No. 17-60836

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

TEXAS ASSOCIATION OF MANUFACTURERS,
TEXAS CHEMICAL COUNCIL, TEXAS ASSOCIATION OF BUSINESS,
NATIONAL ASSOCIATION OF MANUFACTURERS, and
AMERICAN CHEMISTRY COUNCIL,
Petitioners,

v.

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,
Respondent.

On Petition for Review of a Final Rule
of the U.S. Consumer Product Safety Commission

RESPONSE BRIEF FOR RESPONDENT-INTERVENORS

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November 5, 2018

CERTIFICATE OF INTERESTED PERSONS

No. 17-60836

TEXAS ASSOCIATION OF MANUFACTURERS,
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Respondent.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Petitioners:

Texas Association of Manufacturers, Texas Chemical Council, Texas Association of Business, National Association of Manufacturers, and American Chemistry Council

Respondent:

United States Consumer Product Safety Commission

Intervenors:

Natural Resources Defense Council, Inc., Environmental Justice Health Alliance for Chemical Policy Reform, and Breast Cancer Prevention Partners

Proposed Amici:

American Public Health Association, Learning Disabilities Association of America, National Hispanic Medical Association, Dr. Stephanie M. Engel, Dr. Chris Gennings, Dr. Russ Hauser, Dr. Bruce Lanphear, Dr. Heather Patisaul, Dr. Robin Whyatt, Dr. R. Thomas Zoeller, and Dr. Ami Zota

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STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Fifth Circuit Rule 28.2.3 and Federal Rule of Appellate Procedure 34(a)(1), respondent-intervenors submit that oral argument is needed in this case given the complexity and import of the regulatory questions presented. Respondent-intervenors request that they have the opportunity to present argument before the Court.

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INTRODUCTION

In 2008, Congress directed the U.S. Consumer Product Safety Commission to adopt a rule addressing the potentially devastating human health effects of exposure to phthalates, a class of chemicals used in some children's products, such as baby teethers and rattles. Nearly a decade later, the Commission adopted a rule banning the manufacture, sale, and importation into the United States of children's toys and child care articles containing five specific phthalates. The rule builds on painstaking research and recommendations from a statutorily mandated panel of scientists, and it carefully addresses public comments in the record, including critiques filed by industry groups. Five industry groups now ask this Court to invalidate the rule for what amount to methodological quibbles and a mischaracterization of the Commission's action. This Court should dismiss the petition for review because petitioners have not demonstrated they have Article III standing to bring their claims. In the alternative, because the Commission's rule is in every respect consistent with the agency's statutory mandate and the Administrative Procedure Act, the petition should be denied.

STATEMENT OF JURISDICTION

Petitioners assert that this Court has jurisdiction to review the Commission's rulemaking under 15 U.S.C. § 2060(a) and (c), which give this Court authority to review the Commission's "consumer product safety rule[s]." The Commission filed

a motion to dismiss the petition for lack of jurisdiction or, in the alternative, to transfer to an appropriate federal district court because it argued that the rule at issue does not constitute a "consumer product safety rule." Respondent-intervenors filed a response to that motion arguing that, even if petitioners are correct that jurisdiction lies in this Court under § 2060, they are incorrect in asserting that § 2060's reference to substantial-evidence review applies here. *See generally* Respondent-Intervenors Response to Mot. To Dismiss. This Court carried the Commission's motion to dismiss and associated briefing with the case. *See* 5th Cir. Order of Apr. 10, 2018.

ISSUES PRESENTED

1. Whether the petitioners have demonstrated that they have Article III standing to bring their claims.

2. Whether the petition for review should be dismissed or transferred for lack of jurisdiction.

3. Whether the Commission acted contrary to law in making the findings specified by Congress for the regulation of phthalates and in prohibiting children's toys and child care articles containing certain phthalates.

4. Whether the Commission reasonably interpreted the statutory standards for regulating phthalates and whether it acted arbitrarily and capriciously in applying those standards to the scientific data.

5. Whether petitioners were entitled to an additional opportunity to comment on the rulemaking before the Commission promulgated the final rule.

STATEMENT OF THE CASE

In 1972, Congress enacted the Consumer Product Safety Act, Pub. L. No. 92-573, to address the problem that an "unacceptable number of consumer products" presented "unreasonable risks of injury" to the public and that the complexities of those products rendered users unable to "anticipate risks" and "to safeguard themselves adequately." 15 U.S.C. § 2051(a)(1), (2). The Act established the Commission and tasked it with, among other mandates, the protection of "the public against unreasonable risks of injury associated with consumer products." *Id.* § 2051(b)(1).

Nearly four decades later, in 2008, Congress enacted the Consumer Product Safety Improvement Act (CPSIA), Pub. L. No. 110-314. The CPSIA amended several consumer protection laws, including the Consumer Product Safety Act, to limit the public's exposure to toxic chemicals, including phthalates. Phthalates are chemicals used to soften plastics. *See* Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 79 Fed. Reg. 78,324, 78,324 (Dec. 30, 2014) (proposed rule). Although they are common in toys and child care products, *see id.*, phthalates can leach from plastics, leading to human exposure through both the mouth and skin, *id.* at 78,327. Some phthalates are "antiandrogenic"—meaning

they interfere with hormone production and have been associated with reproductive abnormalities, *see id.* at 78,326—which is especially problematic in utero, during infancy, and in childhood. Exposure to phthalates during these sensitive periods of development may cause permanent reproductive harm. A number of studies have linked exposure to certain phthalates with decreases in testosterone, genital malformations, and reduced sperm production, among other adverse effects. *See id.* at 78,327.

The CPSIA permanently banned the manufacture, sale, distribution, or importation of children's toys and child care articles that contain more than 0.1 percent of any of three different phthalates, known as DEHP, DBP, and BBP. *See* 15 U.S.C. § 2057c(a). The CPSIA also banned, on an interim basis, the manufacture, sale, distribution, or importation of a subset of children's toys (those that can be placed in a child's mouth) and child care articles containing more than 0.1 percent of three other phthalates—known as DINP, DIDP, and DnOP. *Id.* |§ 2057c(b)(1).

The CPSIA directed the Commission 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). The CHAP was tasked with recommending to the Commission whether any phthalates or phthalate alternatives, in addition to those already banned, should be prohibited. *Id.* § 2057c(b)(2)(C). The 2008 law instructed the

Commission, after it received the CHAP's report, to "promulgate a final rule" addressing whether to continue the interim prohibitions of child care articles and small children's toys containing DINP, DIDP, or DnOP, "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). In addition, the CPSIA directed the Commission to "declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. § 2057), as the Commission determines necessary to protect the health of children." *Id.* § 2057c(b)(3)(B).

The Commission appointed a panel of scientific experts to comprise the CHAP. The CHAP began meeting in 2010 and submitted its peer-reviewed final report to the Commission in 2014. Proposed Rule, 79 Fed. Reg. at 78,325-26. The final report included a comprehensive examination of animal and human studies bearing on the potential health effects of exposure to phthalates. *See id.* at 78,326-27. The CHAP concluded that many of the phthalates studied were associated with harmful effects on male reproduction, neurobehavioral functions, and other health endpoints. *See id.* It recommended continuing the interim ban for DINP, one of the phthalates listed in the CPSIA, and expanding that ban to all children's toys, not just those that can be placed in a child's mouth. *Id.* at 78,329. It also recommended banning children's products containing four more phthalates (DIBP, DPENP,

DHEXP, and DCHP) not specified in the CPSIA. *Id.* at 79,330. The CHAP's recommendation of a permanent ban on children's products containing these five phthalates was based largely on the risk of harm to male reproductive development caused by exposure to these phthalates. *Id.*

In response to the CHAP report, the Commission in late 2014 published a proposed rule. *See generally* Proposed Rule, 79 Fed. Reg. 78,324. The Commission proposed to follow the CHAP's recommendation to make permanent the interim statutory ban on child care articles and small children's toys containing DINP and to expand the ban to larger children's toys as well. *Id.* at 78,334-35. It also proposed to ban all children's toys and child care articles containing four additional phthalates (DIBP, DPENP, DHEXP, and DCHP). *Id.* at 78,336-37.

The Commission received 91 comments on the proposed rule. Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938, 49,939 (Oct. 27, 2017) (final rule). As it reviewed those comments, more recent data became available from the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES), one of the data sources on which the CHAP had based its recommendations. *Id.* Adopting the same methodology used by the CHAP, Commission staff updated the analysis of NHANES data and provided additional opportunities for public comment. *Id.* at 49,939-40.

In 2017, the Commission published a rule (hereinafter, the Phthalates Rule) permanently prohibiting child care articles and children's toys containing the five types of phthalates addressed in the proposal. *See generally* Final Rule, 82 Fed. Reg. 49,938. The rule was identical to the proposed version in all material respects, although for the sake of clarity the Commission incorporated additional language directly from the CPSIA regarding component parts of banned children's products. *Id.* at 49,940. The Commission considered the cumulative effects of exposure to phthalates, both through children's products and other means. Based on that review, the Commission found that women in the NHANES dataset had levels of phthalate exposure that were not considered safe under the CHAP's methodology. *Id.* at 49,958, 49,963. It thus concluded that the continuation of Congress's interim ban on child care articles and small children's toys containing DINP was needed to ensure a reasonable certainty of no harm to children, pregnant women, and other susceptible individuals, with an adequate margin of safety. *Id.* at 49,963, 49,966. It likewise determined that the expansion of the interim ban on products containing DINP to include larger children's toys, and the implementation of new bans on children's products containing DIBP, DPENP, DHEXP, and DCHP, were necessary to protect the health of children. *Id.* at 49,964, 49,969-70.

Petitioners, five trade associations, filed a petition for review in this Court challenging the Phthalates Rule.

SUMMARY OF ARGUMENT

This Court should dismiss the petition for review for lack of standing. Petitioners, five trade associations, have not identified any member of any of the five associations that is directly regulated by the Phthalates Rule, and they have failed to identify any other interest of their members that would confer standing. Four petitioners' declarations identify no specific members at all—a fatal flaw under the Supreme Court's decision in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009). And the fifth, while specifically stating that Exxon is a member, does not demonstrate that Exxon seeks to manufacture DINP or any other covered phthalate for use in children's products within the scope of the rule.

In the alternative, this Court should deny the petition because the Phthalates Rule is consistent with the agency's statutory mandate and is reasonable.[1] First, the Commission correctly concluded that § 2057c(b)(3)(B) offers a standalone route for the agency to ban children's products containing phthalates where necessary to protect children's health. Section 2057c indicates that if the Commission bans any children's products beyond those covered by Congress's interim prohibition, those products will be deemed "banned hazardous products" under § 2057. In other words, they will for legal purposes be treated as such products. But § 2057c decidedly does

[1] Intervenors do not restate here their arguments regarding this Court's jurisdiction to review the petition under 15 U.S.C. § 2060 and instead direct the Court to the parties' briefing on the motion to dismiss.

not incorporate the procedures of § 2057 and, by § 2057's cross-reference, § 2058. Petitioners' contrary reading is unnatural under traditional tools of statutory construction and would make a mess of the statutory scheme.

Second, the Commission reasonably assessed the evidence and applied the statutory standards consistent with their health-protective focus. The Commission rationally determined that the standards for banning children's products containing phthalates—where such prohibitions were "necessary to protect the health of children" and to ensure a "reasonable certainty of no harm" to vulnerable individuals—were met where the data on which it relied demonstrated that a portion of women of reproductive age continued to have unsafe exposure levels. It also reasonably relied on biomonitoring data based on urine samples and incorporated findings from rodent-based studies.

Third, the Commission indisputably provided petitioners and their members with a sufficient opportunity to comment on the rule and the data on which the rule relies. The final rule is in all material respects identical to the proposal. And the rationale underlying the final rule was foreseeable to petitioners; indeed, some commented on precisely that rationale during the rulemaking.

STANDARD OF REVIEW

If this Court concludes that 15 U.S.C. § 2060 provides jurisdiction over the petition for review, then it should apply the judicial-review provisions of the

Administrative Procedure Act (APA), which § 2060 incorporates by reference. *See* 15 U.S.C. § 2060(c) (stating that "the court shall have jurisdiction to review the consumer product safety rule in accordance with chapter 7 of Title 5"). The APA authorizes this Court to set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and agency action adopted "without observance of procedure required by law," *id.* § 706(2)(D). This Court's review under the APA is "most deferential to the agency where, as here," the agency's "decision is based upon its evaluation of complex scientific data within its technical expertise." *BCCA Appeal Grp. v. EPA*, 355 F.3d 817, 824 (5th Cir. 2003) (internal quotation marks omitted).

ARGUMENT

I. THE PETITIONERS HAVE NOT DEMONSTRATED THAT THEY HAVE STANDING TO CHALLENGE THE RULE.

Article III of the U.S. Constitution limits the jurisdiction of federal courts to "[c]ases" and "[c]ontroversies." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559 (1992) (internal quotation marks omitted). A key component of Article III's case-or-controversy requirement is the doctrine of standing, which requires that a petitioner have a sufficient "personal stake" in the case "to warrant his invocation of federal-court jurisdiction." *Summers*, 555 U.S. at 493 (internal quotation marks and emphasis omitted). Petitioners—five trade associations—bring this case on their members' behalf using a theory of associational standing. Because they have not

made the showing required to establish associational standing, this Court should dismiss the petition for review.

Where a party seeks to establish associational standing, the Supreme Court has required that the organization "make specific allegations establishing that at least one *identified* member ha[s] suffered or would suffer harm." *Id.* at 498 (emphasis added); *see Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (stating that association has standing where at least one "member[] would otherwise have standing to sue in [its] own right"); *see, e.g., Ala. Legislative Black Caucus v. Alabama*, 135 S. Ct. 1257, 1270 (2015) (holding that a district court erred by not permitting a plaintiff an opportunity "to file its list of members" to show that it had at least one member in each majority-minority district at issue in a racial gerrymandering case); *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 820 (D.C. Cir. 2006) (holding, in a case involving one of the petitioners, that "[a]t the very least, the identity of the party suffering an injury in fact must be firmly established" and refusing to find standing on the basis of the associations' unnamed members); *see also Ga. Republican Party v. SEC*, 888 F.3d 1198, 1203 (11th Cir. 2018); *Ouachita Watch League v. U.S. Forest Serv.*, 858 F.3d 539, 543 (8th Cir. 2017); *S. Walk at Broadlands Homeowner's Ass'n, Inc. v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013); *Funeral Consumers All., Inc. v. Serv. Corp. Int'l*, 695 F.3d 330, 343-44 (5th Cir. 2012). The "requirement of naming" affected

members can only be dispensed with "where *all* the members of [an] organization are affected by the challenged activity." *Summers*, 555 U.S. at 498-99 (citing *NAACP v. Alabama ex rel. Patterson*, 357 U.S. 449, 459 (1958)).

Only one petitioner, the Texas Chemical Council, identifies any member by name, and its discussion of the interests of that member, ExxonMobil Chemical Company, cannot support a finding of Article III standing. The declaration states that Exxon "manufactures phthalates regulated by the Phthalates Rule," Ex. 3 ¶ 5, and it cites a 2015 Exxon comment in the administrative record describing the company as a "major producer of [the phthalate] DINP," *see* Comment of Exxon, Apr. 14, 2015, Index No. 361, at 1-1. The rule, however, does not regulate the manufacture or production of DINP. Rather, it prohibits "the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States *of any children's toy or child care article*," or a "component part" of one of these products, that contains more than .1% of DINP. 16 C.F.R. § 1307.3(b), (c) (emphasis added).

Thus, to show standing for any of petitioners' claims, a phthalate manufacturer like Exxon must show that it would like to sell at least one phthalate for use in children's toys and child care articles, and would do so but for the Phthalates Rule. And to establish standing to challenge the Commission's decision to ban products containing phthalates beyond those covered by Congress's interim ban, as petitioners do (*see infra* Part II), petitioners must show that a member

manufacturer seeks to sell DINP for use in children's toys other than those that can be placed in a child's mouth, or that it seeks to sell another of the four phthalates covered by the rule for use in children's toys or child care articles. Exxon, for example, would lack standing to challenge the expansion of the DINP ban if it only asserted that it sought to sell DINP for inclusion in child care articles or small-sized children's toys, because those uses were covered by the interim ban and the Commission applied a different standard before determining to keep that ban in place. In any event, the Texas Chemical Council has made none of these showings. Indeed, its declaration does not say that Exxon has manufactured or sold DINP or any of the other four banned phthalates for use in any children's products in the past, nor does it indicate that Exxon would like to do so or could do so in the future absent the Phthalates Rule. Because Exxon lacks standing, so does the Texas Chemical Council.

The remaining four petitioners—while referring to hundreds of petitioners' member groups—do not identify a single member by name. *See* Ex. 1 ¶¶ 2, 5; Ex. 2 ¶¶ 2, 5; Ex. 4 ¶¶ 2, 5; Ex. 5 ¶¶ 2, 5. Although they cross-reference an Exxon comment in their declarations without expressly noting the submitter of the comment, *see* Ex. 1 ¶ 4; Ex. 2 ¶ 4; Ex. 4 ¶ 4; Ex. 5 ¶ 4, these four petitioners do not expressly state that Exxon is a member, and they make no specific statements about Exxon's interest in the rule. They assert that they have members that "manufacture,

sell, or use products containing one or more of the five banned phthalates." Ex. 1 ¶ 5; Ex. 4 ¶ 5; Ex. 5 ¶ 5; *see also* Ex. 2 ¶ 5 (stating that members "manufacture, sell, and use one or more of the five banned phthalates and/or products containing one or more of the five banned phthalates"). However, they do not assert that these products are "consumer product[s]" covered by the rule, 15 U.S.C. § 2052 (defining "consumer product"), much less the narrow subset of such products constituting "children's toy[s]" and "child care article[s]," 16 C.F.R. § 1307.2 (defining those terms), or their "component parts," *id.* § 1307.3(c).

These petitioners also state that they represent companies that "manufacture or import consumer products or components of such products that contain phthalates." Ex. 1 ¶ 2; Ex. 4 ¶ 2; Ex. 5 ¶ 4; *see also* Ex. 2 ¶ 2 (members that "manufacture, sell or import consumer products or components of such products that contain phthalates"). But that assertion again does not indicate that the companies manufacture or import the *children's* consumer products actually covered by the rule. Although petitioners contend that their members will "no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles," Ex. 1 ¶ 5; Ex. 2 ¶ 5; Ex. 4 ¶ 5; Ex. 5 ¶ 5, they have not established that any member actually seeks to do so for any of the regulated phthalates, or would be able to do so in the current market. They accordingly have not met their burden to demonstrate standing under *Summers* and *Lujan*.

Petitioners also suggest that they have standing to challenge the rule because their members "suffered various procedural injuries" during the rulemaking. Ex. 1 ¶ 6; Ex. 2 ¶ 6; Ex. 4 ¶ 6; Ex. 5 ¶ 6. In a procedural-rights case, Article III's normal standards for immediacy and redressability are relaxed. *See Lujan*, 504 U.S. at 572 n.7. Nonetheless, petitioners must show cognizable injury-in-fact beyond the procedural violation. *See, e.g.*, *id.* at 573-74 & n.8. "[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Summers*, 555 U.S. at 496. Petitioners' alleged procedural-injury arguments, therefore, cannot save them from their failure to identify a concrete injury to an identified member fairly traceable to the Phthalates Rule.

II. THE COMMISSION MADE ALL STATUTORILY REQUIRED FINDINGS AND FOLLOWED ALL REQUIRED PROCEDURES.

Petitioners contend that, before adopting the Phthalates Rule, the Commission was required to comply not only with 15 U.S.C. § 2057c, which specifically addresses the regulation of phthalates, but also with other provisions of the Consumer Product Safety Act that pertain to consumer product safety rules banning hazardous products. Petitioners' complicated theory of statutory construction is at odds with the law's plain text and in conflict with its purpose. It should be rejected.

Under 15 U.S.C. § 2057c, the Commission had a statutory mandate to promulgate a final rule "pursuant to section 553 of Title 5" regarding the regulation of phthalates. The Commission was to:

> (A) determine, based on [a Chronic Hazard Advisory Panel, or CHAP] report, whether to continue in effect [Congress's interim statutory prohibition on any children's toy that can be placed in a child's mouth or child care article containing the three phthalates DINP, DIDP, and DnOP], in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and
>
> (B) evaluate the findings and recommendations of the [CHAP] and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

15 U.S.C. § 2057c(b)(3).

After appointing a CHAP and considering its report, along with comments in the underlying record, the Commission relied on subsection (b)(3)(A) of § 2057c to make permanent Congress's interim ban on DINP in children's toys that can be placed in the mouth and child care articles. In so doing, it determined that extending the interim ban on these products was needed 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); *see* Final Rule, 82 Fed. Reg. at 49,963. Petitioners do not contend that the Commission was obliged to look beyond § 2057c for the requisite findings and procedures necessary to make that determination.

However, the Commission's Phthalates Rule also expanded the ban on DINP to include *all* children's toys, and instituted a ban on all children's toys and child care articles containing four additional phthalates (DIBP, DPENP, DHEXP, and DCHP) not covered by Congress's permanent or interim phthalate bans in § 2057c. Petitioners argue (Br. 25-33) that before regulating beyond Congress's interim phthalate ban, the Commission was required to make the findings and follow the procedures set out in §§ 2057 and 2058, not just § 2057c. The Commission determined—as was required by § 2057c(b)(3)(B)—that the new bans were "necessary to protect the health of children," Final Rule, 82 Fed. Reg. at 49,940, 49,969-70, but it explained in the final rule that §§ 2057 and 2058 did not apply to the rulemaking, *id.* at 49,944.

As the Commission has explained, § 2057c acts as a standalone route, available only with respect to phthalates, for the Commission to declare a product "to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057)," where "necessary to protect the health of children." Commission Br. 26. Section 2057c provides that when the Commission declares a children's product to be a "banned hazardous product," the product is deemed to be a banned hazardous product with all the requirements and restrictions on that product that apply under § 2057. The language "under … [section 2057]" thus answers the question of *what kind* of banned hazardous product is created when the Commission

exercises its authority to adopt a final rule under § 2057c(b)(3)(B). The Commission reasonably concluded that there is no statutory basis or evidence in the legislative record to support petitioners' contrary reading, which would ignore Congress's singular focus on health in § 2057c, and instead force the Commission to undertake a cost-benefit analysis and consider other factors at odds with congressional purpose. *See* Final Rule, 82 Fed. Reg. at 49,944 (discussing § 2057c's text and the legislative record).

Other indicia in the statute's text and structure support the Commission's view. Although petitioners contend (Br. 32) that Congress "expressly direct[ed] the Commission to act 'under [s. 2057]' when" adopting a final rule to regulate phthalates, that reading of § 2057c(b)(3)(B) is unnatural. It "disregards—indeed, is precisely contrary to—the grammatical 'rule of the last antecedent,' according to which a limiting clause or phrase … should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). "[U]nder … [§ 2057]" refers only to a "banned hazardous product," which immediately precedes it in the sentence, not to the Commission's act of "declar[ing]" the product as such. *Cf. Nw. Forest Res. Council v. Glickman*, 82 F.3d 825, 832 (9th Cir. 1996), *as amended on denial of reh'g* (May 30, 1996) (examining statutory provision addressing "all timber sale contracts offered or awarded before [the enactment of a law] in any unit of the National Forest System or district of the

Bureau of Land Management subject to section 318" and holding that "subject to section 318" modified only the portion of the sentence beginning with "any unit"). Section 2057c assuredly does not direct the Commission to "declare under 15 U.S.C. § 2057" or "declare pursuant to 15 U.S.C. § 2057" that a product is to be a banned hazardous product. Yet that is precisely the way one must read the statute to accept petitioners' view.

Petitioners also ignore other statutory indicators at odds with their reading, even beyond those identified in the Commission's brief. For example, § 2057c makes adoption of a ban on hazardous phthalates in children's products mandatory upon a finding by the Commission that such ban is "necessary to protect the health of children." 15 U.S.C. § 2057c(b)(3)(B) (stating that the Commission "shall … promulgate a final rule" in such circumstances). In contrast, § 2057 is permissive, providing that the Commission "may" promulgate a rule declaring a product a banned hazardous product if it finds that the product presents an "unreasonable risk of injury" from which the public cannot otherwise be protected by a safety standard. Petitioners do not explain how to reconcile these two distinct regimes that combine not only different standards but also different charges for the Commission.

Moreover, under petitioners' reading, Congress gave conflicting instructions with respect to the procedure for rulemaking in § 2057c(b)(3) and § 2058, which

§ 2057 cross-references. Section 2058 is a general section governing procedures applicable to the promulgation of "consumer product safety rule[s]." It states that "[c]onsumer product safety rules shall be promulgated in accordance with section 553 of Title 5, *except that* the Commission shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions." *Id.* § 2058(d)(2) (emphasis added). In contrast, § 2057c(b) states that the "Commission shall, pursuant to section 553 of Title 5, promulgate [its] final rule" on children's products containing phthalates. Section 2057c(b), unlike § 2058, does not add any procedural requirements beyond what the APA itself requires for notice-and-comment rulemaking. Petitioners do not explain why Congress would have set forth two separate procedural schemes for the same type of rule.

In this case, the Commission's interpretation of § 2057c(b)(3) is the most consistent with the text, structure, and purposes of the CPSIA. It is also eminently reasonable and, therefore, must be sustained by the Court. *See ConocoPhillips Co. v. EPA*, 612 F.3d 822, 831 (5th Cir. 2010) ("The question of reasonableness is not whether the agency's interpretation is the only possible interpretation or whether it is the most reasonable, merely whether it is reasonable *vel non*.").

III. THE COMMISSION REASONABLY INTERPRETED THE "REASONABLE CERTAINTY OF NO HARM" AND "NECESSARY TO PROTECT THE HEALTH OF CHILDREN" STANDARDS.

Petitioners contend that the Commission interpreted "reasonable certainty of no harm … with an adequate margin of safety," and "necessary to protect the health of children" to require an "absolute certainty of no risk." Pet'r Br. 34. They repeat this assertion at least *seven* times in their brief but notably never cite any part of the final rule to support it. There is a reason for that: The Commission did not demand absolute certainty of no risk to health. Indeed, although it believed Congress had set "a highly protective standard" focused on health under § 2057c, it expressly disavowed requiring "100 percent certainty of no harm." Final Rule, 82 Fed. Reg. at 49,944.

Petitioners' arguments in this context are methodological quibbles masquerading as legal-error claims. They are also meritless. The Commission acted reasonably in assessing the evidence, and it made choices consistent with its statutory mandate to use a highly protective standard.

First, petitioners question the Commission's use of a cumulative assessment to estimate the overall impact of phthalate exposure. But as the Commission reasonably explained, the CPSIA "required the CHAP to use some method to evaluate the health effects of multiple phthalates from multiple products," including products beyond children's toys. *Id.* at 49,943. Indeed, the law all but demands a

cumulative assessment. *See* 15 U.S.C. § 2057c(b)(2)(B)(ii) (directing the CHAP to consider the health effects of phthalates "in combination with other phthalates"); *see also* Commission Br. 43. This "comprehensive approach" to phthalate hazards, "rather than a piecemeal[,] one-by-one 'whack-a-mole' plan," is at the core of § 2057c. Minutes of Commission Meeting Regarding Final Phthalates Rule, Oct. 18, 2017, Statement of Commissioner Adler at 1, Index No. 462.

Furthermore, the approach is reasonable. The effects of antiandrogenic phthalates are "additive." Final Rule, 82 Fed. Reg. at 49,946. That is, "exposures to multiple phthalates at lower doses act in concert to produce the same effect as a higher dose of a single phthalate." *Id.* "Due to the additive effects of certain phthalates," the CHAP determined and the Commission reasonably agreed "that it is appropriate to conduct a cumulative risk analysis to assess … antiandrogenic phthalates." *Id.* This approach is consistent with the Commission's statutory mandate of making permanent the interim bans where needed to ensure that there is a "reasonable certainty of no harm … with an adequate margin of safety" and of banning all children's products containing phthalates where "necessary to protect the health of children." 15 U.S.C. § 2057c(b)(3).

Second, petitioners contend that the Commission adopted an "unreasonably sensitive [Hazard Index, or] HI metric." Pet'r Br. 38. As the Commission explained, however, the HI metric is an approach "widely used in cumulative risk assessments

of chemical mixtures," Final Rule, 82 Fed. Reg. at 49,946, and is "consistent with the [Commission's] chronic hazard guidelines," which have been in place since 1992, *id.* at 49,962-63. An HI is determined by first calculating a "hazard quotient" for each phthalate, equal to "the estimated exposure to [the] phthalate" divided by "the level of exposure that, generally speaking, would be acceptable." Commission Br. 10 (citing Proposed Rule, 79 Fed. Reg. at 78,328). "[H]azard quotients for individual phthalates are summed to determine" the HI. *Id.* at 11.

Petitioners argue that data from one source—the NHANES dataset—overestimated exposure levels because the data were based on urine samples and did not demonstrate long-term exposure levels. Pet'r Br. 37, 40. But the Commission directly addressed this contention in the rule, explaining why the urine samples—collected from participants at different times throughout the day—provide exposure data that are representative of the U.S. population. Final Rule, 82 Fed. Reg. at 49,960. It also explained that "[s]imilar data with 24-hour or longer sampling times are not available," and that urine samples, because they offer "a direct measure of human exposure," are "superior to alternatives such as modeled exposures." *Id.* It was not arbitrary or capricious for the Commission to rely on this data source, among others, to calculate HIs. *See Texas Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 934 (5th Cir. 1998) ("If the agency's reasons and policy choices conform to minimal standards of rationality, then its actions are reasonable and must be upheld.").

Third, petitioners argue (Br. 36-37) that the Commission should not have regulated phthalates covered by the rule where the HI only exceeded one at the 99th percentile of women of reproductive age because the findings were too unstable at that level. However, the data made clear that between two and nine women, out of a sample of 538, were *actually* observed with HIs above one. Final Rule, 82 Fed. Reg. at 49,963. The Commission reasonably relied on that finding to regulate phthalates even though it could not reliably "estimate the percentage of [women of reproductive age] with an HI greater than one" among the U.S. population. *Id.* at 49,958.

Put another way, the Commission was not able to say with scientific certainty that 600,000 women of reproductive age, or 1% of that universe of women in the United States, had HIs greater than one. Perhaps the number was twice that (1.2 million women), half that (300,000 women), or even one-tenth of that (60,000 women). Under any scenario, though, a "portion of" women of reproductive age had HIs above one—that is, the women were "exposed to phthalates at levels that can induce [male reproductive developmental effects] or other phthalate syndrome effects." *Id.* at 49,943 (footnote omitted and emphasis added). And, as the Commission emphasized, this data on exposures and risks in women "probably underestimate the risks to infants and children," who generally have exposures two to three times higher than adults. *Id.* at 49,958. Based on these findings, it was reasonable for the Commission to determine that regulation of children's products

containing the five phthalates covered by the rule was "necessary to protect the health of children" and (for continuation of the interim ban of DINP) to ensure that there was a "reasonable certainty of no harm … with an adequate margin of safety." 15 U.S.C. § 2057c(b)(3).

Fourth, petitioners fault the Commission for relying in part on data that pre-dated the CPSIA's 2008 permanent ban on DEHP and interim ban on DINP. That reliance, however, was reasonable, and the Commission expressly addressed petitioners' argument in the final rule. As the Commission explained, it relied in part on 2005/2006 NHANES data to "satisfy the CPSIA's charge" that it examine, among other things, likely levels of pregnant women's exposure to phthalates. Final Rule, 82 Fed. Reg. at 49,943 (citing 15 U.S.C. § 2057c(b)(2)(B)(iii)). "This data set was the most recent data on pregnant women available at the time the CHAP completed its analysis in July 2012, and it was the last data set to include a larger sample of pregnant women." *Id.* (citation omitted). Moreover, because the ban on DEHP and DINP extended only to certain children's products, women of reproductive age and children continue to be exposed to these phthalates from other sources, *see id.*, meaning that these phthalates continue to present a risk to health under a cumulative-effects analysis, *see id.* at 49,960. In any event, before issuing the final rule, Commission staff analyzed NHANES data from subsequent years, using women of reproductive age in those datasets "as a surrogate for pregnant women." *Id.* at

49,942-43. The Commission concluded that the "CHAP and subsequent staff analyses provide a robust assessment of the 'likely levels' of current exposures to phthalates." *Id.* at 49,943; *see also id.* at 49,958 (explaining that "DINP's contribution to the cumulative risk has greatly increased").

Fifth, petitioners disagree with the Commission's calibration of the "HI metric according to the most sensitive health effect"—male reproductive developmental effects. Pet'r Br. 38 (internal quotation marks omitted). Again, the Commission's approach, based on the CHAP report, was reasonable. As the Commission explained, although "phthalates cause a wide range of toxicities," Final Rule, 82 Fed. Reg. at 49,946, male reproductive developmental effects are not only "the most sensitive" endpoint for phthalates, but also the most "extensively studied," *id.* at 49,945. The CHAP's reliance on these effects to regulate phthalates was also consistent with the approach taken by the National Research Council in 2008. *Id.* Petitioners cavalierly assert that some male reproductive developmental effects are "not even harmful" to babies and other children. Pet'r Br. 38. It is unclear which of the many effects identified by the Commission—"such as reduced anogenital distance [i.e., the "[d]istance between the anus and genitals, which is greater in males than in females], reduced sperm quality and infertility"—petitioners have in mind. Final Rule, 82 Fed. Reg. at 49,946. In any event, medical authority supports the Commission's findings. Proposed Rule, 79 Fed. Reg. at 78,326 (citing the CHAP report); *see also* Comments

of Physicians for Social Responsibility, Mar. 16, 2015, Index No. 335, at 2 (describing "reduced anogenital distance," "reduced sperm quality[,] and infertility" as "adverse health outcomes").

Sixth, the Commission did not act arbitrarily, as petitioners contend, by relying in part on rodent-testing data to assess the effects of phthalate exposure. *See* Pet'r Br. 38-39; *id.* at 13. As the Commission explained, "studies in rats currently offer the best available data for assessing human risk." Final Rule, 82 Fed. Reg. at 49,946 (internal quotation marks omitted). Although some studies have involved other types of animals, those studies have been plagued by data limitations, such as "small number[s] of animals exposed," or exposure only to a single phthalate or single dose. *Id.* In addition, as the Commission explained, "the most sensitive species is generally used in assessing risks to humans," and the CHAP "concluded that rats provide the most sensitive and most extensive studies in male developmental toxicity." *Id.* at 49,951.

IV. THE COMMISSION PROVIDED A MEANINGFUL OPPORTUNITY FOR COMMENT.

Petitioners wrongly contend that they were deprived of "fair notice and a reasonable opportunity to comment on the methodology that ultimately underpinned the Phthalates Rule." Pet'r Br. 49. Under the APA, a notice of proposed rulemaking must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). The courts have "generally

interpreted" this mandate "to mean that the final rule [an] agency adopts must be a logical outgrowth of the rule proposed." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (internal quotation marks omitted); *accord United Steelworkers of Am., AFL-CIO-CLC v. Schuylkill Metals Corp.*, 828 F.2d 314, 318 (5th Cir. 1987). However, "courts must proceed with caution before deeming a Final Rule too attenuated from the Proposed Rule, lest [they] supplant the agency's role in the nation's regulatory scheme." *ConocoPhillips*, 612 F.3d at 834.

There is no question that the Commission satisfied the APA's procedural notice requisite here. As an initial matter, the Commission did not—as petitioners contend (Br. 48)—justify the proposed rule by relying only on HIs at the 95th percentile. Although the proposal identified the HIs for pregnant women, women of reproductive age, and infants at the 95th percentile level, the Commission made clear that the presence of HIs greater than one guided its analysis. *See* Proposed Rule, 79 Fed. Reg. at 78,335 (determining that an "HI <1 is necessary to protect the health of children" in proposal to ban four phthalates not covered by the interim prohibition (internal quotation marks omitted)); *id.* at 78,334-35 (justifying the continued ban on DINP by finding that an "HI <1 is necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety" (internal quotation marks omitted)). Using this standard as a guide, the Commission explained that "up to 10 percent of pregnant women and

up to 5 percent of infants" had an HI greater than one and were therefore at risk of adverse cumulative health effects from phthalate exposure. *Id.* at 78,328; *see also id.* at 78,332-33 (explaining HI calculation necessary to avoid "an overestimate of the 95th percentile exposures *and* the percentage of pregnant women and infants with HIs greater than one" (emphasis added)). Notably, under one of the datasets used by the CHAP and discussed in the proposed rule, the 95th percentile HIs did *not* exceed one. *See id.* (noting that Study for Future Families data showed that the 95th percentile HI for infants was "between .5 and 1.0")). It is, therefore, unsurprising that the Commission did "not establish directly" that "there was a specific proportion of the population that must have an HI less than or equal to one to ensure a 'reasonable certainty of no harm with an adequate margin of safety' or to 'protect the health of children.'" Final Rule, 82 Fed. Reg. at 49,963.

Moreover, the "terms" of the proposed and final rules are, in fact, identical, save the addition of a paragraph that "does not make any substantive change" to the rule, but instead places certain statutory language regarding plasticized component parts in the regulation itself. *Id.* at 49,940. There is therefore no question that the substance of the rule was "reasonably foreseeable" to petitioners. *Long Island Care at Home*, 551 U.S. at 175; *see also Tex. Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 326 (5th Cir. 2001) (rejecting a logical outgrowth argument where the modified version of an order "retained the essential framework of the original

proposal, but … added a few provisions to allay affordability concerns"); *Brazos Elec. Power Co-op., Inc. v. Sw. Power Admin.*, 819 F.2d 537, 543 (5th Cir. 1987) (holding that a final order was an "obvious logical outgrowth" of a preliminary version even if the plaintiff was "disappointed by a particular [hydroelectric power] allocation" settled by the order).

The rationale on which the Commission based its final rule was likewise foreseeable—a point best evidenced by comments of petitioners or their members during the rulemaking. For example, Texas Chemical Council member Exxon commented on what it deemed an inappropriate focus on the HIs of women of reproductive age at the 99th percentile. *See* Comment of Exxon Mobil, Mar. 24, 2017, Index No. 437, at 11-12, 14; *see also* Comment of the American Chemistry Council, Mar. 24, 2017, Index No. 438, at 5-6 (calling "inappropriate" any "predictions of the percent of women who exceed" an HI of one and stating that "HI calculations for the 99th percentile" were "biased high"). Where more than one party "saw fit to comment on precisely" the issue now raised by petitioners, the Commission's final rule adopting a highly protective standard for health was a logical outgrowth of the proposal. *United Steelworkers of Am.*, 828 F.2d at 318; *see also Am. Trucking Ass'ns, Inc. v. FMCSA*, 724 F.3d 243, 253 (D.C. Cir. 2013). The Commission was not obliged to "spell out" the entirely foreseeable possibility that it might adopt the exact substantive terms of the proposed rule even if, prior to the

final rule's issuance, the percentage of women with HIs exceeding one was reduced. *United Steelworkers of Am.*, 828 F.2d at 318. Certainly nothing more was needed in the proposed rule and the Commission's subsequent data analyses to keep "sophisticated industry members who had challenged the" rule "along every step of the road" fairly apprised of the agency's proposal. *Id.*

CONCLUSION

For the foregoing reasons, this Court should dismiss the petition for review because petitioners have not demonstrated they have standing or, in the alternative, deny the petition because petitioners' claims have no merit.

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November 5, 2018

CERTIFICATE OF SERVICE

I hereby certify that on November 5, 2018, I filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. All parties in the case are represented by registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Julie A. Murray
Julie A. Murray

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 7,358 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and type-style requirements of Fed. R. App. P. 32(a)(6) because it was prepared in a proportionally spaced, 14-point typeface, Times New Roman.

/s/ Julie A. Murray
Julie A. Murray

CERTIFICATE UNDER ECF FILING STANDARDS

Pursuant to paragraph (A)(6) of this Court's ECF Filing Standards, I certify that (1) required privacy redactions have been made, Fifth Circuit Rule 25.2.13; (2) the electronic submission is an exact copy of the paper document, Fifth Circuit Rule 25.2.1; and (3) the document has been scanned for viruses with the most recent version of a commercial virus scanning program and is free of viruses.

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