TESTIMONY

SB2473

HTH Committee Hearing 2/08/2012

WRITTEN TESTIMONY ONLY

NEIL ABERCROMBIE
GOVERNOR OF HAWAII

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In reply, please refer to:
File:

SENATE COMMITTEE ON HEALTH/COMMERCE AND CONSUMER PROTECTION

S.B. 2473, RELATING TO HEALTH

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

Wednesday, February 8, 2012
2:45 pm

Department's Position: Support Part 1 restriction on the manufacture or distribution of packaging materials with regulated metals. Support Part II Infant and Toddler Safety with suggested amendment.

Fiscal Implications: ½ FTE and $13,000/year to implement the toxics in packaging measure.

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

Part I seeks to prohibit the sale or distribution of packaging containing intentionally added cadmium, lead, mercury and hexavalent chromium. 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 II 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 amended to ban the sale of reusable food and beverage containers

intended for use by a child under three years of age that contain BPA, instead of toys or child care articles.

The Department agrees with the need to protect young children from exposure to these persistent and potentially toxic compounds. The National Toxicology Program at the National Institutes of Health in 2008 and the Food and Drug Administration 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. Several large manufacturers have already stopped producing BPA containing baby bottles and infant feeding cups for the United States market.

DOH suggests an amendment to this measure that seeks to prohibit the manufacture, sale and distribution of toys or child care articles for young children containing BPA. In general, children's toys are made of plastics that are not made with BPA. BPA has been used for more than 40 years in the manufacture of many hard plastic food containers such as baby bottles and reusable cups and the lining of metal food and beverage cans, including canned liquid infant formula. Studies have found that BPA in plastics and other packaging materials can transfer to food and liquids, especially when the liquid is hot. Some states have banned BPA in children's bottles and drinking cups while others have expanded the ban to reusable food containers intended for use by young children. 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 III-The Hawaii health systems shall award contracts with a preference to intravenous products that do not contain polyvinyl chloride. We are currently researching this aspect of the measure with the department's procurement personnel as well as the State Procurement Office and have no definitive position at this time.

NEIL ABERCROMBIE
GOVERNOR

AARON S. FUJIOKA
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TESTIMONY
OF
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ADMINISTRATOR
STATE PROCUREMENT OFFICE

TO THE
SENATE COMMITTEES
ON
HEALTH
AND
COMMERCE AND CONSUMER PROTECTION

February 8, 2012

2:45 p.m.

SB 2473

RELATING TO HEALTH.

Chairs Green and Baker, Vice Chairs Nishihara and Taniguchi, and committee members, thank you for the opportunity to testify on SB 2473. The State Procurement Office (SPO) comments are limited to Section 4 of this bill that proposes to create a new section in HRS chapter 103D which requires the Hawaii Health Systems Corporation (HHSC) to "award contracts to the lowest responsible and responsive bidder, with preference being given to intravenous products that do not contain polyvinyl chloride."

Section 4 will have no effect, since Act 290, SLH 2007, gave the HHSC Regional Systems Boards and its hospitals autonomy from HRS chapter 103D, the procurement code. For the procurement code to be effective, the exemption from the procurement code for the Regional Systems Boards should be repealed (§103D-102(c)(1)).

Public procurement's primary objective is to provide everyone equal opportunity to compete for government contracts, to prevent favoritism, collusion or fraud in awarding of contracts. To legislate that any one entity should be exempt from compliance with HRS chapter 103D conveys a sense of disproportionate equality in the law's application.

Thank you.

American Chemistry Council

February 6, 2012

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

The Honorable Rosalyn Baker, Chair
Members, Hawaii Senate Committee on Commerce & Consumer Protection

From: Tim Shestek, Senior Director
State Affairs

Re: **SB 2473 – OPPOSE**

The American Chemistry Council (ACC) must respectfully oppose **SB 2473**, legislation that, among things, proposes to restrict certain chemical ingredients – specifically phthalates and Bisphenol-A (BPA) - that may be used in identified children's products. The bill would also direct the Hawaii Health Systems Corporation to give a contract bid preference to certain medical devices that do not contain polyvinyl chloride (PVC).

In short, ACC believes the legislation as drafted conflicts with federal law governing the use of phthalates; 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; and the proposed anti-PVC contract bid preference 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. *(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 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). 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 was 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)*

As it relates to phthalates, SB 2473 as drafted would be in direct conflict with Federal law.

BISPHENOL-A (BPA)

SB 2473 also proposes to restrict the use of BPA in children's products like baby bottles, sippy cups, and toys. The scientific evidence supporting the safety of BPA has been comprehensively examined by many government and scientific bodies worldwide in recent years who have consistently re-affirmed the safety of BPA containing products. I urge you to consider the following.

Recently, many domestic and international regulatory bodies have reviewed many scientific studies and information relative to BPA containing products. Listed below are excerpts from many of these organizations.

- **HEALTH CANADA: Survey of Bisphenol A in Canned Food Products from Canadian Markets (2010)**
  "The results of this survey confirm that exposure to BPA from canned food products is very low and poses no health or safety concerns to the general population."

- **HEALTH CANADA: Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature – Summary (2010)**
  "The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including newborns and infants."

- **FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ): Bisphenol A and food packaging (2010)**
  "FSANZ has evaluated the safety of BPA in food, including that consumed by infants and concluded that levels of intake of BPA are very low and do not pose a significant human health risk for any age group."

  FSANZ also points out that while some countries (e.g. Canada) have announced a precautionary ban on BPA containing baby bottles this "decision was taken even though the Canadian Government agreed with Health Canada's risk assessment that levels of BPA were safe in infant foods."

  FSANZ further notes that the voluntary phase out of BPA containing bottles in Australia "is in response to consumer preference and demand and not an issue about product safety."

  FSANZ responds to the question "Haven't some studies suggested health effects from BPA?"
  "BPA belongs to a group of substances that can act in a similar way to some hormones and, as such, are sometimes called 'endocrine disruptors'. Some studies in laboratory animals have suggested that low levels of BPA may have an effect on the reproductive system while other studies indicate no effect. However, similar

consequences in consumers at these low concentrations are considered unlikely because BPA is rapidly inactivated and then excreted in the urine in humans. BPA does not cause cancer."

- **GERMAN SOCIETY OF TOXICOLOGY: Critical evaluation of key evidence on the human health hazards of exposure to bisphenol A (2011)**
  A comprehensive review by the German Society of Toxicology published in April, 2011 concluded "BPA exposure represents no noteworthy risk to the health of the human population, including newborns and babies."

- **EUROPEAN FOOD SAFETY AUTHORITY (2010)**
  Scientists with the European Food Safety Authority (EFSA) reviewed more than 800 new studies on BPA and concluded they "could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake," which is a safe intake level.

- **US FOOD AND DRUG ADMINISTRATION (2010)**
  FDA has not – either under the Bush or Obama Administrations – taken any restrictive regulatory action to prohibit the use of BPA. While FDA has expressed "some concern" about the potential effects of BPA it has not taken any regulatory action.

  *When asked if the FDA thought BPA was unsafe, FDA responded **"If we thought it was unsafe, we would be taking strong regulatory action."** In cooperation with the National Toxicology Program, FDA's National Center for Toxicological Research is currently carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA. To date, FDA researchers have published seven of these studies in the scientific literature. The new data from these studies strongly supports FDA's position on the safety of BPA and provides no basis whatsoever for any regulatory action.*

- **CALIFORNIA'S OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (2009)**
  California's Office of Environmental Health Hazard Assessment's (OEHHA) Development and Reproductive Toxicant Identification Committee (DARTIC) *unanimously voted not to add BPA to that state's Proposition 65 chemical warning label list.* The Committee – consisting of experts from several California universities spanning a wide range of relevant scientific disciplines - serves as the "State's Qualified Experts" for determining whether a chemical has been clearly shown, through scientifically valid testing according to generally accepted principles, to cause reproductive or developmental toxicity.

Shouldn't Hawaii 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.

POLYVINYL CHLORIDE-FREE INTRAVENOUS PRODUCTS

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.

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.

www.toyassociation.org

TESTIMONY OF

TOY INDUSTRY ASSOCIATION (TIA)

SUBMITTED TO

HAWAII HOUSE COMMITTEE ON HEALTH
IN OPPOSITION TO SB 2473
"RELATING TO TOXIC PRODUCTS"

FEBRUARY 8, 2012

www.toyassociation.org

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Chairman Green, Chairwoman Baker and members of both the Committee on Health and the Committee on Commerce and Consumer Protection, the Toy Industry Association (TIA) appreciates this opportunity to provide testimony in opposition to Senate Bill 2473. TIA is a not-for-profit trade association composed of more than five hundred (500) members, both large and small in size, located throughout North America. TIA is proud to say that Toy Industry directly supports employment for over 700 Hawaiians and has a total economic impact of $138 million in the state.

Toy Industry Association and its members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S.'s risk-based standards are widely used as models around the globe. TIA commends the bill sponsors for their keen interest in the safety of children. We share that interest, and our industry is founded on the mission of bringing fun and joy to children's lives – and in that pursuit protecting the safety of our young consumers is our top priority.

TIA would like to specifically address concerns with Senate Bill 2473 that would establish broad restrictions on Bisphenol-A or BPA used in many children's product applications.

BPA is Necessary for Product Safety and Essential Product Characteristics

Polycarbonate is lightweight, highly shatter-resistant, clear, extremely strong, and has high heat resistance, which makes it ideal for use in a wide variety of products. BPA is found in trace amounts in polycarbonate and is not an additive. If you ban BPA, you ban polycarbonate.

BPA as used in polycarbonate plastic *is specifically chosen for the safety it imparts to products, making them shatter-resistant and hygienic.* Some of the products that utilize BPA for these safety properties include protective gear such as bicycle helmets, protective shields used in sporting goods and safety glasses, as well as eyeglass lenses, and contact lenses.

BPA is approved by the U.S. Food and Drug Administration (FDA) for very sensitive applications, including medical and food contact use, and, as such, is used widely in food storage containers and medical equipment. These food applications are far more sensitive than toys; where exposure to BPA containing compounds is limited and occasional.

BPA is used less extensively in children's toys but is utilized when shatter-resistant properties are called for to eliminate the risk of breakage – which can lead to the creation of hazards such as small parts (potential choking hazard) and/or sharp edges in a child's environment which can cause laceration injuries. BPA is also UV-resistant and in a toy application provides strength and durability, reducing breakdown, again, reducing potential small part or sharp edge hazards. Elimination of BPA in these important applications could degrade the safety of toys and other consumer products where no safer alternative has been identified.

Scientific Bodies Have Verified the Safe Use of BPA

There is strong science to support the safe use of BPA in toys and consumer product applications. There is extensive research and testimony from experts on the science demonstrating the very low risk associated with

BPA as well as the unique safety benefits it provides. Specifically the following authoritative scientific bodies have found BPA to be safe or to not warrant special restrictions or handling:

- In July of 2011 a study solely funded by the U.S. EPA concluded, "Blood concentrations of the bioactive form of BPA throughout the day are below our ability to detect them, and orders of magnitude lower than those causing effects in rodents exposed to BPA."

- In April 2011, a comprehensive review by the German Society of Toxicology approximately 5,000 studies on BPA concluded, "[BPA] exposure represents **no noteworthy risk to the health of the human population, including newborns and babies.**"

- In November of 2010, an international panel of experts convened by the World Health Organization to examine the health risks from exposure to the chemical bisphenol A (BPA) agreed that it would be "premature" to take any public health measures to regulate or ban BPA.

- In September of 2010, the European Food Safety Authority (EFSA) concluded a review of over 800 studies on BPA and reconfirmed current safe levels of BPA in food products.

- In July of 2009, the California Developmental and Reproductive Toxicant Identification Committee voted unanimously against placing BPA on Proposition 65 - a list of chemicals believed to cause cancer, birth defects or other reproductive harm.

- In 2009, the German Federal Institute for Risk Assessment found that BPA is safe for "normal" use in many product applications and should not be banned.

- In 2010, the U.S. Food and Drug Administration re-reviewed its assessment of the safety of BPA and expressed the need for additional research; but did not propose banning the use of BPA in any product category.

- The U.S. Toxicology Program, in September 2008, issued a report with that did not find BPA to warrant any special restrictions.

A ban on BPA in such broad categories of products; as currently proposed by this legislation does not take into consideration the science supporting its safe use -- or its benefits.

BPA is not restricted <u>in toys</u> by any state, federal or national government anywhere in the world.
Inconsistency with existing international, federal and all other state requirements, without regard to scientific risk, threatens the viability of toy manufacturers, distributors and retailers in the State. A broad ban of BPA in toys, as currently proposed in SB 2473 could also force toy manufacturers to use less-tested alternative materials, that may not have the benefits that BPA offers and could result in products that do not hold up to the rigors of children's play.

Federal Regulation of Phthalates in Children's Products is Preemptive

Senate Bill 2473 proposes to ban di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP) in products intended for use by children under the age of 3. However, the Consumer Product

Safety Improvement Act (CPSIA), (H.R. 4040) was signed into law on August 18, 2008, by President Bush. This law has already restricts the use of these specific phthalates in toys and children's products and has the effect of expressly preempting states and localities from imposing similar restrictions on phthalates in these product categories.

Specifically, the U.S. Consumer Product Safety Commission (CPSC) has issued the following guidance on this topic: "The new lead limits for lead paint and lead content preempt state law as do the new provisions on phthalates and ATVs"[1] Therefore, these provisions relating to phthalates in Senate Bill 2473 are preempted and are unnecessary to include in this legislation.

Additionally, if these provisions remain in this legislation it would both confuse retailers, consumers and could cause unnecessary disruption in the marketplace, with the worst case scenario of products being mistakenly sent back to manufacturers and retailers.

Conclusion

The Toy Industry Association and its members have always recognized the special relationship we have with children, who are our principal consumers; their safety and well-being is always our top priority. As parents ourselves and an industry devoted to bringing joy (and safety) to childhood, we share your interest in the safety of toys and we urge you to carefully consider the unintended consequences of the provisions proposed in this legislation and how this bill will hurt those doing business in Hawaii, and force Hawaiian consumers to source products through other means, at no measurable increase to product safety. Therefore, TIA respectfully urges you **to oppose broad restrictions on BPA such as those contained in Senate Bill 2473**

On behalf of the members of the Toy Industry Association and our approximately 500 member companies, we thank you for consideration of these concerns. If you or the Committee has any questions with regard to our concerns on this legislation please do not hesitate to contact Joe Gregorich, Director of State Government Affairs for TIA, at 916-454-4281 or jgregorich@toyassociation.org.

[1] U.S. Consumer Product Safety Commission guidance on CPISA Section 231 – Preemption, http://www.cpsc.gov/ABOUT/Cpsia/sect231.html