

STATEMENT OF
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BEFORE THE SUBCOMMITTEE ON COMMERCE, MANUFACTURING
AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES
DISCUSSION DRAFT OF H.R. _____, A BILL THAT WOULD REVISE THE
CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008

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SUMMARY

The Consumer Product Safety Improvement Act of 2008 (CPSIA) includes some important updates to the Consumer Product Safety Commission's (CPSC) authority that generated considerable support from businesses and consumer groups alike. However, other provisions were and remain controversial because they depart from sensible risk-based decision-making designed to be protective of public health. CPSIA adopted an unduly proscriptive scheme of absolute limits on total lead and phthalates, setting standards inconsistent with risk-based measures commonly adopted by other regulatory agencies and indeed by CPSC itself. Those limits were coupled with 1) an exemption process that has proven to be meaningless, in the case of the lead limits, or non-existent, in the case of phthalates limits, 2) arbitrary reduction schedules for lead content, 3) retroactive effect, and 4) a confusing, burdensome testing scheme. The result is legislation that bars the CPSC from making common sense decisions about protecting the public, and thus results in bans on safe products, costing both money and jobs since the law went into effect. We need and want a strong and effective CPSC with both the authority and the resources necessary to adopt and enforce national consumer product safety standards based on science and risk. The draft legislation offers some positive steps towards this goal, but further revisions should be considered to advance a consistent public policy framework that assures that children are protected and that responsible businesses can continue to produce safe, affordable compliant products for children.

Chairman Bono-Mack and members of the Subcommittee, my name is Sheila Millar. I am a partner with the law firm of Keller and Heckman LLP. Thank you for the opportunity to appear before you today to discuss reform of the Consumer Product Safety Improvement Act of 2008 (CPSIA). I have represented manufacturers, importers, retailers, and trade associations who make consumer products, packaging, medical devices, and other products, as well as suppliers of raw materials used in these products, for over 30 years. My practice involves issues before many different regulatory agencies, often involving the intersection of law and science, so I will focus principally on the provisions relevant to children's products. My comments reflect my personal views, drawn from my years of regulatory experience, on how to advance a strong, national, uniform consumer product safety law that achieves the goal of protecting children without eliminating products that, by any reasonable and accepted objective health measure, are safe. The draft CPSIA reform bill offers some modest steps towards this goal.

1. **Defining a "child."** CPSIA defines "children" to be those 12 and younger. Children are not "little adults." Nor, however, should all children in this age group be treated identically.

"Children under 12" have physical and developmental differences and interact with consumer products differently. This is reflected in current law, which establishes different requirements for particular hazards based on the age of a child. Adopting a risk-based policy framework will allow for the development of health-protective standards for children's products keyed to the actual intended user.

2. **Lead substrate limits.** The cornerstone of a sound health and safety public policy is risk-based regulation. This is reflected in laws administered by health and safety agencies such as the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Consumer Product Safety

Commission (CPSC) pursuant to the Federal Hazardous Substances Act (FHSA). It is a well-acknowledged law of science that hazard is a function of toxicity plus exposure. Risk is the potential hazard posed by the exposure, which in turn requires an assessment of the type of material, the type of product, foreseeable handling and use, and age of the intended user. In enacting CPSIA's arbitrary total content limits on lead in substrate, Congress departed from well-established health risk management concepts. It first adopted a 600 ppm limit, then dropped to 300 ppm, with an impending 100 ppm limit coming up this summer unless modified. These limits are not related to actual risk, since the presence, existence or content of a substance in a product or component does not automatically result in potential harm to health. As a result, CPSIA imposes burdens beyond those needed to address the potential risk of harm through reasonably foreseeable handling and use, obsoleting products that are "safe" one day and banned the next. Although the revisions in the draft legislation are a positive step, they do not restore a risk-based framework. Consequently, the likelihood remains that safe products will be banned by the legislation even as revised. Other agencies, like FDA and EPA, have developed health-protective risk-based approaches to managing potential lead exposure which may offer useful alternatives to the current framework.

3. **The lead exemption process should be modified.** If CPSIA is not modified to establish a more sensible basic policy framework in regulating lead in children's products, the exemption process in Section 101(b) should be modified to allow for exemptions for materials or products that will not pose a potential health risk based on reasonably foreseeable use and abuse. The proposed legislation is an improvement to the current exemption process, which has resulted in no exemptions despite demonstrated *de minimis* risk of exposure. However, the new exemption process remains unnecessarily complex and restrictive. It establishes two

approaches for exemptions, one for certain specific metals (steel, copper and aluminum alloys), and one for materials that pose a *de minimis* risk, provided, in each case, that they are not small parts. The scientific rationale for this limited two-step exemption process is not apparent. Any product or material that does not result in anticipated adverse health effects based on appropriate science relevant to the reasonable worst-case anticipated exposure route should be exempt. In some cases that may be hand to mouth contact. In others it may be mouthing, and in still others it may be accidental ingestion. If a product or material is demonstrated to be reasonably safe, utilizing appropriate scientific methodology to assess exposure via the anticipated potential route of exposure, there is simply no health or policy reason to ban it. In contrast, the suggested phthalates exemption process in Section 6 of the draft bill authorizes the Commission to exempt from the phthalates limits products or materials where the Commission determines that compliance with the prohibition is not necessary to protect children's health. This is a more sensible way to address the issue, and we believe that you should create a consistent and scientifically appropriate path for all health-based exemptions.

4. **Phthalates provisions.** The proposed bill includes a much-needed exception for inaccessible component parts that contain phthalates, similar to the inaccessible component parts exemption from the lead limits, and allows the Commission to grant an exclusion when it determines that compliance with the limits is not necessary to protect children's health. This is a sound risk-based approach that could easily substitute for the more complex and restrictive lead exemption options offered in the draft bill. Inclusion of an accessibility requirement will also assure that the phthalates limits apply only to products that will result in direct exposure through interaction of a child. Again, the risk of actual exposure to children

in the age range of concern is key. Products like breast pumps and bottle warmers, among others, should obviously be exempt from the phthalates limits, as should toys or child care articles that realistically would not likely involve health risks to children.

5. **Lead and phthalates standards should be prospective.** We support clarifications to CPSIA to assure that limits apply prospectively to products manufactured after the effective date.

The lost businesses and lost jobs that were the result of the earlier implementation schedule of CPSIA cannot be restored, but further adverse impact to businesses whose products comply one day but not the next, or are otherwise safe, can be avoided.

6. **Modify unduly burdensome testing requirements.** Manufacturers have an obligation to meet applicable standards and to take appropriate measures to assure that they do. Otherwise, they face recalls and possible penalties for non-compliance. Testing has an important and ongoing role in compliance. However, micromanaging the test process by statute is not the best way to achieve the most cost-effective compliance, nor does it allow companies to rely on other compliance strategies or to leverage existing federal and other regulatory requirements to assure compliance. The draft bill offers important modifications to the current burdensome CPSIA testing scheme, recognizing that a system of compliance must be predicated on the specifics of the product category and supply chain. A few additional suggestions include:

- a. **Allow for supplier self-certifications, including as a mechanism to establish a reasonable basis of compliance with chemical content limits for components and raw materials.** Manufacturer certifications are a proven legal method to establish compliance under many laws, including the Flammable Fabrics Act, for example. CPSC's proposed final testing rule suggests that component testing will

be a solution to the costs and burden of mandatory third party testing of children's products. However, to take advantage of component testing, the raw material supplier must agree to subject itself to the jurisdiction of the CPSC and meet the requirements of a "reasonable test program." Raw material producers often do not themselves produce a consumer product, and may not be willing to subject themselves to the jurisdiction of CPSC for this purpose, particularly the burdensome production testing approach. However, they can often offer assurances of compliance. For example, many consumer product companies specify FDA-compliant raw materials for use in children's products, sourcing materials from reputable third parties who can provide written supplier assurances of compliance with FDA requirements adequate to assure that the material meets lead limits. A company that is willing and able to offer low lead materials safe for use in contact with food surely offers adequate assurances of safety for use in a consumer product.

- b. **If production testing is retained, refer to "representative samples" rather than "random samples" in Section 102(b).** The draft bill now allows the CPSC to prescribe reasonable testing programs to be used as the basis for certification for test requirements not yet in effect. However, further guidance on the parameters of a reasonable testing program in general may be needed. For example, with regard to production testing, the CPSC's proposed definition of the term "random samples" requires manufacturers to adopt a complicated statistical approach to the selection of samples. A better term to substitute for "random samples" is "representative samples," meaning samples that are selected in a

manner intended to assure that they are representative of actual production, avoiding preselected or “golden” samples, not implementation of a complicated and expensive statistical selection process.

- c. **Direct the CPSC to issue public guidance on inter-laboratory variability in total lead and phthalate test results.** Many reports have been submitted to CPSC documenting inconsistent results from laboratory to laboratory on total lead and phthalate content when the same product or component is tested. Products that meet lead or phthalates limits based on tests by one laboratory may fail when the same product is tested by another laboratory. Many companies require that tests be conducted by “their” laboratory so that they have consistent results for just that reason. This adds cost to the process, defeating one of the purposes behind third party testing. Products tested by any party that do not meet the applicable lead or phthalates limits by even a small margin cannot be sold and will not be accepted by customers. By virtue of failing a test these products are treated as banned hazardous products, subject to reporting and recall, irrespective of any actual potential risk of harm to a child. The problem is exacerbated as small differences in inter-laboratory results can have an enormous impact as regulatory limits drop, even as manufacturers operate on tighter and tighter tolerances in an effort to assure compliance. Adoption of an inter-laboratory uncertainty factor is a much-needed step in addition to adopting a risk-based framework of regulation.

The revisions in the draft bill are a good start towards ameliorating some of the adverse impacts of CPSIA, but further changes along the lines I have outlined here will help maintain a strong national safety net for consumers and reduce unnecessary burdens on the regulated community by restoring to the CPSC its authority to make sound risk-based determinations. The result will be an improved CPSIA, grounded in a public policy framework that draws on proven health-protective approaches to risk. I appreciate the opportunity to appear here today and would be happy to respond to questions.