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.	:	

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

Table of Contents

Table of Authorities

Page(s)

Cases

Statutes

Other Authorities

Proposed intervenor the National Association of Manufacturers (the "NAM") submits this memorandum of law in support of its motion to dismiss the Complaint for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure.

Preliminary Statement

Plaintiffs in this action seek to compel the Consumer Product Safety Commission ("CPSC") to promulgate "as soon as possible" a final rule, pursuant to Section 108(b)(3) of the Consumer Product Safety Improvement Act ("CPSIA"), 15 U.S.C. § 2057c(b)(3), that would ban the use of five organic compounds, known as "phthalates," from use in children's toys and child care articles. As set forth below, the Complaint should be dismissed for lack of subject-matter jurisdiction because plaintiffs have no standing to sue under Article III of the U.S. Constitution. The administrative record in the underlying rulemaking proceeding, which the Court can consider on this Rule 12(b)(1) motion to dismiss,[1] establishes that plaintiffs cannot meet their burden to allege sufficient facts showing that their members have suffered any actual "injury in fact" caused by the CPSC's delay in publishing the final regulation that would likely be redressed by any of the relief plaintiffs seek from this Court.[2]

In conclusory fashion, the Complaint alleges that plaintiffs and their members "are concerned about the health risks to their children from exposure to phthalates in toys and child care articles." (Compl. ¶ 8.) Plaintiffs further allege that they "have been and continue to be injured by the CPSC's unlawful delay in publishing the final phthalate regulation" (*id.*), because the "delay is causing continued human exposure to five phthalates that would be banned

[1] *McDermott v. N.Y. Metro LLC*, 664 F. Supp. 2d 294, 298 (S.D.N.Y. 2009) (Castel, J.) ("In deciding a Rule 12(b)(1) motion, the Court is free to consider materials outside the pleadings.") (citation omitted).

[2] *NRDC v. FDA*, 710 F.3d 71, 79 (2d Cir. 2013) (citing U.S. Const. art. III, § 2; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

from children's products if the proposed rule were finalized as proposed" (*id.* ¶ 26). At the heart of these allegations of generalized harm is plaintiffs' claim that the phthalates purportedly "are common in toys and child care products." (*Id.* ¶ 1.)

Based on these minimal allegations, plaintiffs can establish no "injury in fact" that is "reasonably traceable" to the CPSC's delay in publishing a final rule, because there is no "concrete or particularized" evidence of any "actual or imminent" human exposure to any of the phthalates at issue in toys or child care products. The record demonstrates that those particular phthalates simply are not "common" in such products, as plaintiffs allege. In fact, the CPSC and its expert Chronic Hazard Advisory Panel (the "CHAP") specifically found that four of the five phthalates at issue here *are not even currently used in children's toys or child care articles*, and further found "*[n]o quantifiable exposures*" to the fifth phthalate in such products.[3] One of the phthalates (DINP) has been subject to an interim ban since February 2009, and thus has not been used in children's toys and child care articles for more than eight years. That interim ban will remain in place until the CPSC's final rule is published, either making the ban permanent or lifting the ban based on a determination of reasonable certainty of no harm to children, pregnant women, or other susceptible individuals.[4] The CHAP similarly "found that three of these phthalates (DPENP, DHEXP, and DCHP) are not currently used in children's products."[5] Thus, plaintiffs cannot establish that they "have been and continue to be" exposed to any of these four phthalates in such products. The CPSC likewise determined that the fifth phthalate (DIBP) "is

[3] (*See* Declaration of Rosario Palmieri, sworn to on April 6, 2017 ("Palmieri Decl."), ¶¶ 24-26 (emphasis added).)

[4] *See* 15 U.S.C. § 2057c(b)(3)(A).

[5] (Palmieri Decl. ¶ 25 & Ex. H, *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates*, 79 Fed. Reg. 78324, 78340 (Dec. 30, 2014).)

not widely used in toys and child care articles,"[6] and the CHAP found that there were "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products" with respect to DIBP.[7] The Complaint therefore fails to establish any actual or imminent injury in fact based on purported current exposure to these phthalates in such products.

Accordingly, because the CPSC and its experts have determined that the phthalates at issue currently are not used in children's toys and child care articles, or present no quantifiable exposure in such products, plaintiffs cannot establish that they "have been and continue to be harmed" by actual or imminent "human exposure" to any of the phthalates at issue here that is caused by, or reasonably traceable to, the CPSC's delay in issuing a final rule. Plaintiffs simply cannot show any actual or imminent injury caused by the CPSC's delay based on current exposure to these phthalates in such products.

For the same reasons, plaintiffs cannot establish that there is any injury caused by the CPSC's delay that could be redressed by a favorable decision from this Court compelling publication of a final rule "as soon as possible." Because these phthalates currently are not present in toys and child care articles, the CHAP itself determined that a permanent ban on DINP, DPENP, DHEXP, and DCHP, if implemented, would not be expected to reduce actual exposure to children from these phthalates in such products.[8] The CHAP similarly found that "[t]here would be little reduction in exposure" to DIBP in such products if the recommended permanent ban of DIBP were to be implemented.[9] Accordingly, an order compelling final publication of the proposed rule would not redress any purported injury caused by the CPSC's

[6] (Palmieri Decl. ¶ 26 & Ex. H, 79 Fed. Reg. at 78340 (quoting Ex. I, CHAP Report at 111, 113, 116-17).)

[7] (*Id.* ¶ 26 & Ex. I, CHAP Report at 111.)

[8] (*Id.* ¶¶ 24-25 & Ex. I, CHAP Report at 99 (DINP), 113 (DPENP), 116 (DHEXP), 118 (DCHP).)

[9] (*Id.* ¶ 26 & Ex. I, CHAP Report at 112.)

delayed rulemaking based on negligible or non-existent exposure to any of the five phthalates at issue in such products. That conclusion is even stronger to the extent that plaintiffs claim that they only seek to compel a schedule for implementing the final rule in this action, rather than finalization of the proposed rule that would ban the use of all five phthalates. Under that theory, a court order or consent decree that simply established a schedule for the final rule clearly would not redress any alleged injury caused by the CPSC's delay, because it is possible the CPSC might determine that no ban is necessitated or warranted under the statutory standards.

Accordingly, because plaintiffs cannot meet their burden to adequately allege the requirements of standing under Article III, the Complaint should be dismissed for lack of subject-matter jurisdiction in its entirety.

Statement of Facts

The relevant facts for purposes of this motion are those alleged in the Complaint and the relevant findings from the CPSC and the CHAP in the administrative record in the ongoing CPSC rulemaking. In the CPSIA, Congress directed the CPSC to promulgate a final rule regulating the use of certain phthalates in children's toys and child care products. (Compl. ¶ 3.) At issue here are five specific phthalates, abbreviated as: DINP, DPENP, DHEXP, DCHP, and DIBP. *(id.* ¶¶ 22, 23.) The Complaint alleges that plaintiffs and their members "are concerned about the health risks to their children from exposure to phthalates in toys and child care articles" *(id.* ¶ 8), because such exposure "during infancy and childhood" may "interfere[ ] with natural hormone levels" and "may cause permanent reproductive harm" (*id.* ¶ 2). Plaintiffs allege that they "have been and continue to be injured by the CPSC's unlawful delay in publishing the final phthalate regulation" (*id.* ¶ 8), because the "delay is causing continued human exposure to five phthalates that would be banned from children's products if the proposed

rule were finalized as proposed" (*id.* ¶ 26). The Complaint seeks an order to compel "the CPSC to publish the final regulation required by Congress as soon as possible." (*Id.* ¶ 4.)

A. The Phthalates Rulemaking Proceeding

Pursuant to Section 108 of the CPSIA, Congress enacted a permanent ban on any "children's toy or child care article" containing concentrations of more than 0.1 percent of three phthalates (DEHP, DBP, and BBP). 15 U.S.C. § 2057c(a); Compl. ¶ 14. Congress also enacted an interim ban on the manufacture, sale, distribution, or importation of "any children's toy that can be placed in a child's mouth" or "child care article" containing concentrations of more that 0.1 percent of three other phthalates (DINP, DIDP, and DnOP), only one of which (DINP) is relevant to the relief plaintiffs seek here. 15 U.S.C. § 2057c(b)(1); Compl. ¶ 15. The interim ban on DINP became effective on February 10, 2009 and will remain in place "until a final rule is promulgated" by the CPSC. 15 U.S.C. § 2057c(b)(1).

Congress further directed the CPSC to convene the CHAP, a panel of scientific experts, to "study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." 15 U.S.C. § 2057c(b)(2)(A); Compl. ¶ 16. The statute required the CHAP to complete a final report within two years of its appointment to recommend whether any phthalates or phthalate alternatives, including those already subject to the interim ban, "should be declared banned hazardous substances." 15 U.S.C. § 2057c(b)(2)(B), (C); Compl. ¶ 16. The statute further required the CPSC to conduct a rulemaking based on the CHAP report and to promulgate a final rule, "[n]ot later than 180 days" after receipt of the CHAP Report, to determine whether any such phthalates should be permanently banned. 15 U.S.C. § 2057c(b)(3). Based on the CHAP's report, the CPSC must determine whether to continue the interim ban of DINP "in order 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 ban any children's product containing any other phthalates "as the Commission determines necessary to protect the health of children," *id.* § 2057c(b)(3)(B); *see* Compl. ¶ 17.

Because the CHAP held its first meeting on April 14 and 15, 2010, its final report was due on April 13, 2012. (Palmieri Decl. ¶ 21 & Ex. H, *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates*, 79 Fed. Reg. 78324, 78325-26 (Dec. 30, 2014); *see* Compl. ¶ 20.) However, the CHAP did not submit its 597-page final report to the CPSC until July 18, 2014 (the "CHAP Report"), more than two years after the deadline for that report. (Palmieri Decl. ¶ 21 & Ex. H, 79 Fed. Reg. at 78326; *see* Compl. ¶ 21.) Under the statute, the CPSC deadline for publishing a final rule was therefore January 14, 2015. (Compl. ¶ 24.) Because the CPSC has not yet published a final rule regulating phthalates, "that rule is now almost two years overdue." (Compl. ¶ 25.)

B. Relevant Findings of the CHAP Report and the Notice of Proposed Rulemaking

The CHAP Report recommended that the interim ban on the use of DINP at levels greater than 0.1 percent in children's toys and child care articles should be made permanent. (Palmieri Decl. ¶ 22 & Ex. I, CHAP Report at 99.) The CHAP further recommended that DPENP, DHEXP, DCHP, and DIBP at levels greater than 0.1 percent also should be permanently banned from use in children's toys and child care articles.[10] (*Id.* ¶ 22 & Ex. H, 79 Fed. Reg. at 78330.) The CPSC then issued a notice of proposed rule making (the "NPR") on December 30, 2014 that would permanently ban children's toys and child care articles containing

[10] As part of its analysis, the CHAP assessed human exposure to phthalates, in part, through human biomonitoring data, primarily from the 2005/2006 National Health and Nutrition Examination Survey ("NHANES") data set released by the Centers for Disease Control and Prevention ("CDC"). This was the most recent biomonitoring data available at the time of the CHAP's intial analysis. (Palmieri Decl. Ex. I, CHAP Report.)

five specified phthalates – DINP, DPENP, DHEXP, DCHP, and DIBP. (*Id.* ¶ 23 & Ex. H, 79 Fed. Reg. at 78324.) The NPR summarized the findings and recommendations of the CHAP Report and set forth the CPSC's own adoption of those recommendations for the proposed rule. (*Id.* ¶ 24, Ex. H, 79 Fed. Reg. at 78326-38.)

With respect to DINP, the CHAP found that DINP was "used in children's toys and child care articles in the past," but has been banned for use in such products since February 10, 2009 pursuant to the interim ban. (*Id.* ¶ 24 & Ex. I, CHAP Report at 98-99.) As such, the CHAP determined that the recommended permanent ban of DINP, if implemented, would not be expected to reduce exposure of children to DINP, "because DINP is currently subject to an interim ban on use in children's toys and child care articles at levels greater than 0.1%." (*Id.* ¶ 24 & Ex. I, CHAP Report at 99.)

The NPR also confirmed the CHAP's finding that "three of these phthalates (DPENP, DHEXP, and DCHP) are not currently used in children's products." (*Id.* ¶ 25 & Ex. H, 79 Fed. Reg. at 78324, 78340.) The CHAP Report specifically determined that each of these three phthalates "is currently not found in children's toys or child care articles" and is "not widely found in the environment." (*Id.* ¶ 25 & Ex. I, CHAP Report at 113 (DPENP), 116 (DHEXP), 117-18 (DCHP).) The NPR further confirmed that the CPSC staff itself "has not detected" either DPENP, DHEXP, or DCHP "in toys and childcare articles" during routine compliance testing. (*Id.* ¶ 25 & Ex. H, 29 Fed. Reg. at 78336-37.) As such, the CHAP concluded that the recommended final ban, if implemented, would not be expected to reduce exposure to children from DPENP, DHEXP, and DCHP in such products. (*Id.* ¶ 25 & Ex. I, CHAP Report at 113 (DPENP), 116 (DHEXP), 118 (DCHP).)

With respect to DIBP, the CHAP found that "DIBP has not been detected frequently in toys and child care articles in the United States," but it "has been detected in some toys during routine compliance testing." (*Id.* ¶ 26 & Ex. I, CHAP Report at 111.) The NPR similarly confirmed that although DIBP "has been found in some toys, it 'is not widely used in toys and child care articles'" (*Id.* ¶ 26 & Ex. H, 79 Fed. Reg. at 78340 (quoting Ex. I, CHAP Report at 111, 113, 116-17).) Thus, of the five phthalates at issue, "[o]nly DIBP has been detected in a small portion of toys tested by the staff." (*Id.* ¶ 26 & Ex. H, 79 Fed. Reg. at 78339.) However, the CHAP found that "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products were located" with respect to DIBP. (*Id.* ¶ 26 & Ex. I, CHAP Report at 111.) For this reason, the CHAP also concluded that "[t]here would be little reduction in exposure" to children from DIBP if the recommended permanent ban of DIBP were to be implemented. (*Id.* ¶ 26 & Ex. I, CHAP Report 112.) As summarized in the NPR, the CHAP concluded that "current exposures to DIBP, DPENP, DHEXP, and DCHP are low," and therefore "do not indicate a high level of concern." (*Id.* ¶ 26 & Ex. H, 79 Fed. Reg. at 78330 (quoting Ex. I, CHAP Report at 8).)

Although it found no unacceptable risk posed by DINP, DPENP, DHEXP, DCHP, and DIBP in isolation, the CHAP recommended a final ban based on its view that allowing the future use of the phthalates at issue here in children's toys and child care products could contribute to a "cumulative risk" of exposure to children when aggregated with exposure to other phthalates, including DEHP, DBP, and BBP, from other sources such as food, beverages, drugs, and clothing. (*Id.* ¶ 27 & Ex. H, 79 Fed. Reg. at 78327, 78329, 78334 (DINP); *id.* at 78330, 78336-37 (DIBP, DPENP, DHEXP, and DCHP).) However, the CPSC's newly released assessments and updated estimates of phthalate exposure using more recent NHANES data show

that cumulative risk levels associated with phthalate exposure have declined since the time of the CHAP Report to levels below the margins of safety considered by the CPSC in its proposed rule. (*Id.* ¶ 27 & Ex. B at 1.) In 2015, the CPSC's reanalysis of the CHAP assessments using more recent NHANES biomonitoring data sets from 2007/2008, 2009/2010, and 2011/2012 found that the cumulative risk from phthalate exposures had decreased from the time period reviewed in the CHAP Report to a level below the CHAP's concern. (*Id.* ¶ 27 & Ex. K (2015 CPSC Reanalysis).) In February 2017, the CPSC's analysis using the CHAP cumulative risk methodology applied to NHANES data from 2013/2014 also showed that the cumulative risk from phthalates had decreased even further since the 2015 analysis. (*Id.* ¶ 27 & Ex. L (2017 CPSC Analysis).)

Argument

"A plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." *McDermott v. N.Y. Metro LLC*, 664 F. Supp. 2d 294, 298 (S.D.N.Y. 2009) (Castel, J.) (citing *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)). "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova*, 201 F.3d at 113. In ruling on a Rule 12(b)(1) motion to dismiss, "the Court is free to consider materials outside the pleadings." *McDermott*, 664 F. Supp. 2d at 298 (citation omitted). While "the court must accept as true all material factual allegations in the plaintiff's complaint" under Rule 12(b)(1), it "need not draw inferences favorable to the party asserting jurisdiction." *Taylor v. Bernanke*, No. 13-cv-1013, 2013 WL 4811222, at *6 (E.D.N.Y. Sept. 9, 2013). For this reason, "in adjudicating a motion to dismiss for lack of subject-matter jurisdiction, a district court may resolve disputed factual issues by reference to evidence outside the pleadings." *State*

Emp. Bargaining Agent Coal. v. Rowland, 494 F.3d 71, 77 n.4 (2d Cir. 2007); *see also Makarova*, 201 F.3d at 115 (considering government tax returns in assessing Rule 12(b)(1) motion to dismiss); *Taylor*, 2013 WL 4811222, at *8 (considering agency documents and U.S. government reports and studies in assessing plaintiffs' standing under Rule 12(b)(1)). Furthermore, where plaintiffs, as here, "seek injunctive relief, they must plead a 'real and immediate threat of repeated injury.'" *Nat'l Council of La Raza v. Gonzales*, 468 F. Supp. 2d 429, 436 (E.D.N.Y. 2007) (citation omitted).

I. THE COMPLAINT SHOULD BE DISMISSED FOR LACK OF SUBJECT-MATTER JURISDICTION BECAUSE PLAINTIFFS HAVE NO STANDING UNDER ARTICLE III OF THE U.S. CONSTITUTION

The "'irreducible constitutional minimum of standing' derives from Article III, Section 2 of the U.S. Constitution, which limits federal judicial power to 'cases' and 'controversies.'" *NRDC v. FDA*, 710 F.3d 71, 79 (2d Cir. 2013) (citing U.S. Const. art. III, § 2; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Article III standing is thus "the threshold question in every federal case, determining the power of the court to entertain the suit." *McDermott*, 664 F. Supp. 2d at 297 (citation omitted). "To establish that a case or controversy exists so as to confer standing under Article III, a plaintiff must satisfy three elements: (a) the plaintiff must suffer an 'injury in fact,' (b) that injury must be 'fairly traceable' to the challenged action, and (c) the injury must be likely to be 'redressed by a favorable decision' of the federal court." *NRDC*, 710 F.3d at 79 (quoting *Lujan*, 504 U.S. at 560-61). A plaintiff "must demonstrate standing for each claim and form of relief sought." *Id.* at 86 (quoting *Baur v. Veneman*, 352 F.3d 625, 641 n.15 (2d Cir. 2003)).

The party invoking federal jurisdiction has the burden of establishing all of these elements of standing. *See Lujan*, 504 U.S. at 561. Where, as here, "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone*

else," however, "much more is needed." *Id.* at 562. "Thus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Id.* (citations omitted).

As set forth below, plaintiffs' allegation that their members have been injured because the CPSC's "delay is causing continued human exposure to five phthalates" that are "common" in children's toys and child care articles (Compl. ¶¶ 1, 26) is refuted by facts in the administrative record that the Court may consider on this Rule 12(b)(1) motion to dismiss. That record establishes that four of the five phthalates at issue currently are not even used in such products, and that there are no "quantifiable exposures" to the fifth phthalate from such products. Because plaintiffs cannot establish any actual or imminent harm based on current exposure to phthalates in children's toys or child care articles, they likewise cannot establish that any such purported harm has been caused by or is fairly traceable in any way to the CPSC's delay in publishing a final rule. Accordingly, the relief they seek in this Court would not address their alleged injury caused by the CPSC's delay, because there is no actual or quantifiable current exposure to these phthalates in toys or child care products, and the CHAP itself determined that a permanent ban in fact would not reduce or would do little to reduce current exposure of children to these phthalates from such products. For these reasons, plaintiffs lack standing and the Complaint should be dismissed for lack of subject-matter jurisdiction.

A. Plaintiffs Cannot Establish Any Injury in Fact Based on Actual or Imminent Exposure to Phthalates in Children's Toys and Child Care Articles

"Injury in fact is 'an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.'" *NRDC*, 710 F.3d at 80 (quoting *Lujan*, 504 U.S. at 560). The requirement that a plaintiff must "have suffered a concrete and particularized injury in order to bring an action guarantees that the complaining

party has a 'personal stake' in the outcome of the litigation." *McDermott*, 664 F. Supp. 2d at 299 (citation omitted). The imminence requirement for injury in fact ensures "that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013). With respect to alleged future injury, the Supreme Court has "repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,'" and that allegations "'of *possible* future injury' are not sufficient." *Id.* (citation omitted). "Standing will not be found where the occurrence of the alleged future injury depends on a 'highly attenuated chain of possibilities.'" *Taylor*, 2013 WL 4811222, at *6 (quoting *Clapper*, 133 S. Ct. at 1148). Plaintiffs cannot satisfy the injury-in-fact requirement here for two reasons.

1. Plaintiffs Do Not Adequately Allege That Any Member Has Suffered a Concrete and Particularized Injury for Purposes of Establishing Associational Standing.

As a threshold matter, plaintiffs fail to meet their burden to allege that they have suffered a "concrete and particularized injury" for purposes of obtaining associational standing on behalf of their members in this action. "An association bringing suit on behalf of its members must allege that one or more of its members has suffered a concrete and particularized injury." *Bldg. & Const. Trades Council of Buffalo, N.Y. & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006); *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (plaintiff-organizations must make "specific allegations establishing that at least one identified member had suffered or would suffer harm."). The "'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *McDermott*, 664 F. Supp. 2d at 299 (citation omitted). Because of this "concern that a 'plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the

legal rights or interests of third parties,' organizations suing in a representative capacity face additional scrutiny." *La Raza*, 468 F. Supp. 2d at 436 (citation omitted).

The Complaint's bare-bones allegations are insufficient to establish any concrete or particularized injury in fact to any member or members of the plaintiff organizations. The generalized allegations that plaintiffs' members are "concerned about the health risks to their children from exposure to phthalates in toys and child care articles" (Compl. ¶ 8) do not provide any concrete facts establishing how or why any particular member or members or their children "have been and continue to be injured" by the CPSC's delay, for example, or how they are actually exposed to any phthalates in children's toys or products. As shown below, the Complaint's conclusory allegation that phthalates are "common" in such products is refuted by the findings of the CPSC and the CHAP in the rulemaking proceeding. Plaintiffs thus allege no concrete or particularized facts showing how the CPSC's "delay is causing continued human exposure" to any members, or that any members or their children actually use toys or child care articles that expose them to any of these phthalates. (*Id.* ¶¶ 1, 8, 26); *cf. Downtown Dev.*, 448 F.3d at 143 (reversing denial of motion to dismiss for failure to sufficiently allege organizational standing where plaintiff trade council alleged "that some of its members had worked at" contaminated site and "had been exposed to contaminated soil and waste materials while working there," and that "many of its members reside and work near" second site, "drink water from public water supplies drawn from" polluted lake, and use lake "and the area surrounding" the site "for recreation and enjoy the aesthetic value of the area.").

For these reasons, the Complaint's conclusory allegations are insufficient to establish concrete and particularized injury for organizational standing purposes, because they fail to differentiate any alleged harm to the plaintiffs from harm to the population in general. *See*

also NRDC, 710 F.3d at 85 (finding plaintiff's claimed injury from alleged exposure to chemical triclocarban was not sufficiently concrete and particularized where plaintiffs "provided no evidence that its members were directly exposed to triclocarban," and agreeing that plaintiffs' "members suffer at the hands of this risk 'in no way that distinguishes them from the population at large'") (citation omitted). The Supreme Court has "consistently held that a plaintiff raising only a generally available grievance about government," unconnected with a threatened concrete interest of his own, "and seeking relief that no more directly and tangibly benefits him than it does the public at large – does not state an Article III case or controversy." *Lujan*, 504 U.S. at 573-74. The Complaint should be dismissed for lack of standing based on this reason alone.

2. Plaintiffs Cannot Establish Any Actual or Imminent Injury in Fact Based on Current Exposure to Phthalates in Children's Toys and Child Care Articles.

Plaintiffs claim that their members "have been and continue to be injured" by the CPSC's delay in implementing a final rule because that delay is currently causing actual "human exposure" to five phthalates that purportedly "are common in toys and child care products." (Compl. ¶ 1, 8.) These allegations fail to show "injury in fact" that is "reasonably traceable" to the CPSC's delay in promulgating a final rule, because the administrative record in the rulemaking proceeding establishes that at present there is no "concrete or particularized" evidence of "actual or imminent" harm from exposure to any of the phthalates at issue from toys or child care products. In fact, these phthalates are not "common" in such products at all, and plaintiffs cannot establish any actual or imminent harm from current or "continued human exposure," because the CPSC and the CHAP specifically found that four of the phthalates currently are not even present in any children's toys or child care articles (DINP, DPENP, DHEXP, and DCHP). (Palmieri Decl. ¶ 24-25.) The CHAP further found "no quantifiable exposures" to the fifth phthalate from such products (DIBP). (*Id.* ¶ 26.) Because plaintiffs

cannot establish any "actual, present exposure" to any of these phthalates, they cannot satisfy the injury-in-fact requirement for Article III standing. *See NRDC*, 710 F.3d at 83, 85-86 (finding no standing where plaintiff failed to establish any "present injury" based on "direct, frequent exposure" to triclocarban chemical caused by "FDA's alleged delay in finalizing its regulation of triclocarban").

First, plaintiffs cannot establish actual or imminent exposure or risk of exposure to DINP because it 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. As plaintiffs concede (Compl. ¶ 15), Section 108(b) created an interim ban on the manufacture, sale, distribution, or importation of "any children's toy that can be placed in a child's mouth or child care article" that contains DINP or two other phthalates. 15 U.S.C. § 2057c(b)(1). The interim ban on DINP in such products will remain in place "until a final rule is promulgated" by the CPSC. 15 U.S.C. § 2057c(b)(1). For this reason, the CHAP acknowledged that while DINP had "been used in children's toys and child care articles in the past," it has been banned for use in such products since 2009, and therefore a permanent ban would have no effect on current exposure of children to DINP in such products. (Palmieri Decl. ¶ 24 & Ex. I, CHAP Report at 98-99.) Accordingly, because no children's toys or child care articles now contain DINP, and the interim ban will apply until there is a final rule, plaintiffs cannot show any "actual or imminent" injury based on current exposure to DINP in such products caused by the CPSC's delay. *See NRDC*, 710 F.3d at 80, 85-86; *Taylor*, 2013 WL 4811222, at *7.

Plaintiffs similarly cannot establish any actual or imminent injury in fact that is reasonably traceable to the CPSC's delay based on alleged exposure to three other phthalates at issue here – DPENP, DHEXP, and DCHP – because none of these three compounds exists in

toys or child care products, either. The CPSC explicitly acknowledged that "the CHAP found that three of these phthalates (DPENP, DHEXP, and DCHP) *are not currently used in children's products*," and that the CPSC staff itself "has not detected" three of these phthalates "in toys and childcare articles" during routine compliance testing. (Palmieri Decl. ¶ 25 & Ex. H, 79 Fed. Reg. 78324, 78336, 78337, 78340 (emphasis added).) The CHAP Report specifically determined that each of these three phthalates "is currently not found in children's toys or child care articles" and is "not widely found in the environment." (*Id.* ¶ 25 & Ex. I, CHAP Report at 113 (DPENP), 116 (DHEXP), 117-18 (DCHP).) As such, the CHAP Report noted that current exposures of children to DPENP, DHEXP, and DCHP "do not indicate a high level of concern." (*Id.* ¶ 26 & Ex. H, 79 Fed. Reg. at 78330 (quoting Ex. I, CHAP Report at 8).) Accordingly, because no children's toys or child care articles currently contain any of these three phthalates, plaintiffs cannot establish any injury-in-fact that is reasonably traceable to the CPSC's delays based on actual or imminent exposure to DPENP, DHEXP, and DCHP in such products.

Furthermore, plaintiffs cannot establish actual or imminent harm caused by the CPSC's delay based on exposure to the fifth phthalate at issue, DIBP, because the CHAP found no "quantifiable exposures" of children to DIBP from children's toys and child care articles. The CPSC determined that while DIBP "has been found in some toys, it 'is not widely used in toys and child care articles.'" (*Id.*¶ 26 & Ex. H, 79 Fed. Reg. at 78340 (quoting CHAP Report at 111, 113, 116-17).) For that reason, "the CHAP found that current exposures to DIBP are low" and "do not indicate a high level of concern." (*Id.*¶ 26 & Ex. H, 79 Fed. Reg. at 78336.) Specifically, the CHAP found that "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products were located." (*Id.* ¶ 26 & Ex. I, CHAP Report at 111).) Based on these findings, the CHAP concluded that "[t]here would be little reduction in

exposure" of children to DIBP from toys or child care articles if the proposed rule banning DIBP were implemented. (*Id.* ¶ 26 & Ex. I, CHAP Report at 112).)

For these reasons, the scientific record in the administrative rulemaking shows that plaintiffs' allegations of injury caused by the CPSC's delay are not based on actual, present exposure to the five phthalates at issue, and thus are not sufficient to confer standing in this case. The claims here are analogous to the plaintiff's claims relating to the second of two chemicals at issue in *NRDC v. FDA* – triclocarban, a chemical used in over-the-counter antiseptic and antimicrobial soap. *See* 710 F.3d at 74, 85-86. The Second Circuit found that the plaintiff organization lacked standing to compel the FDA to finalize a rule regulating triclocarban because it submitted "no evidence that its members were directly exposed to triclocarban," and only claimed that "the proliferation of triclocarban may lead to the development of antibiotic-resistant bacteria" or "microbes that NRDC members may not ever come into contact with." *Id.* at 85-86. The court held that the plaintiff's claim of injury based on triclocarban exposure "thus seems less like a present injury and more like a *threatened* injury that is contingent and far-off rather than imminent," concluding that the plaintiff lacked standing to challenge the regulation of triclocarban. *Id*. at 86. Notably, the Court found that even though the FDA itself recognized a risk that antibiotic-resistant bacteria could potentially develop, the claim seemed "too causally remote" to establish a concrete risk of actual, imminent injury. *Id.* at 86. By contrast, the court explained that the plaintiff did have standing relating to the first chemical at issue in that case, triclosan, because the plaintiff organization established that at least one member had "direct, frequent exposure to triclosan" because she frequently washed her hands with soap containing triclosan at work as a veterinarian, and there was "no uncertainty that any harm [would] be directly caused by frequent direct exposure to triclosan." *Id.*

Here, by contrast, plaintiffs cannot allege any direct or frequent exposure to the phthalates at issue because those compounds currently are not found in toys or children's products or present no "quantifiable exposure" to children from such products. Furthermore, the CPSC and the CHAP have concluded that the risk of exposure does "not indicate a high level of concern." (Palmieri Decl. ¶ 26 & Ex. H, 79 Fed. Reg. at 78330.) For this reason, plaintiffs cannot allege any "direct risk of harm which rises above mere conjecture." *Baur*, 352 F.3d at 636; *cf. NYPIRG v. Whitman*, 321 F.3d 316 (2d Cir. 2003). In *Baur*, by contrast, the court found a "credible threat of harm" that the plaintiff would be exposed to contaminated beef because the government's testing methods were unreliable, making it impossible to determine whether a "downed animal" was contaminated and rendering the potential likelihood of any exposure uncertain. 352 F.3d at 630, 638-41 (noting that government would be unable to detect contaminated beef in U.S. market). Here, however, the CPSC and the CHAP relied on a sophisticated testing regimen to determine that four of the five phthalates are not found in children's products and that the fifth presents no quantifiable exposures in such products. Because the CPSC and the CHAP have confirmed that four of the phthalates are not currently present in such products and the fifth is minimally present, and that current exposure in such products does "not indicate a high level of concern" (Palmieri Decl. ¶ 26 & Ex. H, 79 Fed. Reg. at 78330), there is no uncertainty as to potential exposure, nor any "credible threat of harm" based on risk of actual exposure.[11] *Id.* at 634, 639.

The decision in *Whitman*, a case under the Clean Air Act, is similarly inapposite, because the plaintiff there (unlike the plaintiffs here) alleged concrete and particular facts

[11] Furthermore, as set forth in the accompanying Palmieri Declaration, more recent data analyzed by the CPSC since the time of the CHAP Report has established that even the "cumulative risk" of exposure to phthalates from such other sources has decreased markedly since that time to levels that are broadly beneath the CPSC's risk threshold. (Palmieri Decl. ¶ 27 & Exs. K, L.)

establishing that certain of its members actually lived near facilities that potentially emitted air pollutants in excess of legal levels, and thus had standing based on increased health-related uncertainty caused by the EPA's failure to enforce the Clean Air Act regulations. 321 F.3d at 325. Here, by contrast, plaintiffs have not alleged any particularized, concrete, or non-conclusory allegations establishing that any members are specifically at risk of harm from actual exposure to any of the five phthalates in such products.

For these reasons, plaintiffs have not established any "credible threat of harm" from actual exposure or increased risk of exposure to phthalates in such products, nor any "probability of harm" from such exposure that is caused by the CPSC's delay, because the phthalates at issue are not found in such products or present no quantifiable risk of exposure from such products. *See NRDC*, 710 F.3d at 81; *La Raza*, 468 F. Supp. 2d at 438-39 (plaintiffs alleging injuries of heightened risk of unlawful arrest failed to establish non-trivial "probability of harm" factored against the "severity of the probable harm" because, among other reasons, alleged risk was speculative) (citation omitted). Furthermore, the Supreme Court recently emphasized that such allegations "'of *possible* future injury' are not sufficient" to establish standing, because the "threatened injury must be *certainly impending* to constitute injury in fact." *Clapper*, 133 S. Ct. at 1147 (citation omitted); *see also La Raza*, 468 F. Supp. 2d at 438-39. In any event, the Complaint does not allege any "certainly impending" risk of threatened injury or possible future injury caused by the CPSC's delay. *See Taylor*, 2013 WL 4811222, at *7 (finding alleged injury based on increased risk too speculative to confer standing where "risk alleged by plaintiffs requires the type of 'highly attenuated chain of possibilities' contingent upon 'guesswork' as to the actions of third parties") (quoting *Clapper*, 133 S. Ct. at 1148-50, 1150 n. 5)). For these reasons, plaintiffs fail to satisfy the injury-in-fact requirement.

B. Plaintiffs Cannot Establish Any Injury That Is Fairly Traceable to the CPSC's Delay in Rulemaking

Plaintiffs similarly cannot allege sufficient facts to establish that any purported harm has been caused by the CPSC's delay in issuing a final regulation based on actual exposure to phthalates in children's toys or child care products. To satisfy the causation requirement for Article III standing, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" *Lujan*, 504 U.S. at 560-61 (citation omitted). The law is also clear that where, "as here, (1) plaintiffs challenge governmental agencies on the basis of third party conduct," and "(2) the government regulates the third parties . . . rather than plaintiffs directly, it is 'substantially more difficult' to meet the causation requirement for standing." *Taylor*, 2013 WL 4811222, at *9 (quoting *Warth v. Seldin*, 422 U.S. 490, 505 (1975)).

As discussed above, the CPSC's delay in issuing a final regulation has not caused any harm to plaintiffs based on actual exposure or continued exposure to these phthalates in children's toys or child care articles. Again, the CPSC and its experts have determined the phthalates currently either are not found in such toys or present no quantifiable exposure from such products. The timing for the finalization of the CPSC's rulemaking thus has no impact whatsoever on the fact that plaintiffs currently are not exposed to, and therefore are not injured by, toys or child care articles that contain the phthalates at issue. DINP, in fact, is subject to the interim ban and will remain subject to the interim ban until the CPSC publishes a final rule, so the CPSC's delay obviously cannot cause any injury based on exposure to DINP. Furthermore, plaintiffs do not even allege that any third-party manufacturer will begin producing toys and child care articles using any of these phthalates at levels of quantifiable risk of harm before the

CPSC's publication of a final rule. But even if they had, such speculative allegations involving the potential future conduct of third parties are too contingent and could not satisfy the causation requirement for standing. *See, e.g.*, *Taylor*, 2013 WL 4811222, at *9-10 (finding no causation or redressability where plaintiffs failed to show that finalization of joint rulemaking "would result in any changes to banks' alleged proprietary trading activities," that proprietary trading was "an inevitable result of the lack of final regulations," and that many banks had "halted their proprietary trading activities in anticipation of" the final rule's implementation).

Accordingly, plaintiffs' alleged injury from purported exposure to these phthalates cannot be fairly traceable to the CPSC's delay. "While the delay in the final rulemaking may be a source of great frustration for plaintiffs, they have failed to establish any injury in fact traceable to that delay that would confer standing to bring this case in federal court." *Id.* at *1. Plaintiffs thus fail to satisfy the causation requirement for Article III standing.

C. An Order from the Court Will Not Redress Plaintiffs' Claimed Injuries Caused by the CPSC's Delay

The Complaint alleges that plaintiffs' purported harm caused by the CPSC's delay "would be redressed by an order directing the CPSC to publish the required final rule as soon as possible." (Compl. ¶ 8.) As the administrative record establishes, however, an injunction compelling the CPSC to publish a final rule will not redress any claimed injury based on CPSC's delay, because there is no current, actual exposure or any quantifiable exposure to any of the phthalates at issue in any toys or child care articles. To satisfy the redressability requirement, a plaintiff must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan,* 504 U.S. at 561 (internal quotation marks and citation omitted); *see also Town of Babylon v. Fed. Hous. Fin. Agency*, 699 F.3d 221, 229 (2d Cir. 2012) (plaintiff challenging agency action that 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."). Plaintiffs cannot meet that standard whether the relief they seek is the imposition of a final ban in the form of the current proposed rule, or the imposition of a deadline for publishing a final ban only.

First, because DINP is subject to an interim ban until the final rule is in place, an order compelling implementation of the final rule "as soon as possible" would not redress any alleged injury based on purported exposure to DINP. DINP simply is not present in toys or child care articles and has not been since the interim ban was implemented in 2009. For this reason, the CHAP itself determined that a permanent ban on DINP, if implemented, would not be expected to reduce actual exposure to children from DINP, "because DINP is currently subject to an interim ban on use in children's toys and child care articles at levels greater than 0.1%." (Palmieri Decl. ¶ 24 & Ex. I, CHAP Report at 99.) Because plaintiffs can show no injury in fact based on exposure to DINP in such products, the relief plaintiffs seek likewise would not redress their purported injury.

Similarly, an order compelling publication of the final rule "as soon as possible" would not redress plaintiffs' claimed injury based on exposure to DPENP, DHEXP, or DHEXP, because those phthalates are "currently not found in children's toys or child care articles" and "not widely found in the environment." (*Id.* ¶ 25 & Ex. I, CHAP Report at 113 (DPENP), 116 (DHEXP), 117-18 (DCHP).) For these reasons as well, the CHAP concluded that the recommended final ban, if implemented, would not be expected to reduce actual exposure of children to DPENP, DHEXP, and DCHP in toys and children's products. (*Id.* ¶ 25 & Ex. I, CHAP Report at 113 (DPENP), 116 (DHEXP), 117-18 (DCHP).) The relief plaintiffs seek thus

would not redress their claimed injuries based on alleged actual exposure from these three phthalates in such products. *See Taylor*, 2013 WL 4811222, at *9-10.

The injunction plaintiffs seek also would not redress any claimed injury based on exposure to DIBP in such products. Again, the CHAP found "[n]o quantifiable exposures to infants, toddlers, or children from toys or children's personal care products" with respect to DIBP. (Palmieri Decl. ¶ 26 & Ex. I, CHAP Report at 111.) For this reason, the CHAP concluded that "[t]here would be little reduction in exposure" to children from DIBP if the recommended permanent ban of DIBP were to be implemented. (Palmieri Decl. ¶ 26 & Ex. I, CHAP Report at 112.) Accordingly, an order compelling final publication of the proposed rule would not redress any purported injury from exposure to DIBP in such products caused by the CPSC's delay. *See Town of Babylon*, 699 F.3d at 230 (affirming dismissal for lack of standing where plaintiffs failed to show it was likely, rather than merely speculative, that order compelling agency to vacate guidance would cause third-party banks to take any action to relieve alleged harm).

Finally, the result is the same if the Court accepts plaintiffs' claim that this lawsuit only seeks to compel a schedule for implementing the final rule by the CPSC, rather than implementing the proposed rule in its current form. An order requiring a final rule by a date certain, on its own, would not redress or mitigate the alleged – but currently non-existent – exposure to these phthalates in toys and child care articles caused by the CPSC's delay, because such an order (as plaintiffs claim) would not dictate the content of the final rule either way. Even under such a scheduling order, the CPSC could either impose a permanent ban or lift the interim ban of DINP and decline to regulate the other phthalates based on a determination of reasonable certainty that there is no harm to children, pregnant women, or other susceptible

individuals from the phthalates at issue in such products.[12] It is therefore entirely speculative that a favorable decision entering an order that sets a deadline for the final rule would redress plaintiffs' alleged injury caused by the CPSC's delay. That result would be based on a "double contingency" in which the Court must first enter a scheduling order, and the CPSC subsequently would issue a final rule banning the use of the phthalates at issue in children's toys and child care articles.

Conclusion

For the foregoing reasons, intervenor the National Association of Manufacturers respectfully requests that the Court issue an order dismissing the Complaint in its entirety for lack of subject-matter jurisdiction, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, because plaintiffs lack standing under Article III of the U.S. Constitution to compel the CPSC to issue a final rule pursuant to Section 108(c)(3) of the CPSIA, and granting such other and further relief as the Court deems appropriate.

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Respectfully submitted,

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[12] *See* 15 U.S.C. § 2057c(b)(3)(A).