SB640
TESTIMONY

WRITTEN TESTIMONY ONLY

NEIL ABERCROMBIE
GOVERNOR OF HAWAII

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In reply, please refer to:
File:

COMMITTEE ON HEALTH

S.B. 640, RELATING TO HEALTH

Testimony of Loretta J. Fuddy, A.C.S.W., M.P.H.
Director of Health

February 8, 2013
2:30 P.M.

Department's Position: The Department supports this measure.

Fiscal Implications: $34,000 annually (½ Environmental Health Specialist (EHS) III at $31,000 and $3,000 OCE/year to implement the toxics in packaging measure).

Purpose and Justification: This measure has three parts. Part I is infant and toddler safety, Part II is toxics in packaging, and Part III is procurement of polyvinyl chloride-free intravenous products.

Part I seeks to prohibit the manufacture, sale, and distribution in Hawaii of any toy or child care article for young children containing phthalates and bisphenol-A (BPA). We agree with this measure but recommend that the measure be expanded to ban the sale of reusable food and beverage containers intended for use by a child under three years of age that contain BPA.

The Department agrees with the need to protect young children from exposure to these persistent and potentially toxic compounds. In July 2012, the United States Food and Drug Administration (FDA) banned the use of BPA in infant feeding bottles and spill-proof cups. Previously, in 2008, the National Toxicology Program at the National Institutes of Health and the FDA in 2010 have expressed some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children. The American Medical Association recently developed a policy supporting

industry action to stop producing BPA containing baby bottles and infant feeding cups and supports a ban on the sale of such products.

We note that several other states have banned the sales of children's bottles, empty food containers and drinking cups that contain BPA. The Department suggests that Hawaii follow the lead of other states and ban the sale of reusable food and beverage containers intended for use by a child under three years of age that contain BPA.

With regard to phthalates, effective February 2009, the Consumer Product Safety Improvement Act of 2008 permanently bans the sale of children's toys or child care articles containing DEHP, DBP, and BBP and bans on an interim basis the three phthalates, DINP, DIDP, and DnOP, listed in this measure. This interim prohibition applies to child care articles or toys that can be placed in a child's mouth or brought to the mouth and kept in the mouth. The Department continues to support the ban on phthalates in children's toys or child care articles intended for young children.

Part II seeks to prohibit the sale or distribution of packaging containing intentionally added cadmium, lead, mercury and hexavalent chromium in excess of 100 parts per million by weight. This legislation will curb the amount of heavy metals entering the municipal solid waste stream and, ultimately, landfills and incinerators. Nineteen states have already enacted legislation for toxics in packaging. The DOH will work with the Toxics in Packaging Clearinghouse to implement this important measure.

Part III states that The Hawaii Health Systems Corporation shall not purchase or use any vinyl intravenous solution bags or vinyl tubing for use in any healthcare application. We will defer this part of the measure to the Corporation.

Thank you for the opportunity to present testimony on this measure.

February 6, 2013

To: The Honorable Josh Green, Chair
Members, Senate Committee on Health

From: Tim Shestek, Senior Director
State Affairs

Re: **SB 640 – OPPOSE**

The American Chemistry Council (ACC) must respectfully oppose **SB 640**, legislation that, among other things proposes to restrict certain chemical ingredients – specifically phthalates and Bisphenol-A (BPA) - that may be used in child care articles. Furthermore, the bill proposes to prohibit the Hawaii Health Systems Corporation from purchasing and using vinyl intravenous solution bags and tubing.

In short, ACC believes the legislation conflicts with federal law governing the use of phthalates and the proposed restriction on BPA containing products runs contrary to the consensus of the scientific community and international regulatory agencies that have concluded BPA is safe as used. ACC also believes the PVC prohibition would unnecessarily restrict the availability and use of certain health care devices that are already regulated by the US Food and Drug Administration (FDA).

PHTHALATES

In 2008, the federal government enacted the Consumer Product Safety Improvement Act (CPSIA), (H.R. 4040). 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 became effective February 10, 2009. The new law preempts state laws that impose similar restrictions on phthalates. http://cpsc.gov/Regulations-Laws--Standards/CPSIA/Phthalates/Phthalates-Information/

The 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 was 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). The interim restriction was effective February 10, 2009. "Child care articles" are defined as consumer products that are designed or intended by the manufacturer for a child who is 3 years old or younger, to facilitate sleeping or feeding, or to help a child who is sucking or teething.

As it relates to phthalates, SB 640 as drafted would be in direct conflict with Federal law.

BISPHENOL-A (BPA)

SB 640 also proposes to restrict the use of BPA in child care articles. The Committee may be interested to know that in July 2012, the U.S. Food and Drug Administration (FDA) amended the federal food additive regulations to no longer allow for the use of BPA containing polycarbonate plastic in products such as infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids. This action was taken because manufacturers are no longer using BPA containing materials to make these products.

The abandonment of these products by manufacturers however should not be interpreted to be an indication that BPA containing products are somehow harmful to human health. The scientific evidence supporting the safety of BPA has been comprehensively and recently examined by many government and scientific bodies worldwide. The weight of evidence consistently supports the safety of BPA containing products. Please consider the following:

Health Canada
In September 2012, Health Canada released an updated assessment of BPA. Experts 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 young children."

U.S. Food and Drug Administration (FDA)
In a March 2012 update, FDA stated that it has found "no convincing evidence" to support the belief that bisphenol A (BPA) is a hazard to people. As noted by FDA: "We make public health decisions based on a careful review of well performed studies, not based on claims or beliefs." Based on its objective review, FDA's assessment is that "the scientific evidence at this time does not suggest that the very low levels of human exposure to BPA through the diet are unsafe." To address remaining uncertainties about the safety of BPA, FDA is carrying out in depth studies with the National Toxicology Program. The studies published to date provide additional strong support for the safety of BPA in food-contact materials

Food Standards Australia New Zealand (FSANZ)
In April 2012, FSANZ, an independent statutory agency responsible for setting food standards in the two countries, reaffirmed the safety of BPA and stated: "The weight of scientific evidence indicates that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels."

European Food Safety Authority (EFSA)
In December 2011, EFSA updated their comprehensive scientific assessment of BPA that had been conducted by a panel of independent scientific experts from throughout the European Union. The update reaffirmed the panel's previous conclusion (September 2010) that they "could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake," which is a safe intake level.

World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO)
In September 2011, an international panel of experts organized by WHO and FAO released a report on their review of all the latest scientific evidence on BPA and concluded that "initiation of public health measures would be premature." The experts also concluded that BPA does not accumulate in the body, is rapidly eliminated in urine, and that it is difficult to interpret the relevance of studies claiming adverse health effects from BPA.

Japanese National Institute of Advanced Industrial Science and Technology (AIST)
In July 2011, AIST concluded that "the risk of BPA with regard to human health was believed to be very small." This conclusion is consistent with AIST's previous 2005 BPA risk assessment. Of note, in its 2011 assessment, the data uncertainty factor was reduced to 25 as compared to 100 in the previous assessment, indicating higher confidence in the scientific data supporting the 2011 conclusion.

Advisory Committee of the German Society for Toxicology

In its April 2011 review published in *Critical Reviews in Toxicology*, the Advisory Committee concluded, that "BPA exposure represents no noteworthy risk to the health of the human population, including newborns and babies." After reviewing all available evidence and controversial arguments, the Committee concluded that the "current Tolerable Daily Intake (TDI) level for BPA is adequately justified." In its specific evaluation of studies reporting that low doses of BPA cause adverse health effects in laboratory animals, the Committee found that these studies "failed to meet minimal quality criteria for experimental design and statistical analysis" and that their results were inconsistent with more robust studies on similar endpoints.

POLYVINYL CHLORIDE (PVC, Vinyl) INTRAVENOUS PRODUCTS PROHIBITION

For more than 50 years, PVCs performance and protectiveness have made it a critical material in such health care products and procedures as blood and intravenous bags, kidney dialysis and blood transfusions, cardiac catheters and endotracheal tubes. Vinyl has a number of characteristics that together make it uniquely suited to medical use:

- It is optically clearer than many alternatives.
- It is kink-resistant. Alternatives frequently kink when bent to angles of 90 degrees or more, which can cut off the flow of blood or vital fluids to a patient if left undetected for any length of time.
- It resists "necking down" – that is, constricting when pulled. Vinyl alternatives can neck down when inadvertently stretched, which can result in a changed inner tubing diameter that affects the fluid delivery rate.
- Medical kits made of vinyl are factory assembled using a technique known as solvent cementing, in which tubing is locked to its connectors and ports by a solvent that evaporates after application. Most PVC substitutes cannot be bonded this way. If joints yank loose and leaks occur, patients can be exposed to flow interruptions, and care givers can be exposed to potentially contagious body fluids.
- Vinyl medical products can also be steam-sterilized and frozen.
- Vinyl is compatible with virtually all pharmaceutical products in healthcare facilities and its relatively low cost helps healthcare facilities contain rising costs.

Policymakers should be aware that FDA officials and others have noted that efforts to replace vinyl in medical products with alternative materials must be carefully judged to ensure the alternatives are as safe, perform as well, are available, and meet other critical product requirements. Medical devices made from PVC plastic are regulated for safety by the FDA and ACC believes this agency is the most appropriate venue to regulate these and other medical type products.

For the above listed reasons, ACC urges you to oppose SB 640. Thank you in advance for considering our views. If you have any questions or comments, please do not hesitate to contact me or ACC's Hawai'i based representatives Red Morris and/or John Radcliffe at 808-531-4551.