

## BPA-Free and Beyond: Protecting Reproductive Health from Environmental Toxins

By Sneha Barot

In a long-awaited announcement in January, the federal Food and Drug Administration (FDA) officially acknowledged concern about the effects of bisphenol A (BPA) on the health of fetuses, infants and young children. BPA is a chemical commonly found in food and beverage containers and in a host of other everyday products. The statement, which had been highly anticipated by environmental and reproductive health advocates, marked a notable reversal of the agency's earlier position that BPA at typical exposure levels did not pose a health risk to humans. Equally notable, however, was the fact that FDA took no steps to restrict BPA's use. Instead, it provided recommendations for parents to reduce exposure to BPA and said the government would continue to study the chemical's toxicity.

Some 2,000 new chemicals are introduced into the U.S. marketplace every year, according to the federal interagency National Toxicology Program (NTP). Yet, the NTP and others widely acknowledge that in many cases, neither corporations nor the government have adequately researched the ways in which exposure to these chemicals can affect people's health and how much exposure is sufficient to constitute an unsafe risk. Meanwhile, powerful trade interests aggressively fight against industry regulation by employing a range of strategies, such as disputing scientific studies about the health effects of chemical exposures, mounting public relations campaigns against unfavorable media coverage and rising consumer backlash, and even hiding which chemicals are used in their products.

Against this backdrop, advocates seeking to safeguard reproductive health from environmental toxins through more effective government regulation are fighting an uphill battle. Although state and local efforts to enact protective legislation have picked up steam in the last few years, securing meaningful action at the federal level has proved decidedly more difficult. This may be because advocates increasingly believe that although bans or restrictions on the use of individual chemicals such as BPA are valuable, an overhaul of the regulatory framework is what is really necessary so that the burden of proof with regard to safety is shifted from government to companies.

### Science as Battleground

A large body of evidence has amassed over recent years indicating that numerous environmental contaminants can lead to serious and irreparable adverse health outcomes, particularly in regard to reproduction. Chemicals known as endocrine disruptors deserve special attention because of their potent influence on reproductive capacity, the wide number of contaminants they encompass and their ubiquitous presence (see box). As an endocrine disruptor, BPA has the ability to wreak havoc on an organism's hormonal system in a wide variety of ways. It mimics the hormone estrogen, which is critical to development of both men and women during puberty and adulthood, and is also key to organ and systems development during the prenatal, infancy and childhood phases. As an imitator of estrogen, BPA disrupts hormonal processes, which can lead to cancerous cell growth, particularly breast cancer. And because fetuses and

infants are unable to metabolize BPA as efficiently as adults, they may be even more susceptible to hormone disruption and subsequent abnormal development.

However, it is also true that it is notoriously difficult to establish a definitive, cause-and-effect relationship between exposure to a specific chemical and health problems that may not develop until many years later. Largely at issue is the determination of the amount and timing of exposure that is dangerous to humans. Not surprisingly, the chemical industry routinely argues that the science around BPA is inconclusive and that its dangers have been exaggerated. In contrast to industry claims, recent studies demon-

strate that the chemical is harmful at both low and high doses of exposure, and that the timing of exposure during critical windows of development—especially during fetal development—may cause irreversible and grave problems with the reproductive system both earlier and later in life.

Logistical and ethical reasons prevent testing of BPA exposure directly in humans, especially pregnant women; therefore, much of the evidence on BPA comes from hundreds of animal studies widely extrapolated to human conditions, as is common when studying the toxicity of chemicals. These studies have found that some of the possible overall health consequences of BPA include higher rates of heart disease, dia-

### Here, There, Everywhere

*Endocrine disruptors are natural or synthetic compounds that interfere with the body's own hormonal ability to regulate vital processes of the endocrine and reproductive systems. These disruptions can have severe consequences for prenatal and human development, and their effects can even be transmitted to subsequent generations through modifications of gene expression. Endocrine-disrupting chemicals are found in numerous types of products, including cosmetics, personal-care products (e.g., shampoo, lotion and soap), mattresses, padded chairs, televisions and other electronics, medical equipment, plastics, solvents, cleaning products, and by-products of waste, as well as in soil, water, air and food.*

*BPA—a common endocrine-disrupting chemical—gained a strong foothold in the 1950s, when it came into widespread commercial use as a key industrial chemical in the production of polycarbonate, a hard plastic, and in epoxy resin, frequently used in the linings of cans and in other adhesive*

*products. Ironically, BPA was first developed in the 1930s as a pharmaceutical estrogen; however, unlike diethylstilbestrol (DES), a synthetic estrogen that was promoted to pregnant women to prevent miscarriage, it was never used for reproductive health purposes. A generation later in the 1970s, DES turned out to be a highly dangerous and carcinogenic endocrine disruptor that increased the risk of vaginal cancer, birth defects and other reproductive health disorders in the daughters of women treated with DES and genital anomalies and other problems in their sons.*

*Over six billion pounds of BPA are made on an annual basis, with two billion pounds created in the United States. The primary route of human exposure is through consuming foods or drinks that come from containers with BPA: Today, BPA is found in many everyday items, such as water bottles, plastic baby bottles, certain microwavable or reusable food and drink containers, baby pacifiers, toys, and the lining of metal food cans*

*(including infant formula cans), drink cans, wine vats and water pipes. Secondary sources of exposure include cell phones, CDs and DVDs, carbonless paper receipts, computers, dental sealants, medical tubing, enamels, paints, eyeglass lenses, car parts and plastic dinnerware.*

*A study published in 2008 by the Centers for Disease Control and Prevention reported widespread exposure when it detected BPA in 93% of Americans aged 6 and older, with significantly higher concentrations in children and adolescents than in adults, in females than in males and in the lowest-income brackets than in the highest-income. In 2009, the Environmental Working Group released the results of a biomonitoring investigation that found BPA along with dozens of other chemicals in the cord blood of nine of 10 newborns from ethnic and racial minority groups, providing further evidence that newborns are contaminated with BPA prior to birth.*

betes, liver abnormalities, obesity, neurological problems, altered immune system and other disorders. Effects particular to reproduction in males include abnormal development of the prostate and urethra, decreased sperm count and quality, sexual dysfunction and increased risk of prostate cancer. In females, reproductive health consequences include recurrent miscarriages, early puberty, abnormal uterus development, polycystic ovarian syndrome, uterine fibroids, increased risk of breast cancer and oocyte (egg) chromosome abnormalities.

After conducting a broad review of the science, the NTP issued a report on the effects of BPA in 2008. NTP concluded that there was “some concern”—the middle ranking in a five-point scale—that BPA can affect the brain, behavior and prostate glands of fetuses, infants and children. The January announcement by FDA echoed this conclusion—a marked departure from the stance taken by the agency under the Bush administration. In a 2008 draft assessment, FDA concluded that BPA did not pose a health risk to humans at current levels of exposure. That decision was widely criticized, including by the agency’s own scientific board of advisors, for relying on two industry-funded studies to reach its conclusion and for using an inappropriate standard to assess safe levels of BPA exposure.

### Limited Regulation

Although FDA’s belated acknowledgment of concern about the impact of BPA is heartening to reproductive health and environmental advocates, many are frankly disappointed that the agency did not issue a definitive statement labeling BPA as unsafe. Moreover, they are unhappy that the agency’s announcement focused only on infant exposure, ignoring precautions for other vulnerable populations, such as pregnant women, breast-feeding mothers and women undergoing chemotherapy for breast cancer, not to mention all other children and adults who are exposed daily to the chemical. For its part, FDA maintains that it is waiting for further evidence, noting that the National Institutes of Health is investing \$30 million over the next 18–24 months in BPA research, including investigation of low-dose effects, human health effects and reproduc-

tive disorders. It also maintains that its current ability to act is too constrained and is asking Congress for additional regulatory authority that it could use if and when the evidence supports limiting BPA in food and beverage containers.

The other government agency with a potentially major stake in BPA regulation is the Environmental Protection Agency (EPA), which is authorized to monitor and regulate the approximately 80,000 chemicals currently in commercial use in the United States under the Toxic Substances Control Act (TSCA). Whereas FDA’s authority over BPA stems largely from its mandate to protect the food supply, EPA’s authority over chemical regulation, at least in theory, is much broader. In practice, however, that authority is quite limited. Under TSCA, the burden falls on EPA to prove that chemicals have an “unreasonable risk” of injury, instead of requiring manufacturers themselves to prove that their products are safe before being distributed commercially. Moreover, when the law was enacted in 1976, it grandfathered in existing chemicals without requiring any assessment of their toxicity, and further failed to provide EPA with sufficient authority to review these chemicals on an ongoing basis as new evidence warrants.

Last fall, under the new EPA administrator, Lisa Jackson, the agency flexed its small muscles under TSCA and identified BPA as one of six chemicals that would be prioritized for regulatory attention. While it is developing action plans on these chemicals, the agency is publicly and actively calling for legislative reform that would empower it, too, with greater authority to compel safety information from industry, to shift the burden for demonstrating safety to companies and to ban chemicals of concern—recommendations that have been supported by the Government Accountability Office, which has found that EPA’s ability to protect the public from toxic chemicals is severely handicapped because of the current law.

### Looking to Legislation

Efforts to regulate the chemical industry at the federal level have been slow-moving, although several bills are currently pending that would directly affect BPA. Legislation sponsored by

Rep. Edward Markey (D-MA) and Sen. Dianne Feinstein (D-CA) in the House and Senate, respectively, would ban BPA from all food and beverage containers; Markey was able to include limited provisions on BPA in a food safety bill that passed out of the Energy and Commerce Committee last June. Companion bills introduced by Rep. Anthony Weiner (D-NY) and Sen. Charles Schumer (D-NY) would ban BPA in children's food and beverage containers. Rep. Tim Ryan (D-OH) has introduced legislation to require a warning label for any food container that contains BPA or that could release BPA into food. And, Rep. Jim Moran (D-VA) and Sen. John Kerry (D-MA) have sponsored the Endocrine Disruption Prevention Act, which would establish a research program to help identify endocrine disrupting chemicals and determine their safety.

Action at the state and local levels has been more vigorous. In the last two years alone, hundreds of pieces of legislation were proposed that in one way or another would have addressed exposure to substances known to have a serious reproductive health impact. Of these, nearly 40 were enacted in 19 states and the District of Columbia. With respect to BPA, in 2009, Minnesota became the first state to pass a BPA ban: Beginning in January 2011, BPA will be prohibited in food containers (such as baby bottles and sippy cups) designed for children younger than three years old. A ban enacted in Connecticut not only prohibits the sale of reusable food containers containing BPA (which include baby bottles, sippy cups, sports bottles and thermoses), but also bars the sale of infant formula and baby food packaged in containers that include BPA. Most recently, Wisconsin barred the chemical in baby bottles and sippy cups for children three and younger. Eleven other states and the District of Columbia are considering legislation to ban BPA in certain children's products or food containers. In addition, Massachusetts public health officials issued a consumer warning last year to parents of children under the age of two and to pregnant and breast-feeding women to avoid BPA. And, in February, California's Environmental Protection Agency indicated that it was considering including BPA on its list of chemicals known to cause

cancer or reproductive toxicity, based on the NTP's findings.

Local governments have also been active in the BPA debate. Chicago passed a ban last spring on the sale of baby bottles and sippy cups that contain BPA, becoming the first city to do so. Additionally, four New York counties banned BPA in baby bottles and sippy cups last year.

### **The Sounder Approach**

Even as advocates work to see BPA bans passed, they have set their sights on a more comprehensive approach to the issue of chemical regulation. For one thing, they acknowledge that banning chemicals like BPA on an individual basis, however valuable in the short term, could lead to substitutes that might be equally or even more dangerous than the chemical being replaced. In fact, government representatives have voiced this concern, and it may be one of the reasons for the cautious approach taken by regulatory agencies before acting on BPA bans. More importantly, advocates argue that EPA's current authority under TSCA is simply too weak, making it an ineffectual agency to fulfill its mission to protect human health from toxic chemicals.

In response, scientists and advocates are increasing their calls for codification under TSCA of the "precautionary principle," which enshrines the belief that when there is sufficient evidence of a risk of severe or irreversible harm, public policy should fall on the side of protecting the public, despite the lack of scientific consensus on direct proof of causation. This approach, they argue, may be especially important in a society in which consumers cannot buy their way out of using harmful substances because chemical exposure is so omnipresent. Moreover, even when market demands force some producers to develop safer alternatives (for example, the six major baby-bottle manufacturers have gone BPA-free), lower-income individuals may not be able to purchase these often-costlier options. Finally, it is worth noting that many citizens may incorrectly believe that under our regulatory structure, if a product is being sold on store shelves, their government must have ensured its safety.

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The precautionary principle has been embraced by the international environmental community and adopted by the European Union. Last year, Canada justified its new ban on BPA-containing baby bottles by citing this principle. Even though Canada's assessment concluded that infant exposure to BPA was below levels that had been determined to directly cause effects, it nonetheless proceeded with caution, because of the risk found in low-dose-exposure studies.

It is, frankly, unlikely that sweeping regulatory reform will be enacted in the United States anytime soon, but the groundwork is being laid. In 2008, major TSCA reform legislation was introduced by Sen. Frank Lautenberg (D-NJ) and Rep. Hilda Solis (D-CA, now Labor Secretary). Similar companion bills are expected to be introduced

again this year by Lautenberg, who has already held two hearings on the issue, and by Reps. Bobby Rush (D-IL) and Henry Waxman (D-CA). If TSCA reform were to be enacted, the burden of proving safety for newly developed chemicals would be shifted from the EPA to the chemical industry. Chemicals already in use that have known adverse reproductive health impacts would be considered for inclusion on a priority list for government regulation. Chemical reform would not only cover BPA, which would fall under the authority of the new bill, but also better protect reproductive health from toxic exposure to the thousands of other, yet-undeveloped chemicals that are expected to enter the market, and inevitably our bodies.

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