Reversing Itself: FDA’s Latest Position on Bisphenol A

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In an effort to show that it is getting tough against certain threats to public health, the Food and Drug Administration (FDA) recently expressed concern regarding the use of bisphenol A, or BPA, a chemical found in plastic bottles and food packaging.1 The FDA previously declared BPA safe to use in 2008.2 But shortly after that decision, the National Toxicology Program published a report expressing its concerns about the possible effects of exposure to bisphenol A on human development and reproduction.3 The FDA then altered its stance by saying that it had “some concern about the potential effects of BPA on the brain, behavior, and prostate gland of fetuses, infants and children.”4 Its concerns about the chemical product are based on scientific evidence which has concluded that BPA has resulted in producing harmful effects in animals and on the recognition that BPA can leach into food and baby formula. According to the Centers for Disease Control and Prevention (CDC), more than 90 percent of the U.S. population has traces of BPA in its urine.5 Despite this notable statistic, some health officials have said there is a lack of evidence that BPA is dangerous to humans. “If we thought it was unsafe, we would be taking strong regulatory action,” said Dr. Joshua Sharfstein, the principal deputy commissioner of the FDA.6 Despite his statement, the FDA decided to join other federal health agencies to study in more detail the effects of the chemical in both animals and human beings. The Department of Health and Human Services has released recommended ways for the public to reduce exposure to BPA.7

Food and Drug Administration Background

The Food, Drug, and Cosmetic Act of 1938, as amended, makes the FDA “responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, food supply, cosmetics, dietary supplements, and products that give off radiation.”8

To fulfill the purpose of its statutory function, the FDA relies on the following definition

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4 Grady, supra note 1.
6 Grady supra note 1.
8 21 USC § 301 et seq.
of safety: “[s]afe or safety means that there is reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”9 This definition goes on to state that complete certainty of absolute harmlessness is scientifically impossible to establish.

The FDA regulates more than $1 trillion worth of consumer goods, which amounts to about 25 cents of every consumer dollar spent in the United States.10 As a result of its broad regulatory functions, FDA decisions are carefully monitored by governmental and non-governmental organizations. The FDA also enforces other laws and works in conjunction with other federal agencies, local and state government agencies to provide regulatory inspections and enforcement action.

**Bisphenol A (BPA)**

Bisphenol A (BPA) is an industrial chemical that has been used primarily to make plastic bottles and metal-based food and beverage cans since the 1960s. BPA is not a food additive, but a monomer used in the manufacture of food additives. This chemical compound acts as an endocrine disruptor; it can mimic the body’s own hormones which may lead to negative health effects. It is well documented that BPA binds to estrogen receptors, which has variable effects on several genes involved in estrogen metabolism and may also affect human reproduction.11 In 2009, the Endocrine Society released a scientific statement expressing concern over current human exposure to BPA.12 The statement includes scientific evidence of the effects of endocrine-disrupting chemicals on male and female reproduction, thyroid, metabolism and obesity, among other harmful mechanisms. Bisphenol A can possibly leach into food from the protective internal epoxy resin coatings of canned foods and from consumer products such as polycarbonate tableware, food storage containers, water bottles, and baby bottles. The degree to which BPA leaches from polycarbonate bottles into liquid may depend more on the temperature of the liquid or bottle than the age of the container.

FDA has never established an acceptable daily intake for BPA exposure through food additive use; however, the U.S. Environmental Protection Agency (EPA) has published a reference dose (RfD, 0.05mg/kg/day) for BPA.13

**What is the FDA Doing?**

With growing public concern about the harmful effects of BPA, the FDA has begun a

9 21 CFR § 170.3(i).
more thorough analysis of the chemical. In cooperation with the National Toxicology Program, FDA’s National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA. Meanwhile, last month, the FDA published an update with information and recommendations for the public about BPA exposure. The FDA is taking the following measures to reduce human exposure to BPA in the food supply:

- supporting the industry’s actions to stop producing BPA-containing baby bottles and infant feeding cups for the U.S. market;
- facilitating the development of alternatives to BPA for the linings of infant formula cans;
- supporting efforts to replace BPA or minimize BPA levels in other food can linings;
- supporting a shift to a more robust regulatory framework for oversight of BPA; and
- seeking further public comment and external input on the science surrounding BPA.

Infants are particularly vulnerable to the effects of BPA exposure because (1) their neurological and endocrine systems are still developing; and (2) their hepatic system for detoxification and elimination of such substances as BPA is immature. The American Academy of Pediatrics and other health authorities recommend breastfeeding as the optimal nutrition for infants. FDA is also supporting recommendations from the Department of Health and Human Services for infant feeding and food preparation to reduce exposure to BPA.

**Conclusion**

The change in the policy of the FDA about the safety of BPA in such a short time may create doubts about the ability of the agency to protect the American public, but at the same time we must be calm because the agency has demonstrated that it does not fear criticisms nor hesitate to review decisions over products that can have harmful effects in our lives. Right now that is what the American people want.

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The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors

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15 Id.
16 Id.
18 *See Bisphenol A (BPA) Information for Parents*, supra note 7.
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