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' REPLY BRIEF

BAKER BOTTS L.L.P.
Aaron M. Streett
J. Mark Little
Travis L. Gray
One Shell Plaza
910 Louisiana St.
Houston, Texas 77002
Tel: (713) 229-1234
Fax: (713) 229-1522

Counsel for Petitioners

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INTRODUCTION

Over 100 pages of responsive briefing from the Commission, Intervenors, and *amici* cannot save the profoundly flawed Phthalates Rule from the defects identified by Petitioners and two dissenting Commissioners. Like the Final Rule itself, the briefing cannot explain how the Commission could promulgate a rule dramatically expanding the interim statutory prohibition without following the exclusive statutory path for doing so: "declar[ing] 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). Nor can the Commission excuse its multiple violations of the Administrative Procedures Act. The Commission's use of admittedly unstable data and internally contradictory analysis was both arbitrary and capricious and a violation of the regulatory thresholds set by the phthalates statute. Finally, the Commission's newly announced rationale for the Final Rule—which misconstrued the updated (and inconvenient) data to justify adhering to the Proposed Rule's ban—compounded the Rule's arbitrariness and deprived Petitioners of an opportunity to comment on the Commission's novel approach. The Rule must be vacated in its entirety.

ARGUMENT

I. Petitioners have standing.

Petitioners are trade associations with members who manufacture, distribute, and sell the phthalates covered by the Rule. Opening Br., Exs. 1-5. They and their

members actively participated in the rulemaking under review. *Id.* Despite this self-evident showing of standing, Intervenors demand more. It is notable that the Commission apparently does not share Intervenors' views. Nevertheless, because standing presents a threshold issue, Petitioners address Intervenors' contention at the outset.

Regulations that impair market conditions create a cognizable economic injury for market participants. Kristin E. Hickman & Richard J. Pierce, Jr., Administrative Law Treatise § 18.4.1 (6th ed. 2018). "The [Supreme] Court routinely recognizes probable economic injury resulting from agency actions that alter competitive conditions as sufficient to satisfy the first part of the standing test." *Id.* (collecting cases); *see also Pac. Gas & Elec. Co. v. FERC*, 106 F.3d 1190, 1194 (5th Cir. 1997) (finding standing where gas-distribution companies would "inevitably be forced to pay higher gas prices if FERC ends its regulation of the rates"); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497-99 (D.C. Cir. 1996) (drug manufacturer had standing to challenge agency action allowing a competing drug). Where, as here, petitioners manufacture a regulated chemical, and the regulation bans its use in certain end-products, the lessened demand for the chemical caused by the rule necessarily harms petitioners.

Moreover, the Phthalates Rule's effect goes beyond merely banning certain phthalates' use in a narrow range of products. The CHAP was charged with

examining the risks posed by all phthalates in a wide range of products—including those outside the Commission's jurisdiction. Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, 82 Fed. Reg. 49,938, 49,943 (hereinafter "Phthalates Rule" or "Final Rule"). Indeed, the Commission justified its ban based on the risks cumulatively posed by phthalates via all exposure vectors. *E.g.*, *id.* at 49,958-59. The Rule's finding of cumulative harm from phthalates' widespread use inflicts a stigma that extends far beyond children's products.

Tozzi v. HHS, 271 F.3d 301 (D.C. Cir. 2001), is instructive. HHS listed dioxin as a "known human carcinogen." *Tozzi*, 271 F.3d at 303-04. A medical-device manufacturer, Brevet, challenged the agency's action, claiming standing based on the rule's detrimental effect on the market for PVC plastics, which contain dioxin. *Id.* at 307-08. Finding standing, the court concluded that given the stigmatic effect of the "pejorative and damaging . . . carcinogen" label, it was "not at all 'speculative' to expect that Brevet, a company whose revenues depend almost entirely on the continued use of PVC plastic in the medical industry, will experience reduced profits." *Id.* at 308.

The Phthalates Rule similarly harms the market for certain phthalates that Petitioners' members, including ExxonMobil Chemical Company ("EMCC"), manufacture. Ex. A, Wallace Decl. ¶ 2. If the "pejorative" connotation of being

labeled a carcinogen was sufficient to make the "probability of economic harm increase[] exponentially," a permanent ban on certain phthalates' use in children products would surely be a "substantial factor" in causing EMCC's economic injury. *Tozzi*, 271 F.3d at 309. Vacating the Phthalates Rule "would redress at least some of [EMCC's] economic injury" by keeping the phthalates market free from government prohibition and stigma. *Id.* at 310.

Petitioners' members need not show that they sell phthalates that do (or would) end up in children's toys. That they produce and sell phthalates into the stream of commerce is sufficient. All market-based injuries are based on actions of third parties that create demand for a given product. *E.g.*, *Bristol-Myers Squibb*, 91 F.3d at 1499 ("[I]t is no answer to say that the [agency] is merely permitting a competitive product to enter the market and leaving the purchasing decision to the consumer."); *Tozzi*, 271 F.3d at 308-09 (upholding standing "even though the harm resulted most directly from independent purchasing decisions of third parties"). If the Phthalates Rule stands, it is undisputed that Petitioners' members "will lose a market for their products." *E.g.*, Opening Br., Ex. 3, Landwehr Decl. ¶ 5. Indeed, EMCC's supplemental declaration makes clear that the Phthalates Rule has an ongoing detrimental effect on the overall phthalates market. Ex. A, Wallace Decl. ¶ 9. That amply establishes standing, as proving injury-in-fact does not "require an empirical analysis linking specific [agency actions] to specific, demonstrated

economic harms (e.g., lost sales, decreased market share)." *Canadian Lumber Trade All. v. United States*, 517 F.3d 1319, 1332 (Fed. Cir. 2008).

While the foregoing demonstrates Petitioners' standing, out of an abundance of caution Petitioners have provided a supplemental declaration that further details the injury EMCC will suffer as a result of the Phthalates Rule. Ex. A, Wallace Decl. That declaration establishes beyond doubt that EMCC will suffer an economic injury that is fairly attributable to the Phthalates Rule and redressable by its vacatur.

II. The Commission cannot justify its refusal to follow the statutory requirements for declaring the named phthalates to be banned hazardous products.

The Commission concedes that the Phthalates Rule goes well beyond the interim statutory prohibition on mouthable children's toys and childcare articles containing DINP. CPSC Br. 12, 23-24. And it concedes that its *only* authority for 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)." § 2057c(b)(3)(B); CPSC Br. 23-24, 30. Yet the Commission also candidly acknowledges 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* CPSC Br. 30 ("[T]he Commission's phthalates rule is not a hazardous product ban under

section 2057 . . . .” (emphasis omitted)). Indeed, the Commission freely admits that the Final Rule does not even “use the words ‘banned hazardous product[s].’” CPSC Br. 30. The Court need not go further to vacate the Phthalates Rule because it dramatically expands the interim statutory prohibition without “declar[ing] any children’s product containing any phthalates to be a banned hazardous product [under § 2057].” § 2057c(b)(3)(B).[1]

Like the Rule itself, the Commission’s briefing fails to offer a reasonable interpretation of § 2057c(b)(3)(B) that allows the Commission to ban phthalates-containing products *without* declaring such products to be banned hazardous products under § 2057. To the contrary, the Commission’s interpretation renders wholly superfluous the words “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).” Indeed, the Commission argues that it must completely ignore § 2057’s requirements. CPSC Br. 24. Thus, the Commission cannot explain how its obligations or the statute’s meaning would be different if these words were omitted altogether.

[1] The Commission cannot selectively support parts of the Phthalates Rule with § 2057c(b)(3)(A)’s standard. It promulgated the Phthalates Rule as a unitary regulation and interpreted § 2057c(b)(3)’s two standards to be identical. Opening Br. 33. The Rule must therefore be evaluated holistically.

An interpretation that nullifies a key phrase of a statute cannot be a reasonable interpretation entitled to *Chevron* deference. *E.g.*, *Massachusetts v. U.S. Dep't of Transp.*, 93 F.3d 890, 896 (D.C. Cir. 1996) ("We are particularly reluctant to accept such a reading of such a provision when its implications would render superfluous at least two other segments of that provision's statutory scheme . . . ."); *Mont. Air Chapter No. 29, Ass'n of Civilian Technicians, Inc. v. Fed. Labor Relations Auth.*, 898 F.2d 753, 759 (9th Cir. 1990) (finding agency's interpretation unreasonable where "[s]uch a gloss on § 7116(a) changes the entire character of that section and renders superfluous subsection (5)."). Nor may agencies ignore statutory phrases by characterizing them as cross-references. *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 630-31 (2018) (rejecting agency's interpretation as unreasonable for rendering "superfluous" a statute's "cross-references" to other statutes). In any event, the phrase in question is far more than a cross-reference, for it describes the only way in which the Commission may regulate beyond the interim ban.

The Commission's principal interpretive argument appears to be that § 2057's requirements are inconsistent with those in § 2057c, and that the Commission was therefore empowered to ignore § 2057. CPSC Br. 18, 26. But the Commission never gives an account of why, if that were so, Congress included the disputed language in § 2057c(b)(3)(B). To the extent it interprets that language

at all, the Commission does so through italics, emphasizing that the statute requires 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)." CPSC Br. 25, 31. But the Commission never explains what it means by italicizing these words. The reader is left to infer that, in the Commission's view, the words "to be" seemingly authorize the Commission to deem phthalates to be banned hazardous products without following § 2057's requirements referenced in § 2057c(b)(3)(B). Not since Shakespeare penned *Hamlet* have the words "to be" been assigned such weight, and they cannot bear it here. There is no plausible meaning of "declar[ing] products . . . to be banned hazardous products" that is satisfied by a rule that does not even make such a declaration (much less follow the procedures for doing so "under [§ 2057]").

What is more, Congress knows how to deem something a banned hazardous product outside of § 2057's procedures. It did just that in § 2057a(a), mandating that "butyl nitrite shall be considered a banned hazardous product under section 2057." *See also* § 2057b(a) ("volatile alkyl nitrite shall be considered a banned hazardous product under section 2057"). There is no similar "shall be considered" language in § 2057c(b)(3)(B), however. Instead, the phthalates provision tracks § 2057's language for "declaring such product a banned hazardous product." The

statute therefore requires the Commission to follow § 2057's requirements for banning hazardous products.

In any case, the Commission overreaches in asserting that § 2057's requirements (and those of § 2058, which § 2057 incorporates) are inconsistent with § 2057c's requirements. If there is any conflict, the correct course is to attempt to reconcile the statutory provisions, not to discard one entirely. *See Trout Point Lodge, Ltd. v. Handshoe*, 729 F.3d 481, 488 n.8 (5th Cir. 2013) ("[I]f possible, the court interprets provisions of a statute in a manner that renders them compatible, not contradictory."); *Citizens to Save Spencer Cty. v. EPA*, 600 F.2d 844, 870-71 (D.C. Cir. 1979) (the "rule that the maximum possible effect should be afforded to all statutory provisions, and, whenever possible, none of those provisions rendered null or void . . . applies with equal strength when statutory provisions are in certain respects inconsistent"). The Commission never made this effort to honor Congress's intent, rendering its interpretation unreasonable.[2]

[2] The Commission also invokes the rule that specific statutes control over general ones. CPSC Br. 22. But here there are two specific statutory standards referenced in § 2057c(b)(3)(B), not one specific and one general. The statute's incorporation of §§ 2057 and 2058's procedures carries equal weight with its inclusion of the "necessary to protect the health of children" requirement; indeed, they are part of the same statutory sentence. This structure indicates Congress's intent for the standard in § 2057c to co-exist with the CPSA procedures in §§ 2057 and 2058—a structure common in the CPSIA. *E.g.*, 15 U.S.C. § 2056a(d)(1) (providing product-specific standards and directing that "the Commission shall, pursuant to its authority under section 2065(b) [of the Consumer Product Safety Act], promulgate a final consumer product safety rule").

To the extent irreconcilable conflicts exist, the Commission could perhaps reasonably apply the phthalates-specific test. For example, the Commission perceives a conflict between the "necessary to protect the health of children" standard and § 2058's "unreasonable risk of injury" standard. But even if that perception is accurate, there is no warrant for the Commission to wholly ignore the numerous non-conflicting procedural safeguards contained in §§ 2057 and 2058 that Congress required the Commission to follow when declaring phthalate-containing products to be "banned hazardous products [under § 2057]." *See* Opening Br. 26-28 (detailing various §§ 2057 and 2058 procedures). For example, under § 2057 the Commission must find a "consumer product is being, or will be, distributed in commerce." It is unsurprising that Congress would ask the Commission to make this threshold finding before expending resources banning products that may no longer exist. Similarly, § 2058(f)(1) requires the Commission to "make appropriate findings" regarding:

> (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;
>
> (B) the approximate number of consumer products, or types or classes thereof, subject to such rule;
>
> (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and
>
> (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation

> of manufacturing and other commercial practices consistent with the public health and safety.

Nothing in § 2057c prevents the Commission from taking these important steps before announcing its rule (certainly, the Commission has identified no conflict). Yet the Commission failed to follow even these plainly non-conflicting procedures.

The Commission particularly objects to the cost-benefit analysis that is one aspect of banning hazardous products under § 2057. But nothing in § 2057c(b)(3) prohibits the Commission from weighing costs and benefits through the lens of the phthalates-specific standards. Indeed, § 2057c(b)(3)(A) directs the Commission to achieve "reasonable" certainty of no harm—and references to reasonableness are often interpreted to allow consideration of costs. *E.g.*, *UAW v. Occupational Safety & Health Admin.*, 938 F.2d 1310, 1319 (D.C. Cir. 1991) ("'Reasonableness' has long been associated with the balancing of costs and benefits."). Unlike in *Whitman v. American Trucking Associations Inc.*, 531 U.S. 457 (2001), Petitioners do not seek to read an "implicit" cost-benefit requirement into the statute, but rather urge that the Commission must follow §§ 2057 and 2058's cost-benefit requirement that is expressly incorporated into § 2057c.

Contrary to the Commission's plea, there is no reason that health-based standards cannot co-exist with the cost-benefit consideration Congress mandated. Much as here, the Clean Air Act directs EPA to regulate the "threat of adverse effects to human health or the environment." *Michigan v. EPA*, 135 S. Ct. 2699,

2707 (2015) (quoting 42 U.S.C. § 7412(c)(3)). Yet even where the statute did *not* expressly direct a cost-benefit analysis, the Supreme Court held that "it is unreasonable to read an instruction to an administrative agency to determine whether 'regulation is appropriate and necessary' as an invitation to ignore cost." *Id.* That holding applies *a fortiori* here.

Indeed, Congress uses clear language when it wants an agency to conduct a purely health-based analysis, without considering costs. In amending the Toxic Substances Control Act (TSCA), Congress provided that the agency must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, *without consideration of costs* or other nonrisk factors." 15 U.S.C. § 2605(b)(4)(A)) (emphasis added). Notably, even though Congress instructed the agency to disregard costs when conducting the health-based "risk evaluation," *id.*, TSCA nonetheless requires the agency to assess the "economic consequences" and "costs" of its ultimate proposed rules. § 2605(c)(2). Unlike TSCA, § 2057c contains no express proscription against considering cost at any stage of the Commission's analysis, and the Commission's attempt to read one into the statute is unreasonable.

Finally, Intervenors' attempt to shore up the Commission's statutory arguments is unavailing. They suggest that the disputed language merely "answers the question of *what kind* of banned hazardous product is created." Intervenors'

Br. 17-18. But there is only *one kind* of banned hazardous product under the CPSA and CPSIA, and §§ 2057 and 2058 describe the procedures for declaring it. That plain fact renders the "under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057)" language a nullity under the Intervenors' interpretation.

In sum, the Final Rule does not contain a statutory interpretation worthy of *Chevron* deference. The Court should vacate the Phthalates Rule for the Commission's failure to follow the explicit statutory requirements.

III. The Commission's misuse of concededly unreliable statistical data was arbitrary and capricious and departed from statutory standards.

The Rule cannot be sustained even if the Commission were correct that it need only apply the phthalates-specific statutory standards found in § 2057c(b)(3). The Commission does not meaningfully contest that it revamped its rationale for the Rule when updated science revealed no risks at the statistically standard 95th percentile. Relying on spot-sample data, the Commission reached beyond the "unstable" 99th percentile of data to declare that "actual women" were being exposed to harmful levels of phthalates. The Commission's unscientific approach, as well as its conclusion, was arbitrary and capricious. The Rule likewise violated the statutory standards by effectively requiring an absolute certainty of no risk.

A. The Commission's conclusion that "actual" women are being exposed to unsafe levels of phthalates is arbitrary and capricious.

The Commission's defense of its ban as consistent with the "reasonable certainty of no harm" and "necessary to protect the health of children" standards rests on its foundational premise that "actual women were exposed to phthalates at unsafe levels." CPSC Br. 37-38. Without that premise, the Rule cannot be justified under any rational standard, much less the "harm"-based, reasonableness standards applicable here. Multiple flaws in the Commission's analysis render that premise—and thus the Rule—unsupportable.

1. The Commission's defense of its use of transient spot samples to assess long-term health effects is self-contradictory.

Perhaps the most egregious of these analytical missteps occurred when the Commission made the final leap from its updated data to the "actual women" conclusion. That is where the Commission strained to shove the square peg of its spot-sample data into the round hole of its HI metric calibrated to longer-term phthalates exposure. The Commission appears to recognize this problem. It concedes that "spot urine samples are variable and are not representative of long-term exposures." CPSC Br. 41 (quoting Opening Br. 39). And it does not dispute

that the HI metric was calibrated to levels of longer-term phthalates exposure rather than snapshot values.[3]

The Commission's attempt to reason its way out of this bind only highlights its self-contradictory analysis. It asserts that "the spot urine samples were not being used to provide 'average daily estimates of an individual's exposure across time,'" but instead to "estimate[] population per capita phthalate exposure" over a longer-term period. CPSC Br. 41-42 (quoting Final Rule at 49,955). In other words, the Commission was not measuring the real HI—the one based on longer-term exposure—of any of the "actual women" in the sample. Instead, the spot samples from those women were being used as a tool to project the longer-term phthalates levels of the overall population, thereby (in theory) obtaining the longer-term exposure data needed for the longer-term-calibrated HI metric.

That creates two insoluble problems for the Commission. First, it completely undermines the Commission's stated ground for the Rule—"that actual women from the NHANES sample have HIs greater than one." Final Rule at

[3] The Commission claims that "studies show that male reproductive effects 'can occur after one or a few doses' and longer-term exposures are not necessarily required to cause adverse health outcomes." CPSC Br. 41 (quoting Final Rule at 49,955). But it ignores that—as Petitioners pointed out in their opening brief (at 40 n.13)—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, at A-2, A-9 (July 18, 2014). They thus cannot be used to shore up the Commission's calibration of the HI metric.

49,961. Nothing supports that statement because, as the Commission admits, its spot sample-based analysis did not calculate real HIs based on the "average daily estimates of an individual's exposure across time." CPSC Br. 41-42 (quoting Final Rule at 49,955). There is simply no data on the longer-term phthalates levels of the 538 women in the study, and thus it is impossible to determine the real HI—the one based on longer-term exposure levels—for any of those individual women. That is why the Commission defended its spot-sample method not as one for measuring the HIs of those particular women but rather for projecting the HIs of longer-term exposures for the population at large. CPSC Br. 41-42. Thus, if spot sample-derived HIs are the basis for the Commission's crucial claim that "actual women were exposed to phthalates at unsafe levels," then it is wholly groundless.

Second, to the extent the Commission claims to be using the results of its analysis to project "estimated population per capita phthalate exposure" over a longer-term period, that directly contradicts the Commission's statement in the Final Rule that "[t]he 2013/2014 NHANES data cannot be used to estimate how many WORA in the U.S. population have HIs greater than one." Final Rule at 49,961. No projection is possible because the HIs of those spot samples exceeded one only at the extreme ends of the statistical distribution, around the 99th

percentile or beyond.[4] Such upper ends of the distribution "are not considered stable." Staff Report Regarding 2005-2012 NHANES Data Sets, Index No. 377, at 13 (June 2015) (Table 6). As the Commission explained, that means they cannot be used to project values for the overall population: "[T]he national population projection for HI greater than one is not estimable at the upper percentiles of the distribution due to sampling variability." Final Rule at 49,958.

Thus, under the Commission's own reasoning, the results of its spot-sample analysis cannot be used to project any number of "actual women" with even a short-term HI greater than one in the population, much less how many, if any, "actual women" had a real, longer-term HI greater than one.[5] This "no confidence" data is even worse than the "low confidence" data held to invalidate agency action in *Sierra Club v. EPA*, 895 F.3d 1, 10-11 (D.C. Cir. 2018).[6] *See also Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1227 (5th Cir. 1991)

[4] Tellingly, the Commission does not dispute that the 95th percentile—at which HI is lower than one—is the scientific standard. *See* Opening Br. 46-47.

[5] Intervenors vividly illustrate this point when they pluck numbers out of the air, claiming that the number of women with a real HI greater than one in the population might be "1.2 million," "300,000," or "60,000." Intervenors' Br. 24. There are no constraints on the estimate because the data provides no guidance whatsoever. Pure conjecture cannot be the foundation of agency action.

[6] The Commission distinguishes *Sierra Club* because that court purportedly "faulted the EPA for failing to use a sufficiently conservative approach." CPSC Br. 44. The Commission misses the court's point that the rule was arbitrary

("express[ing] concern with the EPA's cavalier attitude toward the use of its own data" and noting that "a conclusion is no better than the methodology used to reach it"); *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1146 (9th Cir. 2015) (vacating rule where "the results the model predicts in this case are too insignificant for the [agency's] model to measure"). The Commission's "mismatch" between its unreliable data and its conclusion renders the Rule arbitrary and capricious. *See Sierra Club v. EPA*, 884 F.3d 1185, 1195 (D.C. Cir. 2018) ("That mismatch—treating data EPA had viewed as not reliable at low emission levels as if it were affirmative support for a breakdown of the correlation at those levels—makes EPA's decision arbitrary and capricious.").

In short, the Commission has no sound basis for asserting that "actual women were exposed to phthalates at unsafe levels." CPSC Br. 37. The Rule cannot survive without that "actual women" premise. Faced with those undeniable facts, the Commission appears to argue that its utter lack of reliable scientific evidence somehow justifies the ban. CPSC Br. 42-43. To be sure, an agency must work with the data it has. But when even the most hypersensitive test of that data demonstrates no harm within the region of stable statistics, the lack of better data

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because it unjustifiably relied on "low confidence" data. That principle applies whether the agency's use of unreliable data makes the rule more or less stringent.

cannot support imposing a ban anyway. That is the epitome of agency action with no rational scientific basis.

2. The Commission's defense of its hypersensitive HI metric both misses the point and fails on the merits.

Tracing the Commission's reasoning further back from its last, fatal misstep reveals more infirmities that Petitioners identified in their opening brief. The Commission responds to these serious criticisms by misunderstanding Petitioners' arguments or ignoring them entirely. Reviewing Petitioners' actual critiques of the Commission's approach only heightens the irrationality underpinning the final leap from the unstable data to the Commission's "actual women" conclusion.

The principal problem with the Commission's analysis arises not from any one of the layers of conservatism it employed, but rather from combining their collective effect with unstable statistical returns. The Commission stacked layer upon layer of conservatism—some more defensible than others—in building its HI metric. In doing so, it created an HI metric on a hair trigger that would exceed one at levels of phthalates more than 100 times lower than those that cause the most sensitive antiandrogenic effects in rats. The Commission's HI metric tests the boundaries of the Commission's statutory mandate to regulate only to ensure "reasonable certainty of no harm" and as "necessary to protect the health of children." Yet even with that hypersensitive HI metric *and* the use of spot-

sampled data that systematically overestimated longer-term phthalates levels,[7] the Commission's updated data still found no risk at the 95th percentile. It thus had to strain into the unstable 99th percentile to find the results it needed to construct its self-contradictory "actual women" justification for the Rule. When this final, arbitrary step is added to the prophylactic measures already built into the HI metric, it becomes plain that the Commission failed to rationally implement § 2057c(b)(3)'s "reasonable" and "necessary" to prevent "harm" standard.

Although the Commission ignores the combined effect of its many layers of conservatism with its final stretch into unstable statistical returns, it does defend some individual components of the HI metric. But even at this granular level, the Commission's arguments cannot withstand scrutiny.

The Commission defends many points that Petitioners did not challenge, or at least challenged only in part. For example, Petitioners have never questioned the HI methodology generally, but rather have criticized the way in which the

[7] The Commission points out that spot samples might actually "underpredict[] the actual exposure" of the relevant longer-term period. CPSC Br. 42 (quoting Final Rule at 49,960). That is correct, but not in a way that helps the Commission. The snapshot spot samples capture transient extremes on both ends of the spectrum. The extreme upper percentiles reflect temporary spikes that will quickly fall as the phthalates are metabolized, and the extreme lower percentiles reflect temporary dips that will rise when the subject encounters phthalates again. The fact that the extreme lower percentiles underpredict longer-term exposure levels is irrelevant, however, because the Commission justified its Rule based upon the extreme higher percentiles—indeed the highest percentile. And those are the spot samples that systematically overpredict longer-term exposure levels.

Commission constructed and applied that methodology here. Nor was the Commission wrong to assess risk cumulatively, although it crossed the line into arbitrary action when it banned the five phthalates that posed no risk themselves and contributed only minimally to the cumulative risk that was driven by the "dominat[ing]" effects of DEHP, which § 2057c(a) had already permanently banned in children's products. Final Rule at 49,947, 49,963; Opening Br. 40-41.

The Commission fails to rebut Petitioners' arguments on the aspects of the Commission's HI analysis that Petitioners actually challenged. It claims that "[P]etitioners raise no specific objections to [Cases 1 and 2]," CPSC Br. 40, but Petitioners detailed the serious deficiencies in those cases in its opening brief (at 12-13). The Commission similarly claims that "Petitioners do not specify which scientific studies they are relying on" to criticize the Commission's unsupported assumption that humans are more sensitive to phthalates than the rodents in the studies that calibrated the HI metric. CPSC Br. 40. Yet Petitioners cited a comment surveying the "strong evidence that humans are much less sensitive than rats to the potential anti-androgenic effects of phthalates." Opening Br. 13 (quoting Comment of Feb. 22, 2017, Index No. 437, at 20-23).[8] Nor does the

[8] *Amici* blatantly misstate the science on this point by claiming that "humans experience negative effects from phthalate exposure at doses thousands of times *lower* than those administered to laboratory rats." *Amici* Br. 25-26 (emphasis added). They cite two scientific studies, one on rats and one on humans. *Amici* Br. 26 n.72. But the rat study did not find that rats only exhibit effects at much

Commission have any real answer as to why it calibrated its HI metric to fetuses, the most sensitive human population, when it is undisputed that neither fetuses nor their mothers mouth children's toys. Opening Br. 42-44. The consistent theme is that many of the Commission's individual layers of conservatism are questionable at best; combined, they go well beyond what is rational.

B. The Commission effectively interpreted the statutory standards to require an absolute certainty of no risk.

Backing up even further along the Commission's analytical path reveals that its analysis was doomed from the start. That is because the Commission started by improperly interpreting the "reasonable certainty of no harm" and "necessary to protect the health of children" standards as effectively requiring an absolute certainty of no risk. The Commission insists it did not, but offers sparse explanation.

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higher doses of phthalates than humans. Rather, it tested two relatively high doses of DBP, a phthalate § 2057c(a) permanently banned, and found that effects occurred at both doses. Norman Barlow et al., *Male Reproductive Tract Lesions at 6, 12, and 18 Months of Age Following in Utero Exposure to Di(n-butyl) Phthalate*, 32 Toxicologic Pathology 79 (2004). It did not attempt to find the lowest possible dose that would produce effects. A later and larger human study, *cited by amici earlier in their brief* (at 9), found no association between seven of eight phthalates and the effect at issue (including DINP, DIBP, and DBP), identifying an association only with the statutorily banned DEHP. Shanna Swan et al., *First Trimester Phthalate Exposure and Anogenital Distance in Newborns*, 30 Human Reproduction 963 (2015). *Amici*'s misleading summary on this point unfortunately exemplifies their selective and sensationalist review of the science—much of which is outside the administrative record.

Notably, the Commission does not dispute Petitioners' textual analysis of Congress's choice to tie regulation to "harm" rather than "risk." *See* Opening Br. 34-35. The Commission's approach of combining a hypersensitive HI metric with spot samples at the extreme ends of the statistical distribution does not reliably identify risk, much less harm. The Commission also deprives "reasonable" certainty of any meaning, arguing that it does not permit consideration of costs and does not constrain the Commission's use of unreliable data. CPSC Br. 26-27, 36-37. In other words, under the Commission's view of the statutory standards, preventing a risk of harm—which is all an HI greater than one represents—to even one person would justify *any* amount of costs. That is in no sense a "reasonable" certainty of no harm, especially given the unstable data used here. Thus, the Commission effectively interpreted and applied the statutory standards to require an absolute certainty of no risk.

IV. The Commission failed to give notice and an opportunity to comment on its last-minute decision to justify the rule based on "unstable" data beyond the 99th percentile.

After realizing that the Proposed Rule was no longer supported by the updated NHANES data at the scientifically standard 95th percentile, the Commission shifted the analytical goalposts to justify the ban in the Final Rule with data at the 99th percentile and beyond. The Commission thereby denied the public a meaningful opportunity to comment on its revised rationale for the Final

Rule. The Commission argues that "the final rule is materially identical to the proposed rule" and that Petitioners had adequate notice because they were able to anticipate the Commission's shifting rationale. These contentions are refuted by the facts and the law.

As previously explained, the Commission twice updated its calculations with new NHANES data after promulgating the Proposed Rule. Realizing that the 95th percentile threshold used in the Proposed Rule no longer justified the ban, Final Rule at 49,958, the Commission's Final Rule abandoned the 95th percentile and moved above the 99th percentile to an "actual women" standard, seemingly abandoning the percentile approach altogether. *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.").

The Commission first asserts that there was no need to provide additional opportunity for comment on the Commission's new rationale because the Final Rule was substantively identical to the Proposed Rule. CPSC Br. 47. But this Court's precedent makes clear that *the rationale* for the Rule—not only the substantive scope of the Rule—must be noticed and subjected to public comment. *See* Opening Br. 53 (discussing *Corrosion Proof Fittings*, 947 F.2d at 1201). 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." *Corrosion Proof Fittings*, 947 F.2d at 1212. That is precisely what the Commission did here by refusing to reveal its actual-women-at-any-percentile rationale until the Final Rule. In fact, the words "actual [WORA/women]" were not inserted until minutes before the Commission voted on the Final Rule. Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 3 (Oct. 18, 2017). It is revealing that neither the Commission nor Intervenors even acknowledge *Corrosion Proof Fittings.*

The Commission next argues that "[b]oth times that the Commission staff updated their analysis of NHANES data, the Commission provided public notice, a link to its analysis of the data, and an opportunity to comment." CPSC Br. 48. Those analyses updated the Commission's calculations to take account of more recent data, but they did not reveal the rationale that the Commission ultimately employed in the Final Rule. A single table in the 2015 document listed HIs at the 99th percentile—as well as at the median and 95th percentile—but it then disclaimed the 99th percentile values as "not . . . stable." Staff Report Regarding 2005-2012 NHANES Data Sets, Index No. 377, at 13 (June 2015) (Table 6). The 2017 document—which contained the most recent data—did not mention the 99th percentile at all, providing HIs only at the median and 95th percentile. Staff Report Regarding 2013/2014 NHANES Data Set, Index No. 431, at 4 (Table 5). It

also included a table listing the percentages of WORA in the sample with spot-sampled HIs of greater than one, but made clear that those values were "not considered stable." *Id.* at 4-5 (Table 6). In neither of the two documents was there any statement that the Commission intended to depart from the standard 95th percentile approach, much less adopt the "actual women" standard that the Final Rule reflects. Rather, the documents, like the Proposed Rule, gave the appearance that the 95th percentile was the metric. Commenters are not required to "divine [the Agency's] unspoken thoughts" from raw numbers presented by Commission staff. *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1260 (D.C. Cir. 2005).

Finally, the fact that one commenter, while broadly condemning the Commission's misleading scientific basis, pointed out that "[g]oing above the 95th percentile (for example, at the 99th percentile), the values are too unstable to provide a reliable basis for decision-making" does not excuse the Commission's failure to provide adequate notice. Comment of Mar. 24, 2017, Index No. 437, at 14. That comment does not address the Commission's ultimate abandonment of the percentile approach for the "actual women" standard.[9] And it would make no

[9] If the Commission had given adequate notice of its "actual women" rationale, Petitioners would have directly confronted that flawed approach and pointed out its many infirmities they have identified in this appeal. *Contra* CPSC Br. 50-51 (claiming that Petitioners suffered no prejudice by any lack of notice because they would not have offered different comments).

difference even if one commenter had happened to guess the Commission's unnoticed rationale. Indeed, "[e]ven if the [final rule] [was] widely anticipated, comments by members of the public would not in themselves constitute adequate notice." *Shell Oil Co. v. EPA*, 950 F.2d 741, 750-51 (D.C. Cir. 1991). That is because "[a]mbiguous comments and weak signals from the agency do not give interested parties an opportunity to anticipate and criticize the rules or to offer alternatives." *Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522, 536 (7th Cir. 1993) (alterations and quotation marks omitted); *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) ("The fact that some commenters actually submitted comments suggesting the creation of administrative exemptions is of little significance."). In other words, the Commission "may not 'bootstrap notice from a comment.'" *Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 443 n.14 (D.C. Cir. 2018) (quoting *Fertilizer Inst.*, 935 F.2d at 1312). The regulated community should not be forced to prophesy what rationale will ultimately grow out of reams of data or a vague proposed rule.

As Commissioner Mohorovic aptly summarized, the Final Rule "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." Minutes of Commission Meeting Re: Final Phthalates Rules, Index No. 462, at 22

(Oct. 18, 2017). By failing to give notice that the Commission was considering a new rationale to justify the Proposed Rule, the Commission deprived all participants—and the Commission itself—of the benefits of the full public-comment process the APA requires.

CONCLUSION

Petitioners request that the Phthalates Rule be held unlawful and set aside.

December 3, 2018

Respectfully submitted,

By: */s/ Aaron M. Streett*
BAKER BOTTS L.L.P.
Aaron M. Streett
J. Mark Little
Travis L. Gray
One Shell Plaza
910 Louisiana St.
Houston, Texas 77002
Tel: (713) 229-1234
Fax: (713) 229-1522

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

CERTIFICATE OF SERVICE

On this 3rd day of December, 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 6,490 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 A

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 CHRISTOPHER WALLACE
IN SUPPORT OF THE PETITIONERS' PETITION FOR REVIEW

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

1. I hold the position of Intermediates Sustainability and Regulatory Affairs Manager at ExxonMobil Chemical Company ("EMCC" or "the Company"). I submit this declaration in support of the Petitioners in the above-captioned petition

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

2. EMCC is an unincorporated division of Exxon Mobil Corporation. The Company is a major domestic producer of certain phthalates, such as diisononyl phthalate ("DINP") and diisodecyl phthalate ("DIDP"). EMCC is committed to product stewardship and ensuring the safety of its products. In that effort, EMCC has sponsored a multitude of toxicological studies on phthalates, including robust cancer bioassays, two-generation reproductive toxicity studies, and developmental studies. DINP and DIDP are used in many vinyl products because of their excellent functionality, low volatility, low toxicity, high durability, and value across a spectrum of end-uses.

3. EMCC was an active participant during the Phthalate Chronic Hazard Advisory Panel ("CHAP") process and the Commission's notice-and-comment period for the Phthalates Rule. EMCC submitted constructive comments designed to help the Commission identify errors in the CHAP report and develop the requisite scientific and legal confidence in its rulemaking. *See, e.g.*, Comment of Apr. 14, 2015, Index No. 361. It also met with the Commission multiple times and provided the Commission with relevant scientific studies, as well as analysis from world-class scientists affiliated with EMCC.

4. EMCC was producing, testing, and evaluating phthalates well before the Commission developed its initial regulatory interest in DINP in 1998. At that time, EMCC was able to sell its products widely into a broad variety of end uses in compliance with all existing regulations and safety assessments and without significant market concern.

5. Starting with the Commission's investigation into phthalate safety in 1998, however, EMCC has seen rising market concern surrounding the safety of phthalates. The initial Chronic Hazard Advisory Panel on DINP declared it to have extremely low to non-existent carcinogenic or reproductive and developmental toxicity risk. Nonetheless, some market hesitancy toward phthalates remained, due in large part to the specter of future regulatory attention, which occurred in 2008 when Congress enacted the permanent and interim bans. These bans focused on specific phthalates and specific children's products. The CHAP and Commission's subsequent evaluation and rulemaking, however, was not so narrow. The Commission studied many types of phthalates and considered the alleged harmful exposure from a broad spectrum of household products and other sources. In fact, the cumulative risk assessment that undergirds the Proposed and Final Rules' ban of five phthalates was based on biomonitoring that integrates exposure from all sources. And the Final Rule covers a different set of five phthalates than the initial Congressional interim ban. According to EMCC's employees and customers during

that time, the broad scope of the CHAP evaluation and Commission's rulemaking injected substantial uncertainty into the phthalate market. The Commission Final Rule undoubtedly imposed a substantial and detrimental influence on the public perception of phthalates and phthalate-containing personal-care items.

6. As a result, EMCC has seen a negative impact on the market demand for the phthalates it manufactures. Because EMCC sells to a variety of downstream customers, it has a unique perspective to observe the market-wide impact on phthalate demand. EMCC has experienced significant collateral damage to the marketability of its phthalates that stems from a market aversion caused in part by the current regulatory status.

7. One clear example of negative stigma impacting market conditions is in the flooring sector. Following pressure from interest groups that specifically cited the Commission's rulemaking process as evidence, major vinyl floor retailers like Home Depot and Lowe's announced that they would no longer carry flooring tile that contains phthalates. Given the size of these major retailers, their decision had a significant effect on the flooring market, from producers of raw materials like EMCC to downstream manufacturers of vinyl flooring and wholesalers. As a direct result of the market stigma against phthalates and the Commission's regulation, EMCC experienced significant losses in its once-profitable flooring market revenue stream.

8. Despite the Final Rule's significant contribution to the public stigma and consequent reduced market demand for phthalates, EMCC has continued to trust its scientific evidence showing that its phthalates are safe as used and has thus continued to sell those phthalates in sectors of the market that are not covered by the Final Rule. EMCC currently sells to a broad array of companies throughout the value chain, including distributors, resellers, formulators, and article manufacturers. Although EMCC does not catalogue all of its customers' many downstream uses, my understanding is that EMCC's phthalates are eventually incorporated into products that are—or could be—used in relation to childcare products such as car seats, clothing, and printable inks.

9. EMCC anticipates that the Final Rule will continue to cause economic injury unless the rule is vacated. EMCC anticipates that vacating the Final Rule—either by agency or judicial decision—would have a positive impact on EMCC's ability to market its phthalate products. To state the obvious, such a decision would alleviate the direct regulatory barrier on the market for certain phthalates in child care products—a market in which EMCC strongly believes its products could be safely and beneficially incorporated. Beyond the direct effect, it would also liberate other phthalates from the negative stigma that currently inhibits market demand. In fact, this benefit—along with its phthalate expertise and commitment to product safety—was one of the reasons EMCC chose to participate in the initial notice-and-

comment process for this rule. EMCC hoped that the process would produce an affirmative Commission finding that phthalates like DINP do not cause harmful reproductive effect—as shown by a number of authoritative body reviews as well as EMCC's internal studies. Armed with such an affirmative finding, EMCC's sales staff could reassure skeptical customers of its products' safety.

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

Executed on December 3, 2018.

Christopher Wallace