August 7, 2015

Comments from the Breast Cancer Fund
To the U.S. Consumer Product Safety Commission

Regarding: ''Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012).''

Docket No. CPSC– 2014–0033

The Breast Cancer Fund is a national non-profit organization committed to preventing breast cancer by reducing exposure to chemicals and radiation linked to the disease. We base our work on a foundation of sound, peer-reviewed science showing increased risk of breast cancer from exposure to chemicals, including carcinogens and endocrine-disrupting compounds (EDCs), such as phthalates. The Breast Cancer Fund, along with the other undersigned organizations, have followed the implementation of Section 108 of the Consumer Product Safety Improvement Act (CPSIA) (15 U.S.C. §2057c.) and the resulting Chronic Hazard Advisory Panel (CHAP) process closely and have participated in many of the numerous opportunities for public comment.

After carefully reviewing the June 2015 CPSC staff analysis entitled "Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012)," we urge the CPSC to finalize the proposed rule *in its current form*[1]. The analysis does not provide sufficient justification to lift the ban on diisononyl phthalate (DINP), as industry has argued.

Congressional Charge to the CHAP and CSPC

Sec. 108 of the CSPIA (15 U.S.C. §2057c.) provided a clear mandate from Congress to review the toxicity of phthalates cumulatively and to ensure for DINP, DIDP and DnOP that a "reasonable certainty of no harm" would result from the exposure to all sources of these chemicals. Congress based this charge on the recommendations of a National Academy of Sciences report[1] that called for the assessment of safety of chemicals based on real world exposures and reflecting our current scientific understanding of toxicity.

[1] This statement reflects our strong support for the majority of the provisions within the CPSC's proposed rule and the critical importance of avoiding further delay in finalizing the rule. We note, however, that our April 15, 2015, comments to CPSC on the proposed rule urged the Commission to revise the rule to make permanent the interim bans on DIDP and DNOP and permanently ban DIOP. We continue to urge the Commission to take these steps, for the reasons explained in our April comments. Breast Cancer Fund et al., Comments on the Notice of Proposed Rulemaking: Prohibition of Children's Toys and Child Care Articles Containing Specific Phthalates, CPSC-2014-0033-0095 (Apr. 15, 2015) (online at www.regulations.gov/#!documentDetail;D=CPSC-2014-0033-0095).

The old adage of "the dose makes the poison" does not apply when considering the potential harm from chemicals, such as many phthalates, that impact the endocrine system. In fact, current science shows that in the case of EDCs, lower exposures, more in keeping with the level at which hormones act within the human system, may be more harmful than higher doses. This dynamic makes identification of the No Observable Adverse Effects Level, or NOAEL, extremely difficult for these chemicals.

For far too long, the chemical industry has enjoyed an "innocent until proven guilty" approach by government to assessing the safety of its products. Chemicals come on the market with little or no safety data, and the regulatory assumption is that "no data equals safety." While innocent until proven guilty may work for our criminal system, it is wholly inappropriate and ineffective at protecting the public from dangerous chemical exposures.

The Consumer Product Safety Commission's first responsibility is to ensure the safety of products and the protection of public health. The CHAP report and subsequent analysis of the more recent NHANES data provide ample evidence of why the CSPC must act in the public interest and make permanent the ban on DINP and the other phthalates listed in the CHAP report in children's toys.

NHANES and Toxicity Data

The trends in exposure to DINP over time, coupled with the growing scientific evidence of the chemical's toxicity, are deeply concerning and warrant action by the CPSC to continue to protect children from exposures from toys. While it is true that DEHP is a more potent anti-androgen than DINP, and that more recent NHANES data show exposure to DEHP decreasing; the concomitant increase in exposure to DINP and recent science further confirming the toxicity of DINP continue to justify the permanent ban on DINP within the proposed rule on the "Prohibition of Children's Toys and Child Care Articles Containing Specific Phthalates." In fact, ensuring the "reasonable certainty of *no* harm" (emphasis added) required by statute strongly supports the need to maintain the ban on DINP in child care products and toys.

Exposure to DINP is on the rise with no end in sight. The NHANES data on DINP exposure between 2001 and 2010 shows a 150% increase over that time,[2] and that trend continues in the 2011/2012 data. Not only is the contribution of DINP to the cumulative risk as calculated by this report significant, but this skyrocketing increase in exposure raises serious concerns for the impact of DINP in the future as exposure levels continue to rise. The analysis of the more recent NHANES data does show a decrease in the percentage of women of reproductive age with a hazard index of >1, however the Case 2 calculation for the 2011/2012 still shows 2.3% of women with a HI of greater than 1, which represents approximately 1.4 million women at risk; clearly a significant concern that must be addressed.

It is also worth noting that the NHANES data does not cover children younger than 6 years of age, which is the primary population targeted by the proposed rule. Children have often been found to have higher exposures to chemicals than adults and to be more sensitive to those

exposures. Science is showing in utero exposures to be the most detrimental; however exposure to young children as they continue to develop is also of serious concern.

The CHAP chose to analyze the cumulative impact of anti-androgenic effects from certain phthalates largely because the impact on the male reproductive system was the best documented of the health concerns. However, the CHAP acknowledged that this was not the only health concern for this family of chemicals, citing neurobehavioral effects in children (reductions in mental and psychomotor development, increases in attention deficits and behavioral symptoms) and liver, kidney thyroid and immune system toxicity.[3] DINP was included in the cumulative risk analysis because of its anti-androgenic properties, but the science shows a relationship with other serious health impacts. For instance, in 2013, the state of California designed DINP as a chemical "known to the state to cause cancer" under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).[4]

The science showing harm from phthalates generally, and DINP specifically, has continued to grow since the CHAP finished their literature review. A search of the science published in the past year and a half found numerous studies documenting the adverse effects of DINP in humans (adolescent boys and infants), rats, mice and zebrafish embryos. In addition to further documentation of the adverse impact on the male reproductive system articulated above, studies have shown associations between DINP exposure and brain damage, preterm birth, liver and kidney tissue toxicity and allergenic reactions.[5,6,7,8, 9, 10, 11, 12]

The CHAP had to limit its analysis in terms of health endpoints considered in order to make its charge doable; however the CPSC has an obligation to consider all of the potential harms from exposures to phthalates, including DINP.

Time to Act is Now

Scientists have been raising concerns about phthalates for years and the first regulatory actions banning the use of certain phthalates in children's toys happened almost a decade ago. In 2006, the European Union banned the use of six phthalates (DEHP, BBP, DBP, DINP, DIDP, DnOP) in child care products and toys. Congress acted in 2008 to ban those same phthalates and called on the CPSC, through the CHAP, to consider the toxicity of other phthalates and their replacements. It has taken seven years for the scientific and regulatory process to get to this point. If the CPSC fails to act now to ban the use of the phthalates recommended by the CHAP, based on a snap shot of NHANES data (2011/2012) and without taking into account the future exposure trends, we could well end up having to start this incredibly burdensome process all over again. In the meantime, Americans will continue to be put at risk for the dangerous effects of phthalates.

DEHP, DBP, BBP, DINP, DIDP and DnOP have been banned in child care products and children's toys for almost seven years at the federal level, and even longer in the EU and three states. The toy industry has functioned perfectly well during that time and the market has by necessity shifted away from these phthalates. In fact, the Toy Industry Association stated that the proposed rule will "…likely have limited practical effects on Toy Industry Association (TIA) members..."[13] While the market may have moved, it is important to lock in that change through

regulation to ensure that companies do not return to using toxic chemicals, hence the need for the CPSC to finalize the proposed rule in its current form. Continued delay also means continued exposure to the additional four phthalates banned by the rule beyond those in the statute.

Conclusion

We urge the Consumer Product Safety Commission to act now to finalize the proposed rule in its current form. The additional information provided by the "Estimated Phthalate Exposure and Risk to Pregnant Women and Women of Reproductive Age as Assessed Using Four NHANES Biomonitoring Data Sets (2005/2006, 2007/2008, 2009/2010, 2011/2012)'' does not obviate the obligation of the Commission to act in the best interest of the public's health by protecting children from exposure to these toxic chemicals.

Thank you for the opportunity to comment.

Respectfully,

Jeanne Rizzo, R.N.
President and CEO

Supported By:

Consumer Federation of America
Consumers Union
Greenpeace
Commonweal Biomonitoring Resource Center
TEDX, The Endocrine Disruption Exchange

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