Case 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 Consumer Product Safety Commission

PETITIONERS' OPENING BRIEF

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Petitioners,

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UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Local 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.

A. PETITIONERS: Texas Association of Manufacturers, Texas Chemical Council, Texas Association of Business, National Association of Manufacturers, and American Chemistry Council

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B. RESPONDENT: United States Consumer Product Safety Commission

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

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D. INTERESTED NON-PARTIES: Manufacturers, importers, processors, and distributors of phthalates and phthalate products, including members of Petitioners.[1]

/s/ Aaron M. Streett
Aaron M. Streett
Attorney of Record for Petitioners

[1] For example, American Chemistry Council brought this litigation on behalf of its High Phthalates Panel, which includes manufacturers, importers, processors, and distributors of certain high phthalates.

STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Fifth Circuit Rule 28.2.3 and Federal Rule of Appellate Procedure 34(a)(1), Petitioners submit that oral argument would be helpful in this case given the complex regulatory issues involved.

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JURISDICTIONAL STATEMENT

This Court has jurisdiction under 15 U.S.C. §§ 2060(a) & (c), which authorize parties adversely affected by a "consumer product safety rule" to petition for review in the court of appeals within 60 days after the rule is promulgated by the Consumer Product Safety Commission ("Commission"). On October 27, 2017, the Commission published a final rule, Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938 (hereinafter "Phthalates Rule" or "Final Rule"). On December 15, 2017, Petitioners timely filed the Amended Petition for Review challenging the Phthalates Rule.[2]

Petitioners have standing to challenge the Phthalates Rule.[3] Certain Petitioners and their members actively participated in the rulemaking process. *See, e.g.*, Comment of Mar. 23, 2017, Index No. 436; Comment of Apr. 14, 2015, Index No. 361; Comment of Apr. 14, 2015, Index No. 360. Petitioners are trade associations that represent hundreds of member companies. Members include companies that manufacture, sell, or use products containing one or more of the five phthalates addressed in the Phthalates Rule. *See* Comment of Apr. 14, 2015,

[2] On January 25, 2018, the Commission moved to dismiss the Petition for lack of jurisdiction or, in the alternative, to transfer to a district court. Petitioners defended this Court's jurisdiction under 15 U.S.C. §§ 2060(a) & (c) in their brief in opposition to the Commission's motion, filed on February 5, 2018. This Court carried the motion with the case on April 10, 2018.

Index No. 360, at 1. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, Petitioners' members will lose a market for their products. *Clinton v. City of New York*, 524 U.S. 417, 433 (1998) ("The Court routinely recognizes probable economic injury resulting from [governmental actions] that alter competitive conditions as sufficient to satisfy the [Article III 'injury-in-fact' requirement]. . . . It follows logically that any . . . petitioner who is likely to suffer economic injury as a result of [governmental action] that changes market conditions satisfies this part of the standing test." (quoting 3 K. DAVIS & R. PIERCE, ADMINISTRATIVE LAW TREATISE 13-14 (3d ed. 1994) (alterations in original)). Because the Phthalates Rule is generally applicable to all producers and consumers nationwide, "neither the claim asserted nor the relief requested requires the participation of [Petitioners'] individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

Additionally, Petitioners allege various procedural injuries under the Administrative Procedure Act ("APA"). "Where, as here, a party alleges deprivation of its procedural rights, courts relax the normal standards of

[3] The facts supporting this Jurisdictional Statement are established by the attached declarations submitted by Petitioners.

redressability and imminence." *Am. Rivers v. FERC*, 895 F.3d 32, 42 (D.C. Cir. 2018) (quoting *Sierra Club v. FERC*, 827 F.3d 59 65 (D.C. Cir. 2016)). "To establish causation, [Petitioners] need demonstrate only that the procedural step was connected to the substantive result, not that the agency would have reached a different substantive result but for the alleged procedural error." *Id.* (quotation marks omitted). Here, the Commission's failure to follow various procedural requirements directly led to its promulgation of the Phthalates Rule. Thus, Petitioners and their members have standing to raise the various procedural errors discussed in detail below.

ISSUES PRESENTED

1. Whether the Commission acted contrary to law in promulgating the Phthalates Rule, which "declare[s] [certain] children's product[s] containing any phthalates to be . . . banned hazardous product[s]," without following the statutorily required procedures for rules banning hazardous products.

2. Whether the Commission acted contrary to law by effectively redefining the statutory standards of "reasonable certainty of no harm" and "necessary to protect the health of children" to require an absolute certainty of no risk from phthalates.

3. Whether the Commission acted arbitrarily and capriciously when new scientific data undermined the stated rationale for the Proposed Rule, by adopting an entirely new rationale to support a Final Rule that adhered to the Proposed Rule.

4. Whether the Commission deprived Petitioners of the opportunity to meaningfully comment on its ultimate methodology by shifting the central scientific premises of the rulemaking without notice in the Final Rule.

INTRODUCTION

In 2008, Congress charged the Consumer Product Safety Commission with a difficult and important task—one that ultimately stretched the Commission beyond its traditional expertise of regulating the safety of consumer products. Congress directed the Commission to evaluate the health effects of chemical compounds known as phthalates and decide whether particular phthalates should be banned from children's toys and childcare articles. Congress laid down statutory standards and procedures for making this determination. Despite an eight-year evaluation and rulemaking process, the Commission breached its statutory duties and fell far short of the reasoned, scientific decision-making the law requires.

Congress invoked a well-established statutory mechanism for the Commission to use if it wished to "declare any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057)." But the Commission simply declared the ban, without following section 8's standards and procedures for banning hazardous products. This fundamental failing dictates vacatur of the Phthalates Rule.

The Commission compounded its error by applying the wrong statutory threshold. The statute enjoins the Commission to determine whether a ban is "necessary to protect the health of children" or to "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an

adequate margin of safety." Rather than focus on preventing actual "harm" to human "health," the Commission devised a testing metric that sought to eliminate even the most infinitesimal level of "risk." Congress knows the difference between "risk" and "harm," but the Commission ignored it here.

The rulemaking also suffered from fatal procedural and scientific flaws. In the proposed rule, the Commission pointed to risk data at the 95th percentile of women to propose a permanent ban on five phthalates. Between the rule's proposal and its finalization, however, the Commission reviewed updated scientific data that showed no cognizable risk at the 95th percentile (even under the Commission's ultra-conservative and statutorily infirm approach). Rather than accept this data and abandon the proposed ban, the Commission moved the goalposts. Its final rule relied on risk findings that were at or above the 99th percentile, even as it acknowledged that data at the 99th percentile is "unstable." The Commission's use of an arbitrary methodology to reverse-engineer the science to fit the previously proposed ban flouts the norms of lawful rulemaking. Equally troubling, the Commission's midstream reversal hobbled the ability of Petitioners to comment on the 99th-percentile-and-beyond approach. The Commission's ultimate methodology was never subjected to notice and comment, thus producing a rule based upon shoddy science and enabled by violations of the APA.

Consumers and regulated companies alike are entitled to a scientifically sound and statutorily compliant rule regulating phthalates. The Commission did not produce one here. This Court should vacate the rule and remand for the Commission to scrupulously execute the task assigned to it by Congress.

STATEMENT OF THE CASE

I. The CPSA creates the Commission, charges it with protecting against unreasonable risks from consumer products, and provides the guidelines for its rulemaking.

In 1972, Congress enacted the Consumer Product Safety Act ("CPSA") establishing the Commission. The CPSA charges the Commission with "protect[ing] . . . the public 'against unreasonable risks of injury associated with consumer products' and assist[ing] . . . consumers 'in evaluating the comparative safety' of such products." *Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 835 (5th Cir. 1978) (quoting 15 U.S.C. § 2051(b)).[4]

The CPSA empowers the Commission to (1) "promulgate consumer product safety standards," § 2056(a), and (2) "declar[e] [a] product a banned hazardous product," § 2057. "Consumer product safety standards" impose "performance requirements" or "[r]equire[] that a consumer product be marked with or accompanied by clear and adequate warnings or instructions." § 2056(a). A rule

[4] All U.S.C. citations are to title 15 unless otherwise noted. The relevant statutes and the Final Rule are included in an addendum filed with this brief.

"declaring [a] product a banned hazardous product," in contrast, completely bans a product. § 2057.

The CPSA details the rulemaking procedures for promulgating such standards and bans. Section 2058 describes the process for the Commission's notice-and-comment rulemaking. It requires the Commission to follow specified steps and to make various findings before promulgating any "consumer product safety rule," § 2058(f), a term that includes both consumer product safety standards and rules banning hazardous products, § 2052(a)(6). Before it can promulgate a banned hazardous product rule, the Commission must meet more requirements and make more findings than for a consumer product safety standard. *See* §§ 2057, 2058(f)(3)(C).

II. The CPSIA directs the Commission to make rules regarding phthalates in toys and childcare articles.

In 2008, Congress enacted the Consumer Product Safety Improvement Act ("CPSIA"). Adding to the CPSA's generalized approach, the CPSIA specifically identified several types of products and directed the Commission to promulgate rules banning or regulating those products. *See* § 1278 (labeling requirements for advertising toys and games); § 1278a (children's products containing lead); § 2056a (durable nursery products); § 2056b (toy-safety standards); § 2057c (phthalates in children's toys); § 2089 (all-terrain vehicles). The CPSIA selectively incorporated CPSA procedures and standards and added product-

specific standards and procedures for these new sets of regulations. *See, e.g.*, §§ 2056b(b), 2057c(b).

Certain children's products containing phthalates are among the products covered by the CPSIA. § 2057c. Phthalates "are a class of organic compounds used primarily as plasticizers," meaning that they increase flexibility and reduce brittleness. Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 79 Fed. Reg. 78,324, 78,324 (Dec. 20, 2014) (hereinafter "Proposed Rule"). Phthalates are used in a variety of common products, including "plastic toys, home furnishings, air fresheners, automobile interiors, cosmetics, medications, [and] medical devices." *Id.* "Phthalates are also found in food, indoor air, outdoor air, household dust, soil, and other environmental media." *Id.* at 78,325. An individual's exposure to phthalates from all sources can be measured via "biomonitoring."

The CPSIA enacted a permanent prohibition on all children's toys and child care articles containing concentrations of over 0.1 percent of three types of phthalates (DEHP, DBP, and BBP). § 2057c(a). The CPSIA also enacted a narrower interim prohibition on "any children's toy that can be placed in a child's mouth" or "child care article" containing over 0.1 percent of three other types of phthalates (DINP, DIDP, and DNOP). § 2057c(b)(1). By its terms, the interim

prohibition would expire upon the Commission's promulgating a final rule regarding those phthalates. *Id.*

The CPSIA then directed the Commission to convene a Chronic Hazard Advisory Panel ("CHAP") and instructed the CHAP to "complete an examination of the full range of phthalates that are used in products for children." § 2057c(b)(2)(B). Upon receiving the report of the CHAP, the Commission was charged with specific rulemaking duties, namely to:

> (A) determine, based on such report, whether to continue in effect the [interim] prohibition under paragraph (1), 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 Chronic Hazard Advisory Panel 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.

§ 2057c(b)(3). Thus, if the Commission opts to go further than "continu[ing] in effect" the interim statutory ban, § 2057c(b)(3)(A), it must proceed according to the standards and procedures for declaring "banned hazardous product[s] under section 8 of the [CPSA]," § 2057c(b)(3)(B).

III. The Commission appoints a CHAP that employs a flawed methodology to recommend a ban on toys and childcare articles that contain any of five phthalates.

The Commission proceeded with the phthalates rulemaking under § 2057c by first appointing a CHAP. Proposed Rule at 78,325-26. The CHAP decided to

employ a "hazard index (HI) approach to assess the cumulative risk [from phthalates]." *Id.* "Although the HI approach is widely accepted, the CHAP introduced a novel process to calculate the HI." *Id.* at 78,332. The CHAP first calculated the individualized "'hazard quotient' (HQ)" for each of five phthalates, the three permanently banned under § 2057c(a) and also DINP and DIBP. *Id.* at 78,328. The CHAP explained that "[i]f the HQ is greater than one for a given phthalate, there may be a concern . . . in the exposed population due to the effect of an individual phthalate." *Id.* The CHAP combined the HQs of the individual phthalates to determine the cumulative HI. *Id.* According to the CHAP, "[i]f the HI is greater than one, there may be a concern . . . in the exposed population due to the cumulative effects of phthalates." *Id.* In other words, the CHAP designed its HI metric as a threshold set at one. An HI greater than one meant that there *might be* a potential risk.[5]

The CHAP's HI approach—adopted and applied by the Commission—was not designed to identify actual harm or even meaningful risks from phthalates. Instead, it incorporated so many layers of conservatism that, at best, it identified the remotest risks imaginable, and at worst, produced completely unreliable results.

[5] "The portion of the population with a HI greater than one may be at risk for the adverse effects of phthalates. This does not necessarily mean that anyone will suffer adverse effects; however, one cannot rule out the possibility of adverse effects. The greater the HI, the greater the risk." Proposed Rule at 73,332.

First, the CHAP based the HI metric on the "most sensitive health effect" from phthalates exposure in animal studies on rodent fetuses, which were "[m]ale developmental reproductive effects." *Id.* at 78,331-32. These are known as antiandrogenic effects. Antiandrogenic effects occur when pregnant rats are dosed in a fashion to represent longer-term exposures. *Id.* at 78,332. Some effects, such as reduced anogenital distance, do not cause actual harm to the rodents, yet the CHAP used these effects as proxies for harmful exposure to humans.[6] *See id.*

The CHAP used three different sets of information (referred to as "Cases") to determine the level of phthalates exposure that caused antiandrogenic effects in rodents. *Id.* at 78,328. Only the last of these, Case 3, used recent studies and direct data. *Id.*; Final Rule at 49,961. Case 1, in contrast, was based on an older study for DINP that was unable to directly determine a "no effect level" for antiandrogenic effects. Proposed Rule at 78,328; Final Rule at 49,961. Case 2 was based on a rough estimate of the no effect levels for four of the phthalates by comparing them to DEHP; those estimates contradict the actual no effect levels from direct studies of those phthalates (including the no effect levels derived by the CHAP for Case 3). Proposed Rule at 78,328; Final Rule at 49,961. Despite the methodological and scientific deficiencies of Cases 1 and 2, the CHAP—and the

[6] Anogenital distance is the "[d]istance between the anus and genitals." Proposed Rule at 78,326 n.6.

Commission—continued to rely on them. Proposed Rule at 78,328; Final Rule at 49,961. Indeed, the Commission often used Case 2—which artificially indicated that antiandrogenic effects occurred at levels of phthalates exposure significantly lower than in Case 3 and Case 1—to emphasize the risk purportedly posed by phthalates. *E.g.*, Final Rule at 49,958, 49,961-62, 49,967, 49,969.

Next—despite numerous studies showing that humans are *less sensitive* to phthalates than are rodents—the CHAP divided the no effect level in rodents by 10 to extrapolate from rodents to humans. Final Rule at 49,951-52; Comment of Feb. 22, 2017, Index No. 437, at 20-23 (surveying the "strong evidence that humans are much less sensitive than rats to the potential anti-androgenic effects of phthalates"). And then it divided that number by 10 again "to account for differences in sensitivity among individuals." Final Rule at 49,952. Consequently, an HI greater than one means that phthalates are present at a level more than *100 times lower* than the level known to cause the most sensitive observable effects in rodent fetuses.

The CHAP then applied that overly conservative HI metric to data that systematically overestimated longer-term human exposure to phthalates. The rodent studies used for the metric tested the effects of sustained exposure to high levels of phthalates over several days. But the CHAP used spot samples, rather than sustained exposure, for its human data. It used "human biomonitoring data

from the Centers for Disease Control and Prevention's (CDC) National Health and Nutrition Examination Survey (NHANES)," specifically "from NHANES' 2005/2006 data cycle" to determine the level of human exposure to phthalates. *Id.* at 49,939. NHANES "measures phthalates and other chemicals in human urine and blood" based on spot sampling of U.S. pregnant women. Proposed Rule at 78,327. Because humans metabolize phthalates quickly, those spot samples do not accurately reflect a person's exposure levels over part of a day, much less the average exposure over the course of several days. Final Rule at 49,960 ("Staff concurs that spot urine samples are variable and are not representative of long-term exposures."). The CHAP's methodology means that although the HI calculation was based on rodent studies with longer-term exposures, the extreme, ephemeral peaks the spot samples captured in a few women (likely because the measurement was taken just after eating) do not represent the women's longer-term exposures.

The CHAP further increased the conservatism of its assessment by adding together the effects of each individual phthalate—however miniscule—to create the "cumulative risk" HI metric. Proposed Rule at 78,327-28. Considered individually, none of the five phthalates that the Commission ultimately banned presented an identifiable potential risk to humans. *See* Final Rule at 49,947 ("The CHAP found that, with the exception of DEHP [which was permanently banned in § 2057c(a)], for all phthalates that it evaluated in isolation, the [indications of risk]

were within acceptable ranges."); *see, e.g.*, *id.* at 49,963 ("[The Commission] agrees with the CHAP's analysis that . . . DINP in isolation, did not present a risk."). Yet the CHAP managed to find a cumulative risk from the phthalates due to the "dominat[ing]" effects of DEHP, which § 2057c(a) had permanently banned in new children's products. *Id.* at 49,947; *see also* Proposed Rule at 78,329 ("[T]he CHAP noted that DEHP contributes more than half of the cumulative risk from phthalates.").

Applying this highly sensitive cumulative HI metric, the "CHAP concluded that there may be a concern for adverse effects from the cumulative effects of phthalates in individuals with a hazard index greater than one, representing up to 10 percent of pregnant women and up to 5 percent of infants." Proposed Rule at 78,328. Based on this cumulative-risk rationale, the CHAP recommended that DINP, DIBP, DPENP, DHEXP, and DCHP "at levels greater than 0.1 percent should be permanently prohibited from use in children's toys and child care articles." *Id.* at 78,329-30.[7]

[7] Although not included in the HI metric, the CHAP recommended including DPENP, DHEXP, and DCHP in the ban because they contributed to the "cumulative risk" at some unspecified level. Final Rule at 49,958-59 ("Although DIBP, DPENP, DHEXP, and DCHP are not currently found in children's toys and child care articles (or only rarely), these phthalates also cause [antiandrogenic effects] and contribute to the cumulative risk.").

IV. When updated data reveal no statistically identifiable risk from phthalates, the Commission moves the goalposts to justify the recommended ban.

The Commission issued a Proposed Rule that expressed agreement with the CHAP's analysis and recommended ban. *Id.* at 78,334-39. The Proposed Rule focused on the HI at the 95th percentile of the various data sets in justifying its decision to ban the five phthalates, concluding that the spot sample-derived HIs surpassed the HI-greater-than-one threshold at that percentile. *See id.* at 78,328-29, 78,332-33. As the Commission later acknowledged, "values associated with the upper tail of the distribution of HIs (e.g., above the 95th percentile) have large variance estimates, due to sample size (i.e., statistically unstable)." Final Rule at 49,961. Based on that analysis, the Proposed Rule followed the CHAP's recommendations of banning DINP, DIBP, DPENP, DHEXP, and DCHP in children's toys and childcare products. Proposed Rule at 78,330, 78,339.

The Commission's rationale changed drastically after it promulgated the Proposed Rule. Prompted by comments, the Commission recognized the need to update its analysis to account for new human exposure data, as the CHAP had considered NHANES data only from the 2005/2006 data cycle. Final Rule at 49,939. Accordingly, the Commission had its own staff "replicate the CHAP's methodology" on NHANES data through the 2013/2014 data cycle. *Id.* The CHAP had studied pregnant women in the NHANES data, but the Commission's

staff "used women of reproductive age (WORA; 15-45 year[s] of age) as the population of interest, because NHANES data sets after 2005/2006 did not have sufficient numbers of pregnant women to be statistically relevant."[8] *Id.*

This "most recent data" revealed a marked decrease in phthalates exposure levels, likely due in part to the intervening enactment of § 2057c(a)'s permanent ban on DEHP in children's toys and childcare products. *Id.* at 49,958. The staff's analysis of this new data showed that the "[m]edian and 95th percentile HIs for WORA were both less than one"; indeed, "between 98.8 and 99.6 percent of WORA have HIs less than or equal to one." *Id.* The Commission thus acknowledged that 99 percent of the data set had *no* discernible risk from phthalates—even when including the still-"dominat[ing]" effects of DEHP. *See id.*

If the Commission had applied the statistically standard 95th percentile approach from the Proposed Rule to this updated data, the result would have been no regulatory ban of any phthalates. But the Commission decided to shift rationales rather than follow the science. It claimed that it had not set forth any specific definition of either statutory standard in the Proposed Rule: "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

[8] The staff "determined that WORA are a suitable surrogate for pregnant women." Final Rule at 49,954.

'reasonable certainty of no harm with an adequate margin of safety' or to 'protect the health of children.'" *Id.* at 49,958. Then it emphasized that "some individuals in the [most recent data set] still have an HI greater than one." *Id.* at 49,963; *see also id.* at 49,961 ("[F]or the [most recent data set], between two and nine real women from the sample of 538 WORAs had an HI greater than one . . . ."). In other words, even though no risk was discernible at the scientifically standard 95th percentile, the Commission looked at HI values at or above the 99th percentile to identify individual spot sample-derived results that met the Commission's risk threshold—which itself was calibrated to capture infinitesimal risk.

The Commission thus based its rule on not one, but two scientifically unreliable peaks in the data. It focused on a few outliers at the extreme—and admittedly "unstable"—ends of the statistical distribution. *Id*. And those outliers themselves were a product of the Commission's improper use of the spot sample-based method to treat temporary spikes in phthalate levels as if they were longer-term exposures. The Commission had to leverage both of these methodological infirmities to achieve the few instances of an HI greater than one that formed the basis of its rule.[9] Instead of reopening the record for comments on this novel

[9] Because those HI values were based on spot samples taken at or near an ephemeral peak in their phthalates levels—as opposed to a sustained, longer-term exposure—those HI-greater-than-one results do not indicate that even those few women face the potential risks associated with longer-term phthalates exposure at those levels.

statistical approach, the Commission issued and defended its Final Rule banning the five phthalates on that new basis. *See id.* ("The rule is not based on any particular percentile, but on the observation that actual women from the NHANES sample have HIs greater than one.").

V. By a 3-2 vote, the Commission promulgates a final rule banning five phthalates in all toys and childcare articles.

The Commission ultimately voted 3-2 to issue a Final Rule that was substantively identical to the Proposed Rule. Final Rule at 49,938 n.1. It expanded the statute's interim prohibition in two ways. First, the Commission extended the interim prohibition on DINP to include all children's toys (*i.e.*, mouthable and non-mouthable ones) and childcare articles.[10] *Id.* at 49,972 ("Section 1307.3(b) changes the scope of regulation of DINP from the current interim scope of 'any children's toy that can be placed in a child's mouth' (and child care articles) to include all children's toys."). Second, it prohibited all children's toys and childcare articles containing four new phthalates (DIBP, DPENP, DHEXP, and DCHP) that were not subject to the interim statutory ban.[11]

[10] In accordance with the CHAP's recommendations, the Final Rule did not continue the interim statutory ban on DNOP or DIDP. Final Rule at 49,973.

[11] The Final Rule bans products containing 0.1 percent of the specified phthalates. The 0.1 percent limit was intended only to allow for trace amounts and thus prohibit intentional inclusion of those phthalates. *See* Final Rule at 49,971 ("[T]he 0.1% limit prohibits the intentional use of phthalates as plasticizers in children's

Id. at 49,972-73. The Commission asserted that the ban was required to "ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety" and was "necessary to protect the health of children." *Id.* at 49,972-73; *see* § 2057c(b)(3) (setting forth those statutory standards). Yet despite invoking the "health of children" language from the statute, the Commission disclaimed any obligation to comply with the statutorily required standards and procedures for banning hazardous products to protect children. *Compare* § 2057c(b)(3)(B) (requiring 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" (emphasis added)) *with* Final Rule at 49,944 ("The requirements stated in section 108(b)(3) of the CPSIA, rather than sections 7, 8 and 9 of the CPSA, apply to this rulemaking.").

Two dissenting commissioners strongly disagreed with the Final Rule. Commissioner Mohorovic accused the Commission of "willfully ignor[ing] the data to justify its predetermined decision to approve the Final Rule." Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 22 (Oct. 18,

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toys and child care articles but allows trace amounts of phthalates that might be present unintentionally.").

2017) (Statement of Comm'r Joseph P. Mohorovic). He drew that conclusion in part because "the most recent biomonitoring data shows that the cumulative risk of adverse effects from phthalate exposure has decreased to such a statistically insignificant amount that it cannot even be calculated with certainty," meaning that the "Commission cannot say with confidence that *any* of the general population is exposed to an unacceptable level of risk." *Id.* at 22-23. Commissioner Mohorovic also opposed the Final Rule because, *inter alia*, "it is in no way a logical outgrowth of the proposed rule. It differs so significantly from the proposed rule in the fundamental basis, scientific rationale, and technical justification that I could not have seen this coming, nor could anyone else really, in looking at the [Notice of Proposed Rulemaking] and the Final Rule." *Id.* at 23.

Commissioner Buerkle also filed a lengthy dissent that pointed out numerous problems with the Final Rule. *Id.* at 4-16 (Statement of Comm'r Ann Marie Buerkle). Besides echoing Commissioner Mohorovic's criticisms, Commissioner Buerkle explained why "it is inappropriate to treat the exposure estimates calculated from spot samples as if they represent an individual's exposure over a full day or even longer." *Id.* at 8. She also criticized the Commission for effectively adopting an extreme definition of the statutory "reasonable certainty of no harm" standard. *Id.* at 14.

SUMMARY OF THE ARGUMENT

The Phthalates Rule suffers from a host of deficiencies, each of which independently mandates its vacatur. The Commission acted under an authorization to "declare [certain] children's product[s] containing any phthalates to be . . . banned hazardous product[s] under [§ 2057]." § 2057c(b)(3)(B). But it openly refused to follow the statutory procedures and requirements under § 2057 for rules banning hazardous products.

The Commission, moreover, effectively redefined the statutory standards that allowed banning phthalates in children's products to achieve a "reasonable certainty of no harm" and where "necessary to protect the health of children." The Commission employed an unscientific approach that justified a ban unless the data showed an *absolute* certainty of no *risk* from phthalates.

The Commission compounded its statutory errors by flouting APA mandates. It acted arbitrarily and capriciously when it reacted to new data by re-engineering its rationale to support the proposed ban, rather than applying its original methodology to updated data that would have mandated no regulatory phthalates ban. In doing so, the Commission invoked concededly unreliable results beyond the 99th percentile to justify its rule. Because this abrupt methodological shift was a late-breaking announcement in the Final Rule, the Commission's

actions also deprived Petitioners of the opportunity to meaningfully comment on the rule.

The Court should vacate the rule and remand for the Commission to follow the statute's commands and pursue a rulemaking process that honors the APA.

ARGUMENT

I. Standard of review.

This Court reviews the Commission's rulemaking under the Administrative Procedure Act, 5 U.S.C. § 706. Section 706 requires a reviewing court to:

> hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> . . .
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or]
>
> (D) without observance of procedure required by law.

5 U.S.C. § 706(2); 15 U.S.C. § 2060(c) ("[T]he court shall have jurisdiction to review the consumer product safety rule in accordance with chapter 7 of Title 5"); *Zen Magnets, LLC v. CPSC*, 841 F.3d 1141, 1147 (10th Cir. 2016) ("Exercising jurisdiction pursuant to 15 U.S.C. § 2060(c), we [exercise] judicial review [as] set forth in the Administrative Procedures Act ('APA'), 5 U.S.C. ch. 7.").

II. The Commission failed to make the statutorily required findings and follow the statutory procedures in promulgating the Phthalates Rule.

A. Section 2057c(b)(3)(B) authorized the Commission to promulgate the Final Rule by following the statutory requirements for banning hazardous products.

Section 2057c(b)(3) is the Commission's only source of rulemaking authority regarding phthalates. Entitled "[p]ermanent prohibition by rule," it directs the Commission to:

> promulgate a final rule to—
>
> (A) determine, based on [the CHAP] report, whether to continue in effect the prohibition under paragraph (1), 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 Chronic Hazard Advisory Panel 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.

§ 2057c(b)(3) (emphasis added). Accordingly, the statute set two tasks before the Commission: (1) decide whether to "continue in effect" the interim statutory prohibition, § 2057c(b)(3)(A), and (2) evaluate whether to ban new phthalates or products not covered by the interim ban, § 2057c(b)(3)(B). Section 2057c(b)(3) thus provides the Commission only one procedural route if it opts to go beyond the

interim statutory prohibition: "declar[ing] any children's product containing any phthalates to be a banned hazardous product under [§ 2057]." *Id.*

B. The Phthalates Rule goes beyond the interim statutory prohibition and thus was required to comply with the procedures for banning hazardous products.

If the Commission had merely "continued in effect" the interim statutory prohibition, it could have proceeded under § 2057c(b)(3)(A) without the need to declare covered phthalate-containing children's products to be "banned hazardous products" under the CPSA's procedures. But the Phthalates Rule goes well beyond the interim prohibition; the Commission was thus required to comply with § 2057c(b)(3)(B)'s mandate to "declare any children's product containing any phthalates to be a banned hazardous product *under [§ 2057]*."

The interim statutory prohibition applied to "any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of [DINP], [DIDP], or [DNOP]." § 2057c(b)(1). By contrast, the Phthalates Rule bans "any children's toy or child care article that contains concentrations of more than 0.1 percent of [DINP], [DIBP], [DPENP], [DHEXP], or [DCHP]." Final Rule at 49,982.[12] Consequently, the Phthalates Rule expands

[12] On July 23, 2018, the Commission published a correction to the Phthalates Rule. 83 Fed. Reg. 34,764. The Commission corrected a misspelling of "di-(2-ethylhexyl)" and replaced an "and" with an "or." Thus, the quote above originally read, "any children's toy or child care article that contains concentrations of more

the interim statutory prohibition in two ways. First, it broadens the interim ban's scope from "any children's toy *that can be placed in a child's mouth*" to "any children's toy," period. *See* Final Rule at 49,940 ("The final rule . . . expands th[e] [interim] restriction to prohibit all children's toys (not just those that can be placed in a child's mouth) . . . ."). Second, it adds four new phthalates—DIBP, DPENP, DHEXP, and DCHP—that had not been subject to the interim statutory ban at all. *See id.* (explaining that the Final Rule adds "four additional phthalates" to those covered by the interim statutory ban).

Because the Commission went well beyond "continu[ing] in effect" the interim ban, it necessarily acted pursuant to § 2057c(b)(3)(B), which required it 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)*." § 2057c(b)(3)(B) (emphasis added). Section 2057, in turn, requires the Commission to make two findings as prerequisites to declaring a product to be a banned hazardous product, mandating that first "the Commission [must] find[] that":

> (1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and

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than 0.1 percent of [DINP], [DIBP], [DPENP], [DHEXP], and [DCHP]." Final Rule at 49,982.

> (2) no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product,

§ 2057. Section 2057 then directs the Commission to follow the procedures contained in section 2058 to declare a product to be a banned hazardous product. *Id.* ("[T]he Commission may, in accordance with section 2058 of this title, promulgate a rule declaring such product a banned hazardous product.").

Section 2058 directs the Commission to make a number of findings and follow specific procedures when promulgating "consumer product safety rule[s]," which include "rule[s] . . . declaring a consumer product a banned hazardous product." § 2052(a)(6). Importantly, § 2058(f)(3) specifies that "[t]he Commission shall not promulgate a consumer product safety rule unless it finds (and includes such finding in the rule)," *inter alia*, "that the promulgation of the rule is in the public interest," "that the benefits expected from the rule bear a reasonable relationship to its costs," and "that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." § 2058(f)(3). Section 2058(f)(2) further provides that "[t]he Commission shall not promulgate a consumer product safety rule unless it has prepared . . . a final regulatory analysis of the rule." § 2058(f)(2). That final regulatory analysis must be "publish[ed] . . . with the rule" and contain, *inter alia*:

> A description of the potential benefits and potential costs of the rule, including costs and benefits that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs[, and]
>
> [a] description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen.

§ 2058(f)(2).

By expressly incorporating § 2057's roadmap for banning hazardous products into § 2057c(b)(3)(B), Congress directed the Commission to follow a familiar rulemaking path if it opted to go beyond the interim ban established by Congress.

C. The Commission openly declined to follow the statutory requirements for banning hazardous products when it promulgated the Phthalates Rule.

In expanding the interim ban to cover all children's toys and in adding four phthalates to the prohibited list, the Commission indisputably proceeded under § 2057c(b)(3)(B). Yet, despite acknowledging its expansion of the interim prohibition, the Commission made no effort to comply with § 2057c(b)(3)(B)'s instructions that it must "declare any children's product containing any phthalates to be *a banned hazardous product under [§ 2057]*, as the Commission determines necessary to protect the health of children." § 2057c(b)(3)(B) (emphasis added). The Commission made neither of the two findings that § 2057 requires as prerequisites to "declaring [a] product a banned hazardous product." § 2057. Nor

did it make the mandatory findings under § 2058(f)(3) that the Phthalates Rule is "in the public interest," that its "benefits . . . bear a reasonable relationship to its costs," and that it is the "least burdensome" means of achieving its objective. § 2058(f)(3). Additionally, the Commission conceded that it did not prepare the cost-benefit regulatory analysis that § 2058(f)(2) requires for all "consumer product safety rule[s]," § 2058(f)(2), which includes "rule[s] . . . declaring a consumer product a banned hazardous product," § 2052(a)(6). Final Rule at 49,974 (admitting that the Commission "did not prepare a regulatory analysis of the costs and benefits of the rule").

The Commission's wholesale failure to make the required findings and follow the statutory procedures for declaring products to be banned hazardous products requires the Phthalates Rule to be set aside in its entirety as contrary to law. *See Steere Tank Lines, Inc. v. I.C.C.*, 714 F.2d 1300, 1314 (5th Cir. 1983) ("[t]he absence of [statutorily] required findings is fatal even though there may be ample evidence to make the finding."); *Oglala Sioux Tribe v. NRC*, 896 F.3d 520, 532 (D.C. Cir. 2018) (rejecting agency action as contrary to law for failure to follow statutory requirements where "[n]othing in [the statute's] text suggests that the required environmental analysis . . . is optional"); *S. Coast Air Quality Mgmt. Dist. v. EPA*, 882 F.3d 1138, 1150-51 (D.C. Cir. 2018) (vacating a rule that was "inconsistent with the clear text of [the statute]" because it "d[id] not include all

five statutory requirements"); *Zen Magnets*, 841 F.3d at 1144 ("We conclude that the Commission's prerequisite factual findings, which are compulsory under the Consumer Product Safety Act are incomplete . . . ." (citation omitted)).

D. The Commission's insistence that the statutory requirements for banning hazardous products do not apply cannot be squared with the plain text of § 2057c(b)(3)(B).

In its motion-to-dismiss briefing in this Court, the Commission conceded that it did not make the required findings and observe the necessary procedures for "declar[ing] . . . [a product] a banned hazardous product under [§ 2057]." § 2057c(b)(3)(B). The Commission instead remarkably claimed that "the [Phthalates Rule] . . . does *not* declare [products containing the five phthalates] to be banned hazardous products." Commission's Mot. to Dismiss at 14 (emphasis added); *see also id.* at 13 ("The phthalates prohibition is also not a rule 'declaring a consumer product a banned hazardous product.'" (quoting § 2052(a)(6)). If that is true, then this case is over. After all, § 2057c(b)(3)(B)—the Commission's only authority for going beyond the interim prohibition—directs the Commission to "evaluate the findings and recommendations of the Chronic Hazard Advisory Panel 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." § 2057c(b)(3)(B) (emphasis added). Accordingly, if, as the Commission claims,

the Phthalates Rule is not "a rule 'declaring a consumer product a banned hazardous product,'" Commission's Mot. to Dismiss at 13, then it must be vacated as an action "in excess of statutory . . . authority," 5 U.S.C. § 706(2)(C).

The Commission attempts to avoid that result by claiming that § "2057c . . . authoriz[es] the Commission to declare that a product is '*to be* a banned hazardous product,'" without engaging in the rulemaking mandated by the CPSA. Commission's Mot. to Dismiss Reply at 5. In other words, despite § 2057c(b)(3)(B)'s directive that the Commission's sole means of expanding the interim prohibition is 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),*" the Commission claims that that provision in fact does not mean that the Commission must follow the § 2057 procedures for declaring a product to be a "banned hazardous product." § 2057c(b)(3)(B) (emphasis added). Instead, according to the Commission, the statute creates a novel, standalone way to declare banned hazardous products without making the statutory findings or going through any of the relevant statutory procedures. In the Commission's view, it may expand the interim prohibition merely by finding that doing so is "necessary to protect the health of children." Commission's Mot. to Dismiss Reply at 5 (quoting § 2057c(b)(3)(B)). That reading cannot be squared with § 2057c(b)(3)(B)'s textual command that the Commission may enact a rule that

covers new phthalates or products only through the well-worn statutory path of banning hazardous products under § 2057.

The Commission's position would be slightly more plausible if Congress had referred only to declaring phthalate-containing children's products "to be banned hazardous products" without expressly directing the Commission to act "under [§ 2057]" when doing so. But Congress made its intent crystal-clear by directing the Commission to a specific statutory section. If the Commission disagreed with this straightforward reading of the statute, the Phthalates Rule could have attempted to explain why the statute is ambiguous and provided a reasoned statutory interpretation of § 2057c(b)(3)(B) that excuses the Commission from complying with one or more specific requirements in §§ 2057 and 2058. But the Commission presented no such statutory interpretation and instead summarily declared that it was excused from complying with the CPSA's requirements for banning hazardous products, despite the statute's clear command. Final Rule at 49,944 ("The requirements stated in section 108(b)(3) of the CPSIA, rather than sections 7, 8 and 9 of the CPSA, apply to this rulemaking."); *id.* at 49,974 ("Because CPSC followed the rulemaking requirements stated in section 108 of the CPSIA, which differ from rulemaking requirements under the CPSA . . . CPSC did not prepare a regulatory analysis of the costs and benefits of the rule."). *Ipse dixit* of this nature would be undeserving of deference even if the statute were

ambiguous, and this one is not. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1322 (Fed. Cir. 2017) (refusing to give agency deference when it failed to provide a "cogent, considered examination of the relevant statutory provisions"); *Banner Health v. Price*, 867 F.3d 1323, 1345 (D.C. Cir. 2017) (vacating rule where agency "failed to offer a reasoned basis for making [its] assumption"); *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1143 (9th Cir. 2015) (refusing to defer to "EPA's unexplained assertions" that were "unsupported by any explained reasoning"). Because the Commission circumvented the unambiguous route set forth by Congress, its rule is incurably defective and must be set aside.

III. The Commission acted contrary to the statutory standards by choosing to ban phthalates in toys and childcare articles unless the data showed absolute certainty of no risk.

In addition to ignoring the requirements for banning hazardous products under § 2057, the Commission also effectively redefined the phthalates-specific statutory standards in a manner contrary to their plain text. Section 2057c(b)(3)(A) directs the Commission to continue the interim statutory prohibition if it is necessary to ensure "reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." Section 2057c(b)(3)(B) instructs the Commission to expand the interim ban as "necessary to protect the health of children." The Commission purported to apply both standards to its entire rule and treated them as having identical meanings. But the

Commission never engaged in any meaningful interpretation of the disparate words contained in the respective subsections. Worse, the Commission did not actually assess whether its ban achieved a *reasonable* certainty of no *harm* or was *necessary* to protect *health*. It instead applied those standards to demand an *absolute* certainty of no *risk*.

A. The Commission improperly interpreted the statutory standards to require an absolute certainty of no risk.

Congress directed the Commission to continue the interim prohibition if required to achieve a "reasonable certainty of no harm" and to expand it if "necessary to protect the health of children." § 2057c(b)(3). That language reflects two key choices.

First, Congress tied the Commission's authority to continue or expand the interim prohibition to what is "*necessary* to protect . . . *health*" and prevent actual "*harm*," rather than to guard against potential "*risks*." This linguistic choice was deliberate, as Congress knows how to condition the Commission's regulatory authority on preventing "risks" rather than "harm." *See, e.g.*, § 2056b(2)(B) (directing the Commission to promulgate more stringent children's product safety rules "if the Commission determines that more stringent standards would further reduce the *risk* of injury of such toys" (emphasis added)); § 2057(1) (empowering the Commission to ban a consumer product if it "presents an unreasonable *risk* of injury" (emphasis added)). "Risk" is different than "harm." Risk refers only to

"the chance of injury, damage, or loss." *Risk*, BLACK'S LAW DICTIONARY (10th ed. 2014); *see Risk*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (11th ed. 2009) (defining "risk" as "the possibility of loss or injury"). Harm, by contrast, means actual "[i]njury, loss, damage[,] [or] material or tangible detriment." *Harm*, BLACK'S LAW DICTIONARY (10th ed. 2014); *see Harm*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (11th ed. 2009) (defining "harm" as "physical or mental damage").

Second, Congress permitted the Commission to ban phthalates only as required to ensure a "reasonable certainty"—not an "absolute certainty"—of no harm, and only to the extent that is truly "necessary" to protect health. This textual choice raises the bar for regulation because, as the Commission admitted, that language did not authorize banning phthalates when necessary to achieve "100 percent certainty of no harm," but rather only a "reasonable" certainty of no harm. Final Rule at 49,944. Congress also did not permit the Commission to pursue certainty at all costs, but only certainty that is reasonable, *i.e.*, taking into account costs and other circumstances. *See Forester v. CPSC*, 559 F.2d 774, 788-89 (D.C. Cir. 1977) (interpreting the Federal Hazardous Substances Act's "unreasonable risk of personal injury" language as requiring the agency to consider costs); *accord Aqua Slide*, 569 F.2d at 839.

The Commission paid mere lip service to these statutory standards. Final Rule at 49,944. It admitted that the "most recent data" demonstrated a near-total absence of risk from phthalates. *Id.* at 49,958. Specifically, the "[m]edian and 95th percentile HIs for WORA are both less than one" and "between 98.8 and 99.6 percent of WORA have HIs less than or equal to one." *Id.* In other words, 99 percent of the relevant data set showed no risk from phthalates—even under the Commission's highly protective metric. And even at the 99th percentile, the Commission admitted that HIs over one did not purport to show actual *harm* to women whose spot tests produced those results:

> If the HI is greater than one, there *may be* a *concern* for antiandrogenic effects in the exposed population due to the cumulative effects of phthalates. . . . Having a HI greater than one *does not necessarily mean that adverse effects will occur*; however, this possibility cannot be ruled out.

Proposed Rule at 78,328 & n.8 (emphases added); *see also* Final Rule at 49,946, 49,957 (similar).

Nonetheless, the Commission attempted to justify the Phthalates Rule with those remote *risks* that registered only at or above the 99th percentile of spot samples. Yet the Commission was forced to admit that the data showing those extremely speculative risks was "not considered stable" because it came from the tail-end of the statistical distribution. Final Rule at 49,961 ("[V]alues associated with the upper tail of the distribution of HIs (e.g., above the 95th percentile) have

large variance estimates, due to sample size (i.e., statistically unstable)."); Staff Report Regarding 2005-2012 NHANES Data Sets, Index No. 377, at 13 (June 2015) (Table 6) ("Variance estimates are not possible for the 99th percentile estimates or are very large. These estimates are not considered stable."). That would be precisely why the Commission initially cited the more reliable 95th percentile values in its Proposed Rule. *E.g.*, Proposed Rule at 78,328, 78,332-33.

In sum, the Commission exceeded its statutory authority to protect against a "*reasonable* certainty of no *harm*" and to regulate as "*necessary* to protect . . . *health*" by justifying its ban on the grounds that the data did not show *absolute* certainty of no *risk*. Although the Commission acknowledged that absolute certainty was not required and conceded that even its most extreme spot samples did not reflect actual harm, it nonetheless based the Phthalates Rule on the remotest risks evidenced by a few transient spot samples in the "unstable" data region at or above the 99th percentile. Whatever the precise meaning of the statutory standards, the Commission went far beyond any permissible reading.

The Commission's "mere lip service or verbal commendation of a standard" cannot save it when, as here, it "fails to abide the standard in its reasoning and decision." *Nat. Res. Def. Council, Inc. v. Pritzker*, 828 F.3d 1125, 1135 (9th Cir. 2016). Its redefinition of statutory terms—evident on the face of the Phthalates Rule—renders the Commission's actions contrary to law. *See S. Coast Air Quality*

Mgmt. Dist., 882 F.3d at 1152 ("[T]he EPA must ground its reasons for action or inaction in the statute, rather than on reasoning divorced from the statutory text." (internal quotation marks omitted)); *Nat. Res. Def. Council v. EPA*, 777 F.3d 456, 468 (D.C. Cir. 2014) (same); *see also Am. Rivers*, 895 F.3d at 48-49 ("The [statutory] requirement to include a trigger for reinitiation of consultation necessitates more than lip service. The lack of a clear trigger point to reinitiate consultation renders the Opinion unlawful.").

B. The Commission's unreasonably sensitive HI metric further skewed the analysis into the realm of highly speculative risk rather than actual harm.

The more deeply one examines the data behind the Commission's calculations, the more speculative—and the less "reasonable"—even the *risk* identified by the Commission appears. The Commission's HI metric incorporated many layers of conservatism. First, the Commission calibrated the HI metric according to the "most sensitive health effect"—"[m]ale developmental reproductive effects," some of which were not even harmful—from phthalates exposure in rodent fetuses. Proposed Rule at 78,332; *see supra* at 12. It then determined "acceptable" exposure levels using three separate sets of data, only one of which used the most recent, actual data for all five phthalates. Final Rule 49,961-62; *see supra* at 12-13. Even in the face of comments pointing out the deficiencies in Cases 1 and 2, the Commission continued to calculate HIs for all

three cases and emphasize the artificially magnified risks that Case 2, in particular, produced. Final Rule at 49,961; *see Sierra Club v. EPA*, 863 F.3d 834, 838 (D.C. Cir. 2017) ("We have frequently held in various contexts that, in APA review, we will often find agency decisions arbitrary or capricious where the agency has failed to respond to major substantive comments."). Then the Commission assumed, contrary to the science, that humans are more sensitive to phthalates than rodents, leading to a safety level more than 100 times lower than the level that causes antiandrogenic effects in rodent fetuses. Final Rule at 49,958; *see supra* at 13.

The Commission applied that exquisitely sensitive HI metric to data that systematically overestimated human exposure to phthalates. As Commissioner Buerkle explained, "it [was] inappropriate [for the Commission] to treat the exposure estimates calculated from spot samples as if they represent an individual's exposure over a full day or even longer." Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 8 (Oct. 18, 2017) (Statement of Comm'r Ann Marie Buerkle). Indeed, even the Commission conceded that such "spot urine samples are variable and are not representative of long-term exposures" due to the high rate at which humans metabolize phthalates. Final Rule at 49,960. The result was a gross overestimation of the highest human exposure levels because a temporary spike following exposure to phthalates (likely through food)

was treated as representing the sustained, longer-term exposure level needed to cause adverse effects.[13] *See supra* at 13-14.

Adding yet another layer of conservatism to the Commission's calibration of its HI metric and overestimation of human phthalates exposure, the Commission added together the individual effects of several phthalates to create the HI metric. Proposed Rule at 78,328; *see supra* at 14-15. The result was that even though none of the five banned phthalates presented identifiable risk to humans even under the Commission's metric, it was able to create an HI greater than one at the extreme ends of the statistical range. And even this cumulative result was due to the "dominat[ing]" effects of DEHP, which § 2057c(a) permanently banned in new children's products. *See* Final Rule at 49,947, 49,963. Indeed, the Commission disclaimed even the ability to quantify the additional risk posed by the non-DEHP phthalates. *See, e.g.*, *id.* at 49,963 ("Staff is . . . unable to quantify the impact of increased DINP exposure on the percent of WORA or infants that have an HI less than or equal to one."). That explains why the phrase "cumulative risk" appears well over a hundred times in the Phthalates Rule, as it became the Commission's

[13] The Commission pointed out that in some "studies in animals have demonstrated that . . . effects can occur after one or a few doses," Final Rule at 49,955, but those studies involved doses of phthalates far greater than the sustained doses that yielded effects in the animal studies used to formulate the HI metric. CHAP Report, Index No. 232, Appendix A at A-2, A-9 (July 18, 2014). They thus cannot be used to shore up the Commission's calibration of the HI metric.

catchall response to any comment criticizing the potential of any of the five banned phthalates to cause actual risk, much less harm.

The Commission thus improperly premised the Phthalates Rule on an HI threshold that is surpassed at the most speculative and miniscule possibility of risk.[14] Even setting aside the numerous prophylactics arbitrarily built into the rule, it is difficult to imagine how admittedly unreliable, unstable data points can be used to determine anything with *reasonable* certainty. *See Sierra Club v. EPA*, 895 F.3d 1, 10-11 (D.C. Cir. 2018) (vacating rule based on agency's use of "low confidence value" data that it insisted was "reliable enough for regulatory use"). *Sierra Club* illustrates this point. In that case, the petitioners challenged, *inter alia*, EPA's reliance on "low confidence" data. *Id.* at 10. EPA explained that the "'low confidence' label means that it has low confidence in the derivation of the [chemical] concentration below which no adverse health risks were expected to occur because the existing data were incomplete," but it nonetheless averred that the "low confidence [data] is reliable enough for regulatory use." *Id.* at 10-11.

[14] Even if one of the many buffers discussed above could be justified as providing the "adequate margin of safety" called for by the statute, § 2057c(b)(3), that language cannot transform a standard that requires a "reasonable certainty of no harm" to "health" into one that requires elimination of the most attenuated and illusory risks imaginable. In any event, the Commission supplied no statutory construction of the "adequate margin of safety" text, much less one tailored to supporting any—let alone all—of the layers of conservatism arbitrarily built into the HI methodology of the Final Rule.

The D.C. Circuit vacated that portion of the regulation, agreeing with petitioners that "any deference to the EPA's interpretation of [the statutory standard] does not extend to allowing the EPA to use a single low-confidence, low-quality risk assessment to conclude that a threshold is 'established.'" *Id.* at 11.

Likewise here, the extreme statistical methods employed and the multilevel buffers built into the HI metric confirm that the Commission strayed far from the statutory thresholds for action. Instead of following the test mandated by Congress, the Commission demanded that the data rule out all *risk* with *absolute* certainty. The irrational and contradictory components of its approach add arbitrary-and-capricious action to the Commission's statutory violation.

C. The Commission's other methodological errors resulted in further deviations from the statutory standards.

Other methodological defects resulted in the Commission straying even further from the statutory standards. Most problematic, the Commission's methodology relied on data that cannot rationally support its ultimate ban. Specifically, the rodent studies the Commission used to develop the HI metric were based on exposing pregnant rodents to phthalates and then measuring the effects of that exposure on the rodent fetuses. Proposed Rule at 78,331-32. Thus, the Commission's HI metric was calibrated to measure the risk to human fetuses from the mother's phthalates exposure. Yet the Commission relied on that mother-to-fetus metric to ban phthalates *in toys and child care articles*, despite admitting that

those items caused negligible phthalates exposure to fetuses and their mothers. Final Rule at 49,953; Comment of Apr. 14, 2015, Index No. 361, at 31-35 ("For women of reproductive age (and thus for the fetus), the portion of DINP exposure due to children's products . . . is negligible compared to the portion coming from the diet."); *id.* ("The CHAP's calculated Hazard Index for antiandrogenic effects does not apply to human male infants as they are not in a period of reproductive tract development."). After all, neither fetuses nor pregnant women make it a habit to mouth children's toys. Nor could the HI metric justify banning the five phthalates to protect children generally because fetuses are significantly more sensitive to phthalates than children, meaning that the HI metric geared to the risk to fetuses would grossly overestimate the risk to children. Comment of Apr. 14, 2015, Index No. 362, at 7 ("While the fetus may still be a susceptible population, the toxicological effects considered in the CHAP CRA are not directly relevant to *children*[.]" (emphasis added)).

The Commission offered no response to comments on this point other than the non-sequiturs that "infants, toddlers, and children also are susceptible to the effects of phthalates" and that its method of risk calibration is standard practice. Final Rule at 49,953. This response ignores that the *magnitude* of the effect is what renders a metric calibrated to fetuses—the most sensitive population—inappropriate for assessing phthalates risks to other, less sensitive populations such

as children. The Commission's failure to rationally confront this defect in its methodology requires vacatur. *See Sierra Club*, 863 F.3d at 838 ("We have frequently held in various contexts that, in APA review, we will often find agency decisions arbitrary or capricious where the agency has failed to respond to major substantive comments."); *FiberTower Spectrum Holdings, LLC v. FCC*, 782 F.3d 692, 700 (D.C. Cir. 2015) ("An agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence." (quoting *Ctr. for Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 314 (D.C. Cir. 1992))); *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010) ("Conclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice to meet the deferential standards of our review.") (citation omitted).

Additionally, the Commission revealed more methodological deficiencies in its attempts to explain away its reliance on spot sampling to study effects that occur only with longer-term exposures. The Commission insists that "the estimated daily intakes and the resulting HQs and HIs represent estimated population per capita phthalate exposure across the 2-year NHANES cycle, *not average daily estimates of an individual's exposure across tim*e." Final Rule at 49,951 (emphasis added). But if the HI metric measures only "estimated population per capita" and not "an[y] individual's exposure across time," then the

Phthalates Rule fails on two separate grounds. First, the Commission's justification for the Phthalates Rule—that it "is not based on any particular percentile, but on the observation that actual women from the NHANES sample have HIs greater than one," *id.* at 49,961—contradicts the Commission's rationale that the HI metric does not measure "average daily estimates of an individual's exposure across time." *Id.* at 49,955. In other words, the HIs for those "actual women" are based on ephemeral spot samples that do not reflect their longer-term phthalates exposure—the relevant exposure period for the HI metric.

Second, since the HI metric is actually being used to project "estimated population per capita" with an HI greater than one, the extreme percentiles at which it exceeds one cannot be used for that purpose because they "are not considered stable." Staff Report Regarding 2005-2012 NHANES Data Sets, Index No. 377, at 13 (June 2015) (Table 6); *see also* Final Rule at 49,958 ("[T]he national population projection for HI greater than one is not estimable at the upper percentiles of the distribution due to sampling variability."); *id.* at 49,961 ("[V]alues associated with the upper tail of the distribution of HIs (e.g., above the 95th percentile) have large variance estimates, due to sample size (i.e., statistically unstable)."). The Commission's internally inconsistent explanation exposes the infirmities of the Phthalates Rule and the Commission's radical deviation from the statutory standards. *See Chamber of Commerce of United States of Am. v. United*

States Dep't of Labor, 885 F.3d 360, 382 (5th Cir. 2018) ("Illogic and internal inconsistency are characteristic of arbitrary and unreasonable agency action."); *Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm'n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018) (similar).

IV. The Commission acted arbitrarily and capriciously by retrofitting its rationale at the eleventh hour to justify its Proposed Rule, depriving Petitioners of an opportunity to comment on its key methodology.

A. Rather than allowing the updated data to drive the analysis, the Commission shifted its methodology to make the science produce the Proposed Rule's result.

Instead of defining a regulatory threshold based on sound science and statutory standards, the Commission continuously moved the goalposts to justify its Proposed Rule. In the Proposed Rule, the Commission indicated only that it "considers that a HI <1 is necessary" to satisfy the statutory standards. Proposed Rule at 78,334 ("reasonable certainty of no harm" standard); *id.* at 78,355 ("necessary to protect the health of children" standard). It then focused on the HI at the 95th percentile of the various data sets in determining whether and how broadly to ban the phthalates. *See id.* at 78,328-29, 78,332-33. The Proposed Rule thus applied the two statutory standards as if they translated to a requirement that the HI be less than one at the 95th percentile of the data set. This approach was consistent with established scientific practices, which accept results at the 95th percentile, but discard returns at the tail end of statistical distributions as unstable.

See DAVID W. BARNES, STATISTICS AS PROOF 246-48 (Little, Brown & Co. 1983) (explaining that "[a] 95% confidence interval is customary" in statistical analysis); MICHAEL O. FINKELSTEIN, ET AL., STATISTICS FOR LAWYERS 171-81 (Springer-Verlag 1990) (describing standard formulas for normalizing statistics at the 95th percentile); *see also* CHAP Report, Index No. 232, Appendix E1 (presenting only the mean, median, and 95th percentile values); Comment of Mar. 24, 2017, Index No. 437, Appendix A (demonstrating that if the HI is less than one at the 95th percentile, all women would be protected).

In finalizing the rule based on updated 2013/2014 NHANES data, the Commission changed course after it realized that the Proposed Rule's 95th percentile approach would result in no regulatory ban of any phthalates. Under the new data, the "[m]edian and 95th percentile HIs for WORA are both *less than one*" and "between 98.8 and 99.6 percent of WORA have HIs *less than or equal to one*." Final Rule at 49,958 (emphases added). Rather than follow standard statistical methods and accept that the new data could not support a regulatory ban on any phthalates, the Commission instead insisted that it had not given any specific definition of either statutory standard in the Proposed Rule: "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.'" *Id.*

The Final Rule instead applied the standards as if they mandated a ban when there was an HI greater than one at or even beyond the 99th percentile. Indeed, the Commission at times appeared to abandon the percentile approach altogether and instead act as if the statutory standards required a ban whenever any proportion—no matter how small—of a data set had an HI greater than one. *See id.* at 49,961 ("The rule is not based on any particular percentile, but on the observation that actual women from the NHANES sample have HIs greater than one."); *id.* at 49,963 ("[S]ome individuals in the [most recent data set] still have an HI greater than one."). Thus, despite previously relying on a 95th percentile approach and disclaiming that the statutory standards require "100 percent certainty of no harm," *id.* at 49,944, the Commission effectively required far more than that: It required the virtual elimination of all risk, by regulating based upon the spot-sample HI results of individual women beyond the 99th percentile of the data set.

The Commission's shifting and contradictory methodologies enabled it to retrofit its statutory definitions to whatever the science showed. Its abandonment of an accepted scientific approach in favor of *concededly* unstable and unreliable returns requires, at minimum, some compelling explanation. But none was forthcoming. The Commission's behavior thus embodies the kind of arbitrary agency rulemaking that mandates vacatur. *Cf. Sierra Club*, 895 F.3d at 14 (vacating rule based on "low confidence value" data where "EPA failed . . . to

adequately explain adjustments it made to five of the [data results]" used to formulate the statutory standard); *Am. Rivers*, 895 F.3d at 46 ("By discarding the methodology set forth in its own handbook and its own regulatory definitions, the Fish and Wildlife Service acted arbitrarily."); *Gulf Power Co. v. FERC*, 983 F.2d 1095, 1101 (D.C. Cir. 1993) ("[W]hen an agency takes inconsistent positions, as FERC did here, it must explain its reasoning."). Congress mandated—and consumers and stakeholders deserve—a phthalates rule based on reliable science and a rational decision-making process.

B. The Commission's failure to clearly articulate a standard deprived Petitioners of the opportunity to meaningfully comment on the central scientific premises of the rulemaking.

The Commission's shifting regulatory threshold deprived Petitioners of fair notice and a reasonable opportunity to comment on the methodology that ultimately underpinned the Phthalates Rule. The notice requirements in 5 U.S.C. § 553—which are explicitly referenced in § 2057c(3)—are designed

> (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.

Int'l Union, United Mine Workers of Am., 407 F.3d at 1259. To achieve these aims, courts require the final rule to be a "logical outgrowth of the rulemaking

process"—including the key aspects of the proposed rule. *See ConocoPhillips Co. v. EPA*, 612 F.3d 822, 834 (5th Cir. 2010).

While "the Final Rule and the Proposed Rule need not be identical," *id.* at 834, a change from the proposed rule to the final rule meets the "logical outgrowth" standard "only if interested parties 'should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period,'" *Int'l Union, United Mine Workers of Am.*, 407 F.3d at 1259 (quoting *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004)). A court "must be satisfied, in other words, that given a new opportunity to comment, commenters would not have their first occasion to offer new and different criticisms which the Agency might find convincing." *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 642 (1st Cir. 1979); *accord Kennecott v. EPA*, 780 F.2d 445, 460 (4th Cir. 1985) (adopting same standard); *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1225 (D.C. Cir. 1980) (same). After all, interested parties should not be expected to "divine [the Agency's] unspoken thoughts." *Int'l Union, United Mine Workers of Am.*, 407 F.3d at 1260 (quoting *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000)).

The Phthalates Rule does not meet the "logical outgrowth" standard because the Commission drastically changed its analytical justifications for the ban with no notice to Petitioners. As Commissioner Mohorovic explained:

> I think there was a reasonable understanding that the 95th percentile was the key percentile to evaluate results. What we didn't do and what we hadn't done through the whole promulgation of this rule is to give any indication that we might be making regulatory decisions based on the 99th percentile.

Commission Briefing Re: Final Phthalates Rules, Index No. 456, Video Two at 42:15-42:34, Transcript at 26-27 (Oct. 11, 2017) (Statement of Comm'r Joseph P. Mohorovic). For that reason, he concluded that "the Final Rule . . . is in no way a logical outgrowth of the proposed rule. It differs so significantly from the proposed rule in the fundamental basis, scientific rationale, and technical justification that I could not have seen this coming, nor could anyone else really . . . ." Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 23 (Oct. 18, 2017) (Statement of Comm'r Joseph P. Mohorovic).

The facts back up that description. The Proposed Rule gave every indication (short of an explicit statement) that the Commission was following the scientifically accepted practice of basing its rule on the results at the 95th percentile of its studies. However, rather than apply the reasoning of the Proposed Rule to conclude that the updated data did not support a ban, the Commission instead decided to radically change its understanding of the statutory standards to

support the ban contained in the Proposed Rule. Under the new guiding principle, the statutory standards mandated a ban if individuals in a data set exhibited an HI greater than one, even if only above the 99th percentile. *See* Final Rule at 49,961. Applying that novel and scientifically dubious approach, the Commission banned the five phthalates because "some individuals in the [most recent data set] still have an HI greater than one." *Id.* at 49,963; *see also id.* at 49,961 ("[F]or the [most recent data set], between two and nine real women from the sample of 538 WORAs had an HI greater than one . . . .").[15]

Assuming based on all the evidence that the Commission would be applying the standard approach of accepting results at the 95th percentile, stakeholders like Petitioners could not reasonably anticipate the Commission's draconian and unscientific new standard, much less the Commission's application of that test. The Commission's moving of the ball resulted in the Phthalates Rule being based on a "complex mix of controversial and uncommented upon data and calculations." *BASF Wyandotte Corp.*, 598 F.2d at 642. The Commission's attempt to defend its eleventh-hour shift by saying the Proposed Rule never "establish[ed] directly . . . that there was a specific proportion of the population" whose HI must exceed one

[15] Because of the HI metric's ultra-sensitivity, arbitrary methodology, and reliance on spot sampling, the HI greater than one for those few women does not connote an identifiable risk. *See supra* at 36-46.

only confirms that Petitioners lacked notice of the statutory threshold the Commission would employ. Final Rule at 49,963.

This case is analogous to *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). There, EPA promulgated a regulation under the Toxic Substances Control Act. It based its final rule in part on "analogous exposure estimates," but it did not give notice of this approach. *Id.* at 1211. This Court explained that "EPA's use of the analogous exposure estimates . . . should have been subjected to public scrutiny before the record was closed[,] . . . as they are used to support a substantial part of the regulation finally promulgated by the EPA." *Id.* at 1212. An agency "should not hold critical analysis in reserve and then use it to justify its regulation despite the lack of public comment on the validity of its basis." *Id.* The Court consequently vacated the rule.

The same result should follow here. The Commission never subjected the Final Rule's 99th-percentile-and-beyond methodology to public comment. "[G]iven a new opportunity to comment, [Petitioners] would . . . have their first occasion to offer new and different criticisms which the [Commission] might find convincing." *BASF Wyandotte Corp.*, 598 F.2d at 642. For example, Petitioners could have pointed out the unprecedented nature of the Commission's approach. No agency has ever employed such an unfounded analytical method, and for good reason. As the Commission itself acknowledged, percentiles at the extreme ends

of a distribution "are not considered stable." Staff Report Regarding 2005-2012 NHANES Data Sets, Index No. 377, at 13 (June 2015) (Table 6); *see also* Final Rule at 49,961 ("[V]alues associated with the upper tail of the distribution of HIs (e.g., above the 95th percentile) have large variance estimates, due to sample size (i.e., statistically unstable)."). Petitioners also could have elaborated on the effects that the Commission's arbitrary HI metric and extreme analytical conservatism had on these already unstable results. But Petitioners were deprived of this opportunity, and the Commission plowed forward by reverse-engineering the science to fit the outcome.

Courts "have refused to allow agencies to use the rulemaking process to pull [such] a surprise switcheroo on regulated entities." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). In these circumstances, vacatur and remand is required to permit an effective notice-and-comment process. *E.g.*, *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 210 (5th Cir. 1979) ("set[ting] aside the designations and remand[ing] to the Agency so that it may repromulgate the Alabama nonattainment list after proper public notice and opportunity to comment").

CONCLUSION

For these reasons, Petitioners request that the Phthalates Rule be held unlawful and set aside.

August 20, 2018

Respectfully submitted,

By: */s/ Aaron M. Streett*

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CERTIFICATE OF SERVICE

On this 20th day of August, 2018 a true and correct copy of the foregoing was filed with the electronic case filing (ECF) system of the U.S. Court of Appeals for the Fifth Circuit, which currently provides electronic service on the counsel of record.

/s/ Aaron M. Streett
Aaron M. Streett

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 12,570 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman font, size 14.

/s/ Aaron M. Streett
Aaron M. Streett

CERTIFICATIONS UNDER ECF FILING STANDARDS

Pursuant to paragraph A(6) of this Court's ECF Filing Standards, I hereby certify that (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 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.

/s/ Aaron M. Streett
Aaron M. Streett

Exhibit List

Exhibit 1—Declaration of Erik Glavich in Support of the National Association of Manufacturers' Petition for Review

Exhibit 2—Declaration of Eileen Conneely in Support of the American Chemistry Council's Petition for Review

Exhibit 3—Declaration of Martha K. Landwehr in Support of Texas Chemical Council's Petition for Review

Exhibit 4—Declaration of Tony Bennett in Support of the Texas Association of Manufacturers' Petition for Review

Exhibit 5—Declaration of James Hines in Support of the Texas Association of Business's Petition for Review

Exhibit 1

Case 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 United States Consumer Product Safety Commission

DECLARATION OF ERIK GLAVICH IN SUPPORT OF THE NATIONAL ASSOCIATION OF MANUFACTURERS' PETITION FOR REVIEW

I, Erik Glavich, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I hold the position of Director of Legal and Regulatory Policy for the National Association of Manufacturers ("NAM"). I submit this declaration in support of the NAM's petition for review in the above-captioned action. I am of the age of majority, am competent to make this declaration, and make this declaration based on my personal knowledge.

2. The NAM is the nation's largest industrial trade association, representing more than 13,000 small and large manufacturers in every industrial sector and in all 50 states. Our membership includes companies that manufacture or import certain organic compounds at issue in this lawsuit, known as phthalates, that are generally used to soften plastics such as polyvinyl chloride. We also represent companies that manufacture or import consumer products or components of such products that contain phthalates. The NAM and its members are committed to providing safe products and support effective regulation and oversight by the U.S. Consumer Product Safety Commission ("the Commission"), because it complements our shared commitment to safety and excellence in products used by American consumers.

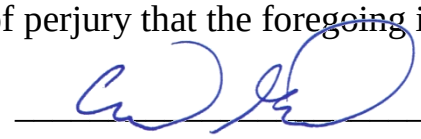
3. In 2008, Congress directed the Commission to determine whether phthalates present a threat to human health, and thus whether particular phthalates should be banned from children's toys and child-care articles. *See* 15 U.S.C. § 2057c. In 2017, the Commission promulgated a final rule (the "Phthalates Rule") that effectively banned five phthalates—known as DINP, DIBP, DPENP, DHEXP, and DCHP—in children's toys and child-care articles. *See* Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates ("Phthalates Rule"), 82 Fed. Reg. 49,938 (Oct. 27, 2017) (codified at 16 C.F.R. pt. 1307).

4. The NAM and its members were active participants in the Commission's rulemaking process. *See, e.g.*, Comment of Mar. 23, 2017, Index No. 436; Comment of Apr. 14, 2015, Index No. 361.

5. Many of the NAM's members have their principal place of business in Texas. The NAM's members include companies that manufacture, sell, or use products containing one or more of the five banned phthalates addressed in the Phthalates Rule. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of those five phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, the NAM's members will no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles.

6. Moreover, as active participants in the administrative process, the NAM and its members suffered various procedural injuries that can only be remedied by vacating and remanding the Phthalates Rule for further Commission proceedings. For example, by explicitly refusing to follow the statutorily mandated procedures for banning a hazardous product, the Commission caused the NAM and its members to suffer procedural injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on Aug. 10, 2018. 

Erik Glavich

Exhibit 2

Case 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 United States Consumer Product Safety Commission

DECLARATION OF EILEEN CONNEELY IN SUPPORT OF THE AMERICAN CHEMISTRY COUNCIL'S PETITION FOR REVIEW

I, Eileen Conneely, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I hold the position of Director, Chemical Products and Technology Division at the American Chemistry Council ("ACC") and I act as the manager of ACC's High Phthalates Panel within that Division. I submit this declaration in support of the ACC's petition for review in the above-captioned action. I am of

the age of majority, am competent to make this declaration, and make this declaration based on my personal knowledge.

2. The ACC is a trade association representing a diverse set of more than 170 companies engaged in the business of chemistry. Our membership of leading U.S. chemical manufacturers includes a High Phthalates Panel comprised of companies that manufacture, compound, convert or import certain organic compounds at issue in this lawsuit, known as phthalates, that are generally used to soften plastics such as polyvinyl chloride. The ACC also represents companies that manufacture, sell or import consumer products or components of such products that contain phthalates. The ACC and its members are committed to providing safe products and support effective regulation and oversight by the U.S. Consumer Product Safety Commission ("the Commission"), because it complements our shared commitment to safety and excellence in products used by American consumers.

3. In 2008, Congress directed the Commission to determine whether phthalates present a threat to human health, and thus whether particular phthalates should be banned from children's toys and child-care articles. *See* 15 U.S.C. § 2057c. In 2017, the Commission promulgated a final rule (the "Phthalates Rule") that effectively banned five phthalates—known as DINP, DIBP, DPENP, DHEXP, and DCHP—in children's toys and child-care articles. *See* Prohibition of

Children's Toys and Child Care Articles Containing Specified Phthalates ("Phthalates Rule"), 82 Fed. Reg. 49,938 (Oct. 27, 2017) (codified at 16 C.F.R. pt. 1307).

4. The ACC's High Phthalates Panel and its members were active participants in the Commission's rulemaking process. *See, e.g.*, Comment of Apr. 14, 2015, Index No. 361; Comment of Apr. 14, 2015, Index No. 360.

5. Many of the ACC's members have their principal place of business in Texas. The ACC's members include companies that manufacture, sell, and use one or more of the five banned phthalates and/or products containing one or more of the five banned phthalates addressed in the Phthalates Rule. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of those five phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, the ACC's members will no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles.

6. Moreover, as active participants in the administrative process, the ACC and its members suffered various procedural injuries that can only be remedied by vacating and remanding the Phthalates Rule for further Commission proceedings. For example, by explicitly refusing to follow the statutorily

mandated procedures for banning a hazardous product, the Commission caused the ACC and its members to suffer procedural injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on Aug. 13th, 2018.

Eileen Conneely

Exhibit 3

Case 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 United States Consumer Product Safety Commission

DECLARATION OF MARTHA K. LANDWEHR IN SUPPORT OF THE TEXAS CHEMICAL COUNCIL'S PETITION FOR REVIEW

I, Martha K. Landwehr, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I hold the position of General Counsel and lead the Texas Chemical Council's legal and regulatory advocacy efforts at the state and federal level. I submit this declaration in support of Texas Chemical Council's ("TCC") petition for

review in the above-captioned action. I am of the age of majority, am competent to make this declaration, and make this declaration based on my personal knowledge.

2. TCC is a statewide trade association of chemical manufacturing facilities in Texas. TCC represents approximately 70 member companies who operate over 200 manufacturing and research facilities across the state. Our membership includes companies that manufacture or import certain organic compounds at issue in this lawsuit, known as phthalates, that are generally used to soften plastics such as polyvinyl chloride. We also represent companies that manufacture or import consumer products or components of such products that contain phthalates. TCC and its members are committed to providing safe products and support effective regulation and oversight by the U.S. Consumer Product Safety Commission ("the Commission"), because it complements our shared commitment to safety and excellence in products used by American consumers.

3. In 2008, Congress directed the Commission to determine whether phthalates present a threat to human health, and thus whether particular phthalates should be banned from children's toys and child-care articles. *See* 15 U.S.C. § 2057c. In 2017, the Commission promulgated a final rule (the "Phthalates Rule") that effectively banned five phthalates—known as DINP, DIBP, DPENP, DHEXP, and DCHP—in children's toys and child-care articles. *See* Prohibition of Children's

Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938 (Oct. 27, 2017) (codified at 16 C.F.R. pt. 1307).

4. TCC's members were active participants in the Commission's rulemaking process. *See, e.g.*, Comment of Apr. 14, 2015, Index No. 361.

5. Many of TCC's members have their principal place of business in Texas. TCC's members include companies that manufacture, sell, and use products containing one or more of the five banned phthalates addressed in the Phthalates Rule. For example, TCC member ExxonMobil Chemical Company manufactures phthalates regulated by the Phthalates Rule. *See id.* at 1. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of those five phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, TCC's members will no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles.

6. Moreover, as active participants in the administrative process, TCC's members suffered various procedural injuries that can only be remedied by vacating and remanding the Phthalates Rule for further Commission proceedings. For example, by explicitly refusing to follow the statutorily mandated procedures for banning a hazardous product, the Commission caused TCC's members to suffer procedural injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 13, 2018.

Martha K. Landwehr

Exhibit 4

Case 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 United States Consumer Product Safety Commission

DECLARATION OF TONY BENNETT IN SUPPORT OF THE TEXAS ASSOCIATION OF MANUFACTURERS' PETITION FOR REVIEW

I, Tony Bennett, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I hold the position of President for the Texas Association of Manufacturers ("TAM"). I submit this declaration in support of the TAM's petition for review in the above-captioned action. I am of the age of majority, am competent to make this declaration, and make this declaration based on my personal knowledge.

2. The TAM is a trade association representing over 450 large and small manufacturing companies located throughout the State of Texas. Our membership includes companies that manufacture or import certain organic compounds at issue in this lawsuit, known as phthalates, that are generally used to soften plastics such as polyvinyl chloride. We also represent companies that manufacture or import consumer products or components of such products that contain phthalates. The TAM and its members are committed to providing safe products and support effective regulation and oversight by the U.S. Consumer Product Safety Commission ("the Commission"), because it complements our shared commitment to safety and excellence in products used by American consumers.

3. In 2008, Congress directed the Commission to determine whether phthalates present a threat to human health, and thus whether particular phthalates should be banned from children's toys and child-care articles. *See* 15 U.S.C. § 2057c. In 2017, the Commission promulgated a final rule (the "Phthalates Rule") that effectively banned five phthalates—known as DINP, DIBP, DPENP, DHEXP, and DCHP—in children's toys and child-care articles. *See* Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates ("Phthalates Rule"), 82 Fed. Reg. 49,938 (Oct. 27, 2017) (codified at 16 C.F.R. pt. 1307).

4. The TAM's members were active participants in the Commission's rulemaking process. *See, e.g.*, Comment of Apr. 14, 2015, Index No. 361.

5. Many of the TAM's members have their principal place of business in Texas. The TAM's members include companies that manufacture, sell, or use products containing one or more of the five banned phthalates addressed in the Phthalates Rule. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of those five phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, the TAM's members will no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles.

6. Moreover, as active participants in the administrative process, the TAM's members suffered various procedural injuries that can only be remedied by vacating and remanding the Phthalates Rule for further Commission proceedings. For example, by explicitly refusing to follow the statutorily mandated procedures for banning a hazardous product, the Commission caused the TAM's members to suffer procedural injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 9, 2018.

Tony Bennett

Exhibit 5

Case 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 United States Consumer Product Safety Commission

DECLARATION OF JAMES HINES IN SUPPORT OF THE TEXAS ASSOCIATION OF BUSINESS'S PETITION FOR REVIEW

I, James Hines, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I hold the position Senior Vice President of Advocacy and In-House Counsel for the Texas Association of Business ("TAB"). I submit this declaration in support of the TAB's petition for review in the above-captioned action. I am of the age of majority, am competent to make this declaration, and make this declaration based on my personal knowledge.

2. The TAB is the state chamber of commerce for Texas, advocating for policies favorable to businesses on behalf of Texas employers and businesses of all sizes and representing more than 4,000 business members and their over 600,000 employees at the state and federal levels. Our membership includes companies that manufacture or import certain organic compounds at issue in this lawsuit, known as phthalates, that are generally used to soften plastics such as polyvinyl chloride. We also represent companies that manufacture or import consumer products or components of such products that contain phthalates. The TAB and its members are committed to providing safe products and support effective regulation and oversight by the U.S. Consumer Product Safety Commission ("the Commission"), because it complements our shared commitment to safety and excellence in products used by American consumers.

3. In 2008, Congress directed the Commission to determine whether phthalates present a threat to human health, and thus whether particular phthalates should be banned from children's toys and child-care articles. *See* 15 U.S.C. § 2057c. In 2017, the Commission promulgated a final rule (the "Phthalates Rule") that effectively banned five phthalates—known as DINP, DIBP, DPENP, DHEXP, and DCHP—in children's toys and child-care articles. *See* Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates ("Phthalates Rule"), 82 Fed. Reg. 49,938 (Oct. 27, 2017) (codified at 16 C.F.R. pt. 1307).

4. The TAB's members were active participants in the Commission's rulemaking process. *See, e.g.*, Comment of Apr. 14, 2015, Index No. 361.

5. Many of the TAB's members have their principal place of business in Texas. The TAB's members include companies that manufacture, sell, or use products containing one or more of the five banned phthalates addressed in the Phthalates Rule. The Phthalates Rule inflicts a concrete and particularized injury on these member organizations because it bans the use of those five phthalates in all children's toys and childcare articles. If the Phthalates Rule stands, the TAB's members will no longer be able to manufacture, sell, or use the banned phthalates for inclusion in children's toys and childcare articles.

6. Moreover, as active participants in the administrative process, the TAB's members suffered various procedural injuries that can only be remedied by vacating and remanding the Phthalates Rule for further Commission proceedings. For example, by explicitly refusing to follow the statutorily mandated procedures for banning a hazardous product, the Commission caused the TAB's members to suffer procedural injury.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 16, 2018.

James Hines

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