ORAL ARGUMENT NOT YET SCHEDULED
No. 23-1045 (consolidated with Nos. 23-1047, 23-1085)

In the United States Court of Appeals For the District of Columbia Circuit

Huntsman Petrochemical LLC,
Petitioner,

v.

Environmental Protection Agency,
Respondent.

ON PETITION FOR REVIEW FROM FINAL ACTIONS OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, 85 FED. REG. 49084 (AUG. 12, 2020) AND 87 FED. REG. 77985 (DEC. 21, 2022)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS AND VACATUR

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Certificate as to Parties, Rulings, and Related Cases

In accordance with D.C. Circuit Rule 28(a)(1), *amici curiae* state as follows:

I. Parties and *Amici Curiae*

Except for the following, all parties, intervenors, and *amici* appearing in this Court are listed in the Brief for Petitioners at pages iii–iv:

Amici curiae in support of Petitioners are the Chamber of Commerce of the United States of America, the National Association of Manufacturers, the Ethylene Oxide Sterilization Association, Inc., and Sterigenics U.S., LLC.

II. Rulings Under Review

References to the rulings at issue appear in the Brief for Petitioners at page iv.

III. Related Cases

Huntsman Petrochemical LLC v. EPA, No. 20-1414 (D.C. Cir.), *RISE St. James et al. v. EPA, et al.*, No. 20-1417 (D.C. Cir.), and *American Chemistry Council v. EPA*, No. 20-1418 (D.C. Cir.), involve the underlying Rule in this case. *Amici curiae* are aware of no other related cases.

Corporate Disclosure Statements

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 National Association of Manufacturers ("NAM") is a non-profit, tax-exempt organization incorporated in New York. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

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Glossary

APA: Administrative Procedure Act

Board: EPA Science Advisory Board

Chamber: Chamber of Commerce of the United States of America

Commission: Texas Commission on Environmental Quality

EPA: Environmental Protection Agency

Institute: National Institute for Occupational Safety & Health

IRIS: Integrated Risk Information System

NAM: National Association of Manufacturers

Reconsideration: 2022 Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

Rule: 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

National Academies: National Academies of Sciences, Engineering, and Medicine

Statutes and Regulations

All applicable statutes and regulations are included in Petitioners' addendum.

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 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters 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 and 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.

All parties consent to *amici*'s participation and, as indicated in the accompanying motion, also do not oppose the filing of two briefs by non-governmental *amici* in support of Petitioners.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.91 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

This case stems from three actions taken by EPA over the last seven years. The second and third are the actions formally under review, but all stages are important.

First, in a 2016 Integrated Risk Information System ("IRIS") assessment, the Environmental Protection Agency ("EPA") developed a number (or "value") that estimates the cancer-causing risk of inhalation exposure to ethylene oxide—a chemical with a variety of applications. An IRIS analysis and its resulting value are not regulations. No statute governs their preparation, and they are not adopted through notice-and-

comment rulemaking.

Second, in 2020, EPA used that value as the basis for limiting the air emissions of ethylene oxide from over 200 chemical manufacturing facilities in the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (the "Rule").

Third, in 2022, EPA issued a decision on reconsideration of the Rule ("Reconsideration Decision"), reaffirming the Rule and its reliance on the 2016 IRIS value.

Amici are well-situated to aid the Court's review of the Reconsideration Decision, as well as the processes used by EPA in developing the IRIS value and implementing that value in the Rule. Their membership includes not only companies regulated by EPA that will be affected by the Reconsideration Decision, but also a wide range of businesses regulated by numerous federal agencies, such as EPA, that sometimes fail to comply with core administrative law requirements, including those that ensure the use of robust, reliable scientific processes.

Introduction and Summary of Argument

Ethylene oxide is an important chemical used carefully by

businesses. It sterilizes half of all sterile medical devices in America. For many such devices, it "may be the only [substance] that effectively sterilizes and does not damage the device."[2] Similarly, herb-and-spice processors use ethylene oxide to eliminate food-borne pathogens, and it may be the only "viable option for the treatment of certain spices and spice forms."[3] At the same time, businesses have collaborated with governments to reduce ethylene oxide emissions by half in less than a decade.[4]

But in the actions at issue here, EPA has not shown the same care in imposing further regulation in this area. Specifically, it failed to follow its own guidance regarding the consideration of best available science and alternative modeling approaches, and did not provide a reasonable explanation for those deviations. For example, its 2016 IRIS assessment, upon which EPA relied for the Rule and Reconsideration Decision,

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[2] U.S. FOOD AND DRUG ADMIN., *Sterilization for Medical Devices*, https://goo.by/LVAdA (last visited July 9, 2023).

[3] EPA, EPA-HQ-OPP-2013-0244, ETHYLENE OXIDE: PROPOSED INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 2275 70 (MAR. 28, 2023).

[4] EPA, *Toxic Release Inventory National Analysis: Ethylene Oxide*, (Mar. 2022), https://goo.by/aqZav (last visited July 9, 2023) (reflecting 48% drop from 2012 to 2020).

developed cancer values for ethylene oxide without taking into account the best available science and without giving adequate consideration to significant disagreement within the scientific community as to the proper approach to calculating cancer risks. Further, EPA's Reconsideration Decision dismisses that persistent disagreement as well as peer-reviewed values—determined by other regulatory bodies—which contradict the IRIS value.

EPA had tools available to resolve these problems and thereby follow its own guidance, but it has not reasonably explained why it failed to use them. For example, in both 2011 and 2014, the National Academies of Sciences, Engineering, and Medicine (the "National Academies") recommended reforming the IRIS program to use updated methodology. But EPA did not use those updated methods when creating the 2016 IRIS value, even though it did end up fully implementing those recommendations in 2022. The agency has not reasonably explained this decision. As another example, EPA guidance recommends that the agency use independent peer review to resolve disputes like those concerning ethylene oxide. But EPA did not submit its final processes and IRIS value to any peer review, and has not reasonably explained that decision, either.

These shortcomings trigger this Court's duty to assess EPA's processes. While a measure of deference can be appropriate when agencies conduct scientific and technical analyses, the judiciary is nevertheless charged with ensuring that agencies do so within limits that the APA, and other statutes, establish. Accordingly, this Court should grant the petition and require EPA to utilize more robust and reliable processes, consistent with EPA's own guidance, before deciding whether to use the IRIS value in the Rule.

Argument

I. Deference to agency technical determinations is not boundless.

Courts must ensure that agencies conduct scientific and technical analyses within the limits that the law places upon them, including when an agency fails to heed its own guidance. That's true even in a "Battle of Acronyms" over EPA scientific processes, as a court must still make the predicate determination that the agency is indeed acting scientifically. *Am. Petroleum Inst. v. EPA*, 661 F.2d 340, 341 (5th Cir. 1981). Otherwise, "expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962) (citation and internal

quotation marks omitted).

Judicial review of agency action, even science-related action, thus includes inquiry into the processes used in reaching a particular decision or scientific value. *See* 5 U.S.C. § 706; *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (noting that the APA "require[s] . . . substantial inquiry," *i.e.*, "a thorough, probing, in-depth review"). Those limits sometimes arise from specific statutory regimes. But in all events, the APA provides a backdrop requirement that agency action not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

An agency's scientific decision-making processes can run afoul of the APA. An agency might mishandle models and studies, *e.g.*, by using a "model [that] 'bears no rational relationship to the reality it purports to represent,'" *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998) (quotation omitted), or "irrational[y]" relying on a study while making assumptions that contradict the study. *Nat. Res. Def. Council v. EPA*, 31 F.4th 1203, 1209 (9th Cir. 2022). An agency might also rely on "outdated" standards, *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1015 (5th Cir. 2019), use "old data" in the absence of reasoning or legal requirement

that compels continued reliance on that data, *Sierra Club v. EPA*, 671 F.3d 955, 968 (9th Cir. 2012),[5] or fail to "[re]examine key assumptions as part of its affirmative burden of promulgating and explaining a non-arbitrary, noncapricious rule," *Columbia Falls Aluminum*, 139 F.3d at 923. Each of these kinds of errors violates an agency's obligation under the APA to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation omitted).

While EPA's actions violate several administrative-law principles, including those codified in the Clean Air Act,[6] this brief focuses on one

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[5] *See also Am. Petroleum Inst.*, 661 F.2d at 357 (remanding EPA decision at request of a national trade association to "consider the problem again in light of . . . new information"); *Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 218 (2d Cir. 2011) (vacating portion of EPA order that was not based on "reliable data").

[6] The Clean Air Act applies many of the same principles as the APA, while augmenting those requirements with several more robust standards. S*ee* 42 U.S.C. § 7607(d)(9); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. EPA*, 768 F.2d 385, 389 n.6 (D.C. Cir. 1985) (declining to decide whether to apply the APA or Section 706(d) of the Clean Air Act because the standard "is the same under either Act"). Petitioners' Brief covers those standards in detail. *Amici* supplement Petitioners' Brief by focusing on the broad problems with EPA's processes under general APA background principles.

particular APA violation—EPA's failure to follow applicable and comprehensive guidance without adequate explanation. Although such guidance is not binding in the sense of a statute or regulation, agencies are nevertheless required to follow that guidance or to adequately explain departing from it. *See id.* Thus, when agency processes "conflict[] with the guidelines [the agency] purports to follow," those processes bear "the hallmark[s] of arbitrary action" absent adequate explanation. *Nat. Res. Def. Council v. EPA*, 38 F.4th 34, 46–47, 51 (9th Cir. 2022) (quotation omitted); *see also Gen. Chem. Corp. v. United States*, 817 F.2d 844, 851 (D.C. Cir. 1987) (rejecting agency analysis that "ignore[d]" agency's "own guidelines"). And the agency must have "a sound justification for" deviating from "standard operating procedure" beyond "blandly stat[ing] that" it "believe[s]" that a contrary assumption, process, or approach is a "better" fit for the subject matter. *Nat. Res. Def. Council*, 31 F.4th at 1210.

II. EPA failed, without adequate explanation, to follow its own guidance and to heed recommendations from the National Academies.

A. EPA did not employ the best available science or consider contrary scientific evidence in a manner consistent with its own guidelines.

EPA's guidance instructs it to use the best available scientific

information and to consider alternative approaches. EPA's Risk Characterization Handbook states that risk assessments should use the "best available scientific information."[7] Other EPA guidance echoes that instruction and "recognizes that scientific knowledge about risk is rapidly changing and that risk information may need to be updated over time."[8] EPA must also, when conducting risk assessments, ascertain "how generally [EPA's] assessment is accepted by the scientific and regulatory community at large by comparing" that assessment with others.[9] Specifically, EPA must consider "plausible alternative estimates of risk" by identifying and explaining them.[10]

EPA failed to follow this guidance. The IRIS cancer value relies almost entirely on a 2003 study by the National Institute for Occupational

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[7] EPA, SCI. POL'Y COUNCIL, EPA 100-B-00-002, RISK CHARACTERIZATION HANDBOOK 18 (2000) (hereinafter "Risk Characterization Handbook").

[8] EPA, EPA/260R-02-008, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY, OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY 21–23 (Oct. 2002).

[9] Risk Characterization Handbook at 38.

[10] *Id.* at 18, 26, 29.

Safety & Health ("the Institute").[11] To support that reliance, EPA baldly claimed that the Institute's data is the best available and that there is no "new epidemiological, toxicological, or basic scientific research that suggest[s]" that EPA's IRIS assessment could be flawed.[12]

That claim is not accurate. Commenters submitted on reconsideration many scientific analyses that are more recent than EPA's 2016 IRIS assessment, including a 2020 peer-reviewed risk assessment by the Texas Commission on Environmental Quality (the "Commission") which found that "[t]he epidemiological evidence for [ethylene oxide] causing human breast cancer is very weak, with most of the available studies showing no association."[13] And the Institute's 2003 study itself disclaims that any "causal interpretation [between ethylene oxide and

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[11] EPA also relies on a 2004 mortality study. But this study relies on the defective incidence study.

[12] *See* EPA, OFF. OF AIR QUALITY PLANNING AND STANDARDS, SUMMARY OF PUBLIC COMMENTS AND RESPONSES FOR THE RECONSIDERATION OF THE 2020 NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS: MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING RESIDUAL RISK AND TECHNOLOGY REVIEW 17 (Dec. 2022) (hereinafter "EPA MON Response").

[13] TEX. COMM'N ON ENV'T QUALITY, CAS Reg. No. 75-21-8, ETHYLENE OXIDE CARCINOGENIC DOSE-RESPONSE ASSESSMENT (May 15, 2020).

cancer] is weakened" by "inconsistencies . . . and possible biases."[14] In short, EPA ignored relevant studies and myopically interpreted one despite its self-declared commitment to a thorough exploration of the best available science and alternative approaches.

B. EPA did not use National Academies-recommended methodology to resolve some of these problems, and did not adequately explain its refusal to do so.

EPA had tools available to avoid this flawed approach, but it did not use them or adequately explain why it refused to. The National Academies twice recommended that EPA improve the IRIS process before the agency developed the 2016 value. In 2011, the National Academies recommended that EPA change its IRIS assessment process to better reflect the best practices of the scientific community—including the use of a "systematic review" methodology.[15] In 2014, after a second review, the National Academies specifically emphasized the importance of adopting that

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[14] Steenland, K., et al., *Ethylene oxide and breast cancer incidence in a cohort study of 7576 women (United States)*, 14 CANCER CAUSES & CONTROL 531, 539 (2003).

[15] Krewski, D., et al., *Development of an Evidence-Based Risk Assessment Framework*, 39(4) ALTEX 667, 669 (2022).

methodology.[16]

Systematic review is best practice in the scientific community when conducting chemical assessments—as the IRIS program does.[17] Properly conducted systematic review provides a complete and reproducible review of *all* relevant scientific information. It starts by defining the research question—*e.g.*, what is the added risk of cancer from ethylene oxide—before defining objective criteria to use in selecting and analyzing existing scientific information.[18] By gathering all relevant data and evaluating it consistently using pre-defined principles, systematic review provides a transparent and reproducible chemical assessment.[19] It avoids the very cherry-picking and tunnel-vision that plagued EPA's process here.

But despite the National Academies' recommendations, and despite using systematic review for *other* IRIS values, EPA did not employ it in

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[16] EPA, OFF. OF RSCH. AND DEV., EPA 600/R-22/268, ORD STAFF HANDBOOK FOR DEVELOPING IRIS ASSESSMENTS xiv (Dec. 2022).

[17] Krewski, D., et al., *supra* n.15 at 670 (describing systematic review as "essential").

[18] *Id.* at 674–75.

[19] *Id.* at 684–85.

developing the value here and failed to adequately explain its refusal to do so. On December 22, 2022—one day after issuing the Reconsideration Decision—EPA implemented the National Academies recommendations in a handbook for all IRIS values.[20] And even before that adoption, EPA applied systematic review in developing some IRIS values (but not others). It has not reasonably explained why it failed to use systematic review for *this* IRIS value. Even in the face of strong protestations from commenters and the importance of ethylene oxide,[21] EPA still refuses without adequate explanation to update that value using this best-practice methodology that the agency itself has now adopted.[22]

C. EPA's inadequately explained decision to reject National Academies peer review contradicts its own guidance.

EPA also failed without reasonable explanation to use peer review to

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[20] Press Release, EPA, EPA Publishes IRIS Handbook (Dec. 22, 2022) (accessible at https://goo.by/m16ut).

[21] In fact, the American Chemistry Council told EPA that it would be willing to delay pending litigation to permit EPA to apply the National Academies recommendations to the IRIS value. American Chemistry Council, Comment on EPA MON Reconsideration 51 (Apr. 6, 2022) https://goo.by/S93vd.

[22] *See* EPA MON Response at 10, 13.

ensure that its IRIS value was based upon the best available science and that it had adequately considered alternatives. EPA's Peer Review Handbook prioritizes National Academies peer review for high-visibility and controversial actions.[23] Both factors are met here, yet EPA never submitted the IRIS value to National Academies review or adequately explained that decision.

First, ethylene oxide is a high-visibility product. EPA itself has acknowledged that ethylene oxide is "critical for the sterilization of new and reusable medical devices" and that "there are currently no available alternatives . . . for some devices."[24] Disruption of the supply of ethylene oxide would result in "disruption to the medical device supply chain" at large, causing "a nationwide public health crisis."[25] Moreover, ethylene oxide is critical to the herb-and-spice industry.[26]

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[23] EPA, SCI. AND TECH. POL'Y COUNCIL, EPA/100/B-15/001, PEER REVIEW HANDBOOK 68 (4th ed. Oct. 2015).

[24] EPA, EPA-HQ-OPP-2013-0244, ETHYLENE OXIDE: PROPOSED INTERIM REGISTRATION REVIEW DECISION CASE NUMBER 2275 69 (MAR. 28, 2023).

[25] *Id.*

[26] *Id.* at 70.

Second, EPA's regulation of ethylene oxide is based on controversial scientific claims. As discussed above, EPA's methodology suffers from significant disagreement within the scientific community. Further, EPA has dismissed alternative studies and approaches to modeling carcinogenic risk for ethylene oxide. Yet EPA has itself acknowledged ongoing "differences in the approach[es]" the scientific community takes regarding ethylene-oxide cancer risks and lack of "agreement on the . . . modeling approaches used to characterize carcinogenic potency."[27]

Both the importance of ethylene oxide and the lack of consensus should have prompted EPA to follow its own guidance and seek National Academies review. Indeed, the Commission requested that EPA agree to National Academies review of the IRIS value.[28] Yet EPA refused.

EPA justified that refusal by invoking its Science Advisory Board (the "Board") as a shield, arguing that the Board's review fulfills the Peer Review Handbook's instructions.[29] That is wrong. The Board only reviewed

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[27] EPA, D458706, ETHYLENE OXIDE DRAFT HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENT IN SUPPORT OF REGISTRATION REVIEW 4 (NOV. 3, 2020).

[28] EPA MON Response at 17.

[29] *Id.* at 17, 21.

drafts of the IRIS assessment, not EPA's final methodology and value.[30] Those drafts did not provide all relevant information. For example, the Board noted that EPA's submission did not provide "enough detail" regarding "the [Institute's] exposure data for the Board to determine the appropriateness of the data," so it responded "on the assumption that the . . . data are appropriate."[31]

So, while the Board recommendations led to changes in EPA's final IRIS assessment, that assessment has *never* undergone peer review.[32] EPA obtained and provided additional exposure data in its final assessment, but those data were never peer reviewed. Commenters raised this issue to EPA, which provided no substantive response.[33] Instead, EPA simply recited that the IRIS value underwent Board review, but that does not

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[30] EPA, OFF. OF THE ADMIN.: SCI. ADVISORY BD., EPA-SAB-15-012, SCIENCE ADVISORY BOARD REVIEW OF THE EPA'S EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE 1 (Aug. 2015) (2015 review of 2014 draft).

[31] EPA, EPA/635/R-16/350fb, EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE (ETO) APPENDICES I-10 (2016).

[32] *See* EPA MON Response at 15.

[33] *Id.*

answer the question. While the Board reviewed a draft, it was never asked to review the final IRIS assessment or the data and modeling that created it.[34]

In short, EPA's final IRIS-assessment data, modeling, and value never underwent peer review. That contravenes EPA's own guidance, particularly given ethylene oxide's importance, EPA's controversial processes, and important data suggesting that those processes reached an incorrect conclusion. EPA has provided no reasonable explanation for its persistent refusal to do so.

Conclusion

The Court should grant the Petition for Review.

[34] *Id.* at 15–16.

Respectfully submitted,

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Certificate of Compliance

This brief contains 3,309 words excluding the parts of the brief that Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1) exempt. The brief thus complies with Federal Rules of Appellate Procedure 32(g) and 29(a)(5), as well as D.C. Circuit Rule 32(e)(3), because the collective word count between this brief and the other brief of non-governmental *amici curiae* does not exceed the 6,500 words permitted under those rules.

The brief also complies with Federal Rule of Appellate Procedure 32(a)(5)'s typeface requirements and Federal Rule of Appellate Procedure 32(a)(6)'s type style requirements because the brief has been prepared in a proportionally spaced type-face using Microsoft Word in Century Schoolbook 14-point font.

Certificate of Necessity

Pursuant to D.C. Circuit Rule 29(d), a separate brief is necessary because *amici curiae* supporting Petitioner present different arguments on the issues before the Court. In an unopposed separate filing, all non-governmental *amici* in support of Petitioners have jointly moved for permission to file separate briefs that together do not exceed 6,500 words.

Certificate of Service

I hereby certify that, on July 31, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit via the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by that system.

/s/ *Elbert Lin*
Counsel for *amici curiae*