COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

U.S. CONSUMER PRODUCT SAFETY COMMISSION

Concerning

PROHIBITION OF CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING SPECIFIED PHTHALATES (DOCKET NO. CPSC-2014-0033)

Mark S. Chenoweth
Richard A. Samp
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, D.C. 20036

April 15, 2015

Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
(202) 588-0302

April 15, 2015

FILED ELECTRONICALLY AT:
http://www.regulations.gov

Attn: Alberta E. Mills
Acting Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway, Room 820
Bethesda, MD 20814

Re: Comments on Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

Dear Commission:

Washington Legal Foundation (WLF) thanks the U.S. Consumer Product Safety Commission (CPSC or "the Commission") for the opportunity to comment on its Proposed Rule to prohibit children's toys and child care articles containing specified phthalates. These comments will address the Notice of Proposed Rulemaking published in the Federal Register on December 30, 2014 at 79 FR 78324.

I. Interests of WLF

Founded in 1977, WLF is a nonprofit, national public-interest law firm and policy center with supporters throughout the United States. WLF devotes a substantial portion of its resources to advocating for free-market principles, limited and accountable government, individual rights, business civil liberties, and the rule of law through litigating, disseminating legal publications, and filing comments with regulatory agencies. WLF believes free enterprise leads to a more

prosperous and peaceful society, and so WLF is particularly motivated to intervene in federal regulatory proceedings where proposed regulations threaten to interfere with free markets in ways that contradict an agency's governing statutes and do not otherwise have a valid legal basis.

WLF also has a longstanding interest in promoting sound science and stopping the proliferation of junk science in federal courts and federal regulatory agencies. To that end WLF has filed *amicus curiae* briefs in landmark cases such as *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997), *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and most recently filed in *Accenture, LLP v. Wellogix, Inc*. In addition, WLF's Legal Studies Division regularly publishes articles on junk science in federal agencies. *See, e.g.*, Evan M. Tager, Miriam R. Nemetz, and Carl J. Summers, *Sixth Circuit Slams the Door on Federal Agency's Unreliable, Result-Oriented Expert Testimony*, WLF LEGAL OPINION LETTER (May 9, 2014). Finally, in a further expression of its concern for promoting the use of sound science, WLF has filed regulatory comments with multiple agencies that have attempted to promulgate regulations based on questionable science. For instance, WLF filed comments last year in *In re: OSHA's Proposed Rule to Improve Tracking of Workplace Injuries and Illnesses* (Docket No. OSHA-2013-0023) (March 10, 2014).

WLF also follows the activities of the CPSC closely and publishes articles covering its regulations on a frequent basis. *See, e.g.*, Sheila A. Millar and Kathryn M. Biszko, *CPSC's Misuse of RCO Doctrine Bodes Ill for CEOs and Consumers*, WLF LEGAL BACKGROUNDER (August 23, 2013); Cheryl A. Falvey and Natalia R. Medley, *Upsetting the Confidentiality Balance?: CPSC Proposes Revisions to Its Section 6(b) Information Disclosure Regime*, WLF LEGAL BACKGROUNDER (February 28, 2014); Nancy Nord, *Why CPSC Should Voluntarily Recall*

Its New Voluntary Recall Proposal, WLF LEGAL BACKGROUNDER (April 25, 2014), and Mark Chenoweth, *Two Cheers for the Tenth Circuit's Temporary Stay of the CPSC's New Magnet Safety Standard*, Forbes.com (April 14, 2015). Thus WLF is pleased to participate in this rulemaking in an effort to improve the quality of the Final Rule.

II. Introduction

WLF shares the Commission's concern for protecting children from harmful products and applauds CPSC's commitment to that goal. Part of ensuring that Commission and industry resources are best allocated to protect children requires sound science to be used in assessing actual risk. Wasting resources chasing risks that are non-existent or negligible means those same resources cannot be allocated to reduce genuine risks that do threaten children. WLF is interested in the proper regulation of phthalates precisely because of public policy concerns that phthalates are not being regulated appropriately at the local, state, or federal levels.

Specifically with regard to CPSC, WLF has heard criticisms of the Proposed Rule prohibiting specified phthalates from several sources. Complaints have come from a wide variety of industries and from suppliers, manufacturers, and retailers. WLF believes the distress arising over this issue derives in large part from the novel approach taken by the Commission in this rule (novel because it addresses speculative risk and assesses cumulative exposure), which observers fear will set a precedent for future regulatory efforts at CPSC.

WLF's concerns with the Proposed Rule fall into four broad areas. First, by relying on outdated data regarding phthalate exposure, the agency violates both the Consumer Product Safety Improvement Act of 2008 (CPSIA) and the Information Quality Act (IQA), opening the

Proposed Rule to serious legal challenge on both fronts. Second, by relying on a flawed cumulative risk assessment (CRA) to extend permanently the temporary ban on diisononyl phthalate (DINP) and newly to ban several other phthalates, the Commission commits serious scientific error that, again, opens the Proposed Rule to legal challenge. Third, CPSC has made the DINP permanent ban broader than the foregoing temporary ban. Whether CPSC has met the appropriate legal standard for broadening the ban is subject to question. Finally, although WLF appreciates CPSC's acknowledgement of the express preemptive effect of the Commission's consumer product safety rules on phthalates in superseding contradictory state and local laws, the Proposed Rule could go further in giving preemptive effect to areas where the Commission has deliberately chosen not to regulate.

Before proceeding to discuss these concerns in detail, it is worth pausing to highlight the fact that CPSIA temporarily banned certain phthalates that the Commission now concedes do not pose a threat to children, yet it will wind up having taken the Commission more than seven(!) years to lift what was supposed to be only an interim prohibition of two or three years. Congress instructed CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to assess whether or not to keep the statute's temporary ban in place. CPSIA ordered the CHAP to complete its report within two years of its appointment, *i.e.*, by April 13, 2012. §§ 108(b)(2)(B) and (b)(2)(C) of CPSIA. The CHAP submitted its final report to the Commission on July 18, 2014—some 27 months late. In other words, the CHAP's report was more months late than the entire CHAP study was supposed to take to complete from start to finish. That is appalling.

Moreover, such brazen disregard for Congressional timelines has produced numerous negative consequences. First, it kept non-harmful phthalates off the market for years that could

have been used in place of some other phthalates about which the CHAP and the Commission have expressed greater concern. Second, it increased compliance costs for regulated entities by forcing them to test for phthalates that did not pose a risk to consumers. Third, it preoccupied the agency for several extra years with a matter of lesser risk that distracted it from its fundamental mission to protect consumers from unsafe products. Lastly, it jeopardized the likelihood of obtaining industry buy-in to follow a similar temporary ban evaluation process in the future. The Commission—and particularly the CHAP—deserve harsh criticism for subverting the will of Congress to such a significant degree. In particular, once CPSC decided to accept the CHAP's recommendation to lift the ban on two phthalates, it could have expedited a rule to lift that ban without further delay.

Putting aside the inordinate delay in proposing this rule, the remainder of this comment will spell out the concerns mentioned above in greater detail and suggest some possible remedies for the Commission's further consideration. WLF hopes these comments will assist the Commission in addressing these concerns, so that the regulation of phthalates will be based on sound science, the Commission will refocus its efforts on regulating genuine risks and protecting consumers from hazardous products, and the Proposed Rule will not set a precedent of trying to regulate speculative risk on a precautionary basis. In this way, the Final Rule may avoid being subjected to legal challenge in federal court.

III. The Commission Is Unjustifiably Relying on Old Phthalates Exposure Data

The first problem with the data CPSC relies on for this Proposed Rule is that the data set is old. Depending on a nearly 10-year-old data set (2005-06) is less than ideal in the best of

circumstances, but it is utterly inexcusable when there is more than one newer data set available from the Centers for Disease Control for the Commission's consideration. Using an older biomonitoring data set necessarily raises suspicion that the data set was selected for reasons other than its reliability—for example, it may have been selected because the data set better supports a decision to regulate in a manner that the CHAP and the Commission prefer than newer data sets that show lower exposure levels to phthalates. Whether or not such a cherry-picking suspicion is accurate, an old data set creates other problems as well.

A. The Data Set Used Predates the Permanent Statutory Ban on Certain Phthalates

In particular, the CHAP has picked a data set that is highly unlikely to accurately reflect current exposure levels because it predates the ban on certain phthalates. The CPSIA permanently banned three phthalates from children's toys and child care articles. Among the three banned phthalates was the seemingly ubiquitous di-(2-ethylhexyl) phthalate (DEHP). The permanent ban went into effect 180 days after CPSIA was signed into law in August, 2008. Hence, a data set from 2005-06 includes exposure information to a then-widely-used phthalate that has not been legal to use in children's toys and child care articles for over six years now. Given that DEHP is being used much less frequently today, the likelihood that the older data set better reflects current exposure levels than more recent data sets seems quite low.

B. Relying on Outdated Data Violates the CPSIA

Completely apart from the policy wisdom of relying on outdated data, doing so flies in the face of the statute that set up the CHAP. CPSIA instructs the CHAP to "Examine the *likely*

levels of children's, pregnant women's, and others' exposure to phthalates, based on a *reasonable estimation* of normal and foreseeable use and abuse..." § 108(b)(2)(B)(iii) (emphasis added). It also instructs the CHAP to "review all relevant data, including the *most recent*, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data …" § 108(b)(2)(B)(v). A decade-old data set does not meet the requirement of examining the *likely* levels of exposure to phthalates. Furthermore, an obsolete data set does not meet the statutory requirement of basing recommendations on a *reasonable estimation* of normal and foreseeable use when the biggest phthalate culprit in the data set is no longer in the products to which the relevant consumers are currently exposed. And, finally, of course a long-since-superseded data set is obviously not the *most recent*, best-available study.

C. Relying on Obsolete Data Violates the Information Quality Act

Perhaps relying on the superseded data set would not matter if it did not make a difference in the CHAP's or the Commission's recommendations. However, it appears that more recent data would in fact have driven a different decision. That is, the use of bad data by the CHAP is directly responsible for bad decision-making by the agency. Not only does the CHAP's use of obsolete data violate the CPSIA, but it also likely violates the Information Quality Act.

WLF has published an extensive recent WORKING PAPER on the Information Quality Act and its availability to challenge regulations based on bad data. The article, entitled *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, was written by Lawrence A. Kogan and introduced by Dr. John D. Graham, Dean of the School of Public and Environmental Affairs at Indiana

University.[1] The Proposed Rule contains two perfunctory sentences indicating that the Paperwork Reduction Act is not applicable to this rule because it does not include any information-collection requirements. However, that statement does not get CPSC off the IQA hook. Congress passed the Information Quality Act in 2000 to implement and amend the Paperwork Reduction Act. The IQA requires federal agencies to use objective and high quality scientific data when disseminating information to the public and when adopting regulations that impose costs on regulated entities.

The WLF/Kogan paper explains how regulated entities may seek judicial enforcement of the IQA when agencies promulgate federal rules in reliance on flawed data, and those rules impose compliance burdens on the regulated community. Given the substantial compliance costs involved with phthalates testing, there is little doubt that an effective IQA lawsuit could be brought against the CPSC if it persists in basing the Proposed Rule on flawed data. Furthermore, because the Commission seems to be consciously setting a precedent in its promulgation of this novel rule, industry is likely to have a significant incentive to seek enforcement of the IQA with regard to this particular rulemaking.

The White House Office of Management and Budget (OMB) is responsible for implementing the IQA. OMB's IQA Guidelines require each federal agency to develop and adhere to their own IQA guidelines, and set out minimum criteria for scientific peer review of agency-drafted and third-party studies and scientific assessments. OMB dictated that these peer-review standards be especially rigorous for "highly influential scientific assessments" like the CHAP report. Moreover, federal agencies must provide an administrative review mechanism

[1] The full article is available at <http://www.wlf.org/publishing/publication_detail.asp?id=2479>.

that will allow affected entities to seek correction of agency-disseminated information that was not adequately validated. Agencies routinely carry out this mandate, as the CPSC is attempting to do here, by addressing requests for correction as part of their responses to public comments in a final regulation. The WLF/Kogan paper argues that approach does not afford sufficient due process to aggrieved stakeholders.

Although the WLF/Kogan paper was written as a case study of greenhouse gas regulations, it could just as easily have been written as a case study of the problems with the approach taken by CPSC in the Proposed Rule. A review of the extensive record behind this rulemaking shows CPSC did not consider stakeholders' challenges regarding IQA violations in a timely or sufficiently specialized manner. Stakeholders faced with such adverse, final agency actions would traditionally consider legal action against the responsible federal agency. To be sure, as the paper explains, federal courts have been generally skeptical of regulated entities' private causes of action to redress agencies' noncompliance with IQA standards. Those complaints have foundered on plaintiffs' standing to sue, as well as their assertion of a "positive" right to properly peer-reviewed government information. That unsuccessful litigation history may explain CPSC's apparent insouciance when it comes to IQA compliance.

However, the WLF/Kogan paper proposes an alternative approach to judicial enforcement of the IQA, one which addresses past lawsuits' shortcomings and promises to reinvigorate the IQA. The contemplated cause of action is based on the theory that Congress intended the IQA, as an implementation of the Paperwork Reduction Act, to protect the *negative* right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations. The lawsuit would

formally be brought as an action under the Administrative Procedure Act (APA). Regulated entities could establish standing to sue based on the particularized economic injuries they have suffered from regulatory burdens. A narrowly-pled, factually-supported challenge utilizing the APA would not only be consistent with the longstanding presumption that Congress intends judicial review of administrative action, but it would also be sufficient to overcome some federal courts' presumption against implied causes of action.

If promulgated 'as is' the Proposed Rule provides an inviting test case for potential IQA enforcement under the WLF/Kogan paper's rubric. Even if CPSC were to prevail in a legal challenge under IQA, the agency should not rely on shoddy science—science that a *Daubert* proceeding would kick out and not permit a jury to hear if the CHAP study were invoked in federal court. Federal law requires CPSC to comply with the IQA regardless of whether federal courts ultimately conclude that CPSC's failure to adhere to the IQA is subject to judicial review.

IV. The Proposed Rule Bans DINP Based on a Flawed Cumulative Risk Assessment

Putting to one side the issue of using obsolete data, the agency exaggerates the risk posed by DINP by employing a novel and flawed cumulative risk assessment (CRA). Only one of the three exposure scenarios considered by the CHAP (which also happens to be the one scenario the CHAP invented for itself, rather than the two it evaluated from independent, objective sources) even arguably finds DINP exposure at a level of more than negligible concern.

Other comments have critiqued the numbers in the three scenarios to demonstrate that the CHAP's approach to cumulative risk assessment is flawed. Suffice it to say that the CHAP report makes it clear that overall risk from phthalates is overwhelmingly driven by DEHP

exposure. Nonetheless, the CHAP decided that DINP contributed to the overall risk level because exposure to DINP could be significant when combined with exposure to (already banned) DEHP under one particular scenario crafted by the CHAP itself. But saying that DINP contributes to the risk when combined with DEHP is like saying that together Lebron James and I scored 50 points in last night's game. That is, it is utterly misleading and does not reflect an accurate appraisal of the risk contributed by the far lesser player, DINP. This fact is made even more compelling when one considers that overall phthalates exposure is driven more by exposure to food and other products not within the CPSC's jurisdiction than it is by exposure to children's toys and child care articles. The data simply do not support a finding that a minor reduction in exposure to DINP in children's toys and child care articles is necessary to protect children's health. If CPSC promulgates a Final Rule based on such flawed science, it should expect a legal challenge under the Information Quality Act.

V. CPSC Cannot Justify a Permanent DINP Ban Broader than the Temporary Ban

Not only does CPSC propose to ban DINP based on a flawed CRA, but it also proposes to broaden the scope of the temporary ban. Whereas the temporary ban only extended to child care articles and children's toys that can be put in the mouth, for some unspecified reason the Proposed Rule widens the ban to cover all children's toys. Thus some products already tested will likely have to be retested unless the agency grandfathers products already manufactured and tested in the Final Rule. It is unclear whether the proposed 180-day delay before the rule is implemented will suffice to prevent duplicative testing. As noted above, DINP is not driving the overall risk. Also, what risk there is seems to be coming from mouthing, so expanding the ban to

explicitly cover toys that are *not* mouthed would only reduce risk a negligible amount, if that. As the EU has stated in its own comments responding to the Proposed Rule, the European Chemicals Agency looked carefully at the DINP exposure issue in 2010 and found that this particular phthalate does not present further risk beyond exposure from mouthing. Hence, expanding the ban makes little sense and would open the Proposed Rule up to legal challenge on yet another front.

Expanding the scope of the ban also raises serious questions about whether a different legal standard should govern such an expansion to things not previously banned under the CPSIA rather than merely continuing the temporary ban. CPSIA § 108(b)(3)(A) appears to authorize an agency decision to merely keep the interim prohibition in place. However, by expanding the scope of the ban in addition to making it permanent, the Commission may exceed the scope of what the statute authorizes. Specifically, it does not appear that the findings made by the Commission with regard to non-mouthable children's toys would suffice to support a declaration of a banned hazardous product under § 8 of the Consumer Product Safety Act.

CPSC relies heavily for its ability to widen the scope of the ban on language in the statute instructing the Commission to "evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act …, as the Commission determines necessary to protect the health of children." CPSIA § 108(b)(3)(B). That language, however, refers to children's products, not the discrete categories of "children's toy that can be placed in a child's mouth or child care article," which are subject to more specific statutory instructions at § 108(b)(3)(A). In addition, the language only permits the Commission

to ban a product where doing so is "necessary" to protect children's health. As discussed above, the primary mode of exposure to phthalates is oral, so widening the scope of the ban to cover non-mouthable children's toys hardly seems necessary to protect children's health.

At a minimum, the CHAP and the Commission have not demonstrated the necessity for widening the ban's scope. The Commission appears unaware of what reason the CHAP had for widening the scope, and it is even possible the wording was just an oversight on the CHAP's part. The vague reason the Commission staff provides for accepting the CHAP recommendation is that it surmises the additional testing costs for widening the scope of the ban would be low. But low cost, even if true, cannot justify a decision that the statute requires to be risk-based.

A broader DINP ban is not necessary to protect children's health, nor does DINP in non-mouthable toys present an "unreasonable risk of injury" under 15 U.S.C. § 2057. The Commission explains its decision not to expand the phthalate ban beyond children's toys to the category of children's products because "staff believes that increased exposure to phthalates from most children's products would be negligible." Why would it be negligible? Because, says the agency staff, those other products are not frequently mouthed. So why then widen the scope of the ban to non-mouthable toys? The logic on the Commission's part is utterly inconsistent. The very rationale the agency provides for not expanding the overall phthalates ban to all children's products suffices as a reason not to extend the DINP ban beyond children's toys that can be placed in a child's mouth and child care articles.

Besides which, if the Commission's legal position is that the language in § 108(b)(3)(B) authorizing it to "declare any children's product containing any phthalates a banned hazardous substance" alone suffices to permit it to *widen* the scope of the DINP ban, then that same

language likewise empowers the agency to *narrow* the scope of the ban. Particularly given the codicil "as the Commission determines necessary to protect the health of children," if the agency were to follow the data gathered by the CHAP rather than the CHAP's recommendation, it could use the latitude afforded by the statute to not ban any additional phthalates. Or, it could recommend a ban on the four new phthalates that is limited to child care articles, or child care articles and mouthable children's toys, or even child care articles and toys intended for children under age 7. The latter decision could be justified on the basis that children age 7 and up are much less likely to mouth their toys and will therefore be exposed to a far lower quantity of phthalates from chewing and sucking on toys than will younger children.

Commission leadership has consistently and publicly bemoaned the lack of flexibility under the CPSIA as a reason why it has not done more to reduce testing and compliance costs—including when confronted by Members of Congress at subcommittee oversight hearings. If Commissioners are serious about a desire to ease the burden, they should not miss this opportunity to reduce testing.

For now, the Commission proposes to begin banning several additional phthalates, and its primary justification for doing so, despite limited scientific support, is that the testing costs for additional phthalate bans are minimal once some phthalate testing is already mandatory. But that rationale is not risk-based, and it understates the costs of testing and compliance. Every test creates new and additional compliance obligations and legal risk that companies have to wear, and that risk is more than marginally significant. It is no argument against death by a thousand cuts to say that the victim will have already been cut 900 times when the Commission's latest regulations kick in.

Particularly given the current instructions from Congress to the CPSC to find ways to reduce compliance testing and cost, the CPSC should give serious consideration to *not* widening the scope of the DINP ban, *not* banning any additional phthalates based on limited evidence (on a precautionary basis, for fear that they might be used more frequently once other phthalates are banned), and *not* including all children's toys in any further bans that the Commission does decide to implement.

VI. Preemption

WLF appreciates CPSC's acknowledgement of the express preemptive effect of the Commission's consumer product safety rules on phthalates in superseding state and local laws. However, the Proposed Rule could and should go further in specifying where it has deliberately chosen not to regulate. By remaining silent with regard to phthalate alternatives for which the CHAP and the Commission have found no evidence of risk, the agency leaves open the very real possibility that less sophisticated state and local legislative or regulatory bodies will ban phthalates or phthalate alternatives that the best-available science obtained by the CPSC suggests poses little or no risk.

For example, the Office of Environmental Health Hazard Assessment (OEHHA) in California has proposed a new Article 6 in the Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Title 27, California Code of Regulations (commonly known as Prop 65). Part of the proposed article would designate (apparently all) "phthalates," as one of 12 specific chemicals that must be listed on new "clear and reasonable" warnings. Every consumer product sold containing phthalates must contain a warning stating that the labeled product "can expose

you to phthalates known to the State of California to cause cancer and birth defects or other reproductive harm."

Given that the CHAP and the Commission have carefully distinguished among phthalates that they believe pose risk and phthalates they believe do not pose more than negligible risk, the Final Rule should not permit such state laws to falsely and sloppily conflate relatively harmful phthalates with relatively harmless phthalates. Even if WLF would not sort those phthalates in the same way (and thus not draw the line in the exact some place) as the Commission, it is still valuable to the regulated community for the Commission to assert its line to the exclusion of contradictory state and local laws. If CPSC instead abdicates the ability to preempt state and local laws that are based on unsound science, then it will waste regulatory and compliance resources that could be better directed to managing genuine risk.

VII. Conclusion

WLF thanks the Consumer Product Safety Commission for the opportunity to comment on this very important public policy issue. WLF will continue to follow the phthalates issue closely and will hope to see marked improvement in a Final Rule that advances the goals of CPSIA § 108 consistent with sound science.

Respectfully submitted,

/s/ Mark S. Chenoweth

General Counsel
Washington Legal Foundation

/s/ Richard A. Samp

Chief Counsel
Washington Legal Foundation