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COMPETITIVE ENTERPRISE INSTITUTE
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PUBLIC COMMENT TO THE CONSUMER PRODUCT SAFETY COMMISSION

RE: CPSC Proposed Rule — Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates Docket No. CPSC-2014-0033.

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Summary: Since the release of the Chronic Hazard Advisory Panel (CHAP) report in July, many stakeholders have raised serious concerns about the process and report methodologies. Key complaints include the lack of transparency in regard to the peer review process, the refusal to allow public comment on a draft version of the CHAP, reliance on outdated exposure data, and questionable approaches employed for the cumulative exposure assessment. Less often noted is the fact that the CHAP report authors did not adequately consider the impacts on public health that might result from inferior substitute products.

An open and transparent process of peer review and public comment is essential to securing the best possible policy outcomes, particularly when complex scientific issues are involved. Accordingly, we don't only need an open process simply to make it fair to all stakeholders, we it need to best serve the public at large. Indeed, we need it to *protect the public from rash, and dangerous decisions.* And we did not have a fair and open process leading up to this proposed rule.

In any case, the science outlined in the CHAP and elsewhere does not support regulatory action on any of the phthalates. Such regulatory actions will have unanticipated impacts on the markets for a variety of products above and beyond those regulated in this rule. Forced product reformulations for the children's products regulated under the rule, along with resulting market deselection of other products, threatens to undermine public health, innovation, and economic well-being.

Accordingly, the CPSC should not impose any regulations in addition to those already mandated under the Consumer Product Safety Improvement Act of 2008 (CPSIA) because such regulations are not warranted by the science, unjustified based on close inspection of CPSC's own assessment, and likely to do more harm than good. At a very minimum, the CPSC should hold off on issuing a rule until the CHAP can be revised to include the most current exposure data and to allow public comment and open peer review to take place.

CHAP Report and Underlying Science is Deficient.

The CHAP report itself offers no justification for regulation. It relies on a selective review of limited studies that present little evidence that individual phthalates or cumulative exposure pose any significant risk to humans at current exposure levels.

Most of the CHAP-report-identified "evidence" that these chemicals pose health risks comes from lab tests that over-dose rodents to cause health effects. Such tests are not particularly relevant to humans that better metabolize the substance and who are exposed to traces that are many multitudes lower.[1]
The human research highlighted in the CHAP report is not particularly compelling either. Many of these human studies are noted to be "small," which limits their value for drawing any conclusions. And many of them report associations between potential health effects in babies whose mothers' phthalate exposure levels were measured in single "spot" urine samples during pregnancy.[2] Given that humans metabolize phthalates relatively quickly, one time spot measurements may be misleading about actual exposures, raising important questions about the value of such studies.[3]

We must remember that associations do not prove cause and effect. Accordingly, if we are to use such statistical tests to draw conclusions, the body of research should include larger-scale studies that report consistently positive, relatively strong associations. But that is not the case in this situation. It is clear from simply reading the executive summary of the report that, overall, the human data is weak, inconsistent, and of limited value. The report itself reads:

> Overall, the epidemiological literature *suggests* [emphasis added] that phthalate exposure during gestation may contribute to reduced AGD [reduced anogenital distance] and neurobehavioral effects in male infants or children. Other *limited* [emphasis added] studies *suggest* [emphasis added] that adult phthalate exposure *may be associated* [emphasis added] with poor sperm quality. The AGD effects are consistent with the phthalate syndrome in rats. However, it is important to note that the phthalates for which associations were reported were not always consistent and differed across publications. In some cases, adverse effects in humans were associated with diethyl phthalate exposure, although diethyl phthalate does not cause the phthalate syndrome in rats.

Judging from this statement, at best, the studies used for this CHAP report show either no associations or weak associations. Moreover, a body of research that merely "suggests" a relationship and is based on "limited studies" that are "not always consistent" does not sound at all compelling. Such terminology reveals that these studies are not particularly useful for drawing the conclusions found in the CHAP report. [4]

Such concerns are detailed in an external scientific peer review published by ToxStrategies, which was funded by the American Chemistry Council and released in September 2014. In the ToxStrategies report, scientists offered independent opinions about the science and methodologies employed by CHAP report authors. And their comments underscore the panel's highly questionable conclusions. For example, Douglas L. Weed, M.D., M.P.H., Ph.D, explained:

> "The CHAP report is not a systematic review of the available scientific evidence and, as such, is of questionable reliability and validity, lacking in the objectivity and transparency generally recognized as critical by the scientific community. The credibility of the recommendations in this report are therefore questionable, given that they are not "evidence-based" as the co-chair of the committee, Dr. Hauser, recognized and mentioned in a separate review published in the peer-reviewed literature (Braun et al., 2013)."[5]

Dr. Weed details further that the CHAP failed to provide a "critical and balanced review of the epidemiological evidence," omitting "a relatively large number" studies that found no association between the chemicals and human health. "In addition," he points out that "many of these reviews disagree with the CHAP report's assessment of the epidemiology (and of the use of animal models to represent adverse health events in humans)." He continues: "The CHAP report misrepresents the results of some (but not all) of the available epidemiological evidence, ignoring or downplaying negative results and emphasizing positive (i.e. apparently harmful) results."

In the absence of any compelling body of data that any individual phthalate is the cause of human health effects, the panel relied on the possibility that the cumulative effects of phthalates as a class have health effects. The problem is they were not able to actually demonstrate any such effects. The report notes: "Experimental data on combination effects of phthalates from multiple studies provide strong evidence that dose addition can produce good approximations of mixture effects when the effects of all components are known."

The panel's claim to have found "strong evidence" of cumulative health effects based on the limited research and data is highly suspect. Pharmacologist Christopher J. Borgert, Ph.D., in the ToxStrategies report observes that the panel's cumulative risk assessment: "failed to recognize obvious inconsistencies with human experience and clinical evidence"; "overstates the accuracy of its cumulative risk methods and conclusions"; and "appears to have grossly overestimated chemical potencies." In other words, the panel failed to properly apply the available data and research.

To make matters worse, they used old and irrelevant data for their human exposure assessments even though more accurate and recent data was available. Former and current CPSC commissioners have noted that had the panel used the most recent data, their risk assessment would have produced the opposite result.[6] This issue raises the prospect that the panel members were intentionally "selective" in their use of data because they desired to generate a particular conclusion, as appears to be the case with their selection of studies.

For more perspective on this issue, former CPSC Commissioner Nancy Nord explains:

> The CHAP found that "food, rather than children's toys or child care articles, provides the primary source of exposure to both women and children…." Nevertheless, the CHAP expressed its concern "that toys and child care articles ***may*** contribute to the overall

> exposure." (See staff briefing package, "Prohibition of Children's Toys and Child Care Articles Containing Phthalates", page 13, emphasis added.)
>
> Cumulative risk assessments can be a useful analytic tool in certain circumstances where risks come from identified multiple sources. However, in this instance, it is very clear that the CHAP had issues about how to do the risk assessment and then how to use it. Cutting through the scientific jargon, the CHAP report and the CPSC's proposed rule based on it address a potential health risk by proposing to ban a speculative contributor to the risk. The notion that this rule will make the marketplace safer is belied by the fact that the CHAP report describes the many other and more primary exposure routes from the other products that contain phthalates—most of which are outside the jurisdiction of the CPSC and many of which are not being used by children. …
>
> These concerns are amplified by the fact that the CHAP based its findings on stale data, when there is ample evidence that had it used the most recent data available to it, the analysis may well have reached a different conclusion. For the CPSC, which prides itself on being a "data-driven agency", to acquiesce in such an inexplicable use of flawed data, much less base a proposed rule on it, is puzzling. It might lead a cynic to wonder if this was a politically driven decision rather than a scientifically driven one.[7]

Nord's comments offer an excellent summation of this issue. That is: The CHAP should not have drawn conclusions from studies that are largely inconclusive, nor did they have the "strong science" they claim to have demonstrated "cumulative risk." And finally, it is unacceptable for the agency to rely on old exposure data when better data is available. The only time that an agency would pursue such "science" appears to be when the science is "political science" rather than hard science.

The body of science related to synthetic chemicals and endocrine disrupters reveals very low risk.

On a more fundamental level, regulating trace chemicals in consumer products simply because regulatory agencies or others have dubbed them as "endocrine disrupters," as is the case with phthalates, is unjustified. The reality is there is no hard evidence to suggest that the chemicals in these consumer products actually have such effects on humans at current exposure levels. In fact, evidence points to the opposite conclusion: these chemicals are far too weak and human exposure too low to produce any measurable impacts.

As a panel of scientists assembled by the American Council on Science and Health pointed out more than a decade ago: "Aside for exposure itself, perhaps the two most important factors [for understanding the effects of endocrine disrupters] are potency and dose."[8] The ACSH panel report notes that to put exposure rates in perspective people should compare the potency of the exposure to synthetic chemicals to that of the human estrogen, 17b-estradiol, which is commonly used in medications such as birth control and for hormone replacement therapy. Scientists have found the synthetic chemicals DDT and PCBs (the most studied chemicals claimed to be endocrine disrupters) to be up to *one million times* less potent than 17b-estradiol when used in similar doses.

Some animal studies do show associations between high-levels of certain chemical and endocrine-related health effects in lab animals. But the relevance of these animal studies to human health is limited as the potency and dose of human exposures is multitudes lower. In its review of the issue, the NRC found no compelling body of data demonstrating health effects on humans from trace synthetic chemical exposures.[9] In a recent scientific review of the research on the topic, the authors reported: "Overall, despite of 20 years of research a human health risk from exposure to low concentrations of exogenous chemical substances with weak hormone-like activities remains an unproven and unlikely hypothesis."[10]

Effects on humans have only been demonstrated when both dose and potency has been high, such as in medical administration of hormones. For example, between 1940 and 1970, many women took the drug diethylstilbestrol (DES) to prevent miscarriages, but it was eventually associated with higher incidences of reproductive problems. Toxicologist Stephen Safe notes: "DES is not only a potent estrogen, but it was administered at relatively high doses.… In contrast, synthetic environmental endocrine-disrupting compounds tend to be weakly active."[11]

The entire theory that manmade chemicals are causing significant endocrine disruption falls apart when you consider exposures to naturally occurring endocrine mimicking chemicals. Plants naturally produce such chemicals called *phytoestrogens*, to which we are exposed at levels that are thousands of times higher than those of synthetic chemicals. Human exposure to synthetic estrogens is minute, particularly when compared to that of naturally occurring estrogens found in fruits and vegetables.[12]

As researcher Jonathan Tolman points out, humans consume these naturally occurring endocrine mimicking chemicals every day without ill effect. He reports:[13] Lab tests have discovered endocrine mimicking chemicals in 43 foods in the human diet.[14] Soy products, particularly soybean oil, are found in hundreds of products, many of which we safely consume on a regular basis.[15] Although we safely consume them, phytoestrogens, are 1,000 to 10,000 times more potent than synthetic estrogens. And because we consume far more phytoestrogens in our diet, the estrogenic effects of the total amount we consume are as much as *40 million times* greater than those of the synthetic chemicals in our diets.[16]

Failure to adequately consider all potential impacts of substitute products may undermine public health and well-being.

Before initiating a rule that may remove chemical technologies from the marketplace that have been safely used for decades, we should consider whether replacement products pose greater risks. The CHAP allegedly addresses replacement products by reviewing data on the potential environmental health effects of other chemical substitutes, as noted in the proposed rule (page 78326) and in the CHAP report in the section on recommended substitutes (pages 121-142). But the CHAP did not address whether the substitutes that might actually win a place in the market would affect product performance in ways that help or harm public health and safety.

Yet the rule should ensure *net safety*, considering all such factors. It is incumbent that regulators don't inadvertently increase risks with short-sighted decisions. Based on the CHAP, we lack

reasonable assurance that regulatory action will increase net safety, and in fact such actions might accidentally introduce new hazarded and even greater public health and safety risks.

Still some people argue that we should at least seek substitutes to "be on the safe side," employing a precautionary approach. They forget that every product on the market prevailed because it was the best to perform the job at an acceptable price. Politically driven substitutes by definition will always be inferior. Unnecessary regulations and product substitutions also reduce consumer choice by eliminating safe and effective products. In some cases, many valued brands and products completely disappear. Such policies waste investment, discourage innovation, and divert resources from useful enterprises into production of second, best substitutes.

In the case of children's toys, we need to know whether such product failures could increase risks for children. For example, journalist Jon Entine points out that substitute products might increase choking hazards for children. He notes:

> The forced conversion to non-phthalates would force reformulation to products that will cost more or offer poorer performance or both," professor Godwin [Allen Godwin, chemist with Texas A&M] told me. "The poorer performance could mean reduced product lives. They won't last as long. Because the substituted additives are more volatile, as the plasticized PVC product ages, it becomes brittle. If this were a childcare article or toy, it could potentially become a choking hazard. If it's made from organic materials, it could develop an unpleasant oily finish and odor.[17]

When one use of a product is regulated, the product may lose market share for other uses because such regulations often create misperceptions about risk. For example, phthalates still have valuable uses for wiring and have an excellent safety record. Entine points out that if wire manufacturers respond to hype about phthalates, replacement products could prove dangerous. "The new products could also be more hazardous," Entine quotes Godwin explaining. "For example some alternatives are more volatile than the higher molecular weight phthalates."

A similar example already exists for the phthalate DEHP, which, as the Commission knows, Congress banned in amounts more than 0.1 percent in toys. While it is not banned in medical applications, hype about DEHP risks has led the medical community to seek alternatives for such vital products as blood bags.[18] This is occurring despite the fact that the chemical is very valuable in medical applications, and risks are very minute from such exposures.[19] As one journal article notes: "For RBCs [red blood cells], however, there are few convincing alternatives offering RBC the same protecting qualities of DEHP and allowing their long-term storage with equal qualities."[20] The sad reality is that our blood supply can be placed in jeopardy because of misinformation and hype about the risks of these valuable chemicals.[21] Regulators should not contribute to such alarmism by acting on weak science and unsubstantiated claims about risk.

Conclusion.

Based on the current state of the science, the CPSC should not issue any new rules related to phthalates other than those specifically enumerated by Congress in the CPSIA. At a bare minimum, the agency should not rely on the CHAP report in its current form an instead launch

an official public comment period for stakeholders to outline proposed revisions to the report. Then the CHAP should convene to draft a new report using the best and most current data and a more thorough review of the science, followed by an open and transparent peer review process. It can then again open a revised CHAP report to public comment before making the report final and issuing any new regulatory proposals.

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[1] Kathleen Meister (Editor), *America's War on "Carcinogens": Reassessing the Use of Animal Tests Predict Human Cancer Risk* (New York: American Council on Science and Health, 2005).
[2] See charts of identified key studies on pages 29, 31, 32, 33 of the CHAP report.
[3] Mandy Fisher et al., "Bisphenol A and Phthalate Metabolite Urinary Concentrations: Daily and Across Pregnancy Variability," *Journal of Exposure Science and Environmental Epidemiology*, September 24, 2014, http://www.nature.com/jes/journal/vaop/ncurrent/pdf/jes201465a.pdf.
[4] See Angela Logomasini, *A Consumer's Guide to Chemical Risk: Deciphering the Science Behind Chemical Scares* (Washington D.C.: Competitive Enterprise Institute, 2014), http://www.safechemicalpolicy.org/science-facts-and-chemical-scares.
[5] *Independent Expert Peer Review of the Final CHAP Report on Phthalates and Phthalate Alternatives* (Austin: ToxStrategies, 2014), http://phthalates.americanchemistry.com/Regulators/Independent-Scientific-Experts-Question-the-Recommendations-of-the-CHAP-Report-on-Phthalates/Executive-Summary-of-the-ToxStrategies-Report.pdf.
[6] Ann Marie Buerkle, "Commissioner Buerkle Statement on the Phthalates NPR," December 17, 2014 http://www.cpsc.gov/en/About-CPSC/Commissioners/Ann-Marie-Buerkle/Ann-Marie-Buerkle-Statements/Commissioner-Buerkle-Statement-on-the-Phthalates-NPR.
[7] Nancy A. Nord "Phthalates NPR: Flawed Theory Supported by Flawed Data, Conversations with Consumers," March 7, 2015, http://nancynord.net/2015/03/07/phthalates-npr-flawed-theory-supported-by-flawed-data/http://nancynord.net/2015/03/07/phthalates-npr-flawed-theory-supported-by-flawed-data.
[8] ACSH, *Endocrine Disrupters: A Scientific Perspective* (New York: ACSH, 1999), 9.
[9] National Research Council, *Hormonally Active Agents in the Environment* (Washington, D.C.: National Academy Press, 1999), see pages 269, 208, 272.
[10] G.J. Nohynek, C.J. Borgert, D. Dietrich, and K.K. Rozman, "Endocrine Disruption: Fact or Urban Legend?" *Toxicology Letters* 223, no. 3 (2013): 295-305.
[11] Stephen Safe, "Endocrine Disrupters: New Toxic Menace?" in *Earth Report 2000*, Ronald Bailey, ed. (New York: McGraw- Hill, 2000), 192.
[12] National Research Council, *Hormonally Active Agents in the Environment*, see chart on page 68.
[13] Jonathan Tolman, *Nature's Hormone Factory: Endocrine Disrupters in the Natural Environment (*Washington DC: Competitive Enterprise Institute, March 1996).
[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] Jon Entine, "Can't Get Pregnant? Blame It On Plastics!" *Forbes* (online), November 14 2013, http://www.forbes.com/sites/jonentine/2013/11/14/cant-get-pregnant-blame-it-on-plastics-well-not-if-science-matters.
[18] Juliane Simmchen, Rosa Ventura, and Jordi Segura, "Progress in the Removal of Di-[2-ethylhexyl]-phthalate as Plasticizer in Blood Bags," *Transfusion Medicine Review* 26, no. 1 (January 2012): pp. 27-37. http://www.tmreviews.com/article/S0887-7963%2811%2900056-3/fulltext
[19] Bill Durodie, *Poisonous Propaganda: Global Echoes of an Anti-Vinyl Agenda* (Washington D.C.: Competitive Enterprise Institute, 2000), http://cei.org/pdf/1784.pdf.
[20] Simmchen et al., "Progress in the Removal of Di-[2-ethylhexyl]-phthalate as Plasticizer in Blood Bags,"
[21] See Angela Logomasini, "Blood Supply Besieged," *Washington Times*, August 10, 2000, https://cei.org/op-eds-and-articles/blood-supply-besieged-logomasini-op-ed-washington-times.