new findings expected, it should be clear soon enough just how seriously a risk EPA considers the chemical.

New Regulations

Remarkably, many of these exaggerations are making their way into policy recommendations, including the most recent President's Cancer Panel report, released in May. If you read the executive summary, you could be forgiven if you came away convinced that chemicals were the primary cause of the 1.5 million cases diagnosed in the United States each year. BPA is singled out for particularly harsh criticism. In the opening letter to the president, the panel notes BPA "is still found in many consumer products and remains unregulated in the United States, despite the growing link between BPA and several diseases, including various cancers." In fact, BPA has been linked to cancer or other diseases only in animal studies of questionable significance.

The White House panel makes a highly selective case. For example, it never mentions that FDA has concluded on two separate occasions that BPA is safe for adults and infants. It does claim — erroneously — that the NTP said, "There is cause for concern" about the chemical's link with reproductive abnormalities, when the NTP in fact concluded most recently there was "negligible concern." The cancer panel also endorsed the application of precautionary regulations used in Europe, but ignored the fact that the EU has given BPA a clean bill of health.

Most egregiously, the panel claims that the chemical is linked to various diseases such as breast cancer,

which is speculative, alarmist, and disputed by every major regulatory body in the world. The hysteria over that claim ricocheted throughout the Internet. It became so widespread that in May, Susan G. Komen For the Cure, a major breast cancer research and support organization, issued a special alert reaffirming "there is no evidence to suggest a link between BPA and risk of breast cancer."

Unable to prevail on the science, ban proponents have shifted their focus from the laboratory to the legislature. Activists are targeting state and local governments, employing tactics that have influenced media coverage and fanned public anxiety. New York, California, Minnesota, Connecticut, Washington, and Wisconsin have passed bans on products or beverage containers for children.

That fear strategy prevailed in Canada in 2008. Activists mounted a massive campaign designed to frighten parents and pressure the media. Public concern led to an investigation by Health Canada. When Mark Richardson, its chief scientist, said the evidence showed that the dangers of BPA were "so low as to be totally inconsequential" and compared its estrogenic effects to tofu, activists and the media mounted an attack on his credibility that led to his reassignment. When the report was finally issued, Health Canada firmly rejected claims that BPA was unsafe to adults, teenagers and children. "The current research tells us the general public need not be concerned," the report declared.

Nonetheless, the precautionary principle is embodied in Canadian law. Considering the hysteria generated, and even absent convincing scientific evidence, Health Canada believed it was compelled to ban BPA in baby products. "Even though scientific information may be inconclusive," it wrote, "decisions have to be made to meet society's expectations that risks be addressed and living standards maintained."

The stage then shifted to Europe, which has even stricter precautionary standards than Canada. In a stunning turn of events, health authorities in France rejected the opportunity to follow in Canada's footsteps. "Canadian authorities banned BPA under public pressure and without any serious scientific study," Minister of Health Roselyne Bachelot said during an inquiry at the National Assembly in 2009. "The precautionary principle is a principle of reason and under no circumstances a principle of emotion," she concluded, noting, "It applies when there are no reliable studies. Here, there are reliable studies, which conclude, with current scientific data, that baby bottles containing this chemical compound are innocuous."

After a controversial report known as the Stump study was released earlier in 2010, both the French and Danish legislators approved precautionary bans. That prompted the European Food Safety Authority to revisit the issue. Its panel of 21 scientists consulted with international risk assessment authorities, including the FDA, Health Canada and the WHO, and conducted a comprehensive review of the Stump study and all research on BPA toxicity through July 2010. On September 30, the EFSA reasserted there is no "convincing evidence" of neurobehavioral toxicity of BPA, concluding, "these studies have many shortcomings" and are not relevant to human health. Once again, what is most notable is that even though obligated to assess chemical exposures on precautionary grounds, EFSA has continued to find that the low-dose rodent studies are not methodologically or statistically convincing.

The debate over BPA has turned political in the United States. Democratic legislators have proposed bills in both the Senate and House to outlaw the use of BPA in food container linings for infants and toddlers, legislation would short-circuit the scientific evaluation process that underpins the regulatory system. In 2010, French legislators put aside the scientific recommendations and approved a ban.

The debate over BPA has turned political in the United States. New York Democratic Senators Charles Schumer and Kirsten Gillibrand have proposed the BPA-Free Kids Act, intended to outlaw the use of BPA in food container linings for infants and toddlers. Senator Diane Feinstein (D-California) has drawn up an even tougher law, banning BPA. In either case, legislation would short-circuit the scientific evaluation process that underpins the regulatory system.

Wal-Mart, Toys "R" Us, and CVS all have announced plans to phase out polycarbonate bottles. Seeing a market opportunity, one bottle maker, Nalgene, says it is responding to "consumer concerns" and is transitioning to BPA-free containers, although it contends, "We are confident that the bottles which contain BPA are safe for their intended use." But most other companies are unable to justify changes that could potentially create worse problems and increase prices. Oleoresin — an alternative often promoted for use as a metal-can liner — costs 14 percent more than BPA and does not work for acidic foods like tomatoes. According to Aaron Brody, a food-packaging expert at the University of Georgia, "If [food packagers] had an economic can coating that could be applied to food and/or beverage cans today, the coatings industry, the canning industry, would have applied it instantly to get this monkey off their back."

If the loudest voices in the environmental movement are to be believed, we are in the throes of a health epidemic because of chemical contamination from BPA. But in the balance between protecting human health based on scientific research and providing for a growing world population, is a measure of balance getting lost? •