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Written by
Rachel L. Gibson

Environment California Research and Policy Center

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Acknowledgments

Written by Rachel L. Gibson, Environmental Health Advocate and Staff Attorney, Environment California Research & Policy Center.

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Environment California Research & Policy Center
3435 Wilshire Boulevard, Suite 385
Los Angeles, CA 90010

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Executive Summary

Products marketed for infants and children are not always completely safe for their use. Many contain toxic chemicals that may have detrimental health impacts for children exposed during critical stages of development.

In this report, we analyze the extent to which five popular brands of baby bottles leach bisphenol A, a developmental, neural, and reproductive toxicant, into liquids coming into contact with them. We found that all five brands leach bisphenol A at dangerous levels found to cause harm in numerous laboratory animal studies.

California and the U.S. should reform chemical policy to ensure that all products on the market are safe for children.

Bisphenol A is a Developmental, Neural, and Reproductive Toxicant

- Scientists have linked very low doses of bisphenol A exposure to cancers, impaired immune function, early onset of puberty, obesity, diabetes, and hyperactivity, among other problems.
- For example, in one recent study, a single, low dose of bisphenol A administered to a newborn rat resulted in hyperactive behavior.

Exposure to Bisphenol A is Widespread

- Bisphenol A is most commonly used to make clear polycarbonate plastic for consumer products, such as baby bottles. Through use, this plastic breaks down and leaches bisphenol A into liquids and food to which it comes into contact.
- The U.S. Centers for Disease Control and Prevention found bisphenol A in the urine of over 95% of people they tested.
- Alarmingly, the median level of bisphenol A in humans is higher than the level that causes adverse effects in animal studies.

Popular Baby Bottles Sold in California Leach Bisphenol A at Harmful Levels

- Based on a consumer survey of the most popular baby bottle brands on the market, we selected five bottle types to determine the amount of leaching from each bottle. We found that the bottles tested from all five brands leached bisphenol A at levels found to cause harm in numerous laboratory studies, including:
  - Avent
  - Dr. Brown's
  - Evenflo
  - Gerber
  - Playtex

Recommendations for Parents

Parents have the right to know about chemicals in the products they purchase for their children. In the absence of good government regulations, but armed with the knowledge that some chemicals are a cause for concern, parents can take a few simple actions to limit their child's exposure to these and other toxic chemicals.

At the store, parents should select baby bottles that are made from glass or a safer non-polycarbonate plastic. At home, parents should avoid washing plastic dishware with harsh dishwashing soap and hot water, which may allow chemicals to leach out of the plastic. For a useful tip sheet, parents should visit www.EnvironmentCalifornia.org.

Recommendations for Policymakers

Parents cannot deal with these issues alone. The government must ensure the safety of all products on the market for children. California and the U.S. should:

Phase Out Hazardous Chemicals

Based on the weight of the scientific evidence showing the harm caused by exposure to bisphenol A, the government should act now. Given that data from the U.S. Centers for Disease Control and Prevention show that bisphenol A is present in humans at levels found to be harmful in laboratory studies, California and the U.S. should phase out the use of bisphenol A, especially in products used by children.

Inform Consumers about the Presence of Dangerous Chemicals

Parents currently have little information to inform their decisions when purchasing products for their family. Manufacturers should be required to label children's products with the name of any potentially dangerous chemical and the specific health risks associated with the chemical.

Reform Chemicals Policy

Currently, manufacturers can put chemicals on the market without proving they are safe. Chemical manufacturers should be required to provide all hazard and health-effects information to the government so agencies can begin to assess the thousands of chemicals currently on the market for which little or inadequate data are available. Next, pre-market hazard and health-effects testing should be required for all new chemicals before they are introduced into commerce. Finally, the California Environmental Protection Agency must have the authority to protect public health by banning or restricting the use of a chemical if evidence shows that it can harm human health.

Introduction

Becoming a mother was an amazing and alarming experience for me. Amazing because my daughter was *finally* here. Alarming because now that she was here, there was suddenly so much to worry about. Is she nursing enough? Sleeping enough? Sleeping too much? I learned early on that the questioning never really ends. The difficulty lies in knowing which questions to ask.

After I returned to work, my daughter began attending daycare. I continued to feed her breast milk, which had been stored and frozen in plastic baby bottles. At the time, it felt good to know that she would be getting all the benefits of breast milk even while I was away. What I didn't realize at the time, was that in addition to the enzymes and antibodies she would receive as she drank from the bottle, she also could be exposed to a chemical linked to dangerous developmental and reproductive health effects.

There is a wealth of information available to help new parents choose the safest product at the best value for their babies. Whether it's safety ratings on that new car seat, or a friend's recommendation on the sturdiest stroller, parents have the information they need to make informed choices about most of the products they buy for their child. Except, that is, when it comes to determining which products might contain dangerous chemicals.

Toxic chemicals, many linked to significant health problems, can be found in a wide variety of children's products. Sadly, baby bottles are no exception. Most popular baby bottles on store shelves are made with bisphenol A, a chemical known to disrupt the hormone system even when exposed to extremely low doses. And like me, most parents have no idea that a dangerous chemical is lurking in their baby's bottle.

Even the most educated parents have a hard time figuring out which products are safe and which may be harmful. I've spent hours researching everything from the safest bottle to the safest teether, and yet, it's impossible to know with any certainty whether an individual product falls into the safe or hazardous category.

The only way children will be protected from dangerous chemicals is for the government to take bold steps and prohibit the use of chemicals in children's products that are known or suspected of causing harm.

Parents must speak out. I was scared when I first started uncovering information about the dangerous chemicals found in common children's products. But I turned the fear into action. Parents can and should reach out to their elected officials to demand that they do more to protect children's health.

Mary Brune
Co-founder, Making Our Milk Safe (MOMS)

Bisphenol A: Developmental, Neural, And Reproductive Toxicant

Bisphenol A is a chemical commonly used in the manufacture of clear polycarbonate plastic. It is one of the top 50 products produced by the chemical industry, generating revenues on the order of $6 million per day in the United States, Europe, and Japan alone.[1] Global bisphenol A production exceeds 6.4 billion pounds per year.[2]

Bisphenol A can be found in a wide variety of consumer products, including clear plastic baby bottles. Dozens of other common household and consumer items contain bisphenol A, including some types of reusable water bottles and microwaveable food containers, electronic equipment, automobiles, sports helmets and pads, eyeglass lenses, and more. Bisphenol A is also used in epoxy resins found in white dental sealants, printed circuit boards, paints, glues, protective coatings, and—more worrisome—in the lining of metal cans containing food and drink.[3] It is also an additive in other types of plastic used to make children's toys.

However, bisphenol A is also a developmental, neural, and reproductive toxicant. When in the body, it can act as a substitute for the female hormone estrogen, interfering with the normal process of signaling that is critical for the healthy growth, development, and function of the human body.

Scientists first learned that bisphenol A could act as a synthetic substitute for estrogen in the 1930s, close to 30 years after its invention.[4] It wasn't until 1953 that chemists discovered bisphenol A could be made into polycarbonate plastic. Despite the fact that bisphenol A was known to mimic estrogen, it went on to become commonplace in the manufacture of a variety of consumer products.

A Small Sample of Bisphenol A Uses Include…

…polycarbonate plastic, including most plastic baby bottles
…children's toys
…dental sealants
…epoxy lining of food and beverage cans
…reusable drink containers
…microwavable food containers
…electronic equipment
…sports helmets
…eyeglass lenses

Bisphenol A Causes Health Problems

Extensive scientific literature reports adverse health effects from bisphenol A at very low doses. Studies show that bisphenol A can alter the expression of several hundred genes with effects varying among specific tissues and depending upon the timing of exposure. More than 150 laboratory animal studies suggest that bisphenol A exposure at very low doses is linked to a staggering number of health problems, including prostate and breast cancer, obesity, hyperactivity, diabetes, altered immune system, lowered sperm count, and early puberty.

Adverse Health Effects of Bisphenol A Include…

…early onset of puberty
…obesity
…diabetes
…hyperactivity
…increase in aggression
…changes in response to painful or fear-provoking stimuli
…impaired learning and memory
…reversal of normal sex differences in the brain structure
…elimination of sex differences in behavior
…decreased maternal behavior
…impaired immune function
…breast cancer
…prostate disease and cancer
…sperm defects
…impaired female reproductive development
…miscarriage

Children are Most at Risk

Growing children are particularly at risk to toxic chemicals in their environment because they are physiologically more susceptible to them.[5] Children's exposures begin at conception, as chemicals, including bisphenol A, cross the placenta in a pregnant woman's body, potentially affecting the embryo or fetus during critical periods of development.[6] Even after birth, children's bodies remain immature with underdeveloped detoxification mechanisms to protect them from toxic chemicals. Children's brains and other organ systems are constantly developing, undergoing periods of particular sensitivity to damage or disruption.

Like over-the-counter medications, which children's bodies cannot tolerate or can only tolerate in extremely low levels, children are particularly susceptible to the harmful effects of bisphenol A. However, there is now extensive evidence that many of the problems associated with bisphenol A exposure during these critical stages of development may not come to light until years after exposure.

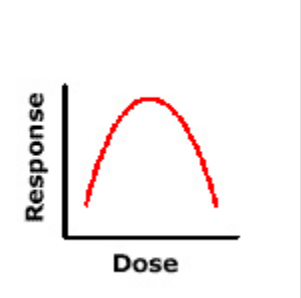
Especially because growing children are particularly at risk from bisphenol A exposure and because adverse effects on intellectual ability, social behaviors, fertility, and potential for disease may take decades to detect, measures must be taken to protect children from exposure to products containing bisphenol A that they use every day.

The Dose Does Not Make the Poison

For decades, scientists in the field of toxicology have assumed that the higher the dose of a chemical the greater the harm. Decades of studies of hormones by endocrinologists, and recent application of methods used to study hormones to the study of hormone-mimicking chemicals such as bisphenol A, invalidate this prediction that the dose makes the poison. Numerous studies show that bisphenol A and other hormone-mimicking chemicals result in great harm at very low doses that is not predicted by studies with only very high doses. Rather than having a linear dose-response curve, the dose-response curve for bisphenol A appears more like an inverted "U" in which lower doses of exposure cause greater harm than higher doses. The standard tests used in toxicology to set health standards have assumed that the dose makes the poison, thereby ignoring the low-dose impacts of chemicals that mimic hormones. The implications of this fact are stark: the health standards set by the government may not in reality be protecting human health.

Linear Response Curve

Inverted U-Shaped Curve



Bisphenol A Can Induce Chromosome Sorting Errors

Bisphenol A recently burst onto the scene as a potential factor in the incorrect sorting of chromosomes. In 2003, Dr. Pat Hunt and her colleagues made an accidental but dramatic discovery: bisphenol A can cause chromosomes to sort incorrectly, even at very low doses.[7] Germ cells normally split into two cells when forming eggs, separating chromosomes equally into each daughter cell. These cells then enter the reproductive process, and when fertilized by sperm, develop into new organisms. Dr. Hunt showed that exposure to bisphenol A prevents the chromosomes from lining up correctly, resulting in chromosome sorting errors like the kind that cause Down syndrome. While a variety of possible events could also lead to the same genetic outcome, the fact that a common chemical can cause this effect is cause for concern.

The Bisphenol A – Down Syndrome Connection

When chromosomes sort incorrectly in a father's sperm or mother's egg, diseases—and, quite frequently, miscarriages—result. Incorrect sorting of chromosomes leads to diseases like Down syndrome, in which a child has an extra copy of chromosome 21 and suffers multiple mental and physical impairments; Turner syndrome, in which a female has only one X-chromosome and never develops ovaries; and Klinefelter syndrome, in which a male has one or more extra X-chromosomes and is sterile. Dr. Hunt's findings show that extremely low doses of bisphenol A exposure are linked to an error in cell division called aneuploidy, which causes 10-20 percent of all birth defects in people, including Down syndrome.[8]

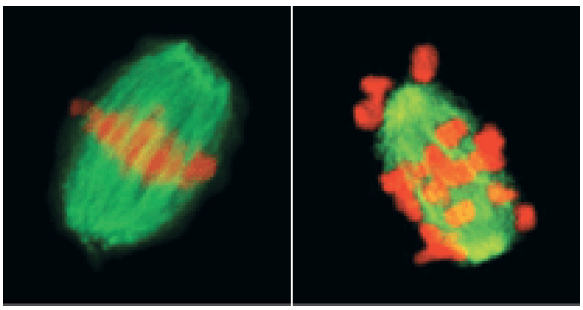
While a variety of possible events could also lead to the same genetic outcome, the fact that a common chemical can cause this effect is cause for concern.

At the time of Dr. Hunt's discovery linking bisphenol A to chromosome sorting errors, her research team was not studying bisphenol A. The lab was using mice for their research, and lab staff kept the mice in plastic cages and fed them water from plastic water bottles. The staff were shocked when they discovered severe chromosome sorting problems in developing egg cells of mice they were expecting to be normal. Dr. Hunt faced the question of how untreated mice developed such striking damage to their egg cells.

The answer to the mystery turned out to be contamination from the polycarbonate plastic cages and water bottles. Bisphenol A leached out of these items into the mice in appreciable quantities. Lab staff were able to replicate the effect in several ways: by feeding mice through polycarbonate plastic bottles purposefully washed to accelerate leaching of bisphenol A, and by directly administering small doses of pure bisphenol A to the mice.

Even at the lowest dose tested of 20 micrograms per kilogram per day (20 µg/kg/day) for 6 to 8 days, Dr. Hunt found that bisphenol A caused significant and observable damage to developing eggs (Figure 1, next page).

Figure 1: Bisphenol A Causes Chromosomes to Sort Incorrectly During the Development of Egg Cells[9]



In normal development (left), eggs and sperm develop when a germ cell splits in two, giving an equal set of chromosomes to each germ cell. The chromosomes (red) line up on the spindle (green) to ensure equal separation. However, bisphenol A prevents the chromosomes from lining up correctly (right), resulting in chromosome sorting errors like the kind that cause Down syndrome.

Interviewed by the *Los Angeles Times* about this finding, Dr. Frederick vom Saal at the University of Missouri, a leading bisphenol A scientist, noted that "these effects in the Hunt study and other studies happen at lower doses than what is actually found in human fetal blood—umbilical cord blood." In fact, tests of placental tissue and amniotic fluid of women in Germany and Japan found bisphenol A at high levels—from 1 to 105 parts per billion (ppb), which is above the range found in mice administered doses that caused chromosome sorting errors in Dr. Hunt's study.[10]

Subsequent research by Dr. Hunt and her colleagues shows that exposure to bisphenol A can lead to chromosomal abnormalities that affect future generations as well.[11] This is because female mammals, including mice and humans, form their eggs while still in their mother's womb. Thus, the eggs that will become a female's grandchildren are affected through in utero exposure to bisphenol A.

Prior to this finding by Dr. Hunt and her colleagues, researchers believed that fetal exposure to bisphenol A could be avoided simply by staying away from the chemical during pregnancy. Dr. Hunt's research team demonstrated, however, that "[bisphenol A] can lie inside [a female] like a time bomb ready to detonate once she becomes pregnant."[12] This is a classic example of the consequences of fetal exposure not being realized until long after the exposure occurred.

Specifically, in this recently published study, Dr. Hunt exposed pregnant female mice to low doses of bisphenol A in the 20 µg/kg/day range. Dr. Hunt found that the undeveloped eggs inside the developing fetuses of the exposed mice showed chromosomal abnormalities. As many as 40 percent of these eggs had chromosome abnormalities. Normally less than 1 percent would show problems. The abnormalities suggest that the eggs would not be able to create viable offspring, highlighting the concern that bisphenol A could affect the grandchildren of an exposed pregnant female.

Bisphenol A Can Lead to Early Onset of Puberty

Bisphenol A from polycarbonate plastic accelerates the timing of puberty in laboratory studies. Indeed, several studies reveal the early onset of sexual maturation in females occurring at maternal doses between 2.4 and 50 µg/kg/day.[13] For example, Dr. Kembra Howdeshell and her colleagues found that when a pregnant mouse was given an extremely small bisphenol A dose of 2.4 µg/kg/day, their female offspring tended to grow larger and ovulate earlier (i.e., signs of early puberty).[14] A Japanese lab confirmed these findings in 2002.[15]

Bisphenol A Exposure May Lead to Obesity and Diabetes

A study by Dr. Beverly Rubin and her colleagues at Tufts University Medical School showed that bisphenol A makes rodents grow larger after they are exposed in the womb, confirming similar findings from previous studies.[17] When rats were fed 100 µg/kg/day of bisphenol A during pregnancy through lactation, their offspring were notably heavier after birth and into adulthood.

Significantly, in the female offspring, the lower of the two bisphenol A doses used in the study produced a larger and more persistent effect on body weight relative to the higher dose. In addition, the fact that the effect persisted long after exposure for the female offspring suggests that bisphenol A may increase the number of fat cells in the rats and predispose them to heavier weight throughout life.

In 2002, a team of researchers at the Ehime College of Health Science in Japan discovered that bisphenol A can increase the conversion of embryonic cells into fat cells.[18] In the body, this effect could result in larger numbers of fat cells developing. In addition to converting to fat cells, treated cells increased their fat content by 150 percent over 11 days. Combined with insulin, bisphenol A increased the fat content of cells by 1300 percent. In other words, this experiment documented that bisphenol A could trigger and promote the two main processes in developing obesity. In 2004, another study confirmed these findings, showing that bisphenol A alone and with insulin increased the uptake of sugar into fat cells.[19]

A recent study by Dr. Paloma Alonso-Magdalena and her colleagues showed that low-level, chronic exposure of adult mice to 10 µg/kg/day of bisphenol

U.S. Environmental Protection Agency's Current Safety Threshold for Bisphenol A

The current safety threshold established by the U.S. EPA—called the reference dose (i.e., safe dose)—was set based on animal experiments conducted prior to 1988 showing that 50 milligrams per kilogram of body weight caused weight loss in rodents. U.S. EPA declared 50 mg/kg/day the lowest observed adverse effect level, or LOAEL. To arrive at the current reference dose, U.S. EPA assumed without further study that a dose 1000 times lower than the LOAEL (i.e., 50 micrograms per kilogram per day, or 50 µg/kg/day) would be an acceptable reference dose. As over 40 studies now illustrate, the official reference dose of 50 µg/kg/day is well above the levels at which adverse affects have been found in numerous animal studies over the past decade.

For example, Dr. Kembra Howdeshell and her colleagues found that the female offspring of pregnant mice fed bisphenol A at the low dose of 2.4 micrograms per kilogram per day experienced the early onset of puberty.[16] If U.S. EPA were to use 2.4 µg/kg/day as a LOAEL and apply the same logic used to establish the current standard, the reference dose would be 2.4 nanograms per kilogram per day (ng/kg/day). A reference dose of 2.4 ng/kg/day would eliminate commercial uses of bisphenol A in food and beverage containers and products that babies are likely to put in their mouths.

A caused insulin resistance, which is a precursor to Type II diabetes in people as well as hypertension and cardiovascular disease.[20] Dr. Alonso-Magdalena's study showed that even a single dose of bisphenol A at levels currently found in humans can result in altered levels of blood glucose and insulin, and twice-daily exposure for just four days results in insulin resistance.

Several studies show an increased rate of postnatal growth in both males and females as a result of maternal doses between 2.4 and 500 µg/kg/day.[21] Accelerated postnatal growth is associated not just with obesity but with insulin-resistant diabetes, hypertension, and heart disease as well.

Figure 2: Rising Obesity Trend in Adolescents[22]

	Children 6-11 Years	Adolescents 11-19 years
1972	4%	6%
1978	6%	5%
1991	11%	10%
2000	15%	15%

Bisphenol A Exposure Leads to Impaired Brain Development

In most studies, bisphenol A has been found to mimic the actions of estrogen in developing neurons. In specific areas of the brain, however, bisphenol A can have the paradoxical effect of *inhibiting* the activity of estrogen, which normally increases the growth and regulates the viability of connections between neurons. In this regard, bisphenol A is similar to the breast cancer drug tamoxifen, which stimulates estrogenic responses in some tissues and inhibits estrogenic responses in other tissues. The concern

relating to this inhibitory effect of bisphenol A is that this type of disruption is associated with impaired learning and memory.[23]

Whether bisphenol A is mimicking or inhibiting estrogen, bisphenol A appears to trigger steps important in the development of the brain at the wrong times or encourages improper connections in the brain to be made. Mounting evidence from the last several years shows that bisphenol A alters brain development, leading to a number of different potential problems, including:

- *Hyperactivity*: Dr. Masatoshi Morita and his colleagues at the Japanese National Institute for Environmental Studies reported that a single 30 µg/kg/day bisphenol A dose given to a 5-day old rat lead to hyperactive behavior.[24] The scientists also found that bisphenol A exposure changed how the dopamine signaling system developed in brain cells, resulting in

less dopamine receptors and transporters. Dopamine is an important transmitter of nerve signals in the brain, and loss of neurons that produce dopamine occurs in Parkinson's disease.

- *Increase in aggression*: At doses between 2 and 40 µg/kg/day, fetal exposure to bisphenol A led to increased aggressive behavior by male mice, which could not be attributed to an elevation in testosterone concentration.[25]
- *Changes in response to painful or fear-provoking stimuli*: Dr. Anna Maria Aloisi and her colleagues injected pregnant and lactating rats with 40 µg/kg/day of bisphenol A. The scientists found that exposure to bisphenol A during these times modified the activity of neural pathways and changed the rats' perception of pain.[26]
- *Impaired learning and memory*: Male offspring of rats exposed to 0.1 mg/kg/day of bisphenol A consistently failed to avoid electrical shocks at a significantly increased rate compared with the control offspring, revealing that bisphenol A exposure during brain development had resulted in impaired memory.[27]
- *Reversal of normal sex differences in the brain structure and elimination of sex differences in behavior*: At 30 µg/kg/day, exposure to bisphenol A before birth and during nursing reversed the sex differences between male and female rats in an area of the brain—the locus coeruleus—which is believed to be a key brain center for anxiety and fear and is normally larger in females than in males. Exposure also eliminated the usual sex differences found in tests used to quantify both exploratory behavior and fear response.[28]
- *Decreased maternal behavior*: Dr. Paola Palanza and her colleagues exposed female mice to bisphenol A at the 10 µg/kg/day level and measured several different characteristics of maternal behavior. Some of the mice were exposed while in the womb by feeding their pregnant mothers. Some were exposed in adulthood while lactating. Others were exposed both in the womb and during adulthood. The scientists' findings showed that maternal behavior was altered in a number of ways. Females exposed to bisphenol A only as fetuses or only as adults exhibited lower levels of nursing behavior toward their offspring, increases in time resting away from offspring, and increases in time spent out of the nest. In most measurements, females exposed both in the womb and as adults did not differ from controls.[29]
- *Altered play and other socio-sexual behaviors*: At 40 µg/kg/day, the male and female offspring of rats fed bisphenol A from conception to weaning led to a masculinization of female behavior in two behavioral categories—play with females and sociosexual exploration (i.e., genital and body sniffing).[30]

Bisphenol A May Lead to Impaired Immune Function

Several studies show that altered immune function occurs at doses of bisphenol A between 2.5 and 300 µg/kg/day.[31] These studies show that immune responses may be augmented as a result of either prenatal or postnatal exposure to bisphenol A.

Bisphenol A is Linked to Increased Cancer Cell Growth

Breast cancer

A recent study showed that prenatal exposure to bisphenol A causes mammary gland cancer in adult rats.[32] Prior research had shown that bisphenol A altered the growth of mammary tissues in ways that increase the risk of breast cancer and increase the sensitivity of breast tissue to cancer causing agents.[33] In one of these earlier studies, scientists exposed mouse fetuses to doses of 25 and 250 ng/kg/day—2,000 times lower than the amount deemed safe by the U.S. EPA for humans in the U.S—causing increased breast tissue development.[34] Higher density breast tissue is a risk factor for cancer.[35]

In the most recent study by Dr. Ana Soto and her colleagues, prenatal exposure of both rats and mice to bisphenol A at doses ranging from 0.25 to 25 µg/kg/day lead to the formation of mammary gland cell growth patterns that are considered to be the precursors of breast cancer.[36]

Prostate disease and cancer

Along with breast cancer, low-dose exposure to bisphenol A is implicated in prostate cancer, as it can significantly increase prostate size. Several studies show an increase in prostate size due to hyperplasia in male mouse offspring caused by very low maternal doses of bisphenol A.[37] A more recent study shows that exposure to a very low dose of bisphenol A for just a few days after birth predisposes male rats to develop prostate cancer in adulthood.[38]

In addition to causing prostate cancer, bisphenol A can interfere with traditional methods for treating prostate cancer. In a study by Dr. Yolanda Wetherill and her colleagues, bisphenol A stimulated human prostate cancer cells, which would interfere with the standard hormone treatment used to force prostate cancer into remission.[39] This effect occurred at exactly the concentration of bisphenol A present in over 95 percent of people in the U.S according to the U.S. Centers for Disease Control and Prevention.

Bisphenol A is Associated with Sperm Defects

In 1998, Dr. Frederick vom Saal and his colleagues at the University of Missouri at Columbia published one of the first studies linking reduced sperm production with bisphenol A exposure. The scientists fed bisphenol A to female rats at a dose of 20 µg/kg/day for six days during pregnancy. They found that males born to exposed rats produced 20 percent less sperm after they matured than normal males.[40] They also found that treated offspring had physical changes in hormone-secreting glands not found in untreated mice, even at a dose 10 times smaller.

A few years later, Dr. Motoharu Sakaue and his colleagues in Japan added to these findings, discovering that bisphenol A reduces the number of sperm in rats, even when given doses after puberty.[41] After feeding small doses to rats (20 µg/kg/day for six days at week 13 of life), they noted a generalized decline in the ability of treated rats to produce sperm. The scientists concluded that bisphenol A retarded the development of germ cells that normally takes place as the male rat's reproductive system matures from week 14 to week 18. The scientists further concluded that the effects occurred in a dose range "relevant to the daily level of exposure in man."

Figure 3: Average Decline in Sperm Density Across North America and Europe in the 20th Century[42]

	Sperm Density (million/ml)	
Year of Sample Collection	North America	Europe
1934	108	
1945		169.5
1996	59	58
Decline in Sperm Density	45%	66%

A 2002 study also found lowered sperm production as a result of bisphenol A exposure, in addition to other problems. Adult male mice having ingested 5 to 100 µg/kg/day of bisphenol A showed a significant reduction in testicular sperm counts, the efficiency of sperm production, and the weight of the testes.[43] According to the study's authors, the "results suggest that male fertility and reproduction is impaired by bisphenol A."

Additional studies have confirmed the 2002 findings of reduced testes weight. One lab demonstrated that fetal exposure to bisphenol A causes reduced testes weight at concentrations found in humans.[44] Another found that bisphenol A-treated rats had a significant decrease in the weight of the testes in addition to a reduction in sperm motility and sperm count.[45]

Bisphenol A is Linked to Impaired Female Reproductive Development

In 2002, evidence of impaired female reproductive development as a result of bisphenol A exposure was published. Pregnant rats given 0.1 mg/kg/day of bisphenol A gave birth to female offspring with vaginal deformations, apparently caused by a disruption of the estrogen signal required for normal development.[46]

Bisphenol A Exposure May Lead to Miscarriage

Low-dose bisphenol A exposure is also associated with miscarriages in women.[47] In one recent study, scientists found levels of bisphenol A three times higher in women with a history of recurrent miscarriage than in women who had normal pregnancies.[48] The results of this study were predicted by an earlier study by Dr. Hunt and her colleagues that found bisphenol A causes meiotic aneuploidy in mice, a condition that is the largest known cause of spontaneous miscarriage in people.

Animal Studies Predict Human Health Outcomes

Although a few studies on bisphenol A rely on human data, most studies on the effects of bisphenol A exposure involve laboratory animal experiments. At this time there is inadequate information to determine whether the absorption, distribution, and excretion of bisphenol

A is identical in rodents and humans. There is extensive evidence, however, that the sensitivity of tissues to bisphenol A in the animals used in experiments is virtually identical to the sensitivity of human tissues to bisphenol A.

Indeed, the U.S. government has concluded that animal studies are a vital guide to identifying health risks for humans.[49] And, it is clear from a large number of studies that the concentration of biologically active bisphenol A in the blood, tissues, and urine of the average person is higher than levels that cause harm due to administration of the doses in the animal experiments described above.

Because the chemical bond between bisphenol A molecules in polycarbonate plastic is unstable, the plastic can degrade over time and leach bisphenol A into materials with which it comes into contact. As a result, exposure to bisphenol A is widespread.

Bisphenol A Levels in Humans are Above Harmful Levels Found in Studies

According to the U.S. Centers for Disease Control and Prevention (CDC), 95 percent of Americans have detectable levels of bisphenol A in their bodies.[50] In a recent CDC study, the observed bisphenol A levels detected—0.1 to 9 ppb—were at and above the concentrations known to reliably cause adverse effects in laboratory experiments. Of significant concern, the median bisphenol A level in human blood and tissues, including in human fetal blood, is higher than the level that causes adverse effects in rodents.[51]

Despite the fact that bisphenol A is metabolized by the body, the CDC's findings provide strong evidence that exposure to the chemical is very frequent or nearly continuous. Otherwise, over 95 percent of the people examined would not have had detectable bisphenol A in this relatively high range. While 0.1 to 9 ppb may not seem like a high concentration, one recent study found significant increases in calcium inflow even at the lowest levels of bisphenol A exposure in the low part per trillion (ppt) range.[52] Increases in calcium within the cell initiate a wide array of processes within the cell such as regulating hormone secretion and controlling gene activity. The CDC data show that people contain BPA in the *parts per billion* level—1,000 times higher than the lowest exposure at which an effect was seen on calcium influx.

The CDC's findings are confirmed by numerous studies conducted in other countries showing virtually identical levels of bisphenol A in blood and tissues collected from human fetuses and adults.[53] These findings suggest that human exposure to significant amounts of bisphenol A must be continuous and via multiple sources.[54]

How Bisphenol A Gets into Our Body

Bisphenol A leaches into our bodies through our everyday contact with household products containing the chemical. The following have all been shown to result in an increase in the rate of leaching of bisphenol A:[55]

- the presence of acidic or basic food or beverages stored in cans lined with epoxy resin containing bisphenol A or in polycarbonate plastic;
- heating of polycarbonate plastic containers; and
- repeated washing of polycarbonate products.

Another potential source of human exposure to bisphenol A is through water used for drinking or bathing.[56] This is because bisphenol A contamination is widespread in the environment. For example, bisphenol A can be measured in rivers and estuaries at concentrations that range from under 5 ng/L (5 ppt) to over 1900 ng/L (1.9 ppb). Sediment loading can also be significant, with levels ranging from under 5 ppb to over 100 ppb.[57] Moreover, studies conducted in the U.S. and Japan have shown that bisphenol A accounts for the majority of estrogenic activity that leaches from landfills into the surrounding ecosystem.[58]

Report Findings: All Baby Bottles Tested Leach Bisphenol A

Do all baby bottles leach bisphenol A? To answer this question, we analyzed five of the most popular brands of baby bottles to determine whether bisphenol A leaches into liquid with which it comes into contact. Laboratory tests found that all five bottle brands leached levels of bisphenol A exceeding the levels found to cause harm in scientific studies.

As described above, bisphenol A is the building block for polycarbonate plastic. Polycarbonate plastic is a very hard, unbendable plastic and typically clear in appearance. It should be noted, however, that some polycarbonate plastic is colored with bright colors. Polycarbonate plastic baby bottles can be distinguished from bottles made of other types of plastic—primarily polypropylene-based plastic—because the latter is squeezable and typically opaque in appearance. Also, polycarbonate plastic bottles often have the number "7" in the recycling triangle on the bottom of the bottle and, in some cases, the letters "PC" next to the recycling triangle. The five bottle brands we tested were made from polycarbonate plastic.

The five bottle brands we tested are a sample of the bottles on the market and are not intended to represent a comprehensive list. We did, however, rely on data collected from an extensive parent survey to determine the most popular brands of bottles to test. For more information, refer to Appendix A.

This section describes the baby bottle brands testing positive in the lab for bisphenol A leaching. Appendix A reports the specific type of bottle by brand and the level of bisphenol A found to leach from each product. The presence of bisphenol A at any level in baby bottles is cause for concern, as there is no safe level.

These findings are clearly alarming for parents and others who care about the health and safety of their children. Unfortunately, parents do not have the information they need to ensure the products they purchase do not contain toxic chemicals. In "Recommendations for Parents," later in this report, we give parents some tips they need in order to begin to protect their children. Parents will be unable to fully protect their children, however, without adequate action by policymakers. We list these actions in "Recommendations for Policymakers."

Polycarbonate Baby Bottles Leach Bisphenol A

Numerous laboratory studies show that polycarbonate plastic breaks down and leaches bisphenol A into food or beverages in contact with the plastic.[59] Bisphenol A molecules are bound by ester bonds to form a polymer used

to make polycarbonate plastic. These studies demonstrate the instability of the chemical bond between bisphenol A molecules. The instability causes the polymer to decay with time and bisphenol A to be released into materials with which it comes into contact.

Polycarbonate baby bottles are no different. In a 2003 study conducted in Norway, bisphenol A leaching was detected in 12 polycarbonate baby bottles subjected to simulated use—dishwashing, brushing, and boiling. Levels of bisphenol A detected in liquids held in these bottles exceeded 8 ppb.[60]

Our study confirmed the findings of the Norway study. We tested five popular baby bottle brands. All five bottles leached bisphenol A at varying levels in the same range detected in the Norway study (Table 1).

Table 1: Summary of Testing for Bisphenol A Leaching in Baby Bottles

Baby Bottle Brand	Range of Bisphenol A Detected (parts per billion)
Avent	8 – 10 ppb
Dr. Brown's	6 – 7 ppb
Evenflo	8 – 9 ppb
Gerber	6 – 7 ppb
Playtex	5 – 6 ppb

Natural Feeding Bottle by Avent:

Testing Found Leaching of Bisphenol A at 8-10 ppb Level

Classic by Evenflo:

Testing Found Leaching of Bisphenol A at 8-9 ppb Level

Natural Flow by Dr. Brown's:

Testing Found Leaching of Bisphenol A at 6-7 ppb Level

Premium Feeding System by Gerber:

Testing Found Leaching of Bisphenol A at 6-7 ppb Level

VentAire by Playtex:

Testing Found Leaching of Bisphenol A at 5-6 ppb Level

Alarmingly, all five polycarbonate plastic bottles leached bisphenol A at levels found to cause harm in numerous animal studies evaluating various health effects from exposure to the chemical. Although consumers can try to avoid polycarbonate plastic bottles, most parents are unaware that toxic chemicals can leach from these products. Rather than put the burden on consumers, California and the U.S. should do more to protect its children by banning such products from store shelves.

The Government Fails To Protect Consumers From Toxic Chemicals

Many people think, incorrectly, that the government would prohibit chemicals from entering the market if they were not safe. In truth, the regulatory process has failed to work the way the public believes it should.

Chemicals Enter the Market Before Being Proven Safe for Human Health

The U.S. government's regulation of chemicals is based on the presumption that chemicals are innocent until they are proven to harm human health or the environment. This presumption is startling, especially when you consider:

- There are an estimated 80,000 chemicals registered for commercial use in the U.S.[61]

photo: Jellyphotography.com

- Only a very small percent of these chemicals have been tested for safety to human health.[62]
- An estimated 2,000 new chemicals are introduced each year, or an average of seven new chemicals each day.[63]

In 1976, Congress passed the primary law regulating toxic chemicals in the U.S., the Toxic Substances Control Act (TSCA), which grandfathered all existing chemicals on the market into use without health-effects testing or analysis.[64] Most of these chemicals emerged in the 1940s and 1950s when few laws governed chemical safety.

TSCA divides all the chemicals on the market into two categories: existing chemicals and new chemicals. Existing chemicals are chemicals on the market as of 1979. These make up approximately 99 percent by volume of the chemicals on the market today.[65] Existing chemicals are considered safe unless U.S. EPA can establish that: 1) they will in fact present an unreasonable risk to human health or the environment, 2) the agency is choosing the least burdensome regulation to reduce risks to a reasonable level, and 3) the benefits of regulation outweigh the costs to industry.[66] Such a high burden has essentially paralyzed the U.S. EPA from regulating or restricting chemicals predating 1980.

Companies that wish to introduce new chemicals to the U.S. market must notify U.S. EPA at least 90 days before producing or importing a new chemical. However, TSCA only requires that manufacturers submit health-effects testing information that is "in their possession," thereby creating a disincentive for manufacturers to conduct any

testing.[67] In fact, the U.S. EPA reports that the vast majority of pre-market notices by manufacturers contain no information on health or environmental impacts.[68]

Throughout its 30-year history, TSCA has rarely been amended, yet it clearly fails to effectively regulate toxic chemicals. Since the law's inception, U.S. EPA has never used its authority to ban a chemical and has only formally regulated five different chemicals, including polychlorinated biphenyls (PCBs), which Congress ordered regulated through TSCA. U.S. EPA's lax regulation can be attributed to the unreasonably high burden of proof the law places on the agency to show that a chemical poses an unreasonable risk to human health or the environment.

Numerous studies—including those conducted by the National Academy of Sciences, the U.S. General Accounting Office, the Congressional Office of Technology Assessment, and the U.S. EPA—have concluded that TSCA does not provide an effective means for assessing the hazards of chemicals or controlling those of greatest concern.[69]

U.S. EPA should be able to guarantee that chemicals on the market are safe for human health and the environment. The agency estimates the cost for a full round of basic screening tests, including tests for reproductive and developmental toxicity, at about $205,000 per chemical.[70] Although these tests have been conducted for a limited number of chemicals, we need this basic information for all chemicals currently in use. The chemical industry, with profits in excess of $45 billion in 2005, should pay this price to protect both human health and the environment.[71]

Regrettably, California relies on the federal government's failed regulatory system to protect its residents from chemicals used in commerce. California has no regulatory framework for reviewing chemicals prior to their introduction on the market and use in consumer products.

Labels are not Required for Consumer Products Even if They Contain Potentially Hazardous Chemicals

Because chemicals are not sufficiently tested and regulated before they enter into commerce, manufacturers of consumer products often use chemicals with unknown—and in some cases, known—health hazards to make products ranging from children's toys to medical devices. In some cases, manufacturers of consumer products have no information on whether the chemicals they are using to make their products are harmful. In other cases, scientific evidence shows that a chemical used in a particular product may be harmful.

Just as the law fails to require chemical manufacturers to prove the safety of their chemicals, the law fails to require adequate warning for consumers even when scientific evidence shows that a chemical used in a particular product may be harmful. For example, extensive scientific evidence shows that bisphenol A may be harmful to human health. Yet, manufacturers of baby bottles and other products containing bisphenol A are not required to label their products as containing bisphenol A.

Proposition 65, which is a law passed by voters in 1986, requires California to establish and update a list of chemicals known to the state to cause cancer or reproductive toxicity.[72] One major provision of the law requires that "clear and reasonable" warnings be provided for listed chemicals if exposure would

exceed the maximum allowable level designated by the state. Importantly, exposures at any level above the maximum allowable level are permitted by the law as long as an appropriate warning is provided.

Proposition 65 warnings are required in a variety of contexts, including for various consumer products, discharges from manufacturing or distribution facilities, and exposures that may occur as a result of entering or residing in certain buildings. For consumer products, the law does not require that an individual product be labeled. The law simply requires that a warning be "clear and reasonable," which could include labeling but also permits the posting of notices. Moreover, Proposition 65 warnings do not identify the chemical or chemicals to which the warning refers, nor do they provide any information on levels of exposure that are expected to occur as a result of using the product or the potential hazards associated with those levels of exposure.

Although Proposition 65 has served as an incentive for some manufacturers to reformulate their products, it does not provide consumers with sufficient information to make better choices about products that are safe for their children.

Consumers have the right to know whether products they use every day contain chemicals that are known or have the potential to cause harm to them or their families. And they need enough specificity about an individual product to be able to properly evaluate whether they should avoid particular products.

Parents cannot be expected to track the thousands of potentially harmful toxic chemicals they and their families come into contact with every day. In light of the federal government's failure to adequately protect human health, California must act to adequately protect those most vulnerable in its population. Parents should call on policymakers to take the following actions.

Phase Out Hazardous Chemicals

Based on the weight of the scientific evidence showing the harm caused by exposure to bisphenol A, California should act now. Given that data from the U.S. Centers for Disease Control and Prevention show that bisphenol A is present in humans at levels found to be harmful in laboratory studies, California should phase out the use of bisphenol A, especially in products used by children.

In the absence of both federal and state action, the city of San Francisco has already taken steps to protect children's health. In June 2006, San Francisco passed a prohibition on the use of bisphenol A in toys and child care articles intended for use by children under the age of three.[73] California will likely consider similar legislation this year.

Label Products Containing Hazardous Chemicals

Parents currently have little information to inform their decisions when purchasing products for their family. With no government-mandated labels on products and no ability to readily gain information about the ingredients used in a product, parents are left in the dark as to how they can best protect their children. The first step to protecting children is to give parents the tools they need to make safer choices. Manufacturers should be required to label children's products if they contain a chemical that is either known to be hazardous or has the potential to be hazardous. In addition to listing the hazardous or potentially hazardous ingredient, the specific health risks associated with the chemical should be described on the product.

Reform Chemicals Policy

In order to better protect human health and the environment, California must adopt strong chemicals policies. First, chemical manufacturers should be required to provide all hazard and health-effects information to the government so agencies can begin to assess the thousands of chemicals currently on the market for which little or inadequate data are available. Next, pre-market hazard and health-effects testing should be required for all new chemicals before they are introduced into commerce. Finally, the California Environmental Protection Agency must have the authority to ban or restrict the use of a chemical if it can harm human health. To that end, California must establish a regulatory framework for regulating chemicals in commerce without the legal barriers that make the federal Toxic Substances Control Act ineffective.

Recommendations For Parents

A few small, easy changes in the products you buy and use can help reduce your child's exposure to toxic chemicals.

At the Store

Choose safer toys and teethers.

- **Look for "PVC-free" on the labels of soft plastic toys and teethers.** Another class of chemicals shown to disrupt the hormone system—phthalates—is found in polyvinyl chloride (PVC) plastic. PVC plastic is used to make different types of children's products, including some teethers and soft plastic toys. Some manufacturers have removed PVC from their children's products, especially products intended to be put into children's mouths. Unfortunately, no law requires or regulates these labels, and few products are labeled as such. When parents have a question about the chemicals in a product, they should call the manufacturer.
- **Choose wooden toys.** There are countless manufacturers of high quality wooden toys in the market. Everything from baby rattles to kitchen play-sets are now made out of wood. Some commonly available brands include Plan Toys, Haba, Turner Toys, Selecta, and Holztiger.

Choose safer food packaging and serving containers.

- **Avoid polycarbonate plastic in food containers.** Check the bottom/underside of the product. If you see "PC" (usually in or near the recycling triangle) signifying polycarbonate plastic, do not purchase it. Often a number "7" on the bottom in the recycling triangle, by itself, also means the material is polycarbonate, but not always. To be safe, avoid #7 plastic. Choose plastics labeled #1, #2, or #5 in the recycling triangle, but do not heat beverages or food in plastic containers of any kind.
- **Avoid PVC plastic in food containers.** Check the bottom/underside of the product. If you find the number "3" in the recycling triangle, it is made from PVC plastic and should be avoided. Choose plastics labeled #1, #2, or #5 in the recycling triangle, but do not heat beverages or food in plastic containers of any kind.
- **Avoid canned foods:** Unfortunately, bisphenol A can leach from metal can lining into the foods and liquids contained within. Buy baby food in glass containers, and avoid feeding your child food from cans as much as possible. You can often find popular children's foods, such as tomato sauce, applesauce, and black beans, in glass jars.
- **Choose safer containers for sippy cups and water bottles.** Look for plastics labeled #1, #2, or #5 in the recycling triangle. As an alternative to hard plastic water bottles (such as the polycarbonate Nalgene bottles), try a lightweight stainless steel bottle instead.
- **Choose glass or safer-plastic baby bottles.** Almost all plastic baby bottles are made from polycarbonate plastic containing bisphenol A, but they are rarely labeled as such. With as few as 50-100 washings—even before you see wear—significant amounts of bisphenol A can leach into your baby's

milk. For the best protection, switch to using glass bottles for all or most of baby's use. Contrary to claims by the plastics industry, glass bottles are extremely durable and safe (and wash well in the dishwasher). And after all, they were good enough for you when you were a baby! Evenflo is one of the only glass bottle makers around (some Babies "R" Us stores carry them and they are available on-line). A couple of manufacturers make their baby bottles from a safer polypropylene-based plastic (a softer, opaque plastic), which has not been associated with the developmental problems linked to bisphenol A.

- **Choose metal feeding utensils and enamel or ceramic plates.** While many manufacturers have removed phthalates from products intended to be put into young children's mouths, without a law prohibiting their use, there is no guarantee that these products, such as soft, plastic-coated feeding spoons, are made without phthalates. Look for PVC-free labels or buy stainless steel, enamel, ceramic, or glass. (Note that enamel cannot be put in the microwave, and you should not use old pottery that could have lead-based glazes).
- **Avoid foods wrapped in plastic.** Almost all commercial grade plastic cling wrap contains PVC plasticized with phthalates, and other plastic food packaging may be made of PVC, as well. Avoid buying foods wrapped in plastic, especially cheeses and meats. Buy deli-sliced cheeses and meats and have them wrapped in paper. If you can't avoid buying plastic-wrapped foods, cut off a thin layer of the cheese or meat when you get home and store the remainder in glass or less-toxic plastic.

At Home

- **Use glass to heat food or liquid in the microwave. You should not heat food in plastic containers or on plastic dishware, or heat liquids in plastic baby bottles.** Heating food and liquids in plastic containers can cause chemicals and additives in the plastics to leach out more readily—right into baby's food and milk. While some plastic containers are marketed as "microwave safe," it is safest to avoid them for heating.
- **If you do use plastic bottles, containers, or dishware, avoid harsh detergents or hot water when washing them to reduce exposure.** Do not put plastic bottles, containers, or dishware in the dishwasher. Also, throw out any plastic bottles, containers, and dishware that start to look scratched or hazy. Do not let milk sit for long periods of time in plastic.
- **Avoid letting your child put plastic toys in his/her mouth.** Toys designed for older children are more likely to contain phthalates or bisphenol A. It is assumed that young children will not mouth these toys—such as action figures and Barbie dolls. To be safe, keep all plastic toys out of children's mouths. Call the manufacturer if you want to know if a product contains phthalates or bisphenol A.

Methodology

Based on a 2005-06 consumer survey that we conducted of over 2,800 parents, we selected the most popular baby bottle brands to test for the presence of bisphenol A. Respondents of the survey were given a list of 11 brand names from which to select the brand or brands they used with their children. The top five brands used by the respondents included: Avent, Dr. Brown's, Evenflo, Gerber, and Playtex. For this study, we tested bottles from these five brands to determine the amount of bisphenol A that leaches into liquid contained therein.

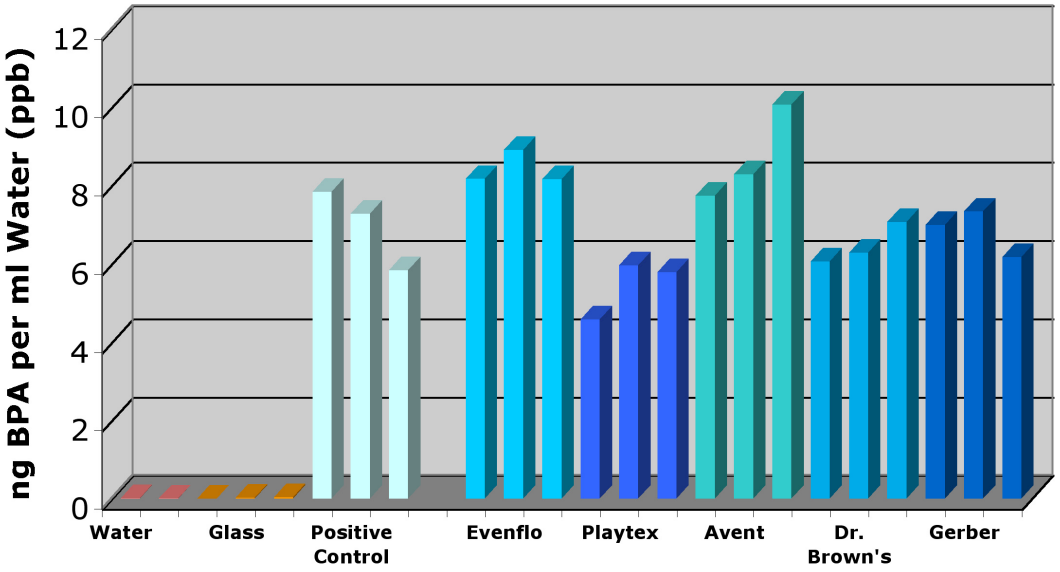
To ensure the reproducibility of the results, we tested three of each baby bottle brand. We bought each of the three bottles from a different retailer in California to avoid the possibility that the bottles were from the same stock. We purchased the bottles from four popular retailers in the state, patronizing multiple locations of two of the retailers.

We provided funds to conduct a research project at a lab (XenoAnalytical) at the University of Missouri-Columbia to measure bisphenol A at environmentally relevant concentrations of leaching from baby bottles. The investigators at the University of Missouri were chosen for this project because they were the first to predict and measure the low-dose effects of bisphenol A in animal studies and had also previously reported findings concerning leaching of bisphenol A from polycarbonate.

The lab used published procedures with sensitivities below 0.01 nanograms (ng) per milliliter (ml) of bisphenol A in water (0.01 ppb bisphenol A in water) by high-performance liquid chromatography (HPLC) with CoulArray detection, and multiple-point standard curves over the full range of sample values. The purified water used to extract bisphenol A from the bottles contained bisphenol A at less than 0.01 ng/ml. The assay of the baby bottles included three negative and three positive control bottles. The negative controls were glass baby bottles to control against introduction of bisphenol A during any technical handling. The positive controls were Lexan(r) polycarbonate sport water bottles known to release bisphenol A in prior studies; positive controls were to confirm effectiveness of the leaching procedure. The bisphenol A determination by HPLC was confirmed by estrogenic activity in an estrogen-sensitive cell culture bioassay, and the estrogenic activity was confirmed by inhibition with an antiestrogen.

The assays were conducted on the 15 polycarbonate baby bottles, three glass baby bottles as negative controls against introduction of bisphenol A in water or technical handling, and three polycarbonate sport water bottles known to release bisphenol A from prior studies as positive controls to confirm effectiveness of the leaching procedure. All bottles were incubated with water at 80 degrees centigrade for 24 hours to simulate 50 to 75 dishwashing cycles using the sanitize cycle. The range of bisphenol A detected in the 15 polycarbonate baby bottles was 4 to 10 parts per billion (ppb), while the bisphenol A extracted from the negative control glass baby bottles was less than 0.05 ng/ml (Figure 4, next page). The levels detected in the 15 polycarbonate baby bottles varied based on the brand tested, as detailed in Appendix A.

Figure 4: Bisphenol A Extracted from Polycarbonate Baby Bottles



Appendix A

Bottle Brand	Type	Product Number	Bisphenol A Level Detected (ppb) (Bottle #1)	Bisphenol A Level Detected (ppb) (Bottle #2)	Bisphenol A Level Detected (ppb) (Bottle #3)
Avent	Natural Feeding Bottle (9 oz)	UPC Code: 61269 00230	7.74	8.29	10.07
Dr. Brown's	Natural Flow (8 oz)	UPC Code: 72239 00250	6.07	6.29	7.07
Evenflo	Classic (8 oz)	UPC Code: 42700 12113	8.17	8.91	8.16
Gerber	Premium Feeding System (9 oz)	UPC Code: 15000 78715	6.99	7.34	6.18
Playtex	VentAire (9 oz)	UPC Code: 78300 01162	4.58	5.96	5.79

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