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.	:	

ADDITIONAL REPLY MEMORANDUM OF LAW IN RESPONSE TO DEFENDANT CPSC'S OPPOSITION AND IN FURTHER SUPPORT OF THE NATIONAL ASSOCIATION OF MANUFACTURERS' MOTIONS TO INTERVENE AND TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION

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Preliminary Statement

At the outset of this lawsuit, CPSC asserted an affirmative defense based on lack of subject-matter jurisdiction and advised the Court that it contemplated a motion for summary judgment because plaintiffs could not "present sufficient evidence to satisfy the 'injury-in-fact' requirement for standing." (Joint Letter, D.E. 20 at 3 (citing *NRDC v. FDA*, 710 F.3d 71, 81, 85-86 (2d Cir. 2013).) Although CPSC has now reversed its position for settlement purposes (CPSC Mem. at 13-14), plaintiffs still lack standing to pursue their claims. Key findings in the administrative record show that plaintiffs can establish no "'credible threat'" of current or future injury in fact based on exposure to "'a sufficiently serious risk of medical harm'" from phthalates in toys and child care articles. (*Id.* at 16 (citation omitted).) CPSC likewise shows no credible threat of harm from exposure to phthalates in the products at issue, and ignores the undisputed fact that cumulative risk of harm from exposure to phthalates from *all sources* is actually diminished, rather than enhanced, based on CPSC's own analyses of risk using more recent phthalate exposure data. Furthermore, in addition to the reasons in the NAM's prior submissions, intervention should be granted because CPSC has not adequately represented the NAM's interests in preventing plaintiffs who lack standing from imposing an unrealistic deadline that will harm the NAM's interests in obtaining a scientifically sound final rule.

Argument

I. PLAINTIFFS LACK STANDING UNDER ARTICLE III

A. Plaintiffs Have Not Satisfied the Injury-In-Fact Requirement

In its half-hearted opposition, CPSC presents no declarations of its own but merely reiterates arguments made by plaintiffs that the NAM has already refuted. First, CPSC concedes that plaintiffs' conclusory standing allegations "are presented at a high level of generality," but mistakenly contends that "the Court, at this stage, *may presume* that such

allegations embrace those specific facts." (*Id.* (emphasis added).) Such a presumption is unwarranted and erroneously treats the NAM's 12(b)(1) motion as a facial, rather than a factual, challenge to subject-matter jurisdiction based on extensive record evidence from the rulemaking. "While a court must accept as true all the material allegations of the complaint in a *facial* attack," in a "*factual* challenge, by contrast, 'no presumptive truthfulness attaches to the complaint's jurisdictional allegations; rather, the burden is on the plaintiff to satisfy the Court, as fact-finder, of the jurisdictional facts.'" *Tasini v. N.Y. Times Co.*, 184 F. Supp. 2d 350, 353-54 (S.D.N.Y. 2002) (citations omitted). Because a "*factual* jurisdictional challenge is involved" on this motion, "the court is permitted to refer to evidence extrinsic to the pleadings." *Id.* at 354. Jurisdiction "must be shown affirmatively, and that showing is not made by drawing from the pleadings inferences favorable to the party asserting it." *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 607 F. Supp. 2d 500, 503 (S.D.N.Y. 2009) (Castel, J.), *aff'd*, 671 F.3d 140 (2d Cir. 2011).

The Court therefore cannot simply "presume" that plaintiffs' standing allegations are "sufficient, *at this stage of the litigation*," as CPSC repeatedly asserts. (CPSC Mem. at 14, 16 (emphasis added).) Although made at a "preliminary stage" of this litigation (*id.* at 14), the NAM's motion is based on substantial record evidence from seven years of rulemaking proceedings by the CHAP and CPSC. In fact, CPSC concedes that the record evidence is material because "issues fundamental to the standing analysis—*i.e.*, whether Plaintiffs' members are experiencing an injury in fact based on exposure to phthalates in children's toys and child care articles—are intertwined with the substantive analysis being undertaken by CPSC as part of the rulemaking process." (*Id.* at 14.) Plaintiffs' allegations are thus entitled to no presumption or inference of sufficiency "at this stage" of the litigation.

Second, CPSC falsely contends that "the NAM does not appear to contest any of the allegations as to potential harms to human health from exposure to phthalates." (*Id.* at 16.) As the NAM's moving papers showed, 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 2015 and 2017 analyses using more recent data. That evidence shows there is no human health harm because CPSC's updated estimates of phthalates exposure confirm that "cumulative risk" of harm from exposure to phthalates from all sources has declined below the margin of safety used by CPSC to issue the proposed rule in 2014. (Palmieri Decl. ¶ 27.) Significantly, CPSC does not address, let alone contest, its own 2015 and 2017 cumulative risk analyses in its brief.

Third, CPSC incorrectly asserts that there are "specific facts" in the administrative record that adequately support plaintiffs' standing allegations, but simply states that "Plaintiffs point to evidence to indicate that a meaningful number" of children's toys and child care articles "contain two of the phthalates – DINP and DIBP." (*Id.* at 16-17.) CPSC thus relies entirely on the same October 2014 CPSC testing memorandum cited in plaintiffs' opposition brief in which DINP was detected in "approximately 8 percent of samples," and DIBP "was found in nearly 12 percent of samples tested." (CPSC Mem. at 17; *see* NAM 4/25/17 Reply Mem. at 4-5.)

But the broader record refutes CPSC's claim that those few testing samples are "meaningful" at all in terms of presenting any current credible risk of harm from exposure to DIBP or DINP.[1] (CPSC Mem. at 16-17.) The CHAP in fact determined that any such risk of

[1] CPSC does not dispute that (i) the CHAP determined that DPENP, DHEXP, and DCHP are "not 'currently found'" in such products (CPSC Mem. at 4); (ii) CPSC staff has not detected DPENP, DHEXP, and DCHP during compliance testing; 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.

harm from exposure is "low" and does "'not indicate a high level of concern,'" notwithstanding the presence of DIBP in a few testing samples. (Palmieri Decl. ¶ 26 (citations omitted)). CPSC in the cited memo admitted that 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 market would have been far lower.[2] CPSC further noted that even though "DIBP has been detected in a small portion of toys tested by the staff," it "is not widely used in toys and child care articles." (*Id.* ¶ 26 & Ex. H, 79 Fed. Reg. at 7839-40.) The CHAP therefore "found that current exposures to DIBP are low," and "do not indicate a high level of concern." (*Id.* Ex. H at 78330, 78336.) Significantly, CPSC does not dispute that the CHAP found "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products" from DIBP, and ignores the CHAP's conclusion that "[t]here would be little reduction in exposure" to children from DIBP if the ban of DIBP were implemented. (*Id.*)

Similarly, CPSC ignores that its own "staff concluded that DINP *would not present a hazard to consumers*" when exposures are "[c]onsidered in isolation." (*Id.* Ex. H, 79 Fed. Reg. at 78334 (emphasis added).) Therefore, the presence of DINP in a small number of test samples does not indicate a "meaningful" level of safety concern. (CPSC Mem. at 17.) CPSC also ignores the CHAP's determination that while DINP had been "used in children's toys and child care articles in the past," a permanent ban would not reduce current exposure to children from DINP, "because DINP is currently subject to an interim ban on use" in such products. (Palmieri Decl. ¶ 24.) Although CPSC claims that the NAM "overstates" the

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(*See* NAM Dismiss Mem. at 7, 15-16); *see also NRDC*, 710 F.3d at 86 (plaintiffs must establish standing "'for each claim and form of relief sought.'") (citation omitted).

[2] CPSC further explained 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.*)

significance of the interim ban,[3] the presence of a "small number" of samples containing DINP that were "too large to be subject to the interim ban" does not suggest, as CPSC contends, that "there is very likely an additional degree of exposure to DINP in products" not currently subject to the ban that would raise a meaningful health concern. (CPSC Mem. at 17 & n.17.) In fact, CPSC noted less than 1 percent (5 of 93) of samples containing DINP were not considered mouthable (*i.e.*, not subject to the ban). (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." (Palmieri Decl. Ex. H, 79 Fed. Reg. at 78340.)

For these reasons, plaintiffs cannot establish any "credible threat of harm" from exposure 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). Any probability of harm is vanishingly low because the phthalates at issue either are not found in such products or are present at non-quantifiable levels that pose no concern for safety. (*See* NAM Dismiss Mem. at 8-9, 15-17.) Furthermore, CPSC's 2015 and 2017 analyses also show that the cumulative risk of harm from

[3] CPSC claims that the interim ban "theoretically should have eliminated the potential for exposure to DINP" in mouthable toys but "did not even do that" because DINP was found in a small number of testing samples. (CPSC Mem. at 17.) The logic of CPSC's argument would further undermine plaintiffs' redressability argument because it is unlikely that the Consent Decree—or even a permanent ban—would be any more effective in preventing exposures from violations of the interim ban on using DINP in mouthable toys. In any event, it is likely that most of the 93 DINP-detected toys cited in the October 2014 testing memorandum 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).

exposure to all sources of phthalates is below the level of concern, a fact that CPSC ignores.[4] That cumulative risk assessment was based on exposures given by biomonitoring data from 2005/2006, using a "Hazard Index" in which a value above one indicated a risk of concern from cumulative exposure, while a value below one indicated no risk of concern. (Palmieri Decl. 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 and found the Hazard Index dropping, with the value at the 95th percentile using 2011-2012 data well below one. (*Id.* Ex. K at ii-iii, 2, 13, Table 6.) In 2017, using 2013/2014 data, CPSC determined the 95th percentile Hazard Index was even lower than in the 2015 analysis.[5] (*Id.* Ex. L at 4, Table 5.) This shows there is no concern for cumulative risk of harm from exposure to phthalates from *all* sources.

For these reasons, it is not "credible" that exposure to any of the phthalates at issue in toys or child care articles could pose a "sufficiently serious risk of medical harm" to establish injury in fact. *NRDC*, 710 F.3d at 81 (quotation omitted). Plaintiffs thus can establish no "direct risk of harm which rises above mere conjecture." *Baur v. Veneman*, 352 F.3d 625, 636 (2d Cir. 2003). In *Baur*, by contrast, 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

[4] Although CPSC states that it "generally concluded that a permanent ban of all five of these phthalates is necessary to protect the health of children" (CPSC Mem. at 4), it does not mention that the basis for the ban was to prevent hypothetical future use of these phthalates in toys and child care articles from contributing to a "cumulative risk of harm" from aggregate exposure to phthalates from all sources (*see* NAM Dismiss Mem. at 8-9).

[5] CPSC found that Hazard Index values above the 95th percentile are "statistically unstable" and unreliable. (Palmieri Decl. Ex. L at 4.)

potential exposure. *Id*. at 638-41. Here, the record shows that the CHAP and CPSC reliably determined that risk of harm from exposures is "low" and does "not indicate a high level of concern." (NAM Dismiss Mem. at 8, 18.) Plaintiffs also can establish no credible threat of *future* harm based on hypothetical cumulative exposures to phthalates, particularly given the undisputed downward trend in risk shown in CPSC's 2015 and 2017 analyses. Allegations of such "'*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 v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013) (citation omitted). Plaintiffs' subjective "fears of hypothetical future harm" from phthalates exposure are speculative, and there is no record of such "certainly impending" injury. *Id.* at 1151; *see also NRDC*, 710 F.3d at 85-86.

B. Plaintiffs Have Not Satisfied the Causation and Redressability Requirements

CPSC's perfunctory discussion of causation and redressability (CPSC Mem. at 18-19) does not address the Second Circuit's requirement that "a litigant complaining of procedural or substantive injury" who "*is not the regulated party*" 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). Plaintiffs are not the regulated parties here and the procedural violation they assert relates only to CPSC's delay. (*See* NAM Dismiss Mem. at 20-24.)

Plaintiffs can show no causal "link" between that procedural delay and their alleged harm because the CPSC has determined that the risk of current or future harm from exposure is low, and does not indicate a credible safety concern. (*Id*. at 20-22.) CPSC's argument that its "delay" is "contributing to the continued exposure of Plaintiffs' members to certain phthalates" thus is not supported by the record, and does not establish causation. (CPSC

Mem. at 18.) CPSC's reliance on *NRDC v. FDA* for the proposition that causation may be shown by conduct that merely "contributes" to the alleged harm is also misplaced (*id.* at 18), because causation there depended on a "but for" relationship between the agency's delay and the alleged exposure. The plaintiff 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, because the phthalates at issue currently have no significant presence in the children's product marketplace, and an order setting a deadline may or may not result in a permanent ban that eliminates the hypothetical harm from phthalates exposure.[6]

CPSC's claim that plaintiffs' injury is redressable (CPSC Mem. at 18-19) also ignores the Second Circuit's requirement that plaintiffs in procedural rights cases who are "not the regulated party" must "show that it is *likely*, as opposed to merely speculative," that the alleged injury will be redressed by the relief sought. *Babylon*, 699 F.3d at 229-30 (emphasis added). Plaintiffs 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," *id.* at 229, because "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" (D.E. 42 at 8 (emphasis added).) Because the outcome of the final rule is contingent and unaffected either way by the Consent Decree,

[6] *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007), on which CPSC relied, is also inapposite because the case 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 cannot "show that it is likely, as opposed to merely speculative," that the Consent Decree will redress their alleged harm. *Babylon*, 699 F.3d at 230.

II. THE NAM MEETS THE REQUIREMENTS FOR INTERVENTION

CPSC argues that the NAM has not satisfied the related interest, impairment or adequacy of representation requirements for intervention under Rule 24(a). (CPSC Mem. at 7.) The NAM has already addressed the sufficiency of the first two requirements in its moving and reply brief in response to plaintiffs' opposition. (NAM Int. Mem. at 11-21; NAM 4/27/17 Reply Mem. at 2-9.) CPSC's arguments that the NAM's interests are adequately protected are similarly meritless, and the NAM easily meets its "minimal" burden of showing that representation of its interests here "may be" inadequate. (NAM Int. Mem. at 21.)

First, CPSC does not and cannot dispute that its decision to settle means the agency will not adequately represent the NAM's interests by vigorously contesting subject-matter jurisdiction. (CPSC Mem. at 11.) It is absurd for CPSC to characterize this obvious diversion of interests as a mere difference in "'views'" about the "'likelihood of success of a particular litigation strategy.'" (*Id.* (citation omitted).) CPSC has affirmatively opposed the NAM's motion to dismiss for lack of subject-matter jurisdiction so there can be little doubt that its representation of the NAM's interests on this fundamental issue is not only inadequate, but inimical. Indeed, courts have recognized that intervention is appropriate in such circumstances where "neither party has an interest in contesting jurisdiction," and the court's jurisdictional "inquiry is aided by the presence" of an intervenor that will challenge jurisdiction. *Elliott Indus. L.P. v. BP Am. Prod. Co.*, 407 F.3d 1091, 1103-04 (10th Cir. 2005).

Second, the "presumption" that the government's interests are "aligned" with those of the NAM (CPSC Mem. at 12-13) does not apply here because CPSC's broader regulatory interests clearly diverge from the NAM's narrower private interests (NAM Int. Mem.

at 22-23). This is true even if those interests are limited to timing (CPSC Mem. at 12), because in seeking to settle this litigation, the CPSC necessarily would have moved away from its optimal view of the amount of time needed to implement a scientifically sound rule in order to reach a compromise with plaintiffs. That concern is compounded by CPSC's admission that it negotiated the Consent Decree before it received and reviewed all of the comments to the 2017 reanalysis. (*Id.* at 9.) CPSC attempts to minimize this fact by emphasizing the "modest volume" of pages of comments (*id.* at 10), when the relevant issue is that CPSC negotiated a deadline without analyzing the scientific substance of those comments. CPSC historically has not been an accurate judge of the time needed to conduct such a scientifically complex rulemaking (*see* NAM Int. Mem. at 2, 16), and the NAM thus has ample support to claim that its interests in ensuring sufficient time to produce a scientifically sound rule are not adequately represented by CPSC. Finally, permissive intervention is also appropriate because it will not cause delay or prejudice, but in fact will assist the Court's jurisdictional inquiry. (*Id.* at 23-25.)

Conclusion

For the foregoing reasons, in addition to those in its moving papers, the NAM respectfully requests that the Court grant its motions to intervene and to dismiss the complaint for lack of subject-matter jurisdiction.

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Respectfully submitted,

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