

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 17, 1998

Decided May 14, 1999

No. 97-1440

American Trucking Associations, Inc., et al.,
Petitioners

v.

United States Environmental Protection Agency,
Respondent

Commonwealth of Massachusetts, et al.,
Intervenors

Consolidated with

Nos. 97-1546, 97-1548, 97-1551, 97-1552, 97-1553,
97-1555, 97-1559, 97-1561, 97-1562, 97-1565, 97-1567,
97-1571, 97-1573, 97-1574, 97-1576, 97-1578, 97-1579,
97-1582, 97-1585, 97-1586, 97-1587, 97-1588, 97-1592,
97-1594, 97-1596, 97-1597, 97-1598

No. 97-1441

American Trucking Associations, Inc., et al.,
Petitioners

v.

United States Environmental Protection Agency,
Respondent

Commonwealth of Massachusetts, et al.,
Intervenors

Consolidated with

Nos. 97-1502, 97-1505, 97-1508, 97-1509, 97-1510,
97-1512, 97-1513, 97-1514, 97-1518, 97-1519, 97-1526,
97-1531, 97-1539, 97-1566, 97-1568, 97-1570, 97-1572,
97-1575, 97-1584, 97-1589, 97-1591, 97-1595, 97-1619

On Petitions for Review of an Order of the
Environmental Protection Agency

F. William Brownell argued the cause for the Non-State Clean Air Act Petitioners/Intervenors in 97-1441. With him on the briefs were Henry V. Nickel, Edward W. Warren, Gary E. Marchant, Robert R. Gasaway, Daniel R. Barney, Lynda S. Mounts, Stephen A. Bokat, Robin S. Conrad, Dimitri G. (Jim) Daskal, Peter S. Glaser, G. William Frick, M. Elizabeth Cox, Jan Amundson, David E. Menotti, William F. Pedersen, Julie C. Becker, Harold P. Quinn, Jr., David M. Flannery, L. Poe Leggette, Russell S. Frye, Kathy D. Bailey, Roy S. Belden, Cynthia H. Evans, Maurice H. McBride, David F. Zoll, Alexandra Dapolito Dunn, Jeffrey

L. Leiter, Chet M. Thompson, Douglas I. Greenhaus, Grant Crandall, Eugene M. Trisko, David M. Friedland, Gary H. Baise, Steven F. Hirsch, Erika Z. Jones, Timothy S. Bishop, Timothy L. Harker, Thomas J. Graves and James M. Rinaca.

Edward W. Warren argued the cause for Small Business Petitioners and Intervenor in 97-1440 and 97-1441. With him on the briefs were Daniel R. Barney, Lynda S. Mounts, Gary E. Marchant, Robert R. Gasaway, Stephen A. Bokat, Robin S. Conrad, Dimitri G. (Jim) Daskal, Jan S. Amundson, Henry V. Nickel, F. William Brownell, Ross S. Antonson, Jeffrey L. Leiter, Chet M. Thompson, Douglas I. Greenhaus, David M. Friedland, Gary H. Baise, Steven F. Hirsch, Erika Z. Jones, Timothy S. Bishop, Barry M. Hartman and Leif King.

Susan E. Ashbrook and Andrew S. Bergman, Assistant Attorneys General, State of Ohio, Thomas L. Casey, Solicitor General, John C. Scherbarth and Todd B. Adams, Assistant Attorneys General, State of Michigan, and Mark J. Rudolph, Deputy Chief, State of West Virginia Division of Environmental Protection, were on the briefs for the State Petitioners in 97-1440 and 97-1441.

David J. Kaplan, Attorney, U.S. Department of Justice, and Robert G. Dreher, Counsel, U.S. Environmental Protection Agency, argued the cause for respondent in 97-1441.

With David J. Kaplan on the brief were Lois J. Schiffer, Assistant Attorney General, Alice L. Mattice and Naikang Tsao, Attorneys, U.S. Department of Justice, Amey W. Marrella, Michael L. Goo and Gerald K. Gleason, Counsel, U.S. Environmental Protection Agency.

Howard I. Fox argued the cause in 97-1441 and filed the briefs in 97-1440 and 97-1441 for intervenor American Lung Association.

Edward G. Bohlen, Assistant Attorney General, State of Massachusetts, Catherine A. Tormey, Deputy Attorney General, State of New Jersey, Kimberly P. Massicotte, Assistant

Attorney General, State of Connecticut, John H. Hasen, Assistant Attorney General, State of Vermont, Jared Snyder and Andrew J. Gershon, Assistant Attorneys General, State of New York, and Maureen D. Smith, Assistant Attorney General, State of New Hampshire, were on the brief for intervenor Massachusetts and New Jersey, and amici curiae New York, et al. in 97-1441. John M. Looney, Jr., Assistant Attorney General, State of Connecticut, entered an appearance.

C. Boyden Gray and Alan Charles Raul were on the brief for Amicus Curiae Congressman Tom Bliley in 97-1441.

David E. Menotti and William F. Pedersen argued the cause for Non-State Petitioners on Fine Particulate Matter National Ambient Air Quality Standards in 97-1440. With them on the briefs were David H. Kim, Jeffrey A. Knight, Daniel R. Barney, Lynda S. Mounts, Steven A. Bokas, Robin S. Conrad, Julie Becker, David M. Flannery, L. Poe Leggette, Edward W. Warren, Gary E. Marchant, Robert R. Gasaway, Dimitri G. Daskal, Harold P. Quinn, Jr., Russell B. Frye, Kathy D. Bailey, Cynthia H. Evans, Jan S. Amundson, Douglas I. Greenhaus, G. William Frick, M. Elizabeth Cox, Victoria A. Cochran, Henry V. Nickel, F. William Brownell, Ross S. Antonson, David M. Friedland, Jeffrey L. Leiter, Chet M. Thompson, Gary H. Baise, Steven F. Hirsch, Erika Z. Jones, Peter S. Glaser, Kurt E. Blase, Timothy S. Bishop, Maurice H. McBride, David F. Zoll, Kathryn Smith, Christina Franz, Michael A. McCord and James M. Rinaca.

Robert E. Yuhnke argued the cause for Environmental Group and Citizen Petitioners in 97-1440. With him on the briefs was David S. Baron.

Steven J. Burr argued the cause for the Industry Petitioners on Coarse Particulate Matter National Ambient Air Quality Standards in 97-1440. With him on the briefs were Harold P. Quinn, Jr., Erika Z. Jones, Timothy S. Bishop and Vicki Arroyo Cochran.

Mary F. Edgar, Attorney, U.S. Department of Justice, and Robert G. Dreher, Counsel, U.S. Environmental Protection Agency, argued the cause for respondent in 97-1440. With Mary F. Edgar on the brief were Lois J. Schiffer, Assistant Attorney General, Norman L. Rave, Jr., Naikang Tsao and Cecilia E. Kim, Attorneys, U.S. Department of Justice, Gerald K. Gleason and Michael L. Goo, Counsel, U.S. Environmental Protection Agency. Karen L. Egbert, Attorney, U.S. Department of Justice, and Amey W. Marrella, Counsel, U.S. Environmental Protection Agency, entered appearances.

Edward G. Bohlen, Assistant Attorney General, State of Massachusetts, Catherine A. Tormey, Deputy Attorney General, State of New Jersey, John M. Looney, Jr., Assistant Attorney General, State of Connecticut, William H. Sorrell, Attorney General, and Ronald A. Shems, Assistant Attorney General, State of Vermont, Jared Snyder, Assistant Attorney General, State of New York, and Maureen D. Smith, Assistant Attorney General, State of New Hampshire, were on the brief for intervenors Massachusetts and New Jersey, and amici curiae New York, et al. in 97-1440. Andrew J. Gershon, Assistant Attorney General, State of New York, entered an appearance.

C. Boyden Gray and Alan Charles Raul were on the brief for amicus curiae Senator Orrin Hatch in 97-1440.

Before: Williams, Ginsburg and Tatel, Circuit Judges.

Opinion for the Court filed PER CURIAM.1

Separate opinion dissenting from Part I filed by Circuit Judge Tatel.

PER CURIAM:

Introduction

The Clean Air Act requires EPA to promulgate and periodically revise national ambient air quality standards

1Judge Williams wrote Parts I and III.B; Judge Ginsburg wrote Parts II, III.A, and IV.D; Judge Tatel wrote Parts IV.A-C.

("NAAQS") for each air pollutant identified by the agency as meeting certain statutory criteria. See Clean Air Act ss 108-09, 42 U.S.C. ss 7408-09. For each pollutant, EPA sets a "primary standard"--a concentration level "requisite to protect the public health" with an "adequate margin of safety"--and a "secondary standard"--a level "requisite to protect the public welfare." Id. s 7409(b).

In July 1997 EPA issued final rules revising the primary and secondary NAAQS for particulate matter ("PM") and ozone. See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652 (1997) ("PM Final Rule"); National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (1997) ("Ozone Final Rule"). Numerous

petitions for review have been filed for each rule.

In Part I we find that the construction of the Clean Air Act on which EPA relied in promulgating the NAAQS at issue here effects an unconstitutional delegation of legislative power. See U.S. Const. art. I, s 1 ("All legislative powers herein granted shall be vested in a Congress of the United States."). We remand the cases for EPA to develop a construction of the act that satisfies this constitutional requirement.

In Part II we reject the following claims: that s 109(d) of the Act allows EPA to consider costs; that EPA should have considered the environmental damage likely to result from the NAAQS' financial impact on the Abandoned Mine Reclamation Fund; that the NAAQS revisions violated the National Environmental Policy Act ("NEPA"), Unfunded Mandates Reform Act ("UMRA"), and Regulatory Flexibility Act ("RFA").

In Part III we decide two ozone-specific statutory issues, holding that the 1990 revisions to the Clean Air Act limit EPA's ability to enforce new ozone NAAQS and that EPA cannot ignore the possible health benefits of ozone.

Finally, in Part IV we resolve various challenges to the PM NAAQS. We agree with petitioners that EPA's choice of PM₁₀ as the indicator for coarse particulate matter was arbitrary and capricious; we reject petitioners' claims that EPA must treat PM_{2.5} as a "new pollutant," that EPA must identify a biological mechanism explaining PM's harmful effects, and that the Clean Air Act requires secondary NAAQS to be set at levels that eliminate all adverse visibility effects.

The remaining issues cannot be resolved until such time as EPA may develop a constitutional construction of the act (and, if appropriate, modify the disputed NAAQS in accordance with that construction).

I. Delegation

Certain "Small Business Petitioners" argue in each case that EPA has construed ss 108 & 109 of the Clean Air Act so loosely as to render them unconstitutional delegations of legislative power. We agree. Although the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable, EPA appears to have articulated no "intelligible principle" to channel its application of these factors; nor is one apparent from the statute. The nondelegation doctrine requires such a principle. See *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928). Here it is as though Congress commanded EPA to select "big guys," and EPA announced that it would evaluate candidates based on height and weight, but revealed no cut-off point. The announcement, though sensible in what it does say, is fatally incomplete. The reasonable person responds, "How tall? How heavy?"

EPA regards ozone definitely, and PM likely, as non-threshold pollutants, i.e., ones that have some possibility of some adverse health impact (however slight) at any exposure level above zero. See Ozone Final Rule, 62 Fed. Reg. at 38,863/3 ("Nor does it seem possible, in the Administrator's

judgment, to identify [an ozone concentration] level at which it can be concluded with confidence that no 'adverse' effects are likely to occur."); National Ambient Air Quality Standards for Ozone and Particulate Matter, 61 Fed. Reg. 65,637, 65,651/3 (1996) (proposed rule) ("[T]he single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur."). For convenience, we refer to both as non-threshold pollutants; the indeterminacy of PM's status does not affect EPA's analysis, or ours.

Thus the only concentration for ozone and PM that is utterly risk-free, in the sense of direct health impacts, is zero. Section 109(b)(1) says that EPA must set each standard at the level "requisite to protect the public health" with an "adequate margin of safety." 42 U.S.C. s 7409(b)(1). These are also the criteria by which EPA must determine whether a revision to existing NAAQS is appropriate. See 42 U.S.C. s 7409(d)(1) (EPA shall "promulgate such new standards as may be appropriate in accordance with ... [s 7409(b)]"); see also *infra* Part II.A. For EPA to pick any non-zero level it must explain the degree of imperfection permitted. The factors that EPA has elected to examine for this purpose in themselves pose no inherent nondelegation problem. But what EPA lacks is any determinate criterion for drawing lines. It has failed to state intelligibly how much is too much.

We begin with the criteria EPA has announced for assessing health effects in setting the NAAQS for non-threshold pollutants.¹ They are "the nature and severity of the health

¹Technically, EPA describes the criteria as used only for setting the "adequate margin of safety." There might be thought to be a separate step in which EPA determines what standard would protect public health without any margin of safety, and that step might be governed by different criteria. But EPA did not use such a process, and it need not. See *NRDC v. EPA*, 902 F.2d 963,

effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed." Ozone Final Rule, 62 Fed. Reg. at 38,883/2; EPA, "Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information: OAQPS Staff Paper," at II-2 (July 1996) ("PM Staff Paper") (listing same factors). Although these criteria, so stated, are a bit vague, they do focus the inquiry on pollution's effects on public health. And most of the vagueness in the abstract formulation melts away as EPA applies the criteria: EPA basically considers severity of effect, certainty of effect, and size of population affected. These criteria, long ago approved by the judiciary, see *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1161 (D.C. Cir. 1980) ("Lead Indus-

tries"), do not themselves speak to the issue of degree.

Read in light of these factors, EPA's explanations for its decisions amount to assertions that a less stringent standard would allow the relevant pollutant to inflict a greater quantum of harm on public health, and that a more stringent standard would result in less harm. Such arguments only support the intuitive proposition that more pollution will not benefit public health, not that keeping pollution at or below any particular level is "requisite" or not requisite to "protect the public health" with an "adequate margin of safety," the formula set out by s 109(b)(1).

Consider EPA's defense of the 0.08 ppm level of the ozone NAAQS. EPA explains that its choice is superior to retaining the existing level, 0.09 ppm, because more people are exposed to more serious effects at 0.09 than at 0.08. See Ozone Final Rule, 62 Fed. Reg. at 38,868/1. In defending the decision not to go down to 0.07, EPA never contradicts the intuitive proposition, confirmed by data in its Staff Paper, that reducing the standard to that level would bring about comparable changes. See EPA, "Review of National Ambient Air Quality Standards for Ozone: Assessment of Scientific

973 (D.C. Cir. 1990). Thus, the criteria mentioned in the text govern the whole standard-setting process.

and Technical Information: OAQPS Staff Paper," at 156 (June 1996) ("Ozone Staff Paper"). Instead, it gives three other reasons. The principal substantive one is based on the criteria just discussed:

The most certain O₃-related effects, while judged to be adverse, are transient and reversible (particularly at O₃ exposures below 0.08 ppm), and the more serious effects with greater immediate and potential long-term impacts on health are less certain, both as to the percentage of individuals exposed to various concentrations who are likely to experience such effects and as to the long-term medical significance of these effects.

Ozone Final Rule, 62 Fed. Reg. at 38,868/2.

In other words, effects are less certain and less severe at lower levels of exposure. This seems to be nothing more than a statement that lower exposure levels are associated with lower risk to public health. The dissent argues that in setting the standard at 0.08, EPA relied on evidence that health effects occurring below that level are "transient and reversible," Dissent at 5, evidently assuming that those at higher levels are not. But the EPA language quoted above does not make the categorical distinction the dissent says it does, and it is far from apparent that any health effects existing above the level are permanent or irreversible.

In addition to the assertion quoted above, EPA cited the consensus of the Clean Air Scientific Advisory Committee ("CASAC") that the standard should not be set below 0.08. That body gave no specific reasons for its recommendations, so the appeal to its authority, also made in defense of other standards in the PM Final Rule, see PM Final Rule, 62 Fed. Reg. at 38,677/2 (daily fine PM standard); *id.* at 38,678/3 (annual coarse PM standard); *id.* at 38,679/1 (daily coarse PM standard), adds no enlightenment. The dissent stresses the undisputed eminence of CASAC's members, Dissent at 4, but the question whether EPA acted pursuant to lawfully delegated authority is not a scientific one. Nothing in what CASAC says helps us discern an intelligible principle derived by EPA from the Clean Air Act.

Finally, EPA argued that a 0.07 standard would be "closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O₃ precursors, and thus more likely to be inappropriately targeted in some areas on such sources." Ozone Final Rule, 62 Fed. Reg. at 38,868/3. But a 0.08 level, of course, is also closer to these peak levels than 0.09. The dissent notes that a single background observation fell between 0.07 and 0.08, and says that EPA's decision "ensured that if a region surpasses the ozone standard, it will do so because of controllable human activity, not uncontrollable natural levels of ozone." Dissent at 6. EPA's language, coupled with the data on background ozone levels, may add up to a backhanded way of saying that, given the national character of the NAAQS, it is inappropriate to set a standard below a level that can be achieved throughout

the country without action affirmatively extracting chemicals from nature. That may well be a sound reading of the statute, but EPA has not explicitly adopted it.

EPA frequently defends a decision not to set a standard at a lower level on the basis that there is greater uncertainty that health effects exist at lower levels than the level of the standard. See Ozone Final Rule, 62 Fed. Reg. at 38,868/2; PM Final Rule, 62 Fed. Reg. at 38,676/3 (annual fine PM standard); *id.* at 38,677/2 (daily fine PM standard). And such an argument is likely implicit in its defense of the coarse PM standards. See PM Final Rule, 62 Fed. Reg. at 38,678/3-79/1. The dissent's defense of the fine particulate matter standard cites exactly such a justification. See Dissent at 6 ("The Agency explained that 'there is generally greatest statistical confidence in observed associations ... for levels at and above the mean concentration [in certain studies]' ") (emphasis added in dissent). But the increasing-uncertainty argument is helpful only if some principle reveals how much uncertainty is too much. None does.

The arguments EPA offers here show only that EPA is applying the stated factors and that larger public health harms (including increased probability of such harms) are, as expected, associated with higher pollutant concentrations. The principle EPA invokes for each increment in stringency

(such as for adopting the annual coarse particulate matter standard that it chose here)--that it is "possible, but not certain" that health effects exist at that level, see PM Final Rule, 62 Fed. Reg. at 38,678/32--could as easily, for any non-threshold pollutant, justify a standard of zero. The same indeterminacy prevails in EPA's decisions not to pick a still more stringent level. For example, EPA's reasons for not lowering the ozone standard from 0.08 to 0.07 ppm--that "the more serious effects ... are less certain" at the lower levels and that the lower levels are "closer to peak background levels," see Ozone Final Rule, 62 Fed. Reg. at 38,868/2--could also be employed to justify a refusal to reduce levels below those associated with London's "Killer Fog" of 1952. In that calamity, very high PM levels (up to 2,500 Sg/m³) are believed to have led to 4,000 excess deaths in a week.³ Thus, the agency rightly recognizes that the question is one of degree, but offers no intelligible principle by which to identify a stopping point.

The latitude EPA claims here seems even broader than that OSHA asserted in *International Union, UAW v. OSHA* ("Lockout/Tagout I"), 938 F.2d 1310, 1317 (D.C. Cir. 1991), which was to set a standard that would reduce a substantial risk and that was not infeasible. In that case, OSHA thought itself free either to "do nothing at all" or to "require precautions that take the industry to the brink of ruin," with "all positions in between ... evidently equally valid." *Id.* Here, EPA's freedom of movement between the poles is equally unconstrained, but the poles are even farther apart--the maximum stringency would send industry not just to the

²EPA did cite qualitative evidence for further support for its annual standard, and argued that the evidence "does not provide evidence of effects below the range of 40-50 Sg/m³," the standard level. PM Final Rule, 62 Fed. Reg. at 38,678/3. The referenced document, however, bears no indication that the qualitative evidence demonstrates effects at the level of the standard, either. See EPA, "Air Quality Criteria for Particulate Matter," at 13-79 (April 1996).

³See W.P.D. Logan, "Mortality in the London Fog Incident, 1952," *The Lancet*, Feb. 4, 1953, at 336-38.

brink of ruin but hurtling over it, while the minimum stringency may be close to doing nothing at all.

In *Lockout/Tagout I* certain special conditions that have justified an exceptionally relaxed application of the nondelegation doctrine were absent, *id.* at 1317-18, and they are equally absent here. The standards in question affect the whole economy, requiring a "more precise" delegation than would otherwise be the case, see *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 553 (1935). No "special theories" justifying vague delegation such as the war powers of the President or the sovereign attributes of the delegatee have been or could be asserted. Nor is there some inherent

characteristic of the field that bars development of a far more determinate basis for decision. (This is not to deny that there are difficulties; we consider some below.)

EPA cites prior decisions of this Court holding that when there is uncertainty about the health effects of concentrations of a particular pollutant within a particular range, EPA may use its discretion to make the "policy judgment" to set the standards at one point within the relevant range rather than another. *NRDC v. EPA*, 902 F.2d 962, 969 (D.C. Cir. 1990); *American Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Lead Industries*, 647 F.2d at 1161 (D.C. Cir. 1980). We agree. But none of those panels addressed the claim of undue delegation that we face here, and accordingly had no occasion to ask EPA for coherence (for a "principle," to use the classic term) in making its "policy judgment." The latter phrase is not, after all, a self-sufficient justification for every refusal to define limits.

It was suggested at oral argument that EPA's vision of its discretion in application of s 109(b)(1) is no broader than that asserted by OSHA after a remand by this court and upheld by this court in *International Union, UAW v. OSHA* ("Lock-out/Tagout II"), 37 F.3d 665 (D.C. Cir. 1994). But there, in fact, OSHA allowed itself to set only standards falling somewhere between maximum feasible stringency and some "moderate" departure from that level. *Id.* at 669. As our prior discussion should have indicated, here EPA's formulation of

its policy judgment leaves it free to pick any point between zero and a hair below the concentrations yielding London's Killer Fog.

The dissent argues that a nondelegation challenge similar to this one was rejected in *South Terminal Corp. v. EPA*, 504 F.2d 646 (1st Cir. 1974), and cites that case's language that "the rationality of the means can be tested against goals capable of fairly precise definition in the language of science," *id.* at 677. See Dissent at 2. But the action challenged in *South Terminal* was EPA's adoption of a plan for ending or preventing violations in Boston of already-established NAAQS, not its promulgation of the NAAQS themselves. Thus, it seems likely that the "means" were the plan's provisions--e.g., a prohibition on most new parking in the city, see 504 F.2d at 671, and the "fairly precise[ly] defin[ed]" goals were the NAAQS themselves.

Where (as here) statutory language and an existing agency interpretation involve an unconstitutional delegation of power, but an interpretation without the constitutional weakness is or may be available, our response is not to strike down the statute but to give the agency an opportunity to extract a determinate standard on its own. *Lockout/Tagout I*, 938 F.2d at 1313. Doing so serves at least two of three basic rationales for the nondelegation doctrine. If the agency develops determinate, binding standards for itself, it is less likely to exercise the delegated authority arbitrarily. See *Amalgamated Meat Cutters v. Connally*, 337 F. Supp. 737, 758-59 (D.D.C. 1971) (Leventhal, J., for three-judge panel). And such standards enhance the likelihood that meaningful judicial review will prove feasible. See *id.* at 759. A remand of this sort of course does not serve the third key function of non-delegation doctrine, to "ensure[] to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will," *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 685 (1980) ("Benzene") (Rehnquist, J., concurring). The agency will make the fundamental policy choices. But the remand does ensure that the courts not hold unconstitutional a statute

that an agency, with the application of its special expertise, could salvage. In any event, we do not read current Supreme Court cases as applying the strong form of the nondelegation doctrine voiced in Justice Rehnquist's concurrence. See *Mistretta v. United States*, 488 U.S. 361, 377-79 (1989).

What sorts of "intelligible principles" might EPA adopt? Cost-benefit analysis, mentioned as a possibility in *Lock-out/Tagout I*, 938 F.2d at 1319-21, is not available under decisions of this court. Our cases read s 109(b)(1) as barring EPA from considering any factor other than "health effects relating to pollutants in the air." *NRDC*, 902 F.2d at 973; see also *Lead Industries*, 647 F.2d at 1148; *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998); *American Petroleum Inst.*, 665 F.2d at 1185 (echoing the same themes).

In theory, EPA could make its criterion the eradication of any hint of direct health risk. This approach is certainly determinate enough, but it appears that it would require the agency to set the permissible levels of both pollutants here at zero. No party here appears to advocate this solution, and EPA appears to show no inclination to adopt it.⁴

EPA's past behavior suggests some readiness to adopt standards that leave non-zero residual risk. For example, it has employed commonly used clinical criteria to determine what qualifies as an adverse health effect. See *Ozone Staff*

4A zero-risk policy might seem to imply de-industrialization, but in fact even that seems inadequate to the task (and even if the calculus is confined to direct risks from pollutants, as opposed to risks from the concomitant poverty). First, PM (at least) results from almost all combustion, so only total prohibition of fire or universal application of some heretofore unknown control technology would reduce manmade emissions to zero. See *PM Staff Paper* at IV-1. Second, the combustion associated with pastoral life appears to be rather deadly. See *World Bank, World Development Report 1992: Development and the Environment* 52 (1992) (noting that "biomass" fuels (i.e., wood, straw, or dung) are often the only fuels that "poor households, mostly in rural areas" can obtain or afford, and that indoor smoke from biomass burning "contributes to acute respiratory infections that cause an estimated 4 million deaths annually among infants and children.").

Paper at 59-60 (using American Thoracic Society standards to determine threshold for "adverse health effect" from ozone). On the issue of likelihood, for some purposes it might be appropriate to use standards drawn from other areas of the law, such as the familiar "more probable than not" criterion.

Of course a one-size-fits-all criterion of probability would make little sense. There is no reason why the same probability should govern assessments of a risk of thousands of deaths as against risks of a handful of people suffering momentary shortness of breath. More generally, all the relevant variables seem to range continuously from high to

low: the possible effects of pollutants vary from death to trivialities, and the size of the affected population, the probability of an effect, and the associated uncertainty range from "large" numbers of persons with point estimates of high probability, to small numbers and vague ranges of probability. This does not seem insurmountable. Everyday life compels us all to make decisions balancing remote but severe harms against a probability distribution of benefits; people decide whether to proceed with an operation that carries a 1/1000 possibility of death, and (simplifying) a 90% chance of cure and a 10% chance of no effect, and a certainty of some short-term pain and nuisance. To be sure, all that requires is a go/no-go decision, while a serious effort at coherence under s 109(b)(1) would need to be more comprehensive. For example, a range of ailments short of death might need to be assigned weights. Nonetheless, an agency wielding the power over American life possessed by EPA should be capable of developing the rough equivalent of a generic unit of harm that takes into account population affected, severity and probability. Possible building blocks for such a principled structure might be found in the approach Oregon used in devising its health plan for the poor. In determining what conditions would be eligible for treatment under its version of Medicaid, Oregon ranked treatments by the amount of improvement in "Quality-Adjusted Life Years" provided by each

treatment, divided by the cost of the treatment.⁵ Here, of course, EPA may not consider cost, and indeed may well find

5The "quality" of various health states was determined by poll, and medical professionals determined the probabilities and durations of various health states with and without the treatment in question.

Oregon was twice forced to revise its system because the United States Department of Health & Human Services determined that the original proposal and a revision violated the Americans with Disabilities Act, 42 U.S.C. ss 12101-12213. The reason given for this determination was that both versions undervalued the lives of persons with disabilities: The original plan measured quality of life according to the attitudes of the general population rather than the attitudes of persons with disabilities. See HHS, "Analysis Under the Americans with Disabilities Act ('ADA') of the Oregon Reform Demonstration" (Aug. 3, 1992), reprinted in 9 Issues in L. & Med. 397, 410, 410 (1994). The revised plan ranked treatments leaving the patient in a "symptomatic" state lower than those leaving the patient asymptomatic, and certain disabling conditions were considered "symptoms." See Letter from Timothy B. Flanagan, Assistant Attorney General, to Susan K. Zagame, Acting General Counsel, HHS (Jan. 19, 1993), reprinted in 9 Issues in L. & Med. 397, 418, 421 (1994). The Department's determination was extensively criticized when issued. See Maxwell J. Mehlman et al., "When Do Health Care Decisions Discriminate Against Persons with Disabilities?" 22 J. Of Health Politics, Policy & L. 1385, 1390 (1997) (HHS's "decision provoked a storm of disbelief and denunciation").

We take no position on whether HHS's view was correct, or if the underlying norm also governs EPA's decisions under s 109(b)(1). An affirmative answer, however, would not seem to preclude use of some of Oregon's approach. The first step would be giving appropriate weight to the views of persons with disabilities. The second might be measuring the seriousness of a pollution-induced health effect by the absolute level of well-being that the effect brings about, not by the decrease in level that the effect causes. In other words, if the maximum well-being level is 100 and the average asthmatic whose asthma constitutes a disability has a well-being of 80 in the absence of air pollution (according to a measure that appropriately considers asthmatics' own assessments of their condi-

a completely different method for securing reasonable coherence. Alternatively, if EPA concludes that there is no principle available, it can so report to the Congress, along with such rationales as it has for the levels it chose, and seek legislation ratifying its choice.

We have discussed only the primary standards. Because the secondary standards are at least in part based on those, see Ozone Final Rule, 62 Fed. Reg. at 38,875/3-76/1; PM Final Rule, 62 Fed. Reg. at 38,680/3, we also remand the cases to the agency with regard to the secondary standards as well, for further consideration in light of this opinion.

II. Other General Claims

The petitioners and amici contend that the EPA erroneously failed to consider a host of factors in revising the PM and ozone NAAQS. We reject each of these claims in turn.

A. Consideration of Cost in Revising Standards

As this court long ago made clear, in setting NAAQS under s 109(b) of the Clean Air Act, the EPA is not permitted to consider the cost of implementing those standards. See *Lead Industries*, 647 F.2d at 1148 (D.C. Cir. 1980); see also *NRDC*, 902 F.2d at 973 (following *Lead Industries* in reviewing particulate matter NAAQS); *American Petroleum Inst.*, 665 F.2d at 1185 (same, in reviewing ozone NAAQS). The petitioners make four unsuccessful attempts to distinguish *Lead Industries* and its progeny.

First, the petitioners claim that in *Lead Industries* we held only that the Clean Air Act does not compel the EPA to consider the costs of implementation in setting a NAAQS; on the contrary, we held that the Act precludes the EPA from doing so. See *Lead Industries*, 647 F.2d at 1148 ("the statute

tion), then a response to air pollution that reduces the asthmatics' well-being to 70 could be counted as an effect of magnitude 30 (the difference from full health), rather than 10 (the difference from the level without the pollution). That approach would ensure that effects on persons with disabilities were not underestimated, even in the broad sense of that term apparently adopted by HHS.

and its legislative history make clear that economic considerations play no part in the promulgation of [NAAQS]").

Second, that we decided *Lead Industries* prior to the Supreme Court's decision in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984) does not, as the petitioners suggest, require us to revisit the earlier case. The *Lead Industries* decision was made in *Chevron* step one terms, see *id.*, as the post-*Chevron* progeny of *Lead Industries* have made clear. See *NRDC*, 902 F.2d at 973 ("Consideration of costs ... would be flatly inconsistent with the statute, legislative history and case law on this point"); *NRDC v. EPA*, 824 F.2d 1146, 1158C59 (D.C. Cir. 1987) (in banc) ("*Vinyl Chloride*") ("[S]tatute on its face does not allow consideration of technological or economic feasibility.... Congress considered the alternatives and chose to close down sources or even industries rather than to allow risks to health").

Third, though the petitioners are correct that in *Lead Industries* we interpreted s 109(b), which governs the setting of NAAQS, and not s 109(d), which governs the revising of NAAQS, we can discern no legally relevant difference in the two sections that would make *Lead Industries* inapplicable to s 109(d). Section 109(d)(1) directs the EPA to:

complete a thorough review of the criteria published under section 7408 of this title and the [NAAQS] promulgated under this section and [to] make such revisions in such criteria and standards and promulgate such new

standards as may be appropriate in accordance with
section 7408 of this title and subsection (b) of this section.

42 U.S.C. s 7409(d)(1). The petitioners contend that consideration of costs is one pertinent factor in determining whether revision of a NAAQS is "appropriate," but this argument ignores the clause immediately following "appropriate," which incorporates s 109(b) and thereby affirmatively precludes consideration of costs in revising NAAQS. Section 108(b), 42 U.S.C. s 7408(b), does require the EPA to provide the States with information on the cost of implementing NAAQS, but the reference to s 108 does not permit consideration of costs in setting NAAQS because it clearly relates back to the require-

ment that the EPA "make ... revisions in ["the criteria published under section 7408"] ... as may be appropriate." And insofar as the air quality criteria do apply to the setting of NAAQS, they do so through s 109(b), which (again) precludes the consideration of costs and which is explicitly incorporated into s 109(d)(1). See id. s 7409(b)(1) (primary NAAQS to be "based on [the air quality] criteria" issued under s 108).

Fourth, the petitioners point to s 109(d)(2), which creates the CASAC and requires it to advise the EPA about, among other things, "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such [NAAQS]." Id. s 7409(d)(2)(C)(iv). Why, ask the petitioners, would the CASAC be required to advise the EPA about these matters if the EPA were not then supposed to consider its advice in the course of revising the NAAQS? As above, however, the petitioners overlook that s 109(d)(1) directs the EPA to review and to revise, as appropriate, the air quality standards issued under s 108 as well as the NAAQS promulgated under s 109(b). The advice required in s 109(d)(2)(C)(iv) is pertinent only to the EPA's duty under s 108 to provide the States with control strategy information.

B.Environmental Consequences of Implementing NAAQS

The State Petitioners argue that the EPA erred in failing "to consider the environmental consequences resulting from the financial impact of the [revised PM2.5 and ozone NAAQS] on the federal Abandoned Mine Reclamation Fund Act." This argument is squarely foreclosed by our decision in NRDC. In reviewing the EPA's previous revision of the PM NAAQS, we rejected the argument that the EPA "erred in refusing to consider the health consequences of unemployment in determining the primary [NAAQS] for particulate matter" and held that "[i]t is only health effects relating to pollutants in the air that EPA may consider." 902 F.2d at 972-73 (emphasis in original). Unlike the positive health benefits of ozone that we hold (in Part III.B, below) the EPA

must consider, any detrimental health effects resulting from the financial impact upon the mine fund, like the health consequences of unemployment, are traceable to the cost of complying with the revised PM2.5 and ozone NAAQS and not to the presence of those pollutants in the air.

C.The National Environmental Policy Act

In challenging both the revised PM2.5 and ozone NAAQS, the State Petitioners also argue that the EPA failed to comply with certain requirements of the NEPA. The petitioners recognize that the Congress has exempted all actions under the Clean Air Act, including the setting of NAAQS, from the central requirement of the NEPA, namely, the preparation of an Environmental Impact Statement. Compare 42 U.S.C. s 4332(2)(C)-(D) (agency must prepare EIS in all "major Federal actions significantly affecting the quality of the human environment"), with 15 U.S.C. s 793(c)(1) ("No action taken under the Clean Air Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of the [NEPA]"). Nonetheless, they suggest that the EPA is required to complete the functional equivalent of an EIS and also to comply with other requirements in the NEPA, see 42 U.S.C. s 4332(2)(B), (E), (G). State Petitioners' PM Brief at 20; State Petitioners' Ozone Brief at 19. We reject each of these suggestions.

First, the State Petitioners contend that this court has "recognized that the '[CAA], properly construed, requires the functional equivalent of a NEPA impact statement,' " *id.* (quoting *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 384 (1973)). Our decision in *Portland Cement*, however, actually construed only "section 111 of the Clean Air Act." By replacing these words with "[CAA]" in their briefs, the petitioners misrepresent our interpretation of a single section of the Clean Air Act, dealing with emission standards for stationary sources, as an interpretation of the entire Act. Even if the petitioners were correct, however, *Portland Ce-*

ment predated, and is now superseded by, the statutory exemption in 15 U.S.C. s 793(c)(1), which the Congress added in 1974.

Second, the State Petitioners contend that a provision of the NEPA "requires that EPA weigh 'economic considerations.' " The section to which the petitioners refer reads as follows: "all agencies of the Federal Government shall ... identify and develop methods and procedures ... which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations." 42 U.S.C. s 4332(2)(B). Even if this section is properly read generally to require an agency to consider implementation costs, s 109(d)(1) specifically prohibits the EPA from doing so. And the NEPA provides that it shall not "in any way affect the specific statutory obligations of any Federal agency ... to comply with criteria or standards of environmental quality." 42 U.S.C. s 4334(1). Therefore, s 4332(2)(B) cannot require the EPA to disregard the prohibition in s 109(d)(1) upon the consideration of costs in setting NAAQS.

The State Petitioners' remaining arguments--that the EPA failed to comply with two other sections of the NEPA--fare little better. Section 4332(2)(E) requires federal agencies to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." As with s 4332(2)(B), insofar as s 4332(2)(E) can be read to require the EPA to consider the costs of implementing NAAQS when revising those standards, contrary to the prohibition in s 109(d)(1), s 4334(1) prevents it from having any effect.

If, on the other hand, s 4332(2)(E) is understood in the context of the Clean Air Act to require the EPA merely to discuss implementation alternatives, then it, like the similar s 4332(2)(G) with which the petitioners also claim the EPA failed to comply, is the functional equivalent of s 108(b)(1). That section requires the EPA to provide the States with, among other things, "such data as are available on available

technology and alternative methods of prevention and control of air pollution." As we recognize with regard to the requirement that the agency prepare an EIS, "[c]ompliance with NEPA's ... requirement[s] has not been considered necessary when the agency's organic legislation mandates procedures for considering the environment that are 'functional equivalents' of the [NEPA's] process." Izaak Walton League of Am. v. Marsh, 655 F.2d 346, 367 n.51 (1981). The rationale for the functional equivalence doctrine is the well-established principle that a "general statutory rule usually does not govern unless there is no more specific rule." Green v. Bock Laundry Mach. Co., 490 U.S. 504, 524 (1989); see also Alabama ex rel. Siegelman v. EPA, 911 F.2d 499, 504-05 (11th Cir. 1990) (citing cases). The NEPA is the general statute requiring agencies to consider environmental harms, whereas the Clean Air Act is the more specific and its equivalent provisions apply in place of those in the NEPA. See Portland Cement, 486 F.2d at 386 (finding functional equivalence when more specific statute strikes "workable balance between some of the advantages and disadvantages of full application of NEPA").

Our analysis of the petitioners' contentions leads us to conclude that nothing in the NEPA requires the EPA in setting NAAQS to consider or to discuss matters that the Clean Air Act does not already permit or require.

D. The Unfunded Mandates Reform Act

The State Petitioners in the particulate matter case and Congressman Bliley in the ozone case both contend that the EPA is required by the Unfunded Mandates Reform Act, 2 U.S.C. s 1501 et seq., to prepare a Regulatory Impact Statement (RIS) when setting a NAAQS, see id. s 1532, and to choose the least burdensome from a range of alternative permissible NAAQS, see id. s 1535. Even if the petitioners and the amicus are correct regarding the interaction of the UMRA and the CAA--a point the EPA strongly contests--we can provide them with no relief. See id. s 1571(a)(3) ("[T]he inadequacy or failure to prepare [a RIS] ... shall not be used as a basis for staying, enjoining, invalidating or

otherwise affecting [an] agency rule"); id. s 1571(b) ("Except as provided in [s 1571(a), which does not mention s 1535,] ... any compliance or noncompliance with the provisions of this chapter ... shall not be subject to judicial review; and no provision of this chapter shall be construed to [be] ... enforceable by any person in any ... judicial action").

The State Petitioners, recognizing the limitations upon judicial review in s 1571, contend that the EPA's failure to prepare a RIS can nonetheless render the NAAQS arbitrary and capricious, see 42 U.S.C. s 7607(d)(9), relying upon *Thompson v. Clark*, 741 F.2d 401 (D.C. Cir. 1984). In that case, we interpreted a statute that, like the UMRA, both specified that the RIS be included in the record for judicial review and precluded judicial review of an agency's compliance with the RIS requirement. We held that a "reviewing court will consider the contents of the [RIS], along with the rest of the record, in assessing not the agency's compliance with the [requirement to prepare the RIS], but the validity of the rule under other provisions of law." Id. at 405. No information in a RIS, however, could lead us to conclude that the EPA improperly set the PM and ozone NAAQS; the only information such a statement would add to the rulemaking record for a NAAQS would pertain to the costs of implementation, see 2 U.S.C. s 1532(a), and the EPA is precluded from considering those costs in setting a NAAQS. Accordingly, the failure to prepare a RIS does not render the NAAQS arbitrary and capricious.

E.The Regulatory Flexibility Act

In both the ozone and particulate matter cases, the Small Business Petitioners argue that the EPA improperly certified that the revised NAAQS would not have a significant impact upon a substantial number of small entities. The Regulatory Flexibility Act, 5 U.S.C. s 601 et seq., as amended in 1996 by the Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, tit. II, 110 Stat. 857-74 ("SBREFA"), requires an agency, when engaging in notice and comment rulemaking, to "prepare and make available for public comment an initial regulatory flexibility analysis.... [that] de-

scribe[s] the impact of the proposed rule on small entities," 5 U.S.C. s 603(a), including small businesses, small organizations, and small governmental jurisdictions, see id. s 601(6). When promulgating a final rule, an agency must describe "the steps ... taken to minimize the significant economic impact on small entities." Id. s 604(a)(5). According to the petitioners, if the EPA had complied with the RFA, it would likely have promulgated less stringent PM and ozone NAAQS than those actually chosen, which would have reduced the burden upon small entities.

A regulatory flexibility analysis is not required, however, if the agency "certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." Id. s 605(b). Further, the SBREFA made no change in the requirement that a regulatory flexibility analysis conducted pursuant to the RFA include estimates of "the number of small entities to which the proposed rule will apply" and of "the classes of small entities which will be subject to the requirement." 5 U.S.C. s 603(b)(3)-(4). We have consistently interpreted the RFA, based upon these sections, to impose no obligation upon an agency "to conduct a small entity impact analysis of effects on entities which it does not regulate." *Motor & Equip. Mfrs. Ass'n v. Nichols*, 142 F.3d 449, 467 & n.18 (1998).

The EPA certified that its revised NAAQS will "not have a significant economic impact on small entities within the meaning of the RFA." PM Final Rule, 62 Fed. Reg. at 38,702/2; Ozone Final Rule, 62 Fed. Reg. at 38,887/2-3. According to the EPA, the NAAQS themselves impose no regulations upon small entities. Instead, the several States regulate small entities through the state implementation plans (SIPs) that they are required by the Clean Air Act to develop. See 42 U.S.C. s 7410. Because the NAAQS therefore regulate small entities only indirectly--that is, insofar as they affect the planning decisions of the States--the EPA concluded that small entities are not "subject to the proposed regulation." See *Mid-Tex Elec. Coop., Inc. v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985); see also id. at 343 ("Congress did not intend to require that every agency consider every indirect effect

that any regulation might have on small businesses in any stratum of the national economy.").

The EPA's description of the relationship between NAAQS, SIPs, and small entities strikes us as incontestable. The States have broad discretion in determining the manner in which they will achieve compliance with the NAAQS. The EPA "is required to approve a state plan which provides for the timely attainment and subsequent maintenance of ambient air standards" and cannot reject a SIP based upon its view of "the wisdom of a State's choices of emission limitations," *Train v. NRDC*, 421 U.S. 60, 79 (1975) (emphasis in original), or of the technological infeasibility of the plan. See *Union Elec. Co. v. EPA*, 427 U.S. 246, 265 (1976). Therefore, a State may, if it chooses, avoid imposing upon small entities any of the burdens of complying with a revised NAAQS. Only if a State does not submit a SIP that complies with s 110, 42 U.S.C. s 7410, must the EPA adopt an implementation plan of its own, which would require the EPA to decide what burdens small entities should bear. The agency has stated, however, that it will do a regulatory flexibility analysis before adopting an implementation plan of its own, as it did in 1994 when proposing such a plan for Los Angeles. See *Ozone Final Rule*, 62 Fed. Reg. at 38,891/1; *PM Final Rule*, 62 Fed. Reg. at 38,705/3.

The responses of the Small Business Petitioners do not persuade us to reject the EPA's argument or to deviate from our holdings in *Mid-Tex* and its progeny. First, the Small Business Petitioners contend that we must defer to the Small Business Administration's interpretation of the Act, as expressed in a letter to the EPA from the SBA's Chief Counsel for Advocacy, that the NAAQS do impose requirements upon small entities. The SBA, however, neither administers nor has any policymaking role under the RFA; at most its role is advisory. See, e.g., 5 U.S.C. ss 601(3), 602(b), 603(a), 605(b), 609(b)(1), 612. Therefore, we do not defer to the SBA's interpretation of the RFA. See *Scheduled Airlines Traffic Offices, Inc. v. Department of Defense*, 87 F.3d 1356, 1361 (D.C. Cir. 1996) (no Chevron deference owed to agency interpretation of statute it does not administer). Nor do we

defer to the EPA's interpretation of the RFA, for it does not administer the Act either. We do, however, find the EPA's interpretation of the statute persuasive.

Second, the Small Business Petitioners argue that the EPA cannot claim both that the NAAQS will have no effect upon small entities and that it will have positive health effects. Clearly, however, the EPA can maintain that the NAAQS will have health effects because the Clean Air Act empowers the agency to ensure that such benefits accrue; and it can maintain that the NAAQS will not directly affect small entities because it has no authority (short of imposing its own implementation plan upon a non-complying state) to impose any burdens upon such entities.

Third, the Small Business Petitioners attempt to distinguish the possible effects upon small entities in this case from the indirect effects that, as we found in *Mid-Tex*, are not within the contemplation of the RFA. But *Mid-Tex* is not so easily distinguished. The petitioners in that case argued that the RFA required the FERC to consider economic effects not only upon regulated industries but also upon the small entities that are their wholesale customers, even though the customers were not directly regulated by the FERC. We rejected that argument, finding a "clear indication" in the language of s 603 that the RFA is "limited to small entities subject to the proposed regulation." *Mid-Tex*, 773 F.2d at 342; see also *Motor & Equip. Mfrs. Ass'n*, 142 F.3d at 467 n.18 ("The RFA itself distinguishes between small entities subject to an agency rule, to which its requirements apply, and those not subject to the rule, to which the requirements do not apply."); *United Distribution Cos. v. FERC*, 88 F.3d 1105, 1170 (1996) (regulatory flexibility analysis provision applies only to "small entities that are subject to the requirements of the rule") (emphasis in original). That the Clean Air Act requires the States to submit SIPs that will achieve compliance with the NAAQS does not, in view of the States' nearly complete discretion to determine which entities will bear the burdens of a revised NAAQS, make such small entities as the SIPs may regulate any more subject to the

EPA's regulation than were the wholesalers in Mid-Tex subject to regulation by the FERC.

Finally, the Small Business Petitioners suggest that the Congress in enacting the SBREFA overruled our prior interpretation of the RFA in Mid-Tex and its progeny. The SBREFA made a number of changes in the RFA, but it did not change anything in s 603 upon which we relied in Mid-Tex. And although the Congress made a slight modification in s 605(b), we do not understand it to alter our analysis in Mid-Tex. Prior to 1996, s 605(b) required an agency to provide "a succinct statement explaining the reasons" for its certification that the promulgated rule would not have a significant economic impact upon small entities. That section now requires "a statement providing the factual basis for such certification." Our decision in Mid-Tex contemplates that an agency may justify its certification under the RFA upon the "factual basis" that the rule does not directly regulate any small entities. Nothing in the change to s 605(b) suggests that basis for certification is no longer permissible. (Indeed, the section of the statute amending s 605(b) is labeled "Technical and Conforming Amendments," see SBREFA s 243, 110 Stat. at 866.) We therefore conclude that the EPA properly certified that its NAAQS would not have a significant impact upon a substantial number of small entities.

III. Ozone

A.Subpart 2 and the Revised Ozone Standard

In 1990 the Congress substantially revised the Clean Air Act by, among other things, adding specific enforcement provisions for carbon monoxide, particulate matter, sulfur oxides, nitrogen dioxide, lead, and as pertinent here, ozone. Previously, the Act required that all areas of the country not attaining the primary ozone standard, no matter how far from attainment, come into compliance "as expeditiously as practicable but not later than December 31, 1987." 42 U.S.C. s 7502 (1988). Many areas had not attained the primary ozone NAAQS by that date; some were still a long way from

doing so. The Congress responded to the continued ozone problem by enacting a new enforcement scheme, which it codified as Subpart 2 of Part D of the Clean Air Act, 42 U.S.C. ss 7511-7511f, redesignating the original provisions as Subpart 1.

Subpart 2 requires the EPA to classify nonattainment areas based upon their design value, which is a rough measure of whether an area complies with the 0.12 ppm, 1-hour primary ozone standard.⁶ A table in Subpart 2, set out here in the margin,⁷ establishes classifications ranging from marginal

⁶More specifically, the design value is the fourth-highest daily maximum ozone concentration in an area over three consecutive years for which there are sufficient data. If that value is less than or equal to 0.12 ppm, then an area will have only three expected values above that level and it will be in attainment with the ozone NAAQS. See EPA, The Clean Air Act Ozone Design Value Study: Final Report 1-1 to 1-22 (1994) (filed pursuant to 42 U.S.C. s 7511b(g), which required the EPA to conduct "a study of whether the [existing design value] methodology ... provides a reasonable indicator of the ozone air quality of ozone nonattainment areas"; the EPA concluded it did).

⁷This table appears in Clean Air Act s 181(a)(1), 42 U.S.C. s 7511(a)(1):

TABLE 1		
Area Class	Design value [ppm]	Primary standard attainment date
Marginal	0.121 up to 0.138	3 years after November 15, 1990
Moderate	0.138 up to 0.160	6 years after November 15, 1990
Serious	0.160 up to 0.180	9 years after November 15, 1990
Severe	0.180 up to 0.280	15 years after November 15, 1990
Extreme	0.280 and above	20 years after November 15, 1990

The Severe Area category is later subdivided, creating a sixth classification for ozone nonattainment areas. See id. s 7511(a)(2)

to extreme, and provides an attainment date for each class. See id. s 7511(a)(1)-(2). Subpart 2 also specifies, for each class of nonattainment areas, both measures that the States must take to reduce emissions of the chemicals that are precursors of ozone and information that the States must report to the EPA. See id. s 7511a. In short, Subpart 2 is the Congress's comprehensive plan for reducing ozone levels throughout the country.

The State and Non-State Petitioners, along with Congressman Bliley appearing as an amicus curiae, argue that Subpart 2 precludes the EPA from revising the primary and secondary ozone NAAQS. We reject this argument (in Part III.A.1)

insofar as it pertains to the EPA's continued ability to promulgate a revised ozone NAAQS or to designate areas as not in attainment with a revised NAAQS. We agree (in Part III.A.2) with those petitioners, however, insofar as they maintain, based upon the text and structure of Subparts 1 and 2, that the EPA is precluded from enforcing a revised primary ozone NAAQS other than in accordance with the classifications, attainment dates, and control measures set out in Subpart 2. Further, we conclude (in Part III.A.3) that the EPA may not require a State to comply with a revised secondary ozone NAAQS in any area that has yet to attain the 0.12 ppm primary standard.

1. The EPA's Power to Revise the Ozone NAAQS and Designate Areas as Nonattainment

The 1990 amendments did not alter the section of the Clean Air Act that provides for setting and revising primary and secondary NAAQS. See 42 U.S.C. s 7409. The Administrator, therefore, still must "at five-year intervals [from December 31, 1980] ... complete a thorough review of ... the [NAAQS] promulgated under this section and ... make such revisions in such ... standards ... as may be appropriate." Id. s 7409(d)(1). The Second Circuit held that this section continues to "set[] forth a bright-line rule for agency action,"

("Notwithstanding table 1, [for] a severe area with a 1988 ozone design value between 0.190 and 0.280 ppm, the attainment date shall be 17 years ... after November 15, 1990").

American Lung Ass'n v. Reilly, 962 F.2d 258, 263 (1992), and we agree. Nothing in the Act modifies this "bright-line rule" or otherwise makes it inapplicable to revision of the ozone NAAQS.

To the extent that the 1990 amendments shed any light upon this question, they suggest that the EPA retains its authority to revise the ozone NAAQS. For example, if the EPA relaxes a NAAQS after enactment of the 1990 amendments, then "the Administrator shall ... promulgate requirements applicable to all areas which have not attained that [relaxed] standard as of the date of such relaxation.... [which] shall provide for controls ... not less stringent than the controls applicable to areas designated nonattainment before such relaxation." 42 U.S.C. s 7502(e). Although two other subsections of s 172 are expressly made inapplicable to the ozone regulations in Subpart 2, see id. s 7502(a)(1)(C), (a)(2)(D), this so-called anti-backsliding provision contains no such exemption. Accordingly, as the EPA notes, this section specifically contemplates that the agency may relax its ozone NAAQS and, therefore, necessarily implies that it retains the authority to revise that NAAQS. Tellingly, neither the petitioners nor the amicus reply to this point.

The petitioners and amicus raise two other arguments to support their position that the EPA cannot alter the ozone NAAQS without the approval of the Congress. We reject both in short order.

First, the Non-State Petitioners contend that Subpart 2 renders revision of the ozone NAAQS "inappropriate" within the meaning of s 109(d)(1), which provides the EPA shall "make such revisions in such ... standards ... as may be appropriate." 42 U.S.C. s 7409(d)(1). This argument, however, pointedly ignores the text immediately following the word "appropriate," which specifies that appropriateness is to be determined "in accordance with section 7408 ... and [s 7409(b)]" (and which, as we read it, means exclusively in accord with those sections). See, e.g., *American Methyl Corp. v. EPA*, 749 F.2d 826, 835-36 (D.C. Cir. 1984). Because Subpart 2 is neither listed in s 109(d)(1) nor incorporated by

reference in either s 108, id. s 7408, or s 109(b), it cannot render revision of the ozone NAAQS inappropriate.

Second, the State Petitioners and Congressman Bliley argue, based upon the classification table in s 181(a)(1), id. s 7511(a)(1), that Subpart 2 codified the 0.12 ppm ozone NAAQS and, therefore, only the Congress can promulgate a revised NAAQS. Yet not all areas designated nonattainment for ozone will have design values of 0.121 ppm or higher. In fact, this was true of areas designated nonattainment for ozone as a result of the 1990 amendments, see Ozone Final Rule, 62 Fed. Reg. at 38,884/3, at least in part because of the stringent criteria in the Clean Air Act for changing the designation of an area to attainment from nonattainment. See 42 U.S.C. 7407(d)(3)(E)(iii) (redesignation permissible only if area's attainment of NAAQS "is due to permanent and enforceable reductions in emissions"). In short, although the numbers in the classification table are based upon the 0.12 ppm ozone NAAQS, they are neither equivalent to nor a codification of the NAAQS.

Not only does the EPA, as we conclude above, retain authority to promulgate a revised ozone NAAQS; the agency is still required, "in no case later than 2 years from the date of promulgation" of a revised NAAQS, to designate areas as attainment, nonattainment, or unclassifiable under that NAAQS. Id. s 7407(d)(1)(B). Although the 1990 amendments extended by roughly 18 months the maximum time between promulgation of a revised NAAQS and designation of nonattainment areas under that NAAQS, see 42 U.S.C. s 7407(d)(1)-(2) (1988), they made no substantive change in the EPA's authority to designate areas as nonattainment under a revised NAAQS. Therefore, we hold that the EPA retains the power to designate areas as nonattainment under a revised ozone NAAQS.

2. The EPA's Power to Enforce the Revised Ozone Standard

That the enactment of Subpart 2 does not alter the EPA's authority to revise the ozone NAAQS or to designate areas as nonattainment for ozone does not, however, compel the con-

clusion that Subpart 2 has no effect upon the EPA's authority to enforce a revised primary ozone NAAQS. (We consider the enforcement of secondary ozone NAAQS in Part III.A.3, below.) In fact, the text and structure of Subparts 1 and 2 suggest precisely the opposite conclusion. After designating an area as nonattainment under a NAAQS, the EPA normally looks to Subpart 1 for authority to "classify the area for the purpose of applying an attainment date." 42 U.S.C. s 7502(a)(1)-(2). The cited provisions, however, do not apply "with respect to nonattainment areas for which classifications [and attainment dates] are specifically provided under other provisions of [Part D of Subchapter 1 of the Clean Air Act]." Id. s 7502(a)(1)(C), (a)(2)(D).

The EPA argues that Subpart 2 specifically provides classifications and attainment dates only for nonattainment designations under the 0.12 ppm ozone NAAQS. The State and Non-State Petitioners counter that Subpart 2 specifically provides classifications and dates for all areas designated nonattainment under any ozone NAAQS. We agree with the petitioners.

The pertinent provision of Subpart 2 reads as follows:

(a) Classification and attainment dates for 1989 nonattainment areas. -- (1) Each area designated nonattainment for ozone pursuant to section 7407(d) of this title shall be classified at the time of such designation, under table 1, by operation of law, as a Marginal Area, a Moderate Area, a Serious Area, a Severe Area, or an Extreme Area....

Id. s 7511(a)(1). As the petitioners note, s 107(d), 42 U.S.C. s 7407(d), specifies three different times at which an area can be designated "nonattainment for ozone": immediately following enactment of the 1990 amendments, id. s 7407(d)(4); after the EPA revises the ozone NAAQS, id. s 7407(d)(1); and when an area that was in attainment, either when the Congress enacted the 1990 amendments or when the EPA promulgated a revised ozone NAAQS, later ceases to comply, id. s 7407(d)(3). The petitioners conclude from the general reference to s 107(d) that the classifications and attainment

dates in Subpart 2 apply to areas designated under ss 107(d)(1), (3), and (4). The EPA gamely responds that the reference to s 107(d) includes only subsection (4), but we do not defer to the agency's interpretation because we find that the Congress has spoken on the "precise question at issue" and we "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc.*, 467 U.S. 837, 842-43 & n.9 (1984). We canvass the two reasons that lead us to this conclusion before returning to the EPA's argument.

First, the reference to s 107(d) in s 181(a)(1) appears to have been purposeful and not the drafting error that the EPA's interpretation implies. The Congress considered but did not adopt bills that clearly would have limited the reach of Subpart 2 to nonattainment designations made immediately following enactment of the 1990 amendments. The Senate bill contained a version of Subpart 2 that classified only those areas designated nonattainment for ozone under its equivalent of s 107(d)(4). See S. 1630, 101st Cong. ss 101, 107, reprinted in III Legislative History of the Clean Air Act Amendments of 1990, at 4124-25, 4195 [hereinafter 1990 Legislative History]. The version of Subpart 2 in the House bill, as originally introduced, similarly referred only to designations made under its equivalent of s 107(d)(4). See H.R. 3030, 101st Cong. ss 101(a), 103, reprinted in II 1990 Legislative History, at 3748-49, 3795-96. The House committee, however, replaced the specific reference to what is now s 107(d)(4) with a general reference to s 107(d). See H.R. Rep. No. 101-490, at 3-6, 17 (1990), reprinted in II 1990 Legislative History, at 3027-30, 3041. The Conference committee then reported the text of the House bill rather than that of the Senate. See H.R. Rep. No. 101-952, at 335 (1990), reprinted in I 1990 Legislative History, at 1785.

Second, our conclusion that the Congress intentionally referred to s 107(d) as a whole is supported by a comparison of Subparts 1 and 2. The Congress enacted Subpart 2 because of the failure of the controls in Subpart 1 to bring areas into attainment with the 0.12 ppm standard in the allotted time. See H.R. Rep. No. 101-490, at 145-50, reprinted in II 1990 Legislative History, at 3169-74. Rather than continue treat-

ing all ozone nonattainment areas alike, the Congress allowed the various areas between 3 and 20 years to attain the ozone NAAQS, depending upon the extent of the area's ozone problem. See *id.* at 146-47 ("In 1977, Congress tried to waive [sic] a 'magic wand' and command that all nonattainment areas [for ozone] will meet the applicable [NAAQS].... by December 31, 1987. ... [That] date[] ha[s] come and gone and it is clear that ... we had no 'magic' solutions."), reprinted in II 1990 Legislative History, at 3170-71. As the petitioners argue, because the 1990 amendments extended the time for nonattainment areas to comply with the 0.12 ppm ozone NAAQS, they must preclude the EPA from requiring areas to comply either more quickly or with a more stringent ozone NAAQS.

Subpart 1 requires compliance with a primary NAAQS "as expeditiously as practicable, but no later than 5 years from the date such area was designated nonattainment." 42 U.S.C. s 7502(a)(2)(A). All nonattainment areas would have until 2012 to comply with the revised ozone NAAQS if the EPA and the States were to take the full time authorized in Subpart 1 for making attainment designations and the EPA were to approve every possible extension for each area. See *id.* ss 7407(d)(1)(A)-(B), 7502(a)(2)(A), (C). Such wide discretion is inconsistent, however, with Subpart 2, in which the Congress stripped the EPA of discretion to decide which ozone nonattainment areas should receive more time to reach attainment (with two limited exceptions not relevant here, see *id.* s 7511(a)(4), (5)). Moreover, under s 181(a) of Subpart 2, Los Angeles, the nation's only Extreme Area, has until 2010 to attain the 0.12 ppm ozone NAAQS, and the possibility of extending that deadline until 2012. That Los Angeles should also have to attain a more stringent ozone standard by that same year, if not earlier, clearly runs counter to the comprehensive enforcement scheme enacted in Subpart 2.

The EPA offers two arguments against this interpretation of Subparts 1 and 2. First, the EPA contends that a recent statute confirms its power to designate nonattainment areas under the revised ozone standard. See Pub. L. No. 105-178, s 6103(a), 112 Stat. 465 (1998) (extending time to two years

from one year for governor to submit proposed designation under 0.08 ppm ozone NAAQS). That statute also specifically states, however, that "[n]othing in section[] ... 6103 shall be construed by the Administrator of Environmental Protection Agency or any court ... to affect any pending litigation or to be a ratification of the ozone ... standard[]." Id. s 6104. Further, even if the EPA were correct that s 6103 confirms the agency's power to designate areas under a revised ozone NAAQS, that power was never in doubt, as we concluded above. Indeed, s 6104 simply does not bear upon the question we address here: whether Subpart 1 or Subpart 2 provides the applicable enforcement mechanisms for an area designated nonattainment under a revised ozone NAAQS.

Second, the EPA argues that read in context the reference to s 107(d) in s 181(a)(1) relates only to designations made under s 107(d)(4). Because the table in s 181(a)(1) classifies areas based upon a design value that roughly measures attainment of the 0.12 ppm ozone NAAQS, the EPA contends that the nonattainment designations referenced in s 181(a)(1) are only those designations made under the 0.12 ppm ozone NAAQS. This explanation, however, does not square with either the Congress's decision not to refer to s 107(d)(4) specifically or the long-term nature of the attainment scheme enacted in Subpart 2; on the EPA's interpretation, that scheme would have been stillborn had the EPA revised the ozone NAAQS immediately after the Congress enacted the 1990 amendments.

The EPA points next to s 181(b)(1), which specifies the attainment dates for areas that met the 0.12 ppm standard when the Congress enacted the 1990 amendments but that later cease to comply. That section, however, applies only to areas designated under s 107(d)(3) that previously were "designated attainment or unclassifiable for ozone under section [107(d)(4)]." That s 181(b)(1) provides special rules for such areas, but not for areas designated under s 107(d)(3) that had previously been designated attainment for ozone or unclassifiable under s 107(d)(1), does not support the EPA's argument that the phrase in s 181(a)(1) "designated nonattainment for ozone pursuant to section 107(d)" denotes only those designa-

tions made under s 107(d)(4). If anything, the specification of s 107(d)(4) in s 181(b)(1) makes its absence from s 181(a)(1) all the more striking.

The final bit of context to which the EPA points is the title of s 181(a): "Classification and attainment dates for 1989 nonattainment areas." Because the title specifies "1989 nonattainment areas," we are told, s 181(a) must refer only to nonattainment designations made immediately after enactment of the 1990 amendments, that is, designations made under s 107(d)(4). Although "the title of a statute or section can aid in resolving an ambiguity in the legislation's text," *INS v. National Ctr. for Immigrants' Rights, Inc.*, 502 U.S. 183, 189 (1991), a title cannot be allowed to create an ambiguity in the first place. See *Maguire v. Commissioner of Internal Revenue*, 313 U.S. 1, 9 (1941) ("[T]he title of an act will not limit the plain meaning of the text."). The text of s 181(a) clearly encompasses nonattainment designations made under all subsections of s 107(d). There simply is no ambiguity in need of resolution by reference to the title of the section.

In sum, s 181(a) "specifically provide[s]" for classifications and attainment dates for areas designated nonattainment for ozone pursuant to s 107(d)(1). Accordingly, Subpart 2, not Subpart 1, provides the classifications and attainment dates for any areas designated nonattainment under a revised primary ozone NAAQS, see 42 U.S.C. s 7502(a)(1)(C), (a)(2)(D), and the EPA must enforce any revised primary ozone NAAQS under Subpart 2.

3. The Secondary Ozone NAAQS

The Non-State Petitioners briefly contend that our conclusion that Subpart 2 provides the classifications and attainment dates for areas designated nonattainment under a revised primary ozone NAAQS is equally applicable to the enforcement of a revised secondary ozone NAAQS. We find it impossible to conclude, however, that Subpart 2 "specifically provide[s]" for classifications and attainment dates for areas designated nonattainment with a revised secondary ozone NAAQS; s 181(a)(1) expressly refers only to primary

NAAQS and Subpart 2 not once mentions secondary NAAQS. Further, attainment dates in Subpart 1 for secondary standards are less stringent than for primary standards, making comparison with the more lenient dates in Subpart 2 less troubling. Compare id. s 7502(a)(2)(B) (attainment of secondary NAAQS "shall be ... achieved as expeditiously as practicable after the date such area was designated nonattainment"), with id. s 7502(a)(2)(A) (attainment of primary NAAQS "shall be ... achieved as expeditiously as practicable, but no later than 5 years from the date such area was designated nonattainment"). Nonetheless, we understand Subpart 2 to codify the Congress's judgment as to what is "as expeditiously as practicable" in reducing an area's level of ozone. Consequently, the EPA is precluded from requiring any steps toward compliance with a revised secondary ozone NAAQS prior to an area's attainment of the 0.12 ppm standard. In areas that meet the 0.12 ppm standard, however, Subpart 2 erects no bar to the EPA's requiring compliance with a revised secondary ozone NAAQS "as expeditiously as practicable."

B.Ozone's Health Benefits

Petitioners presented evidence that according to them shows the health benefits of tropospheric ozone as a shield from the harmful effects of the sun's ultraviolet rays--including cataracts and both melanoma and nonmelanoma skin cancers. In estimating the effects of ozone concentrations, EPA explicitly disregarded these alleged benefits.

EPA explained its decision first as a matter of statutory interpretation. Under the Clean Air Act, EPA's ambient standards for any pollutant are to be "based on [the] criteria" that EPA has published for that pollutant. 42 U.S.C. s 7409(b)(1) & (2). The "criteria," in turn, are to "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." Id. s 7408(a)(2). The reference to "all identifiable effects" would seem on its face to include beneficent effects.

EPA attempts to avoid this straightforward reading in several ways. First, it points to the term "such pollutant," arguing that the statute requires it to focus exclusively on the characteristics that make the substance a "pollutant." But the phrase "pollutant" is simply a label used to identify a substance to be listed and controlled by the statute. While it is perfectly true that a substance known to be utterly without adverse effects could not make it onto the list, this fact of nomenclature does not visibly manifest a congressional intent to banish consideration of whole classes of "identifiable effects."

EPA also relies on the fact that two of the three specified considerations under s 108(a)(2)'s general mandate refer to "adverse effect[s]":

The criteria for an air pollutant, to the extent practicable, shall include information on--

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

Id. s 7408(a)(2) (emphasis added). EPA's argument would be of uncertain force even if all three types of effects specifically required to be considered were spoken of as "adverse effects"; there is no reason to read "adverse" back into the "all identifiable effects" of s 108(a)(2). But as one of the three specified classes refers to "effects" unmodified, id. s 7408(a)(2)(A), we can reject EPA's argument without even reaching that issue. That Congress qualified "effects" in clauses (B) and (C) with "adverse" seems only to strengthen the supposition that in (A)--and in the general mandate--it intended to cover all health or welfare effects. Therefore if petitioners' contentions are right, clause (A) applies to ozone:

the presence of ultraviolet radiation at various levels "alter[s] the effects [of ozone] on public health or welfare" by making them on the whole less malign--perhaps even beneficial.

EPA next argues that Title VI of the Clean Air Act, id. ss 7671-7671q, which mandates certain measures to preserve stratospheric ozone, represents a complete consideration of ozone's beneficial role as a UV shield. Petitioners' claim, however, is that ground-level (tropospheric) ozone--the subject of this rule--has a UV-screening function independent of the ozone higher in the atmosphere. EPA points to nothing in the statute that purports to address tropospheric ozone.

Finally, EPA directs us towards legislative history from the 1970 and 1990 Clean Air Act Amendments. The "all identifi-

able effects" language, however, dates to the 1967 Amendments. Legislative history from the 1970 and 1990 Congresses cannot be "an authoritative interpretation of what the [1967] statute meant," because it is "the function of the courts and not the Legislature, much less a Committee of one House of the Legislature, to say what an enacted statute means." *Pierce v. Underwood*, 487 U.S. 552, 566 (1988).

Under *Chevron*, we defer to an agency's interpretation of a statute if "the statute is silent or ambiguous with respect to the specific issue" and "the agency's answer is based on a permissible construction of the statute." 467 U.S. at 843. We find no such ambiguity in this case. Further, EPA's interpretation fails even the reasonableness standard of *Chevron*'s second part: it seems bizarre that a statute intended to improve human health would, as EPA claimed at argument, lock the agency into looking at only one half of a substance's health effects in determining the maximum level for that substance. At oral argument even EPA counsel seemed reluctant to claim that the statute justified disregard of the beneficial effects of a pollutant bearing directly on the health symptoms that accounted for its being thought a pollutant at all (suppose, for example, a chemical that both impedes and enhances breathing, depending on the person or circumstances); he also seemed unable to distinguish that case from

the one here--where the chemical evidently impedes breathing but provides defense against various cancers.

Legally, then, EPA must consider positive identifiable effects of a pollutant's presence in the ambient air in formulating air quality criteria under s 108 and NAAQS under s 109. EPA's other arguments are technical, and are of two sorts: those that allegedly show petitioners' studies to be fatally flawed and those that allegedly show specific inflation of results in these studies. We need only consider the first sort, for EPA chose to give the studies no weight at all.

Petitioners rely primarily on studies by Lutter and Cupitt. EPA found that these could be ignored because the marginal benefits are difficult, if not impossible, to quantify reliably and because there is "no convincing basis for concluding that any such effects ... would be significant." But these are not the criteria by which EPA assesses adverse health effects. It does not rigorously or uniformly demand either quantifiability, see, e.g., Ozone Final Rule, 62 Fed. Reg. at 38,860/3 (admitting that "quantitative risk estimates could not be developed" for certain adverse effects of ozone on which EPA regulated); EPA Ozone Brief at 48 (defending consideration of various effects that "played an important role in the Administrator's final decision" despite absence of quantification: "EPA did not estimate the risk for such effects because 'information [was] too limited to develop quantitative estimates,'--not because there is doubt the effects occur.") (alteration and emphasis in original) (citation omitted), or any specific level of significance. As we can see no reason for imposing a higher information threshold for beneficent effects than for maleficent ones, we have no basis for affirming EPA's decision to disregard the studies.

As we said above, we are remanding to EPA to formulate adequate decision criteria for its ordinary object of analysis--ill effects. We leave it to the agency on remand to determine whether, using the same approach as it does for those, tropospheric ozone has a beneficent effect, and if so, then to assess ozone's net adverse health effect by whatever criteria it adopts.

IV. Particulate Matter

A. PM₁₀ as Coarse Particle Indicator

We now turn to petitioners' challenges to the Agency's regulation of coarse particulate pollution. Both the 1987 NAAQS and the proposed standards regulate all particles with diameters under 10 micrometers, signified by the indicator PM₁₀. The PM₁₀ spectrum includes both coarse and fine particles. While the main distinction between coarse and fine particles is the process by which they are produced, EPA and epidemiologists who study the health effects of particulate pollution identify coarse and fine particles through rough approximations of those particles' diameters. Coarse particles, which become airborne usually from the crushing and grinding of solids, generally have diameters between 2.5 and 10 micrometers and can thus be identified by the indicator PM_{10-2.5}. Fine particles, indicated in these new NAAQS by PM_{2.5}, come mainly from combustion or gases and generally have diameters of 2.5 micrometers or less.

Despite EPA's conclusion that coarse and fine particles pose independent and distinct threats to public health, the Agency chose not to adopt an indicator, such as PM_{10-2.5}, that would measure only the coarse fraction of PM₁₀. Petitioners make two arguments: that there is no scientific basis for regulating coarse particles at all, and that even if there were, retention of the PM₁₀ indicator simultaneously with the establishment of the new fine particle indicator is unsupported by evidence in the record and arbitrary and capricious. We agree with this latter argument.

Beginning with petitioners' first challenge, we think the record contains sufficient evidence to justify the Agency's decision to regulate coarse particulate pollution. While the relationship between PM₁₀ pollution and adverse health effects justifying the 1987 NAAQS was well-established, see *NRDC v. EPA*, 902 F.2d 962, 967-68 (D.C. Cir. 1990), two studies contained in the record of these proceedings concentrated specifically on the health effects caused by the coarse fraction of PM₁₀ pollution. See Mary Ellen Gordian et al., "Particulate Air Pollution and Respiratory Disease in Anchor-

age, Alaska," 104 *Envtl. Health Persp.* 290 (1996) (studying volcanic ash); Brockton J. Hefflin et al., "Surveillance for Dust Storms and Respiratory Diseases in Washington State, 1991," 49 *Archives of Env'tl. Health* 170 (1994) (studying fugitive dust). In addition, the record contains at least nine multivariate analyses finding statistically significant relationships with health effects for both PM_{2.5} and PM₁₀, suggesting that the portion of PM₁₀ pollution unaccounted for by PM_{2.5} (i.e., coarse particles) explains some of the observed adverse health effects. In other words, because regression analysis holds the PM_{2.5} component constant, the PM₁₀ effect recognized in these equations actually evidences results from coarse particulate pollution. To be sure, petitioners have pointed to some evidence to the contrary. But given that our review is limited to "ascertaining that the choices made by

the Administrator were reasonable and supported by the record," and does not include "judg[ing] the merits of competing expert views," *Lead Industries*, 647 F.2d at 1160, we find ample support for EPA's decision to regulate coarse particulate pollution above the 1987 levels.

Having found independent health consequences from coarse particulate pollution, EPA nevertheless decided to regulate the coarse fraction of PM₁₀ indirectly, using PM₁₀ (which includes both coarse and fine PM) as a "surrogate for coarse fraction particles." PM Final Rule, 62 Fed. Reg. at 38,668/2. While recognizing that PM₁₀-2.5 would have served as a satisfactory coarse particle indicator, EPA offers three justifications for its decision to use PM₁₀ instead: (1) Both the Gordian and Hefflin studies used PM₁₀, not PM₁₀-2.5, as the variable in their models, (2) the PM₁₀ standards will work in conjunction with the PM_{2.5} standards by regulating the portion of particulate pollution not regulated by the PM_{2.5} standards, and (3) a nationwide monitoring program for PM₁₀ already exists. We find none of these explanations persuasive.

As to the first argument, while acknowledging that the indicator used in the studies captures both coarse and fine particles, EPA nevertheless maintains that PM₁₀ is an effective indicator for the regulation of coarse particulate pollu-

tion. "Adopting the indicator used in the studies," the Agency says, "increases the likelihood that the level selected will result in the health protections predicted." But as EPA's own staff paper suggests, PM₁₀ is "inherently confounded" by the presence of PM_{2.5} particles, meaning that any regulation of PM₁₀ pollution will include both coarse and fine particles. See PM Staff Paper at V-59. Using PM₁₀ as the coarse particle indicator, instead of PM_{10-2.5}, will thus regulate more than just the coarse fraction of PM₁₀, and the amount of coarse particulate pollution permitted will depend (quite arbitrarily) on the amount of PM_{2.5} pollution in the air. For example, assuming the 50 microgram annual PM₁₀ level adopted by the Agency and a region with an annual PM_{2.5} pollution level of 15 micrograms, the PM₁₀ indicator would prohibit coarse particulate (PM_{10-2.5}) pollution from exceeding 35 micrograms. But in an area with only 5 micrograms of PM_{2.5} pollution, the NAAQS would permit coarse particulate pollution to reach as high as 45 micrograms.

EPA's second argument--that the PM₁₀ standard will work in conjunction with the PM_{2.5} standard--suffers from the same deficiency. Accepting EPA's finding of "profound physicochemical differences" between coarse and fine PM, PM Staff Paper at V-59, such that each requires independent regulation, we cannot discern exactly how a PM₁₀ standard, instead of a PM_{10-2.5} standard, will work alongside a PM_{2.5} standard to regulate only the coarse fraction of PM₁₀. EPA provides no explanation to aid us in understanding its decision. In fact, as the example above indicates, it is the very presence of a separate PM_{2.5} standard that makes retention of the PM₁₀ indicator arbitrary and capricious. Far from working in conjunction to regulate coarse particles, PM₁₀ and PM_{2.5} indicators, when used together, lead to "double regulation" of the PM_{2.5} component of PM₁₀ and potential underregulation of the PM_{10-2.5} component since the amount of PM_{10-2.5} permitted will always depend on the amount of PM_{2.5} in the air.

EPA's final argument is pragmatic. It maintains that PM₁₀ is a better indicator than PM_{10-2.5} for coarse particulate pollution because a nationwide monitoring program for PM₁₀

already exists. But as EPA acknowledges elsewhere in its brief, NRDC bars EPA from considering factors unrelated to public health in setting air quality standards. Echoing our decision in Vinyl Chloride, NRDC held that "the Administrator may not consider cost and technological feasibility in determining what is 'safe'; such a determination 'must be based solely upon the risk to health.'" NRDC, 902 F.2d at 973 (quoting Vinyl Chloride, 824 F.2d 1146, 1166 (D.C. Cir. 1990) (in banc)); see also American Petroleum Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981); Lead Industries, 647 F.2d at 1148-55. The administrative convenience of using PM10 cannot justify choosing an indicator poorly matched to the relevant pollution agent.

In view of our conclusion that PM10 amounts to an arbitrary indicator for coarse particle pollution, we need not address petitioners' separate challenge to the PM10 levels or secondary standards. We note, however, that whatever levels the Agency ultimately selects for coarse particle pollution will need to comply with the requirements set forth in Part I of this opinion.

B.Fine Particles as "New Pollutant"

The Attorneys General of Ohio, Michigan, and West Virginia ("state petitioners") argue that EPA is regulating PM2.5 for the first time. Because they consider PM2.5 to be a "new pollutant," they argue that s 108 of the Clean Air Act requires EPA to conduct further research on PM2.5's health effects before listing it as a pollutant, to issue an air quality criteria document reflecting the latest science on the health effects of the pollutant, and to assist states by developing "data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology." 42 U.S.C. s 7408(b)(1).

Although EPA never responds to this argument, five northeastern states (as respondent intervenors and amici) do. Pointing out that previous NAAQS have always included PM2.5, these attorneys general support the EPA's decision not to list PM2.5 separately as a new pollutant. We agree.

The state petitioners cannot escape the fact that the original standards for particulate pollution using Total Suspended Particulates (TSP) as indicator, as well as the 1987 NAAQS that used PM10, included by definition every particle 2.5 micrometers and smaller. Moreover, in some areas fine particles often dominate PM10 pollution. See PM Staff Paper at V-63. By refining the NAAQS to focus on smaller particles that EPA found posed distinct threats to public health, EPA has done with these regulations exactly what we held it could do in 1987 when it made the change from Total Suspended Particulates to PM10. See NRDC, 902 F.2d at 965-66. EPA's decision to update the NAAQS to focus on PM2.5 merely continues a trend based on evolving science. It does not violate the provisions of s 108 of the Clean Air Act.

C.Failure to Identify a Biological Mechanism for Particulate Pollution's Relationship to Adverse Health Effects

Also challenging the establishment of a fine particle standard, non-state petitioners argue that EPA failed to explain the biological mechanism through which particulate pollution causes adverse health effects. Even if epidemiological studies show robust statistical relationships between pollution and health effects, they say, the absence of proof of causation--i.e., how particles actually interact with cells and organs to cause sickness and death--is fatal to the standard. We disagree.

To begin with, the statute itself requires no such proof. The Administrator may regulate air pollutants "emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. s 7408(a)(1)(A) (1994) (emphasis added). Moreover, this court has never required the type of explanation petitioners seek from EPA. In fact, we have expressly held that EPA's decision to adopt and set air quality standards need only be based on "reasonable extrapolations from some reliable evidence." *NRDC v. Thomas*, 805 F.2d 410, 432 (D.C. Cir. 1986). Indeed, were we to accept petitioners' view, EPA (or any agency for that matter) would be powerless to act whenever it first recognizes clear trends

of mortality or morbidity in areas dominated by a particular pathogen.

The numerous epidemiological studies appearing in this record, some of which EPA also used to support the 1987 NAAQS, easily satisfy the standard articulated in the statute and emphasized repeatedly in decisions of this court. Covering diverse geographic locations with widely varying mixes of air pollution, the studies found statistically significant relationships between air-borne particulates signified by a variety of indicators and adverse health effects. Given EPA's statutory mandate to establish standards based on "the latest scientific knowledge," 42 U.S.C. ss 7408(a)(2), 7409(d), the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.

D. Visibility Effects

The Environmental Petitioners challenge the EPA's decision to set the secondary PM_{2.5} NAAQS at levels equivalent to the primary NAAQS. According to the petitioners, the EPA's failure to set the secondary NAAQS at more stringent levels will result in "adverse visibility impacts" in parts of the country. In view of our conclusion in Part I, above, that the EPA has not adequately explained the principles upon which it relied in setting the levels in the NAAQS for PM, we need not reach the main thrust of the petitioners' challenge to the secondary NAAQS. On the other hand, the Environmental Petitioners have also raised a question of statutory interpretation, the resolution of which should assist the EPA if it revisits its decision to set the secondary PM_{2.5} NAAQS.

In the PM Final Rule, the EPA decided "to address the welfare effects of PM on visibility by setting secondary standards identical to the suite of PM_{2.5} primary standards, in conjunction with the establishment of a regional haze program under s 169A of the Act." PM Final Rule, 62 Fed. Reg. at 38,679/3. Section 169A "declares as a national goal the prevention ... and the remedying of any ... impairment of visibility in mandatory class I Federal areas ... result[ing] from manmade air pollution." 42 U.S.C. s 7491. Mandatory

class I areas include all international parks, and national parks and wilderness areas of a certain size. See 42 U.S.C. s 7472(a). The EPA concluded that reduction of PM_{2.5} levels in class I areas would benefit the surrounding areas as well because "the same haze that degrades visibility within or looking out from a national park also degrades visibility outside it." PM Final Rule, 62 Fed. Reg. at 38,682/1.

The Environmental Petitioners argue that s 109(b)(2), 42 U.S.C. s 7409(b)(2), requires the EPA to set secondary NAAQS at a level sufficient to eliminate all adverse visibility effects and that it leaves the EPA no discretion to decide that some visibility impairment is better remedied through another program. This argument must be wrong. For, as the EPA argues, the Congress required the EPA to implement a regional haze program specifically in order to address adverse visibility effects that persist in class I areas after attainment of the secondary NAAQS. See 42 U.S.C. s 7470(1) (purpose of this part of Clean Air Act is "to protect public ... welfare from any actual or potential adverse effect which ... may reasonably be anticipate[d] to occur ... notwithstanding attainment and maintenance of all [NAAQS]"). Accordingly, we conclude that the Congress did not intend the secondary NAAQS to eliminate all adverse visibility effects and, therefore, that the EPA acted within the scope of its authority in deciding to rely upon the regional haze program to mitigate some of the adverse visibility effects caused by PM_{2.5}.

Conclusion

We remand the cases to EPA for further consideration of all standards at issue. We do not vacate the new ozone standards because the standard is unlikely to engender costly compliance activities in light of our determination that it cannot be enforced by virtue of Clean Air Act s 181(a), 42 U.S.C. s 7511(a). We vacate the challenged coarse particulate matter standards because EPA will have to develop different standards when it corrects the arbitrarily chosen PM₁₀ indicator. As to the fine particulate matter standards,

we invite briefing on the question of remedy: possibilities include but are not limited to vacatur, non-vacatur subject to application to vacate, and non-vacatur.⁸ An order giving the briefing particulars will follow.

Because of the substantial investment of time this matter has required and the many unresolved issues bearing on application of whatever standards may emerge, this panel will in the interest of judicial economy retain jurisdiction over the cases following remand. See *Sierra Club v. Gorsuch*, 715 F.2d 653, 661 (D.C. Cir. 1983).

⁸Briefing should address the possibility that the previous particulate matter standard will spring back to life in response to our decision to vacate the new coarse particulate matter standard.

Tatel, Circuit Judge, dissenting from Part I:

The Clean Air Act has been on the books for decades, has been amended by Congress numerous times, and has been the subject of regular congressional oversight hearings. The Act has been parsed by this circuit no fewer than ten times in published opinions delineating EPA authority in the NAAQS-setting process. Yet this court now threatens to strike down section 109 of the Act as an unconstitutional delegation of congressional authority unless EPA can articulate an intelligible principle cabining its discretion. In doing so, the court ignores the last half-century of Supreme Court nondelegation

jurisprudence, apparently viewing these permissive precedents as mere exceptions to the rule laid down 64 years ago in *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). Because section 109's delegation of authority is narrower and more principled than delegations the Supreme Court and this court have upheld since *Schechter Poultry*, and because the record in this case demonstrates that EPA's discretion was in fact cabined by section 109, I respectfully dissent.

Section 109 requires EPA to publish air quality standards "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." 42 U.S.C. s 7409(b)(1) (1994). Compare section 109 to the language of section 303 of the Communications Act of 1934, which gave the FCC authority to regulate broadcast licensing in the "public interest," and which the Supreme Court sustained in *National Broadcasting Co. v. United States*, 319 U.S. 190, 225-26 (1943). The FCC's general authority to issue regulations "as public convenience, interest, or necessity requires" was sustained in *United States v. Southwestern Cable Co.*, 392 U.S. 157, 178 (1968). The Supreme Court has sustained equally broad delegations to other agencies, including the Price Administrator's authority to fix "fair and equitable" commodities prices, *Yakus v. United States*, 321 U.S. 414, 426-27 (1944), the Federal Power Commission's authority to determine "just and reasonable" rates,

FPC v. Hope Natural Gas Co., 320 U.S. 591, 600 (1944), the War Department's authority to recover "excessive profits" earned on military contracts, *Lichter v. United States*, 334 U.S. 742, 778-786 (1948), and the Attorney General's authority to regulate new drugs that pose an "imminent hazard to public safety," *Touby v. United States*, 500 U.S. 160, 165 (1991). See also *Milk Indus. Foundation v. Glickman*, 132 F.3d 1467, 1475 (D.C. Cir. 1998) (upholding delegation to Secretary of Agriculture to approve interstate compacts upon a finding of "compelling public interest").

Given this extensive Supreme Court precedent sustaining general congressional delegations, no wonder the First Circuit rejected a similar nondelegation challenge to the Clean Air Act's "requisite to protect the public health" language:

The power granted to EPA is not "unconfined and vagrant". [*Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring).] The Agency has been given a well defined task by Congress--to reduce pollution to levels "requisite to protect the public health", in the case of primary standards. The Clean Air Act outlines the approach to be followed by the Agency and describes in detail many of its powers.... Yet there are many benchmarks to guide the Agency and the courts in determining whether or not EPA is exceeding its powers, not the least of which is that the rationality of the means can be tested against goals capable of fairly precise

definition in the language of science.

Administrative agencies are created by Congress because it is impossible for the Legislature to acquire sufficient information to manage each detail in the long process of extirpating the abuses identified by the legislation; the Agency must have flexibility to implement the congressional mandate. Therefore, although the delegation to EPA was a broad one, ... we have little difficulty concluding that the delegation was not excessive.

South Terminal Corp. v. EPA, 504 F.2d 646, 677 (1st Cir. 1974).

I do not agree with my colleagues that *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991) ("Lockout/Tagout I"), requires a different result. That case remanded to OSHA for a more precise definition of section 3(8) of the Occupational Safety and Health Act, which granted the Agency authority to enact workplace safety standards "reasonably necessary or appropriate to provide safe or healthful employment or places of employment." *Id.* at 1316. The Clean Air Act does not delegate to EPA authority to do whatever is "reasonably necessary or appropriate" to protect public health. Instead, the statute directs the Agency to fashion standards that are "requisite" to protect the public health. In other words, EPA must set pollution standards at levels necessary to protect the public health, whether "reasonable" or not, whether "appropriate" or not.

Moreover, in setting standards "requisite to protect the public health" EPA discretion is not unlimited. The Clean Air Act directs EPA to base standards on "air quality criteria" that "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." 42 U.S.C. s 7408(a)(2); see *id.* s 7409(b)(1); see also *id.* s 7408(a)(2) (requiring air quality criteria, "to the extent practicable," to "include information on--(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant; (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and (C) any known or anticipated adverse effects on welfare"). Indeed, the principles constraining EPA discretion are at least as specific as those this court sustained in *Lockout/Tagout II*, i.e., that OSHA must identify a "'significant' safety risk, to enact a safety standard that provides 'a high degree of worker protection'." *International Union, UAW v. OSHA*, 37 F.3d 665, 669 (D.C. Cir. 1994) ("Lockout/Tagout II"). By directing EPA to set NAAQS at levels "requisite"--

not reasonably requisite--to protect the public health with "an adequate margin of safety," the Clean Air Act tells EPA exactly the same thing, i.e., ensure a high degree of protection.

Although this court's opinion might lead one to think that section 109's language permitted EPA to exercise unfettered discretion in choosing NAAQS, the record shows that EPA actually adhered to a disciplined decisionmaking process constrained by the statute's directive to set standards "requisite to protect the public health" based on criteria reflecting the "latest scientific knowledge." To identify which health effects were "significant enough" to warrant protection, EPA followed guidelines published by the American Thoracic Society. See National Ambient Air Quality Standards for Ozone: Proposed Decision, 61 Fed. Reg. 65,716, 65,722/1 (1996). It then set the ozone and fine particle standards within ranges recommended by CASAC, the independent scientific advisory committee created pursuant to section 109 of the Act. See 42 U.S.C. s 7409(d)(2).

CASAC must consist of at least one member of the National Academy of Sciences, one physician, and one person representing state air pollution control agencies. See *id.* s 7409(d)(2)(A). In this case, CASAC also included medical doctors, epidemiologists, toxicologists and environmental scientists from leading research universities and institutions throughout the country. EPA must explain any departures from CASAC's recommendations. See *id.* s 7607(d)(3). Bringing scientific methods to their evaluation of the Agency's Criteria Document and Staff Paper, CASAC provides an objective justification for the pollution standards the Agency selects. Cf. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) (" 'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology today is what distinguishes science from other fields of human inquiry.' ") (citation omitted). Other federal agencies with rulemaking responsibilities in technical fields also rely heavily on the recommendations, policy advice, and critical review that scientific advisory committees provide. See, e.g., 21 U.S.C.

s 355(n) (describing scientific advisory panels for the Food and Drug Administration); 49 U.S.C. s 44912(c) (creating a scientific advisory panel for the Federal Aviation Administration).

Beginning with CASAC's ozone recommendations--not one member recommended going below .08 ppm--EPA gave two perfectly rational explanations for the level it selected. First, it set the annual level based on the different types of health effects observed above and below .08 ppm. Particularly below .08, the Agency determined, "[t]he most certain [ozone-]related effects, while judged to be adverse, are transient and reversible." National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856, 38,868/2 (1997) (emphasis added). Characterizing this explanation as saying nothing more than that "lower exposure levels are associated with lower risk to public health," Maj. Op. at 10, my colleagues find the Agency's reasoning unintelligible. But EPA did not find simply that public health risks decrease at lower levels. Instead, it found that public health effects differ below .08 ppm, i.e., that they are "transient and reversible."

Second, EPA explained that the level should not be set below naturally occurring background ozone concentrations. The Agency selected .08 ppm because it found that "a 0.07 ppm level would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of [ozone] precursors, and thus more likely to be inappropriately targeted in some areas on such sources." 62 Fed. Reg. at 38,868/3. Of course, any level of ozone pollution above background concentrations is closer to background levels than one just above it. See Maj. Op. at 11. But as I read EPA's explanation, the Agency found that peak background levels sometimes occur at .07 ppm, not at .08 ppm. Indeed, the data EPA provided in its "Responses to Significant Comments" show a range of background concentrations from a low of .042 ppm in Olympic National Park in Washington to a high of .075 ppm in Quachita National Forest in Arizona. No region registered background levels above .075 ppm. See U.S. Environmental Protection Agency, Responses to Significant Comments on the 1996 Proposed Rule on the

National Ambient Air Quality Standards for Ozone 94-96 (July 1997). In other words, by setting the annual standard at .08 rather than .07 ppm, EPA ensured that if a region surpasses the ozone standard, it will do so because of controllable human activity, not because of uncontrollable natural levels of ozone.

EPA offered an equally reasonable explanation for the fine particle pollution standard. Again limiting itself to the range approved by CASAC, EPA set the annual standard for PM_{2.5} pollution at the lowest level where it had confidence that the epidemiological evidence (filtered through peer-reviewed, published studies) displayed a statistically significant relationship between air pollution and adverse public health effects.

Recognizing that its decision must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health," 42 U.S.C. s 7408(a)(2), EPA focused on three studies in the record that displayed a statistically significant relationship between fine particle pollution and adverse health effects: Joel Schwartz et al., *Is Daily Mortality Associated Specifically with Fine Particles?*, 46 J. Air & Waste Mgmt. Ass'n 927 (1996); Joel Schwartz et al., *Acute Effects of Summer Air Pollution on Respiratory Symptom Reporting in Children*, 150 Am. J. Respiratory & Critical Care Med. 1234 (1994); and Douglas W. Dockery et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753 (1993). The Agency explained that "there is generally greatest statistical confidence in observed associations [between fine particle pollution and adverse health effects] for levels at and above the mean concentration [of pollution observed in the studies that showed a statistically significant relationship]." National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,676/1 n.42 (1997) (emphasis added). Allowing "an adequate margin of safety," EPA then set the annual fine particle standard just below the lowest mean pollution levels observed in those studies, at 15 Sg/m³. See *id.* at 38,676/1 ("An examination of the long-term means from the combined six city analyses of daily mortality [Schwartz et al. (1996)] and morbidity [Schwartz et al. (1994)],

together with those from studies in individual cities for which statistically significant PM-effects associations are reported ... finds mean concentrations ranging from about 16 to about 21 Sg/m3...."); id. at 38,676/2 ("[The EPA] Staff Paper assessment of the concentration-response results [from Dockery et al. (1993)], concluded that the evidence for increased risk was more apparent at annual concentrations at or above 15 Sg/m3....").

In a passage directly answering this court's concerns, see Maj. Op. at 11-12, the Staff Paper explained why the long-term mean served as a reasonable level for setting the fine particle NAAQS:

The mean (or median) concentration may serve as a reasonable cutpoint of increased PM health risk since at this point there is generally the greatest confidence (i.e., the smallest confidence intervals) in the association and the reported [relative risk] estimates. The mean concentration considered by staff as most informative to test implications of potential alternative concentration-response functions is the minimum mean concentration associated with a study or studies reporting statistically significant increases in risk across a number of study locations....

Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Review of National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, at E-4 (1996) (emphasis added).

EPA thus did not, as my colleagues charge, arbitrarily pick points on the ozone and particulate pollution continua indistinguishable from any other. Instead, acting pursuant to section 109's direction that it establish standards that, based on the "latest scientific knowledge" are "requisite" to protect the public health with "an adequate margin of safety," and operating within ranges approved by CASAC, the Agency set the ozone level just above peak background concentrations where the most certain health effects are not transient and reversible, and the fine particle level at the lowest long-term

mean concentration observed in studies that showed a statistically significant relationship between fine particle pollution and adverse health effects. Whether EPA arbitrarily selected the studies it relied upon or drew mistaken conclusions from those studies (as petitioners argue), or whether EPA failed to live up to the principles it established for itself (as my colleagues believe, see Maj. Op. at 9-12), has nothing to do with our inquiry under the nondelegation doctrine. Those issues relate to whether the NAAQS are arbitrary and capricious. See *NRDC v. EPA*, 902 F.2d 962, 969, 971 (D.C. Cir. 1989). The Constitution requires that Congress articulate intelligible principles; Congress has done so here.

A final point. Unlike OSHA, which Lockout/Tagout I recognized has authority to reach into every workplace to dictate what is safe, to impose extensive civil and criminal penalties, and "to decide which firms will live and which will die," Lockout/Tagout I, 938 F.2d at 1318, EPA regulates primarily by setting standards for states to develop their own plans. See 42 U.S.C. s 7401(a)(3) (Congress finds "that air pollution prevention ... and air pollution control at its source is the primary responsibility of States and local governments."). Indeed, because states have three years to submit implementation plans, which are themselves subject to notice, comment, public hearing, and frequent renegotiation, we will not know for years precisely how the ozone and particle NAAQS will actually affect individual businesses. Only if a state fails to produce an acceptable plan can EPA terminate federal highway funds or impose its own implementation plan. Because the Clean Air Act gives politically accountable state governments primary responsibility for determining how to distribute the burdens of pollution reduction and therefore how the NAAQS will affect specific industries and individual businesses, courts have less reason to second-guess the specificity of the congressional delegation. Moreover, if the states disagree with the standards EPA has set, they have 535 representatives in Congress to turn to for help. In fact, legislation to overturn the very NAAQS at issue in this case was introduced in the last Congress. See H.R. 1984, 105th Cong. (1997) ("A bill to provide for a four-year moratorium on

the establishment of new standards for ozone and fine particulate matter under the Clean Air Act, pending further implementation of the Clean Air Act Amendments of 1990, additional review and air quality monitoring under that Act."); S. 1084, 105th Cong. (1997) ("A bill to establish a research and monitoring program for the national ambient air quality standards for ozone and particulate matter and to reinstate the original standards under the Clean Air Act, and for other purposes.").