No. 99-1426

IN THE SUPREME COURT OF THE UNITED STATES

AMERICAN TRUCKING ASSOCIATIONS, INC., *ET AL.*,
Petitioners,
v.

CAROL M. BROWNER, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, *ET AL.*,
Respondents,

BRIEF FOR RESPONDENTS APPALACHIAN POWER COMPANY, et al., IN SUPPORT OF PETITIONERS

Filed July 20, 2000

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QUESTION PRESENTED

Whether Sections 101, 108, and 109 of the Clean Air Act require that the Environmental Protection Agency, in evaluating the adequacy of nationwide ambient air quality standards that address predicted "risks" to health, consider the overall societal consequences of managing such risks in determining whether and how to revise such standards?

PARTIES TO THE PROCEEDINGS

1. The parties joining in this brief were petitioners in *American Trucking Ass'ns, Inc. v. United States Environmental Protection Agency*, D.C. Cir. No. 97-1440 (and consolidated cases), and *American Trucking Ass'ns, Inc. v. United States Environmental Protection Agency*, D.C. Cir. No. 97-1441 (and consolidated cases), and are listed below.

Appalachian Power Co.
Baltimore Gas and Electric Company
Carolina Power & Light Company
Central and South West Services, Inc.
Central Power and Light Company
Public Service Company of Oklahoma
Southwestern Electric Power Company
West Texas Utilities Company
Central Illinois Public Service Company
CINergy Corp.
Columbus Southern Power Company
Conectiv (petitioned as Delmarva Power & Light Co. and intervened as Atlantic City Electric Co. in the cases below)
Consumers Energy Company
Dayton Power and Light Company, The
Detroit Edison Company, The
Duke Energy Co.
FirstEnergy (petitioned as Ohio Edison Co. and Centerior Energy Co., (with Centerior Energy Co. subsidiaries Cleveland Electric Illuminating Co. & Toledo Edison Co.) in the cases below)
Florida Power Corporation

Illinois Power Company
Indiana Michigan Power Company
Indianapolis Power & Light Company
Jacksonville Electric Authority
Kansas City Power & Light Company
Kentucky Power Company
LGE Energy Corp. (petitioned as Kentucky Utilities Company and Louisville Gas & Electric Co. in the cases below)
Madison Gas and Electric Company
Minnesota Power Company
Monongahela Power Company, dba Allegheny Power System, Inc.
Northern Indiana Public Service Company
Oglethorpe Power Corporation
Ohio Power Company
Ohio Valley Electric Corporation
Otter Tail Power Company
PacifiCorp
PPL Electric Utilities Corporation dba PPL Utilities (petitioned as Pennsylvania Power & Light Corp.)
Plains Electric Generation & Transmission Cooperative, Inc.
Potomac Edison Company, The dba Allegheny Power System, Inc.
Potomac Electric Power Company
Public Service Company of New Mexico
Salt River Project
South Carolina Electric & Gas Company
Southern Company
Alabama Power Company
Georgia Power Company

Gulf Power Company
Mississippi Power Company
Savannah Electric & Power Company
Tampa Electric Company
Union Electric Company
Virginia Power
West Penn Power Company
dba Allegheny Power System, Inc.
Wisconsin Electric Power Company
Edison Electric Institute
National Rural Electric Cooperative Association
American Chemistry Council (petitioned as Chemical Manufacturers Association in cases below and for a writ of certiorari)
American Forest & Paper Association
American Iron & Steel Institute
American Petroleum Institute
American Public Power Association
Kennecott Energy and Coal Company
Kennecott Holdings Corporation
Kennecott Services Company
Meridian Gold Company
Midwest Ozone Group
National Association of Home Builders
National Mining Association
National Paint and Coatings Association
National Petrochemical & Refiners Association (petitioned as National Petroleum Refiners Association in the case below)
National Stone Association
Nevada Mining Association
Newmont Gold Co.
Phoenix Cement Company

United Mine Workers of America, AFL-CIO
West Virginia Chamber of Commerce
Western Fuels Association, Inc.

2. The following parties were petitioners in the cases whose judgment is under review, but have not joined in filing this brief.

Alliance of Automobile Manufacturers (petitioned as American Automobile Manufacturers Association in the cases below)
American Farm Bureau Federation
American Portland Cement Alliance
American Trucking Associations, Inc.
James Bassage
Burns Motor Freight, Inc.
Central Illinois Light Co.
Chamber of Commerce of the United States of America
Citizens for Balanced Transportation
Commonwealth Edison
Duquesne Light Co.
Equipment Manufacturers Institute
Garner Trucking, Inc.
Genie Trucking Line, Inc.
Gloucester Company, Inc.
Michael Gregory
Idaho Mining Association
Judy's Bakery, Inc.
David Matusow
Brian McCarthy
National Association of Manufacturers
National Automobile Dealers Association
National Coalition of Petroleum Retailers

National Indian Business Association
National Small Business United
Non-Ferrous Founders' Society
Oklahoma Gas & Electric
Richard Romero
Small Business Survival Association
State of Michigan
State of Ohio
State of West Virginia

3. Respondents Carol M. Browner, Administrator of the United States Environmental Protection Agency, and the United States Environmental Protection Agency were the respondents in all of the proceedings below.

4. The following parties were intervenors in the cases whose judgment is under review.
   American Lung Association
   American Road and Transportation Builders Association
   Atlantic City Electric Company
   Commonwealth of Massachusetts
   State of New Jersey

5. The following parties appeared as *amici curiae* in the cases whose judgment is under review.
   Representative Tom Bliley
   Senator Orrin G. Hatch
   State of Connecticut
   State of New Hampshire
   State of New York
   State of Vermont

DISCLOSURE STATEMENT

1. Pursuant to Supreme Court Rules 24.1(b) and 29.6, the following list discloses the parent companies, and any publicly held company that owns 10% or more, of any party joining in this brief.

Alabama Power Company
(a subsidiary of Southern Company)
Appalachian Power Company
(a subsidiary of American Electric Power Company, Inc.)
Baltimore Gas and Electric Company
(a subsidiary of Constellation Energy Group, Inc.)
Carolina Power & Light Co.
(10% or greater owner: State Street Bank & Trust Co. Boston)
Central and South West Services, Inc.
(a subsidiary of Central and South West Corporation)
Central Illinois Public Service Company
(a subsidiary of Ameren Corporation)
Central Power and Light Company
(a subsidiary of Central and Southwest Corporation)
Columbus Southern Power Company
(a subsidiary of American Electric Power Company, Inc.)
Consumers Energy Company
(a subsidiary of CMS Energy Corporation)
Dayton Power & Light Company, The
(a subsidiary of DPL Inc.)
Detroit Edison Co., The

(a subsidiary of DTE Energy Co.)
Florida Power Corporation
(a subsidiary of Florida Progress Corporation)
Georgia Power Company
(a subsidiary of Southern Company)
Gulf Power Company
(a subsidiary of Southern Company)
Illinois Power
(a subsidiary of Dynergy, Inc.)
Indiana Michigan Power Company
(a subsidiary of American Electric Power Company, Inc.)
Indianapolis Power & Light Company
(a subsidiary of IPALCO Enterprises, Inc.)
Kennecott Energy and Coal Co.
(an indirect subsidiary of Rio Tinto PLC)
Kennecott Holdings Corporation
(an indirect subsidiary of Rio Tinto PLC)
Kennecott Services Company
(an indirect subsidiary of Rio Tinto PLC)
Kentucky Power Company
(a subsidiary of American Electric Power Company, Inc.)
Meridian Gold Co.
(a wholly-owned subsidiary of Meridian Gold, Inc.)
Mississippi Power Company
(a subsidiary of Southern Company)
Monongahela Power Company
(a subsidiary of Allegheny Energy, Inc.)
Newmont Gold Co.
(10% or greater owner: Newmont Mining Corporation)

Northern Indiana Public Service Company
(a subsidiary of NiSource Inc.)
Ohio Power Company
(a subsidiary of American Electric Power Company, Inc.)
Otter Tail Power Co.
(10% or greater owner: Otter Tail Power Co. ESOP)
Potomac Edison Company, The
(a subsidiary of Allegheny Energy, Inc.)
Public Service Company of Oklahoma
(a subsidiary of Central and Southwest Corporation)
Savannah Electric & Power Company
(a subsidiary of Southern Company)
South Carolina Electric & Gas Company
(a subsidiary of SCANA Corporation)
Southwestern Electric Power Company
(a subsidiary of Central and Southwest Corporation)
Tampa Electric Company
(a subsidiary of TECO Energy, Inc.)
Union Electric Co.
(a subsidiary of Ameren Corp.)
Virginia Power
(a subsidiary of Dominion Resources, Inc.)
West Penn Power Company
(a subsidiary of Allegheny Energy, Inc.)
West Texas Utilities Company
(a subsidiary of Central and South West Corporation)
Wisconsin Electric Power Company
(a subsidiary of Wisconsin Energy Corporation)

2. The following parties joining this brief have no parent corporations, and no publicly-held companies have a 10% or greater ownership interest in these parties.

American Chemistry Council (formerly Chemical Manufacturers Association)
American Forest & Paper Association
American Iron & Steel Institute
American Petroleum Institute
American Public Power Association
CINergy Corp.
Conectiv
Duke Energy Corp.
Edison Electric Institute
FirstEnergy Corp.
Jacksonville Electric Authority
Kansas City Power & Light Co.
LGE Energy Corp.
Madison Gas and Electric Co.
Midwest Ozone Group
Minnesota Power Company
National Association of Home Builders
National Mining Association
National Paint and Coatings Association
National Petrochemical & Refiners Association (formerly National Petroleum Refiners Association)
National Rural Electric Cooperative Association
National Stone Association
Nevada Mining Association
Oglethorpe Power Corp.
Ohio Valley Electric Corp.
PacifiCorp

PP&L Electric Utilities Corporation dba PPL Utilities
Phoenix Cement Company
Plains Electric Generation & Transmission Cooperative, Inc.
Potomac Electric Power Co.
Public Service Company of New Mexico
Salt River Project
Southern Company
United Mine Workers of America, AFL-CIO
West Virginia Chamber of Commerce
Western Fuels Association, Inc.

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GLOSSARY

The following is a glossary of acronyms and abbreviations used in this brief.

Act	Clean Air Act
Administrator	Administrator of the United States Environmental Protection Agency
Agency	United States Environmental Protection Agency
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
EPA	United States Environmental Protection Agency
JA	Joint Appendix
NAAQS	National Ambient Air Quality Standards
OJA	Joint Appendix in D.C. Cir. Case No. 97-1441
ORTC	Response to Comments on the Proposed Ozone Rule

revised 8-hour NAAQS would "require significantly different emission reduction targets" in some areas,[36] it would disrupt existing control programs and attainment deadlines established in Subpart 2 of the Act – requirements that Congress established to address the same uncertain predictions of health risk that EPA would now address through a Subpart 1 program based on the revised 8-hour NAAQS.[37] Areas with severe nonattainment problems like Los Angeles and Houston would be thrown back into the failed pre-1990 paradigm where unrealistic planning deadlines under Subpart 1 led to regulatory paralysis.[38]

Like the 1-hour ozone NAAQS, the existing PM NAAQS was reducing particulate concentrations around the country.[39]

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[36] *See, e.g.*, EPA, *Regulatory Analyses for the Particulate Matter and Ozone National Ambient Air Impact Quality Standards and Proposed Regional Haze Rule* 7-2, 7-5, 9-3 [hereinafter *RIA*], OJA 2930-31, 2935.

[37] Several of EPA's science advisers recommended against having both 1-hour and 8-hour NAAQS because of the confusion it would cause for achieving ozone reductions. *See, e.g.*, CASAC Transcript of March 22, 1995, at 303, 308, OJA 280, 282 (remarks of James Price and George Wolff). *See also OSP*, *supra* note 13, at 147, OJA 1957 (noting "adequate reduction in risks" can be achieved with either a 1-hour or 8-hour standard).

[38] *See, e.g.*, 136 Cong. Rec. H12867 (daily ed. Oct. 26, 1990) (Rep. Fields) *reprinted in* 1 Sen. Comm. on Env't & Pub. Works, *A Legislative History of the Clean Air Act Amendments of 1990*, at 1236 (Comm. Print 1993) [hereinafter *1990 Legis. Hist.*], OJA 3543 (the Subpart 2 provisions "address the failure of our nonattainment areas to achieve ambient air quality deadlines in existing law.... We have not, however, simply continued to tell the states to do a plan to clean the air. That did not work.").

[39] *See* 62 Fed. Reg. 38666, PMJA 16 (noting the success of the earlier PM NAAQS and "the continued improvement in air quality through the current [PM_{10}] standards").

In contrast to this successful NAAQS program, implementation of the revised $PM_{2.5}$ NAAQS would be impeded by a lack of air quality data and uncertainty as to what constituents of $PM_{2.5}$ should be regulated to reduce predicted health risks.[40] Reflecting these problems, the President and Congress postponed implementation of the revised NAAQS until after the next five-year review cycle, and until after a decision was made on "whether to revise or maintain the new standards."[41]

Besides threatening to disrupt ongoing pollution reductions under the existing NAAQS, the record showed that, by EPA's own admission, the costs of full attainment of the revised ozone NAAQS (estimated by EPA at an additional $9.6 billion per year over the existing NAAQS) would outweigh its benefits (estimated by EPA at $1.5 to 8.5 billion per year).[42] EPA's own estimates showed the cost of attaining the revised particulate standards was extraordinarily high, as much as $37 billion each year.[43]

The record also showed that these costs would reduce average real after tax incomes by 1-2% per person, with the

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[40] *See id.* 38667, 38675 n.38, PMJA 17, 25 (noting the need for additional research "to better identify which species are of concern for human health, and the sources and relative magnitude of such species" and for additional air quality monitoring).

[41] 62 Fed. Reg. 38421, PMJA 195; Transportation Equity Act for the 21st Century, § 6101, Pub. L. No. 105-178, 112 Stat. 463 (1998). App. 111a-113a.

[42] *See RIA, supra* note 36, at ES-11 to ES-12, ES-17, 9-1, OJA 2918-19, 2924, 2934.

[43] *Id.* at 9-1, OJA 2934. Other estimates of the costs of the revised NAAQS ranged up to $150 billion *annually*. Smith, *et al.*, *supra* note 4, at 9, OJA 3323.

General's motion to dispense with printing a joint appendix in Case No. 99-1426.[1]

Article I, Section 1 of the United States Constitution provides in pertinent part that "All legislative Powers herein granted shall be vested in a Congress of the United States...."

The statutory provisions are: the Clean Air Act §§ 101, 42 U.S.C. 7401, App. 105a; 108, 42 U.S.C. 7408, App. 105a-108a; and 109, 42 U.S.C. 7409, App. 108a-111a; and the Transportation Equity Act for the 21st Century, Pub. L. No. 105-178, 112 Stat. 463, §§ 6101, 6102, App. 111a-115a.

The regulatory provisions are: 40 C.F.R. §§ 50.7, 50.9 and 50.10 (1999), App. 100a-103a.[2]

INTRODUCTION

Respondents Appalachian Power Company, *et al.*, do not question the importance of the Clean Air Act or the public health and environmental goals of that Act. As the Environmental Protection Agency ("EPA" or "Agency") continues to regulate air pollution to ever more stringent levels in response to uncertain predictions of health risk, however, the incremental health benefits of these regulations become harder to ascertain and the costs of erroneous or unnecessary regulations – including the risk of indirect health effects and excessive compliance costs – increase. We are concerned that, in such situations, failure to consider all of

[1] Copies of the Joint Appendix filed with the D.C. Circuit are available to the Court, and are referred to in this brief as "PMJA" (D.C. Cir. Case No. 97-1440) and "OJA" (D.C. Cir. Case No. 97-1441).

[2] On July 5, 2000, the Environmental Protection Agency promulgated a revision to 40 C.F.R. § 50.9(b). The revised language is found in the Appendix to this Brief at App. 104a.

the impacts of a regulatory decision on society may result in standards that do more harm than good for the public health.

This case concerns one such situation: the EPA Administrator's revision of National Ambient Air Quality Standards ("NAAQS") for ozone and particulate matter ("PM") under § 109 of the Clean Air Act ("CAA" or "Act"). In this case, EPA revised the existing NAAQS for ozone and PM, standards that EPA previously issued as "requisite to protect the public health" with an "adequate margin of safety" against the same health risks for which the Agency now believes more stringent standards are needed. CAA § 109(b). In both rulemakings, the Administrator was faced *not* with "demonstrated adverse effects" on the public, but rather with a range of uncertain predictions of "health risk."[3] Based on this record, the Administrator made a public health "policy" judgment that "uncertainties associated with inconclusive scientific and technical information" and "hazards that research has not yet identified" justified revised standards reflecting greater margins of safety. *See, e.g.*, 62 Fed. Reg. 38857, OJA 2; *id.* 38653, PMJA 3.

In making this decision, the Administrator concluded that the Act forbade her from considering factors that would allow her to make a reasoned public health policy judgment when confronted with the "uncertainties" and "inconclusive" information concededly at issue here. These prohibited factors include the indirect health, environmental and economic impacts of her decision. *See* 62 Fed. Reg. 38882,

[3] *Cf. Ethyl Corp. v. EPA*, 541 F.2d 1, 13-15 (D.C. Cir. 1976) (*en banc*) (comparing the "adverse effects" language of pre-1977 § 108(a), which "require[d] proof of demonstrable harm," with a "will endanger" standard comparable to that added to § 108(a) in 1977, which authorizes regulation in response to "significant risk of harm").

OJA 27; Brief For Respondent EPA, at 49-51 (D.C. Cir. No. 97-1441).

The Administrator's policy judgment, made with blinders to the overall consequences of those decisions, resulted in some of the most costly regulatory decisions ever made by a federal agency. The record indicates monetary costs to meet the new standards may be up to $150 billion each year,[4] almost an order of magnitude greater than the $18 billion total spent on medical research in the United States the year these standards were promulgated.[5] Equally important, efforts to attain these standards have potentially adverse public health and environmental effects, including an increased risk of premature mortality.

These tradeoffs are part of any sound risk management decision that promotes the public health. Based on a flawed interpretation of the CAA grounded in D.C. Circuit precedent, however, the lower court concluded that the Administrator must ignore these impacts on society when managing public health risk under § 109 of the Act. *See American Trucking Ass'ns v. EPA*, 175 F.3d at 1040, App. 18a (citing *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1148 (D.C. Cir. 1980)).

For the following reasons, this Court should reverse the D.C. Circuit's interpretation of the CAA in this case. The lower court's decision improperly prohibits EPA from exercising sound risk management judgment under CAA § 109 that will promote the public health. Furthermore, the Court should instruct EPA that it must consider the broad

[4] Anne E. Smith, *et al.*, *Costs, Economic Impacts, and Benefits of EPA's Ozone & Particulate Standards* 9 (1997), OJA 3323.

[5] *See* U.S. Dept. of Commerce, *Statistical Abstract of the United States* 118, Table 163 (119th ed. 1999).

impacts on society of its regulatory decisions managing health "risks" through the NAAQS program, so that the Agency's NAAQS decisions will maximize the public good. We do not advocate that consideration of costs be substituted for consideration of health effects, but rather that EPA be required to consider all factors relevant to managing public health risk, in order that NAAQS decisions promote the public health consistent with the statutory purposes of the Clean Air Act.

STATEMENT

I. THE NAAQS PROGRAM

The purpose of the Act, as set forth in § 101(b)(1), is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and productive capacity of its population." This statutory language reflects congressional intent that Clean Air Act programs achieve a balance of social, economic and environmental considerations.

In CAA §§ 108 and 109, the operative regulatory provisions at issue here, Congress called for the establishment of NAAQS for air pollutants that may reasonably be anticipated to "endanger" public health or welfare. Under § 109(b)(1), primary NAAQS are to reflect a level of air quality "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[6]

[6] Secondary NAAQS are to be set at a level that, in the Administrator's judgment, protects the public welfare from "known or anticipated adverse effects." CAA § 109(b)(2). In this case, EPA set secondary NAAQS at the same level as the primary NAAQS. Judicial review of both the

The "criteria" to which § 109(b) refers is an informational document that must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of *all identifiable effects* on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." CAA § 108(a)(2) (emphasis added). While the effects on "public health or welfare" addressed by the air quality criteria document must be related to the "presence of such pollutant in the ambient air," there are otherwise no other limits on the nature of the effects addressed by the criteria document. Rather, this document is to cover "*all* identifiable effects" on the "public health or welfare." *Id.* (emphasis added).

The criteria document is also to "include information on ... those variable factors (including atmospheric conditions) which ... may alter the effects on public health or welfare of such air pollutant." *Id.* § 108(a)(2)(A). Furthermore, § 108(b)(1) provides that "*[s]imultaneously with* the issuance of [the] criteria" document, EPA must issue information on the "cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact" of methods for pollution control or prevention. CAA § 108(b)(1) (emphasis added). All of this information is to be made available *before* EPA undertakes a NAAQS rulemaking.

Once NAAQS are set, the Administrator must review them and the underlying criteria document every five years and revise them "as may be appropriate" in accordance with §§ 108 and 109(b). CAA § 109(d)(1). To help with standard

primary and secondary NAAQS was sought. The lower court remanded the secondary NAAQS to EPA along with the primary NAAQS. 175 F.3d at 1040, App. 18a.

revision, the Administrator appoints "an independent scientific review committee" to provide advice on the scientific basis for setting and revising NAAQS. This committee is to advise the Administrator on, among other things, additional knowledge required to determine the "adequacy" of existing standards and the "basis" for any revisions to them, and on "*any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance*" of revised NAAQS. CAA § 109(d)(2)(C) (emphasis added).

When the air quality standards program was initially enacted in 1970, the Senate Report described the NAAQS as reflecting a "reasonable degree of protection" in the face of uncertain science, rather than reflecting absolute protection from any and all predicted risks.[7] When it amended the Act in 1977, Congress emphasized the importance of protecting public health, but made clear that "public health" protection does not embrace a "no-risk philosophy" because that "ignores all economic and social consequences and is impractical."[8] In 1990, Congress extensively amended the Act, but did not amend § 109, § 108(a) or § 108(b).

[7] S. Rep. No. 91-1196, at 10 (1970), *reprinted in* 1 Sen. Comm. on Pub. Works, 93d Cong., 2d Sess., *A Legislative History of The Clean Air Amendments of 1970*, at 410 (Comm. Print 1974) [hereinafter *1970 Legis. Hist.*], OJA 3687.

[8] H.R. Rep. No. 95-294, at 127 (1977), *reprinted in* 4 Sen. Comm. on Env't and Pub. Works, 95th Cong., 2d Sess., *A Legislative History of the Clean Air Act Amendments of 1977*, at 2594 (Comm. Print 1978) [hereinafter *1977 Legis. Hist.*], OJA 3678; *cf.* 123 Cong. Rec. 18458, 18463 (June 10, 1977), *reprinted in* 3 *1977 Legis. Hist.*, at 1038, OJA 3671 (Sen. Muskie) (When there is "no threshold on health effects ... it [is] very difficult then to apply absolute health protection.").

II. EPA'S POLICY DECISION TO REVISE THE OZONE AND PM NAAQS

In the rulemakings at issue in this case, EPA replaced the existing 1-hour ozone NAAQS with a more stringent 8-hour standard.[9] EPA also replaced the existing particulate matter NAAQS based on a PM_{10} size indicator with standards for both fine particles ($PM_{2.5}$) and for coarse particles (PM_{10}).[10]

As the lower court explained, "EPA regards ozone definitely, and PM likely, as non-threshold pollutants, i.e., [pollutants] ... that have some possibility of some adverse health impact (however slight) at any exposure level above zero."[11] For each of these asserted non-threshold pollutants, EPA was presented with a choice among alternative standard levels characterized by uncertain estimates of health risk, a choice calling for the exercise of judgment regarding how to manage these predicted risks.[12] This is dramatically

[9] 62 Fed. Reg. 38873, 38894, OJA 18, 39.

[10] 62 Fed. Reg. 38677, 38679, PMJA 27, 29. The previous PM_{10} standard controlled both coarse and fine PM. The court of appeals vacated the coarse particle standard as arbitrary and capricious, *see* 175 F.3d at 1054-55, App. 52a, because the PM_{10} indicator included a variable amount of fine particulate matter. EPA has sought no further review of this ruling.

[11] 175 F.3d at 1034, App. 5a; *see also* Letter from Dr. George T. Wolff, Chair, CASAC, to Hon. Carol M. Browner 2 (Nov. 30, 1995) [hereinafter CASAC Ozone Letter], OJA 237 ("[T]here is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations."); EPA, *Review of the National Ambient Air Quality Standards for Particulate Matter* VI-16 (1996) [hereinafter *PMSP*], PMJA 2068.

[12] Risk management requires a regulator to consider predictions of risk and other information to decide on the need for and extent of risk reduction. *See* Stephen Breyer, *Breaking the Vicious Circle* 10 (1993).

illustrated by EPA's rulemaking addressing revision of the ozone NAAQS.

Ozone is a constituent of smog produced by complex chemical reactions in the atmosphere between volatile organic compounds ("VOCs") and nitrogen oxides ("NO_x") emitted by numerous sources over broad areas. The reactions that produce ozone take place over periods of days or longer, through a process influenced by sunlight and other changing atmospheric and meteorological conditions.

Further complicating ozone regulation, NO_x and VOCs that contribute to ozone formation are produced by natural as well as human sources. As a result, short-term (e.g., 1-to-8 hour) ambient ozone concentrations *average* about 0.03 to 0.05 ppm even at remote and rural sites, such as Denali, Glacier and Yellowstone National Parks, which are relatively uninfluenced by mobile and stationary sources. The upper range of short-term readings can exceed 0.07 ppm in such remote areas.[13]

Promulgation of the 1-Hour Ozone NAAQS – The ozone NAAQS that EPA revised in this rulemaking specified an ozone concentration level of 0.12 ppm, based on a 1-hour average, and allowed an average of one exceedance per year over a three-year period. When EPA set this standard in 1979, it did so based on its judgment that "there is no clear threshold... of adverse health effects," and that

[13] *See* EPA, *Review of National Ambient Air Quality Standards for Ozone* 20-21 (1996) [hereinafter *OSP*], OJA 1830-31; EPA, *Responses to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Ozone* 94, 96 (1997) [hereinafter *ORTC*], OJA 176, 178. *See also* 44 Fed. Reg. 8212, OJA 3490 ("Field measurements at some remote sites, where man-caused ozone is likely to be negligible, have shown low – but not insignificant – rates of exceedances of the 0.08 ppm level.").

"physiological responses probably occur in extremely sensitive persons at very low levels."[14]

In 1993, EPA affirmed the appropriateness of this 1-hour NAAQS to address a broad range of predicted and theoretical health risks. In this 1993 decision, EPA was called upon to exercise risk management judgment in making a decision that promotes the "public health."

For example, the Administrator found that revision of the primary 1-hour NAAQS was *not* appropriate because changes in performance on lung function tests after ozone exposures at a 0.12 to 0.15 ppm level (e.g., temporary decreases in lung capacity of 9-16% accompanied by respiratory symptoms) "did not constitute adverse effects for purposes of section 109" even for "sensitive individuals," and health studies suggesting "aggravation of asthma and pre-existing respiratory disease" at 0.12 ppm were limited by "uncertainties about individual exposure levels and the role of other pollutants."[15] In other words, the Administrator found that not every predicted health risk or possible physiological effect associated with exposure to ozone was a potential adverse public health effect.

The Record for Revision of the Existing NAAQS – Following this 1993 decision to reaffirm the existing 1-hour NAAQS as "requisite to protect the public health" with an "adequate margin of safety," EPA in 1995 issued a revised ozone criteria document. In evaluating the new criteria document, the EPA staff explained that the public health

[14] 44 Fed. Reg. 8215, OJA 3493.

[15] 58 Fed. Reg. 13011, 13015, OJA 3452, 3456. These types of "uncertainties embedded in the regulatory process," of course, are a common feature of rulemaking and can lead to overly conservative or "random" regulation. Breyer, *supra* note 12, at 42, 48.

consequences of ozone exposures at levels consistent with the present 1-hour NAAQS remained highly ambiguous for both "chronic" and "episodic" effects.[16] Based on the revised criteria document, the EPA staff concluded that there was an "absence of discernible health effects thresholds and ... that population risk [for respiratory symptoms, lung function changes, and hospital admissions] varies little with small changes in air quality."[17] On this basis, the staff concluded that a 0.09 ppm 8-hour standard (i.e., the 8-hour standard level that EPA concluded was roughly equivalent to the 0.12 ppm 1-hour NAAQS) "would reduce estimated exposures of the at-risk population sufficiently to provide some margin of safety."[18]

The staff concluded that the ranges of estimated risk were little different for the existing 1-hour and alternative 8-hour standards,[19] and that these risk estimates did not even reflect all of the uncertainties associated with the numerous assumptions made to develop the estimates.[20] For example,

[16] *See, e.g., OSP, supra* note 13, at 35, 39, 55, 61, 153, OJA 1845, 1849, 1865, 1871, 1963 (As the EPA staff observed, the database on ozone-induced bronchial responsiveness is "limited and uncertain"; ozone's impact on urban asthmatic morbidity is "not well understood"; no evidence was found that children exposed to low levels of ozone experience respiratory symptoms; the evidence of permanent structural changes in human lungs is "largely hypothetical"; and no association between 6 to 8 hour ozone exposure and hospital admissions could be assessed).

[17] *Id.* 141, OJA 1951.

[18] *Id.* 167, OJA 1977.

[19] *See id.* 125, 130, OJA 1935, 1940.

[20] *See id.* 116, 129-33, OJA 1926, 1939-43. *See also* R.G. Whitfield, *A Probabilistic Assessment of Health Risks Associated with Short-term Exposure to Tropospheric Ozone: A Supplement* 32-33 (1997), OJA 2363-

EPA's January 1997 revised risk assessment showed that the median risk of "large lung function decrements" *would be higher under an 8-hour standard* than under the existing 1-hour NAAQS in 2 of the 9 cities modeled, containing about one-third of the sensitive population,[21] and that risks of coughs and moderate lung function decrements (health "endpoints" considered by EPA) for the 1-hour NAAQS would be *lower* than the risks EPA found acceptable in December 1996, when it proposed a 0.08 ppm 8-hour NAAQS.[22] This EPA risk assessment also reported that risks "are not dramatically different ... among the alternative 1-hour and 8-hour standards" (including the existing 1-hour NAAQS).[23]

EPA's independent Clean Air Scientific Advisory Committee ("CASAC") reviewed the 1995 criteria document and related staff analyses. These independent science advisers concluded (1) that "our understanding of the health effects of ozone is far from complete"; (2) that there are "many gaps" in the science and "large uncertainties" in EPA's risk estimates; and (3) that "there is *no 'bright line'* which distinguishes *any* of the proposed standards (either the

64 (discussing limitations of the modeling); R.G. Whitfield, *et al., A Probabilistic Assessment of Health Risks Associated With Short-Term Exposure To Tropospheric Ozone* 73 (1996), OJA 2312 (discussing "assumptions that could have systematically biased the results").

[21] *See* Memorandum from Harvey M. Richmond to Karen Martin 11 (Feb. 11, 1997) [hereinafter Richmond], OJA 2324; *OSP, supra* note 13, at 80, OJA 1891 (about 1 million out of 3 million "outdoor children" in the risk assessment live in Los Angeles or Houston).

[22] Richmond, *supra* note 21, at 10, OJA 2323.

[23] *Id.* 5, OJA 2318 ("[C]onsidering the uncertainties ... [any] differences [in risk estimates] are not large.").

level or the number of allowable exceedances) as being significantly more protective of public health."[24]

Like the record for the ozone rulemaking, the record for review of the PM NAAQS was characterized by uncertainty about the magnitude and cause of any health risks. For example, the EPA staff "emphasize[d] the *unusually large* uncertainties associated with establishing standards for PM relative to other single component pollutants for which NAAQS have been set."[25] CASAC members could form no consensus regarding the level, averaging time, or form of a revised standard because of the many uncertainties regarding both the existence and nature of any causal relationship between public health and the $PM_{2.5}$ indicator.[26] Reflecting concerns with the lack of air quality data and uncertainty regarding the constituents of $PM_{2.5}$ that should be regulated, the President directed EPA to postpone implementation of the revised $PM_{2.5}$ NAAQS until adequate air quality data were collected and a further review of the standards was completed.[27] Congress subsequently ratified that directive.[28]

[24] CASAC Ozone Letter, *supra* note 11, at 1, 3, 4, OJA 236, 238, 239 (emphasis added).

[25] *PMSP, supra* note 11, at VII-41, PMJA 2153 (emphasis added). For further description of the uncertainties in the PM rulemaking record, see generally, Brief of Petitioners American Trucking Associations, Inc., *et al.*, 11-19 (No. 99-1426), and see also Brief in Response for Respondents National Stone Association, *et al.*, at 2-4 (Nos. 99-1257, 99-1263, 99-1265).

[26] Letter from George T. Wolff, Chair, CASAC, to Hon. Carol M. Browner 2-3 (June 13, 1996), PMJA 3162-63. Moreover, only 2 of the 21 members of the CASAC panel, specifically supported the stringent annual $PM_{2.5}$ standard adopted by EPA. *See id.*, Table 1, PMJA 3165.

[27] 62 Fed. Reg. 38421, PMJA 195.

[28] Transportation Equity Act for the 21st Century § 6101, Pub. L. No. 105-178, 112 Stat. 463 (1998), App. 111a-113a.

EPA's Decisions to Revise the NAAQS – EPA's decisions here were *not* driven by demonstrated health effects caused by small exposures to the pollutants in question, but rather by uncertain estimates of health risk. Reflecting these uncertain risk estimates, the Administrator explained that her decisions on revised NAAQS were the product of "policy" judgment.[29] According to the Administrator, these "policy" judgments represented the degree of protection she declared was "sufficient[]" in light of "[u]ncertainties associated with inconclusive scientific and technical information" and "hazards that research has not yet identified."[30]

The Administrator explained that the level of public health protection that she deemed sufficient for the revised NAAQS was "largely judgmental in nature, particularly with respect to non-threshold pollutants, and *may not be amenable to quantification in terms of what risk is 'acceptable' or any other metric.*"[31] In exercising this "judgment," the Administrator considered "the nature and severity" of predicted health effects, "the size of the sensitive populations at risk," and the "kind and degree of uncertainties."[32] Having said this, the Administrator never explained how consideration of these factors justified a change in the management of predicted risks addressed by the then-current standards, or how the revised standards would fulfill the

[29] *See* 62 Fed. Reg. 38857, 38859, 38861, 38862, 38863, 38867, 38869 n.23, OJA 2, 4, 6, 7, 8, 12, 14; *id.* 38653, 38668, 38669, 38671, 38672, PMJA 3, 18, 19, 21, 22.

[30] 62 Fed. Reg. 38857, OJA 2; *see id.* 38863, 38867, OJA 8, 12; *id.* 38653, PMJA 3.

[31] 62 Fed. Reg. 38883, OJA 28; *id.* 38688, PMJA 38 (emphasis added).

[32] *See supra* note 31.

purposes section of the Act. 175 F.3d at 1034-36, App. 5a-9a; *see also id.* 1034-35, App. 6a-7a (*citing* 62 Fed. Reg. 38883, OJA 28). To the contrary, according to the Administrator, "nothing in the statute requires her to make any specific 'findings,'" even a finding of "significant risk."[33]

In contrast to the uncertain and inconclusive nature of the Administrator's predictions of health risk, the records for these rulemakings made quite clear that EPA's standards would have profound impacts on society, and might be impossible to attain. According to the Administrator, however, her judgment regarding standard revision could *not* be informed by consideration of any information related to their collateral health, social or economic consequences.[34]

For example, as part of its decision adopting the revised 8-hour NAAQS, EPA promulgated a rule requiring the development of a new, more stringent ozone reduction program under Subpart 1 of the Act, in place of the program that Congress had adopted when it enacted Subpart 2 in 1990.[35] Because the new Subpart 1 program based on the

[33] Brief of Respondent EPA, at 43 (D.C. Cir. No. 97-1441).

[34] 62 Fed. Reg. 38878-80, OJA 23-25; *ORTC*, *supra* note 13, at 123-24, 128-33, OJA 205-06, 210-15.

[35] 62 Fed. Reg. 38873, OJA 18, *as revised in 1-Hour Ozone Standard: Reinstatement: Final Rule* (reinstating the 1-hour ozone standard and Subpart 2 requirements only until the legal status of the 8-hour standard is resolved). App. 104a. Subpart 1 appears at CAA §§ 171-179B. The Subpart 2 program that Congress added in 1990 spelled out a detailed and comprehensive program addressing what could, and could not, be required to reduce ozone to address the public health concerns associated with the existing 1-hour NAAQS. *See* CAA §§ 181-185B.

revised 8-hour NAAQS would "require significantly different emission reduction targets" in some areas,[36] it would disrupt existing control programs and attainment deadlines established in Subpart 2 of the Act – requirements that Congress established to address the same uncertain predictions of health risk that EPA would now address through a Subpart 1 program based on the revised 8-hour NAAQS.[37] Areas with severe nonattainment problems like Los Angeles and Houston would be thrown back into the failed pre-1990 paradigm where unrealistic planning deadlines under Subpart 1 led to regulatory paralysis.[38]

Like the 1-hour ozone NAAQS, the existing PM NAAQS was reducing particulate concentrations around the country.[39]

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[36] *See, e.g.*, EPA, *Regulatory Analyses for the Particulate Matter and Ozone National Ambient Air Impact Quality Standards and Proposed Regional Haze Rule* 7-2, 7-5, 9-3 [hereinafter *RIA*], OJA 2930-31, 2935.

[37] Several of EPA's science advisers recommended against having both 1-hour and 8-hour NAAQS because of the confusion it would cause for achieving ozone reductions. *See, e.g.*, CASAC Transcript of March 22, 1995, at 303, 308, OJA 280, 282 (remarks of James Price and George Wolff). *See also OSP*, *supra* note 13, at 147, OJA 1957 (noting "adequate reduction in risks" can be achieved with either a 1-hour or 8-hour standard).

[38] *See, e.g.*, 136 Cong. Rec. H12867 (daily ed. Oct. 26, 1990) (Rep. Fields) *reprinted in* 1 Sen. Comm. on Env't & Pub. Works, *A Legislative History of the Clean Air Act Amendments of 1990*, at 1236 (Comm. Print 1993) [hereinafter *1990 Legis. Hist.*], OJA 3543 (the Subpart 2 provisions "address the failure of our nonattainment areas to achieve ambient air quality deadlines in existing law.... We have not, however, simply continued to tell the states to do a plan to clean the air. That did not work.").

[39] *See* 62 Fed. Reg. 38666, PMJA 16 (noting the success of the earlier PM NAAQS and "the continued improvement in air quality through the current [PM_{10}] standards").

In contrast to this successful NAAQS program, implementation of the revised $PM_{2.5}$ NAAQS would be impeded by a lack of air quality data and uncertainty as to what constituents of $PM_{2.5}$ should be regulated to reduce predicted health risks.[40] Reflecting these problems, the President and Congress postponed implementation of the revised NAAQS until after the next five-year review cycle, and until after a decision was made on "whether to revise or maintain the new standards."[41]

Besides threatening to disrupt ongoing pollution reductions under the existing NAAQS, the record showed that, by EPA's own admission, the costs of full attainment of the revised ozone NAAQS (estimated by EPA at an additional $9.6 billion per year over the existing NAAQS) would outweigh its benefits (estimated by EPA at $1.5 to 8.5 billion per year).[42] EPA's own estimates showed the cost of attaining the revised particulate standards was extraordinarily high, as much as $37 billion each year.[43]

The record also showed that these costs would reduce average real after tax incomes by 1-2% per person, with the

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[40] *See id.* 38667, 38675 n.38, PMJA 17, 25 (noting the need for additional research "to better identify which species are of concern for human health, and the sources and relative magnitude of such species" and for additional air quality monitoring).

[41] 62 Fed. Reg. 38421, PMJA 195; Transportation Equity Act for the 21st Century, § 6101, Pub. L. No. 105-178, 112 Stat. 463 (1998). App. 111a-113a.

[42] *See RIA, supra* note 36, at ES-11 to ES-12, ES-17, 9-1, OJA 2918-19, 2924, 2934.

[43] *Id.* at 9-1, OJA 2934. Other estimates of the costs of the revised NAAQS ranged up to $150 billion *annually*. Smith, *et al.*, *supra* note 4, at 9, OJA 3323.

impact falling disproportionately on lower income groups. The increased costs and unemployment resulting from the NAAQS therefore would themselves create public health risk,[44] with risk estimates ranging up to 27,000 premature deaths.[45] The revised NAAQS would also prevent highway improvements that were expected to save lives.[46] Even at these extraordinarily high costs, EPA was unable to identify

[44] *See* Ralph L. Keeney, *Mortality Risks Induced By Economic Expenditures*, 10 Risk Analysis 147, 157 (1990) (If the intent of an air quality standard is avoiding adverse public health effects, it is "ridiculous not to consider the potential mortality [and morbidity] implications of implementing the regulation itself."). *See generally* Breyer, *supra* note 12, at 20; W. Kip Viscusi, *The Value of Life in Legal Contexts: Survey and Critique*, 2 Am. L. & Econ. Rev. 195, 200 (2000) (explaining that regulations may create both direct and indirect health risks).

[45] Ralph L. Keeney & Kenneth Green, *Estimating Fatalities Induced By Economic Impacts of EPA's Ozone and Particulate Standards* 13 (1997), OJA 3328. This estimate is based on higher costs for attaining the standards than EPA projects. Up to 1600 predicted fatalities were estimated even under EPA's artificially low cost estimates. *Id.; see also Clean Air Act: Ozone and Particulate Matter Standards: Hearings Before the Subcomm. on Clean Air, Wetlands, Private Property, and Nuclear Safety and the Sen. Comm. on Env't and Pub. Works*, S. Hrg. No. 105-50, pt. 2, at 162 (1997) (prepared statement of Susan E. Dudley, Vice President and Director of Environmental Analysis, Economics, Inc.) (attaining the proposed ozone NAAQS could increase deaths by 4250 to 5667 per year).

[46] *Cf. Hearings on Conformity Under the Clean Air Act Before Sen. Comm. on Env't and Pub. Works*, 106th Cong. 29-30 (1999) (statement of Jim L. Joyner, Chmn. Bd. of Commissioners, Henry County, Georgia) (explaining that Clean Air Act transportation conformity requirements related to implementation of NAAQS are impeding safety-related road construction projects).

control techniques that would bring about nationwide attainment.[47]

Finally, the record showed that revising the existing ozone NAAQS might also increase public health risk through increased incidence of cataracts and cancers associated with increased UVB radiation exposure.[48] And more restrictive NAAQS could increase unemployment, electricity rates, and the costs of food and other consumer products.[49]

As a result, EPA's decisions to revise the existing NAAQS would (1) impose billions of dollars more in costs on society, (2) increase indirect public health risk, (3) in the case of the ozone NAAQS, be implemented in a manner rejected by Congress, and (4) in the case of the PM NAAQS, not be implemented at all until after the next 5 year review of that NAAQS. The Administrator refused to consider any of these consequences of her decision, however, on the grounds that

[47] According to the Administrator, the expenditures assumed in EPA's regulatory analyses – up to $10,000 per ton for the removal of ozone precursor pollutants and up to $1 billion/$\mu g/m^3$ of ambient $PM_{2.5}$ eliminated – were insufficient to provide attainment. *RIA, supra* note 36, at ES-11 to ES-12, OJA 2918-19; *see also* American Petroleum Institute, *Comments on Proposed NAAQS for Ozone*, Appendix B (1997), OJA 3293-3301.

[48] Randall Lutter & Christopher Wolz, *UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standards*, 31 Env. Sci. & Tech. 141, 145 (1997), OJA 2764 (estimating an increase of 25-50 melanoma deaths, 2000 to 11000 skin cancers and 13000 to 28000 cataracts from a reduction in seasonal average ozone levels of 10 parts per billion).

[49] *See, e.g.*, American Farm Bureau Federation, Comments 1-3 (Mar. 12, 1997), OJA 3318-20 (impacts on agricultural sector and increased food prices); Tennessee Valley Authority, Detailed Comments 10 (Mar. 11, 1997), OJA 3317 (11% increase in electric rates and job loss).

she had no statutory authority to consider them, even though EPA purportedly was exercising "policy" judgment to protect the "public health."[50] Indeed, according to the Administrator, even information showing that implementation of a revised NAAQS will be "difficult, counter-productive or confusing do[es] not undermine EPA's [NAAQS] revision authority."[51]

III. THE D.C. CIRCUIT'S DECISION

Because the Agency had interpreted the Act to authorize it to exercise judgment with no guiding principle, the court below remanded the revised standards to EPA for further rulemaking. According to the court, the Agency is obligated to interpret the Act to provide an "intelligible principle" for her exercise of risk management judgment. 175 F.3d 1034, App. 5a.

The lower court also held that EPA must consider *all* effects of an air pollutant in the ambient air – whether adverse or beneficent – when selecting an appropriate NAAQS. *Id.* 1052-53, App. 47a-48a.[52] At the same time, however, the court briefly and emphatically rejected the suggestion that, in developing an intelligible principle to guide its risk management judgment, the Agency may consider factors such as indirect public health and environmental impacts and costs, factors that any rational

[50] 62 Fed. Reg. 38878-85, OJA 23-30; *id.* 38683-88, PMJA 33-38.

[51] Brief of Respondent EPA, at 73 (D.C. Cir. No. 97-1441).

[52] Thus, the lower court directed EPA to consider the scientific evidence that ozone in the ambient air protects against the effects of UVB radiation. EPA did not petition this Court for review of that aspect of the lower court's decision.

person would consider relevant to determining the acceptable level of public health risk.[53]

Quoting earlier decisions of the circuit, the court concluded that this issue was resolved "in *Chevron* step one terms," because the CAA "on its face does not allow consideration of technological or economic feasibility." *Id.* 1040, App. 19a. According to the court, this prohibition on the factors the Administrator may consider in exercising "public health" risk management judgment extends not only to the costs and feasibility of control technologies, but to all the indirect health, environmental and economic impacts that might be caused by a decision to revise an existing NAAQS.

Although the court below made minor modifications to its opinion on rehearing, 195 F.3d 10, App. 79a-80a, it did not change its holding limiting the factors EPA can consider in managing public health risk.

SUMMARY OF ARGUMENT

Section 109 of the Clean Air Act directs the EPA Administrator to set NAAQS that are "requisite to protect the public health" with an "adequate margin of safety," and to make such revisions to those standards as may be "appropriate in accordance with [§§ 108 and 109(b)]." Such standards must be supported by a sound scientific record. In revising the NAAQS for ozone and PM, the Administrator relied on uncertain predictions of health risk to adopt revised standards that will set in motion two of the most costly and

[53] 175 F.3d at 1040, App. 18a-20a. The only example the court gave of how EPA could develop a "principled structure" for setting NAAQS, however, was Oregon's Medicaid program, a program that relied on cost considerations. *Id.* 1039, App. 15a-18a.

burdensome regulatory programs ever required by a federal administrative agency.

Citing uncertain "risk" estimates and reflecting the assumed lack of any level of exposure at which there is an absence of health risk, the Administrator's decisions to revise the NAAQS were "largely judgmental in nature... and may not be amenable to quantification in terms of what risk is 'acceptable' or any other metric." 62 Fed. Reg. 38883, OJA 28 (emphasis added); *id.* 38688, PMJA 38 (emphasis added). The costs of these standards, however, can be measured both in the potential for adverse impacts on public health and the environment, and in the dollars required to attain them (up to $150 billion each year). EPA concedes that the revised ozone NAAQS have costs that may exceed their benefits, and that NAAQS will interfere with a separate congressional program for reducing ozone to address the health risks at issue here.

In revising these NAAQS, the Administrator concluded that she was precluded from considering the indirect health, environmental and economic effects of her policy decision to provide additional margin of safety in response to uncertain health risk – factors that would normally be relevant to sound "public health" policy judgment. The United States Court of Appeals for the District of Columbia Circuit agreed that the Administrator had no authority to consider such factors, relying on its own precedents with *Lead Industries Association v. EPA,* 647 F.2d 1130 (D.C. Cir. 1980). This decision should be reversed.

1. Broad delegations of regulatory authority must be implemented to give effect to congressional purpose, absent statutory language directing a different result. In the Clean Air Act, Congress specified through explicit statutory language that the goal of the Act is to promote the "public

health" which, by its very definition, includes consideration of economic and social realities. The language of § 101(b)(1) of the Act, according to EPA itself, calls for a "balancing of the social and economic considerations with the environmental implications" of a regulatory decision. 39 Fed. Reg. 31000. This Court's precedents have long recognized that the normal meaning of statutory terms as well as the statutory purposes must be used to provide decisional criteria where statutory terms are undefined, unless there is clear statutory evidence requiring a different result. There is no such evidence here.

2. Section 109(b)(1) of the Clean Air Act, directs the Administrator to establish standards at a level "requisite" to protect the "public health" with an "adequate margin of safety." When confronted with predicted but uncertain health risk, as opposed to a demonstrated "adverse effect" on public health, these terms call for the exercise of risk management judgment that involves balancing a broad range of factors consistent with the statutory purposes section of the Act.

a. None of this statutory language directs the Administrator, in exercising this risk management judgment, to ignore factors such as the total health, environmental, and economic consequences of actions that are critical to protecting and promoting the public health. Indeed, consideration of these factors is consistent with the common understanding of "public health" regulation, which contemplates a balancing of factors to improve the conditions in which people live. Consideration of these factors also is essential to fulfilling the Clean Air Act's overriding statutory purpose of protecting the public's health in a way that also promotes the "public welfare" and the "productive capacity" of the people of this country. Finally, the common approach to establishing an "adequate margin of safety" requires

considering both the costs and the benefits of the margin in question.

b. Furthermore, § 109(d)(1) of the Act directs EPA to revise NAAQS "as may be appropriate in accordance with" §§ 108 and 109(b). Those sections then tell the Administrator, as part of this standard revision process, to obtain from her science advisors information on the overall impacts on society of standard revisions. This is consistent with congressional intent that the Agency exercise its judgment to manage public health risk in a manner that promotes the statutory purposes.

c. The Act's legislative history confirms that Congress expected the Administrator to consider practical impacts including societal costs to determine whether the risk posed by a pollutant such as ozone or PM is unacceptable or whether standard revisions were "appropriate." Congress understood that NAAQS were *not* intended to be standards *which eliminate any and all health risk.* Rather, Congress observed in 1970 when it enacted §§ 108 and 109, and again in 1977 when it amended §§ 108 and 109, that these provisions do *not* contemplate "zero risk" regulation, but rather a "reasonable degree of protection."

3. Finally, review of the language, structure and purposes of the Act shows that the circuit precedent on which the lower court relied – *Lead Industries* – was wrongly decided. There is no statutory language providing, as the *Lead Industries* court concluded, that costs and other impacts may "play no part in the promulgation of [NAAQS]." 647 F.2d at 1148. Rather, applying this Court's subsequent decision in *Chevron*, this Court should conclude that, consistent with the congressional purposes stated in § 101(b) of the Act, the statute on its face contemplates consideration

by EPA of the broad impacts on society of its NAAQS decisions when it manages health risks under § 109.

ARGUMENT

The standards before the court are standards that protect against predicted "risk" from pollution, not against pollution that has been shown to cause an adverse public health "effect" like the London "killer fog."[54] Under the Act, NAAQS must be set below the level at which such demonstrated adverse public health effects occur. This case, by contrast, involves pollution levels far below those at which adverse public health effects have been demonstrated. What is at issue here is how EPA manages health "risks."

In making decisions to manage risks (as opposed to eliminating known, adverse public health effects), EPA must act like any other agency with "public health" risk management responsibilities. A mandate to protect the "public health" does not contemplate elimination of all health risk, or absolute protection of any particular individual.[55]

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[54] Historically, increased mortality and morbidity has been observed during episodes of extremely high levels of air pollution *PMSP*, supra note 11, at V-11, PMJA 1962. With fine particles, for example, such effects have been observed with levels reaching 500-1000 $\mu g/m^3$ or more daily. 61 Fed. Reg. 65641-42 & n.7, PMJA 122-23. This is at least an order of magnitude higher than daily fine PM levels observed today in this country. *See PMSP, supra* note 11, at IV-17a, PMJA 1943. By contrast, the studies on which the new standards are based used statistical techniques to predict the possibility that health effects *might* occur at ambient concentrations extending down to background levels.

[55] *See* H.R. Rep. No. 95-294, at 127, *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 8, at 2594, OJA 3678 (a "no-risk philosophy ... ignores all economic and social consequences and is impractical"); 123 Cong. Rec. at 18463 (Sen. Muskie), *reprinted in* 3 *1977 Legis. Hist.*, *supra* note 8, at 1038, OJA 3671; *see also Black's Medical Dictionary* 454 (Gordon

Indeed, EPA agrees that not every predicted "health risk" is a "*public health*" risk.[56]

Rather, as traditionally understood by public health professionals, "many factors such as the social, economic and physical environment in which the people live" can affect the public's health.[57] Regulation that addresses public health risk therefore "operates in a world of choices in the allocation of limited resources,"[58] and contemplates a focus on

Macpherson, ed., 39th ed. 1999) ("Central to understanding public health is recognition that public-health practitioners are concerned not just with individuals, but with whole populations and that improving health care plays only a part of public-health improvement.").

[56] *See* 62 Fed. Reg. 38677, PMJA 27 (noting that the level of the new daily $PM_{2.5}$ standard "is not risk free"); *see also supra* note 15 (discussing 1993 decision to reaffirm the 1-hour NAAQS).

[57] *See, e.g.*, Ben Miller & Claire Brackman Keane, *Encyclopedia and Dictionary of Medicine and Nursing* 410 (1972) (public health is the "field of medicine that is concerned with... the physical, mental and social well-being of the community as a whole"); *Dorland's Illustrated Medical Dictionary* 647 (L.R.C. Agnew *et al.* eds., 24th ed. 1965) (Health is "[a] state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity."); *Black's Medical Dictionary, supra* note 54, at 454; *see also id.* 242 ("Environment, *including living and working conditions*, plays an important part in determining a person's health.") (emphasis added); Roger Detels & Lester Breslow, *Current Scope and Concerns In Public Health in* 1 *Oxford Textbook of Public Health* 3, 3 (Roger Detels et al. eds., 3d ed. 1997) (public health concerns dating back to the early twentieth century include crowding and undernutrition as well as disease).

[58] Lawrence O. Gostin, *et al.*, *The Law and The Public's Health: A Study of Infectious Disease Law in the United States*, 99 Colum. L. Rev. 59, 68 (1999).

"fulfill[ing] society's interest in assuring conditions in which people can be healthy."[59]

As such, "public health, as both a goal and a practice, is as inherently political (i.e., concerned with the allocation of resources in society) as it is technological (i.e., concerned with deployment of professional knowledge of illness)."[60] Developing public health policy necessarily involves tradeoffs in order to choose the risk management option that produces the greatest value for society.

In this case, citing a flawed interpretation of the CAA in the lower court's 1980 *Lead Industries* decision, the D.C. Circuit held that Congress prohibited the EPA from considering factors that are necessary to sound public health risk management judgment in setting or revising NAAQS. For the following reasons, this result is neither consistent with the Act nor logical, and may result in decisions that do *not* promote the public health.

I. THE STATUTORY PURPOSES MUST INFORM AN AGENCY'S IMPLEMENTATION OF A BROAD CONGRESSIONAL DELEGATION.

Broad delegations of congressional authority must be implemented in a manner consistent with the ordinary meaning of undefined statutory terms,[61] and in a manner that furthers Congress' overall purposes in enacting the legislation. As the Court only recently explained, "in the absence of a statutory definition," courts should look to "both the generally accepted meaning of the term and to the

[59] *See* Institute of Medicine, *The Future of Public Health* 7, 40 (1988).

[60] Gostin, *supra* note 58, at 68.

[61] *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995).

purpose of the statute."[62] Furthermore, a court's "obligation is to give effect to congressional purpose so long as the congressional language does not bar that result."[63]

Thus, where Congress has not provided detailed guidance for implementation of a statutory provision, this Court has analyzed the validity of an agency's regulation by examining its conformance with the "fundamental objective" of the statute in question.[64] Only last term, in striking down a regulatory program adopted by the FCC, this Court emphasized that broad delegation of regulatory authority requires the agency "to apply *some* limiting standard rationally *related to the goals of the Act*."[65] Indeed, the failure to apply any limiting standard related to the goals of the Act may raise concerns under the congressional nondelegation doctrine.[66]

As early as 1967, in enacting the first Air Quality Act, Pub. L. No. 90-148, 81 Stat. 485, Congress explained that the development of air quality standards should "be influenced

[62] *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 47-48 (1989).

[63] *Johnson v. United States*, 120 S.Ct. 1795, 1805 n.10 (2000)(citations omitted).

[64] *See Whirlpool Corp. v. Marshall*, 445 U.S. 1, 11-12 (1980).

[65] *AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 388 (1999) (emphasis added).

[66] *Mistretta v. United States*, 488 U.S. 361, 374 n.7 (1989) ("In recent years, our application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional."); *Jones v. United States*, 120 S.Ct. 1904, 1911 (2000) (statute is to be construed to avoid constitutional infirmity).

not only by a concern for the protection of health or welfare, but also by economic, social and technological considerations."[67] In amending the Act in 1977, Congress again emphasized that the Act's purpose was to "insure the protection of the public health and the environment ... *while at the same time considering the energy and economic needs of this Nation.*"[68]

Reflecting these principles, Congress has long recognized, in explicit *statutory* language, that the fundamental objective of the Act is to promote the "public health" consistent with economic and social realities. Thus, Congress stated in § 101(b) of the Act that the purpose of the Act is "to protect and enhance the quality of the Nation's air resources *so as to promote* the *public health* and *welfare* and the *productive capacity* of its population." CAA § 101(b)(1) (emphasis added).

The Agency itself has explained the importance of exercising its discretion in light of the Act's stated goal "to protect and enhance the quality of the nation's air resources so as to promote the public health and welfare and the productive capacity of its population."[69] As EPA has observed, this language contemplates "a balancing of the social and economic considerations with the environmental

[67] S. Rep. No. 90-403, at 28 (1967).

[68] H.R. Rep. No. 95-294, at 34-35 (1977), *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 8, at 2501-02 (emphasis added).

[69] *See* 39 Fed. Reg. 31000; *see also Lead Industries*, 647 F.2d at 1152; *Chrysler Corp. v. EPA*, 631 F.2d 865, 888 (D.C. Cir. 1980); *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1572 n.15 (D.C. Cir. 1984).

implications" of a decision in order "to fulfill the mandate" of the Act.[70]

Framing EPA's responsibilities to accommodate these statutory objectives does not call for the Administrator to ignore the broad impacts on the public of alternative approaches. Rather, it calls for balancing to ensure that the Agency's judgments reflect sound public health policy.

These statutory purposes have special relevance in the context of a regulatory program calling on the Agency to exercise "public health" risk management judgment, a term which by its very definition contemplates consideration of the social and economic realities of an agency's risk management decision. Thus, for example, regulation that trades reduction in some predicted health risks for increases in others may not further the "public health." Similarly, adopting a revised NAAQS that makes implementation of an air quality standard "difficult, counterproductive or confusing"[71] may not promote the "public health." And increasing the costs of regulation to society in an attempt to insure against speculative risk may in fact impair, not protect, the "public health."[72]

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[70] 39 Fed. Reg. 31000. Indeed, the court of appeals itself illustrated the overriding importance of the purposes section of the Clean Air Act by ruling that section 101(b)(1) imposed upon the Administrator the obligation to establish a regulatory program that was not mentioned in the operative provisions of the Act. *See Sierra Club v. EPA*, 540 F.2d 1114 (D.C. Cir. 1976), *vacated sub nom. Montana Power Co.* v. *EPA*, 434 U.S. 809 (1977); *Sierra Club v. Ruckelshaus*, 344 F. Supp. 253 (D.D.C.), *aff'd per curiam*, 4 E.R.C. 1815 (D.C. Cir. 1972), *aff'd by an equally divided Court, sub nom. Fri v. Sierra Club*, 412 U.S. 541 (1973).

[71] Brief of Respondent EPA, at 73 (D.C. Cir. No. 97-1441).

[72] Some studies suggest that $3 million to $7 million spent on regulatory costs may lead to one additional premature death. *See* Mark Shere, *The*

A profligate commitment of money and technology to guard against one set of uncertain health risks may result in inadequate means to cope with other more serious problems.[73] Indeed, without consideration of the unavoidable relationship between the costs of goods produced and the capacity of the public to purchase such goods, stringent margins of safety designed to protect against *hypothetical risks* that by their nature are uncertain could have the effect of increasing the cost of – and perhaps even denying to the poor and those on fixed incomes – products such as electricity for heating and cooling that are essential to the public's health. As Justice Powell recognized in his concurrence in *Union Electric Co. v. EPA*, for example, the "shutdown of an urban area's electrical service could have an even more serious impact on the health of the public than that created by a decline in ambient air quality." 427 U.S. 246, 272 (1976).

In this case, EPA must construe the Act to apply "some limiting standard, rationally related to the goals of the Act"[74] to govern its exercise of public health risk judgment, unless

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Myth of Meaningful Environmental Risk Assessment, 19 Harv. Envtl. L. Rev. 409, 472 nn. 271-72 (Winter 1995) ((*citing International Union, UAW v. OSHA*, 938 F.2d 1310, 1326 (D.C. Cir. 1991) (Williams, J., concurring) (explaining that recent studies predict that "each $7.5 million of costs generated by regulation may ... induce one [premature] fatality" in the public through reduced availability of resources for medical care and safety)).

[73] *See, e.g., Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 669-70 (1980) (Powell, J., concurring); Stephen Breyer, *supra* note 12, at 18-19; *see also* W. Kip Viscusi, *The Value of Life in Legal Contexts: Survey and Critique*, 2 Am. L. & Econ. Rev. 195, 200-01 (2000).

[74] *AT&T Corp.*, 525 U.S. at 388.

this Court finds that Congress explicitly directed EPA to ignore the statutory language defining the purposes of the Act.[75] Because, as discussed below, there is no such explicit constraint on the Agency's regulatory authority in § 109 of the Act, the Agency must look to the concept of "public health" as commonly understood by health professionals and to the purposes section of the Act in formulating decisional criteria to govern management of uncertain health risks under CAA § 109.

II. CONGRESS IN § 109 CONTEMPLATED THAT EPA WOULD CONSIDER THE BROAD IMPACTS ON SOCIETY OF ITS PUBLIC HEALTH RISK MANAGEMENT DECISIONS CONSISTENT WITH THE PURPOSES OF THE ACT.

No one disputes that the NAAQS program has truly extraordinary impacts on the Nation's economy and on society generally. EPA's own analyses show that the revised standards at issue represent perhaps the most costly regulatory decision ever made by that agency.[76] In addition to these very high implementation and control costs, the types of impacts include adverse health impacts associated with increased UVB radiation exposure; increased unemployment; the higher cost of essential products; disruption in the implementation of the congressional ozone reduction program; and disruption of highway safety programs. *See supra* pp. 15-18. Furthermore, EPA has explained that the

[75] *See Johnson*, 120 S.Ct. at 1805 n.10; *Chevron, USA, Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984) (The first inquiry for a reviewing court is whether "Congress has directly spoken to the precise question at issue.").

[76] *See RIA, supra* note 36, at ES-13, ES-19, 7-11, 9-1 (1997), OJA 2920, 2926, 2932, 2934.

revised NAAQS may simply be impossible to achieve in some areas.

These, of course, are the types of concerns that led Congress in 1990 to amend the Act to establish the Subpart 2 program for managing the uncertain public health risks addressed by the 1-hour ozone NAAQS.[77] And concerns about implementation and efficacy of the revised standards also caused Congress to delay implementation of the revised $PM_{2.5}$ NAAQS.[78]

The lower court has held that EPA has no statutory authority to consider any of these impacts when exercising public health risk management judgment under § 109. But there is nothing on the face of either §§ 108 and 109 that prohibits the Administrator from balancing the broad range of factors called for in § 101(b)(1) of the Act in exercising her risk management judgment. To the contrary, the language of §§ 108 and 109 supports the use of the statutory purposes to derive decisional criteria for the Administrator's exercise of risk management judgment.

A. Sections 108 and 109(b) Do Not Mandate Uninformed Public Health Risk Management Decisions.

Under § 109, NAAQS are to be set at a level that, in the "judgment" of the Administrator, is "requisite to protect public health" allowing an "adequate" margin of safety. Nothing in this language tells the Administrator to exercise

[77] H.R. Rep. No. 101-490, pt. 1, 101st Cong., 2d Sess., at 146-47 (1990), *reprinted in* 2 *1990 Legis. Hist., supra* note 38, at 3170-71, OJA 3556-57.

[78] *See* Transportation Equity Act for the 21st Century § 6101(b)(3), Pub. L. No. 105-178, 112 Stat. 463 (1998). App. 113a.

her risk management judgment with blinders to the broad consequences for society of her decisions.

The plain meaning of the word "requisite" is "indispensable" or "necessary,"[79] suggesting that the Administrator must establish a *need* for the revised standard to protect public health.[80] Furthermore, as discussed above, the concept of "public health" calls on regulators to promote the overall health of the population by reducing predicted risks to acceptable levels. *See supra* pp. 24-27.

Whether a standard is "requisite" to protect the "public health" in the face of uncertain predictions of health risk, therefore, does not on its face limit the factors relevant to the Agency's exercise of risk management judgment. To the contrary, a standard cannot be "requisite" to protect the "public health" without some understanding of whether and why predicted health risks are *unacceptable* under the *existing* standard, and yet *acceptable* under the *revised* standard.[81]

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[79] *Webster's Third New International Dictionary of the English Language* 1929 (1993).

[80] As the legislative history explains, this language means that standards must be set at "the maximum permissible ambient air level" that will protect sensitive subgroups in the population. S. Rep. No. 91-1196, at 10 (1970), *reprinted in* 1 *1970 Legis. Hist., supra* note 7, at 410, OJA 3687; *see also* H.R. Rep. No. 95-294, at 127, *reprinted in* 4 *1977 Legis. Hist., supra* note 8, at 2594, OJA 3678; 123 Cong. Rec. 18460, *reprinted in* 3 *1977 Legis. Hist., supra* note 8, at 1030-31, OJA 3669-70 (NAAQS are the "minimum necessary and the minimum reasonably attainable" for achieving public health goals).

[81] *See SEC v. Chenery Corp.*, 332 U.S. 194, 196-97 (1947) ("[i]t will not do for a court to be compelled to guess at the theory underlying the agency's action...."); *see also NRDC v. EPA*, 902 F.2d 962, 969 (D.C. Cir. 1990) (NAAQS needed to avoid "an unacceptable risk" of premature mortality); *American Petroleum Inst. v. Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981) (Section 109 requires "a reasoned analysis and evidence of risk.").

As this Court has "frequently reiterated..., an agency must cogently explain why it has exercised its discretion in a given manner."[82] But, to use the ozone case as an example, where there is no "bright line" distinguishing alternative standards from a public health protection standpoint, *see supra* pp. 12-13, how can the alternative that imposes the greatest overall burdens on society be "requisite" to protect the public's health? How can a standard that imposes enormous costs on society and that cannot be achieved in many areas, *see supra* pp. 15-16, be "requisite" to protect the public's health as compared to a standard that imposes fewer burdens and is being successfully implemented to reduce the same "public health" risks? The Agency never answers these questions on the grounds that Congress told it not to – an illogical and implausible result under a statute whose purpose is to promote the public health and welfare *and* the productive capacity of the country's population. CAA § 101(b)(1).

Similarly, the statutory direction that the Administrator select a margin of safety that is "adequate" does not suggest that she ignore the broad impacts of her decision on society when exercising risk management judgment. To the contrary, as the *en banc* D.C. Circuit observed in addressing the similar language of CAA § 112, a finding that a level of

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[82] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983); *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 740-41 (1996) (explaining that deference accorded under *Chevron* is based on "presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that *the ambiguity would be resolved, first and foremost, by the agency,* and desired the agency... to possess whatever degree of discretion the ambiguity allows.")(emphasis added).

air quality is "safe" does not require that it be "risk free."[83] Furthermore, even a requirement to provide an "ample" margin of safety to protect public health does "*not* ... preclude consideration of any factor."[84]

The "adequa[cy]" of a margin of safety cannot be determined in the abstract. Like purchasing insurance to protect against the possibility that a risk will become a reality, how much margin is "adequate" will depend on a broad range of factors including the certainty, size and nature of the risk, and on the cost of providing that insurance (or "margin" of safety) to protect against that predicted risk.[85]

If insurance can be provided at little cost, it may be worth the price. If insurance is so costly that it would impoverish those to be protected, it should be rejected as doing "more harm than good."[86] Similarly, in the case of a non-threshold pollutant where some health risk is assumed at any level above "zero," what margin of safety is "adequate" can be informed only by striking the balance contemplated by the purposes section of the Act.

Congress in 1977 also adopted a "significant risk" standard as the threshold for regulation under the NAAQS

[83] *NRDC v. EPA, ("Vinyl Chloride")*, 824 F.2d 1146, 1164 (D.C. Cir. 1987) (*en banc*) (*citing Industrial Union Dep't*, 448 U.S. at 642).

[84] *Vinyl Chloride*, 824 F.2d at 1155 (emphasis added).

[85] *Cf. id.* at 1165 (in setting National Emission Standards for Hazardous Air Pollutants, the Administrator "must ... decide what risks are acceptable in the world in which we live.") (*citing Industrial Union Dep't*, 448 U.S. at 642 ("There are many activities that we engage in every day ... that entail some risk of accident or material health impairment [that] few people would consider 'unsafe.'")).

[86] *See* Breyer, *supra* note 12, at 11; *see also Vinyl Chloride*, 824 F.2d at 1148.

program.[87] A number of commentators have explained that the significance of risk cannot be determined in isolation from the costs of eliminating that risk.[88]

In short, determining whether an existing NAAQS provides an "adequate" margin of safety, or whether a revised NAAQS is "requisite" to protect the "public health," are quintessential risk management judgments that require a balancing of all factors relevant to promoting the public's health. This authorizing language does not call on the Administrator *to ignore* the consequences of her decisions; rather, she can promote the public health only by considering those consequences and striking the balance contemplated by § 101(b) of the Act.

This conclusion finds additional support in the language of § 108 describing the information that must be available for NAAQS decisions. For example, § 108(a) provides that the criteria document that is considered in making NAAQS

[87] *See* H.R. Rep. No. 95-294, at 3, 48-49 (1977), *reprinted in* 4 *1977 Legis. Hist., supra* note 8, at 2470, 2515-16, OJA 3675, 3676-77 (adopting the endangerment standard as "the standard of proof which the Administrator must meet *before* promulgating regulations controlling the emissions of any air pollutant ... under this act.") (emphasis added); *Ethyl Corp.*, 541 F.2d at 12, 16, 31-32 (The "will endanger" language has been interpreted to require a finding of "significant risk of harm to the public health.").

[88] Stephen Breyer & Richard Stewart, *Administrative Law & Reg. Policy* 350 (3d ed. 1992); *see also* K. Arrow, *et al.*, *Is There a Role for Benefit-Cost Analysis in Environmental, Health and Safety Regulation?*, 272 Science 221 (1996) (advocating the use of cost benefit analyses in regulatory decisions on environmental protection); R. Morgenstern, ed., *Economic Analyses at EPA*, ix-x (Resources for the Future, Washington, D.C. 1997) ("[T]hough it should never be the only factor on which to base a regulatory decision, economic analysis in its many forms should always be one of the factors.").

decisions is to address "*all* identifiable effects on public health or welfare expected from the presence of such pollutant in the ambient air, in varying quantities," as well as "variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects [of the pollutant] on public health or welfare."[89] A range of health risks might flow from the presence of a pollutant in the ambient air, including both direct effects associated with exposures to the pollutant (e.g., inhalation health risks) and indirect health effects associated with how programs for reducing the pollutant as it is present "in the ambient air" are affected by NAAQS revision.

In other words, a standard that cannot be achieved, or that will render pollutant reduction efforts more "difficult, counter-productive, or confusing," Brief of Respondent EPA, at 73 (D.C. Cir. No. 97-1441), as compared to available alternatives, has identifiable and adverse impacts on public health. "[A]ll identifiable effects" of the pollutant as influenced by such real world factors are appropriate topics for consideration in the criteria document and by EPA during the NAAQS rulemaking. Indeed, in a portion of its decision not challenged by EPA, the lower court rejected EPA's refusal to construe the "all identifiable effects" language to include the UVB radiation effects of ozone reduction. 175 F.3d at 1051-52, App. 43a-46a. Clearly, this language is not limited to inhalation-related effects, as EPA has construed it.

Section 108 also directs EPA to address in its criteria "all identifiable effects" on "public ... welfare," CAA § 108(a)(2), a term that includes "economic values." CAA § 302(h). EPA must also provide "simultaneously" with issuance of the criteria document information on the "cost ...

[89] *See NRDC*, 902 F.2d at 973 (emphasis added) *(citing* CAA § 108(a)(2)).

energy requirements, emission reduction benefit, and environmental impact" of alternative control strategies. CAA § 108(b)(1). In view of this statutory language, EPA is required to have available to it for any NAAQS rulemaking all of the information it needs to exercise sound risk management judgment. That Congress directed EPA to develop this information under § 108 in time for consideration in NAAQS rulemakings does not mean that EPA must ignore it, but rather supports the conclusion that EPA should exercise its risk management judgment in light of this information and consistent with the statutory purposes of the Act.

In sum, Congress in §§ 108 and 109 did not tell EPA to exercise public health risk management judgment by ignoring the overall consequences of its action. Rather, Congress' broad delegation of risk management authority must be implemented by defining limiting standards that protect the "public health" while promoting the statutory purposes of the Act.

B. Section 109(d) Confirms The Need For Consideration of the Impacts on Society of Decisions on Whether to Revise NAAQS.

Once EPA has established a NAAQS for a pollutant, as it has for both pollutants in this case, Congress directed that EPA revise the standard periodically as "may be appropriate" in accordance with §§ 108 and 109(b). CAA § 109(d)(1). In the case of standard revision, there is by definition a standard in place that the Agency previously determined was "requisite to protect public health" with an "adequate margin of safety."

To establish that standard revision is "appropriate" in accordance with §§ 108 and 109(b), the Agency must explain

why a change in the status quo is "requisite" to protect "public health." In other words, the agency must explain why the existing standard is no longer "appropriate" in accordance with §§ 108 and 109(b) and the revised standard is.

This analysis by definition recognizes the need to evaluate a broad range of relevant factors. *See West v. Gibson*, 527 U.S. 212, 218 (1998) ("The meaning of the word 'appropriate' permits its scope to expand" as changes in the law, or in the world, would require). In other words, the "appropriate" language confirms the importance of the ordinary meaning of "public health" and the statutory purposes as a source of decisional criteria for the Agency's exercise of discretion regarding NAAQS revision.

Furthermore, as discussed above, the broad language of § 109(b) contemplates the exercise of risk management judgment, and the information requirements of § 108 ensure that the Administrator will have at her disposal all of the information required for reasoned "public health" risk management. In the context of standard revision, § 109(d) specifically directs the Administrator to make any "appropriate" revisions "in accordance with § 108" – a provision that requires (under § 108(b)) development of information on implementation impacts "simultaneously" with public health information.

Whether standard revision is "appropriate in accordance with" § 108 and § 109(b) therefore does not limit the factors relevant to the exercise of risk management judgment. Rather, it contemplates the balancing of a range of factors consistent with the purposes of the Act.

In exercising her standard revision authority, Congress also required the Administrator to obtain the advice of her science advisers on a number of factors, including areas where additional knowledge is needed to understand the

adequacy of existing and revised NAAQS, and on the "public health, welfare, social, economic, or energy effects which may result" from alternative implementation programs.[90] CAA § 109(d)(2)(C)(iv).

Some of this information goes to the evaluation of the direct health risks of alternative air quality levels and implementation approaches. Other information goes to the risk management judgment on whether standard revision is "requisite" to protect public health, on whether margins of safety under existing and revised standards are "adequate," and on whether existing standards should be revised at all in light of "areas in which additional knowledge is required to appraise the adequacy" of existing standards. CAA § 109(d)(2)(C)(i).

The Administrator does not dispute that certain of the information her science advisers must develop (e.g., information on the "adequacy" and "basis" of existing and revised standards) is relevant to her decision on standard revision. She has asserted, however, that other information that must be developed (e.g., impacts resulting from alternative attainment strategies) is irrelevant to revising the standard.

The statute on its face does *not* direct the Administrator to consider only *some* of these § 109(d) factors and not others in determining what approach to managing uncertain health risk is "appropriate" in accordance with the "adequate" margin of safety and the "requisite" to protect "public health" language of § 109(b). Indeed, it would be unreasonable to conclude

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[90] *See International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 648 (D.C. Cir. 1973) (heightened standard of explanation required to override science advisor's advice).

that Congress wanted EPA to have all of this information before it, but to consider only some of it.[91]

Congress, of course, commented in legislative history that the type of information identified in § 109(d) may be "of interest and assistance to the States and Congress."[92] Nevertheless, Congress directed CASAC *in the statute* "to advise the *Administrator* with respect to any harmful effects" of standard revision in the context of her consideration of standard revision. CAA § 109(d)(2)(C)(i) (emphasis added).

As this Court has recognized, an agency has a heightened burden to explain its decision to change an existing regulatory program.[93] In this case, where existing air quality standards were in place that EPA had previously determined were "requisite to protect the public health" with an "adequate margin of safety," CAA § 109(b)(1), the Agency cannot fulfill its obligation of reasoned decisionmaking by ignoring information that Congress told it to develop.

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[91] *Cf. id.* at 642 (where data are uncertain or ambiguous, EPA must consider the "nature and consequences of the risk of error" in making regulatory decisions).

[92] H.R. Rep. No. 95-294, at 183 (1977), *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 8, at 2650, OJA 3680.

[93] *See MVMA*, 463 U.S. at 42 ("[A]n agency changing its course ... is obligated to supply a reasoned analysis for the change *beyond that* which may be required when an agency does not act in the first instance.") (emphasis added); *see also Public Lands Council v. Babbitt*, 120 S.Ct. 1815, 1828-29 (2000) (O'Connor, J., concurring) ("Under [*MVMA v. State Farm*], an agency that departs from its previous rules will be found to have acted arbitrarily and capriciously, if it fails 'to supply a reasoned analysis for the change ....'").

C. The Legislative History Confirms the Need For Balancing to Promote the Purposes of the Act.

The legislative history confirms the message of the statutory language that Congress intended the Agency to exercise sound public health risk management judgment in light of the purposes of the Act and the commonly understood meaning of "public health."

In enacting the NAAQS program in 1970, the Senate explained that the "primary" NAAQS were to set a "national health minimum" standard which would provide a "reasonable degree of protection." *See* S. Rep. No. 91-1196, at 10, *reprinted in* 1 *1970 Legis. Hist.*, *supra* note 7, at 410, OJA 3687. With this understanding, Congress left States the option to establish an ambient air quality standard "more stringent" than the "national health minimum." *Id.*

In 1977, when it amended the Act, Congress understood that the NAAQS did not incorporate a "no risk philosophy" and explained that NAAQS should reflect the principle that "public [health] policy ... [be] wise policy."[94] Further reflecting Congress' delegation of authority to EPA to manage (not eliminate) health risk to achieve the Act's "public" health objective, Congress established in 1977 an additional CAA program to prevent significant deterioration (PSD) of air quality in areas where air quality is better than the NAAQS.[95]

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[94] *See* H.R. Rep. No. 95-294, at 127, *reprinted in* 4 *1977 Legis. Hist.*, *supra* note 8, at 2594, OJA 3678; *Hearings on S. 251, S. 252 and S. 253 Before the Subcomm. on Environmental Pollution of the Sen. Comm. on Env't and Pub. Works*, 95th Cong., 1st Sess., at 6-7 (1977) (Chmn. Muskie); *see also id.* at 37.

[95] *See* CAA Title I, Part C, §§ 160-169.

In arguing for this "non-degradation" program, Senator Muskie, the Clean Air Act's chief sponsor, explained that

> "the national primary and secondary standards were set for dirty air areas as the minimum necessary and the minimum reasonably attainable in the dirty area areas.... Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.... At any level between zero pollution and *the pollution permitted by national primary standards, there are health effects.*"[96]

This PSD program is intended to address "*any actual or potential* adverse effect," CAA § 160(1) (emphasis added), thereby addressing health risks not addressed by the "public health" standards established under § 109. In other words, Congress in 1977 recognized that not all predicted *health risks* are *public health* risks, and Congress therefore responded with a separate program to address those health and welfare risks at levels of air pollution lower than specified by the NAAQS. Given this statutory matrix, Congress could not have intended that EPA ignore all of the costs and practical impacts of the risk management judgments required in setting the public health-based NAAQS.

In 1990, Congress enacted extensive amendments to the Clean Air Act, but did not amend the NAAQS program in §§ 108 and 109. Thus, Congress left in place a program that delegates to EPA authority to exercise public health risk

[96] *See* 123 Cong. Rec. 18460, *reprinted in* 3 *1977 Legis. Hist.*, *supra* note 8, at 1030 (emphasis added), OJA 3669.

management judgment in setting and revising NAAQS. Implicit in that delegation is the obligation for the Agency to "give clear indication that it has exercised the discretion with which Congress has empowered it."[97] Far from directing the Agency to ignore factors that are relevant to the exercise of reasoned risk management judgment, the legislative history of the 1970 Act and the 1977 Amendments to § 109 confirms that this discretion must be exercised in a manner that furthers the statutory purposes of the Act.

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As the Court has said, judges "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency."[98] In this case, there is nothing on the face of the Act that directs the Administrator, in exercising her judgment to determine whether a standard revision is appropriate, to ignore the broad impacts of her decision on society. To the contrary, the common understanding of "public health" regulation and the explicit statutory language in § 101(b)(1) of the Act requires the Agency to strike a balance considering all factors.

III. *LEAD INDUSTRIES*, WHICH THE LOWER COURT CITES AS THE BASIS FOR ITS DECISION, SHOULD BE OVERRULED.

Without parsing the language of the statute or even mentioning the purposes section of the Act, the lower court has simply relied on *Lead Industries*, and subsequent cases

[97] *Phelps Dodge Corp. v. NLRB*, 313 U.S. 177, 197 (1941).

[98] *FDA v. Brown & Williamson Tobacco Corp.*, 120 S.Ct. 1291, 1301 (2000).

citing *Lead Industries*,[99] for the proposition that the Administrator is precluded from considering the broad impacts of her decision on society in exercising her public health risk management responsibilities. 175 F.3d at 1040-41, App. 19a-21a. According to the court, this is a simple matter of statutory construction that can be resolved under "step one" of *Chevron*. *See id.* at 1040 (explaining that *Lead Industries* was decided "in *Chevron* step one terms").

The *Lead Industries* case, however, was decided before *Chevron* and found clarity of congressional expression in § 109 where none exists. Indeed, as discussed above, a *Chevron* "step one" analysis of all of the relevant Clean Air Act provisions, including the purposes section of the Act, confirms that EPA has broad discretion to consider and to balance all relevant factors in making "public health" risk management decisions. Because *Lead Industries* as applied by the lower court is at odds with the statute, it should be overruled.

First, as discussed above, nothing on the face of the statute directs EPA in exercising risk management judgment to ignore the broad impacts of its decision on society. In fact, as the D.C. Circuit observed in *Lead Industries*, "[s]ection 109(b) does not specify precisely what Congress had in mind when it directed the Administrator to prescribe air quality standards that are 'requisite to protect the public health.'" 647 F.2d at 1152.

Where Congress has delegated in broad terms, it is for the agency to fill out the statutory provision "within the limits of [the congressional] delegation."[100] Reflecting this established principle, the D.C. Circuit has repeatedly held in

[99] *American Petroleum Inst.*, 665 F.2d at 1148; *NRDC*, 902 F.2d at 973.

[100] *Chevron*, 467 U.S. at 865; *see also Smiley*, 517 U.S. at 740-41.

the wake of this Court's decision in *Chevron* that an agency is free to consider costs when not expressly precluded from doing so by statute.[101] Indeed, as discussed above, a determination that regulation is "requisite" to protect the "public health" with an "adequate" margin of safety in response to predicted and theoretical health risk cannot be made *without* considering the overall impacts of the decision on society, including the costs of that decision.

Second, while the *Lead Industries* court asserted that the structure of the Act and legislative history supported its broad statement that costs can play no role in the promulgation of air quality standards, just the opposite conclusion is more appropriate in cases where the Agency must exercise risk management judgment to address uncertain and predicted health risk. In this case, Congress explained that the NAAQS program does not contemplate "zero risk" regulation. Congress therefore called on EPA to exercise judgment as to what risk is acceptable, in setting standards that are "requisite" to protect the "public health" with an "adequate" margin of safety. That judgment cannot be exercised without an understanding of the overall consequences of the Agency's action.

Third, the *Lead Industries* court reasoned that the "technology-forcing" nature of the CAA supports the conclusion that Congress wanted EPA to ignore the costs and feasibility of control technologies in setting NAAQS. 647

[101] *See, e.g., Michigan v. EPA*, No. 98-1497, 2000 WL 180650, at *12 (D.C. Cir. Mar. 3, 2000) ("[O]nly where there is a 'clear congressional intent to preclude consideration of costs' ... [do] we find agencies barred from considering costs."); *see also, e.g., Vinyl Chloride*, 824 F.2d at 1155; *George E. Warren Corp. v. EPA*, 159 F.3d 616, 622-23 (D.C. Cir. 1998); *Grand Canyon Tour Coalition v. FAA*, 154 F.3d 455, 475 (D.C. Cir. 1998).

F.2d at 1149. However, this has little relevance to the exercise of public health risk management judgment. In other words, NAAQS that are set to reflect sound risk management principles will still require industrial sources to install whatever controls it takes to achieve those NAAQS. Similarly, while the D.C. Circuit has pointed to congressional statements that sources would have to shut down if they could not meet the NAAQS as supporting its construction of § 109, *see Vinyl Chloride*, 824 F.2d at 1159, sources would still have to shut down if they could not meet a NAAQS that reflects the exercise of sound public health risk management judgment.

Finally, Congress did *not* re-enact § 109 of the Clean Air Act in 1990, nor did it amend § 109 to codify the lower court's interpretations of § 109. No changes were made to § 109 in 1990. As a result, isolated statements in the 1990 legislative history (which EPA has argued suggest acquiescence to the D.C. Circuit's earlier decisions[102]) should be treated with great skepticism. As this Court has commented, "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."[103] Indeed, where Congress has not been requested to act on a statutory provision, and has taken no action, there is no basis

[102] Brief for the Federal Cross-Respondents in Opposition, at 14-15 (Nos. 99-1426, 99-1431, 99-1442).

[103] *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329, 355 (1998); *Central Bank, N.A. v. First Interstate Bank, N.A.*, 511 U.S. 164, 185-87 (1994) (rejecting application of the "acquiescence doctrine" where Congress had amended other statutory provisions within the Act).

for concluding that Congress as a legislative body had any intent on the matter.[104]

In sum, when EPA regulates pollutant concentrations that are below any known "adverse effects" threshold, there will always be ranges of theoretical and uncertain predictions of health risk. The Agency must examine this range and decide whether standard revision is "appropriate" and will promote the overall goals of the Act.

Congress' delegation to EPA of authority to choose a result that is "appropriate" *does not forbid* consideration of *any* factor relevant to managing public health risks in a way that promotes the purposes of the Act. Therefore, a judicial interpretation of § 109 that precludes consideration of societal costs and related factors must be rejected under any sound *Chevron* "step one" analysis. It is now time to resolve the confusion that has been created by *Lead Industries* by overturning that decision as inconsistent with the Act and the principles enunciated by this Court in *Chevron*.

CONCLUSION

For the reasons stated above, the decision of the lower court that EPA is precluded from considering the broad impacts of its decision on society in exercising risk management judgment under § 109 should be reversed,

[104] *See Central Bank N.A.*, 511 U.S. at 185-87; *id.* at 186 (*citing* U.S. CONST. art. I, § 7, cl. 2). *See also Immigration and Naturalization Serv. v. Chadha*, 462 U.S. 919, 954 (1983) ("Amendment and repeal of statutes, no less than enforcement, must conform with Article I.").

and the standards should be vacated because they were not based on consideration of all relevant factors.

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July 20, 2000