No. 24-60227

In the United States Court of Appeals for the Fifth Circuit

EAST FORK ENTERPRISES, INCORPORATED; EPIC PAINT COMPANY,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; MICHAEL S. REGAN, *Administrator, United States Environmental Protection Agency*,

Respondents.

Consolidated with No. 24-60256

EAST FORK ENTERPRISES, INCORPORATED; EPIC PAINT COMPANY; SIERRA CLUB; AMERICAN CHEMISTRY COUNCIL,

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Respondents.

On Petitions for Review of Final Agency Action of the United States Environmental Protection Agency
89 Fed. Reg. 39,254 (May 8, 2024)

MOTION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE NATIONAL FEDERATION OF INDEPENDENT BUSINESS SMALL BUSINESS LEGAL CENTER, INC. FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF INDUSTRY PETITIONERS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Nos. 24-60227, 24-60256,

EAST FORK ENTERPRISES, INCORPORATED, ET AL.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Respondents.

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that—in addition to the persons and entities listed in the Certificate of Interested Persons filed with the Joint Brief of Industry Petitioners—the following persons and entities have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate potential disqualification or recusal.

1. PARTIES

   (a) Petitioners

      (i) East Fork Enterprises, Incorporated

      (ii) Epic Paint Company

      (iii) Sierra Club

      (iv) American Chemistry Council

   (b) Respondents

      (i) United States Environmental Protection Agency

(ii) Michael S. Regan, Administrator, United States Environmental Protection Agency

(c) *Amici*

(i) The Chamber of Commerce of the United States of America

(ii) The National Federation of Independent Business Small Business Legal Center, Inc.

2. ATTORNEYS

(i) Squire Patton Boggs (US) LLP

(ii) Earthjustice

(iii) Crowell & Moring, L.L.P.

(iv) United States Department of Justice

(v) United States Environmental Protection Agency, Office of General Counsel

(vi) Gibson, Dunn & Crutcher LLP

The undersigned further certifies that the Chamber of Commerce of the United States of America ("Chamber") is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

The undersigned further certifies that the National Federation of Independent Business Small Business Legal Center, Inc. ("NFIB Legal Center") is a 501(c)(3) public interest law firm and is affiliated with the

National Federation of Independent Business, a 501(c)(6) business association. The NFIB Legal Center is incorporated in the State of Tennessee, has no parent corporation, and no publicly held company has 10% or greater ownership in the NFIB Legal Center.

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MOTION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF

Pursuant to Federal Rule of Appellate Procedure 29(a)(3) and Fifth Circuit Rule 29, the Chamber of Commerce of the United States of America ("Chamber") and the National Federation of Independent Business Small Business Legal Center, Inc. ("NFIB Legal Center") move this Court for leave to file the accompanying proposed brief as *amici curiae* in support of Petitioners East Fork Enterprises, Inc., Epic Paint Co., and American Chemistry Council ("Industry Petitioners") and vacatur of the final rule issued by Respondents United States Environmental Protection Agency and Michael Regan ("EPA") pursuant to the Toxic Substances Control Act ("TSCA") on May 8, 2024 ("Rule").[1]

Industry Petitioners and Petitioner Sierra Club have consented to the filing of the accompanying brief. Counsel for EPA took no position on the filing. In further support of this Motion, *Amici* state as follows:

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[1] No counsel for any party authored this brief in whole or in part. No entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

1. The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

2. The National Federation of Independent Business Small Business Legal Center, Inc. is a nonprofit, public-interest law firm established to provide legal resources and advocate for small businesses in the nation's courts through representation on issues of public interest affecting small businesses. It is an affiliate of the National Federation of Independent Business, Inc. ("NFIB"), which is the nation's leading small business association. NFIB's mission is to promote and protect the rights of its members to own, operate, and grow their businesses. NFIB represents the interests of its members in Washington, D.C., and all 50 state capitals, including by filing *amicus curiae* briefs.

3. TSCA encompasses the manufacture, processing, distribution, or use of regulated substances—and, in recent years, has been extended to regulation of substances in some finished articles. The Chamber and NFIB Legal Center have an interest in this challenge to EPA's risk evaluation and risk-management rule for methylene chloride because many of their members are directly or indirectly subject to regulation under TSCA. Indeed, *Amici*'s members include companies across all industrial sectors that are affected (directly or indirectly) by TSCA, ranging from chemicals, coatings, petroleum, and petrochemicals to forestry, wood products, batteries, electronics, energy, and electricity—among others. Many substances regulated under TSCA are integral to the domestic economy and supply chain, contributing to the health and well-being of the American people by providing solutions to problems in health, materials, transportation, agriculture, and energy usage.

This action is important not only in its own right, with implications for Chamber and NFIB members in a range of industries, but also because it will set precedent on key statutory-interpretation issues affecting EPA's administration of TSCA. As *Amici* explained during the rulemaking process, EPA's approach to evaluating and regulating risk was

inconsistent with TSCA and would likely create unnecessary economic and practical burdens if extended to other chemicals going forward. *See* Chamber Rule Comments, EPA-HQ-OPPT-2020-0465-0279; NFIB Rule Comments, EPA-HQ-OPPT-2020-0465-0186; Chamber Evaluation Comments, EPA-HQ-OPPT-2016-0742-0137. Because of *Amici*'s wide-ranging perspectives on how EPA's approach may affect the U.S. business community, the arguments presented in the proposed brief would be useful to the Court's disposition of the case.

4. Under the Federal Rules of Civil Procedure and Fifth Circuit Rule 29.2, this Court may grant leave to file an *amicus curiae* brief when the movant has a sufficient "interest" in the case, Fed. R. App. P. 29(a)(3)(A), the proposed brief is "desirable" and "the matters asserted are relevant to the disposition of the case," Fed. R. App. P. 29(a)(3)(B), and the proposed brief "avoid[s] the repetition of facts or legal arguments contained in the principal brief" and "focus[es] on points either not made or not adequately discussed in those briefs," Fifth Cir. R. 29.2; *see Lefebure v. D'Aquilla*, 15 F.4th 670, 674 (5th Cir. 2021) (per curiam). Consistent with *Amici*'s unique perspectives on issues of interest to the business community, this Court and others regularly grant them leave to

file briefs as *amici curiae*. *E.g.*, Order, *Tex. Chemistry Council v. EPA*, No. 24-60193 (5th Cir. Oct. 15, 2024) (granting Chamber and NFIB Legal Center leave to file in separate TSCA rulemaking challenge); Order, *Harris v. FedEx Corporate Servs., Inc.*, No. 23-20035 (5th Cir. July 7, 2023) (granting Chamber leave to file); *Smyth v. Conservation Comm'n of Falmouth*, 140 S. Ct. 667 (2019) (same for NFIB Legal Center).

5. This Motion and proposed *amicus curiae* brief are timely filed pursuant to this Court's Order of September 24, 2024 (Dkt. 86) granting the parties' joint motion to establish a briefing schedule that included an October 30, 2024 deadline for "Motions to Submit Amicus Briefs in Support of Petitioners" (Dkt. 80 at 3).

Amici respectfully submit that the attached proposed brief satisfies this Court's rules for participation as *amicus curiae*. Given *Amici*'s wide-ranging perspective on how EPA's action here may affect the national business community (including indirectly affected as well as directly regulated parties), *Amici* believe that the perspectives presented in this brief will be useful to the Court's understanding of the broader practical and legal significance of the issues briefed by the parties, and ultimately helpful to this Court's disposition of this case. *See* Fed. R. App. P. 29(a)(3).

Further, *Amici* have endeavored to avoid duplication between their proposed brief and the brief of Industry Petitioners. *See* Fifth Cir. R. 29.2.

CONCLUSION

The Chamber and NFIB Legal Center respectfully request that this Court grant them leave to file the accompanying *amici curiae* brief.

Dated: October 30, 2024

Respectfully submitted,

/s/ David Fotouhi

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CERTIFICATE OF SERVICE

I hereby certify that, on October 30, 2024, I filed the foregoing Motion using the Court's ECF system. Service on all counsel of record for all parties was accomplished electronically using the Court's CM/ECF system.

Dated: October 30, 2024

Respectfully submitted,

/s/ David Fotouhi

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CERTIFICATE OF COMPLIANCE

1. This Motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2) because it contains 1,018 words, excluding the parts exempted by Fed. R. App. P. 32(f) and Fifth Cir. R. 32.2, as counted by the automated function of Microsoft Word Professional Plus 2019.

2. This Motion 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) and Fifth Cir. R. 32.1 because it has been prepared in a proportionally spaced typeface using Microsoft Word Professional Plus 2019 in New Century Schoolbook 14-point font.

Dated: October 30, 2024

Respectfully submitted,

/s/ David Fotouhi

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INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

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[1] No counsel for any party authored this brief in whole or in part. No entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

leading small business association. NFIB's mission is to promote and protect the rights of its members to own, operate, and grow their businesses. NFIB represents the interests of its members in Washington, D.C., and all 50 state capitals, including by filing *amicus curiae* briefs.

The interest of *Amici* and their members in this case—and in the Environmental Protection Agency's ("EPA's") administration of the Toxic Substances Control Act ("TSCA") more broadly—is described in the accompanying motion for leave to file this *amici curiae* brief.

INTRODUCTION

In the 2016 TSCA amendments, Congress instructed EPA to "conduct risk evaluations" to determine "whether a chemical substance presents an unreasonable risk of injury … under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). If it does, EPA must consider whether other authorities could address the unreasonable risk or risks, analyze at least one regulatory alternative, and evaluate costs and benefits before applying TSCA regulations "to the extent necessary so that the chemical substance or mixture no longer presents such risk." *Id.* § 2605(a).

EPA initially interpreted this statutory language to mean what it says, promulgating a 2017 framework rule that required EPA to

determine risk "under each condition of uses within the scope of the risk evaluation." *Procedures for Chemical Risk Evaluation Under the Amended TSCA*, 82 Fed. Reg. 33,726, 33,752 (July 20, 2017). Accordingly, in the risk evaluation for methylene chloride, EPA analyzed 53 conditions of use and found no unreasonable risk for 6 of these conditions, because mandatory personal protective equipment ("PPE") sufficiently reduced the risk. *Risk Evaluation for Methylene Chloride* ("OE") 38–42, 517–20, EPA-HQ-OPPT-2019-0437-0107 (June 2020).

Yet EPA later reversed course, asserting that TSCA was ambiguous and contorting the 2017 rule to confer on EPA the discretion to determine risk for a "whole chemical," rather than for each condition of use. In 2022, EPA issued a revised methylene-chloride risk evaluation that superseded its prior use-by-use determinations, excluded any consideration of PPE use, and found unreasonable risk for methylene chloride as a "whole chemical." *Methylene Chloride; Revisions to TSCA Risk Determination* ("RE") 3–4, EPA-HQ-OPPT-2016-0742-0147 (Oct. 2022). In 2024, EPA doubled down on this approach by banning methylene chloride in most settings and imposing onerous restrictions on the rest, including on the conditions of use that EPA had previously found presented no

unreasonable risk. *Methylene Chloride; Regulation Under TSCA*, 89 Fed. Reg. 39,254, 39,255 (May 8, 2024) ("Rule").

None of this was consistent with TSCA's "unreasonable risk" standard, and none of it accounted for Congress's decision to add "conditions of use" to the statute no fewer than thirty times in the 2016 amendments. Virtually any chemical presents at least some risk, and employers and regulators require safety practices that mitigate risk in particular settings. By overlooking this crucial context, EPA imposed TSCA regulations that are unnecessary to address unreasonable risks. The Rule thus exceeds EPA's authority under TSCA.

Amici respectfully submit that this Court should vacate the Rule, and focus on two principal arguments in this brief:[2]

First, EPA's "whole chemical" approach to the revised evaluation that undergirds the Rule contradicts "the best reading of the statute[.]" *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024). Severing the risks of methylene chloride from the contexts in which it is used and refusing to consider risk-reducing practices violated TSCA's commands

[2] *Amici* agree with Industry Petitioners that the Rule is invalid for other reasons, but do not focus on those other issues in this brief.

to "conduct risk evaluations … under the conditions of use," 15 U.S.C. § 2605(b)(4)(A), and to "integrate and assess available information" about "the likely duration, intensity, frequency, and number of exposures under the conditions of use," *id.* § 2605(b)(4)(F)(i), (iv). EPA was right the first time, and its failure to follow the 2017 regulation compounds the error.

Second, the Rule also violated TSCA by effectively mandating the elimination of *all* risk rather than only *unreasonable* risk—including for conditions of use that EPA previously found did not present *any* "unreasonable risk." 15 U.S.C. § 2605(a). EPA also skipped over TSCA's rulemaking requirements by considering an inadequate alternative, *id.* § 2605(c)(2)(A)(iv)(II)–(III), adopting unreasonable rationales for refusing to refer regulation to the Occupational Safety and Health Administration ("OSHA"), *id.* § 2608(a), and excluding the Rule's substantial costs from its economic analysis, *id.* § 2605(c)(2)(A)–(B).

BACKGROUND

I. Congress enacted TSCA in 1976 to protect against chemical uses that "may present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601(a)(2). From the start, TSCA committed EPA to address risk "in such a manner as not to impede unduly or create

unnecessary economic barriers to technological innovation[.]" *Id.* § 2601(b)(3). To those ends, Congress provided that EPA may address only "unreasonable" risk, "shall consider the environmental, economic, and social impact of any action," and "shall carry out this chapter in a reasonable and prudent manner." *Id.* § 2601(c). This language was essential in responding to legislators' concerns that TSCA "contain[ed] excessive authority for EPA." S. Rep. No. 94-698, at 10 (1976).

Recognizing that TSCA overlapped with existing authorities, Congress required EPA to "consult and coordinate with" other federal agencies for the purpose of "imposing the least burdens of duplicative requirements" on regulated parties. 15 U.S.C. § 2608(d); *see also* S. Rep. No. 94-698, at 11; H.R. Rep. No. 94-1679, at 84 (1976) (Conf. Rep.). If EPA identifies risk that "may be prevented or reduced to a sufficient extent" under another agency's regulatory authority, EPA must refer the matter and "may not take any action" until that agency acts or declines to act. 15 U.S.C. § 2608(a)(1)–(4). And if EPA can address the risk under another of its statutory authorities, it generally must use that authority unless the public interest requires otherwise. *Id.* § 2608(b)(1)–(2).

As originally enacted, TSCA instructed EPA to determine whether "there is a reasonable basis to conclude" that a chemical use presents "an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a) (1976). If EPA made such a determination, and assuming no other authority could address the risk, TSCA instructed the agency to regulate "to the extent necessary to protect adequately against such risk using the least burdensome requirements" set out in the statute. *Id.*

II. Congress amended TSCA in 2016, in part to address concerns with EPA's pace of implementation. *See* Pub. L. No. 114-182, 130 Stat. 448; *Vinyl Inst., Inc. v. EPA*, 106 F.4th 1118, 1122 (D.C. Cir. 2024). While retaining TSCA's "unreasonable risk of injury" framework, coordination requirements, and associated policies, the amendments created a new process for evaluating risk "under the conditions of use" and altered the requirements for risk-management rules.

In the 2016 amendments, Congress added in no fewer than thirty separate instances the phrase "conditions of use"—a defined term meaning "the circumstances … under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). That

was a sensible decision—"a chemical substance's intended conditions of use are important in defining the risk it presents." H.R. Rep. No. 114-176, at 23 (2015); *see also* S. Rep. No. 114-67, at 7 (2015).[3]

As amended, TSCA Section 6(b) authorizes EPA to "conduct risk *evaluations* pursuant to this paragraph to determine whether *a* chemical substance presents *an* unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, … *under the conditions of use*." 15 U.S.C. § 2605(b)(4)(A) (emphases added). In doing so, EPA "shall … integrate and assess *available information* on hazards and exposures *for the conditions of use*" and "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures *under the conditions of use*[.]" *Id.* § 2605(b)(4)(F)(i), (iv) (emphases added).[4]

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[3] As Senator Jim Inhofe, one of the bill's principal sponsors, explained: "EPA will make decisions based on conditions of use, and must consider various conditions of use, so there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others." 162 Cong. Rec. 7,989 (2016).

[4] Senator David Vitter, another principal sponsor, explained that "the safety standard to be applied by EPA" was intended to capture context that reduces risk: "'Unreasonable risk' does not mean no risk; it means

The revised TSCA Section 6(a) no longer uses the phrase "least burdensome" in setting out EPA's risk-management authority. Instead, EPA must regulate "*to the extent necessary* so that the chemical … no longer presents *such risk*." 15 U.S.C. § 2605(a) (emphases added). EPA "shall factor in" cost-benefit considerations, *id.* § 2605(c)(2)(B), including the "effects" and "magnitude of the exposure," the "benefits" of the use, "reasonably ascertainable economic consequences of the rule," *id.* § 2605(c)(2)(A)(i)–(iv), and "potential effects on employment," *id.* § 2623(a). Thus, Congress replaced "least burdensome" with specific—and mandatory—cost factors that inform the ultimate "unreasonable risk" standard.

III. Methylene chloride is a chemical used as a cleaning solvent, adhesive, sealant, and coating material in a broad variety of industrial, commercial, and consumer settings. *Scope of the Risk Evaluation for Methylene Chloride* 9, 22–29, 66, EPA-HQ-OPPT-2016-0742-0061 (June 2017). Furniture refinishers, for example, use it as a solvent to remove

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that EPA must determine, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use." 162 Cong. Rec. 7,990 (2016).

paint without damaging the underlying wood, and certain manufacturers produce the chemical in the United States. *Id.* at 26, 66. EPA already regulates methylene chloride under the Clean Air Act, Comprehensive Environmental Response, Compensation, and Liability Act, and Safe Drinking Water Act, among other authorities. *Id.* at 10, 54–61.

OSHA has regulated methylene-chloride use for decades, and last updated its occupational rules for the chemical in 2019. *Standards Improvement Project—Phase IV*, 84 Fed. Reg. 21,416, 21,544–55 (May 14, 2019). Among other obligations, employers must require workers using methylene chloride to wear respirators and other personal protective equipment, 29 C.F.R. § 1910.1052(g)–(h), and must keep airborne exposures below 25 parts per million ("ppm") in any eight-hour period and 125 ppm in any fifteen-minute period, *id.* § 1910.1052(c). In addition, the Consumer Product Safety Commission ("CPSC") has required labeling for methylene-chloride products since 1987 and recently expanded its label-content requirements. *Labeling of Certain Household Products Containing Methylene Chloride; Supplemental Guidance*, 83 Fed. Reg. 12,254 (Mar. 21, 2018).

ARGUMENT

This Court reviews the challenged Rule and underlying risk evaluation "in accordance with" the Administrative Procedure Act ("APA"), 15 U.S.C. § 2618(c)(1)(A), and must vacate agency actions "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2), (2)(C). Under TSCA's judicial-review provisions, the risk evaluation is subject to challenge after EPA promulgates a corresponding risk-management rule, 15 U.S.C. § 2605(i)(2), and both actions must be vacated if "not supported by substantial evidence in the rulemaking record taken as a whole," *id.* § 2618(c)(1)(B)(i). Review of the challenged actions is thus particularly searching because TSCA's standard of review is "more rigorous than the arbitrary and capricious standard normally applied to informal rulemaking." *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215 (5th Cir. 1991) (quotation omitted).

I. In Revising Its Risk Evaluation, EPA Violated TSCA By Using A "Whole Chemical" Approach That Overstated Risk.

EPA initially evaluated methylene chloride by making individual determinations for each condition of use, finding no unreasonable risk for 6 of 53 conditions evaluated. EPA made these findings largely because OSHA-mandated personal protective equipment mitigated risk

markedly, even under high-end, worst-case exposure scenarios. OE.517–18.[5] That approach was consistent with the 2017 rule, 82 Fed. Reg. at 33,752, and mirrored the way EPA had conducted each of the nine other risk evaluations performed after the 2016 statutory amendments.

Nevertheless, EPA reversed itself to adopt a "whole chemical" approach. "[N]otwithstanding [its] choice to issue condition-of-use-specific risk determinations to date," EPA reinterpreted the 2017 rule to "allow the [a]gency to issue whole-chemical risk determinations." *Methylene Chloride; Draft Revision to TSCA Risk Determination; Notice of Availability and Request for Comment*, 87 Fed. Reg. 39,824, 39,827 (July 5, 2022). EPA asserted that "occupational use of PPE" would be considered only "during the risk management phase as appropriate," *id.* at 39,828, and that this "new policy direction" would be "incorporat[ed]" into the methylene-chloride evaluation "in a surgical manner," *id.* at 39,826. Accordingly, EPA concluded in the revised evaluation that

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[5] Specifically, domestic manufacture; processing use as a reactant; processing use in recycling; distribution in commerce; industrial and commercial use as a laboratory chemical; and disposal. *See* OE.39.

methylene chloride presented unreasonable risk as a "whole chemical," RE.3, excluded personal protective equipment from the analysis, RE.4, and abandoned its earlier no-unreasonable-risk findings, RE.24.[6]

EPA's abrupt policy change was unlawful in its own right, and the "whole chemical" approach it injected into the risk evaluation exceeds the agency's authority (and, separately, flunks TSCA's substantial-evidence standard) for at least two reasons: (A) TSCA requires EPA to determine unreasonable risk for conditions of use, not for the chemical in isolation; and (B) occupational protections like PPE are "available information" that EPA must "integrate and assess" to determine unreasonable risk.

A. EPA's "Whole Chemical" Approach Is Inconsistent With TSCA Requirements For Evaluating Unreasonable Risk.

Congress expressly provided that risk evaluations turn on a chemical's "conditions of use," not merely the inherent qualities of the chemical itself. 15 U.S.C. § 2605(b)(4)(A). Here, all the "traditional tools of statutory construction" point in the same direction—"the best reading

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[6] EPA later finalized an amended framework rule reflecting its flawed "whole chemical" approach, which went into effect after completion of the revised methylene-chloride evaluation. *See Procedures for Chemical Risk Evaluation Under TSCA*, 89 Fed. Reg. 37,028 (May 3, 2024). That rule is being challenged in D.C. Cir. No. 24-1151 *et al.*

of the statute" requires EPA to evaluate risk for conditions of use, not the "whole chemical." *Loper Bright*, 144 S. Ct. at 2266.

I. Under Section 6(b), EPA "shall conduct risk evaluation*s* pursuant to this paragraph to determine whether *a* chemical substance presents *an* unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including *an* unreasonable risk to *a* potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, *under the conditions of use*." 15 U.S.C. § 2605(b)(4)(A) (emphases added). As both text and context make clear, this provision does not allow EPA to conduct a single risk evaluation that determines the presence or absence of unreasonable risk for the "whole chemical."

Congress specified risk "evaluations," plural, and "a chemical substance," singular, meaning that TSCA contemplates more than one risk evaluation for the same chemical. By using the indefinite "an" before "unreasonable risk," and by referencing an unreasonable risk to "a" potentially exposed or susceptible subpopulation, Congress also recognized that "a chemical substance" may present more than one unreasonable risk. And it concluded the provision with "under the

conditions of use," a phrase specifying what the evaluation will determine—whether one or more circumstances in which a chemical is used presents unreasonable risk.

TSCA's definition of "conditions of use"—"the circumstances, *as determined by the Administrator*, under which a chemical substance is … manufactured, processed, distributed in commerce, used, *or* disposed of," 15 U.S.C. § 2602(4) (emphases added)—also envisions that chemicals have multiple, context-specific uses, and that EPA must reach context-specific findings for each. EPA must "determin[e]" the "circumstances" of use, and the disjunctive "or" means that not every chemical will implicate each activity. The inclusion of "disposed of" confirms this reading, as no chemical's *only* use is to be disposed. Congress understood that disposal may carry a different level of risk than the various other uses of a chemical and directed EPA to consider the context of each such circumstance, *including* disposal, to determine whether each condition of use poses unreasonable risk. "Conditions of use" thus may be different for each chemical and involve different contexts for the same chemical.

Each of these drafting choices would be superfluous if TSCA authorized EPA to determine risk for the "whole chemical"—Congress

could have left out "under the conditions of use" from Section 6(b) and the 2016 amendments entirely and simply provided that "EPA shall conduct a risk evaluation to determine whether the chemical under consideration presents unreasonable risk." But Congress made different choices, and "every word" of the statute as written must be "give[n] effect[.]" *ADT, L.L.C. v. Richmond*, 18 F.4th 149, 156 (5th Cir. 2021).

Indeed, Congress used virtually the same language in earlier health-and-safety statutes to the same effect. EPA's authority under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), for example, includes requiring labels that display information "as to render it likely to be read and understood by the ordinary individual *under customary conditions of purchase and use*." 7 U.S.C. § 136(q)(1) (emphasis added). And the Federal Food, Drug, and Cosmetic Act similarly authorizes the Federal Drug Administration to regulate drugs and supplements that "presen[t] a significant or unreasonable risk of illness or injury *under … conditions of use* recommended or suggested in labeling, or … *under ordinary conditions of use*." 21 U.S.C. § 342(f)(1)(A) (emphases added); *see also id.* §§ 348 (food additives), 355 (new drugs), 361 (cosmetics).

II. TSCA's structure reinforces the conclusion that EPA must make risk determinations for conditions of use, not the "whole chemical"—any possible ambiguity is "clarified by the remainder of the statutory scheme—because the same terminology is used elsewhere in a context that makes its meaning clear." *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988); *see, e.g.*, *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 993 (D.C. Cir. 2024) (rejecting EPA interpretation of "new source" that prevented the Clean Air Act from working as a "harmonious whole").

Congress inserted "conditions of use" language into each step of the risk-evaluation process. EPA must prioritize risk evaluations by taking into account "the conditions of use or significant changes in the conditions of use of the chemical substance," 15 U.S.C. § 2605(b)(1)(A), and then must determine the scope of each risk evaluation by identifying the "conditions of use" to be considered, *id.* § 2605(b)(4)(D). In conducting the risk evaluation, EPA must "integrate and assess available information on hazards and exposures for the conditions of use," *id.* § 2605(b)(4)(F)(i), must note whether "aggregate or sentinel exposures to a chemical substance under the conditions of use were considered," *id.*

§ 2605(b)(4)(F)(ii), and must "take into account" the "likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance," *id.* § 2605(b)(4)(F)(iv). None of those additions would have been necessary if EPA were authorized to evaluate risk for the "whole chemical."

Additional provisions assume condition-of-use-specific findings and would be rendered inoperable by the "whole chemical" approach. Under Section 9, EPA must "consult and coordinate" with "the heads of any other appropriate" federal agency to achieve "the least burdens of duplicative requirements on those subject to [TSCA] and for other purposes." 15 U.S.C. § 2608(d). That requirement makes sense if risk is evaluated for individual conditions of use—processing in workplaces regulated by OSHA, for example, or inclusion in consumer products already on CPSC's radar—but falls apart if risk is determined for the "whole chemical," because there is no "appropriate" federal agency for EPA to consult, absent findings in a particular context.

TSCA's preemption provision similarly assumes condition-of-use-specific findings and becomes unworkable under EPA's "whole chemical" approach. Section 18 preempts state regulation when EPA finalizes a no-

unreasonable-risk determination, 15 U.S.C. § 2617(a)(1)(B)(i), or makes an unreasonable-risk determination and finalizes a corresponding risk-management rule, *id.* § 2617(a)(1)(B)(ii). But Congress limited such preemption to "the hazards, exposures, risks and uses *or conditions of use* of such chemical substances" covered by the risk finding or rule. *Id.* § 2617(c)(3). Without specific findings on particular conditions of use, TSCA's preemption provision no longer functions.

III. EPA barely addressed TSCA in reversing its position to adopt the "whole chemical" approach, instead announcing an interpretation of the 2017 framework rule that conferred discretion to use either the "whole chemical" approach or the conditions-of-use approach. 87 Fed. Reg. at 39,827–28. The best EPA had to offer was that the *proposed* 2017 rule had "acknowledged a lack of specificity in statutory text"; EPA had argued that "the word 'the'" in Section 6(b)(4)(A) "call[s] for evaluation that considers all conditions of use." *Id.* at 39,826 (quoting *Proposed Rule: Procedures for Chemical Risk Evaluation Under the Amended TSCA*, 82 Fed. Reg. 7,562, 7,565 (Jan. 19, 2017)).

As Industry Petitioners persuasively explain, EPA's about-face contradicted the 2017 rule's plain meaning and therefore violated the

agency's own regulations. Industry Br. 26–27. EPA's policy reversal also violated TSCA. Under *Loper Bright*, a claim of semantic ambiguity is not sufficient to uphold an agency's interpretation of a statute—particularly one based on so thin a reed. *See U.S. Sugar Corp.*, 113 F.4th at 993. Section 6(b)(4)(A) is not ambiguous: EPA must determine whether a chemical presents an unreasonable risk "under the conditions of use," 15 U.S.C. § 2605(b)(4)(A), and "conditions of use" means, effectively, "circumstances," *id.* § 2602(4). Any apparent ambiguities are resolved definitively in the other direction by context and statutory structure. And "[t]he very point of the traditional tools of statutory construction—the tools courts use every day—is to resolve statutory ambiguities." *Loper Bright*, 144 S. Ct. at 2266.

B. EPA's "Whole Chemical" Approach Unlawfully Excludes Consideration Of Practices That Reduce Risk.

"Congress did not enact TSCA as a zero-risk statute," *Corrosion Proof Fittings*, 947 F.2d at 1215, and the 2016 amendments to TSCA further emphasized that context is critical to evaluating risk by explicitly embedding "conditions of use" into the Section 6(b) risk-evaluation process. Nevertheless, EPA declared in the revised evaluation for methylene chloride that EPA will "not rely on assumptions regarding the

use of [PPE] in making unreasonable risk determinations under TSCA Section 6." RE.4. Instead, "the use of PPE will be considered during risk management." *Id.* That interpretation of TSCA's requirements is flatly inconsistent with the statute.

I. TSCA is unusually specific in setting out the requirements for Section 6 risk evaluations. EPA must "integrate and assess available information on hazards and exposures," 15 U.S.C. § 2605(b)(4)(F)(i), and must "take into account" the "likely duration, intensity, frequency, and number of exposures," *id.* § 2605(b)(4)(F)(iv). Risk determinations must also be based on "the best available science" and consider all "reasonably available information." *Id.* § 2625(h), (k). As a well-documented safety practice required by OSHA regulation and other federal and state laws, PPE is undoubtedly "available information" about hazards and exposure, including the "duration, intensity, frequency, and number of exposures."

Purporting to evaluate risk without considering a principal factor reducing risk cuts out half of the risk-evaluation equation. Water (H_2O), for example, is responsible for thousands of deaths and injuries every year—the risks of using it cannot be understood without accounting for existing protections against such harms.

Congress recognized as much in enacting and amending TSCA, requiring EPA to evaluate and regulate only "*unreasonable* risk of injury … under the conditions of use," 15 U.S.C. § 2605(b)(4)(A) (emphasis added)—analyses that are not possible without accounting for both risk-creating and risk-reducing information, as TSCA requires. EPA cannot "leapfrog" over requirements "fully determined by the text" of the statute. *Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 775 (5th Cir. 2024).

II. EPA initially considered personal protective equipment in each of its first ten risk evaluations after the 2016 statutory amendments—including the challenged evaluation for methylene chloride, in which the agency found no unreasonable risk for 6 of 53 conditions of use largely because OSHA-mandated PPE use mitigated risk. OE.38–41, 517–18. In the revised evaluation, EPA provided no new evidence; acknowledged occupational-safety rules; and did not question the accuracy of employer-provided data, including data submitted to comply with OSHA's methylene-chloride standard, R.4; *see also* 87 Fed. Reg. at 39,828.

Nevertheless, EPA excluded PPE use from its analysis. EPA asserted that this change in course was warranted because certain subpopulations of workers (1) may not be covered by OSHA standards;

(2) may work for employers who are out of compliance with OSHA standards, or (3) may not be adequately protected by "outdated and inadequate" OSHA standards. RE.4. None of the agency's stated rationales stands up to scrutiny, and none justifies EPA's failure to comply with TSCA.

First, although TSCA authorizes EPA to consider subpopulations, the risks to such groups are analyzed in the same way as risks to any other cohort—EPA must "determine whether a chemical substance presents an unreasonable risk of injury … including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). EPA cannot invoke subpopulations as a way around requirements that apply to the risk evaluation as a whole.

Second, EPA provided no evidence to back up its supposition in the revised evaluation that OSHA's methylene-chloride regulations do not apply, or that employers do not comply with them, for any material percentage of potential exposures. Indeed, EPA made no representations at all about the scope of regulatory coverage or noncompliance—it simply

assumed facts not in the record and took the position that, as a matter of law, PPE use need not be considered in the TSCA risk-evaluation process. As explained above, that position is untenable, because EPA lacks discretion to adopt a rule that effectively blinds the agency to this highly relevant information.

Third, EPA's assertion that OSHA regulations are "outdated and inadequate" is based on a single statement on OSHA's website that has nothing to do with PPE or methylene chloride. The web page from which EPA quotes addresses OSHA's *permissible exposure limits*, not PPE.[7] Even if it were true that OSHA's *PPE* mandates are inadequate—a conclusion not supported by substantial evidence—EPA provided no rationale for disregarding them *entirely*. Even imperfect protections are relevant to evaluating whether the residual risk, after considering such PPE use, was unreasonable. All of this helps show why consulting with OSHA was an important step that EPA should have undertaken (and was required to undertake) before issuing the Rule.

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[7] OSHA, Permissible Exposure Limits–Annotated Tables (accessed Oct. 30, 2024), https://www.osha.gov/annotated-pels (stating that "many," but not all, of OSHA's exposure limits were issued "shortly after adoption of the" OSH Act).

II. In Banning Methylene Chloride In Most Settings And Imposing Onerous Restrictions Elsewhere, EPA Violated TSCA's Constraints On EPA's Risk-Management Authority.

EPA compounded its error in the final Rule, which banned methylene chloride in most settings and imposed onerous restrictions on the rest. For workplace settings where EPA allowed continuing use—including the conditions of use the agency previously found presented no unreasonable risk—employers must adopt a workplace chemical protection program that includes existing chemical exposure limits ("ECELs") that are substantially lower than OSHA's permissible exposure limits. 89 Fed. Reg. at 39,255, 39,273–75.

In taking this action, EPA violated TSCA's substantive standard and rulemaking requirements in several ways. EPA (A) exceeded its authority by regulating all risk, not just "unreasonable risk," as evidenced by restrictions for workplaces that the agency found *do not* present unreasonable risk; (B) failed to consider meaningful alternatives other than its preferred ban-and-regulate approach; (C) unreasonably refused to refer the matter to OSHA; and (D) ignored substantial costs that far outweigh the benefits of the Rule.

A. EPA Exceeded Its Statutory Authority By Going Beyond Restrictions Necessary To Address Unreasonable Risk.

EPA made no secret of the fact that the risk-management Rule is based on the agency's assertion of unprecedented authority. According to EPA, the "2016 amendments to TSCA altered both the manner of identifying unreasonable risk and EPA's authority to address unreasonable risk." 89 Fed. Reg. at 39,287. In an apparent reference to this Court's decision in *Corrosion Proof Fittings*—which vacated EPA's 1989 asbestos rule under TSCA—EPA asserted that TSCA "is increasingly distinct from" federal statutes like the "OSH Act" that require balancing the costs and benefits of regulation. *Id.*

But the 2016 amendments *did not* alter TSCA's fundamental reasonableness standard. Both as originally enacted and as amended, TSCA grants EPA authority to address risk *only* until it is no longer "unreasonable." Section 2605(a) provides that upon finding that a chemical "presents an *unreasonable risk* of injury," EPA must select a remedial option that ensures that the chemical "no longer presents *such risk*" in the specified conditions of use. 15 U.S.C. § 2605(a) (emphases added). By imposing measures that effectively remove *all risk* rather

than unreasonable risk, EPA read the critical term "unreasonable" out of the statute.

In the 2016 amendments, Congress removed cost from the risk-evaluation process while retaining and expanding the role of cost in promulgating risk-management rules. TSCA continues to provide that EPA "shall carry out this chapter in a reasonable and prudent manner" and "shall consider the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c). And as amended, EPA "shall factor in," not just consider, costs in selecting restrictions, including "the magnitude of the exposure," "the benefits of the chemical substance or mixture for various uses," "economic consequences," "costs and benefits," and "effects on employment." *Id.* §§ 2605(c)(2)(A)–(B), 2623(a). Each requirement complements TSCA's substantive standard: regulating only as "necessary" to address "unreasonable risk[s] of injury." *Id.* § 2605(a).

None of this is discretionary—Congress consistently used the word "shall," not "may;" and "shall" is "mandatory." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 661 (2007); *NRDC v. Regan*, 67 F.4th 397, 402 (D.C. Cir. 2023). And the 2016 amendments retained TSCA's heightened standard of review that makes these requirements

judicially enforceable. *See* 15 U.S.C. § 2618(c)(1)(B)(i); *Corrosion Proof Fittings*, 947 F.2d at 1214; *accord Vinyl Inst.*, 106 F.4th at 1125 n.6; *Inhance Techs., L.L.C. v. EPA*, 96 F.4th 888, 892 n.5 (5th Cir. 2024).[8]

Nowhere is EPA's exceedance of this standard more evident than its decision to impose TSCA requirements on conditions of use that the agency had previously determined *do not present unreasonable risk*. OE.517–18; *see* 89 Fed. Reg. at 39,255 (confirming "that all TSCA conditions of use of methylene chloride … are subject to this final rule"). EPA presented no new evidence in the revised evaluation and expressly "did not amend" the "underlying scientific analysis of the risk evaluation," RE.4—EPA simply lumped these conditions of use in with the agency's unrelated findings under the "whole chemical" approach. Almost by definition, EPA exceeded its mandate by regulating uses for which *no* TSCA regulation was "necessary" to "address" unreasonable risk. 15 U.S.C. § 2605(a).

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[8] As Senator Vitter explained, TSCA "created a higher level of judicial review," and Congress "ma[de] no changes to the process for judicial review of rulemakings or the standard of review" in the 2016 statutory amendments. 162 Cong. Rec. 7,989 (2016).

More generally, the Rule's broad imposition of duplicative workplace programs and ECELs suffered from the same flawed understanding of EPA's mandate under TSCA. EPA found unreasonable risk using "high-end," 95th-percentile exposure estimates, *e.g.*, OE.502, and refused to consider OSHA-mandated PPE as a risk-reducing factor, RE.4. Despite promising in the revised evaluation to account for OSHA mandates "during risk management," 87 Fed. Reg. at 39,828, that never happened, either—EPA insisted in the Rule that TSCA restrictions must *independently* address the risk, 89 Fed. Reg. at 39,287. The result was TSCA restrictions that addressed a theoretical risk that is already addressed by OSHA regulations. Such restrictions are not "necessary" to address "unreasonable risk," 15 U.S.C. § 2605(a), and they fall well short of TSCA's command to avoid duplicative regulation, *id.* § 2608(d).

B. EPA Did Not Consider Meaningful Alternatives.

TSCA also imposes requirements for issuing risk-management rules, including Section 6(c)'s instruction that EPA analyze the costs and benefits of "1 or more primary alternative regulatory actions." 15 U.S.C. § 2605(c)(2)(A)(iv)(II)–(III). Here, "EPA's primary alternative regulatory action" in the Rule was to "include several conditions of use under the

[workplace restrictions], rather than [the] prohibition." 89 Fed. Reg. at 39,261. If TSCA's alternatives requirement is to have any force, EPA's choice of an alternative to analyze was inadequate.

TSCA does not define the term "primary alternative regulatory actio[n]," but its plain meaning contemplates "a number of possible choices or courses of action" or a "course of action that is mutually exclusive with another." *Alternative*, Am. Heritage Dictionary (5th ed. 2022); *see, e.g.*, *United States v. Ferguson*, 369 F.3d 847, 852 (5th Cir. 2004) (applying similar definition to interpret "as an alternative to incarceration" under 18 U.S.C. § 3563(b)(19)). TSCA includes a menu of restrictions EPA could have considered, including quantity limits, warnings, labeling, recordkeeping requirements, commercial-use regulations, and disposal requirements. 15 U.S.C. § 2605(a)(1)–(7). These options are specific, distinct, and vary in the burdens imposed on regulated parties, all of which suggests the "primary alternative regulatory actio[n]" should be different in kind, not virtually the same.

EPA did not assert, and there is no reason to believe, that additional labeling and warning requirements, for example, could not have addressed risk to an extent, even if EPA had ultimately concluded a more

restrictive approach was required. The Consumer Product Safety Commission already requires labeling for certain methylene chloride-containing products, *see* 83 Fed. Reg. 12,254, and EPA has ample experience with labeling regimes under FIFRA, *see* 7 U.S.C. §§ 136 *et seq*.

TSCA gives EPA discretion in selecting a primary alternative, but that alternative must be *different* from the agency's preferred option. Because "EPA failed to perform the economic analysis required" under the statute for any meaningful alternative, *NRDC v. EPA*, 808 F.3d 556, 575 (2d Cir. 2015), its action was unlawful.

C. EPA Unreasonably Refused To Coordinate With OSHA.

Before imposing TSCA restrictions, EPA must assess whether another federal agency could address the risk "to a sufficient extent" under its more specific regulatory authority. 15 U.S.C. § 2608(a)(1). If so, EPA must refer the matter to that agency and "may not take any action" until the referral agency takes action, responds, or fails to take action within a certain timeframe. *Id.* § 2608(a)(2). Here, EPA unreasonably refused to refer methylene-chloride risk to agencies that undeniably had the authority to address the risk.

OSHA indisputably has adequate authority to address workplace exposures to methylene chloride, and indeed already has done so. *See* 29 C.F.R. § 1910.1052. EPA acknowledged as much in the Rule but nevertheless declined to refer, asserting that "[g]aps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA Section 6." 89 Fed. Reg. at 39,287.

Each of these "gaps" closes on inspection. EPA invoked "state and local government workers," "self-employed workers," and "military personnel" as outside the scope of OSHA's authority. 89 Fed. Reg. at 39,287. But none of these groups is mentioned in the risk evaluation as a population at risk of exposure, so OSHA's authority does not need to extend that far to sufficiently address the risk. EPA also cited "workers whose occupational safety and health hazards are regulated by another Federal agency," *id.*, but that only begs the question why *those* agencies could not adequately address the risk under their authorities—TSCA's consultation provision does not require that a *single* other federal agency be in a position to address on its own the entire scope of risk.

The Consumer Product Safety Commission similarly has adequate authority to address the risk in the consumer-product conduct, but EPA

refused to refer to that agency as well, for the same flawed reasons. EPA asserted that CPSC's authority does not extend to "automobiles, some industrial and commercial products, or aircraft," 89 Fed. Reg. at 39,287, but not all of these uses are relevant to the risks EPA identified, and CPSC need not have the authority to address *all* risk for referral to be appropriate.

EPA thus misread TSCA's coordination provisions, and declined referral for reasons that do not withstand scrutiny. In so doing, EPA violated TSCA and the black-letter principles of administrative law that Congress embedded in the statute. *See* 15 U.S.C. § 2618(c).

D. EPA's Cost-Benefit Analysis Ignored Substantial Costs.

EPA's cost-benefit analysis estimated that the Rule would result in (relatively small) net benefits—but it got there only by excluding the costs of businesses that may close because of the Rule's methylene-chloride ban. 89 Fed. Reg. at 39,286. That was unreasonable and inconsistent with TSCA's cost-consideration requirements.

EPA acknowledged that businesses in the $1.7 billion furniture-refinishing industry, for example, lacked an adequate substitute for methylene chloride and may be forced to close because of the Rule. 89

Fed. Reg. at 39,286. But EPA excluded "closure" costs as "uncertain" because it lacked adequate information to predict precisely how many businesses would close. *Id.*

Given the extensive information submitted to EPA on the subject, *see, e.g.*, U.S. Small Bus. Admin. Comments 5–6, EPA-HQ-OPPT-2020-0465-0235 (warning of the "closure of an unknown number of the 5,000 potentially affected furniture refinishing firms" and that "average lost profits could be as much as $67 million"); NFIB Rule Comments 5–7 (urging EPA to consider closure consequences); Chamber Rule Comments 11–12 (similar), it was unreasonable for EPA to decline to evaluate these costs while employing sophisticated methods to estimate more speculative benefits. "Stating that a factor was considered" is "not a substitute for considering it," *Getty v. Fed. Sav. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986), and "'conclusory statements'" do "not constitute adequate agency consideration of an important aspect of a problem," *Louisiana v. Dep't of Energy*, 90 F.4th 461, 473 (5th Cir. 2024).

CONCLUSION

For the reasons set out above, this Court should vacate the Rule.

Dated: October 30, 2024

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CERTIFICATE OF SERVICE

I hereby certify that, on October 30, 2024, I filed the foregoing Amicus Brief using the Court's ECF system. Service on all counsel of record for all parties was accomplished electronically using the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This Amicus Brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because the Brief contains 6,498 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2, as counted by the automated function of Microsoft Word Professional Plus 2019.

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