LATE

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In reply, please refer to:
File:

COMMITTEE ON HEALTH

HB1633, Relating to Toxic Products

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

February 17, 2009

Department's Position: Given the current state of the law, science, and fiscal difficulties, the Department thinks it would not be prudent to pursue enactment now. We do appreciate the intent of the measure.

Fiscal Implications: An unknown number of staff would be required to investigate the chemical content of toys and child care articles, and to exercise the legislatively-granted authority to stop the sale and distribution of the appropriate toys and child care articles.

Purpose and Justification: HB1633 seeks to prohibit the manufacture, sale, and distribution in Hawaii of plastic toys and child-care articles containing phthalates and bisphenol-A (BPA).

The part of HB 1633 pertaining to phthalates has been superseded by a Federal law and is unnecessary. Effective February 10, 2009, the Consumer Product Safety Improvement Act of 2008 bans the sale of children's products containing phthalates, a class of chemicals used to make plastics soft and pliable. Congress passed the bill in July 2008, and President Bush signed it into law on August 14, 2008.

As for BPA, HB 1633 also seeks to prohibit the manufacture, sale, and distribution in Hawaii of any toy or child care article that is intended for use by a child under three years of age and contains

bisphenol-A (BPA). However, BPA exposure from toys is only the tip of the iceberg. A far greater children's exposure to BPA comes from the inner plastic lining of food cans and from polycarbonate plastic food and water containers that have a triangle on the bottom with the number 7 in it. To prevent total exposure to BPA in children under age 3, the Department and other state agencies would have to stop the sale and distribution of polycarbonate plastic articles and all cans of food, which would severely affect Hawaii's food supply.

At the present time, the U.S. Food and Drug Administration (FDA) states that there is no definitive evidence indicating that exposure to small quantities of BPA will cause negative health effects. HB 1633 would require state government agencies to control certain consumer products where Federal government agencies do not. Health Canada has recently taken steps to reduce the exposure of infants and young children to BPA as a precaution, even though Canada thinks that current dietary exposure to BPA is not expected to pose a health risk to the general population, including newborns and infants. A key issue in the approach to allegedly hazardous substances is the burden of proof. The precautionary principle places a burden of proving safety on the proponent of a product; American law traditionally places a burden of proving harm on the government, though drug law is an exception. Unless and until the legal framework is changed, the Department will continue to monitor the FDA's research into the potential low dose effects of BPA.

Thank you for the opportunity to testify on this matter.

LATE

February 16, 2009

Committee on Health
Representative Ryan I. Yamane, Chair
Representative Scott Y. Nishimoto, Vice Chair

Hearing:
8:30 A.M., Thursday, February 17, 2009
Hawaii State Capitol, Room 329

RE: HB1633, Relating to Toxic Products

COMMENTS

Chair Yamane, Vice Chair Nishimoto, and members of the Committee on Health. My name is George Massengale and I am the Director of Government Relations for the American Cancer Society Hawaii Pacific Inc. Thank you for the opportunity to offer comments on HB1633, which would prohibit the manufacture, sale, or distribution of products for young children that contain bisphenol-A or phthalates. The bill would also require manufactures to choose safe alternatives.

The American Cancer Society Hawaii Pacific Inc., was founded in 1948, and is a community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy, and service. This mission includes advocating for laws that eliminate exposure to cancer causing toxic products.

Products containing or made from bisphenol-A have been in commerce for more than 50 years, and its current uses are numerous.

Bisphenol-A (BPA) is one of the most pervasive chemicals in modern life. More than 2 billion pounds of BPA are produced in the United States each year, and several times that amount is produced globally. BPA is the building block of polycarbonate plastic and is also used in the manufacture of epoxy resins. Significant levels of BPA have been measured in ambient air, house dust and river and drinking water.

BPA is commonly found in the lacquer lining of metal food cans and in some types of plastic food containers, including some baby bottles, water bottles, microwave ovenware and eating utensils. Because BPA is an unstable polymer and is also lipophilic (fat-seeking), it can leach into infant formula and other food products, especially when heated. Once in food, BPA can move quickly into people – a particular concern for women of childbearing age and young children. BPA has been found in blood samples from developing fetuses as well as the surrounding amniotic fluid, and it has been measured in placental tissue and in umbilical cord blood at birth. CDC researchers also found BPA in 95 percent of about 400 urine samples from a broad national sample of adults.

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Recent studies strongly suggest that exposure of the fetus to excess estrogen is believed to increase the risk of developing breast cancer during adult life. Another study recently published by the University of Cincinnati has found that BPA may actually be endangering human health in a whole new way, by protecting cancer cells from the effects of chemotherapy.

The Society position is that additional studies should be conducted to confirm a link between PBA's and specific cancers, as well as chemoresistance.

Mahalo for giving me the opportunity to provide comments on this measure. Please do not hesitate to contact me directly if you require any additional information.

Sincerely,

George Massengale, JD
Director of Government Relations

LATE

February 17, 2009

TO: Members, House Committee on Health

FROM: Tim Shestek
American Chemistry Council

RE: **HB 1633 - OPPOSE**

The American Chemistry Council (ACC) must respectfully oppose HB 1633, legislation that would prohibit the use of bisphenol-A (BPA) and "phthalates" in a wide variety of products. By way of background, BPA is used to make polycarbonate plastic and epoxy resins and can be found in such products as reusable sports bottles, food and drink containers, baby bottles, and sippy cups which are strong, shatter-resistant and approved by the FDA as safe for food contact applications. Phthalates are essentially used to make vinyl soft and pliable.

BISPHENOL-A

The scientific evidence supporting the safety of bisphenol A has been comprehensively examined by many government and scientific bodies worldwide in recent years. These bodies have reached conclusions that consistently support the continued safe use of BPA in its current applications. In fact, FDA has been reviewing emerging literature on BPA on a continuous basis for years, and FDA experts believe there is a large body of evidence indicating that FDA-regulated products containing BPA are safe. FDA concludes that current exposure levels to BPA from food contact materials, including for infants and children, are below those that may cause health effects.

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.***"

  On January 29, 2009 in a statement regarding a regulatory meeting with manufacturers and users of BPA, FDA stated in part "based on all available evidence, the consensus of regulatory agencies in the United States, Canada, Europe, and Japan is that the current levels of exposure

to BPA through food packaging do not pose an immediate health risk to the general population, including infants and young children." (Statement Attached).

- **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 foetuses 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***."

- **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.

Shouldn't New Mexico Take A Precautionary Approach to Protecting Kids?

Of course, and an abundance of precaution is already factored into the existing regulatory programs governing food safety. Consider that most studies consistently show that the potential migration of BPA into food is extremely low, generally less than 5 parts per billion under conditions typical for uses of polycarbonate products. At this level, a consumer would have to ingest more than 1,300 pounds of food and beverages in contact with polycarbonate every day for an entire lifetime to exceed the safe level of BPA set by the U.S. Environmental Protection Agency.

According to data from Health Canada, **a 22 lbs infant would have to drink 423 4 oz. bottles per day to reach the European Food Safety Authority's recently set "safe" intake level of BPA. That "safe" intake level already includes a 100-fold safety factor beyond the no-effect** level determined in studies on laboratory animals. These safety factors are a clear indication that "precautionary measures" are a key element of the existing safety assessment process.

PHTHALATES

In August, 2008, The Consumer Product Safety Improvement Act of 2008 (CPSIA), (H.R. 4040) was signed into law. The CPSIA is a very broad overhaul of the Consumer Product Safety Act, and it responds, in part, to public concerns about imported toys containing lead. Among the CPSIA's provisions are restrictions on six phthalates in toys and children's products. These restrictions will become effective February 10, 2009. The new federal law preempts state laws that impose similar restrictions on phthalates. (See Consumer Product Safety Commission website at http://www.cpsc.gov/about/cpsia/summaries/231brief.html).

The phthalate restrictions of the CPSIA apply to certain specified phthalates in particular products:

- DEHP, DBP, and BBP: there are permanent restrictions on the sale of children's toys and child care articles with concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). The permanent restriction is effective February 10, 2009.

- DINP, DIDP, and DnOP: there are temporary (interim) restrictions on the sale of children's toys that can be placed in a child's mouth and child care articles that contain more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). Toys that can be put in the mouth are defined to include toys or parts smaller than five centimeters in dimension. Toys that cannot be put in the mouth but can be licked are not included. The interim restriction is effective February 10, 2009.

For the three "interim restriction" phthalates, the interim ban will be in place until a final rule is issued based on a scientific study conducted by a Chronic Hazard Advisory Panel, or CHAP, convened by the Consumer Product Safety Commission. A previous CHAP that reviewed the safety of DINP concluded that "For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury."

The restrictions on toys apply to toys for children ages 12 and under, and the new law refers to CPSC's 2002 guidelines for additional age determination guidance. The restrictions on child care articles apply to products to facilitate sleep or feeding, or to help with sucking or teething, for children ages 3 and under.

Children's toys and other children's products will require a general conformity certification which certifies that, based on a test of each product or upon a "reasonable testing program," the toys and products comply with applicable standards. According to materials released by the CPSC on October 2, 2008, a general conformity certification will be required when the phthalate restrictions become effective February 10, 2009. (See CPSC's website, http://www.cpsc.gov/about/cpsia/conformity.pdf)

For the above listed reasons, ACC believes that restrictions on products containing BPA is not supported by the weight of the scientific evidence and state restrictions on specified children's products containing phthalates are preempted by federal law. For these reasons we urge a NO vote on HB 1633.

If you or your staff has any questions or comments, please contact me at 916-448-2581 or via email at tim_shestek@americanchemistry.com or contact Hawaii based representatives Red Morris or John Radcliffe at 808-531-4551.

FDA Statement
Regulatory Meeting with Manufacturers and Users of Bisphenol A-containing Materials

On Jan. 30, 2009, the U.S. Food and Drug Administration and Health Canada's Health Products and Food Branch hosted a meeting of representatives of U.S. and Canadian manufacturers and users of food packaging materials containing bisphenol A (BPA) to discuss what is being done to help minimize the levels of the chemical in food. The meeting was also part of FDA's efforts to assist industry in its voluntary BPA reduction efforts.

The meeting provided a forum for:

- Updating the industry on the FDA's and Health Canada's current activities and planned research to further assess the exposure to BPA and manage any potential risks from the chemical.

- Describing manufacturers' research activities, their work to refine packaging manufacturing practices to minimize migration of BPA into food, and recent marketplace developments.

- Dialogue by the participants about further information from regulated industry stakeholders that would be helpful to the FDA and Health Canada in updating and refining their BPA risk assessments.

- Dialogue about the different uses of BPA in food contact applications and the variation in availability of fully functional and evaluated alternative substances.

- Discussion of the expectation that, because of availability of alternative products, polycarbonate baby bottles could cease to be a substantial component of the North American market in the future.

With regard to BPA generally, based on all available evidence, the consensus of regulatory agencies in the United States, Canada, Europe, and Japan is that the current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and young children.

Health Canada's Health Products and Food Branch has concluded that current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and infants. However, using a precautionary approach, the Government of Canada has taken steps to reduce exposure to BPA for infants and young children.

The FDA is currently preparing a detailed response to the October 2008 review by the FDA Science Board of the agency's draft assessment of the safety of BPA for use in food contact applications. The draft assessment focused on the concerns for developmental toxicity identified in recent assessments of BPA, including those of the National

Toxicology Program and their expert panel. For example, the FDA is reviewing research about the potential low-dose effects of BPA and will carefully evaluate the findings of these studies.

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