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Oversight Hearing on Bisphenol-A, Phthalates, Consumer  
Products and Consumer Health

Before the Subcommittee on  
Consumer Affairs, Insurance and Automotive Safety

The Honorable Mark Pryor, Chairman

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U.S. Senate

Committee on Commerce, Science and Transportation

May 14, 2008

Chairman Pryor, Senator Sununu, members of the committee: I am Elizabeth Hitchcock, public health advocate for the U.S. Public Interest Research Group. U.S. PIRG is the federation of state PIRGs, which are non-profit, non-partisan public interest advocacy organizations with one million members across the country.

We are pleased to present our views at this Oversight Hearing on Bisphenol-A, Phthalates, Consumer Products and Consumer Health. The state PIRGs have long been concerned with the important issues of toxics in consumer products, and the ability of the federal government to protect all of us, but particularly our children, from preventable hazards.

Since 1986, we have conducted toy safety research and education projects to avoid preventable deaths and injuries. While our annual *Trouble In Toyland* toy safety reports<sup>1</sup> have emphasized the hazards posed by choking on small parts, we have expanded the report in the past decade to focus on the chronic hazards posed by unnecessary exposure to lead,<sup>2</sup> phthalates and other chemicals known to be toxic.

## Summary

First, Mr. Chairman, we commend you for your efforts to improve U.S. product safety, including the recent Senate passage of your bill, the CPSC Reform Act. When it is reconciled with the House bill, it will take significant and long overdue steps forward in protecting America's children from unsafe products. We encourage the conference committee to take the strongest parts of each bill.

In particular, we believe that the Senate bill's provisions addressing the toxic hazards of lead and phthalates in children's products are important steps to take preventable hazards out of the marketplace.

Recent headlines about the long overdue acknowledgement of the National Toxicology Program of the U.S. National Institutes of Health of health concerns about children's exposure to Bisphenol-A (BPA) have raised concerns among consumers about this and other toxic chemicals.

In general, U.S. PIRG's policy recommendations concerning toxic chemicals like Bisphenol-A and phthalates are that the federal government should:

- Phase Out Dangerous Chemicals. The U.S. Environmental Protection Agency should take action based on the overwhelming weight of evidence showing that chemicals like phthalates and bisphenol-A may harm human health.
- The U.S. should phase out the use of Bisphenol-A, especially in children's products. Due to the possible increased risks to small children and pregnant women, we strongly urge the removal of BPA from all products intended to contact food.
- Reform U.S. Chemicals Policy. Manufacturers should be required to provide all hazard and health impact information to the EPA so the agency can begin to assess the thousands of chemicals currently on the market for which it has little or inadequate data.

- The Consumer Product Safety Commission should protect consumers, for example, by labeling these products with the names of the chemicals they contain to allow parents to choose less toxic products, among other protective actions.
- The conference committee and the Congress should pass a final version of CPSC reform legislation including the Feinstein amendment banning phthalates in children's products (incorporated as Section 40 of H.R.4040, the CPSC Reform Act, as passed by the Senate<sup>3</sup>).

## 1. Phthalates Are Ubiquitous With Exposure Linked To Health Effects

Phthalates are a family of chemicals, including diethyl phthalate (DEP), diethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), di-n-octyl phthalate (DNOP), and many other distinct types. The polyvinyl chloride (PVC) plastic industry uses large amounts of phthalates as additives to improve the flexibility of its products, including home siding, flooring, furniture, food packaging, toys, clothing, car interiors, and medical equipment, including IV bags. In addition, other manufacturers use phthalates in personal care products such as soap, shampoo, deodorant, hand lotion, nail polish, cosmetics, and perfume, as well as industrial products like solvents, lubricants, glue, paint, sealants, insecticides, detergent, and ink.<sup>4</sup>

Phthalates are pervasive in the environment and in human bodies. In 2000, the Centers for Disease Control (CDC) found high levels of phthalates and their transformation products (known as metabolites) in every one of 289 adult Americans tested, including women of childbearing age.<sup>5</sup> Larger CDC studies in 2003<sup>6</sup> and 2005<sup>7</sup> again found high levels of phthalates in almost every person tested.

Numerous scientists have documented the potential health effects of exposure to phthalates in the womb or at crucial stages of development, including (but not limited to):

- **Reproductive Defects.** Scientists have demonstrated links between exposure to phthalates in the womb with abnormal genital development in baby boys and disruption in sexual development.<sup>8</sup> In October 2005, an independent panel of scientists convened by the National Institute of Environmental Health Sciences and the National Toxicology Program released its review of one type of phthalate, diethylhexyl phthalate (DEHP). The panel confirmed that DEHP poses a risk to reproductive and developmental health.<sup>9</sup>
- **Premature Delivery.** A study published in November 2003 suggests a link between exposure to phthalates and pre-term birth. The scientists found phthalates and their breakdown products in the blood of newborn infants, with higher levels leading to a higher incidence of premature delivery.<sup>10</sup>
- **Early Onset Puberty.** One study of Puerto Rican girls suggests that phthalates may be playing a role in trends toward earlier sexual maturity.<sup>11</sup> Scientists found that levels of DEHP were seven times higher in girls with premature breast development than levels in normal girls.

• **Lower Sperm Counts.** In 2003, Drs. Susan Duty and Russ Hauser of the Harvard School of Public Health published one of the first studies linking phthalate exposure with harm to human reproductive health.<sup>12</sup> Men who had monobutyl or monobenzyl phthalate in their urine tended to have lower sperm counts, with the highest concentrations leading to the lowest sperm counts.

## **2. History of Efforts to Ban Phthalates in Children’s Toys and Products**

In 1998, the state PIRGs and several other environmental and consumer groups petitioned the Consumer Product Safety Commission, asking the agency to ban polyvinyl chloride (PVC) plastic in all toys intended for children under the age of five because of the potential health hazards posed by diisononyl phthalates (DINP). While noting its position that “few if any children are at risk from the chemical,”<sup>13</sup> in December 1998 CPSC asked the toy and baby products industry to remove DINP from soft rattles and teethingers. About 90 percent of manufacturers indicated at that time that they had removed or would remove DINP from soft rattles and teethingers by early 1999. CPSC staff also asked the industry to find a substitute for phthalates in other products intended for children under three years old that are likely to be mouthed or chewed.<sup>14</sup>

CPSC also convened a Chronic Hazard Advisory Panel to examine the existing scientific data concerning the potential risks of phthalates to humans. In June 2001, the panel concluded that while the majority of children would not be adversely affected by diisononyl phthalate, “there may be a DINP risk for any young children who routinely mouth DINP-plasticized toys for seventy-five minutes per day or more.”<sup>15</sup>

Unfortunately, in February 2003, CPSC denied the state PIRGs’ petition to ban PVC plastic in toys for young children.<sup>16</sup>

Some manufacturers are beginning to label their baby products and toys as “phthalate-free,” which should provide parents the information they need to make educated purchasing decisions. The U.S. government, however, does not regulate the “phthalate-free” label or ensure that products labeled “phthalate-free” actually do not contain phthalates. Since the U.S. government has not established any guidelines for what the label means, or established any standards for the phthalate content in children’s products, consumers can only assume that it means phthalates are not present in the item.

In 2005, to test the reliability of the “phthalate-free” label, U.S. PIRG commissioned STAT Analysis Corporation in Chicago, Illinois to test eight soft plastic toys labeled as not containing phthalates. Of the eight toys tested, six contained detectable levels of phthalates.<sup>17</sup> Based on these results, we asked the Federal Trade Commission (FTC) to investigate whether manufacturers’ use of the “phthalate-free” label constitutes unfair or deceptive marketing practices when the product actually contains phthalates.<sup>18</sup>

With the results of the FTC investigation still pending, we once again commissioned STAT Analysis Corporation in the fall of 2006 to test 10 soft plastic toys labeled as not containing phthalates.<sup>19</sup> Of the 10 toys tested, just two contained detectable levels of phthalates. Some of

the items that tested positive for phthalates in the first year did not in the second. While this may be good news for consumers, nothing in U.S. law has changed to hold manufacturers accountable to their “phthalate-free” label or require them to stop using phthalates. Consumers still have no guarantee that the “phthalate-free” products they purchase truly are phthalate-free, as evidenced by our test results.

A number of individual states and other countries have taken action, however, to protect children’s health. In 1999, the European Union (EU) imposed temporary restrictions on the use of six phthalates in toys and childcare products.<sup>20</sup> This ban became permanent in January 2006. The EU banned three phthalates classified as reproductive toxicants – diethylhexyl phthalate (DEHP), butyl benzyl phthalate (BBP), and dibutyl phthalate (DBP) – in all toys and childcare articles. The EU banned three other phthalates – DINP, diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP) – in toys and childcare articles intended for children under three years of age and that can be put in the mouth.<sup>21</sup>

In the past year, California and Washington State have banned phthalates in children’s products; Minnesota and Vermont both have bills on their governor’s desk; and Rhode Island, New York and Massachusetts are considering similar measures.

In March 2008, the U.S. Senate overwhelmingly passed the CPSC Reform Act, with an amendment by Senator Feinstein that eliminates phthalates in children’s products and child care articles, which will serve to significantly curb children’s routes of exposure to these reproductive toxicants. We urge the conferees to retain the phthalate provision, and its state savings clause, in the final bill.

### **3. BISPHENOL-A: Developmental, Neural and Reproductive Toxicant**

Scientists have linked very low doses of bisphenol-A to cancers, impaired immune function, early onset of puberty, obesity, diabetes, and hyperactivity, among other problems.

We know that bisphenol-A can leach from plastic containers and cans and into food and beverages, leading to potentially significant human exposures. A recent study released by the U.S. Centers for Disease Control and Prevention (CDC) found that BPA was in the blood of 95 percent of humans they tested. The median level of BPA found in humans is higher than the level that causes adverse effects in animal studies. BPA raises particularly troubling health questions because it can affect the endocrine system, mimicking the effects of estrogen in the body. Experiments in animals and with human cells strongly suggest exposures typical in the U.S. population may increase susceptibility to breast and prostate cancer, reproductive system abnormalities, and, for exposure in the womb and early childhood, a host of developmental problems. Concerns about early life exposures also extend to early onset of puberty in females, potential prostate problems in males, and obesity.

Last year, U.S. PIRG’s partner organization, Environment California, tested five of the most popular baby bottle brands on the market (Avent, Dr. Brown’s, Evenflo, Gerber, and Playtex) to determine the amount of leaching from each bottle. Our researchers found that the bottles tested

from all five brands leached bisphenol-A at levels found to cause harm in numerous laboratory studies.<sup>22</sup>

The current U.S. Environmental Protection Agency daily upper limit for BPA, 50 micrograms per kilogram of body weight, is based on industry-sponsored experiments conducted in the 1980's. Some animal studies show adverse health affects from exposure of only 0.025 micrograms per kilogram of body weight, yet a polycarbonate baby bottle with room temperature water can leach 2 micrograms of BPA per liter. A 3-month-old baby drinking from a polycarbonate bottle may be exposed to as much as 11 micrograms per kilogram of body weight daily.

Aside from polycarbonate plastic bottles, BPA is also a food additive approved by the Food and Drug Administration (FDA), commonly used in the coatings for the inside of food cans. But a recent report by the National Toxicology Program (NTP) questioned previous FDA findings that BPA is safe for such applications. Their report, issued on April 15, 2008, expressed "some concern" based on animal studies that BPA might affect the neurological systems and behavior of infants and children. Among its conclusions, the NTP report states that, "the possibility that human development may be altered by bisphenol-A at current exposure levels cannot be dismissed."

### **Independent Science Shows Harmful Effects from BPA, while Industry Science Shows None**

A recently-published review of scientific studies shows that, in the last 7 years (through November 2005), 151 studies on the low-dose effects of BPA have been published.<sup>23</sup> None of the 12 studies funded by the chemical industry reported adverse effects at low levels, whereas 128 of 139 government-funded studies found effects. These many studies were conducted in academic laboratories in the U.S. and abroad. Even the 12 industry-funded studies have flaws, however. Of the industry studies, two had its positive control fail—an indication that the entire experiment had failed, not that BPA had not caused an effect.

Another industry study concluded BPA caused no effect, but an independent analysis of the experiment's data by scientists convened by the National Toxicology Program of the U.S. Department of Health & Human Services concluded that in fact there was an effect. Industry scientists had misreported their own results.

The chemical industry relies on an incomplete review of scientific studies by an effort funded by the American Plastics Council at the Harvard Center for Risk Analysis. The panel funded by the American Plastics Council only considered 19 studies in concluding in 2004 that the weight of the evidence for low-dose effects of BPA was weak.<sup>24</sup> As of November 2005, there were 151 published studies on the low-dose effects of BPA.

The last U.S. EPA risk assessment for BPA was based on research conducted in the 1980s and did not consider that BPA was a chemical estrogen. The most recent risk assessment of BPA was based on a comprehensive review of the scientific literature conducted in 1998 by the European Union, with some selected articles added through 2001, at which time few of the

current 151 low-dose BPA studies had been published. The most recent review of scientific studies shows effects from exposure to BPA at levels significantly below the current “safe exposure” level established by the U.S. based on experiments conducted prior to 1988.

#### **4. History of Efforts to Regulate Bisphenol-A**

In April 2008, the National Toxicology Program of the U.S. National Institutes of Health finally acknowledged health concerns about children’s exposure to BPA. Unfortunately, it is unclear whether this determination will lead to any federal policy changes to protect children from BPA. On April 18th, the Canadian Government declared BPA "toxic" under Canadian Law, triggering a ban on BPA baby bottles in Canada. There are current efforts in state legislatures in California, Massachusetts, Illinois, New York and Rhode Island to restrict uses of the chemical. On April 29<sup>th</sup>, Senator Chuck Schumer introduced S.2928 banning BPA in all products intended for infants and children up to age 7. Senators Boxer, Clinton, Durbin, Feinstein, Kerry and Menendez are co-sponsors of the bill, which U.S. PIRG supports. The U.S. Food and Drug Administration announced it would review its regulatory policy on BPA. The FDA's reliance on two industry studies finding BPA safe, despite over 100 independent scientific studies linking the chemical to an array of illnesses, including breast and prostate cancer and obesity, is the subject of a Congressional investigation headed by Chairman John Dingell of the House Energy and Commerce Committee.

In addition, some manufacturers and retailers are taking action on the chemical. Playtex Infant Care announced it will stop selling products made with BPA by the end of the year and will give one million free samples of new BPA-free products to potential customers. Wal-Mart and CVS announced they are phasing out BPA baby bottles in U.S. stores. Nalgene announced it would no longer use plastic made with BPA in its water bottles.

#### **5. U.S. PIRG’s Policy Recommendations**

Consumers cannot be expected to do it alone – as the thousands of harmful and untested chemicals currently on the market pose a super-human challenge to completely avoid exposure. The U.S. government must act in a manner that assists parents, and ensure that products on the market are not potentially harmful for children.

**A. Phase Out Dangerous Chemicals.** The U.S. Environmental Protection Agency should take action based on the overwhelming weight of evidence showing that chemicals like phthalates and bisphenol-A may harm human health. The United States should phase out the use of these chemicals – especially in children’s products. Until the U.S. government acts, state governments should continue to fill the regulatory gap and support policies to phase out these chemicals as well. CPSC should ban the use of phthalates in all toys and products for children five years old and under, and the U.S. should phase out the use of Bisphenol-A, especially in children’s products. The federal government should study the health effects of BPA exposure in all age groups and pregnant women, and should focus on the products that have the greatest potential for causing human harm. Due to the possible increased risks to small children and pregnant women, we strongly urge the removal of BPA from all products intended to contact food.

**B. Reform U.S. Chemicals Policy.** Currently, manufacturers can put chemicals on the market without proving that they are safe. Manufacturers should be required to provide all hazard and health impact information to the EPA so the agency can begin to assess the thousands of chemicals currently on the market for which it has little or inadequate data. Next, manufacturers of chemicals should be required to conduct an alternatives analysis to determine if they are really using the least hazardous chemical for each application. Finally, EPA must have the authority to ban or restrict the use of a chemical if it can harm human health.

**C. Consumer Product Safety Commission Should Protect Consumers.** The Consumer Product Safety Commission (CPSC) has an obligation to protect consumers from dangerous products. The CPSC should first label these products with the names of the chemicals they contain to allow parents to choose less toxic products. Second, the CPSC should take the precautionary approach and require manufacturers to remove chemicals that may pose a particular threat to fetuses, infants and children, particularly when the chemical is not necessary for the product to function according to design. In addition, CPSC and the Federal Trade Commission should look into manufacturers' use of the "phthalate-free" label and take action against manufacturers that may be misleading consumers.

**D. The conference committee and the Congress should pass a final version of CPSC reform legislation including the Feinstein amendment banning phthalates in children's products (incorporated as Section 40 of H.R.4040 as passed by the Senate).** The amendment will:

- Prohibit the use of phthalates (any combination of certain listed chemicals in concentrations exceeding 0.1 %) in any children's product or child care article.
- Require manufacturers to use the least toxic alternative to phthalates.
- Prohibit the use of certain harmful alternatives -- including substances known to be, likely to be, or suggestive of being carcinogens; and reproductive toxicants identified as causing either birth defects, reproductive harm, or developmental harm.
- The amendment also includes an important "savings clause" that would prevent Federal preemption of stronger state laws regulating phthalates in toys or other product categories.

## CONCLUSION

We commend you, Mr. Chairman, for conducting this important hearing. We hope that you find our comments helpful. We look forward to working with you and your committee staff to move legislation addressing these concerns forward. We would also be happy to discuss other possible actions under the committee's jurisdiction to protect consumers from the chronic and developmental hazards from unnecessary exposure to toxic chemicals like Bisphenol-A and phthalates in a variety of consumer products. Thank you.



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<sup>1</sup> These reports and other information about toy safety are available at our website [www.toysafety.net](http://www.toysafety.net). Our main website is [www.uspirg.org](http://www.uspirg.org).

<sup>2</sup> Lead, of course, can also pose acute hazards, at the levels (up to 99% by weight) found in toy jewelry.

<sup>3</sup> The CPSC Reform Act was approved in committee as S. 2045 (Pryor-Inouye) and a substitute was brought to the floor as S. 2663 (Pryor-Inouye-Stevens-Collins). The Senate bill's text was then substituted for that of the House bill and re-numbered on passage as HR 4040. The Feinstein phthalates amendment (Section 40) was accepted on voice vote on the floor.

<sup>4</sup> Phthalate Esters Panel of the American Chemistry Council, *What are Phthalates?*, downloaded from [www.phthalates.org](http://www.phthalates.org) on 14 April 2004; Catherine Dorey, Greenpeace, *Chemical Legacy: Contamination of the Child*, October 2003.

<sup>5</sup> BC Blount et al, "Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population," *Environmental Health Perspectives* 108: 979-982, 2000.

<sup>6</sup> Manori J Silva et al, "Urinary Levels of Seven Phthalate Metabolites in the U.S. Population from the National Health and Nutrition Examination Survey (NHANES) 1999-2000," *Environmental Health Perspectives* 112: 331-338, March 2004.

<sup>7</sup> Centers for Disease Control, "[Third National Report on Exposure to Toxic Chemicals](#)", 2005

<sup>8</sup> Shanna H. Swan et al, "Decrease in anogenital distance among male infants with prenatal phthalate exposure," *Environmental Health Perspectives* 113: 1056-1061, August 2005; LE Gray et al, "Perinatal Exposure to the Phthalates DEHP, BBP, and DINP, but not DEP, DMP, or DOTP, Alters Sexual Differentiation of the Male Rat," *Toxicological Science* 58: 350-365, December 2000; Vickie Wilson et al, "Phthalate Ester-Induced Gubernacular Lesions are Associated with Reduced Ins13 Gene Expression in the Fetal Rat Testis," *Toxicology Letters* 146: 207-215, 2 February 2004; JS Fisher et al, "Human 'Testicular Dysgenesis Syndrome': A Possible Model Using *in-utero* Exposure of the Rat to Dibutyl Phthalate," *Human Reproduction* 18: 1383-1394, 2003.

<sup>9</sup> NIEHS, "Independent Panel to Evaluate a Chemical Used in Some Plastics (Di (2-ethylhexyl) phthalate) for Hazards to Human Development or Reproduction," press release, October 5, 2005.

<sup>10</sup> G Latini et al, "In-Utero Exposure to Di-(2-ethylhexyl)-phthalate and Human Pregnancy Duration," *Environmental Health Perspectives* 111:1783-1785, 2003.

<sup>11</sup> I. Colón, D Caro, CJ Bourdony and O Rosario, "Identification of Phthalate Esters in the Serum of Young Puerto Rican Girls with Premature Breast Development," *Environmental Health Perspectives* 108: 895-900, 2000.

<sup>12</sup> SM Duty et al, "Phthalate Exposure and Human Semen Parameters," *Epidemiology* 14: 269-277, 2003; SM Duty et al, "The Relationship Between Environmental Exposures to Phthalates and DNA Damage in Human Sperm Using the Neutral Comet Assay," *Environmental Health Perspectives* 111: 1164-1169, 2003.

<sup>13</sup> CPSC, "CPSC Releases Study on Phthalates in Teethers, Rattles and Other Children's Products," press release, December 2, 1998, accessed May 12, 2008 at [www.cpsc.gov/CPSCPUB/PREREL/PRHTML99/99031.html](http://www.cpsc.gov/CPSCPUB/PREREL/PRHTML99/99031.html).

<sup>14</sup> CPSC, "CPSC Releases Study on Phthalates in Teethers, Rattles and Other Children's Products," press release, December 2, 1998, accessed May 12, 2008 at [www.cpsc.gov/CPSCPUB/PREREL/PRHTML99/99031.html](http://www.cpsc.gov/CPSCPUB/PREREL/PRHTML99/99031.html).

<sup>15</sup> Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate, June 2001. Accessed May 12, 2008 at <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>.

<sup>16</sup> CPSC, Letter to Jeffrey Becker Wise, National Environmental Trust, February 26, 2003, accessed May 12, 2008 at <http://www.cpsc.gov/library/foia/foia03/petition/ageunder.PDF>.

<sup>17</sup> U.S. PIRG Education Fund, *Trouble in Toyland: The 20th Annual Survey of Toy Safety*, November 2005.

<sup>18</sup> Letter to the Honorable Deborah Platt Majoras, Chairman, FTC, November 21, 2005. On file with the author. Our petition was later denied.

<sup>19</sup> Eight of the toys were labeled "phthalate-free" on the packaging. One item was labeled "phthalate-free" on the manufacturer's website. For the last item, the manufacturer's website claimed not to use phthalates in any of its children's products.

<sup>20</sup> "Results of Competitiveness Council, Brussels, 24<sup>th</sup> September 2004," Memo/04/225.

<sup>21</sup> Bette Hileman, "EU Bans Three Phthalates from Toys, Restricts Three More," *Chemical and Engineering News*, July 11, 2005.

<sup>22</sup> "[Toxic Baby Bottles: Scientific study finds leaching chemicals in clear plastic baby bottles](#)," *Environment California*, 2007

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<sup>23</sup> vom Saal, F and C Hughes, An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment. *Environmental Health Perspectives* 113:926-933 (2005).

<sup>24</sup> vom Saal, F and C Hughes, An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment. *Environmental Health Perspectives* 113:926-933 (2005) (“The charge to the HCRA panel, which was to perform a weight-of-the-evidence evaluation of available data on the developmental and reproductive effects of exposure to BPA in laboratory animals, led to an analysis of only 19 of 47 available published studies on low-dose effects of BPA. The deliberations of the HCRA were in 2001–2002, and accordingly, a cut-off date of April 2002 was selected for consideration of the published literature. It is regrettable that the relevance of the analysis was further undermined by a delay of 2.5 years in publication of the report. During the intervening time, between April 2002 and the end of 2004, a large number of additional articles reporting low-dose effects of BPA in experimental animals have been published. The result is that by the end of 2004, a PubMed (National Library of Medicine, Bethesda, MD) search identified 115 published studies concerning effects of low doses of BPA in experimental animals.”).