IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, *et al.*,	)	
Plaintiffs,	)	
v.	)	16-cv-9401 (PKC)
	)	ECF Case
UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,	)	
Defendant,	)	
and	)	
NATIONAL ASSOCIATION OF MANUFACTURERS,	)	
Proposed-Intervenor-Defendant.	)	

PLAINTIFFS' OPPOSITION TO PROPOSED-INTERVENOR NATIONAL ASSOCIATION OF MANUFACTURERS' MOTION TO DISMISS

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INTRODUCTION

Phthalates are a class of chemicals associated with severe and permanent reproductive and developmental harms in children. They are also commonly used in a variety of plastic products. But because there is no federal labeling requirement for phthalates, parents have no practical way to ensure their children are not exposed to phthalates from those products.

Congress recognized the risk to children from phthalates in 2008, when it permanently banned the use of three types of phthalates in all child care articles and toys, and imposed an interim ban on three additional types of phthalates in child care articles and those toys small enough to be placed in a child's mouth. Congress also directed the U.S. Consumer Product Safety Commission (CPSC) to issue a rule determining whether to make the interim bans permanent and whether to ban any additional phthalates as necessary to protect children's health.

In 2014, the CPSC proposed a rule to make permanent Congress's interim ban for one phthalate—known as DINP—and to extend the ban to all children's toys, no matter the size. The CPSC had found DINP in numerous children's products during testing. Making the interim ban permanent and extending it to all toys was, in the words of the CPSC, "necessary to ensure a reasonable certainty of no harm to children with an adequate margin of safety."

In that same proposed rule, CPSC also proposed to ban four additional phthalates—known as DIBP, DPENP, DHEXP, and DCHP—from use in all child care articles and toys. The CPSC detected DIBP in more than one out of every nine

children's products it had tested, and concluded the other three phthalates might be "substituted" in plastic products to replace the phthalates permanently banned by Congress. The CPSC thus determined that banning these phthalates in children's products was "necessary to protect the health of children."

After the proposed rule, the CPSC took no further action and violated the statutory deadline to issue a final rule determining which phthalates to permanently ban from use in children's products. Plaintiffs sued the CPSC to compel it to issue a final phthalates rule, and the parties have proposed a consent decree to settle the case.

Plaintiffs have standing to bring this case, and the Court has jurisdiction to enter the consent decree. Contrary to the protest of proposed-intervenor National Association of Manufacturers (NAM), Plaintiffs have alleged—and the CPSC's own conclusions establish—a credible threat of harm to Plaintiffs' members' children from phthalates in children's products. NAM is wrong that there is no risk of current exposure to phthalates in children's products: at least two phthalates the CPSC has proposed to ban—DINP and DIBP—are found in up to one in five children's products on the market. NAM also misrepresents the effect of the interim ban on DINP. That ban only applies to a subset of children's toys, and the CPSC has proposed to extend the ban to cover all toys to protect children from an undisputed health risk. The risk to Plaintiffs' members' children is real. And the CPSC's illegal delay in finalizing a phthalates rule is perpetuating this risk. Plaintiffs need not show anything more to seek and secure relief from this Court.

BACKGROUND

I. Children's exposure to phthalates is associated with permanent reproductive harm.

Phthalates are a class of chemicals used to soften plastics. Compl. ¶ 1, ECF No. 1; Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 79 Fed. Reg. 78,324, 78,324 (proposed Dec. 30, 2014). These chemicals are common in a variety of plastic products, including toys and child care articles, such as teething rings. Compl. ¶ 1. Phthalates leach from the products to which they are added, creating human exposure through the mouth and skin. *Id.*

Phthalates are associated with numerous harms to human health, and the CPSC regards many phthalates as "probably toxic to humans." 79 Fed. Reg. at 78,332; Compl. ¶ 2. Phthalates interfere with hormone production, which is especially problematic in utero, during infancy, and during childhood. Compl. ¶ 2. Human exposure to phthalates during those periods can cause permanent reproductive harm, particularly in males. *Id.*; 79 Fed. Reg. at 78,332. A growing body of literature links children's exposure to phthalates with decreases in testosterone, undescended testicles, malformations of the penis, and reduced sperm production. Compl. ¶ 2; 79 Fed. Reg. at 78,326–27, 78,332. Additional studies have found associations between infants' exposure to phthalates and neurobehavioral harm, including "reductions in mental and psychomotor development" and "increases in attention deficits and behavioral symptoms." 79 Fed. Reg. at 78,326.

There is no labeling requirement for phthalates, even for products intended for use by children. As a result, it is "impossible" for parents to ensure that the

plastic toys and child care articles their children use are free of phthalates. Decl. of Janet Friesen ¶ 5; Decl. of Elyssa Getreu ¶ 6; *see also* Decl. of Audrey Sarn ¶ 10.

II. Congress passed the Consumer Product Safety Improvement Act to address the risks associated with phthalates in children's products.

Congress recognized the serious threat that phthalates pose to children when it passed the Consumer Product Safety Improvement Act of 2008 (CPSIA). Pub. L. No. 110-314, 122 Stat. 3016 (2008). The CPSIA established a three-part framework to limit children's exposure to phthalates in children's toys[1] and child care articles.[2]

First, Congress permanently banned the manufacture, sale, distribution, or import of all children's toys and child care articles that contain more than 0.1% of any of three different phthalates, known as DEHP, DBP, and BBP. 15 U.S.C. § 2057c(a). This permanent ban went into effect February 10, 2009. *Id.*; *see also NRDC v. U.S. CPSC*, 597 F. Supp. 2d 370, 379–90 (S.D.N.Y. 2009).

Second, Congress banned on an interim basis the manufacture, sale, distribution, or import of all child care articles and certain children's toys that contain more than 0.1% of any of three other phthalates, known as DINP, DIDP, and DnOP. 15 U.S.C. § 2057c(b)(1). Unlike the permanent ban, the interim ban covers only toys "that can be placed in a child's mouth."[3] *Id.* The interim ban went

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[1] A "children's toy" is any consumer product "designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." 15 U.S.C. § 2057c(g)(1)(B).

[2] A "child care article" is any consumer product "designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." 15 U.S.C. § 2057c(g)(1)(C).

[3] A toy "can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and

into effect February 10, 2009. *Id.*

Third, Congress directed the CPSC to determine whether to make the interim bans permanent and whether to ban additional phthalates from children's products. *See id.* § 2057c(b)(2)–(3). The Act required the CPSC to convene a Chronic Hazard Advisory Panel (CHAP) "to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." *Id.* § 2057c(b)(2)(A). This study must include, among other things, "an examination of the full range of phthalates that are used in products for children," *id.* § 2057c(b)(2)(B), the "potential health effects" of phthalates, and the "cumulative effect of total exposure to phthalates, both from children's products and from other sources," *id.* § 2057c(b)(2)(B)(i)–(ii), (iv). Based on that examination, the CHAP must present a report and recommendations to the CPSC regarding which phthalates or phthalate alternatives, other than those already permanently banned, should be permanently banned from use in children's products. *Id.* § 2057c(b)(2)(C).

After receiving the CHAP's report, the CPSC has 180 days to issue a final phthalates rule. *Id.* § 2057c(b)(3). In that final rule, the CPSC must determine whether to make the interim bans under the CPSIA permanent "to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety," *id.* § 2057c(b)(3)(A), and whether to permanently ban any other phthalate "as the Commission determines necessary to protect the health of children," *id.* § 2057c(b)(3)(B).

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chewed." 15 U.S.C. § 2057c(g)(2)(B).

III. The Chronic Hazard Advisory Panel recommended permanently banning five phthalates from use in children's products.

The CPSC appointed a panel of independent scientific experts to comprise the CHAP in April 2010. The CHAP submitted its extensive, peer-reviewed final report to the CPSC on July 18, 2014. 79 Fed. Reg. at 78,326; *see* CHAP Report, ECF No. 31-9. The CHAP report comprehensively examined animal and human studies regarding the potential health effects from exposure to phthalates, and concluded that many phthalates are associated with harmful effects on male reproduction and neurological function. 79 Fed. Reg. at 78,326–27 (summarizing CHAP report). Based on its study, the CHAP recommended that the CPSC permanently ban five phthalates from use in children's products.

The CHAP first recommended that the interim ban on DINP be made permanent. CHAP Report at 7, 99. The CHAP based its recommendation on its conclusion that DINP induced "antiandrogenic" effects—*i.e.*, effects on male reproductive development—and "therefore can contribute to the cumulative risk from other antiandrogenic phthalates."[4] *Id.* at 99.

The CHAP also recommended that the CPSC permanently ban four phthalates that Congress had not subjected to an interim ban—DIBP, DPENP, DHEXP, and DCHP. As to DIBP, the CHAP concluded that "exposure . . . can cause reproductive and developmental effects," *id.* at 111, and "can contribute to the

[4] Androgens are sex hormones like testosterone that play a central role in male development in utero and throughout childhood and puberty. Androgen levels affect testes formation, penile formation, penile growth, male fertility, and muscle mass, among other things. An "antiandrogen" is a chemical that suppresses androgen production or androgen activity in the body. *See* 79 Fed. Reg. at 78,326.

cumulative risk," *id.* at 8. Further, the CPSC had detected DIBP in recent compliance testing, and evidence indicated that DIBP exposure across the general population had been increasing. *Id.* at 111; *see also id.* at 8. The CHAP also noted that, because DIBP shares many chemical properties with DBP (a banned phthalate), it could be used as a substitute. *Id.* at 111. Based on these conclusions, the CHAP recommended that DIBP "be permanently banned from use in children's toys and child care articles at levels greater than 0.1%." *Id.* at 112.

As to DPENP, DHEXP, and DCHP, the CHAP concluded that their "toxicological profiles . . . are very similar to other antiandrogenic phthalates" already banned by Congress, and that exposure to these phthalates "contributes to the cumulative risk." *Id.* at 8. DPENP is "the most potent phthalate with respect to developmental toxicity," *id.* at 113, and studies indicate that both DHEXP and DCHP "can induce adverse effects in reproductive organs and [are] developmental toxicant[s]," *id.* at 116, 117. While DPENP, DHEXP, and DCHP were not "currently found" in children's products at the time of the CHAP's report, *see id.* at 113, 116, 117, the CHAP nonetheless recommended they be banned from children's products to "prevent future exposure," *id.* at 113, 116, 118. Without a ban, manufacturers would be free to substitute these phthalates for others in children's products, notwithstanding the known health risks and without disclosure to consumers.

IV. The CPSC proposed permanently banning five phthalates from use in children's products.

On December 30, 2014, the CPSC proposed a rule to regulate phthalates in toys and child care articles. *See* 79 Fed. Reg. at 78,343. The CPSC carefully

considered the CHAP's analysis and recommendations, *see id.* 78,326–30, and considered "both cumulative risks and risk in isolation" for each phthalate at issue, *id.* at 78,334–35. Based on this analysis, the CPSC proposed adopting the CHAP's recommendations to permanently ban DINP, DIBP, DPENP, DHEXP, and DCHP from use in toys and child care articles. *Id.* at 78,334–37.

The CPSC proposed not only to make the interim ban for DINP permanent, but to expand the ban to cover "*all* children's toys," not just those "that can be mouthed" by children. *Id.* at 78,335 (emphasis added). The CPSC found that DINP is "associated with adverse effects on male development" and "acts in concert with other antiandrogenic phthalates, including the permanently banned phthalates, thereby contributing to the cumulative risk." *Id.* at 78,334. The CPSC detected DINP in more than 8% of children's products it tested leading up to the proposed rule, including in some toys too large to be placed in a child's mouth. *See* Decl. of Jared E. Knicley Ex. A at 2 ("Dreyfus Mem."). Based on its cumulative risk analysis, the CPSC concluded that permanently banning DINP from children's products was necessary "to ensure a reasonable certainty of no harm with an adequate margin of safety to children, pregnant women, or other susceptible individuals (i.e., male fetuses)." 79 Fed. Reg. at 78,335. It also concluded that expanding the ban to cover all toys was "appropriate because exposure occurs from handling children's toys, as well as from mouthing," and thus was "necessary to ensure a reasonable certainty of no harm to children with an adequate margin of safety." *Id.* at 78,335.

The CPSC also proposed a permanent ban on the use of DIBP in all toys and

child care articles. *Id.* at 78,336. The CPSC found that DIBP "is associated with adverse effects on male reproductive development and contributes to the cumulative risk from androgenic phthalates" and is "'probably toxic' to humans." 79 Fed. Reg. at 78,336. The CPSC also detected DIBP in nearly 12% of children's products it tested leading up to the proposed rule. *See* Dreyfus Mem. 2; *see also* 79 Fed. Reg. at 78,336 (noting "DIBP has been found in some toys and child care articles"). Based on its cumulative risk analysis and the presence of DIBP in children's products on the market, the CPSC concluded that permanently banning DIBP "is necessary to protect the health of children because it would prevent current and future use of this antiandrogenic phthalate in toys and child care articles." *Id.*

The CPSC also proposed a permanent ban on the use of DPENP in all toys and child care articles. *Id.* at 78,336. The CPSC found that DPENP "is associated with adverse effects on male reproductive development and contributes to the cumulative risk from androgenic phthalates" and is "'probably toxic' to humans." *Id.* Although the CPSC did not detect DPENP during its compliance testing, studies had indicated that "exposure to DPENP does occur." *Id.* Based on its cumulative risk analysis, and its recognition that DPENP could be "use[d] as a substitute for other banned phthalates," the CPSC concluded that a permanent ban of DPENP "is necessary to protect the health of children because it would prevent current and future use of this antiandrogenic phthalate in toys and child care articles." *Id.*

Lastly, the CPSC proposed a permanent ban on the use of DHEXP and DCHP in all toys and child care articles. *Id.* at 78,336–37. The CPSC concluded that

both phthalates are "associated with adverse effects on male reproductive development and may contribute to the cumulative risk from antiandrogenic phthalates." *Id.* at 78,336 (DHEXP), 78,337 (DCHP). Although the CPSC did not detect DHEXP or DCHP during its compliance testing, it did find that allowing either phthalate in children's products "would further increase the cumulative risk," and that banning the phthalates would prevent their use "as a substitute for other banned phthalates." *Id.* at 78,336 (DHEXP), 78,337 (DCHP). The CPSC thus concluded that permanently banning DHEXP and DCHP was "necessary to protect the health of children because it would prevent future use of [these] antiandrogenic phthalate[s] in toys and child care articles." *Id.* at 78,336 (DHEXP), 78,337 (DCHP).

V. Plaintiffs sued the CPSC for its failure to issue a final phthalates rule.

Congress directed the CPSC to issue a final rule determining which phthalates to permanently ban from use in children's products by January 14, 2015. Compl. ¶ 24; *see* 15 U.S.C. § 2057c(b)(3). The CPSC did not meet this deadline and—more than two years later—still has not published a final rule.

On December 6, 2016, Plaintiffs Natural Resources Defense Council (NRDC), Environmental Justice Health Alliance for Chemical Policy Reform, and The Breast Cancer Fund (collectively, Plaintiffs) filed this suit against the CPSC to compel the agency to comply with its long overdue statutory duty to issue a final phthalates rule. Compl. 8. Plaintiffs are organizations dedicated to eliminating human health risks associated with exposure to toxic chemicals like phthalates. *Id.* ¶¶ 5–7. Plaintiffs filed this suit on behalf of their members "who are concerned about the

health risks to their children from exposure to phthalates in toys and child care articles." *Id.* ¶ 8.

The CPSC answered Plaintiffs' complaint, *see* ECF No. 18, and admitted that the final phthalates rule is more than two years overdue, *see* Joint Ltr. 2, ECF No. 20. Plaintiffs and the CPSC have agreed to settle this case through a consent decree that sets an enforceable deadline for the CPSC to issue a final phthalates rule. In the consent decree, Plaintiffs and the CPSC state their agreement that the Court has subject matter jurisdiction sufficient to enter the decree. Counsel for the CPSC submitted the consent decree to the Court on March 23, 2017.

On April 6, 2017, proposed-intervenor National Association of Manufacturers (NAM) moved to dismiss this case for lack of subject matter jurisdiction. *See* Mem. in Supp. NAM's Mot. to Dismiss ("Mot."), ECF No. 29. NAM does not dispute that the final phthalates rule is "overdue." *Id.* at 2. Nor does it dispute the serious health harms associated with children's exposure to phthalates. It nonetheless asserts that Plaintiffs lack standing to seek relief from this Court that would require the CPSC to take final action on a proposed rule that—in the agency's own words—is "necessary to protect the health of children because it would prevent current and future use of" harmful phthalates in children's products. *See* 79 Fed. Reg. at 78,336.

ARGUMENT

I. Standard of Review

Article III standing requires a plaintiff to demonstrate (1) an "injury in fact" that is (2) "fairly traceable to the challenged action of the defendant" and (3) likely

to be "redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000). In a case like this one that asserts a procedural injury, the redressability requirement is relaxed: the question is only whether the injury-in-fact could be relieved if the agency fulfilled its statutory duty. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992).

A membership organization has standing to sue on behalf of its members "if, among other requirements not at issue here, it establishes that at least one of its members has standing to sue individually."[5] *NRDC v. U.S. FDA*, 710 F.3d 71, 79 (2d Cir. 2013), *as amended* (Mar. 21, 2013). Article III is satisfied so long as one plaintiff has standing. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

A plaintiff must establish the elements of standing "in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561. Thus, when considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), "the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff." *NRDC v. Johnson*, 461 F.3d 164, 171 (2d Cir. 2006) (internal quotation marks omitted). While "a district

[5] NAM does not dispute that Plaintiffs satisfy the two other requirements for associational standing. *See Laidlaw*, 528 U.S. at 181. Nor could it. The interests Plaintiffs seek to protect are "germane to their [organizational] purposes," *NRDC v. U.S. Army Corps of Eng'rs*, 399 F. Supp. 2d 386, 401 (S.D.N.Y. 2005), of eliminating human exposure to harmful chemicals like phthalates, *see* Compl. ¶¶ 5–7; Decl. of Gina Trujillo ¶¶ 6–8. And, because Plaintiffs seek only declaratory relief and the imposition of a deadline for a final rule, participation of their members in this suit is not necessary. *See Bldg. & Const. Trades Council of Buffalo, N.Y. & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 150 (2d Cir. 2006).

court may consider evidence outside the pleadings" when ruling on a motion under Rule 12(b)(1), *Morrison v. Nat'l Austl. Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008), a plaintiff remains "entitled to rely on the allegations in the [complaint] if the evidence proffered by the defendant is immaterial because it does not contradict plausible allegations that are themselves sufficient to show standing," *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 57 (2d Cir. 2016).

II. Plaintiffs have standing to challenge the CPSC's unlawful delay in issuing a final phthalates rule.

A. Plaintiffs allege a credible threat of harm to their members' children from exposure to phthalates in children's products.

Plaintiffs allege standing based on their members' reasonable concerns that their children currently are being exposed, and will be exposed in the future, to harmful phthalates, including DINP and DIBP, in toys and child care articles. *See* Compl. ¶ 8; *see also* Friesen Decl. ¶¶ 4–5; Getreu Decl. ¶¶ 4–6; Sarn Decl. ¶¶ 4–7.

The Second Circuit has made clear that in the consumer-safety context, "threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes" where "the plaintiff alleges exposure to potentially harmful products." *Baur v. Veneman*, 352 F.3d 625, 633–34 (2d Cir. 2003). In these cases, "the injury contemplated . . . is not the future harm that the exposure risks causing, but the present exposure to risk." *NRDC*, 710 F.3d at 81. Thus, a plaintiff need not show that actual exposure to the harmful product is imminent. *Baur*, 352 F.3d at 641. Instead, she need only show a "'credible threat of harm' . . . based on exposure to enhanced risk." *Id.* at 637.

The credible-threat-of-harm inquiry is "case-specific" and "qualitative, not quantitative." *Id.* Courts must "consider both the probability of harm and the severity of the potential harm." *NRDC*, 710 F.3d at 81. At the same time, courts must be mindful not to "conflate standing with an evaluation of the underlying soundness" of the agency action or inaction at issue. *Baur*, 352 F.3d at 643.

1. Children's exposure to phthalates is associated with significant health harms and constitutes a cognizable injury-in-fact.

There is no dispute that human exposure to phthalates is associated with numerous and significant health harms, particularly for fetuses, infants, and children. Nor is there any dispute that the phthalates the CPSC has proposed to permanently ban—including DINP and DIBP—are associated with irreversible developmental and reproductive harm to children, including genital malformations, reduced fertility, and neurological impairment. Congress recognized these health harms in 2008 when it passed the CPSIA. The CHAP affirmed these harms in 2014 when it recommended a permanent ban of DINP, DIBP, and three other phthalates in children's products. And the CPSC reaffirmed these harms when it proposed to permanently ban those phthalates. *Supra* 4–10. NAM does not question or dispute these health harms in its motion to dismiss.

Given this undisputed evidence, children's risk of exposure to toys and child care articles containing phthalates including DINP and DIBP constitutes a cognizable injury-in-fact. *See Baur*, 352 F.3d at 636. The "tight connection between the type of injury" alleged and the "fundamental goals of the" CPSIA to reduce children's exposure to phthalates reinforces Plaintiffs' showing of injury. *Id.* at 635.

2. Plaintiffs' members' children face a current and future risk of exposure to phthalates in children's products.

Given the undisputed and significant health risks, Plaintiffs' members have reasonable concerns about their children's exposure to phthalates in toys and child care articles. *See* Compl. ¶ 8; Getreu Decl. ¶¶ 4–5; Friesen Decl. ¶ 4; Sarn Decl. ¶¶ 4–7. Their concerns are exacerbated by the reality that "there is nothing [they] can do on their own to eliminate [their] children's exposure to phthalates in toys and child-care products." Sarn Decl. ¶ 10; *accord* Friesen Decl. ¶¶ 4–5; Getreu Decl. ¶ 6. Plastic toys and child care articles are "ubiquitous," Getreu Decl. ¶ 6, and "impossible" for parents and their children to avoid, Sarn Decl. ¶¶ 4–5. The lack of a labeling requirement for phthalates means that Plaintiffs' members cannot be sure that the toys their children encounter, or the teething rings their children need for soothing, are free of phthalates. Getreu Decl. ¶ 6; Friesen Decl. ¶ 5; Sarn Decl. ¶ 10.

Plaintiffs' members' concerns are corroborated by the record underlying the CPSC's proposed rule. *See Baur*, 352 F.3d at 639–40 (finding agencies' proposed plans to "minimize human exposure" to mad cow disease "strongly suggest[s] that they view the potential health risks . . . as both serious and imminent"). Indeed, the CPSC proposed permanently banning two of the five phthalates based on *current* risk of children's exposure to those phthalates in children's products.

For instance, the CPSC concluded that permanently banning DINP in all toys and child care articles was "necessary to ensure a reasonable certainty of no harm to children with an adequate margin of safety." 79 Fed. Reg. at 78,335. NAM's claim that there is no risk of exposure to DINP in children's products because DINP "has

been subject to an interim ban since February 10, 2009, and thus has not been present in children's toys and child care products for more than eight years," Mot. 15, misrepresents the record. The CPSIA's interim ban of DINP applies only to child care articles and the subset of toys "that can be placed in a child's mouth." 15 U.S.C. § 2057c(b)(1). The CPSC's proposed rule would *expand* the DINP ban to cover *all* toys, not just those that can be mouthed. 79 Fed. Reg. at 78,335. This distinction is not merely academic. While NAM claims—without evidence—that "no children's toys or child care articles now contain DINP," Mot. 15, the CPSC's compliance testing leading up to the proposed rule in 2014 showed the opposite: DINP was found in 93 of the 1125 (8.3%) children's products tested, including some toys too large to be placed in a child's mouth, and thus not covered by the interim ban. *See* Dreyfus Mem. 2. "[E]xposure occurs from handling children's toys, as well as from mouthing." 79 Fed. Reg. at 78,335. Until the interim ban of DINP is expanded to cover all toys, Plaintiffs' members' children face a current risk of exposure to DINP.

Plaintiffs' members' children similarly face a current risk of exposure to DIBP in children's products. Unlike DINP, there are no current restrictions on the use of DIBP in *any* toys or child care articles. But like DINP, the CPSC has found DIBP in children's products. In fact, DIBP was detected in 132 of the 1125 (11.7%) children's products tested.[6] *See* Dreyfus Mem. 2. The CPSC therefore concluded that

[6] NAM attempts to minimize the prevalence of DIBP by citing the CPSC's statement that while DIBP "has been found in some toys, it is not widely used in toys and child care articles." Mot. 16 (quoting 79 Fed. Reg. at 78,340) (internal quotation marks omitted). But this only underscores Plaintiffs' members' concerns: that DIBP is in fact present in children's products on the market.

a permanent ban of DIBP "is necessary to protect the health of children because it would prevent *current* and future use of this antiandrogenic phthalate in toys and child care articles." 79 Fed. Reg. at 78,336 (emphasis added). And the CPSC's conclusion has proven correct: in 2015, the U.S. Public Interest Research Group tested a "Fun Bubbles Jump Rope" toy and found DIBP at *190 times* the level that would be allowed under the proposed ban. *See* Knicley Decl. Ex. B at 7, 18. Until the CPSC permanently bans DIBP in children's products, Plaintiffs' members' children face a current risk of exposure to DIBP.

Plaintiffs' members' children also face a cognizable risk of exposure to DPENP, DHEXP, and DCHP in children's products. The CPSC concluded that banning each of these phthalates was "necessary to protect the health of children." 79 Fed. Reg. at 78,336 (DPENP, DHEXP), 78,337 (DCHP). While the CPSC did not detect these phthalates during product testing, each can serve as a substitute for already-banned phthalates. *Id.* Without a ban, there is nothing preventing their use in children's products; nor is there any way for Plaintiffs' members to ensure their children are not exposed to such products. Plaintiffs' members' children therefore face a cognizable risk of exposure to these phthalates as well. *See NRDC v. U.S. EPA*, 735 F.3d 873, 878–79 (9th Cir. 2013) (concluding petitioner had standing to challenge conditional approval of a pesticide when lack of public information would "make it nearly impossible" to avoid products containing that pesticide).

The CPSC's conclusions and proposal to ban these additional phthalates corroborate Plaintiffs' members' concerns about their own children's exposure.

Indeed, the fact that "government studies and statements confirm" Plaintiffs' allegations "weigh[s] in favor of concluding that standing exists in this case." *Baur*, 352 F.3d at 637; *see also NRDC*, 710 F.3d at 82 (finding standing when "the government's own report confirmed the plaintiff's concerns").

NAM attempts to avoid the weight of the record by solely focusing on narrow portions of the CHAP's analysis: namely, findings regarding the risk from exposure to each phthalate in isolation.[7] NAM's approach is flawed. First, it ignores the CPSC's conclusions that the proposed bans are "*necessary* to protect the health of children" from current exposure. *Supra* 9–10. And second, it improperly focuses on isolated, rather than cumulative, risk. Congress directed the CHAP and the CPSC to base their conclusions on the "*cumulative* effect of total exposure to phthalates, both from children's products and from other sources." 15 U.S.C. § 2057c(b)(2)(B)(iv) (emphasis added). This requirement recognizes that the real-world risk to children does not depend on exposure to one phthalate in one toy, but instead depends on cumulative exposure to phthalates across all toys, child care articles, and other consumer products. Because children are exposed to phthalates from a variety of sources, further exposure from children's products—even if small—increases the cumulative risk of permanent developmental and reproductive health problems. Plaintiffs' members are concerned about this cumulative risk. *See* Getreu Decl. ¶ 5; Sarn Decl. ¶ 9. And it is based on this real-world cumulative risk—rather than the

[7] *See, e.g.*, Mot. 15 ("permanent ban" of DINP "will have no effect on current exposure" (citing CHAP Report 98–99)), 15 ("exposures to DPENP, DHEXP, and DCHP 'do not indicate a high level of concern'" (quoting CHAP Report 8)), 16 ("the CHAP found '[n]o quantifiable exposures'" to DIBP (quoting CHAP Report 111)).

isolated risks that NAM emphasizes—that the CPSC proposed the permanent bans. 79 Fed. Reg. at 78,334–35 (DINP), 78,336 (DIBP, DPENP, DHEXP), 78,337 (DCHP).

To the extent that NAM acknowledges the CPSC's ultimate conclusions and cumulative risk analysis, *see* Mot. 8–9, 18 n.11, it does so only to criticize their validity, through opinion testimony provided by NAM's in-house counsel, *see* Palmieri Decl. ¶ 27, ECF No. 31 (noting NAM's "serious concerns about the scientific soundness of the cumulative risk methodology").[8] This is not, however, the proper venue for NAM to air these concerns. Entertaining NAM's protests about the CPSC's cumulative risk analysis would "essentially collapse the standing inquiry" in this case "into the merits" of the CPSC's proposed rule—a rule that is not ripe for review. *Baur*, 352 F.3d at 642.[9] The CPSC's conclusions underlying its proposed rule corroborate Plaintiffs' members' concerns that their children are being exposed to harmful phthalates in children's products. That is enough to satisfy Article III.

3. Plaintiffs have shown a credible threat of harm to their members' children from exposure to phthalates in children's products.

Considering the undisputed, significant health effects associated with

[8] Mr. Palmieri is an in-house attorney for NAM. On several occasions, Mr. Palmieri strays from fact into opinion testimony. *E.g.*, Palmieri Decl. ¶ 6 (describing "cumulative risk assessment methodology" as "untested"), ¶ 13 (stating the CPSC's risk assessment "led to an overestimation of the risk"), ¶ 27 (questioning the CPSC's cumulative risk analysis, and opining on recent biomonitoring data). The Court should disregard this testimony. It is conclusory, immaterial to the narrow issues before this Court, and without foundation under Federal Rule of Evidence 702.

[9] Of course, Plaintiffs strongly disagree with NAM's criticisms of the CPSC's cumulative risk analysis and its interpretations of recent biomonitoring data. *See generally* Knicley Decl. Ex. C (2015 NRDC comments), Ex. D (2015 Breast Cancer Fund comments), Ex. E (2017 NRDC comments). But this dispute will be resolved during the ongoing administrative process and in any future litigation over the substance of the final rule—not in this Court, at this time.

children's exposure to phthalates, and the likelihood that Plaintiffs' members' children are being or will be exposed to the phthalates DINP and DIBP in children's products, Plaintiffs have shown a credible threat of harm. *See Baur*, 352 F.3d at 637. Although this threat of harm is "widely shared," Plaintiffs' members' concerns for their children are "sufficiently concrete and particularized" to establish a cognizable injury in fact. *See id.* at 635; *see also Sierra Club v. Morton*, 405 U.S. 727, 734 (1972).

NAM attempts to circumvent this unavoidable conclusion by citing cases that bear little resemblance to this one—most prominently the portion of the Second Circuit's decision in *NRDC v. U.S. FDA* that concerned FDA's delay in regulating the use of triclocarban in antimicrobial soaps. *See* Mot. 15, 17. In that case, NRDC alleged that "the proliferation of triclocarban, together with other antimicrobial antiseptic chemicals, may lead to the development of antibiotic-resistant bacteria" that could harm its members. *NRDC*, 710 F.3d at 85. The Court identified two problems with this allegation. First, despite the labeling requirements for soaps containing triclocarban, there was "no evidence that NRDC's members were directly exposed to triclocarban."[10] *Id.* And second, the alleged harm hinged on the "causally remote" possibility that triclocarban's use would cause development of antibiotic-resistant bacteria, bacteria that NRDC's "members may not ever come into contact

[10] This distinguished triclocarban from triclosan, the other chemical at issue in that case. NRDC had standing to challenge the FDA's delay in regulating triclosan in antimicrobial soaps because it had shown that its members were exposed to soaps containing triclosan and that triclosan was an endocrine disruptor that may cause cancer. *See NRDC*, 710 F.3d at 86.

with." *Id.* at 86. This case contains no such contingencies: Plaintiffs' members' children are exposed to toys and child care articles every day, and there is evidence that a portion of those products—perhaps up to one in every five—contain the phthalates DIBP or DINP, which the CPSC has proposed to ban due to adverse health effects on children. And unlike for triclocarban, there is no labeling requirement for phthalates, so it is impossible for parents to know what phthalates their children are exposed to, and no way to avoid that exposure.

The significant evidence of children's potential exposure to phthalates in children's products also distinguishes this case from *Clapper v. Amnesty International USA*, 133 S. Ct. 1138 (2013), and *Taylor v. Bernanke*, No. 13-cv-1013, 2013 WL 4811222 (E.D.N.Y. Sept. 9, 2013). This is not a case where a "highly attenuated chain of possibilities" must occur for Plaintiffs' members to be injured. *See Clapper*, 133 S. Ct. at 1148; *see also Taylor*, 2013 WL 4811222, at *7. Plaintiffs' members' children face a current threat of exposure to DINP and DIBP in children's products. The CPSC's failure to ban those phthalates therefore contributes to Plaintiffs' members' "increased health-related uncertainty." *See N.Y. Pub. Interest Research Grp. v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003) (emphasis omitted).[11]

In this way, this case is much more analogous to *Baur*, the Second Circuit's leading case on risk-based injury. In *Baur*, the plaintiff alleged three key facts:

[11] NAM's reliance on *National Council of La Raza v. Gonzales*, 468 F. Supp. 2d 429 (E.D.N.Y. 2007), is also misplaced. In *La Raza*, there was "no statutory mandate seeking to prevent" the plaintiffs from being arrested for outstanding immigration warrants, nor were plaintiffs' fears of potential arrests based on anything more than speculation. *Id.* at 439–40.

(1) that mad cow disease "may already be present in the United States"; (2) that "available testing methods do not adequately detect" mad cow disease "in downed cattle"; and (3) that, under existing government regulations, "infected beef from downed cattle can enter the food stream." 352 F.3d at 640. Government reports confirmed the risk of mad cow disease from downed cattle, as well as the lack of a reliable means of detecting the disease in downed cattle. *Id.* at 639–40. Thus, even though mad cow disease had "not been detected in the United States," Baur had alleged a credible threat of harm that established an injury-in-fact. *Id.*

The threat of harm to Plaintiffs' members is more substantial than that in *Baur*. Plaintiffs have alleged, and the CPSC's findings confirm, that the harmful phthalates DINP and DIBP are already present in up to 20% of children's products. *Supra* 8–9, 16. Yet, without labeling requirements, there is no practical way for Plaintiffs' members to protect their children from exposure. If Plaintiffs' "allegations are to be credited, as they must be at the pleading stage," then Plaintiffs' members' children "face[] a *present, immediate* risk of exposure" to phthalates in children's products—"not a future risk that awaits intervening events." *Baur*, 352 F.3d at 640.

Whitman also supports Plaintiffs' members' standing. In that case, the Second Circuit held that individuals living within a few miles of a facility subject to the Clean Air Act had standing to challenge the EPA's failure to enforce the Act based on their concerns about exposure to *potentially* illegal levels of air pollution. *See* 321 F.3d at 324–26. That court's recognition of standing based on "health-related *uncertainty*," *id.* at 325, applies equally to Plaintiffs' members' reasonable

uncertainty about phthalates that are known to be present in children's products, and that would be banned under the proposed rule.

NRDC v. U.S. EPA illustrates this point as well. In that case, the Ninth Circuit held that NRDC had standing to challenge EPA's conditional approval of a pesticide for use in textiles. 735 F.3d at 878–79. EPA's approval "increase[d] the odds of exposure" to the pesticide, which posed health risks to children. *Id.* at 878. And given "[t]he ubiquity of textiles and the lack of public information concerning the chemical treatments applied to them during the manufacturing process," the court concluded it would be "nearly impossible for NRDC members to eliminate" all likelihood of exposure. *Id.* So too here. The ubiquity of plastics in children's products, and the lack of labeling requirements for phthalates, mean than Plaintiffs' members cannot "fully control their children's exposure" to phthalates. *Id.* at 879. This lack of control underscores the concrete, credible threat of harm faced by Plaintiffs' members' children.

B. The credible threat of harm to Plaintiffs' members' children is fairly traceable to the CPSC's unlawful delay.

A plaintiff's injuries are "fairly traceable" to an agency's delay in issuing a health-protective regulation if the delay "contributes to . . . exposure" to the toxins at issue in the suit. *See NRDC*, 710 F.3d at 85. This is so even if the agency's delay contributes to only a portion—even a small portion—of the risk of exposure. *See Massachusetts*, 549 U.S. at 524–25.

The CPSC has the authority to ban phthalates like DINP and DIBP from all toys and child care articles, and has proposed a rule to do exactly that. "[B]ut for

[the CPSC's] challenged inaction," toys and child care articles containing DINP, DIBP, and the other phthalates proposed to be banned "would not be available on the market." *NRDC*, 710 F.3d at 85. Because the CPSC's failure to finalize the rule "contributes to" the ongoing threat of exposure to phthalates like DINP and DIBP in children's products, Article III's causation requirement is satisfied. *Id.*

NAM's reliance on *Taylor* is again misplaced.[12] *See* Mot. 21. In *Taylor*, plaintiffs failed to show how issuance of the rule would affect the regulated parties' "discretion" to continue the complained-of behavior. 2013 WL 4811222, at *10. Here, a final rule will have the "inevitable" effect of banning regulated parties' use of phthalates, including DINP and DIBP, in toys and child care articles. *Cf. id.* at *9.

C. The credible threat of harm to Plaintiffs' members' children is redressable by this Court.

In procedural rights cases, redressability is satisfied when a plaintiff's injuries *might* be relieved by the agency fulfilling its duty. *Lujan*, 504 U.S. at 572 n.7; *see also Massachusetts*, 549 U.S. at 518 ("[A] litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant."). Plaintiffs' members meet this minimal burden because their concerns about their children's exposure to phthalates would be at least partially redressed if the CPSC finalized the proposed phthalates rule. Compl. ¶ 8; Getreu Decl. ¶ 7; Friesen Decl. ¶ 7; Sarn Decl. ¶ 11.

[12] NAM's principal arguments as to both causation and redressability—that Plaintiffs cannot show that the CPSC caused their members injury or that the Court could redress such injury because they cannot show any injury at all, *see* Mot. 20, 21–23—are tautological and improperly collapse the separate standards for causation and redressability into the injury-in-fact inquiry.

NAM's assertion that redressability is lacking because any order of this Court "would not dictate the content of the final rule," *see* Mot. 23–24, misses *Lujan*'s central point. Under *Lujan*, plaintiffs can challenge violations of procedural rights even if they "cannot establish with any certainty" that compliance with the procedure will ultimately mitigate their injury.[13] 504 U.S. at 572 n.7. The CPSC "is the government actor alleged to have caused [Plaintiffs'] injury, and [the CPSC] is the actor that can provide relief—that arrangement is sufficient to establish that relief is likely." *See Bennett v. Donovan*, 703 F.3d 582, 590 (D.C. Cir. 2013).

* * * * *

As shown above, Plaintiffs' members' children face a credible threat of harm from exposure to the dangerous phthalates that the CPSC proposed to ban from children's products more than two years ago. Those members have standing to ask this Court to compel the CPSC to finally decide whether to institute the bans it has proposed. Plaintiffs accordingly have standing on behalf of these members.

CONCLUSION

For the foregoing reasons, the Court should deny NAM's motion to dismiss.

Dated: April 18, 2017

Respectfully submitted,

/s/ Jared E. Knicley
Jared E. Knicley*

[13] *Town of Babylon v. Federal Housing Finance Agency*, 699 F.3d 221 (2d Cir. 2012), is inapposite. *See* Mot. 23. In *Town of Babylon*, the court found that even if the challenged guidance were vacated, regulated parties "would remain entirely free" to continue the complained-of activities. 699 F.3d at 229. The CPSC's issuance of a regulation banning certain phthalates in children's products would leave manufacturers with no such discretion. *See NRDC*, 710 F.3d at 85.

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CERTIFICATE OF SERVICE

I certify that on April 18, 2017, I caused a copy of the foregoing Plaintiffs' Opposition to Proposed-Intervenor National Association of Manufacturers' Motion to Dismiss to be filed using the Court's ECF system, which will serve the document electronically on all counsel of record.

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