UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, ENVIRONMENTAL JUSTICE HEALTH ALLIANCE FOR CHEMICAL POLICY REFORM, and THE BREAST CANCER FUND,	:	
Plaintiffs,	:	
	:	16 Civ. 09401 (PKC)
- against -	:	
UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,	:	
Defendant.	:	

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THE NATIONAL ASSOCIATION OF MANUFACTURERS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Preliminary Statement

The NAM demonstrated that plaintiffs cannot establish any injury in fact caused by CPSC's delay in publishing a final rule regulating the phthalates at issue here. The CPSC and its panel of scientific experts, the Chronic Hazard Advisory Panel ("CHAP"), determined that the risk of "current exposures" to these phthalates in toys and child care articles is "low" and does "not indicate a high level of concern." (NAM Mem. at 8.) Because the CHAP determined that these phthalates either currently are not found in such products or present no "quantifiable exposures" from such products, it concluded that the proposed permanent ban on these phthalates, if implemented, would provide little or no reduction in exposure to children from these phthalates in such products. (*Id.* at 6-8; Palmieri Decl. ¶¶ 24-26.)

Plaintiffs claim that the NAM "improperly" focuses on "findings regarding the risk from exposure to each phthalate in isolation," rather than on "cumulative risk" of exposure from all sources of phthalates.[1] (Pls. Mem. at 18.) In fact, the NAM showed that the only basis for recommending a permanent ban was that future use of the phthalates in toys and child care articles allegedly would contribute to "cumulative risk" when aggregated with exposure to phthalates from all sources. (NAM Mem. at 8-9.) But the CHAP based that cumulative risk assessment on biomonitoring data from 2005-2006. The CPSC's more recent (2015 and 2017) assessments of cumulative risk, using data from 2007-2014, show there is no concern for cumulative risk from phthalate exposure, because that risk has fallen below the standard CPSC used to determine whether the risk was a health concern in publishing the proposed rule.[2] (*Id.*)

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[1] The statute required the CHAP to consider both isolated and cumulative risk. 15 U.S.C. § 2057c(b)(2)(B)(ii).

[2] Plaintiffs attempt to avoid the import of this new data by falsely asserting that "the CPSC took no further action" after publishing the proposed rule in December 2014. (Pls. Mem. at 2.) In fact, the CPSC subsequently assessed cumulative risk based on updated biomonitoring data, and published these analyses for comment in June 2015 and February 2017. (*Id.* at 8-9.) Although plaintiffs ignore CPSC's 2015 and

These CPSC risk assessments using the most recent exposure data refute plaintiffs' contention that the administrative record "corroborate[s]" their members' "reasonable concerns that their children currently are being exposed, and will be exposed in the future," to harm from these phthalates in toys and child care articles. (Pls. Mem. at 13, 15.) The record demonstrates that plaintiffs cannot establish any "credible threat of harm" based on current or future "exposure to enhanced risk" from phthalates in such products (*id.* at 13-14), nor any "probability of harm" from such exposure caused by CPSC's delay. (*See* NAM Mem. at 14-19.) This conclusion applies whether the purported exposure to "enhanced" risk is assessed in isolation or cumulatively. In fact, CPSC's assessment of the most recent exposure data confirms that exposure to such risk is diminished, not enhanced. Furthermore, any risk of current or future exposure manifestly would not be redressed by the Consent Decree that plaintiffs seek, which sets only a deadline for CPSC to act, but does not dictate the rule's final content. (*Id.* at 21-24.)

Argument

I. THE COMPLAINT SHOULD BE DISMISSED BECAUSE PLAINTIFFS LACK ARTICLE III STANDING

A. Plaintiffs Have Not Adequately Established Associational Standing

Even in "procedural rights" cases (Pls. Mem. at 24), plaintiffs must show injury-in-fact that is "both concrete *and* particularized." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1545 (2016). To be particular, the injury "'must affect the plaintiff in a personal and individual way,'" and to be concrete, it "must actually exist" in the "usual meaning of the term—'real,' and not

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2017 analyses, they imply that the NAM "acknowledges" CPSC's cumulative risk analysis "only" to "criticize" its validity through "opinion testimony" from "NAM's in-house counsel." (Pls. Mem. at 19.) In fact, Mr. Palmieri works on consumer product safety policy issues, and does not serve as NAM's "in-house counsel." He submitted the NAM's comments in the regulatory proceedings. His declaration statements provide necessary context to show that, notwithstanding the NAM's issues with the CHAP's cumulative risk analysis, the CPSC's 2015 and 2017 analyses show that cumulative risk of phthalate exposure is no longer a concern even under the standard used by CPSC in publishing the 2014 proposed rule. (Palmieri Decl. ¶¶ 1-4, 9, 27 & Exs. A-C, F, J-L.)

'abstract.'" *Id.* at 1548. Plaintiffs attempt to cure their failure to adequately allege associational standing by filing declarations from members expressing generalized "concern" and "fear" about their children's potential exposure to phthalates in toys and child care articles.[3] (*See* Sarn Decl. ¶ 4; Getreu Decl. ¶¶ 4-5; Friesen Decl. ¶¶ 4, 7.) These declarations do not establish that any member has suffered a "concrete and particularized injury." *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009). "Mere interest in, or concern over, a prospective defendant's acts—no matter how deeply felt—is insufficient to demonstrate injury in fact." *Evans v. Lynn*, 537 F.2d 571, 591 (2d Cir. 1976). Plaintiffs also "cannot manufacture standing" based on subjective "fears of hypothetical future harm that is not certainly impending." *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1151 (2013). The members' concerns here "'in no way . . . distinguish[] them from the population at large.'" *NRDC v. FDA*, 710 F.3d 71, 85 (2d Cir. 2013).

B. Plaintiffs Have No Injury in Fact Based on Current or Future Exposure

The key findings in the record show that plaintiffs can establish no "credible threat" of current or future injury based on "exposure to enhanced risk" from "harmful" phthalates in toys and child care articles, whether exposure is considered individually or cumulatively. (NAM Mem. at 6-9, 14-19.) First, plaintiffs falsely claim the NAM does not "dispute the serious health harms associated with children's exposure to phthalates." (Pls. Mem. at 11.) The issue is intensely disputed, as evidenced by the hundreds of pages of public comment in response to the CHAP Report, the Notice of Proposed Rulemaking ("NPR"), and CPSC's

[3] The declarations also purport to support the claim that "parents have no practical way to ensure their children are not exposed to phthalates" in such products "because there is no federal labeling requirement for phthalates" (Pls. Mem. at 1; *see* Sarn Decl. ¶ 10), but a basic on-line search for "phthalate-free toys" produces a wealth of options. A search at http://www.google.com/ with the terms "phthalate free toys" on April 23, 2017 returned about 1,000,000 hits. The first three pages provided links to over twenty sites either directly selling phthalate-free toys or providing lists of companies selling such toys. For example, a "Mommy Goes Green" website has blog posts linking to numerous sites for sellers of phthalate-free bath, water, and sand toys. *See* http://mommygoesgreen.com/2014/01/2014-guide-to-safer-bath-toys-pvc-free-phthalate-free-bpa-free/; http://mommygoesgreen.com/2015/08/safe-beach-and-water-toys-guide/. The lists include toys found at "big box" stores. *See* http://mommygoesgreen.com/2009/10/safe-bath-toys/.

2015 and 2017 analyses using more recent data. (*See* Joint Preliminary Conference Letter (Docket Entry No. 20) at 2-3.) Among other reasons, the comments show there is no human health harm because CPSC's 2015 and 2017 updated estimates of phthalates exposure using more recent data confirm that "cumulative risk" of phthalates exposure—from all sources—has declined below the margin of safety used by CPSC in publishing the proposed rule in 2014. (Palmieri Decl. ¶ 27 & Ex. B at 1.) Second, plaintiffs' "concerns" about *current* exposure are not reasonable, and provide no basis for standing, because the CHAP determined that any risk of current exposure is "low" (Palmieri Decl. ¶ 26) and, as plaintiffs concede, does "'not indicate a high level of concern'" (Pls. Mem. at 18 n.7); *see City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983). Plaintiffs do not dispute that (i) the CHAP determined that DPENP, DHEXP, and DCHP are "not 'currently found'" in such products (Pls. Mem. at 7); (ii) the CPSC has not detected DPENP, DHEXP, and DCHP during compliance testing (*id.* at 9, 10); and (iii) the CHAP concluded that the recommended ban, if implemented, would not reduce exposure to children from DPENP, DHEXP, and DCHP in such products.[4]

The CHAP also found that current exposures to DIBP and DINP are low and do not pose a concern, notwithstanding the presence of DIBP in a few testing samples. (NAM Mem. at 8, 14-17.) Plaintiffs assert there is a "risk of current exposure" because DIBP and DINP allegedly "are found in up to one in five children's products on the market." (Pls. Mem. at 2.) They base this claim on a statistically erroneous extrapolation from samples in CPSC's testing program in which "DIBP was detected in 132 of the 1125 (11.7%)" products sampled, and "DINP was found in 93 of the 1125 (8.3%)" samples. (*Id.* at 16.) However, CPSC noted that

[4] (*See* NAM Mem. at 7, 14-15.) Plaintiffs' claim that these three phthalates might potentially be "substitute[d]" for banned phthalates (Pls. Mem. at 7) is too speculative to constitute injury in fact. *See Abidor v. Napolitano*, 990 F. Supp. 2d 260, 272 (E.D.N.Y. 2013) (no standing to assert "claim of alleged injury based on speculation as to conduct which may or may not occur at some unspecified future date").

the samples containing DIBP and DINP had been *pre-screened* for the presence of phthalates for testing purposes; thus, the actual percentages of products with these phthalates in the toy universe would have been far lower.[5] Furthermore, even though "DIBP has been detected in a small portion of toys tested by the staff," the CHAP "found that current exposures to DIBP are low," and "do not indicate a high level of concern." (Palmieri Decl. ¶ 26.) As plaintiffs also concede (Pls. Mem. at 18 n.7), the CHAP found "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products" from DIBP. (Palmieri Decl. ¶ 26.) Plaintiffs ignore the CHAP's conclusion that "[t]here would be little reduction in exposure" to children from DIBP if the ban of DIBP were implemented.[6] (*Id.*)

Similarly, the CPSC "staff concluded that DINP *would not present a hazard to consumers*" when "[c]onsidered in isolation." (*Id.* Ex. H, 79 Fed. Reg. at 78334 (emphasis added).) Thus, the presence of DINP in a small number of toys tested by CPSC (93 of 1125)—even smaller than samples containing DIBP—does not indicate a cognizable level of concern for exposure to enhanced risk. Plaintiffs do not dispute that DINP has been subject to an interim ban since February 10, 2009 that will remain in place until CPSC issues a final rule.[7] Plaintiffs also

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[5] CPSC noted that its samples were "not necessarily an accurate representation of the market" due to "the screening process and the goals of the agency." (Knicley Decl. Ex. A at 1.) There were "biases . . . inherent in the dataset" because, among other reasons, the "samples chosen for testing had been pre-screened" for the presence of phthalates. (*Id.*) Thus, plaintiffs' claims that DINP and DIBP "are already present in up to 20% of children's products" (Pls. Mem. at 22), and that "perhaps up to one in every five" of such products contain DINP or DIBP (*id.* at 21), are statistically flawed and inaccurate.

[6] Plaintiffs cite a 2015 U.S. PIRG report identifying one toy containing DIPB at "*190 times*" (Pls. Mem. at 17; Knicley Decl. Ex. B) the proposed ban on DIPB in concentrations above the *de minimus* 0.1 percent level used for the CPSIA phthalate bans. But the *de minimus* level is not a health limit. Because the CHAP found that exposures to DIPB *from all sources* do not pose a risk of concern, exposure from a single toy does not pose a concern. The 2016 U.S. PIRG report identifies no toys containing phthalates from the several hundred purchased and tested. *See* http://www.uspirg.org/sites/pirg/files/reports/USP%20Toyland%20Report%20Nov16%201.1.pdf (methodology at p. 14).

[7] It is likely that most of the 93 DINP-detected toys were found early in the interim ban period. Violation data posted on the CPSC website (https://www.cpsc.gov/Recalls/violations/) show only two violations of the interim ban on phthalates since 2014 (which may have been due to DIDP or DNOP—phthalates that the CHAP determined should not be banned permanently—rather than DINP).

do not dispute the CHAP's determination that although DINP had been "used in children's toys and child care articles in the past," a permanent ban would not reduce current exposure of children to DINP, "because DINP is currently subject to an interim ban on use" in such products. (Palmieri Decl. ¶ 24.) Likewise, expansion of the DINP ban "to cover *all* toys, not just those that can be mouthed" (Pls. Mem. at 16), does not indicate any enhanced risk of exposure from toys not covered by the interim ban. CPSC noted less than 1% (5 of 93) of samples containing DINP "were considered not able to be placed in a child's mouth." (Knicley Decl. Ex. A at 2.) CPSC thus determined "[t]he percentage of all children's toys that could be impacted by broadening the restrictions on the use of DINP to all children's toys would be substantially less than 1 percent because the only samples reviewed in this analysis were those that were already found to contain phthalates using infrared screening techniques. This would be a small subset of all children's toys." (Ex. H, 79 Fed. Reg. at 78340.)

Thus, plaintiffs cannot establish any "credible threat of harm" based on "exposure to enhanced risk" to phthalates in such products, *NRDC*, 710 F.3d at 81, nor any non-trivial "probability of harm" from such exposure caused by CPSC's delay, *Nat'l Council of La Raza v. Gonzales*, 468 F. Supp. 2d 429, 438-39 (E.D.N.Y. 2007). Because the phthalates at issue either currently are not found in such products or present no quantifiable exposures from such products, current exposures are low and do not pose a concern for safety. The CPSC 2015 and 2017 analyses also show no cumulative risk of concern. Plaintiffs thus cannot establish any "direct risk of harm which rises above mere conjecture." *Baur v. Veneman*, 352 F.3d 625, 636 (2d Cir. 2003). This case is therefore distinguishable from *Baur*, where the court found a "credible threat of harm" from exposure to contaminated beef because unreliable testing methods made it impossible to determine whether a downed animal was contaminated, and thus to assess the likelihood of potential exposure. *Id*. at 638-41. Here, by contrast, the CHAP and CPSC have

reliably determined that current exposures are "low" and do "not indicate a high level of concern." The decision in *NYPIRG v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003), is also inapposite, because here there is no "health-related *uncertainty*" based on phthalate exposure. *See NRDC*, 710 F.3d at 85-86; *La Raza*, 468 F. Supp. 2d at 438-39.

Finally, plaintiffs can establish no credible threat of potential *future* exposure based on "concerns" about potential cumulative exposure to phthalates caused by CPSC's delay. Allegations "'of *possible* future injury' are not sufficient" to establish injury in fact; rather, the "'threatened injury must be *certainly impending* to constitute injury in fact.'" *Clapper*, 133 S. Ct. at 1147 (emphasis added). Plaintiffs' concerns and fears are merely subjective and the record establishes no such "certainly impending" threatened injury caused by CPSC's delay.

In fact, hypothetical injury from potential cumulative risk is too speculative and contingent on the possibility that manufacturers might begin using the phthalates in such products in the future, and on the uncertain assumption that plaintiffs would be exposed to such products and to additional sources of other phthalates not at issue here. *See Taylor v. Bernanke*, No. 13-CV-1013, 2013 WL 4811222, at *6–7 (E.D.N.Y. Sept. 9, 2013). Standing "will not be found where the occurrence of the alleged future injury depends on a 'highly attenuated chain of possibilities'" that are "contingent upon 'guesswork' as to the actions of third parties," such as the unknown future actions of manufacturers or the regulator. *Id.*; *see NRDC*, 710 F.3d at 86 (triclocarban exposure was "less like a present injury and more like a *threatened* injury that is contingent and far-off rather than imminent," and "too causally remote"). Indeed, CPSC acknowledged that the proposed rule "is intended to prevent these phthalates from being used in children's toys and child care articles *in the future*." (Ex. H, 79 Fed. Reg. at 78340 (emphasis added).) The CHAP also determined that the rule, if implemented, would prevent these phthalates from contributing to potential cumulative risk if they were used in the future in toys

and child care articles, and if they were aggregated with exposures from other sources of phthalates. (*Id.* at 78329-30.)

The record establishes that concerns about possible future exposure based on cumulative risk are also unfounded in light of more recent data—which plaintiffs ignore—from CPSC's 2015 and 2017 analyses. (*See* NAM Mem. at 8-9.) The CHAP's cumulative risk methodology assessed the risk from simultaneous exposure to multiple phthalates from all sources. (Palmieri Decl. Ex. H, 79 Fed. Reg. at 78327.) The results of that cumulative risk assessment, used for the CPSC NPR, were based on exposures given by biomonitoring data from 2005/2006. (*Id.* ¶ 6.) The CHAP's methodology yields a value called a "Hazard Index"; if the Hazard Index is above one, there is a risk of concern from cumulative exposure, but if the Hazard Index is below one, there is no risk of concern. (*Id.* Ex. H, 79 Fed. Reg. at 78327-28, 78332, 78334.) Using 2005/2006 data, the CHAP found that, at the 95th percentile (representing a value equal to or higher than the values for 95 percent of the women tested), the Hazard Index was above one, and on that basis recommended a permanent ban. (*Id.* at 78328-30.) But in 2015, CPSC applied the CHAP's methodology to calculate cumulative risk using more recent data from 2007-2012. This showed the Hazard Index dropping, with the value at the 95th percentile, using 2011-12 data, well below one. (*Id.* Ex. K at ii-iii, 2, 13, Table 6.) In 2017, using 2013/1014 data, CPSC determined the 95th percentile Hazard Index was even lower than in the 2015 analysis. (*Id.* Ex. L at 4, Table 5.) Because these assessments show there is no concern for cumulative risk exposure, plaintiffs' concerns about hypotherical future harm based on cumulative risk are too speculative and causally remote to establish injury in fact.

C. Plaintiffs Fail to Satisfy the Causation and Redressability Requirements

Although plaintiffs argue that causation and redressability are "relaxed" in procedural rights cases (Pls. Mem. at 12), these requirements are "not toothless." *NRDC v. Fed.*

Hous. Fin. Agency, 815 F. Supp. 2d 630, 637, 640-41 (S.D.N.Y. 2011). Where, as here, "a litigant complaining of procedural or substantive injury *is not the regulated party* . . . [it] must demonstrate that favorable action by the agency is *likely* to result in favorable action by the regulated party in addition to demonstrating a link between the procedural or substantive injury to the litigant and the adverse agency action." *Town of Babylon v. Fed. Hous. Fin. Agency*, 699 F.3d 221, 229 (2d Cir. 2012) (emphasis added). The Second Circuit has emphasized that such plaintiffs in procedural rights cases must "show that it is likely, as opposed to merely speculative," that the alleged injury will be redressed by the relief sought.[8] *Id.* at 230.

Plaintiffs are not the regulated parties here and cannot establish causation or redressability because the procedural violation they assert relates only to CPSC's *delay* in issuing a final rule. (*See* NAM Mem. at 20-24.) Plaintiffs cannot show the requisite causal "link" between the procedural delay and the alleged harm from risk of exposure, because the CHAP and CPSC have determined that the risk of current exposure or future cumulative exposure is low and does not indicate a cognizable level of concern. (NAM Mem. at 20-21); *see Babylon*, 699 F.3d at 229. Likewise, *NRDC v. EPA* does not support plaintiffs' causation claim (Pls. Mem. at 23), because there the evidence showed that "FDA's conduct contribute[d] to [the plaintiff's] triclosan exposure *because triclosan would not be available on the market but for FDA's failure to finalize its regulation*." *NRDC*, 710 F.3d at 85 (emphasis added). Here, there is no "but for" causal relationship between CPSC's delay and the alleged injury, but only mere "guesswork," because an order requiring a final rule by a date certain may or may not result in a permanent ban that eliminates the hypothetical harm from exposure to the phthalates.

[8] *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007), is inapposite because it depended on the "special solicitude" extended to sovereign states in litigation. *See Arpaio v. Obama*, 797 F.3d 11, 27 (D.C. Cir. 2015) (Brown, J., concurring) (noting that *Massachusetts* is "cast in concerns over state sovereignty" and "likely does not extend to non-state litigants" who "must clear the ordinary hurdles to standing").

Plaintiffs thus cannot show that the relief in the Consent Decree—an end to the agency's delay—"*is likely* to result in a favorable action by the regulated party." *Babylon*, 699 F.3d at 229 (emphasis added). Plaintiffs assert that "the proposed Consent Decree only would set a deadline for the CPSC to fulfill its duty to determine *which, if any,* phthalates to permanently ban. That determination will be part of an administrative process '*separate and distinct from this action*.'" (Docket Entry No. 42 at 8 (emphasis added).) Because the Consent Decree only addresses "timing" and "does not affect or constrain the CPSC's discretion as to the substance of the final rule" (*id.* at 7), plaintiffs cannot establish redressability by arguing hypothetically that their alleged harm from exposure would be "redressed *if* the CPSC finalized the *proposed* phthalates rule." (Pls. Mem. at 24 (emphasis added).) Because the outcome of the final rule is contingent and unaffected either way by the Consent Decree, plaintiffs cannot "show that it is likely, as opposed to merely speculative," that their alleged harm from exposure to enhanced risk will be redressed by entry of the Consent Decree. *Babylon*, 699 F.3d at 230.

Conclusion

For the foregoing reasons and those stated in its moving papers, the NAM respectfully requests an order dismissing the Complaint for lack of subject-matter jurisdiction.

Dated: New York, New York
April 25, 2017

Respectfully submitted,

SIDLEY AUSTIN LLP

By: /s/ John J. Lavelle
John J. Lavelle
Sonia Marquez
Nicholas M. McLean
787 Seventh Avenue
New York, New York 10019
Telephone: (212) 839-5300
Facsimile: (212) 839-5599
jlavelle@sidley.com

Attorneys for Proposed Intervenor the NAM