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WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

2009-10

(session year)

Senate

(Assembly, Senate or Joint)

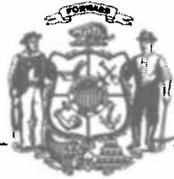
Committee on ... Small Business, Emergency Preparedness, Technical Colleges, and Consumer Protection (SC-SBEPTCCP)

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JULIE LASSA
STATE SENATOR

Date?

Senate Bill 271
Senate Committee on Small Business, Emergency Preparedness, Technical Colleges, and
Consumer Protection
201SE

Good morning Chairman Wirch and committee members,

Thank you for the opportunity to testimony today on Senate Bill 271, the BPA Free Kids Act, which would prohibit the manufacture and sale of empty baby bottles and spill proof "sippy" cups that contain bisphenol-A for use by children five years old and younger.

What is bisphenol-A? BPA was developed in 1891 as a synthetic estrogen. It became popular in the 1950s when scientists found it could harden plastic; it is now produced in mass quantities in the United States in amounts up to 7 billion pounds per year. This estrogen mimicking chemical is commonly found in polycarbonate (clear) plastics and has been shown to leak out of these plastics and into the beverages and food we consume. BPA is an endocrine disruptor that can disrupt human development, especially in fetuses and young children who cannot eliminate BPA from their bodies fast enough to prevent toxicity. BPA has been shown to cause cancer, heart disease, neurological defects, diabetes, hyperactivity and sex hormone problems in fetuses and young children. Hundreds of studies on BPA have shown a host of problems in lab animals such as testicular cancer, lowered sperm counts, early puberty and miscarriages. And, according to an op-ed article in the New York Times from this weekend, each American consumes 6 pounds of this synthetic estrogen every year. You'll hear more about BPA's negative health effects from medical experts later in the hearing.

BPA has received a lot of media attention over the past few years because of growing health concerns in the scientific community and the general public. In response, companies such as Nalgene pulled all of their plastic drinking bottles containing BPA from the marketplace and retailers such as CVS, REI, Gander Mountain, Wal-Mart and Toys R Us have stopped selling baby bottles that contain BPA.

Sen. Lassa's Testimony

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This legislation was drafted in response to the mounting scientific evidence and the public's concern that this estrogen mimicking chemical is not safe, especially for young children. The BPA Free Kids Act not only prohibits the manufacture or sale at the wholesale level of empty baby bottles and sippy cups that contain BPA for use by children 5 years of age and under but also requires that these bottles or sippy cups be clearly labeled as being "BPA free". The legislation provides the same penalties for these manufacturers and wholesalers as those laid out in Wisconsin's current Hazardous Substances Act and allows a 50 percent surcharge from the fines that DATCP would collect from negligent manufacturers and wholesalers to be used for the administration of the program. My office worked closely with the Department of Agriculture, Trade and Consumer Protection on this legislation. You will see in the Department's testimony that they have concerns that the bill, as originally drafted, does not permit retailers to be fined. I have an amendment to address the Department's concerns to create a penalty of \$50-\$200 for retailers who fail to comply. The range of forfeitures in the bill is necessary so that courts have the ability to fit the penalty to the violation.

SB 271 is needed to bolster the efforts of manufacturers of children's products to continue to remove this harmful chemical from empty baby bottles and sippy cups to reduce young children's exposure to it. Popular and well known companies such as Avent, Disney First Years, Gerber, Dr. Brown, Playtex and Evenflo already sell BPA free baby bottles and many make BPA free sippy cups as well. All of these companies also label or advertise their baby bottles as being BPA free, which is why we believe the labeling requirement in the legislation will not be difficult for companies to meet. Labeling these products will make it easier for parents and other consumers to identify BPA free products as well as make it easier for Consumer Protection staff to monitor products being sold at retail stores. It is a simple bill that will have a significant positive impact on the health of our children.

Today you are going to hear from industry groups that this legislation goes too far. They only want to protect children from BPA below the age of 3. I disagree. Besides all the other negative health effects I've already outlined, studies have shown that children's brains between the ages of 3 to 6 experience extensive internal wiring in their frontal lobes and the cortical regions involved in organizing actions, planning activities and focusing attention. By banning BPA in empty baby bottles and sippy cups for children 5 years old and younger, we can help to protect kids from the harmful effect of bisphenol A in the most important years of their brain development. In order to preserve the Committee's time, I will save the details of these studies, including a current Consumer Reports article that recommends that manufacturers and government agencies act to eliminate the use of BPA, for speakers presenting after me.

You're also going to hear today from industry groups opposed to this bill that it isn't necessary because the federal Food & Drug Administration will be submitting its recommendations on the safety of this chemical later this month. Again, I disagree. It is important to understand the history of the federal government's inaction involving this chemical.

Sen. Lassa's Testimony

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In 1996, Congress directed the Environmental Protection Agency to studying 15,000 endocrine disruptors by 1999. However, the EPA didn't start studying any of these chemicals until nearly ten years later; and even then, they only planned to screen a mere 73 of these chemicals. BPA, an endocrine disruptor, was not on the short list to be tested.

In 2008, the National Toxicology Program, an interagency program of the Department of Health and Human Services issued a report that said it had concerns about BPA. However, the FDA ruled that the chemical was safe for all uses. Soon after the FDA's own advisory committee found that FDA scientists had not considered enough of the available literature on BPA as they relied on only two studies, both paid for by chemical manufactures of BPA. A 2007 review by the Milwaukee Journal Sentinel, who won a Polk Award for their work on reporting on BPA, found that 80% of the independent studies found BPA caused cell damage or harmful neurological effects. In fact, during their investigation, the Milwaukee Journal Sentinel found e-mails between FDA scientists and lobbyists for BPA manufacturers discussing how to write the government assessment. The e-mails showed that government scientists relied heavily on industry lobbyists to establish certain safety data and allowed them to write entire sections of their findings.

Finally, you're going to hear from some groups today that this legislation will negatively affect industries that produce food and bottled water. This legislation does nothing of the sort and that is a complete distortion. I want to make it clear to the Committee that this legislation does not impact canned food or bottled water. The bill language clearly states that it applies to empty baby bottles and spill-proof "sippy" cups. I have attached a copy of a memo from the Legislative Council that clearly defines what this bill does, and does not do.

Wisconsin has a proud progressive history in promoting the safety and wellbeing of its residents. It is important for Wisconsin to join Canada, Minnesota, Connecticut, and the City of Chicago in passing legislation to ban BPA and the ten other states in the country that have considered banning BPA in these children's products. I ask for your support in passing this legislation that will help to protect the youngest members of our society, our children, from this harmful chemical.

Thank you for your time and consideration. I would be happy to answer any questions.



WISCONSIN LEGISLATIVE COUNCIL

Terry C. Anderson, Director
Laura D. Rose, Deputy Director

TO: SENATOR JULIE LASSA

FROM: Mary Matthias, Senior Staff Attorney

RE: 2009 Senate Bill 271, Relating to the Manufacture and Sale of Certain Baby Bottles and Cups That Contain Bisphenol A

DATE: September 16, 2009

This memorandum responds to your request for an analysis of the applicability of 2009 Senate Bill 271, relating to the manufacture and sale of certain baby bottles and cups that contain bisphenol A, to the manufacture, packaging, and sale of bottled water and processed food.

Senate Bill 271 prohibits manufacturing or selling, or offering to sell, at wholesale, an empty baby bottle or spill-proof cup (sippy cup) primarily intended for use by a child five years of age or younger if the bottle or cup contains bisphenol A. The bill requires any manufacturer or wholesaler who sells or offers to sell an empty baby bottle or sippy cup in Wisconsin to label the bottle or cup as not containing bisphenol A.

Your request for this analysis was prompted by comments contained in a letter to Senator Robert Wirsch dated September 10, 2009, from several members of the International Bottled Water Association (IBWA). The letter suggests that the labeling requirements be removed from the bill for the following reason:

There is bottled water product in the marketplace intended for children that does not contain BPA, and has never contained BPA. Requiring a bottler to label their product as not containing BPA would be very costly for that bottler, and furthermore, could easily and unnecessarily call the safety of all bottled water products into question.

The IBWA letter also implies that the bill would impose “costly and unnecessary requirements” on food processors. Likewise, in a letter to you dated August 20, 2009, Nick George, president of the Midwest Food Processors Association, Inc., requests that the labeling requirements be removed from the bill, stating that “BPA is a critical element in food packaging that provides important and valuable food



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Wisconsin Public Interest Research Group

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Date?

Stop Toxic Baby Bottles

SB271, the BPA Free Kids Act

Parents shouldn't have to be chemists to know what products are safe.

Bisphenol-A is an industrial chemical used in baby bottles, sippy cups, and many other products. It leaches from these products and may harm children's development; studies link it to cancer, early onset diabetes, puberty, obesity, and hyperactivity.

Despite these toxic development health threats posed to children, many baby bottles and sippy cups on the market are made with bisphenol A. The only appropriate response to evidence that a known toxic chemical leaches from baby products is to phase it out and replace it with safer products.

Scientific studies are clear—BPA is dangerous to children.

In the last decade more than 100 studies have shown BPA to cause permanent harm in lab animals at the low exposure levels found in humans. The Centers for Disease Control (CDC) found 93 percent of Americans age 6 and up were exposed to BPA. Children in the study had the highest levels of BPA, followed by teens and adults.

Safer alternatives are available.

Fortunately, it is possible to make bottles and other containers without BPA. Companies such as Nalgene, Playtex, and Eden foods have all started using BPA-free alternatives. Wal-Mart and Toys "R" Us have also pledged to stop selling baby bottles containing BPA.

Other jurisdictions have taken action, Wisconsin should too.

This year, both Minnesota and Connecticut have passed legislation banning BPA in children's products. The city of Chicago has taken action on BPA as well. Wisconsin should take action to protect kids from BPA too.

Support SB271, the BPA Free Kids Act.

The BPA Free Kids Act will ban the manufacture and sale of bisphenol-A (BPA) in children's bottles and cups. Doing so will protect the most vulnerable from the dangers of toxic BPA.

WISPIRG is a statewide, non-partisan, non-profit public interest advocacy organization. For more information, contact Bruce Speight at bspeight@wispirg.org, or 608-251-9501

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Getting the Facts Straight on Bisphenol A

- 1. Doesn't the federal Food and Drug Administration (FDA) say bisphenol A is safe?**
The FDA's assessment was based mainly on a review of a very small number of flawed chemical industry-funded studies, ignoring over 180 independent studies that have found bisphenol A causes harm. *In fact, a panel of its own scientists recommended the agency abandon its earlier findings that BPA is safe. FDA has indicated that it will reassess its findings.* Moreover, as the Milwaukee Journal Sentinel has reported, the FDA report "was written largely by the plastics industry and others with a financial stake in the controversial chemical."
- 2. Has Europe decided BPA is safe?** Not exactly. The latest opinion of the European Food and Safety Agency (a branch of the E.U. not equipped to take a stand for all 27 countries apart of the E.U.) published was deeply flawed. It was largely based on **one** industry-funded study unpublished at the time; was assessed by a panel composed of food toxicologists, many with industry links; and compromised by a failure to invite experts on BPA or endocrine disruptors to provide their assessment. The EFSA has declared that it may review its opinion on BPA.
- 3. Are there safe alternatives to BPA?** Yes! Safe and cost effective alternatives are on the market today.

For baby bottles and "sippy cups":

- Glass
- Polypropylene and polyethylene plastic
- Bio based plastics

(A three pack of BPA-free baby bottles are only \$2.99 at Babies R Us)

- 4. Does Canada say BPA is safe?** Canada declared BPA toxic under provisions of the Canadian Environmental Protection Act and subsequently banned the import and sale of polycarbonate baby bottles.
- 5. Have low doses of BPA been linked with health problems?** Yes. As of August, 2008, 189 government-funded, low-dose studies found harm from bisphenol A. Chemical corporations had funded 14 low-dose studies at that time, none of which found harm (see table below).

Table showing the funding for low-dose studies of the chemical bisphenol A (BPA) and the study outcome

August 2008--UNIVERSITY OF MISSOURI – COLUMBIA, Dr. Fred vom Saal

SOURCE OF FUNDING	STUDY OUTCOME		
	HARM	NO HARM	TOTAL
Government	189 (93%)	15 (7%)	204
Chemical Corporations	0 (0%)	14 (100%)	14
	189 (87%)	29 (13%)	218

**** ALL STUDIES USING LABORATORY ANIMALS**

SOURCE: <http://endocrinedisruptors.missouri.edu/vomsaal/vomsaal.html>

6. **Are humans exposed to these same low doses used in studies?** Unfortunately, the answer is yes. According to the Centers for Disease Control, BPA is found in 93% of Americans over the age of 6. This statistic would likely be higher if young children were included, since they carry the highest levels of BPA of any age group.
7. **Have we safely been using BPA for decades?** Scientists have known that BPA acts as an artificial estrogen since the 1930s. Without any independent safety testing or government oversight, BPA became a common component of food can linings during the 1970s, and began being used for plastic products in the 1940s and 1950s. BPA exemplifies our broken chemical safety system as it never had to be proven safe before it went on the market. Just because it has been around for a long time, doesn't mean it is safe.





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Chemical Fallout: A Journal Sentinel Watchdog Report

Plastics industry behind FDA research on bisphenol A, study finds

Posted: Oct. 23, 2008

A government report claiming that bisphenol A is safe was written largely by the plastics industry and others with a financial stake in the controversial chemical, the Journal Sentinel found.

Although the Food and Drug Administration will not reveal who prepared its draft, the agency's own documents show that the work was done primarily by those with the most to gain by downplaying concerns about the safety of the chemical.

That includes Stephen Hentges, executive director of the American Chemistry Council's group on bisphenol A, who commissioned a review of all studies of the neurotoxicity of bisphenol A and submitted it to the FDA. The FDA then used that report as the foundation for its evaluation of the chemical on neural and behavioral development. The American Chemistry Council is a trade group representing chemical manufacturers.

The FDA's draft, released in August, found no cause for worry about bisphenol A, which is found in thousands of household products, including baby bottles, infant formula containers and the lining of aluminum cans.

That finding is at odds with the conclusions of the FDA's own advisers from the National Toxicology Program. The NTP announced in September that the chemical is of some concern for effects on the development of the prostate gland and brain, and for behavioral effects in fetuses, infants and children. The NTP also found some concern for the neurodevelopment of young children, infants and fetuses.

Last week, the government of Canada declared that bisphenol A is a toxin and is banning its use in baby bottles and other products used by children.

The FDA draft finding no harm is under review by a subcommittee, which will decide if the conclusions need to be amended. That assessment is expected to be released any day and will be presented Oct. 31 in Washington

The Journal Sentinel reported earlier this month that subcommittee chairman Martin Philbert is founder and co-director of an institute that received \$5 million from a retired medical supply manufacturer who said he considered bisphenol A "perfectly safe." The donor, Charles Gelman, told the newspaper that he has expressed his views to Philbert in several conversations.

Philbert at first denied ever having been contacted by Gelman about bisphenol A. He now says that he is

aware of Gelman's views but is not influenced by them.

Congressional inquiry

A congressional committee launched an investigation into the connection, citing the newspaper report.

Those same congressional investigators are now looking into other possible conflicts of interest. They are scrutinizing the role that ICF, a consulting firm whose clients include the American Chemistry Council and the American Petroleum Institute, had in preparing the FDA draft.

Neither ICF nor the FDA would say what role the consulting firm had in the agency's review of the chemical. But the newspaper found reports issued to the FDA by the consulting firm from 2000 to 2007. Those reports included reviews of government and industry studies on the effects of bisphenol A on animal health.

The task force used ICF's reviews in its draft.

ICF spokesman Douglas Beck declined to comment on his company's involvement in the study of bisphenol A..

FDA spokesman Michael Herndon is referring all questions about the draft to congressional investigators.

The House Committee on Energy and Commerce and its subcommittee on Oversight and Investigation has asked FDA Commissioner Andrew von Eschenbach to appear for an interview by committee staff to explain the agency's decision-making relating to bisphenol A.

"Specifically, why industry-funded studies provide the basis of your regulatory decisions and why the totality of the science around the chemical continues to be ignored by your science-based agency," the committee letter said.

Investigators want transcripts of all communication between ICF and the FDA by Wednesday.

Poring over evidence

The newspaper reviewed the body of evidence that the task force considered. It found memos with entire sections blacked out, reviews commissioned by the American Plastics Council, an arm of the American Chemistry Council, and reviews completed by consulting firms with clients who have financial interests in the sale of bisphenol A.

Many of these reviews of individual studies are at odds with the NTP's reviews of the same studies.

For example, one study funded by the National Institutes of Health and the Department of Defense looked at the effects of bisphenol A on prostate development in rats.

The FDA called it "severely limited," in contrast to the NTP's review, which labeled it of "high utility."

Another government-funded study, which also looked at the effects of the chemical on the prostate, again was considered of "high utility" by the NTP for its evaluation, and it was deemed "very limited" by the FDA.

Much of the science that the task force considered was 20 years old or older, including a study commissioned in 1976.

The older studies are not as sensitive as modern tests. They used high doses of the chemical and did not consider the unique effects on the endocrine system.

Bisphenol A was developed in 1891 as a synthetic estrogen.

It came into widespread use in the 1950s when scientists realized it could be used to make polycarbonate plastic and some epoxy resins to line food and beverage cans.

The chemical is used in a host of products from dental sealants and eyeglasses to CDs and water bottles. Bisphenol A has been detected in the urine of 93% of Americans tested.

Sales of the chemical reached \$6 billion worldwide in 2007.

Last year, the Journal Sentinel reviewed 258 research papers on bisphenol A and found that a large majority showed the chemical was harmful to lab animals. Those that didn't find harm overwhelmingly were paid for by the chemical industry. The newspaper also found that the government was basing its safety recommendations for bisphenol A on outdated studies performed more than two decades ago.

Columbia University professor David Rosner, who researches the relationship of industry and government regulators of toxic substances, has compared the controversy over bisphenol A to tobacco and asbestos.

"It makes sense that we have a process that is not tainted by corruption," he said. "This looks tainted."

A plastics industry spokeswoman defended the role of Hentges and others in shaping the FDA's task force draft. Hentges was out of the country on Wednesday and not available for comment.

Tiffany Harrington, spokeswoman for the American Chemistry Council, said Hentges was acting appropriately in his capacity as an advocate for the plastics industry.

"We are a stakeholder just like anyone else," Harrington said. "It's part of the process."

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<http://www.jsonline.com/watchdog/watchdogreports/34469194.html>

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THE POWER OF INFORMATION

Published on Environmental Working Group (<http://www.ewg.org>)

News Release - Washington Lobbyists Connive to Kill California Public Health Bill

Industry Hired Guns Plan To “Manipulate The Legislative Process,” Deploy “Fear Tactics” Targeting Young Mothers, Hispanics and African Americans

Published June 1, 2009

Oakland, Ca -- Last Thursday, chemical and food industry lobbyists called an emergency brainstorming session to devise an attack plan to stop a California legislative proposal for a virtual ban on the toxic plastics chemical Bisphenol A (BPA) in food and beverage containers for children 3 and under.

According to internal emails obtained by the [Washington Post](#) [1], [Milwaukee Journal Sentinel](#) [2] and Environmental Working Group, Washington representatives of Coca-Cola, Alcoa, Del Monte, Crown, the American Chemistry Council, the North American Metal Packaging Alliance, Inc. and Grocery Manufacturers Association convened behind closed doors at Washington's exclusive Cosmos Club and committed \$500,000 to an effort to “prolong the life of BPA,” an integral plastics component estimated to generate more than \$6 billion in global sales annually.

The chemical, used to harden polycarbonate plastics and epoxy resins used as, among other things, food can linings, is a synthetic estrogen shown in more than 100 laboratory tests to disrupt the endocrine system, disrupt brain and reproductive system development and function and cause other serious conditions such as cancer, behavior and learning problems, cardiovascular disease, diabetes and obesity.

According to the emails, the group, calling themselves the BPA Joint Trade Association, discussed, among other things, tactics to defeat California State Senator Fran Pavley (D-23) measure that would largely eliminate BPA's use in baby bottles, sippy cups, formula cans and baby food jars. The emails said industry lobbyists were deployed in Sacramento, “befriending people that are able to manipulate the legislative process.”

The emails show that the group also discussed California's Proposition 65, which requires the governor's office to publish an annual list of chemicals known to cause cancer or reproductive system damage. They agreed, the emails said, to “build up their contact base in Sacramento” to influence this process to embrace the industry's view of “the benefits of using BPA,” rather than scientists' and environmentalists assertions that BPA is dangerous to human health at current exposure levels and should be restricted from contact with food and beverages.

The rationale, according to the emails: the chemical and food processing industries did not “want to win at the legislative level and then not have anyone buy the product.”

On a national level, the emails say, the lobbyists “suggested using fear tactics (e.g. “Do you want to have access to baby food anymore?”).”

As well, the emails show, they considered “focusing on the impact of BPA bans on minorities (Hispanic and African American) and poor “ by insinuating that without BPA, food prices would rise.

Ironically, the emails show, lobbyists meeting in a club that admitted women only in 1988 agreed

that” legislative and grassroots outreach (to young mothers ages 21-35 and students) is imperative to the stability of their industry.” “Their ‘holy grail’ spokesperson would be a ‘pregnant young mother who would be willing to speak around the country about the benefits of BPA’,” the email said.

“High paid D.C. lobbyists and P.R. professionals are plotting a cynical strategy to reach into the State House in Sacramento and kill legislation that would protect millions of California’s youngest from further exposure to this toxic, hormone-disrupting chemical,” said Renee Sharp Environmental Working Group (EWG)’s California director.

“These emails show that chemical manufacturers and food process know they can’t use science to make their case, so they’ve decided to play on people’s fears,” Sharp said. “Worst of all, they propose to target Hispanics and African Americans, who, they apparently assume, are poor and more vulnerable. There’s nothing about truth in these emails. They’re all about money -- the billions of dollars the food and chemicals industries have invested in the production and use of BPA.”

“We hope that lawmakers in Sacramento will stand with Senator Pavley and pass her important public health legislation,” Sharp said.

Excerpts from the May 28, 2009 BPA Joint Trade Association Meeting on Communications Strategy:

“Attendees suggested using fear tactics (e.g. “Do you want to have access to baby food anymore?”) as well as giving control back to consumers (e.g. you have a choice between the more expensive product that is frozen or fresh or foods packaged in cans) as ways to dissuade people from choosing BPA-free packaging.”

“They hope to form messages relevant to how people live their lives—What does not having BPA mean to your daily lifestyle? Focusing on the impact of BPA bans on minorities (Hispanic and African American) and poor is also important.”

Attending Companies: Coca-Cola, Alcoa, Crown, Del Monte, North American Metal Packaging Alliance, Inc., Grocery Manufacturers Association (GMA), American Chemistry Council.

The text of the meeting minutes can be found at the top right-hand side of this page.

Source URL:

<http://www.ewg.org/BPAindustrylobbyists>

Links:

[1] <http://www.washingtonpost.com/wp-dyn/content/article/2009/05/30/AR2009053002121.html>

[2] <http://www.jsonline.com/watchdog/watchdogreports/46510647.html>





Bill would ban BPA in baby products

State would be third to prohibit chemical

By Meg Kissinger of the Journal Sentinel

Posted: Jun. 9, 2009

Wisconsin would become the third state to ban the sale of baby bottles and cups for children made with bisphenol A under a bill being introduced Wednesday in Madison.

It is the latest in a wave of bills across the country aimed at eliminating the controversial chemical from children's food containers.

The bill would also require manufacturers and retailers of baby bottles and sippy cups to label their products as BPA-free. Most manufacturers already do so, but the requirement was included to help state regulators enforce the law.

State Sen. Julie Lassa (D-Stevens Point), who is introducing the legislation with state Rep. Kelda Roys (D-Madison), said she is expecting little opposition.

"I don't think it should be a problem," she said of the bill's passage. "We're talking about children's health. That is pretty much a bipartisan issue."

The plastics lobby has fought hard against bills in other states and localities to ban BPA. They point to a ruling last September by the U.S. Food and Drug Administration that the chemical is safe.

Lassa said Tuesday that lobbyists for the chemical-makers have been following the issue closely. Representatives of the chemical industry came to her office earlier this year to take a look at the proposed bill, she said.

"I'm not worried about them," she said.

The fact that other states and localities have banned BPA will make a ban here easier, Lassa said.

Similar bans are in effect in Chicago, Minnesota, Connecticut and Suffolk County in New York. The California state Senate voted last week to ban it, and the bill is moving to the Assembly.

Other bans have been proposed in Massachusetts, Michigan and New York.

A federal effort to ban the chemical in all food containers has been introduced in both houses of Congress and is expected to be considered as early as this fall.

The Wisconsin bill is being supported by environmental and consumer groups, including the Wisconsin Public Interest Research Group, the Sierra Club, the League of Conservation Voters, Wisconsin Environment, Clean Wisconsin and the Wisconsin Parent Teacher Association.

BPA, used to make hard, clear plastic, has been linked in a growing number of studies to health problems, including breast and testicular cancer, diabetes, heart disease and hyperactivity.

"This is a chemical that we have been very concerned about for years," said Bruce Speight, an advocate at the Wisconsin Public Interest Research Group, a nonprofit consumer rights group. "Parents shouldn't have to be chemists to figure out what is in the bottles that they use to feed their babies."

The Journal Sentinel has reported that the FDA's assessment declaring BPA to be safe was written largely by lobbyists for the chemical industry. The newspaper also revealed that e-mails, obtained through the Freedom of Information Act, show that the government agency allowed lobbyists easy access to their scientists, allowing them to give advice on certain studies before their own scientists had a chance to look at them.

The Journal Sentinel reported last month that the lobbyists and food packaging executives met to consider hiring a pregnant woman to serve as a spokeswoman for the chemical. They also discussed ways to befriend those who could "manipulate the legislative process."

Those stories prompted congressional leaders to demand that the FDA reopen its assessment of the chemical, which the agency has done. Congress also is investigating whether the FDA had inappropriate ties to the chemical lobby.

Lassa said Tuesday that she hopes her bill would force the federal government to take a more critical look at BPA and other chemicals that leach from products.

"Obviously, the FDA has relied too heavily on industry-funded studies and discounted those that have been conducted by independent scientists," she said.

Lassa, the mother of two young children, said she and other lawmakers have heard from parents who are worried about the chemical in products for children.

The American Chemistry Council, lobbyists for the chemical-makers, did not comment on the proposed bill.





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June 25, 2009

Bisphenol A (BPA) Questions and Answers

Q: Are the large 3 and 5 gallon water cooler bottled used by IBWA's member companies' Home and Office Delivery (HOD) bottles safe?

A: At the International Bottled Water Association, the safety and quality of our members' bottled water products are at the top of our priorities. Members regularly conduct tests on all of their bottles and the water itself for safety, quality and performance, and closely monitor ongoing research on plastic safety.

Nearly all three- and five-gallon Home and Office Delivery (HOD) bottles are made of polycarbonate plastic. The U.S. Food and Drug Administration (FDA) and consumer safety agencies in Canada, Japan and the European Union agree that – based on currently available research – polycarbonate plastic is safe to use for food and beverage packaging. This was reaffirmed on January 30, 2009, when the FDA met with Health Canada to discuss the topic. Polycarbonate plastic is not used in the popular single-serve bottles, made of PET plastic or glass, or any containers smaller than three gallons.

Q: What is polycarbonate plastic?

A: Three- and five-gallon Home and Office Delivery (HOD) bottles are made of polycarbonate plastic. Polycarbonate is a strong, clear and reusable type of plastic. Classified as a type 7 plastic by the Society of the Plastics Industry, polycarbonate is used in a wide range of food storage containers, and is commonly found in the epoxy resin lining of canned food products. It is also found in other products such as lab equipment, medical devices and clear plastic utensils, as well as PVC pipes sometimes used in municipal water delivery systems. Polycarbonate is one polymer that contains trace levels of the chemical bisphenol-A (BPA). Polycarbonate plastic is not used in any single-serve bottles or any containers smaller than three gallons.

Q: Why do IBWA members use polycarbonate plastic for HOD bottles?

A: Polycarbonate has significant advantages over glass, its closest alternative. It is lightweight, transparent and shatter-resistant. It can easily be cleaned, refilled and reused. In fact, each of IBWA's members' three- and five-gallon HOD bottles is cleaned and refilled approximately 25 to 50 times before being turned over to a recycling company, allowing the plastics to be given a new life. In 2006, just one IBWA member, Nestle Waters North America, recycled approximately 900,000 HOD bottles, keeping nearly 800 tons of plastic out of landfills.

Q: What number identifies polycarbonate plastic?

A: There is a #7 in a triangle printed on the bottom of all bottled water industry three- and five-gallon polycarbonate bottles.

Q: What does the number on plastics mean?

A: The numbers on plastics are meant for recyclers. Since different plastics are made with different materials and cannot be mixed, it helps recyclers keep them separate. The codes are not an indication of product safety. In fact, the #7 code, which is found on polycarbonate plastics, is a catch-all code for plastics that do not fit into categories 1-6. The #7 is also used on acrylics, polylactic acid, nylon and fiberglass.

Q: Do IBWA members use polyvinyl chloride (#3) or polystyrene (#6) plastics in any of its products?

A: No.

Q. What is bisphenol-A?

A: Bisphenol-A, also referred to a "BPA," is a chemical component used to make polycarbonate plastic.

Q. Why and how does BPA migrate into water or food?

A. BPA can migrate in very small quantities when polycarbonate plastic is exposed to extreme temperatures. Consumers should store polycarbonate bottles in areas that are not exposed to high temperatures, as they would any other food product.

Q: Why is the media interested in BPA now?

A: BPA is a widely studied compound and new research reports come out about it regularly. Whenever a study result is announced, it becomes a subject of potential media interest.

Q: How is BPA regulated in the United States?

A: The U.S. Food and Drug Administration (FDA) regulates polycarbonate plastic as a food packaging material. The FDA and consumer safety agencies in Canada, Japan and the European Union agree – based on currently available research – that polycarbonate plastic is safe to use for food and beverage packaging. This was reaffirmed on January 30, 2009, when the FDA met with Health Canada to discuss the topic.

The U.S. Environmental Protection Agency (EPA) has determined that people can safely be exposed orally to an "Oral Reference Dose" of 0.023 milligrams of BPA per pound of body weight per day. The amount of exposure to BPA that could come specifically from bottled water is extremely low. In fact, a child would need to drink at least 570 liters per day to reach the EPA's Oral Reference Dose. An adult male of 180 lbs would need to drink at least 4,140 liters per day to reach the Oral Reference Dose.

Q: Do all HOD company bottles contain BPA?

A: BPA is used in polycarbonate plastic, which is used to make the three- and five-gallon bottles. However, it is only found in insignificant amounts in the final polycarbonate materials and generally does not migrate into the water. Note that the bottles used for other products, such as half-liter bottles, are made of different types of plastics and do not contain BPA.

Q: Do IBWA members' single-serve bottles contain BPA?

A: No. They are made from polyethylene terephthalate (PET), an entirely different type of plastic that does not contain BPA.

Q: What science supports your position that your bottles, especially those that contain BPA, are safe for people?

A: The FDA and consumer safety agencies in Canada, Japan and the European Union agree – based on currently available research – that polycarbonate plastic is safe to use for food and beverage packaging. This was reaffirmed on January 30, 2009, when the FDA met with Health Canada to discuss the topic.

In addition, in January 2007, a report in the *International Journal of Toxicology* concluded that there is no compelling evidence that humans are at risk from current exposures to BPA, even at low doses. That includes cancer, reproduction and child development risks. Numerous other international studies have reached similar conclusions."

In a comprehensive review of scientific studies of BPA, the European Food Safety Authority also concluded in January 2007 that there is no risk to human health at the low levels to which people, including infants and children, might be exposed from the use of consumer products. Consumers who would like more information specific to infants and children should consult a pediatrician.

Q: Do IBWA HOD members test for BPA in its water?

A: Yes. Most recent tests by some of IBWA's largest members show that 30 days after bottling and sealing, the water inside the bottles had non-detectable levels of BPA when analyzed at detection limits of less than 1.0 part per billion. This is a very low detection limit achieved with state-of-the-art instrumentation.

Q: How frequently do IBWA member companies test for BPA?

A: Some began testing for BPA in their water more than a decade ago when concerns about its safety were first raised. They continue to conduct BPA migration tests on a regular basis as part of their process for qualifying materials.

Q: Where and how is the testing done?

A: Testing is done both internally and at independent external labs, based on methodologies used in industry and government.

Q: What are the levels of BPA in IBWA member HOD bottles?

A: IBWA's HOD members who have tested their 3 and 5 gallon bottles most recently show that 30 days after bottling and sealing, the water inside the bottles had non-detectable levels of BPA when analyzed at detection limits of less than 1.0 part per billion. This is a very low detection limit achieved with state-of-the-art instrumentation.

Q: Are there BPA-free alternatives to polycarbonate, and do IBWA member use them?

A: The most common alternative to polycarbonate is glass, which is significantly heavier and easier to break. Our members regularly look at new packaging options and are exploring materials that do not contain BPA, but still meet our functionality requirements.

Q: As an HOD customer, if I want a bottle without BPA can you give me one?

A: At this time, polycarbonate plastic is the best material for our three- and five-gallon Home and Office products. Our members, however, are constantly evaluating their packaging materials, and are currently exploring alternatives to polycarbonate. In the meantime, we suggest that customers who prefer something other than HOD polycarbonate bottles consider our single-serve PET bottles and filtration products. Polycarbonate plastic is not used in single-serve bottles or any containers smaller than three gallons.

Q: Is it safe for children and pregnant women to drink water from polycarbonate bottles?

A: The amount of exposure to BPA that could come specifically from bottled water is extremely low. In fact, a child would need to drink at least 570 liters per day to reach the EPA's Oral Reference Dose. An adult male of 180 lbs would need to drink at least 4,140 liters per day to reach the Oral Reference Dose.

In a comprehensive review of scientific studies of BPA, the European Food Safety Authority concluded in January 2007 that there is no risk to human health at the low levels to which people, including infants and children, might be exposed from the use of consumer products.

We recommend that consumers who would like more information specific to infants, children or pregnant women consult a physician.

Q. Is there anything I can do as a Home and Office customer to limit the migration of BPA from the polycarbonate bottles I'm using?

A. Store polycarbonate bottles in areas that will not be exposed to extreme high temperatures.

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The International Bottled Water Association (IBWA) is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA's membership includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with the U.S. Food and Drug Administration (FDA), which regulates bottled water as a packaged food product, and state governments to set stringent standards for safe, high quality bottled water products. In addition to FDA and state regulations, the Association requires member bottlers to adhere to the IBWA Bottled Water Code of Practice, which mandates additional standards and practices that in some cases are more stringent than federal and state regulations. A key feature of the IBWA Bottled Water Code of Practice is an annual, unannounced plant inspection by an independent, third party organization. Consumers can contact IBWA at 1-800-WATER-11 or log onto IBWA's web site (www.bottledwater.org) for more information about bottled water and a list of members' brands. Media inquiries can be directed to Tom Lauria at 703-647-4609 or tlauria@bottledwaterorg.

The New York Times

November 8, 2009

OP-ED COLUMNIST

Chemicals in Our Food, and Bodies

By NICHOLAS D. KRISTOF

Your body is probably home to a chemical called bisphenol A, or BPA. It's a synthetic estrogen that United States factories now use in everything from plastics to epoxies — to the tune of six pounds per American per year. That's a lot of estrogen.

More than 92 percent of Americans have BPA in their urine, and scientists have linked it — though not conclusively — to everything from breast cancer to obesity, from attention deficit disorder to genital abnormalities in boys and girls alike.

Now it turns out it's in our food.

Consumer Reports magazine tested an array of brand-name canned foods for a report in its December issue and found BPA in almost all of them. The magazine says that relatively high levels turned up, for example, in Progresso vegetable soup, Campbell's condensed chicken noodle soup, and Del Monte Blue Lake cut green beans.

The magazine also says it found BPA in the canned liquid version of Similac Advance infant formula (but not in the powdered version) and in canned Nestlé Juicy Juice (but not in the juice boxes). The BPA in the food probably came from an interior coating used in many cans.

Should we be alarmed?

The chemical industry doesn't think so. Steven Hentges of the American Chemistry Council dismissed the testing, noting that Americans absorb quantities of BPA at levels that government regulators have found to be safe. Mr. Hentges also pointed to a new study indicating that BPA exposure did not cause abnormalities in the reproductive health of rats.

But more than 200 other studies have shown links between low doses of BPA and adverse health effects, according to the Breast Cancer Fund, which is trying to ban the chemical from food and beverage containers.

"The vast majority of independent scientists — those not working for industry — are concerned about early-life low-dose exposures to BPA," said Janet Gray, a Vassar College professor who is science adviser to the Breast Cancer Fund.

Published journal articles have found that BPA given to pregnant rats or mice can cause malformed genitals in their offspring, as well as reduced sperm count among males. For example, a European journal found that male mice exposed to BPA were less likely to make females pregnant, and the Journal of Occupational Health found that male rats administered BPA had less sperm production and lower testicular weight.

This year, the journal Environmental Health Perspectives found that pregnant mice exposed to BPA had babies with abnormalities in the cervix, uterus and vagina. Reproductive Toxicology found that even low-level exposure to BPA led to the mouse equivalent of early puberty for females. And an array of animal studies link prenatal BPA exposure to breast cancer and prostate cancer.

While most of the studies are on animals, the Journal of the American Medical Association reported last year that humans with higher levels of BPA in their blood have “an increased prevalence of cardiovascular disease, diabetes and liver-enzyme abnormalities.” Another published study found that women with higher levels of BPA in their blood had more miscarriages.

Scholars have noted some increasing reports of boys born with malformed genitals, girls who begin puberty at age 6 or 8 or even earlier, breast cancer in women and men alike, and declining sperm counts among men. The Endocrine Society, an association of endocrinologists, warned this year that these kinds of abnormalities may be a consequence of the rise of endocrine-disrupting chemicals, and it specifically called on regulators to re-evaluate BPA.

Last year, Canada became the first country to conclude that BPA can be hazardous to humans, and Massachusetts issued a public health advisory in August warning against any exposure to BPA by pregnant or breast-feeding women or by children under the age of 2.

The Food and Drug Administration, which in the past has relied largely on industry studies — and has generally been asleep at the wheel — is studying the issue again. Bills are also pending in Congress to ban BPA from food and beverage containers.

“When you have 92 percent of the American population exposed to a chemical, this is not one where you want to be wrong,” said Dr. Ted Schettler of the Science and Environmental Health Network. “Are we going to quibble over individual rodent studies, or are we going to act?”

While the evidence isn't conclusive, it justifies precautions. In my family, we're cutting down on the use of those plastic containers that contain BPA to store or microwave food, and I'm drinking water out of a metal bottle now. In my reporting around the world, I've come to terms with the threats from warlords, bandits and tarantulas. But endocrine disrupting chemicals — they give me the willies.

I invite you to comment on this column on my blog, [On the Ground](#). Please also join me on [Facebook](#), watch my [YouTube videos](#) and follow me on [Twitter](#).

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It's best to avoid BPA, federal official says

Chemical's effects a concern to head of health agency

By *Meg Kissinger of the Journal Sentinel*

Posted: Dec. 11, 2009

The head of the primary federal agency studying the safety of bisphenol A said Friday that people should avoid ingesting the chemical - especially pregnant women, infants and children.

"There are plenty of reasonable alternatives," said Linda Birnbaum, director of the National Institute of Environmental Health Sciences and the National Toxicology Program, in an interview with the Journal Sentinel.

While stressing she is not a medical doctor, Birnbaum said she has seen enough studies on the chemical to be concerned about its effects on human health.

A grandmother, Birnbaum said she advises her children to avoid using food packaged in containers made with BPA.

Asked if consumers should be worried about BPA, Birnbaum said, "Absolutely."

In August 2008, the U.S. Food and Drug Administration, charged with regulating the use of chemicals in food products, declared BPA to be safe for all uses - a decision chemical-makers routinely point to as proof their product is safe.

However, the agency is reconsidering that ruling after its own advisory board found that FDA scientists ignored valuable studies that found the chemical caused harm.

The agency missed a self-imposed Nov. 30 deadline to review its finding but is expected to issue a new determination any day.

A Journal Sentinel investigation found that lobbyists for industry wrote entire sections of the FDA's original assessment. E-mails obtained by the newspaper found that FDA scientists relied on chemical industry lobbyists to examine BPA's risks, track legislation to ban it and even monitor press coverage.

In formulating its decisions, the FDA considers assessments made by the national institute, Birnbaum's agency.

BPA, developed as an estrogen replacement, is used to make polycarbonate plastic and epoxy resins. It is used to line most metal food and beverage cans and to coat carbonless paper receipts. Last year, six major baby bottle manufacturers promised to discontinue BPA in their products, citing concern for their consumers' safety.

Sunoco, one of the companies that makes BPA, said it would no longer sell the chemical without a guarantee that it would not be used to make baby bottles.

Canada has declared BPA to be a toxin and prohibits its use in baby bottles.

On Friday, health and environmental groups stepped up their call for a ban on BPA.

"About 125,000 babies have been born in the United States since Nov. 30, the FDA's missed deadline," the Breast Cancer Fund said in a news release. "It's time for the FDA to issue an immediate ban on BPA in hard plastic food containers and require labeling of all other food packaging containing BPA."

Compared to lead

In testimony before a Senate panel last week, Birnbaum compared BPA to lead, mercury and polychlorinated biphenyls, all of which have been found to have devastating health effects even at low doses.

Her agency, the NIEHS, is investing \$30 million over the next two years on BPA-related research. She said it will look at the chemical's effects on all stages of development.

She also said that the National Toxicology Program may be revising its 2008 report, which found some concern for fetuses, infants and children regarding their prostate and brain development as well as behavioral effects.

"Science doesn't stay still," Birnbaum said in the Friday interview. "New data continues to be generated that warrants a closer look."

Birnbaum said the traditional ways of looking at a chemical's danger need to be replaced with more precise measures.

"We're not asking the right questions," she said. "We have to look more broadly."

Birnbaum said she would like to see the federal government use the precautionary principle to regulate chemicals. That approach, used in Canada and throughout Europe, requires that a chemical be proved to be safe before it is allowed to be used in commerce.

In the United States, chemicals are allowed on the market and removed only if they have been found to cause harm.

Regarding BPA, Birnbaum said there is enough uncertainty about its safety to caution people to avoid it in food contact items.

"It's simple enough to avoid," she said. "So, why not avoid a problem?"



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Scientists link plastics chemical to health risks

New research finds exposure to Bisphenol A associated with heart disease

By Kate Kelland

Reuters

updated 8:17 a.m. CT, Wed., Jan. 13, 2010

LONDON - Exposure to a chemical found in plastic containers is linked to heart disease, scientists said on Wednesday, confirming earlier findings and adding to pressure to ban its use in bottles and food packaging.

British and U.S. researchers studied the effects of the chemical bisphenol A using data from a U.S. government national nutrition survey in 2006 and found that high levels of it in urine samples were associated with heart disease.

Bisphenol A, known as BPA, is widely used in plastics and has been a growing concern for scientists in countries such as Britain, Canada and the United States, where food and drug regulators are examining its safety.

David Melzer, professor of epidemiology and public health at the Peninsula Medical School in Exeter, England, who led the study, said the research confirmed earlier findings of a link between BPA and heart problems.

The analysis also confirmed that BPA plays a role in diabetes and some forms of liver disease, said Melzer's team, who studied data on 1,493 people aged 18 to 74.

"Our latest analysis largely confirms the first analysis, and excludes the possibility that the original report was a statistical blip," they said in a statement.

BPA, used to stiffen plastic bottles and line cans, belongs to a class of compounds sometimes called endocrine disruptors.

The U.S. Endocrine Society called last June for better studies into BPA and presented research showing the chemical can affect the hearts of women and permanently damage the DNA of mice.

"The risks associated with exposure to BPA may be small, but they are relevant to very large numbers of people. This information is important since it provides a great opportunity for intervention to reduce the risks," said Exeter's Tamara Galloway, who worked on the study published by the Public Library of Science online science journal PLoS One.

Urging bans

U.S. environmental health advocacy groups are urging a federal ban on BPA.

"There's enough research to take definitive action on this chemical to reduce exposures in people and the environment," Dr. Anila Jacob of the Environmental Working Group, a non-profit organization, said in a telephone interview.

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The U.S. Food and Drug Administration is considering whether any action needs to be taken.

U.S. government toxicologists at the National Institutes of Health concluded in 2008 that BPA presents concern for harmful effects on development of the prostate and brain and for behavioral changes in fetuses, infants and children.

Canada's government plans to outlaw plastic baby bottles made with BPA. The charity Breast Cancer UK last month urged the British government to do the same because they said there was "compelling" evidence linking the chemical to breast cancer risk.

Experts estimate BPA is detectable in the bodies of more than 90 percent of U.S. and European populations. It is one of the world's highest production volume chemicals, with more than 2.2 million tonnes produced annually.

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FDA says it's unable to regulate BPA

As 'indirect food additive,' substance is exempt from scrutiny

By [Meg Kissinger](#) of the Journal Sentinel

Posted: Jan. 17, 2010

U.S. Food and Drug Administration officials say they are powerless to regulate BPA, although they have declared the chemical to be a safety concern for fetuses, babies and young children.

A quirk in the rules allows BPA makers to skirt federal regulation.

"We may have to go after legislation to change it," Joshua Sharfstein, the FDA's principal deputy director, told the Journal Sentinel. The newspaper has been investigating the government's lack of regulation regarding BPA for three years.

FDA officials announced Friday that they had reversed their position that bisphenol A is safe. The chemical, used to line most food and beverage cans, has been found in the urine of 93% of Americans tested.

The agency now considers BPA to be of some concern for effects on the brain, behavior and prostate glands of fetuses and the very young. Scientific studies have raised concerns about the chemical's link to breast and prostate cancer, diabetes, obesity, heart disease, reproductive failures and behavioral problems.

The FDA did not ban the chemical, although top scientists, including Linda Birnbaum, director of the National Toxicology Program, say they consider the safety of BPA to be uncertain. An agency source says some from within the FDA wanted to follow Canada's lead and ban it from baby bottles - or from the lining of infant formula cans - but administration officials have resisted, concerned that babies who rely on bottled formula would be left without healthy alternatives.

"They couldn't take it off the shelves when there aren't substitutes in place," said the source, who asked not to be identified because the issue is so politically charged in the agency.

FDA officials - including Sharfstein; Lynn Goldmann, a consultant to the FDA; and Jesse Goodman, the FDA's acting chief scientist - told the Journal Sentinel they were frustrated by the antiquated framework of the FDA's regulatory process.

Officials say they would like chemical manufacturers to report information about the chemical to them, including how much BPA they produce and where and how it is used.

But because BPA was classified years ago as an indirect food additive, it is not subject to the kind of scrutiny that other chemicals are. Without critical data about BPA, it is impossible to regulate the chemical, officials said.

BPA, first manufactured in 1891, was later developed as a plasticizer in the early 1960s. It was classified in 1963 as an indirect food additive and is listed among some 3,000 chemicals that are "generally regarded as safe." That designation exempts them from scrutiny.

According to the FDA's regulations, a substance that is granted that status is not subject to FDA review.

So, while the agency can broadcast its opinion that the chemical is not safe, it can't compel companies to provide certain information about the chemical.

Given concern about BPA, and the ongoing evaluation and studies on its safety, the FDA thinks that the more modern framework is more robust and appropriate for oversight of BPA, agency officials say.

The FDA candidly explains the limitations on its Web site:

Current BPA food contact uses were approved under food additive regulations issued more than 40 years ago. This regulatory structure limits the oversight and flexibility of FDA.

Once a food additive is approved, any manufacturer of food or food packaging may use the food additive in accordance with the regulation. There is no requirement to notify FDA of that use.

For example, today there exist hundreds of different formulations for BPA-containing epoxy linings, which have varying characteristics. As currently regulated, manufacturers are not required to disclose to FDA the existence or nature of these formulations.

Furthermore, if FDA were to decide to revoke one or more approved uses, FDA would need to undertake what could be a lengthy process of rulemaking to accomplish this goal.

Changes needed

FDA Administrator Margaret Hamburg said the agency needs to overhaul its regulatory framework because the structure limits its ability to monitor BPA production.

"We need to be more nimble," she said.

Sharfstein, the deputy director, said the agency can try to get the companies to volunteer the information but might have to get a change in the law.

The FDA's admission of its inability to regulate the chemical should give muscle to legislative efforts for a ban, said Jon Peterson Myers, chief scientist for Environmental Health Sciences, who has advocated for a BPA ban.

"Industry always uses the argument that the chemical is regulated," Myers said. "This shows that it is not. State and federal lawmakers need to consider that. They can't rely on this agency to regulate it if

they don't have the tools to do so."

Minnesota, Connecticut, the City of Chicago and two counties in New York have banned BPA in baby bottles. Other measures are being considered in 30 states and municipalities. A federal ban on BPA in all food contact has been proposed in Congress.

The Journal Sentinel obtained e-mails through the Freedom of Information Act that showed how the agency's look at BPA had been influenced by BPA makers.

The newspaper found that industry scientists wrote sections of the FDA's earlier draft declaring the chemical to be safe for all uses. It later obtained e-mails that showed industry lobbyists were given priority treatment in scrutinizing studies and that FDA regulators looked to them for advice on how to deal with the media.

The newspaper also uncovered documents that showed how BPA makers borrowed the same tactics and some of the same people as the tobacco industry to downplay the health risks of their products. In a meeting held in Washington, D.C., last May, food packaging executives mapped out a public relations strategy that included finding a pregnant woman to serve as a spokeswoman for the benefits of BPA. Notes referred to such a person as "the holy grail."

Last year, more than 6 billion pounds of BPA was made, representing nearly \$7 billion in sales. U.S. companies that make BPA are Bayer Material Science; Dow Chemical Co.; SABIC Innovative Plastics (formerly GE Plastics); Hexion Specialty Chemicals; and Sunoco Chemicals.

Company officials have evaded questions about their product. Rep. John D. Dingell (D-Mich.) has written letters to BPA makers demanding information about their production levels but has gotten no reply.

"They absolutely stonewalled them, just like they stonewall anyone who wants information," said Fred vom Saal, a University of Missouri scientist who has advocated a ban of BPA. Vom Saal has debated against industry lobbyists at government hearings.

Chemical industry scientists maintain that BPA is safe. The American Chemistry Council, the lobby group for the chemical industry, issued a statement Friday saying that BPA is an important ingredient in preserving the integrity of food and drink.

The Obama administration committed \$30 million to studies of BPA. The FDA's Sharfstein said the data is expected to be collected in the next 18 months to two years.

While the FDA considers how to deal with BPA makers, the market is moving away from using BPA in baby products. Last year, the six major baby bottle makers announced they would stop using the chemical in their products.

Susanne Rust, a former Journal Sentinel reporter involved in the paper's BPA investigation and now a freelance writer, contributed to this report.

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Breaking news: New independent study by EPA refutes BPA risk

Trevor Butterworth, October 30, 2009

A major independently-funded study by the EPA fails to find evidence of low dose effects from Bisphenol A. The case against Bisphenol A (BPA), a chemical used to prevent food contamination in canned goods, has just gotten a whole lot weaker. Environmental activists and a small number of scientists have long protested that small amounts of BPA ingested through food and drink are the biological equivalent of global warming or akin to giving a baby a contraceptive pill. Activists have charged that risk assessments by the Food and Drug Administration and other agencies have relied exclusively on flawed industry-funded studies to cover up the risk to the public, while "independent" studies have demonstrated these risks.

But regulatory agencies around the world have rejected many of these independent studies, noting that they are either methodologically flawed or irrelevant for the purposes of assessing risks in humans. Multigenerational studies with large samples, high statistical rigor, and strong experimental design have failed to confirm any risk, and these studies have been either independent, or funded by industry but designed and supervised by independent scientists (such as those employed by the European Union).

Now, a second independent study by the Environmental Protection Agency, published in the leading toxicological journal, *Toxicological Sciences*, has failed to find evidence of the low-dose hypothesis claimed by environmental activists and widely reported in the media.

In the study, "In Utero and Lactational Exposure to Bisphenol A, in contrast to Ethinyl Estradiol, Does not Alter Sexually Dimorphic Behavior, Puberty, Fertility and Anatomy of Female LE Rats" (Ryan et al) researchers fed one group of pregnant rats a range of doses of BPA and another group a range of doses of the synthetic estrogen used in birth control pills ethinyl estradiol.

The choice of the Long Evans Hooded rat was significant, since activists have claimed the findings of a previous multigenerational study using the Sprague Dawley rat (Tyl et al, 2003) were invalid due to the breed being insensitive to estrogens. As Newsweek put it in claiming that the activists were correct,

"...[R]esearch in 2002 used a strain of rat that is extremely insensitive to estrogen; it doesn't even show hormonal effects if it's given 100 times the dose of estrogen in human birth-control pills. Since BPA acts like an estrogen, finding no effect in this insensitive rat is about as illuminating as not finding an effect of rain on a waterproof watch. That doesn't tell you that water can't harm machinery."

The Center for Evaluation of Risks to Human Reproduction disagreed, noting that

"In no case has it been demonstrated that the SD strain is completely insensitive to any known estrogen. It is evident that different traits map to different chromosomes and the degree of estrogen sensitivity varies from tissue to tissue, likely depending on the tissue-specific gene regulated by ER on the chromosome. Therefore, one cannot conclude that the SD is insensitive to estrogens and the results of BPA studies with BPA should be ignored."

The new paper bypasses this firefight. The LE Rats demonstrated significant sensitivity to estradiol and the researchers report reduced body weights, genital malformations and defeminization in pups whose mothers were gavaged (fed by tube) with the hormone.

The pregnant rats gavaged with BPA showed no effects.

Just as significant, the researchers looked at behaviors controlled by estrogens – a topic of “some concern” for the National Toxicology Program based on several papers with limited data. Again, the researchers found that estradiol produced clear effects but BPA did not.

This new study builds on research by the EPA’s Kembra Howdeshell, which found that lactational and gestational exposure to both estradiol and BPA over a broad range of orally-administered low dose endpoints in rats only produces effects for estradiol.

Undoubtedly, the activists and journalists who have subscribed to the view that BPA is deadly and that anyone who says it isn’t is shilling for industry will protest that estradiol shouldn’t be used as a control. As Newsweek once again argued in claiming that the activists on BPA had the better science,

“...Estradiol had never been used to provide such a baseline, so concluding that BPA is less potent than estradiol—as industry does—is like saying one temperature is higher than another when you don’t even know if the thermometer works.”

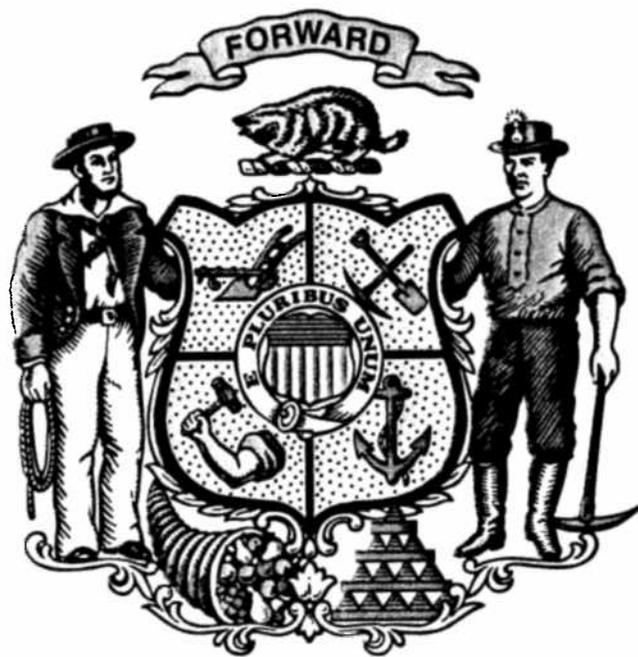
In fact, estradiol has been used as a baseline in studying chemicals with estrogen-like activities since 1998 (Biegel et al.). It was used in Howdeshell (2007) and multiple studies by Tyl et al on BPA. If Newsweek’s claim was correct, it’s hard to see how any of these studies would pass peer-review, let alone form the basis for risk assessment all over the world.

The new study adds a growing body of evidence that BPA is safe. Since the European Union’s risk assessment in 2006, there has been a review by Japan’s National Institute of Advanced Industrial Science and Technology (2007), an examination of claims of neurotoxicity by the Norwegian Scientific Committee for Food Safety, (2008), an update to the European Union’s risk assessment (2008), an evaluation by the French Food Safety Agency (2008), a risk assessment by NSF International, a World Health Organization collaborative center (2008), a review of new data by the German Federal Institute for Risk Assessment (2008), a joint regulatory review for manufacturers by the FDA and Health Canada, a survey by Health Canada (2009), a risk assessment by Food Standards Australia/New Zealand (2009), two more surveys by Health Canada, one on canned powdered infant formula, the second on bottled water products (2009), a hazard assessment by California’s Environmental Protection Agency (2009), and a modeling study of BPA in humans by the German Federal Institute for Risk Assessment (2009).

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Minnesota Session Laws

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Key: (1) ~~language to be deleted~~ (2) new language

2009, Regular Session

CHAPTER 40--S.F.No. 247

An act

relating to public health; protecting the health of children; prohibiting bisphenol-A in products for young children; proposing coding for new law in Minnesota Statutes, chapter 325F.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. ~~[325F.172]~~ **DEFINITIONS.**

Subdivision 1. **Scope.** For the purposes of sections 325F.172 to 325F.173, the following terms have the meanings given them.

Subd. 2. **Child.** "Child" means a person under three years of age.

Subd. 3. **Children's product.** "Children's product" means an empty bottle or cup to be filled with food or liquid that is designed or intended by a manufacturer to be used by a child.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 2. ~~[325F.173]~~ **BISPHENOL-A IN CERTAIN CHILDREN'S PRODUCTS.**

(a) By January 1, 2010, no manufacturer or wholesaler may sell or offer for sale in this state a children's product that contains bisphenol-A.

(b) This section does not apply to sale of a used children's product.

(c) By January 1, 2011, no retailer may sell or offer for sale in this state a children's product that contains bisphenol-A.

EFFECTIVE DATE. This section is effective the day following final enactment.

Presented to the governor May 5, 2009

Signed by the governor May 7, 2009, 4:39 p.m.



BISPHENOL A OVERVIEW

Bisphenol A is one of the most extensively tested of all substances and has been used safely for more than 50 years. It is used to make tough, shatter-resistant polycarbonate plastic and versatile epoxy resins, both of which are used in a wide array of consumer products that we value and use every day.

How It Is Used:

- Polycarbonate plastic is a key component of many vital medical devices. Among others, **incubators, kidney dialyzers, heart-lung machines, and infusion units** all contain polycarbonate components. It offers the unique characteristics of rigidity, strength and heat-resistance, which allow the components to be sterilized and used repeatedly without damage, while its transparency is critical to detecting life-threatening air bubbles.
- **Corrective eyeglass lenses as well as visors and safety goggles** protect the eyes with virtually unbreakable polycarbonate. Likewise, **sports safety equipment such as bicycle helmets** protects children from injury while being lightweight and comfortable to wear.
- Polycarbonate plastic is used for many products that keep food safe, fresh, and readily available for children and adults alike. For instance, **reusable baby bottles, food-storage containers, and tableware** made with polycarbonate are durable, shatter-resistant and heat-resistant.

In addition, most **metal food and beverage containers** have a thin coating of an epoxy resin to prevent the can from corroding, becoming contaminated with bacteria and spoiling the food.

- Many **dental sealants and composites**, which protect children's teeth from decay and help maintain dental health, are based on components derived from bisphenol A.

Why It Is Safe for Use:

The scientific evidence supporting the safety of bisphenol A has been comprehensively examined by many government and scientific bodies worldwide in recent years. These assessments support the conclusion that **bisphenol A is not a risk to human health** at the extremely low levels to which people might be exposed from use of products made from polycarbonate plastic or epoxy resins. Based on these scientific evaluations, **bisphenol A is not banned or restricted anywhere in the world.**

Key examples of the most recent assessments include:

- **US Food and Drug Administration (FDA)** – In August 2008, FDA released a draft safety assessment of bisphenol A in food-contact products (e.g., baby bottles, water bottles, food containers). The assessment was conducted by a cross-agency task force of FDA scientists and comprehensively included data and information from recent government reviews of bisphenol A (see below), as well as from non-governmental sources and the scientific literature. Overall, FDA concluded: *“an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults.”*

In late October, FDA's board of scientific advisors provided their recommendations to FDA from a scientific peer-review of the draft assessment. In response, FDA has outlined additional research and data gathering they will undertake to address the recommendations and has also stated: *“[c]onsumers should know that, based on all available evidence, the present consensus among regulatory*

agencies in the United States, Canada, Europe, and Japan is that current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and babies.”

- **US National Toxicology Program (NTP)** – A final report from NTP on the potential for bisphenol A to affect human reproduction or development, released in September 2008 found no direct evidence for health effects in people and confirmed that human exposure to bisphenol A is very low.

On a standard five-level scale ranging from ‘serious concern’ to ‘negligible concern,’ NTP reported no concerns for any age group at the top two levels and only negligible concern for adults. Based on what NTP characterized as limited and inconclusive evidence from laboratory animal studies, NTP expressed ‘some concern’ regarding effects on the brain, behavior, and the prostate gland but noted that additional research is needed to better understand whether these findings are of any human health significance. The NTP report, while not a safety assessment, was designed to serve as a resource to regulatory agencies such as FDA and was specifically considered in FDA’s safety assessment.

- **European Food Safety Authority (EFSA)** - In January 2007, EFSA released a comprehensive scientific assessment of BPA that was conducted by a panel of independent scientific experts from throughout the European Union. Based on its review of the most recent scientific information, the panel increased by a factor of five the safe intake level for BPA that was established in 2002. The increase in the Tolerable Daily Intake level (TDI) was based on the panel’s view that there is now more certainty about the safety of BPA.

Two updates were released by EFSA in July and October 2008 to further address recent scientific questions. Both updates reaffirm the safety of common consumer products such as baby bottles, water bottles and food containers. Overall, EFSA stated that the previously established safe intake level “*provides a sufficient margin of safety for the protection of the consumer, including fetuses and newborns.*”

In addition, the **French Food Safety Authority (AFSSA, Nov. 13)**, the **Danish Environmental Protection Agency (Oct. 30)**, and the **German Federal Institute for Risk Assessment (BfR, Sept. 19)** have all re-evaluated bisphenol A in light of recent studies and government decisions; **all have concluded that bisphenol A in food contact applications does not create a risk to human health.**

- **European Union (EU)** – In June 2008, the European Commission published a comprehensive update of its risk assessment on bisphenol A. The update confirmed that products made from polycarbonate plastic and epoxy resins are safe for consumers and the environment in current applications. The 2008 update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment process undertaken on BPA over 10 years. Based on this report, no bans or restrictions have been proposed.
- **Health Canada** – In October 2008, the Canadian government announced the conclusion of its screening risk assessment stating: “*The current research tells us the general public need not be concerned. In general, most Canadians are exposed to very low levels of bisphenol A, therefore, it does not pose a health risk.*”

With respect to infants under 18 months, it said “*Science tells us that exposure levels are below those that could cause health effects; however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children.*” Health Canada announced a

voluntary action to achieve the lowest possible levels of bisphenol A in infant formula. Under consideration is a ban of polycarbonate baby bottles, but no action has yet been taken. The proposed ban is limited to baby bottles and, in regard to polycarbonate bottles, tableware and food containers, Health Canada has stated: "*you should not be concerned about using these products.*"

- **Food Standards Australia New Zealand (FSANZ)** – An updated statement from FSANZ regarding the safety of bisphenol A in food packaging, released in March 2009, stated "*FSANZ has assessed the risk to infants from exposure to BPA and concurred with the conclusions reached by the US FDA and the EFSA that the levels of exposure are very low and do not pose a significant health risk.*"
- **Japanese National Institute of Advanced Industrial Science and Technology (NIAIST)** – A comprehensive report published in November 2005 by NIAIST (affiliated with the Japanese Ministry of Economy, Trade and Industry) confirmed no risk of bisphenol A to human health, including infants and children, and noted that no bans or restrictions are needed.

Also in 2005, the **Japanese Ministry of Environment** concluded, based on their own comprehensive testing, that there were no clear endocrine disrupting effects found at low doses and that no regulatory action is required to manage risks.

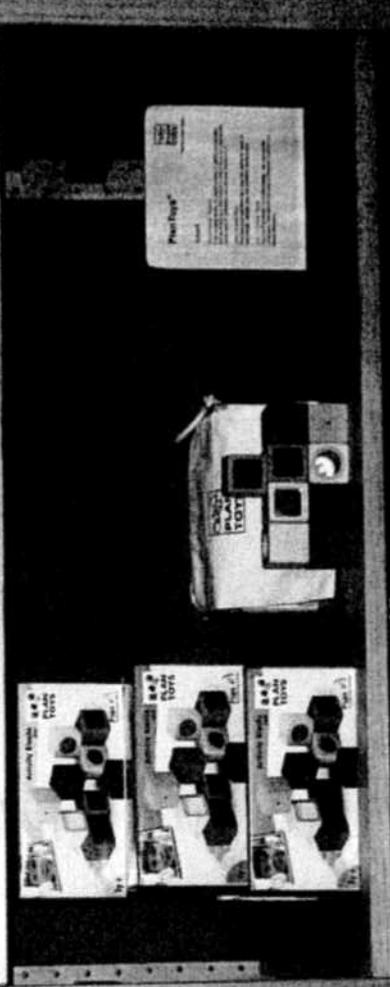
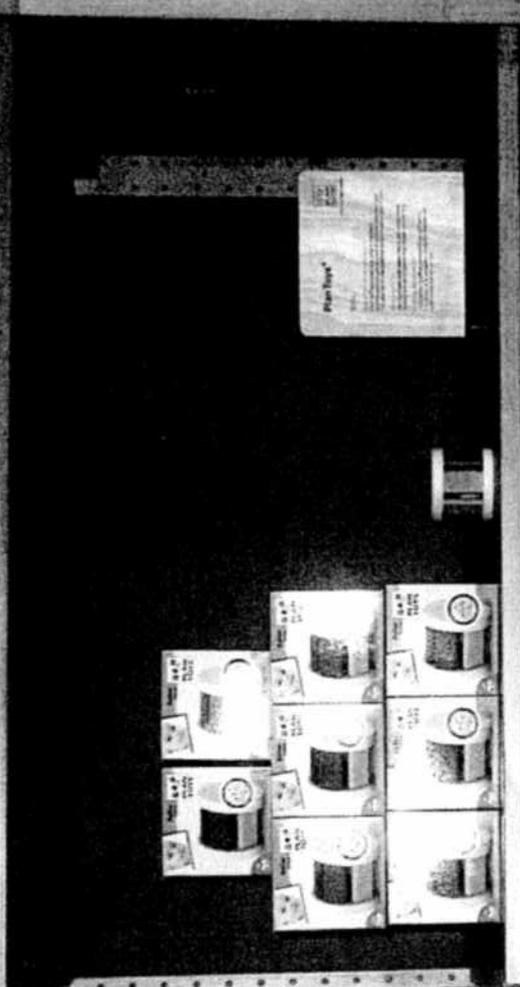
- In October 2008, an **expert scientific panel** published the results of their weight-of-the-evidence evaluation of low-dose reproductive and developmental effects of bisphenol A. This evaluation is the third in a series that began with an evaluation, published in 2004, by an independent panel of scientific experts organized by the Harvard Center for Risk Analysis. Based on their review of scientific literature available through July 2008, the panel concluded: "*The weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health.*"
- In February 2008, **NSF International** (a not-for-profit public health and safety organization) published their comprehensive safety assessment of bisphenol A and established a safe intake level for bisphenol A in drinking water. The level for drinking water is comparable to the level established by the European Food Safety Authority for bisphenol A in food. The assessment was led by Dr. Calvin Willhite, a respected scientist with the California Department of Toxic Substances Control.

In light of the frequency, consistency, and timeliness of government assessments of bisphenol A, it is apparent that there is no need for additional legislation or regulation for bisphenol A. **Existing regulatory processes are adequate to protect human health**, including children's health, and have proven to be functional and timely.

For more information on bisphenol A, please contact:

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Polycarbonate/BPA Global Group
American Chemistry Council
phone: (703) 741-5588
e-mail: steve_hentges@americanchemistry.com
<http://www.bisphenol-A.org>











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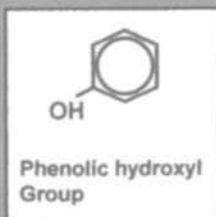
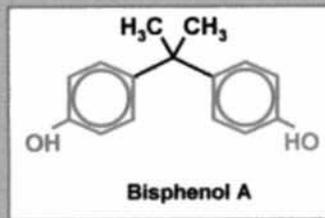
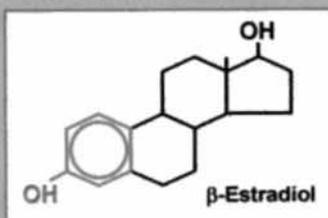
Gail S. Prins, PhD

Professor of Physiology
Department of Urology, College of Medicine
University of Illinois at Chicago

- Expertise in endocrinology, prostate gland and prostate cancer.
- Since 1989, continuous funding by NIH to study effects of early life exposures to estrogens on the prostate gland.
- Currently, Principal Investigator on two NIH grants (totaling 4 million dollars) to study how BPA increases prostate cancer susceptibility in rodent and human models.
- Published > 150 scientific manuscripts.
- Positions held:
 - *President*, American Society of Andrology (2003)
 - *Executive Council*, Prostate Cancer Research Program, Department of Defense (2000-2008)
 - National Toxicology Panel (NTP) Endocrine Disruptors Low-Dose Peer Review Panel, 2001 – *BPA Panel, rapporteur*
 - NIH-EPA Bisphenol A Expert Panel (2007), *BPA and Cancer, chair*

Environmental Endocrine Disruptors

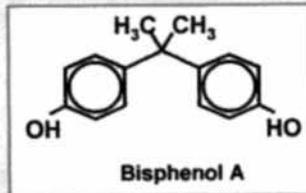
What makes BPA estrogenic?



Sources for BPA

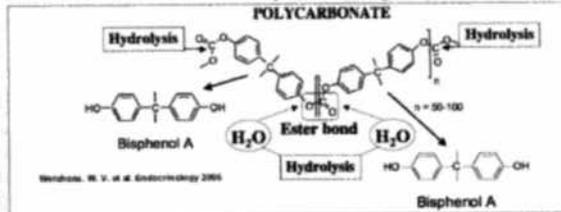


1 Polycarbonate plastic bottles



2 Dental sealings

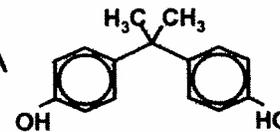
BPA monomers released upon heating, repeated washings



3 Epoxy resins: Tin can linings

Human Exposures and Levels of BPA

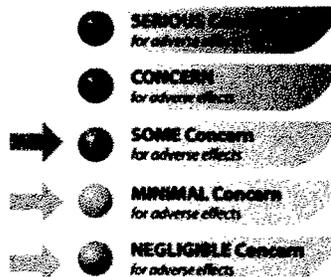
BPA Expert Panel Consensus Statement
NIEHS/EPA, November 2006



- Most humans are chronically exposed.
 - 95% human urines BPA+ (CDC assay)
- Rapidly metabolized by liver in adults, but much less in fetus and newborns.
- *Unconjugated* BPA in human serum is in the 0.3 to 5 ng/ml range.
- Present in breast milk, amniotic fluid, fetal serum, placental and fetal tissue.
- Indicates that the developing *human fetus and newborns* are chronically exposed to BPA:
0.7-9.2 ng/ml range (*unconjugated* BPA).

National Toxicology Program Report on BPA: 2008:

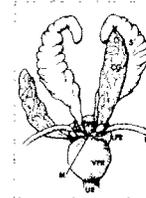
<http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.html>



Conclusions:

1. **Some concern** for neural and behavioral effects of BPA in fetuses, infants and children at current human exposures.
2. **Some concern** for BPA exposure in fetuses, infants and children at current human exposures based on effects *in the prostate gland*.
3. **Minimal concern** for BPA exposure in same cohort based on effects in the mammary gland and early puberty in females.

Developmental Exposure to Bisphenol A: Long-term effects on prostate health



predicted serum *unconjugated* BPA: ~ 0.5 – 2ng/ml

Ho, Wang, Belmonte and Prins, *Cancer Research* 66:5624, 2006

