Bisphenol A Exposure: Human Risk and Health Policy

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Background of Bisphenol A

SINCE 1940, THE chemical Bisphenol A (BPA) has been used to make plastics. It is currently produced in enormous quantities throughout the world to manufacture polycarbonates for hard plastic products and to make epoxy resin linings for metal food and beverage cans. BPA is a single hydrocarbon molecule that binds with other molecules to form polymers, such as polystyrene and polycarbonates (Le, Carlson, Chua, & Belcher, 2008). Although polycarbonates are advantageous for industrial use due to their strong durability, researchers have long recognized and reported the deleterious effect of BPA on humans when it is released from the polycarbonates with its estrogen-like properties.

In 1930, scientists discovered that BPA was an artificial estrogen, and its estrogen effect was used to enhance the rapid growth of cattle and poultry to promote industry profits (Breast Cancer Fund, 2008a, 2008b). BPA was used for a few years in the mid 1930s as an estrogen replacement for women prior to being replaced by diethylstilbestrol (DES). Although DES is a much more potent estrogen than BPA, there are many similarities between the two chemicals.

Ben-Jonathan and Steinmetz (1998) report that BPA shares similarities in structures, metabolism, and action with DES in vivo and that BPA increases prolactin release and stimulates uterine, vaginal, and mammary growth.

In the United States, an estimated 5 to 10 million people were exposed to DES from 1938 to 1971, including pregnant women who were prescribed DES and their children (Centers for Disease Control [CDC], 2008). Because of its link to vaginal cancer and increased breast cancer risk in daughters of mothers prescribed DES and increased incidence of breast cancer in mothers who took DES, it was removed from the market in 1971 and no longer sold in the United States.

On a daily basis, children and adults are exposed to BPA through a vast array of plastics, “microwave-safe” and metal containers that have plastic and epoxy liners. The most prevalent of these products include, but are not limited to, baby bottles, plastic drinking bottles, dental seals, microwave food products, canned beverage drinks, and metal food containers (such as those used for canned fruits and vegetables and canned baby formula). There are also numerous other products made with BPA, such as compact discs, eyeglass wear, toys, bicycle helmets, and medical devices. Approximately 7 billion pounds of BPA are produced annually, with more than 2 billion pounds produced in the United States. Worldwide, BPA generates an estimated $1 million per day in revenue for corporations such as Bayer, Dow Chemical Company, General Electric...
Prevalence of BPA in Humans

Heat and contact with either acidic or basic compounds accelerate hydrolysis of the ester bond linking BPA molecules in polycarbonate and resins (Vom Saal & Hughes, 2005, p. 926). The heat and hydrolysis, such as that which occurs with the pasteurization and canning process, sterilizing, microwave heating, warming prior to serving, and washing of the containers, result in increased leaching of the BPA into the products that are consumed. Because exposure to low levels of BPA has been shown to cause a number of negative physiological consequences, BPA leaching is of serious concern. Not only is BPA present in plastic and metal products, it is also present in the air and in drinking and other water sources. BPA leaches from the soil into fresh water, and because of plastic and metal waste disposal, it is a major contaminant in landfills.

Studies showing the prevalence of human exposure to BPA have been well documented. A number of such research studies exploring BPA in humans have examined urine concentrations, as BPA is excreted almost exclusively in the urine (Wolfgang & Wolfgang, 2008). Calafat, Ye, Wong, Reidy, and Needham (2008) report that 92.6% of participants (n = 2,517), 6 years and older, who completed a National Health and Nutrition Examination Survey (NHANES III) had urinary concentrations of BPA in the range of 0.4 to 149 μg/L (Calafat et al., 2008). The NHANES III survey conducted by the CDC is considered to be representative of the population (Calafat et al., 2008, p. 39).

Research conducted at the University of Michigan by Padmanabhan et al. (2008) reflects the presence of BPA in maternal circulation (n = 40) at levels close to that shown to be detrimental to reproductive, metabolic, and behavioral health in animal models. The authors recommend that follow-up studies be conducted to determine if the maternal levels have an impact on the development of the newborn (Padmanabhan et al., 2008, p. 262).

Significance of the BPA Issue

Some of the earliest research on low-dose BPA documenting adverse effects in animals began to surface in the late 1990s. In 1997, Vom Saal et al. reported that fetal mice exposure to small doses of estradiol and DES resulted in increased prostate size and high doses resulted in the opposite effect (Vom Saal et al., 1997; Vom Saal & Welschons, 2005). These developmental changes have also been reported in other studies (Timms et al., 2005). The high potency of BPA in vivo particularly during fetal and neonatal development is explained not only by limited binding of BPA to plasma estrogen binding proteins that regulate uptake of endogenous estradiol into tissues but also by the limited capacity for the liver to conjugate (deactivate) BPA in fetuses and newborns (Welschons, Nagel, & Vom Saal, 2006, p. 57).

Vandenberg et al. (2008) studied perinatal exposure to BPA in mice and found that female mice exhibited structural changes in mammary duct glands after being exposed during gestation and lactational periods (Vandenberg et al., 2008). These structural changes were evident throughout the first 15 months of life when the study concluded.

The endocrine-disrupting effects (EDE) of BPA have also been reported in studies in humans. Lang et al. (2008) conducted a cross-sectional analysis of BPA concentrations and health status in the general population of the United States from data derived from the NHANES 2003–2004. Based on the measured urinary BPA in subjects (n = 1,455) aged 18 to 74 and regression models adjusted for demographic data, smoking, body mass index, and waist circumference, the researchers found that higher urinary concentration of BPA were associated with increased
incidence of diabetes, cardiovascular disease, and liver enzyme abnormalities (Lang et al., 2008, pp. 1303 and 1310).

**Problem Statement**

For many years there has been disagreement among researchers and federal agencies regarding what constitutes a safe level of human exposure to BPA. The United States EPA considers “low-dose” effects of environmental endocrine-disrupting chemicals to refer to effects being reported for chemicals at doses lower than those used in traditional toxicological studies conducted for risk assessment purposes (Vom Saal & Hughes, 2005, p. 927). The level determined by the EPA to be the lowest observed adverse effect level is 50 mg/kg per day (United States EPA, 1993). This level is the current level used by the EPA for risk assessment. It was established at that level based on research done in the 1980s and has not been adjusted, even in light of published research acknowledging the effects of estrogenic endocrine-disruptor chemicals at lower exposure effects.

The term low-dose BPA throughout the scientific experiments and that cited in animal and human studies generally refers to a BPA level of less than 1 mg/kg. The National Toxicology Program (NTP) has identified low-dose BPA as 0.05 mg/kg per body weight. The Food and Drug Administration (FDA), the agency responsible for regulating BPA, has determined the appropriate no observed adverse effect level of BPA for systemic toxicity to be 5 mg/kg per body weight per day (Federal Drug Administration, 2008, p. 1). This is a level significantly higher than that reported to be safe by scientists and the NTP (Environmental Working Group, August 15, 2008).

In May 2008, the FDA released a report indicating that currently marketed foods containing BPA are safe and that exposures to BPA from foods, including exposures for infants and children, are less than the levels that may cause health effects (U.S. Federal Drug Administration, May 14, 2008). Contrary to the FDA report, the NTP, Center for the Evaluation of Risks to Human Reproduction (CERHR) concluded that current human exposure to BPA is of “some concern” for effects on development of the prostate gland and brain and for behavioral effects in fetuses, infants, and children. The CERHR report also cited “minimal concern” for adverse effects on the mammary glands and early puberty in females and reproductive or developmental toxicity for fetuses, infants, and children or pregnant women (CERHR, September 2008, p. 382–383).

In October 2008, the FDA acknowledged that scientific research was inconclusive to acknowledge a posed risk from BPA at currently established levels of 5 mg/kg per body weight. The report sparked concern among scientists and consumers regarding conflict of interest not disclosed by the FDA’s BPA Subcommittee Chair, Martin Philbert, following a $15 million grant from Dow Chemical Company for the University of Michigan Risk Science Center, which Philbert founded and codirects (Washington Post, 2008b; Washington Post, Com, October 15, 2008). Representative Edward J. Markey (D-MA) called on the FDA to fully respond to media reports of the undisclosed donation and urged the FDA to consider either requiring Dr. Philbert to return the $15 million donation or remove himself from further participation on the BPA panel (Congressman Edward Markey, Oct. 14, 2008, p. 1; Rust & Kissinger, October 12, 2008).

A 6-month Canadian review of 150 research studies resulted in findings contradictory to the FDA. The Canadian Health Minister announced that there is concern for newborn and infants and that Canada is the first country to declare BPA a health hazard and take steps to ban it from products (Schmidt, October 16, 2008, p. 1). Although most of the attention on the effects of BPA has been in high-risk populations, concern has been voiced to study the effects of BPA in adults. According to Rick Smith, Executive Director of Environmental Defense, new evidence continues to pole up pointing to the detrimental health effects of BPA in adults (Schmidt, October 16, 2008, p. 2).

The Internet abounds with public interest and news media Web sites that discuss growing consumer alarm related to the widespread prevalence of BPA, known human exposure, concern regarding increased risk for vulnerable populations (such as developing fetuses and children), along with numerous documented medical alterations related to endocrine-disrupter effects. There is also public unease for the seeming lack of concern at the federal level regarding the potential harm from BPA exposure.

The stakeholders in the BPA exposure issue include the prenatal population through adult, industry, health care workers, politicians, and regulatory agencies. The goals of BPA regulation are to limit human consumption and protect the public from chemical exposure. Alternatives for action include legislation to protect consumers and accountability of retailers and manufacturers to assure that consumer products are safe.

**Proposed State and Federal Legislation**

In 2005, California, Maryland, and Minnesota proposed legislation to ban children’s products containing BPA and to prohibit manufacture, sale, or distribution of a wide range of toys or childcare BPA-containing products intended for use by children 3 years or younger (Bisphenol A Organization, April 12, 2006, p. 1). The proposed legislation in each state was based on the weight of scientific research; however, BPA was not passed in any of the three states at that time.

In 2008, Senator Carol Migden introduced legislation in California entitled “Toxin-free Toddlers and Babies Act, Senate Bill (SB) 1713” that would ban the sale of BPA
products including sippy cups, baby bottles, cans of formula, and baby food jar lids that are often coated with BPA plastic for children 3 years and younger (California General Assembly, 2009; Lazarus, 2008). The proposed legislation met resistance from the American Chemistry Council, a chemical industry-backed lobbying group that mounted a statewide campaign and urged voters to voice opposition to an SB that would outlaw the BPA in products made for young kids (Orange County Register, August 9, 2008, p. 1). In addition, the Dow Chemical Company requested employees to contact legislators to request defeat of SB 1713. The Dow Action Network acknowledged that the Assemblyman

Table 1  State-Proposed BPA Legislation

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Bill Number</th>
<th>Title: Description of Legislation</th>
<th>Status</th>
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<tbody>
<tr>
<td>Massachusetts</td>
<td>2007</td>
<td>Senate Number 545</td>
<td>An Act to Protect Children from Toxic Toys April 28, 2008 S Bill reported favorably by committee and referred to the committee on Senate Ways and Means Committee—January 6, 2009 S No further action taken.</td>
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Note. Data are taken from the following:
California General Assembly (2009).
New York State Assembly (2009a).
New York State Assembly (2009b).
New York State Assembly (2009c).
New York State Assembly (2009d).
representing the district that includes Dow’s Plant is on the record as abstaining from voting on SB 1713 (Dow Action Network, 2008, p. 1). SB 1713 was defeated a week after the FDA declared BPA to be safe for consumption.

Subsequent to the passage of Toxic Toys Legislation (Assembly Bill, 1108) in California in 2007, a number of states introduced legislation to ban toxic chemicals, including BPA (Table 1). In Connecticut, House Bill (HB) 5601 was introduced to phase out BPA and other toxic chemicals in children’s products sold or manufactured in Connecticut (Breast Cancer Fund, p. 1). In Hawaii, proposed HB 2449/SB 2239 would prohibit the manufacture, sale, and distribution of products for young children that contain BPA or phthalates and requires manufacturers to choose safe alternatives (Hawaii State Legislature, 2008; Hawaii State Legislature Bill Status, 2008, p. 1). In January 2008, Maryland HB 56 was introduced to prohibit the use of six different phthalates and BPA in products intended for children younger than 7 years (Maryland Committee for Children, 2008; Maryland General Assembly, 2008; Phthalates and Bisphenol-A—Prohibitions—Toys and Child Care Articles, n.d.; Phthalates and Bisphenol-A—Prohibitions—Toys and Child Care Articles, 2008, p. 1). SB 545, introduced in Massachusetts in 2007 and to become effective

### Table 2 Material Abbreviations for Recycle Codes

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>LDPE</td>
<td>Polyethylene mainly of the linear low-density polyethylene (LDPE)</td>
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<tr>
<td>PP</td>
<td>Polypropylene; can be either homopolymer, random copolymer or impact copolymer</td>
</tr>
<tr>
<td>PP-TLDPE</td>
<td>PP thermoplastic elastomer</td>
</tr>
<tr>
<td>PC</td>
<td>Polycarbonate BPA is a key industrial chemical used to make polycarbonate plastic, epoxy resins and other products</td>
</tr>
<tr>
<td>PA</td>
<td>Polyamide</td>
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### Table 3 Raw Material Symbol for Recycle Codes

- **PETE:** Polyethylene terephthalate ethylene, used for soft drink, juice, water, detergent, cleaner and peanut butter containers.
- **HDPE:** High-density polyethylene, used in opaque plastic milk and water jugs, bleach, detergent and shampoo bottles and some plastic bags.
- **PVC or V:** Polyvinyl chloride, used for cling wrap, some plastic squeeze bottles, cooking oil and peanut butter jars, detergent and window cleaner bottles.
- **LDPE:** Low-density polyethylene, used in grocery store bags, most plastic wraps and some bottles.
- **PP:** Polypropylene, used in most deli soup, syrup and yogurt containers, straws and other clouded plastic containers, including baby bottles.
- **PS:** Polystyrene, used in Styrofoam food trays, egg cartons, disposable cups and bowls, carryout containers and opaque plastic cutlery.
- **Other:** Usually polycarbonate, used in most plastic baby bottles, 5-gallon water bottles, “sport” water bottles, metal food can liners, clear plastic “sippy” cups, and some clear plastic cutlery. New bio-based plastics may also be labeled #7.

January 2008, also prohibits the use of BPA and phthalates in children’s products (Commonwealth of Massachusetts, Senate and House of Representatives, 2007, p. 1; The Commonwealth of Massachusetts, 2008). Minnesota, SF 858/HF2100, and New York, A. 6829/S. 6058, have proposed legislation to phase out BPA and phthalates in children products, with New York proposing $1,000-per-day fine for offenders (Breast Cancer Fund, p. 1). The status of each state’s proposed legislation varies (New York State Assembly, 2009a, 2009b, 2009c, 2009d).

On the national level, SB 2928, BPA-Free Kids Act of 2008 was introduced in April 2008, by Senator Charles Schumer (D, NY) along with co-sponsors, Senators Diane Feinstein (D-CA), Hillary Clinton (D-NY), Robert Menendez (D-NJ), Barbara Boxer (D-CA), John Kerry, (D-MA), Richard Durbin (D-IL), Bill Nelson (D-FL), Bernard Sanders (I-VT), and Tim Johnson (D-SD). The bill intended to ban BPA in children’s products specifically treats as a banned hazardous substance under the Federal Hazardous Substances Act any consumer product that contains a detectable amount of BPA and that is designed for or intended for use by, or care of, a child 7 years or younger (Open Congress, April 29, 2008, p. 1). In addition, it permits state laws to provide equal or greater protection from BPA. The bill would also require the CDC to submit a plan to Congress to study the health effects of BPA exposure in all age groups and in pregnant women (Govtrack.US: A Civic Project to Track Congress, April 29, 2008, p. 2). This bill was referred to Committee on Commerce, Science, and Transportation. SB 2928 is in keeping with legislative steps taken by Canada to ban BPA. Canada has added BPA to its list of toxic substances and has stopped the sale of polycarbonate baby bottles (European Information Centre on Bisphenol A, 2008; Health Canada, April 18, 2008).

A number of retailers have stopped using BPA products. Wal-mart and Toys R Us are no longer stocking baby bottles and other products that contain BPA. In April 2008, Nalgene, a maker of hard plastic sport water bottles, began phasing out production of its Outdoor line of polycarbonate containers that include the chemical BPA (Nalgene, April 2008, p. 1). Playtex Products Incorporated also announced in April 2008 that it will produce products that are BPA-free and products can be identified by a BPA- and phthalates-free icon listed on the products (Playtex Products, Incorporated, April, 2008). Both Dow Chemical Company and Playtex Products Incorporated downplayed any acknowledged risk with BPA but cited the reason for the BPA-free products was due to consumer response. Tupperware, who acknowledges the safety stance of the FDA on its Web site, has BPA-free baby products and includes the polycarbonate (BPA) recycling code for its products that do contain BPA (Tupperware, 2008; Tables 2 and 3).

Five leading manufacturers of polycarbonate baby bottles, namely, Gerber, EvenFlo, Avent, Playtex, and Dr. Brown’s, are facing a class-action lawsuit filed in Los Angeles Superior Court due to the presence of BPA (CALI Class Action Lawsuits.info, April 2007, p. 1). An additional lawsuit has been filed against Playtex by a woman in Arkansas, who claimed that she did not know that the products contained BPA (Washington Post, 2008a, p. 1).

In addition, Nalgene has been sued due to its sports bottles containing BPA. Increasing litigation may be expected as consumers awareness of BPA continues to grow.

Implications for Nurses

Nurses are in key positions to bring attention to the need to establish health care policies that promote well-being. Caring for patients provides an arena to disseminate information and answer questions that patients and families have about health hazards such as BPA. Nurses comprise a large force of health care providers and can influence policy makers through individual efforts or via professional nurse organizations. According to Chapman and Malone (2008), the nursing profession has a growing role in health care policy, with nurses assuming leadership roles in advocacy, research, analysis, policy development, implementation, and evaluation (Chapman & Malone, 2008, p. 1).

Conclusions and Recommendations

There is a strong body of literature showing the EDE of BPA exposure. The most notable effects are evident in fetal through early childhood development and include secondary sexual developmental changes, neurobehavioral alterations, and immune disorders. BPA has also been found in higher levels in the presence of cardiovascular disease, diabetes, obesity, and liver dysfunction. Although populations most at risk from exposure to BPA include the developing fetus, infants, children, and pregnant women, there is concern for the effects of BPA in adults.

There are inconsistencies among the best evidence, industry, and the FDA regarding what constitutes a safe level of BPA exposure. There needs to be congruency among the federal agencies and researchers to clearly define and publicize the level of daily human exposure that constitutes risk. Until there is regulatory agreement on the safety of BPA, exposure should be limited in vulnerable populations such as infants, children, and pregnant women.

BPA-Free Kids Act of 2008 SB 2928 proposed legislation to ban BPA and is targeted toward the protection of children, especially limiting exposure under the age of 7 years. One might assume that this legislation would receive support because of the vulnerability of and need to protect children. One might also assume that there is a strong likelihood of enacting legislation banning BPA because of widespread consumer concern for safety, the elimination of BPA...
products by major corporations, and recent action by the Canadian Health Ministry to ban the manufacture and sell of BPA-containing products. However, there are special interest groups who serve to profit by the manufacturing and selling of BPA products, especially manufacturing companies of plastics who have shown efforts to negate risk or block legislation that bans BPA.

References


Bisphenol A


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