Comments of the
American Lung Association
Appalachian Mountain Club
Earthjustice
Environmental Defense
National Parks Conservation Association
Natural Resources Defense Council
on EPA's Proposed Revisions to the
National Ambient Air Quality Standards for Particulate Matter
71 Fed. Reg. 2620
and
Proposed Coarse Particle Monitoring Regulations
71 Fed Reg. 2710
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Introduction

The American Lung Association, Environmental Defense, Natural Resources Defense Council, Earthjustice, National Parks Conservation Association and the Appalachian Mountain Club file these comments on EPA's proposed revisions to the National Ambient Air Quality Standards (NAAQS) for fine and coarse particulate matter (PM) and the associated proposed monitoring requirements for coarse particles.

For both fine and coarse particulate matter the proposed standards are insufficient to protect public health and welfare with an adequate margin of safety as required by the Clean Air Act. Among other things, in setting the proposed standards EPA has failed to identify appropriate safe levels for ambient exposure to PM based exclusively on protection of public health; ignored or mischaracterized the relevant health studies; overstated uncertainty; refused to adopt an appropriately precautionary approach for interpreting and applying the scientific data; ignored the advice of the panel of scientific experts specifically created to advise the agency on the setting of NAAQS; and impermissibly made decisions regarding the safe level of ambient PM based on factors other than the assessment of relevant health impacts.

Under the Clean Air Act, primary standards must protect public health, including the health of sensitive populations, with an adequate margin of safety. Secondary standards must protect public welfare, including important adverse effects such as visibility impairment and damage to materials and crops. The proposed standards fail on both counts.

The adverse health effects of particulate matter are serious and have been well documented in EPA's Criteria Document and Staff Paper. The thousands of studies published over the last nine years make a much stronger case for the regulation of fine particles than in 1997, and indicate that the current standards must be significantly lowered to protect public health. EPA's staff scientists and experts with the Science Advisory Board's Clean Air Scientific Advisory Committee (CASAC) agree with this conclusion, and both have recommended adoption of standards that are more stringent that those in EPA's proposal.

EPA has invested nine years in the review of these studies and in the publication of a Criteria Document and Staff Paper. The CASAC has convened at least 18 times over this time period to peer review numerous drafts of these documents to ensure that they accurately reflected the science, and public comment has been entertained at every step in the process. With respect to fine particles, the Criteria Document concluded that adverse health effects were occurring at concentrations below the current standards. The Staff Paper recommended a range of options for lowering the standards to protect public health. The CASAC recommended narrowing of the range. We are extremely troubled that the proposed standards for fine particles permit more pollution than the ranges recommended by EPA staff scientists and the CASAC. We believe that the science shows conclusively that standards at levels below those proposed by the Agency are essential to provide the protection to public health that is the sole permissible criteria for the Agency's decision.

Great scientific advances have been made since EPA last reviewed the PM NAAQS in 1997. Controversy over the 1997 standards led to major federal and private investment into research on the health effects of PM, especially fine PM. Congress authorized over $50 million annually for a multi-year federal research program, and directed a special committee of the National Academy of Sciences to recommend research priorities and track progress toward meeting research objectives. The major long-term studies have been audited, analyzed, reanalyzed, and extended, providing overwhelming evidence that long-term exposure to fine particles shortens lives. Many of studies of short-term exposure have been reanalyzed as well, generally reconfirming the original findings – that there is a clear link between daily increases in PM concentrations and increases in respiratory and cardiac effects, hospital admissions, and premature deaths. More than 3,000 new studies have been published, broadening our understanding of PM health effects and endpoints, sensitive populations, and mechanisms. The Clean Air Act compels EPA, in the face of this overwhelming evidence, to establish final standards for fine and coarse particles that line up with the science and that will be fully protective of public health and welfare.

EPA's own risk assessment shows that if EPA adopts the proposed standards thousands of people will die prematurely each year just in the handful of cities analyzed.[1] EPA performed the risk assessment to estimate the public health implications of alternative standards. CASAC reviewed the methodology for this risk assessment and two drafts of the analysis. Numerous conservative assumptions and sensitivity analyses were added as a result of the CASAC review. Yet the EPA proposal cavalierly dismisses the relevance of the risk assessment to decision making on the proposed standards, despite the clear statutory requirement for EPA to evaluate health hazards to the public and to establish a standard that will protect the public from adverse health impacts with an adequate margin of safety.[2] EPA may not decide to deal with uncertainty in data or potential health effects by simply ignoring that data or those effects.[3]

Our organizations strongly support significantly lowering both the annual average and the 24-hour fine particle standard, while tightening the way compliance with the standards is measured. We urge you to adopt protective coarse particle standards that will apply nationwide, with monitoring in both urban and rural areas. We oppose the special exemptions for agribusiness and mining. Furthermore, EPA has no authority to revoke the current PM_{10} standards or the specific pollution controls mandated by the Clean Air Act for PM_{10} nonattainment areas.

In addition, to comply with its statutory obligations, EPA must establish secondary standards for fine particles that protect against deterioration of visibility caused by fine particle pollution, as recommended by the Clean Air Scientific Advisory Committee, and set secondary standards for

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[1] The EPA risk assessment examined the health implications of alternative fine particle standards in just nine U.S. cities: Philadelphia, Pittsburgh, Los Angeles, Boston, Seattle, St. Louis, Detroit, San Jose, and Phoenix.
[2] *See e.g.,* NRDC v. EPA, 824 F.2d 1146, 1164-65 (D.C. Cir. 1987) *Lead Industries Assn. v. EPA*, 647 F.2d 1130 (D.C. Cir. 1980); *Lung Assn. v. EPA,* 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *Whitman v. American Trucking Assn.,* 531 U.S. 457, 464-71 (2001).
[3] *See, e.g.*, Public Citizen v. FMCSA, 374 F.3d 1209, 1219 (D.C. Cir. 2004) ("The mere fact that the *magnitude* of [an effect] is uncertain is no justification for *disregarding* the effect entirely).

coarse particles that apply nationwide to protect against the ecosystem damage and visibility degradation they cause.

At a minimum, the following standards are required for EPA to satisfy its obligations under the Clean Air Act:

- an annual average $PM_{2.5}$ standard of 12 $\mu g/m^3$ or below, with elimination of the spatial averaging loophole;
- a 24-hour $PM_{2.5}$ standard of 25 $\mu g/m^3$, 99^{th} percentile;
- a 24-hour $PM_{10-2.5}$ standard of 25-30 $\mu g/m^3$, 99^{th} percentile, to apply nationally;
- application of the coarse particle standard across the country, with monitoring and implementation in rural areas and elimination of the special exemption for the mining and agriculture industries;
- an annual-average standard for coarse particles to protect against adverse health effects;
- a national $PM_{2.5}$ secondary standard of 20 $\mu g/m^3$ or below, 98^{th} percentile, based upon a rolling 4-hour average; and
- a secondary standard for coarse PM that protects ecosystems and scenic vistas across the country.

The courts have determined that science and public health protection must prevail over any other consideration when EPA sets the final NAAQS for particulate matter. Anything less constitutes an abrogation of the duties and responsibilities that Congress and the American people entrusted to EPA under the Clean Air Act.

EPA's Statutory Obligations under the Clean Air Act

National Ambient Air Quality Standards (NAAQS) drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes a NAAQS, states and EPA cooperate to identify those geographic areas that fail to meet the standards. 42 U.S.C. § 7407(d). Each state must prepare an "implementation plan" designed to demonstrate what the state will do to reduce air pollution emissions in order to reduce the ambient concentrations of regulated pollutants to levels compatible with the NAAQS (including how the state will initially attain the standards, and how it will maintain and enforce the NAAQS). *See generally id.* § 7410.[4]

EPA establishes the NAAQS, which are health- and welfare-based standards according to a process that is clearly laid out in the Clean Air Act. The first step in establishing a NAAQS involves identifying those pollutants "emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources. . . ." 40 U.S.C. § 7408(a)(1)(A)(B). At the second stage, EPA must select

[4] Depending on an area's designation, different pollution control requirements must be included in state plans. *See, e.g., id.* § 7472.

a NAAQS that is based on air quality criteria reflecting "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. . . ." *Id.* § 7408(a)(2). Third, and most importantly, primary NAAQS must be "requisite to protect the public health" with "an adequate margin of safety." *Id.* § 7409(b)(1). Secondary NAAQS, standards intended to protect against pollution concerns other than adverse health effects, must be "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." *Id.* §7409(b)(2); *see also* § 7602(h) (defining effects on welfare).

Thus any primary standards that EPA promulgates under these provisions must be adequate to (1) protect public health and (2) provide an adequate margin of safety. In addition, EPA must promulgate secondary standards to prevent any known or anticipated non health-related effects from polluted air. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level and form for the NAAQS. In exercising its judgment, EPA (1) must err on the side of protecting public health, (2) must base decisions on the latest scientific knowledge giving due deference to the recommendations of the Clean Air Science Advisory Committee, and (3) may not consider cost or feasibility in connection with establishing the numerical NAAQS or other important elements of the standard (e.g., form of the standard, averaging time, etc.). In short, "[b]ased on these comprehensive [air quality] criteria and taking account of the 'preventative' and 'precautionary' nature of the Act, the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that 'research has not yet uncovered.' Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety." *American Lung Assn. v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. American Trucking Assn.,* 531 U.S. 457, 464-71 (2001). *See* H.Rep. 294, 95th Cong., 1st Sess. 49-51 (1977) (explaining amendments designed *inter alia* "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs").

Quite clearly, the Act's mandate requires that in considering uncertainty EPA must err on the side of caution in terms of protecting human health and welfare. As the D.C. Circuit held in reviewing the last round of NAAQS revisions, "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" *Am. Trucking Assoc. v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38653); *id.* (citing Ozone NAAQS, 62 Fed. Reg. 38857 (section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified")).[5]

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[5] Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, as the D.C. Circuit has explained, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Lead Indus. Ass'n*, 647 F.2d at 1154-55.

In the seminal case on the NAAQS, the court held that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement."[6] NAAQS must be set at levels that are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, and people with heart and lung disease. As the U.S. Court of Appeals for the D.C. Circuit has stated, in its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens" – who are particularly vulnerable to air pollution. If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.[7] *See also Washington v. Glucksberg*, 521 U.S. 702 (1997) (people near death are of no less worth than other members of society).

Likewise, "[s]tandards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment." 44 Fed. Reg. 8210 (February 8, 1979). Thus, EPA cannot deny protection from air pollution's effects by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited. To the contrary, the NAAQS mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42381 (December 18, 1970)(remarks of Senator Muskie, floor manager of the conference agreement).[8]

In implementing this mandate, EPA cannot use loose talk of "risk" or "acceptable risk" to deny protection against adverse health and welfare effects. It is inherent in NAAQS-setting that adverse effects are experienced by less than the entire population, and that we do not know in advance precisely which individuals will experience a given effect. In light of these circumstances, opponents of protective NAAQS often argue that NAAQS-setting involves evaluating "risk" and setting a level of risk that is "acceptable." But where—as here—peer-reviewed science shows that adverse effects stem from a given pollutant concentration, EPA must set NAAQS that protect against those effects with an adequate margin of safety. It cannot,

[6] *Lead Industries Assn. v.* EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980).

[7] *American Lung Assn. v.* EPA, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted); *see also Lead Industries Assn, Inc. v.* EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980) (NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals.").

[8] *See also* 116 Cong. Rec. at 32901 (September 21, 1970) (remarks of Senator Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health."); *id*. at 33114 (September 22, 1970) (remarks of Senator Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to breathe, air which does not attack their health."); *id*. at 33116 (remarks of Senator Cooper) ("The committee modified the President's proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); *id*. at 42392 (December 18, 1970) (remarks of Senator Randolph) ("we have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults -- for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id*. at 42523 (remarks of Congressman Vanik) ("Human health and comfort has been placed in the priority in which it belongs -- first place.").

under the guise of risk management, set NAAQS that allow such effects to persist. Indeed, given the scientific evidence documenting the occurrence of adverse effects year after year in numerous populations at levels allowed by both the current NAAQS and EPA's proposal, risks are by definition "significant" enough to require protection under the Act's protective and precautionary approach. *See* H.R. Rep. No. 95-294 at 43-51; *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976). That is all the more true where the effects involved include highly serious ones like death and hospitalization. *See Ethyl*, 541 F.2d at 18 ("the public health may properly be found endangered … by a lesser risk of a greater harm").

In the context of EPA's current proposal, it is clear that EPA has failed to follow the pathway for setting air quality standards that Congress identified through the Clean Air Act, wandering far astray from the established requirements of the law. In this proposal, EPA would adopt standards allowing large continuing adverse health and welfare affects affecting many thousands of Americans each year—including premature death and serious morbidity impacts such as hospitalization and asthma attacks. EPA repeatedly has disregarded levels needed to protect sensitive populations, used uncertainty in a one-directional manner to avoid more stringent regulation of harmful emissions, and failed to address the full range of adverse effects associated with exposure to ambient levels of PM or to ensure that people will be protected with an adequate margin of safety. EPA has, in many instances, insupportably applied the findings of relevant studies to minimize their significance, thereby subverting the precautionary nature of its statutory mandate. The comments herein should be read in the context of the legal framework described above, and the objections to EPA's analyses and conclusions construed in light of the agency's legal obligations as they are here presented.

In addition to flouting its Clean Air Act obligations, the agency's proposal flies in the face of the Administration's professed "commitment to building a culture of life where all individuals are welcomed in life and protected in law," and "to strengthen our resolve in creating a society where every life has meaning and our most vulnerable members are protected and defended—including unborn children, the sick and dying, and persons with disabilities and birth defects." 71 Fed. Reg. 4229 (Jan. 25, 2006).

Scientific Consensus Favors Stricter Standards

Organizational support

It has become increasingly clear since EPA established the PM standards that are currently in force that those standards fail to protect the health of millions of Americans. In fact, there has been an outpouring of support from the scientific and public health community in favor of more stringent standards to protect public health.[9]

In 2004, the American Heart Association completed a thorough review of the science on air pollution and cardiovascular disease and concluded that EPA should seriously consider adopting more stringent air quality standards for $PM_{2.5}$ to prevent ongoing serious health impacts.

[9] All studies referenced in these comments are hereby fully incorporated by reference.

According to the statement, this represents the official finding of the American Heart Association about $PM_{2.5}$:

> "The existing body of evidence is adequately consistent, coherent, and plausible enough to draw several conclusions . . . At the very least, short-term exposure to elevated PM significantly contributes to increased acute cardiovascular mortality, particularly in certain at-risk subsets of the population. Hospital admissions for several cardiovascular and pulmonary diseases acutely increase in response to higher ambient PM concentrations. The evidence further implicates prolonged exposure to elevated levels of PM in reducing overall life expectancy on the order of a few years." [10]

The Heart Association concludes with this recommendation:

> "Because a number of studies have demonstrated associations between particulate air pollution and adverse cardiovascular effects even when levels of ambient $PM_{2.5}$ were within current standards, even more stringent standards for $PM_{2.5}$ should be strongly considered by the EPA." [11]

This official statement was followed later that year by a review of ambient air pollution and the health hazards to children conducted by the American Academy of Pediatrics. The American Academy of Pediatrics specifically concluded that current daily and annual air quality standards for $PM_{2.5}$ and PM_{10} must be lowered to protect the health of fetuses, infants and children.[12]

An editorial published this past winter in the journal of the American Thoracic Society rebuked EPA for proposing standards that will not protect public health. The American Thoracic Society is the leading international medical organization made up of clinicians and researchers dedicated to reducing mortality and morbidity from respiratory disorders. The editorial stated: "In the face of the extensive evidence on PM and health and the strong mandate of the Clean Air Act for public health protection, the PM NAAQS proposed by Administrator Johnson appear lax. Based on the same evidence, the American Thoracic Society and other health organizations have recommended 12 and 25 $\mu g/m^3$ for the average annual and 24-h $PM_{2.5}$ standards, respectively. The proposed, less stringent standard does not protect the nation's health, as required by the Clean Air Act."[13]

A broad consensus in the international scientific and public health communities supports the need to strengthen the air quality standards for particulate matter more than has been proposed by EPA. Leading public health organizations including the American Academy of Pediatrics, the American Thoracic Society, the American Public Health Association, the American College of Cardiology, the American Lung Association, Physicians for Social Responsibility, the

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[10] Brook RD, Franklin B, Cascio W, Hong Y, Howard G, Lipsett M, Luepker R, Mittleman M, Samet J, Smith SC Jr, Tager I; Expert Panel on Population and Prevention Science of the American Heart Association. Air pollution and cardiovascular disease: a statement for healthcare professionals from the Expert Panel on Population and Prevention Science of the American Heart Association. *Circulation* 2004;109:2655-71.
[11] *Circulation* 2004.
[12] Committee on Environmental Health, American Academy of Pediatrics. Ambient Air Pollution: Health Hazards to Children. *Pediatrics* 2004;114:1699-1707.
[13] Rom WN, Samet JM. Small Particles with Big Effects. *Am J Repir Crit Care Med* 2006; 173: 365-366.

American Association of Cardiovascular and Pulmonary Rehabilitation, American Association of Respiratory Care, American College of Preventative Medicine, and the National Association for the Medical Direction of Respiratory Care have urged EPA to set a $PM_{2.5}$ annual average standard of 12 $\mu g/m^3$, and a 24-hour standard of 25 $\mu g/m^3$, with the 99th percentile used for the compliance determination.[14] In March, 2006, the Board of Governors of the American Medical Association adopted a resolution in support of these same recommended levels.[15] The American Diabetic Association, American Nurses Association and the American Cancer Society have also indicated there support for stringent fine and coarse particle standards.[16]

In October 2005, a working group of the World Health Organization (WHO) made up of leading air quality scientists recommended revised air quality guidelines for $PM_{2.5}$ generally consistent with our joint recommendations. After an extensive review of the scientific evidence on air pollution and its health consequences, the WHO working group recommended an annual average $PM_{2.5}$ standard of 10 $\mu g/m^3$, and a daily $PM_{2.5}$ standard of 25 $\mu g/m^3$, based on the 99th percentile.[17] The annual average value of 10 $\mu g/m^3$ was chosen to represent the lower end of the range over which significant effects on survival have been observed in the American Cancer Society Study (Pope et al., 2002). The World Health Organization working group also made recommendations on coarse particles. Using PM_{10} as an indicator and assuming that $PM_{2.5}$ comprises roughly half of PM_{10}, the WHO working group recommended an annual average PM_{10} standard of 20 $\mu g/m^3$, and a daily standard of 50 $\mu g/m^3$, 99th percentile. (The $PM_{10-2.5}$ equivalent would be at half these levels).

The EPA's Children's Health Protection Advisory Committee also concluded that the proposed annual $PM_{2.5}$ standard does not protect infants and children with an adequate margin of safety, and the proposed daily $PM_{2.5}$ standard must be revised downward to protect the health of these susceptible populations.[18] In addition, the Children's Health Protection Advisory Committee recommended that the level of the coarse particle standard be lowered, that standards apply nationwide, with monitoring in both urban and rural areas, and that the exemption for agriculture and mining be withdrawn.

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[14] See, for example: Letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, from the American Thoracic Society, American Association of Cardiovascular and Pulmonary Rehabilitation, American Association of Respiratory Care, American College of Cardiology, American College of Preventative Medicine, American Public Health Association, and National Association for the Medical Direction of Respiratory Care, October 21, 2005.

[15] Personal communication from the American Medical Association to Gary Ewart, American Thoracic Society, April 6, 2006.

[16] Letter from 21 health organizations to Stephen L. Johnson, Administrator, U.S. EPA, April 17, 2006.

[17] World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005. WHOLIS number E87950.

[18] Letter from Melanie A. Marty, Ph.D., Chair, EPA Children's Health Protection Advisory Committee, to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, RE: Proposed NAAQS for Particulate Matter, March 3, 2006.

Governmental Support

In 2002, the California EPA completed a review of the California Ambient Air Quality Standards for particulate matter. After reviewing the essentially same body of evidence as EPA relied upon for its proposal, subjecting it to peer review by an Air Quality Advisory Committee (AQAC), and operating under a statutory mandate identical to the Clean Air Act's charge to "protect public health with an adequate margin of safety" the State adopted substantially more stringent standards than proposed by EPA. Specifically, California adopted an annual average standard of 12 $\mu g/m^3$ for $PM_{2.5}$. Additionally, to protect against the effect of coarse particles, the state lowered its annual average PM_{10} standard from 30 $\mu g/m^3$ to 20 $\mu g/m^3$, while retaining its 24-hour PM_{10} standard of 50 $\mu g/m^3$, already one-third of the federal PM_{10} standard of 150 $\mu g/m^3$.[19] Compliance with the California air quality standards is measured on a "not to be exceeded" basis. These standards were unanimously endorsed by members of the Air Quality Advisory Committee made up of top scientists appointed by the University of California, Office of the President. The AQAC also recommended adoption of a 24-hour standard for $PM_{2.5}$ of 25 $\mu g/m^3$.

Additionally, Canada has adopted nationwide $PM_{2.5}$ standards of 30 $\mu g/m^3$ on a 24-hour basis.[20] The Puget Sound Clean Air Agency has established a goal of 25 $\mu g/m^3$ for 24-hour $PM_{2.5}$ concentrations, on the advice of its Health Committee.[21]

Clearly, the proposed EPA standards are out of step with mainstream scientific opinion as reflected in conclusions of scientific experts and decisions of regulatory bodies that have recently examined precisely the issue now before the agency. Given EPA's misalignment with the rest of the scientific and public health community (including, as discussed below, the opinions of its own science advisors), it is clear that EPA's proposed PM standards fail to identify concentrations of ambient PM that are sufficient to protect the public health with an adequate margin of safety as required by the Clean Air Act.

Individual scientists

Just before EPA announced its proposed regulations, 104 leading physicians and air quality scientists urged EPA to propose an annual average $PM_{2.5}$ standard of 12 $\mu g/m^3$, a 24-hour average $PM_{2.5}$ standard of 25 $\mu g/m^3$ (99th percentile), and a stringent 24-hour average $PM_{10-2.5}$ standard, applied equally to all areas of the country.[22] The scientists wrote:

> "More than 2,000 peer-reviewed scientific studies have been published since 1996 when EPA last updated the NAAQS for particulate air pollution. These studies, as discussed and interpreted in the 2004 EPA Criteria Document, validate earlier epidemiologic studies linking both acute and chronic fine particle pollution with serious morbidity and

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[19] http://www.arb.ca.gov/research/aaqs/std -rs/std-rs.htm

[20] Canadian Council of Ministers of the Environment, Canada-Wide Standards for Particulate Matter (PM) and Ozone, Endorsed by CCME Council Of Ministers, June 5-6, 2000. Available at: http://www.ccme.ca/assets/pdf/pmozone_standard_e.pdf

[21] See report at: http://www.pscleanair .org/news/other/pm2_5_report.pdf , p.2.

[22] Letter from 104 scientists to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency. December 5, 2005.

mortality. The newer research has also expanded the list of health effects associated with PM, and has identified health effects at lower exposure levels than previously reported.

In fact, the science is now sufficiently strong that it is appropriate to conclude that $PM_{2.5}$ is causally associated with numerous adverse health effects in humans, at exposure levels far below the current standards. Such a conclusion demands prompt action to protect human health.

The major health effects of fine particulate matter include reduced lung function, cough, wheeze, missed school days due to respiratory symptoms, increased use of asthma medications, cardiac arrhythmias, strokes, emergency room visits, hospital admissions, lung cancer, and premature death – at levels well below the current national air quality standards.

A growing body of evidence also indicates that short-term exposure to $PM_{10-2.5}$, is associated with hospitalization for cardiopulmonary diseases in children and the elderly, increased respiratory symptoms, and decreased lung function and we believe a new standard for this coarse fraction of PM is now warranted.

Infants and children are especially sensitive, as are the elderly, and people with preexisting heart disease, lung disease, or diabetes. The new EPA standards should be set at levels that will protect these sensitive people."

As the evidence of adverse effects of particulate matter below the level of the current and proposed standards mounts, individual scientists are increasingly vocal in drawing public policy conclusions about the implications of their research in the pages of the nation's leading medical journals. The following selected quotes demonstrate their concern:

"Our findings indicate an ongoing threat to the health of the elderly population from airborne particles and provide a rationale for setting a $PM_{2.5}$ National Ambient Air Quality Standard that is as protective of their health as possible."[23]

Francesca Dominici, Ph.D.
Johns Hopkins University

"These findings provide compelling evidence that fine particle concentrations well below the national standard are harmful to the cardiovascular and respiratory health of our elderly citizens."[24]

David A. Schwartz, M.D.
Director of the National Institute of Environmental Health Sciences

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[23] Dominci F, Peng RD, Bell ML, Pham L, McDermott A, Zeger SL, Samet JM. Fine Particulate Air Pollution and Hospital Admission for Cardiovascular and Respiratory Diseases. JAMA 2006; 295:1127-1134.
[24] National Institute of Health News, March 8, 2006 Press Release. Elderly Have Higher Risk for Cardiovascular, Respiratory Disease From Fine Particle Pollution.

"These results support the hypothesis that elevated levels of particulate air pollution, below the current limits set by the United States Environmental Protection Agency, are associated with an increase in the rate of hospital admission for exacerbation of CHF (congestive heart failure)."[25]

Gregory Wellenius, Sc.D.
Beth Israel Deaconess Hospital

"Our results emphasize the continued need for enforcement of existing standards as well as the importance of considering susceptible subgroups within the population when formulating new standards."[26]

Toby C. Lewis, M.D. M.P.H.
University of Michigan Department of Pediatric Pulmonology

"These results suggest that repeated periods of short-term (eg, several hours) exposures to high particulate matter levels, such that may occur during rush hour traffic, is potentially capable of promoting progression of atherosclerosis, although the mean daytime particulate matter exposure concentration is within national recommendations. This may potentially have implications for the relevance of both the 24-hour and annual average National Ambient Air Quality Standards."[27]

Qinghua Sun, M.D., Ph.D.
Mount Sinai School of Medicine

"Current knowledge about the health effects of air pollution is sufficient for a strong recommendation to reduce children's current exposure to air pollutants."[28]

World Health Organization Panel

"It is becoming more evident from clinical and toxicological studies that ambient fine PM induces respiratory and cardiovascular events that in susceptible, compromised people can explain the morbidity and mortality observed in epidemiological studies. Research

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[25] Wellenius GA, Schwartz J, and Mittleman MA. Particulate Air Pollution and Hospital Admissions for Congestive Heart Failure in Seven United States Cities. *Am J Cardiol* 2006; in press. http://www.ajconline.org/article/PIIS000291490501831X/abstract

[26] Lewis TC, Robins TG, Dvonch JT, Keeler GJ, Yip FY, Mentz GB, Lin X, Parker EA, Israel BA, Gonzalez L, Hill Y. Air Pollution-Associated Changes in Lung Function among Asthmatic Children in Detroit. *Environ Health Perspect* 2005; 113:1068-1075. http://ehp.niehs.nih.gov/members/2005/7533/7533.pdf

[27] Sun Q, Wang A, Jin X, Natanzon A, Duquaine D, Brook RD, Aguinaldo J-GS, Fayad ZA, Fuser V, Lippmann M, Chen LC, Rajagopalan S. Long-term Air Pollution Exposure and Acceleration of Atherosclerosis and Vascular Inflammation in an Animal Model. *JAMA* 2005; 294: 3003-3010. http://jama.ama-assn.org/cgi/content/abstract/294/23/3003

[28] Binková B, Bobak M., Chatterjee A, Chauhan AJ, Dejmek J, Dockery DW, Everard M, Forastiere F, Gilliland F, Holgate S, Johnston S, Krzyzanowski M, Kuna-Dibbert B, Maynard R, Raaschou-Nielsen O, Samet J, Schneider J, Skerrett PJ, Šrám RJ, Walters D, Weiland SK, Winneke G. WHO Monograph: The effects of air pollution on children's health and development: a review of the evidence. WHO Regional Office for Europe 2004. Available at: http://www.euro.who.int/document/EEHC/execsum.pdf.

has documented that components of hypothesized mechanistic sequences do actually take place, supplying a biological basis for explaining some effects of PM observed in susceptible subpopulations."

"Since 1997, the number of studies examining the health effects of air pollution on children has increased substantially. The majority of these studies focused on the effects of PM and, in several cases, copollutants on the health of children with moderate to severe asthma. Taken as a whole, these studies confirm the findings of earlier studies regarding the adverse effects of fine particles and possibly coarse particles as well on the exacerbation of preexisting illness in children with asthma." [29]

National Research Council Committee on Research Priorities for Airborne Particulate Matter

"As patient advocates, physicians, both individually and as members of large health organizations, should support societal control of air pollution and rally against attempts to weaken science-based regulatory air pollution standards." [30]

Jonathan Bernstein, M.D.
University of Cincinnati College of Medicine

"As both epidemiologic and now mechanistic evidence mounts, there is greater urgency to accelerate our efforts to reduce particulate air pollution and to improve cardiovascular health." [31]

Peter H. Stone, M.D.
Harvard Medical School

"Efforts to decrease ozone and PM_{10} concentrations from moderate to low levels can decrease the burden of asthma." [32]

Michael Friedman, M.D.
U.S. Centers for Disease Control and Prevention

"Reductions of annual mean concentrations [of fine particles] below the current EPA air quality standard would significantly reduce mortality rates in the U.S."[33]

[29] National Research Council, Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress, March 24, 2004.
[30] Bernstein JA, Alexis N, Barnes C, Bernstein IL, Nel A, Peden D, Diaz-Sanchez D, Tarlo SM, Williams PB. Health effects of air pollution. *J Allergy Clin Immunol* 2004;114:1116-23.
[31] Stone PH. Triggering myocardial infarction. *N Engl J Med* 2004;351:1716-1718.
[32] Friedman MS, Powell KE, Hutwagner L, Graham LM, Teague WG. Impact of changes in transportation and commuting behaviors during the 1996 summer Olympic games in Atlanta on air quality and childhood asthma. *Journal of the American Medical Association* 2001;285:897-905.

[33] Schwartz J, Laden F. Dose, time and death: Associations with $PM_{2.5}$ in a cohort study. 2004: Poster presentation Available at: http://www.epa.gov/sab/power_point/harvard_six_city_study.ppt #256,1,Slide 1.

Joel Schwartz, Ph.D.
Harvard School of Public Health

"Even modest reductions in air pollution could result in improved respiratory health in children." [34]

Rob McConnell, M.D.
Keck School of Medicine, University of Southern California

The Clean Air Scientific Advisory Committee

In addition to opposing expert opinions of the scientific community, Administrator Johnson disregarded the recommendations of EPA's designated science advisors. The Clean Air Scientific Advisory Committee is established under the Clean Air Act to advise EPA on the review of the NAAQS. The CASAC PM Review Panel is made up of 22 scientists including the heads of the nation's leading PM research programs. Researchers from Harvard University, New York University, University of Rochester, University of Washington, Johns Hopkins University, the University of California and other leading institutions are members of the panel.

As discussed in more detail later in these comments, the CASAC clearly found that $PM_{2.5}$ causes adverse health effects including premature death at annual concentrations below the current annual and 24-hour standards. However, despite the formal role of CASAC in the NAAQS review process, Administrator Johnson ignored the advice of the 22-member panel and substituted his own "policy judgment." In the end, however, the Administrator's proposed policy does not comport with the scientific conclusions of the health experts, including CASAC members. In fact, since EPA issued the proposal, CASAC members have specifically expressed their frustration with EPA's failure to deal adequately with the health risks of $PM_{2.5}$. [35]

EPA must seriously consider the advice of its formal scientific advisory body. EPA owes it to CASAC and to the nation to provide a rational explanation based on permissible criteria for any decision that significantly departs from such recommendations, and indeed, from clear scientific consensus. *See*, *e.g.*, 42 U.S.C. § 7607(d)(3) (where EPA's proposal "differs in any important respect" from CASAC's recommendations, the proposal must present "an explanation of the reasons for such differences"). In this case, however, Administrator Johnson merely cites his role as the final decision maker as providing him with authority to depart from the CASAC's recommendations (and the clear consensus of the scientific community) without any rational explanation of why such departure is justified based on public health considerations.[36]

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[34] McConnell R, Berhane K, Gilliland F, Molitor J, Thomas D, Lurmann F, Avol E, Gauderman WJ, Peters JM. Prospective study of air pollution and bronchitic symptoms in children with asthma. *American Journal of Respiratory and Critical Care Medicine* 2003;168:790-797.
[35] Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, March 21, 2006, Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, EPA-CASAC-LTR-06-002.
[36] Moreover, published reports suggest that rather than adopting a bottom-up, science driven decision making process for selecting the proposed PM NAAQS limits, EPA's predetermined outcome preferences drove the

As a result, EPA's proposal is fundamentally unlawful and arbitrary. EPA must correct this deficiency, and the only way for it to do so, in a manner that is consistent with the relevant information on PM-related health effects, is for EPA to promulgate standards for $PM_{2.5}$ that are far more stringent than those contained in the proposal.

EPA must heed the call of the scientific and public health community, as expressed by prominent researchers, physicians and other experts, to strengthen the air quality standards for particulate matter. To do otherwise is to doom thousands every year to premature death and to allow thousands more to unnecessarily suffer significant adverse health consequences. Moreover, failing to respond to these concerns would constitute a serious breach of both the public trust and agency's core statutory obligations.

Our comments will address the proposed primary and secondary standards for fine particles ($PM_{2.5}$) and coarse particles ($PM_{10-2.5}$) in turn.

EPA Must Set Protective Primary Standards for $PM_{2.5}$

Our comments will address the major issues related to the setting of the fine particle standards: the indicator, the averaging time, the level, and the form of the standards, that is, how compliance with the standards is measured. We will discuss how EPA's proposals fail to provide adequate protection and recommend elements for more protective standards.

As summarized in the EPA Criteria Document[37], Staff Paper[38], and Federal Register notice[39], dozens of epidemiologic studies have demonstrated repeatedly that both long-term and short-term exposures to $PM_{2.5}$ are associated with significant morbidity from both cardiovascular and respiratory disease, and with excess mortality.

Standards Must Protect Susceptible Populations

EPA must ensure that its new NAAQS are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations such as infants, children, the elderly, and persons with particular ailments (like heart disease, diabetes, or

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substantive conclusions. Such an approach would not only be scientifically invalid, but legally unsound as well (since considerations of health effects are meant to drive the standard setting process), and would threaten the integrity of this process. *See Scientists Complain of Diminished Role in Policy Under Bush*, St. Louis Post-Dispatch (Mon, Feb. 27, 2006).

[37] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004.
[38] U.S. EPA, Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information. OAQPS Staff Paper. EPA-452/R-05-005, June 2005.
[39] EPA, National Ambient Air Quality Standards for Particulate Matter; Proposed Rule. 71 Fed. Reg. 2620, January 17, 2006.

respiratory impairments).[40] EPA's broad mandate to protect such "sensitive citizens" must drive its decision-making process.[41]

As the U.S. Court of Appeals for the D.C. Circuit has stated:

> "In its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens" – children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution. If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard."[42]

Millions of Americans face increased susceptibility to health effects of fine particles. As the Criteria Document states (p. 9-89):

> "Considering together the subpopulations of persons with preexisting cardiopulmonary disease, older adults, children, people of lower socioeconomic status and those with higher potential exposure levels as potentially susceptible or vulnerable, it is clear that the impact of PM on public health could be very extensive."

More specifically, 22 million Americans have been diagnosed with heart disease, 39 million with hypertension, almost 12 million with diabetes, 9 million with chronic bronchitis, 3 million with emphysema, while almost 19 million adults and 9 million children have chronic asthma. (CD Table 9.4). The standards must protect these populations with an adequate margin of safety. EPA's proposed standards fall well short of this mark.[43]

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[40] *American Lung Assn. v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted); *see also Lead Industries Assn, Inc. v. EPA,* 647 F.2d at 1153 (NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals").

[41] "Based on these comprehensive [air quality] criteria and taking account of the 'preventative' and 'precautionary' nature of the act, the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that 'research has not yet uncovered.' Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety." *American Lung Assn. v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. American Trucking Assn.,* 531 U.S. 457, 464-71 (2001). *See* H.Rep. 294, 95th Cong., 1st Sess. 49-51 (1977) (explaining amendments designed *inter alia* "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs").

[42] *American Lung Assn. v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted); *see also Lead Industries Assn, Inc. v. EPA,* 647 F.2d 1130, 1153 (D.C. Cir. 1980) (NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals.").

[43] The Clean Air Act requires that EPA adopt standards that protect all Americans, including those with disabling conditions, such asthma, emphysema, and severe heart disease. In fact, courts have suggested, when examining whether the Americans with Disabilities Act ("ADA") or the Rehabilitation Act may be invoked to force a state to adopt more stringent air pollution requirements, that because EPA's standards must be "requisite to protect public health," remedies under the ADA and Rehabilitation Act may not be available later on. *See, e.g., Save Our Summers v. Washington State Dept. of Ecology*, 132 F.Supp. 896, 903 (E. Dist. Wash. 1999). Thus, in order to ensure that persons with disabilities are not allowed to fall through the cracks of the U.S. air pollution regulatory scheme, EPA's standard setting process must specifically ensure that sensitive individuals are protected to the same degree as others. EPA must consider whether its actions here will fully protect persons with disabilities in a manner that is

These subpopulations are mentioned in the Staff Paper,[44] but it does not appear that they were accounted for in setting the proposed NAAQS. It appears that EPA bases the proposed standard primarily on adult mortality, and did not adequately consider data on birth outcomes such as low birth weight and infant mortality. There are numerous strong studies identifying adverse effects of PM on reproductive outcomes,[45] and these should not be dismissed, especially due to the implications of these health effects.

Children are especially vulnerable because they have a higher breathing rate than adults relative to their body weight and lung surface area. These characteristics result in a greater dose of pollution delivered to their lungs.[46] The data are far stronger than EPA usually has available on environmental pollutants. , and the Administrator is holding the data to an insupportedly high standard rather than incorporating reasonable and appropriate precautionary approaches to protect infants and children.

These gaps indicate that the EPA assessment of the implications of various alternative short- and long-term standards may seriously underestimate the human health effects and the populations affected at each alternative level. Since the magnitude of the health effects of PM on infants and children is greater on an absolute basis in some studies,[47] and on a relative basis in many others (due to the lower baseline incidence of disease in children as compared to adults), literally leaving infants and children out of the equation is untenable if the goal – and the legal mandate - is to assure health protection of the entire population, including the most sensitive groups.

Other populations have also been shown to be more susceptible than the average. For example, diabetics have been demonstrated to have decreased vascular reactivity to nitroglycerin after short-term exposure to $PM_{2.5}$.[48] In this study, the ambient fine particulate concentrations were quite low, with a maximum $PM_{2.5}$ level of 40 µg/m^3 and a mean of only 11.5 µg/m^3. This study shows that the vascular endothelium of diabetics may be significantly more susceptible to the adverse effects of $PM_{2.5}$ on the vascular system, compared with effects in the general population.

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consistent with the principles of the ADA and Rehabilitation Act – it may not adopt a standard that fails to protect these citizens.

[44] Staff Paper pp. 3-39 et seq.

[45] See eg.: Wilhelm M, Ritz B. Residential proximity to traffic and adverse birth outcomes in Los Angeles county, California, 1994-1996. *Environ Health Perspect* 2003; 111:207-216; Ritz B, Yu F, Chapa G, Fruin S. Effect of air pollution on preterm birth among children born in Southern California between 1989 and 1993. *Epidemiology* 2000; 11:502-511; Yang CY, Tseng YT, Chang CC. Effects of air pollution on birth weight among children born between 1995 and 1997 in Kaohsiung, Taiwan. *J Toxicol Environ Health* A. 2003; 66:807-816; Jedrychowski W, Bendkowska I, et al. Estimated risk for altered fetal growth resulting from exposure to fine particles during pregnancy: An epidemiologic prospective cohort study in Poland. *Environ Health Perspect* 2004; 112:1398-1402; Lee BE, Ha EH, et al. Exposure to air pollution during different gestational phases contributes to risks of low birth weight. *Hum Reprod* 2003; 18:638-43.

[46] American Academy of Pediatrics Committee on Environmental Health, Ambient Air Pollution: Health Hazards to Children. *Pediatrics* 2004; 114: 1699-1707.

[47] Gouveia N, Fletcher T. Time series analysis of air pollution and mortality: effects by cause, age and socioeconomic status. *J Epidemiol Community Health* 2000; 54:750-755.

[48] O'Neill MS, Veves A, et al. Diabetes enhances vulnerability to particulate air pollution-associated impairment in vascular reactivity and endothelial function. *Circulation* 2005; 111:2913-2920.

Lower short-and long-term standards for $PM_{2.5}$ than proposed are necessary to protect this demonstrably susceptible subpopulation.

By failing to incorporate impacts on infants, children, and other sensitive populations into the standard setting analysis for short term $PM_{2.5}$, even in light of relevant available data, EPA has walked away from a critical element of its statutory obligation. It is, by design, declining to protect part of the population – an outcome that is impermissible under the Clean Air Act. EPA must specifically address the health implications of any PM limit that it selects for infant, children and other sensitive populations. Absent such analysis, EPA's standard setting process is fundamentally flawed and falls short of meeting its legal obligations.

The Evidence is Robust that $PM_{2.5}$ is the Appropriate Indicator Pollutant: Under No Circumstances Should EPA Further Differentiate Fine Particles Based on Source, Chemistry, or For Either Urban or Rural Areas

We support EPA's proposal to retain the mass-based $PM_{2.5}$ as the indicator for fine particles. The Administrator's determination that $PM_{2.5}$ is the appropriate indicator is consistent with the bulk of the science reviewed in the Criteria Document and Staff Paper. (71 Fed. Reg. 2645.) The $PM_{2.5}$ indicator is fully supported by CASAC. There is simply insufficient scientific data available at this time to justify limiting the indicator to one or more specific components or sources.

The Administrator correctly concludes that: "There is no evidence that would lead toward the selection of one or more PM components as being primarily responsible for effects associated with fine particles, nor is there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles."[49] Future research will likely include investigation of toxic constituents of $PM_{2.5}$, as well as investigation of health effects related to ultrafine particles. However, it is scientifically unjustifiable at this time to attempt to set a standard for any individual constituents of $PM_{2.5}$. In light of the extensive evidence that this indicator is associated with serious health effects, hospitalizations, and death in humans, it is also scientifically unjustifiable, as well as inconsistent with the requirements of the Clean Air Act, for EPA to fail to set a standard for $PM_{2.5}$ as the indicator pollutant.

The Administrator has solicited comment on "approaches to assessing the available and future research results to determine whether alternative indicators for fine particles are warranted." Such differentiation is unnecessary and unwarranted based on the existing scientific data.

Any change in the indicator pollutant relied upon for protecting public health would constitute a fundamental alteration of the nature of the proposed rule. Because the current proposal contains no discussion or analysis that specifically evaluates the appropriateness of another indicator pollutant, a final action adopting a standard based on an indicator pollutant other than $PM_{2.5}$ could not be considered a reasonable outgrowth of the existing proposal. Accordingly, as a

[49] 71 FR 2644 (January 17, 2006).

procedural matter, EPA may not adopt any such change. In any event, there is no valid technical justification for adopting any other indicator pollutant.

Consideration of Studies Published Since the Completion of the Criteria Document Must Not Delay Promulgation of the Standard

Under the Clean Air Act NAAQS must be reviewed on a five year cycle. This five year cycle is intended to protect public health by ensuring that the latest scientific evidence is continually reviewed and considered for its relevance to standard setting. As soon as a Criteria Document is completed, work must begin assessing new studies that are published for inclusion in the next criteria document. We have articulated repeatedly to EPA in writing and in legal briefs that we support the continual review of the science as the Congress intended.

Many hundreds of studies have been published in the intervening years since the publication of the final Criteria Document in October 2004. The vast majority of these studies substantiate the findings of the earlier studies. EPA has identified a preliminary list of 181 potentially significant studies published since April 2002 that will be assessed in light of the literature evaluated in the Criteria Document.[50] This list was generated in response to an inquiry from Senator Inhofe.[51] Senator Inhofe requested that EPA identify recent studies that may be of relevance to assessing the relative importance of specific particle components or source categories. EPA solicits comment on other relevant studies that may be added to this list (71 Fed. Reg. 2625).

The studies included in the Criteria Document and Staff Paper clearly show adverse effects below the level of the current standards (and below the levels contained in EPA's proposal) and demonstrate the need for EPA to take immediate action to protect public health. Many more recent studies not included in the Criteria Document provide additional compelling evidence of harmful effects at low levels of exposure, and similarly demonstrate the need for swift and decisive action to set strong standards to protect public health. We discuss a number of the most significant new studies in our comments, as requested by EPA. In addition to the studies referenced or discussed in the text of these comments, we have identified a handful of additional new studies of potential interest in Appendix 1. However, the studies reviewed in the Criteria Document and Staff Paper stand on their own as fully compelling justification for the standards we advocate.

Under no circumstance should EPA's consideration of additional scientific studies serve as a justification for postponing action to tighten the NAAQS. Delaying promulgation of the standard based on the existence of new studies would violate the consent agreement.[52] However, if EPA does consider additional studies beyond those reviewed by the Criteria Document and Staff Paper, it may not select studies for examination that provide an unbalanced view of the impact of PM on public health and welfare. Any such review must include consideration of the important new studies that demonstrate health impacts from PM at levels well below the current

[50] U.S. EPA. Preliminary List of Potentially Significant Studies of Particulate Matter and Health Published Since April 2002.
[51] Letter from Senator James Inhofe to EPA Administrator Steven Johnson, October 25, 2005.
[52] Order of December 16, 2004 in *American Lung Assn. v. Whitman*, D.D.C. 03cv778 ESH.

and newly proposed standards. In particular, it is important for EPA to consider the new studies that directly interpret, extend , or evaluate the results of the core studies upon which EPA's conclusions rely (e.g., the Six Cities and ACS studies). EPA's decision to consider additional studies cannot appropriately function to prolong this NAAQS standard-setting process.

Evidence in the Criteria Document Fully Supports EPA's Proposed Daily and Annual Averaging Times

EPA has selected the appropriate averaging times for the fine particle standards. Specifically, EPA determined that a 24-hour average standard is needed to control daily exposures (as evidenced by numerous time-series and other studies of daily exposures), and that an annual average standard is appropriate to reduce chronic exposures. These conclusions are both correct and unavoidable. Moreover, to adequately protect public health, each of these standards must be set at a level that is independently protective for the targeted health effects. That is, the 24-hour standard must be set at a level that fully protects the public from acute effects, but cannot function as a justification for adopting a less stringent annual standard to protect the public from chronic effects, and vice versa.

An Annual Average $PM_{2.5}$ Standard is Warranted to Control Chronic Exposures

The evidence of long-term effects of fine particles is stronger and even more compelling than it was nine years ago when the first $PM_{2.5}$ standards were established, providing additional support for an annual average standard. The major cohort studies have been audited replicated, reanalyzed, and extended. New long term studies such as the California Children's Health Study have been completed. Long-term exposure to $PM_{2.5}$ causes mortality from cardiopulmonary diseases and lung cancer and is associated with reduced lung function and development of chronic respiratory disease.

Available scientific evidence, as assessed in the Criteria Document, provides compelling evidence that serious adverse health effects -- including early death -- occur at levels below the current standards for fine particles. The cohort studies show increased risk down to the lowest levels studied, documenting that an annual average $PM_{2.5}$ standard of 12 $\mu g/m^3$ or below is necessary.

The strength of the evidence regarding long-term mortality effects has greatly increased. There is new evidence of other health effects associated with PM exposures including increases in lung cancer, asthma-related physician visits and symptoms, heart attacks and other cardiac risk factors, and infant mortality and developmental effects, all with significant public health implications.

Finally, the new research provides evidence of the extent of life shortening attributable to particulate exposures. According to the Criteria Document (p. 9-94) loss of population life expectancy may be substantial -- on the order of a year or so -- with long term exposure to PM.

A 24-Hour $PM_{2.5}$ Standard is Needed to Protect Against Short-term Spikes

There are literally hundreds of new studies referenced in the Criteria Document on the effect of short-term spikes in fine particle pollution, with many reporting effects on new health endpoints such as heart attacks, strokes, and congestive heart failure. While a few of the studies are based on sub-daily exposures, the vast majority of the evidence in hand points to the need for a 24-hour average standard. With the deployment of new continuous monitors for $PM_{2.5}$, we expect that new studies will be available for EPA's next review regarding the effects of sub-daily exposures on human health.

As the Staff Paper notes (p. 3-34): "Much more evidence is now available related to the coherence and plausibility of effects than in the last review. For short-term exposures, the Criteria Document finds that the integration of evidence from epidemiologic and toxicological studies indicates both coherence and plausibility of effects on the cardiovascular and respiratory systems, particularly for fine particles (CD, p. 9-78)."

Also there is evidence supporting coherence and plausibility for the observed associations between long-term exposures to fine particles and lung cancer mortality" (CD, p. 9-78).

The Staff Paper concludes that:

> "Short-term exposure to $PM_{2.5}$ is likely causally associated with mortality from cardiopulmonary diseases, hospitalization and emergency department visits for cardiopulmonary diseases, increased respiratory symptoms, decreased lung function, and physiological changes or biomarkers for cardiac changes. Long-term exposure to $PM_{2.5}$ is likely causally associated with mortality from cardiopulmonary diseases and lung cancer, and effects on the respiratory system such as decreased lung function or the development of chronic respiratory disease." (Staff Paper, p. 3-57 to 3-58).

This evidence indicates that the annual average and 24-hour averaging times as proposed, are appropriate for the primary $PM_{2.5}$ standards. These averaging times were fully supported by CASAC.

EPA Must Strengthen Both the Annual Average and 24-hour $PM_{2.5}$ Standards to Protect the Public from Health Effects of Short- and Long-Term Exposures and to Provide Uniform Protection Across the U.S.

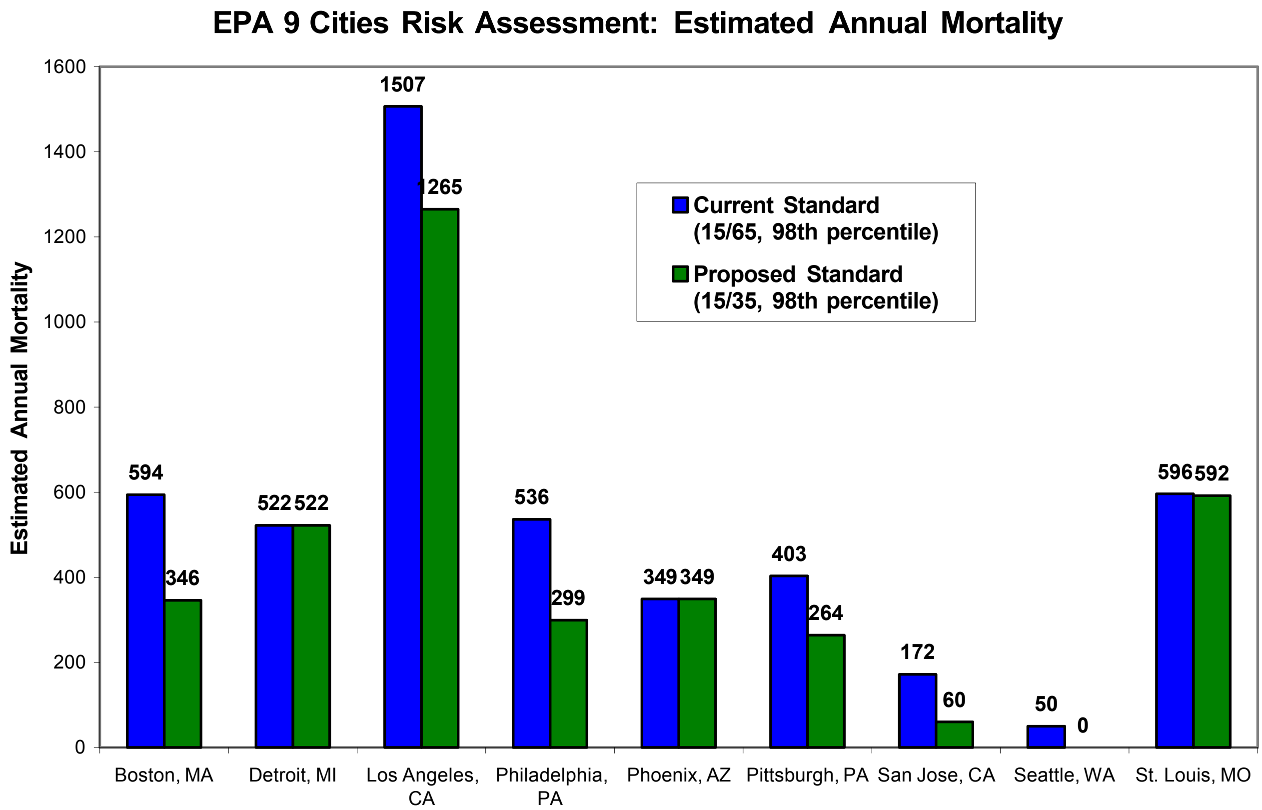
EPA proposes to retain the existing annual standard, while modestly lowering the 24-hour average standard. However, in order to adequately protect citizens across the country, both the annual average and the 24-hour standard need to be substantially tightened. The scientific evidence supporting this conclusion demonstrates that EPA's proposed standards are not adequate to protect public health, and will result in thousands of additional deaths and illnesses every year, particularly when compared to the levels we advocate here. Moreover, EPA has clearly failed to justify its decision to set $PM_{2.5}$ standards at the levels it has proposed. Absent a justification for its decision, that demonstrates that its proposal provides clear public health protection, EPA cannot satisfy the agency's statutory obligations under the Clean Air Act.

A tighter annual average standard is required to provide equitable protection against long-term health impacts of PM in all regions of the county. An independent analysis of air quality monitoring data by NESCAUM found that a 30/12 $\mu g/m^3$ (daily/annual) suite of standards provides nearly equivalent 24-hour and annual control of $PM_{2.5}$ distributions across the U.S., thus ensuring a more uniform and consistent level of protection than achieved by lowering only the daily standard.[53] This analysis demonstrates the importance of tightening both standards.

The risk assessment reinforces the need to lower the annual average standard. EPA's nine-city risk assessment shows that lowering the 24-hour standard alone will not reduce risk of long-term mortality that exists under the current standards in three of the nine cities -- Detroit, St. Louis, and Phoenix. (See Figure 1 below.) This was an important factor cited by CASAC in recommending a lower annual standard in conjunction with a lower daily standard.[54]

[53] Johnson PRS, Graham JJ. Analysis of Primary Fine Particle National Ambient Air Quality Standard Metrics. *JAWMA* 2006; 56:206-218.
[54] Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, March 21, 2006, Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, EPA-CASAC-LTR-06-002.

Figure 1



U.S. Environmental Protection Agency. Particulate Matter Health Risk Assessment for Selected Urban Areas. December, 2005. Available at www.epa.gov/ttn/naaqs/standards/pm/data/PMrisk20051220.pdf Accessed March 29, 2006.

Under the EPA proposal, all the reductions that would be required beyond the reductions needed for attainment of the current NAAQS are attributable to the tighter 24-hour NAAQS because the annual NAAQS remains the same. Places where the air quality is already in compliance with the proposed 24-hour NAAQS --fully 73 percent of the counties with monitors -- will achieve no benefit from the proposed rule.[55] A reduction in the annual NAAQS is more likely to instigate long-term emissions reduction measures that will protect the public from the adverse health effects associated with recurring exposure to ambient PM levels below the 24-hour standard.

Monitoring Data Show EPA Proposal Leaves Millions Unprotected

An analysis of EPA annual and 24-hour design values based on 2002-2004 air quality monitoring data reveals that with a 24-hour $PM_{2.5}$ standard of 35 µg/m^3 98th percentile, 158 counties with a total population of more than 36 million people that currently attain the proposed daily standard

[55] Staff Paper Table 5B-1(a).

have annual average concentrations between 12 μg/m^3 and 15 μg/m^3. Appendix 2 identifies the specific counties and their annual average levels.[56]

The people who live in these counties are exposed to concentrations of fine particles that clearly cause some of them to experience premature death or other health effects, but they will not be protected by the proposed standards. For instance, the counties of Richmond Georgia and Mecklenburg North Carolina will easily attain the proposed 24-hour $PM_{2.5}$ standard. However their citizens will be exposed to annual average $PM_{2.5}$ concentrations of 14.9 μg/m^3 – a level that is just below the proposed annual average standard. The South and Midwest contains a large number of these unprotected counties, for example in North Carolina, Kentucky, Indiana, Georgia, and Alabama. This air quality analysis provides additional evidence that the proposed lowering of the 24-hour standard alone is insufficient to protect against annual average concentrations of concern. It also shows that lowering the annual average standard by one microgram, to 14 μg/m^3, would likely provide protection to the residents of only 29 additional counties.

We will discuss the level and form of the annual average and the daily $PM_{2.5}$ standards in turn.

EPA Must Lower the Level of the Annual Average $PM_{2.5}$ Standard

The Administrator Disregarded the Recommendation s of EPA Staff Scientists

Balanced consideration of the scientific evidence laid out in the Criteria Document, along with consideration of the results of the risk assessment, led EPA staff scientists to recommend two policy options for lowering the level of the $PM_{2.5}$ standards. Option 1 would make reductions only in the level of the 24-hour standard. As described in more detail later in these comments, the EPA proposal falls outside the ranges recommended by staff scientists because of failure to propose changes to the form of the 24-hour standard. Option 2 would reduce the annual average standard within the range of 12 to 14 μg/m^3, together with a revised 24-hour standard in the range of 30 to 40 μg/m^3. Staff scientists recommended selecting either the annual or the 24-hour standard, or both, from the middle to lower end of the ranges to "provide an appropriate degree of protection against serious mortality and morbidity effects associated with long- and short-term exposure to fine particles." (Staff Paper p. 5-47). In the proposed rule, the Administrator rejected this recommendation and proposed to retain the current annual average $PM_{2.5}$ standard. Historically, the EPA Administrator has relied on staff scientists' interpretation of the evidence to ensure that standards are based solely on public health considerations, and not biased by political considerations, as required by the Clean Air Act.

[56] 2002-2004 Design Values, Personal communication from Mark Schmidt, OAQPS, EPA, October 15, 2005. Analysis by Environmental Defense.

EPA Dismissed the Findings of the CASAC and Arbitrarily Failed to Follow their Clear Recommendation to Tighten the Annual $PM_{2.5}$ Standard

In its review, CASAC largely concurred that the scientific rationale for the recommendations in the Staff Paper was sound, but somewhat narrowed the recommended ranges. The CASAC was adamant that the annual average standard must be lowered to protect public health.[57] The Administrator has substituted his own opinion for the judgment of 20 of the nation's leading scientific experts on the adverse effects of PM. Moreover, he has done so without any valid health-based justification – instead of recognizing the health consequences associated with long-term $PM_{2.5}$ exposures, and addressing those consequences by tightening the annual PM standard, the Administrator elected to ignore those effects and leave in place a standard that is demonstrably inadequate. This decision is without merit as a matter or either science or law.

The CASAC panel recommended lowering the annual average $PM_{2.5}$ standard, in conjunction with a reduction in the 24-hour standard. Its original letter to EPA clearly stated:

> "…the panel did not endorse the option of keeping the annual standard at its present level of 15 μg/m^3. It was appreciated that some cities have relatively high annual PM concentrations, but without much variation in concentrations from day to day. Such cities would only rarely exceed a 24-hour $PM_{2.5}$ standard, even if set at levels below the current standard. This observation indicates the desirability of lowering the level of the annual $PM_{2.5}$ standard as well."[58]

The CASAC panel clarified its position in a follow-up letter to EPA, issued after the proposed rule failed to follow their original advice. The follow-up letter states:

> "The CASAC would like to reiterate and elaborate on the scientific basis for the PM Panel's earlier recommendation, as follows:"
>
> "First, the Agency's risk assessment indicating reduced health risks at annual $PM_{2.5}$ levels below the current standard was a key component in the PM Panel's recommendation to lower the current annual level. While the risk assessment is subject to uncertainties, most of the PM Panel found EPA's risk assessment to be of sufficient quality to inform its recommendations. The authors of the Agency's risk assessment followed CASAC's advice in conducting extensive sensitivity analyses and in revising the threshold assumptions as published in the final PM Staff Paper. The risk analyses indicated that the uncertainties would increase rapidly below an annual level of 13 μg/m^3 — and that was the basis for the PM Panel's recommendation of 13 μg/m^3 as the lower bound for the annual $PM_{2.5}$ standard level."

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[57] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, March 21, 2006, Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, EPA-CASAC-LTR-06-002.

[58] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, June 6, 2005. EPA-SAB-CASAC-05-007.

"In our June 6, 2005 report, the PM Panel noted that 'some cities have relatively high annual $PM_{2.5}$ concentrations, but without much variation in concentrations from day-to-day.' Dependence on a lower daily $PM_{2.5}$ concentration limit alone cannot be relied on to provide protection against the adverse effects of higher annual average concentrations The changes suggested in the 24-hour standard will have significant impact when done "in concert" with a change in the annual standard. The effect of changing the short-term (98^{th} percentile) and long-term standard levels in concert can be seen in Figures 5-1 and 5-2 of the Agency's staff paper. The cities of St. Louis and Detroit are examples of cities where the estimated reduction in $PM_{2.5}$-related short-term and long-term mortality risk with a daily standard of 35 $\mu g/m^3$ would be enhanced by a concerted reduction in the annual standard below the current level of 15 $\mu g/m^3$."

These first two points indicate the confidence the CASAC panel places in the results of the risk assessment to inform decision making. Nevertheless, the EPA Administrator had disregarded the risk assessment results terming them too uncertain. The letter continues:

"While the risk analysis is the primary means of determining the effects on risk of changes in the 24-hour and annual $PM_{2.5}$ standards in concert, there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the current annual standard level of 15 $\mu g/m^3$. Studies described in the PM Staff Paper indicate that short-term effects of $PM_{2.5}$ persist in cities with annual $PM_{2.5}$ concentrations below the current standard. In a Canadian study (Burnett *et al.*, 2000; and Burnett and Goldberg, 2003), significant associations with total and cardiovascular mortality were present at a long-term mean $PM_{2.5}$ concentration of 13.3 $\mu g/m^3$. There were also positive findings in studies in Phoenix, AZ (Mar *et al.*, 1999, 2003) and in Santa Clara County, CA (Lipsett *et al.*, 1997) in which long-term mean concentrations of $PM_{2.5}$ were approximately 13 $\mu g/m^3$."

Here, the CASAC is emphasizing the evidence-based arguments in support of a lower annual average standard. The letter goes on to say:

"In summary, the epidemiologic evidence, supported by emerging mechanistic understanding, indicates adverse effects of $PM_{2.5}$ at current annual average levels below 15 $\mu g/m^3$. The PM Panel realized the uncertainties involved in setting an appropriate, health-protective level for the annual standard, but noted that the uncertainties would increase rapidly below the level of 13 $\mu g/m^3$. That is the basis for the PM Panel recommendation of a level at 13 - 14 $\mu g/m^3$."

"Therefore, the CASAC requests reconsideration of the proposed ruling for the level of the annual $PM_{2.5}$ NAAQS so that the standard is set within the range previously recommended by the PM Panel, i.e., *13 to 14 $\mu g/m^3$.* [Emphasis in the original]"[59]

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[59] Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, March 21, 2006, Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, EPA-CASAC-LTR-06-002.

This position was fully endorsed by all seven appointed members of the CASAC, and all but two of the 22 member panel as a whole.

While CASAC did not go far enough, EPA chose not to follow even its modest recommendations, giving only lip service to the "great importance" of CASAC's advice (Fed. Reg. 2651). EPA's dismissal of the health-based recommendations of this expert panel of scientists runs directly counter to EPA's statutory obligation to identify NAAQS based exclusively on an assessment of the public health requirements.[60] EPA simply cannot ignore the CASAC's health-based advice and then reach contrary conclusions about the need for more stringent standards without giving proper weight to the core public health considerations compelled by the Clean Air Act and that underlie the CASAC analysis and conclusions.

EPA Discounts Evidence Indicating that Levels of $PM_{2.5}$ below 15 µg/m^3 Cause Significant Harm to Human Health

EPA's proposed annual fine particle standard clearly does not protect the public health with an adequate margin of safety, including the health of susceptible populations. Available evidence as summarized below supports an annual average standard of 12 µg/m^3 or lower.

The original Six Cities and American Cancer Society (ACS) cohort studies provided clear evidence of a linear dose response relationship between fine particle pollution and mortality down to the lowest levels studied, that is, 11 µg/m^3 in the Six Cities study, and 9 µg/m^3 in the ACS study.[61] The HEI reanalysis of the ACS cohort study provided direct evidence for premature mortality associated with annual exposures below 15 µg/m^3.[62] For example, the standardized residual plot for all-cause and cardiopulmonary mortality shown in figure 6 of Part II of the Krewski et al. 2000 reanalysis shows the upper 95% confidence limit has a downward trend from 15 to 10 µg/m^3 (see Figure 3 below).[63]

The fact that this dose response relationship continues below levels of 15 µg/m^3 -- and is in fact strongest in that range -- is supported by further analysis of the ACS data set by Abrahamowicz

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[60] *See, e.g.,* NRDC v. EPA, 824 F.2d 1146, 1164-65 (D.C. Cir. 1987);); *American Lung Assn. v. EPA*, 134 F.3d 388, (D.C. Cir. 1998) (citations omitted); *see also Lead Industries Assn, Inc. v. EPA,* 647 F.2d 1130 (D.C. Cir. 1980).

[61] Dockery DW, Pope CA 3rd, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG Jr, Speizer FE. An Association Between Air Pollution and Mortality in Six U.S. Cities. *N Engl J Med* 1993; 329:1753-1759; and Pope CA 3rd, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, Speizer FE, Heath CW Jr. Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults. *Am J Respir Crit Care Med* 1995; 151:669-74.

[61] Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute. July 2000.

[63] Krewski et al., Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality A Special Report of the Institute's Particle Epidemiology Reanalysis Project) HEI 2000 p. 175.

et al.[64] This important study provides critical additional analysis relevant to the level of the annual standard, and must be added to the record now. This study, which used a flexible regression spline model to more accurately examine the nature of the dose response relationship at different levels of exposure, concluded that most of the increase in mortality risk from $PM_{2.5}$ exposure occurs between the low end of the range (around 9.5 $\mu g/m^3$ in this study) and 16 $\mu g/m^3$. This directly counters the hypothesis that the observed linear relationship between $PM_{2.5}$ exposure and cardiovascular mortality is driven by a stronger association at exposure levels above 15 $\mu g/m^3$.

[64] Abrahamowicz M, Schopflocher T, Leffondre K, du Berger R, Krewski D. Flexible Modeling of Exposure-Response Relationship Between Long-Term Average Levels of Particulate Air Pollution and Mortality in the American Cancer Society Study. *J Toxicol Environ Health A*. 2003; 66:1625-54.

Figure 2

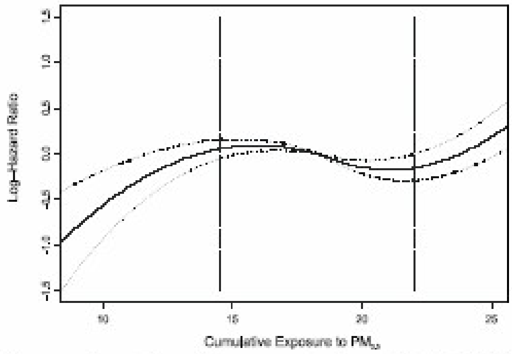

Figure 10. Impact of cumulative exposure to fine particles in the ACS Study. Flexible quadratic spline estimate (3 *df*) of the nonlinear effect of increasing the exposure to fine particles on the log–hazard ratio of mortality in a case-cohort subset of the ACS Study, adjusted for BMI, education level, and pack-years of smoking for current- and former-smokers. The log–hazard ratio was associated with a change in fine particles (24.5 μg/m^3) equal to the difference in mean concentrations between the most-polluted city and the least-polluted city. Along the horizontal axis, the solid curve represents the point estimate of the log–hazard ratio and the dashed curves the point-wise 95% confidence interval. The left and right dashed vertical lines indicate the first and third quartiles of fine particles in the sample of 2,500 individuals included in the ACS Study.

From Krewski et al., Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality A Special Report of the Institute's Particle Epidemiology Reanalysis Project) HEI 2000 p. 175

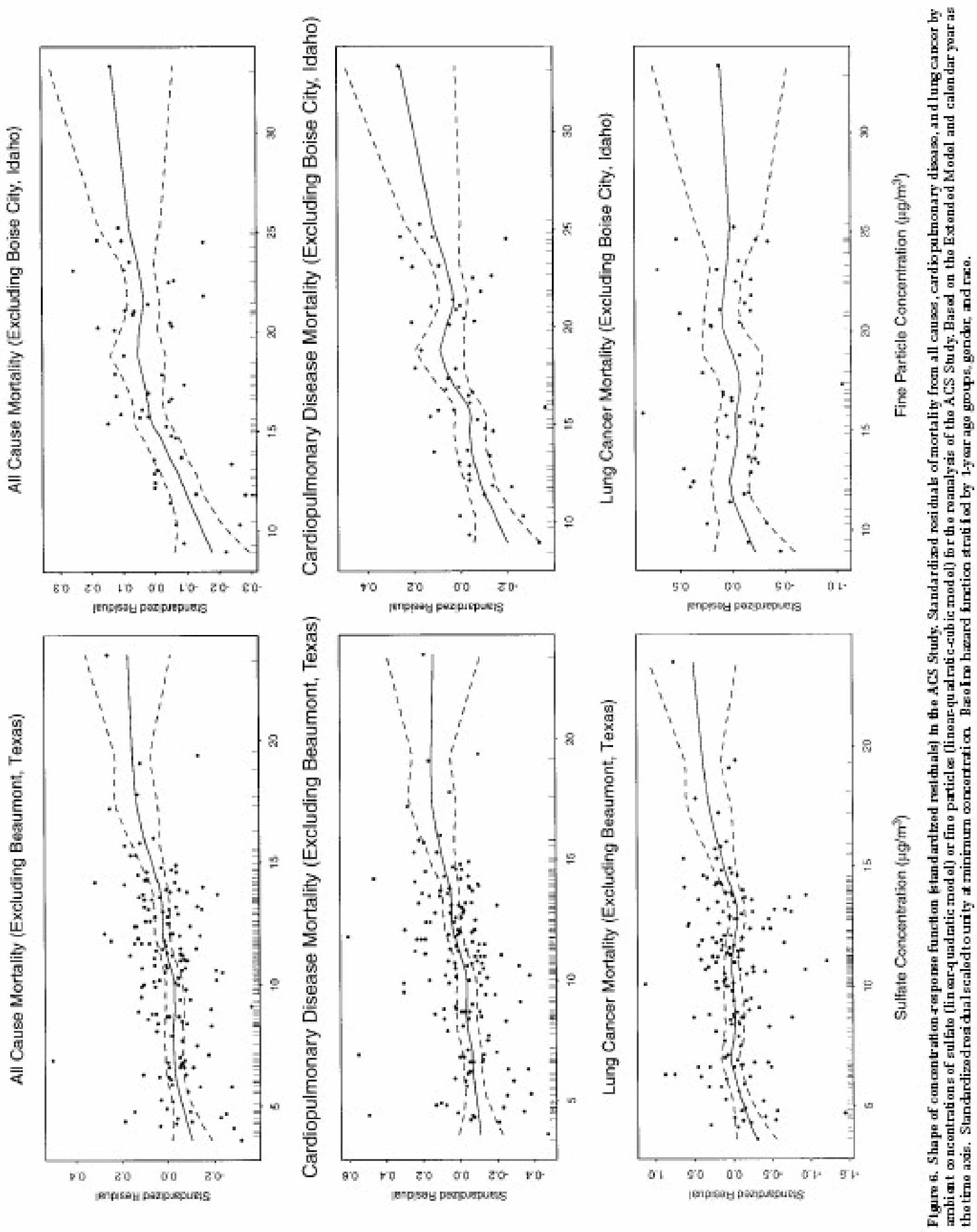

Figure 3

From Krewski et al., Part II, Sensitivity Analysis, (Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality A Special Report of the Institute's Particle Epidemiology Reanalysis Project) HEI 2000 p. 162

Additional evidence for significant effects of long-term exposures below 15 μg/m^3 is the increase in effect estimates for a 10 μg/m^3 increase in $PM_{2.5}$ in the ACS cohort follow-up as average exposure levels decreased from 21.1 μg/m^3 to 14.0 μg/m^3, and subject-weighted relative risks of death and lung cancer at the mean exposure level of 14.0 μg/m^3 remained significantly increased.[65] This empirical evidence as shown in the preceding Figures 2 and 3 directly counters the EPA's argument that there is insufficient justification for lowering the annual standard from its current value of 15 μg/m^3. Nor does EPA provide any legitimate basis for dismissing this data. EPA may not ignore the relevant science.

Examination of the mean $PM_{2.5}$ concentration levels reported in the key long-term studies also indicates that an annual average standard of 12 μg/m^3 or below is needed to protect public health with an adequate margin of safety, to protect sensitive subpopulations, as required by the Clean Air Act.[66] This was the approach used by the State of California when it determined that the annual average fine particle standard should be set at 12 μg/m^3.[67]

In the ACS extended analysis dataset for $PM_{2.5}$ measurements from 1999-2000, the mean concentration was 14 μg/m^3, with a standard deviation of 3.0. (Pope 2002, 2004). The mean plus or minus one standard deviation ranged from 11 μg/m^3 to 17 μg/m^3. This indicates that a standard as low as 10 μg/m^3 may be necessary to protect public health and provide a margin of safety to prevent premature deaths.

In fact, the recommendation of the World Health Organization working group to set an annual average guideline value of 10 μg/m^3 places significant weight on the ACS and Harvard Six City data. This guideline value was chosen to represent the lower end of the range over which significant effects on survival have been observed in these studies where robust associations have been reported between long-term exposure to $PM_{2.5}$ and mortality, and thresholds are not apparent. (Dockery et al., 1993; Pope et al., 1995; Krewski et al., 2000; Pope 2002; Jerrett 2005). According to the WHO report:

> "In the Dockery et al. study, the risks are similar in the cities at the lowest long-term $PM_{2.5}$ concentrations of 11 and 12.5 μg/m^3. Increases in risk are apparent in the city with the next-lowest long-term $PM_{2.5}$ mean of 14.9 μg/m^3, indicating likely effects in the range

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65 Pope CA III, Burnett RT, Thun MJ, Calle EE, Krewski K, Ito K, Thurston GD. Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution, *Journal of the American Medical Association* 2002; 287: 1132-1141. See Table 2 and Figure 5.

66 In fact, courts have repeatedly held that, EPA must demonstrate that standards are set at a level that ensure "an absence of adverse effect" on sensitive individuals. *See, e.g.*, *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980); *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). Moreover, this is an affirmative obligation. *See American Trucking Ass'n v. Whitman*, 283 F.3d 355, 369 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree' . . . .") (quoting EPA's PM NAAQS Federal Register notice, 62 Fed. Reg. at 38653); *Lead Indus. Ass'n*, 647 F.2d at 1155 ("[R]equiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to human health before it acts is inconsistent with both the Act's precautionary and preventative orientation and the nature of the Administrator's statutory responsibilities.").

67 California Environmental Protection Agency, Air Resources Board. Staff Report: Public Hearing to Consider Amendments to the Ambient Air Quality Standards for Particulate Matter and Sulfates. May 3, 2002. p. 2-6.

of 11 to 15 µg/m^3. Therefore, an annual concentration of 10 µg/m3 would be below the mean of the most likely effects in the available literature."[68]

This recommended level also places some weight on the results of daily exposure time-series studies, with long-term (three- to four-year) means in the range of 13 to 18 µg/m^3.

A newly-published extension of the Six Cities study provides direct, specific evidence for an increased population risk of cardiopulmonary mortality at annual exposure levels well below the current standard.[69] Average $PM_{2.5}$ concentrations during the 1990-1998 follow-up period ranged from 10.2 µg/m^3 in Portage to 22 µg/m^3 in Steubenville. Long-term average concentrations were at or below 13.4 µg/m^3 in four of the six cities. Yet the linear dose-response association between $PM_{2.5}$ concentrations and total mortality persists even at these lower concentrations. Mean concentrations across the six cities in the second period of the study, from 1990 to 1998, were 14.8 µg/m^3, with a standard deviation ± 4.2, suggesting a range of 10.6 to 19.0 where most effects occurred. This study provides strong additional support for lowering the annual average $PM_{2.5}$ standard below 12 µg/m^3. The Laden et al. study reported that an average of three percent fewer people died for every one µg/m^3 reduction in the annual average levels of $PM_{2.5}$. Such "intervention" studies in environmental health documenting changes in health outcomes in response to decreases in exposure are rare and extremely valuable.

Jerrett et al. 2005 used interpolation to more closely model the exposure of over 22,900 individuals participating in the ACS cohort in the Los Angeles area.[70] Forty-four potential confounding variables were included in this very thorough analysis. This study had a dose-response estimate for cardiovascular mortality that was three times greater than the estimate from the Pope et al., 2002 study. The Jerrett et al. 2005 study shows that people living in more polluted neighborhoods are at much greater risk than previously believed. An increase in effect estimate with more accurate exposure assessment is strong evidence in support of a causal association, and also increases the probability of significant underestimate of the true health benefits of lowering exposure when using the Pope coefficients for risk assessments. The greater effect estimate in the face of more rigorous control of confounding also further demonstrates the invalidity of concerns about confounders relied upon by the agency to retain the current standard.

Epidemiological studies measure the effects of real world concentrations of air pollutants on community populations. As such, there are extremely valuable for assessing the health impacts of ambient air pollution. Because of the time and long-term funding commitment needed to conduct long-term epidemiological studies, there are relatively few such studies available. Nonetheless, in the case of PM pollution, we are fortunate to have a number of well-conducted long-term studies to provide the foundation for decision-making on the level of the annual average standard. EPA should not delay action to lower the annual average standard while awaiting the results of future research. (Staff Paper pp. 2652-2653).

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[68] World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005. WHOLIS number E87950.
[69] Laden F, Schwartz J, Speizer FE, Dockery DW. Reduction in Fine Particulate Air Pollution and Mortality: Extended Follow-up of the Harvard Six Cities Study. *Am J Respir Crit Care Med* 2006; 173: 667-672
[70] Jerrett M, Burnett RT, Ma R, Pope III CA, Kerewski D, Newbold KB, Thurston G, Shi Y, Finkelstein N, Calle EE, Thun MJ. Spatial Analysis of Air Pollution and Mortality in Los Angeles. *Epidemiology* 2005; 16:727-736.

In addition to these studies of the effects of chronic exposures to $PM_{2.5}$ on mortality, there is evidence from the literature of acute effects of fine particulates to corroborate that health effects occur from chronic exposures below 15 μg/m^3. In further analysis of the Six City data set, Schwartz et al. used a variety of curve smoothing techniques which demonstrated concentration response relationships well below mean concentrations of 15 μg/m^3.[71]

Importantly, the long-term mean $PM_{2.5}$ concentrations in ten of the short-term studies examined in the EPA staff memo indicate mean concentrations less than 15 μg/m^3, providing support for an annual average standard of 12 μg/m^3 or below.[72] See Table 1 below. More specifically, a study on air pollution and mortality in Phoenix, Arizona, found statistically significant associations with an annual average $PM_{2.5}$ concentration of 13.5 μg/m^3.[73] Similar results were found in Santa Clara County, California, where the annual average is 13.6 μg/m^3.[74] A study in Montreal identified a significant association between emergency department visits among older adults and $PM_{2.5}$ at mean levels as low as 12.1 μg/m^3.[75] EPA must set the long-term standard well below the mean concentrations in these studies to protect against cardiopulmonary mortality and morbidity.

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[71] Schwartz J, Laden F, Zanobetti A. The Concentration-Response Relation Between $PM_{2.5}$ and Daily Deaths. *Environ Health Perspect*. 2002; 110:1025-1029.

[72] Ross M, Langstaff J. Updated statistical information on air quality data from epidemiologic studies. Memorandum to PM NAAQS review docket OAR-2001-0017. January 31, 2005.

[73] Mar TF, Norris GA, et al. Associations between air pollution and mortality in Phoenix, 1995-1997. *Environ Health Perspect* 2000;108:347-353.

[74] Fairley D. Daily mortality and air pollution in Santa Clara County, California: 1989-1996. *Environ Health Perspect* 1999;107:637-641. .

[75] Delfino RJ, Murphy-Moulton AM, et al. Effects of air pollution on emergency room visits for respiratory illnesses in Montreal, Quebec. *Am. J. Respir. Crit. Care Med* 1997;155: 568-576.

Table 1

Air Quality Statistics from U.S. and Canadian Health Studies of Short-term Exposure to Fine and Coarse Fraction Particles

A-1. Statistics for 24-hour $PM_{2.5}$ Concentrations from Health Studies (up to means of 18 µg/m³)

Study Location	Air Quality Distribution Statistics *Italics = not year-round data*						
	mean	95%	96%	97%	98%	99%	max
Stieb, et al., 2000 St. John	8.5	20.5	22	23.4	27.3	30.9	53.2
Yu et al., 2000 Seattle ($PM_{1.0}$)	*10.4*						*61.7*
Schwartz 2003a Portage	11.2	26.2	29	31	34.3	39.7	63
Schwartz 2003a Topeka	12.2	26	27	29.4	32	37	56
Delfino, et al., 1997 Montreal (summer 1993)	*12.1**	*29.9*	*30.7*	*30.8*	*31.2*	*31.4*	*31.4*
Peters et al., 2001 Boston	12.1	24.3					
Peters et al., 2000 Boston	12.7	26.6					53.2
Burnett and Goldberg, 2003 8 Canadian Cities	13.3	32**	31.1**	34.3**	38.9**	45.4**	86
Mar, et al., 2003 Phoenix	13.5*	27.8	28.5	30.2	32.2	34.1	41
Fairley, 2003 Santa Clara County	13.6*	43	46.2	49	59	69.2	105.4
Gold et al., 2000 Boston	*15.5*						*45.1*
Schwartz 2003a Boston	15.7	34.5	35.4	37.2	42	45	70.8
Ostro, et al., 2003 Coachella Valley	15.8*	28.6	29.8	30.5	33.8	37.0	48.3
Thurston, et al., 1994 Toronto	*15.8-22.3*				*51*		*66*
Liao et al., 1999 Baltimore	*16.1*						*32.2*
Sheppard, et al., 2003 Seattle	16.7	37.3**	40.2**	41.7**	46.6**	54.7**	96h
Burnett, et al., 1997 Toronto	*16.8*	*39.8*	*40.5*	*43.5*	*47.4*	*54.9*	*66.4*
Lipfert et al., 2000 Philadelphia	17.3	35.7	37.4	40.9	44.2	49.1	72.6
Goldberg and Burnett, 2003 Montreal	17.4*	39.5	44.4	46.6	53.1	59	72
Ito, 2003 Detroit	18	42.6	47.4	50.3	55.2	59.2	86

Source: Memo from Mary Ross and John Langstaff to PM NAAQS Review Docket (OAR-2001-0017) re: Updated Statistical Information on Air Quality Data from Epidemiologic Studies, January 28, 2005.

The largest ever epidemiological study of the effects of $PM_{2.5}$ in 204 U.S. counties with 11.5 million Medicare enrollees from 1999-2002 was published in the *Journal of the American Medical Association* in March 2006.[76] This study showed clearly that the proposed standards for $PM_{2.5}$ fail to protect public health as required by the Clean Air Act. At levels below what EPA proposes as an annual standard, the findings showed cardiovascular and respiratory hospital admissions for the elderly increasing as concentrations $PM_{2.5}$ increased. Specifically, in the 204 counties considered in 2002, there were 1.4 million hospitalizations for cardiovascular and respiratory diseases. An estimated 11,000 extra hospitalizations were attributable to each increase of 10 $\mu g/m^3$ of $PM_{2.5}$.[77] In this study, the average of the county mean annual values was 13.4 $\mu g/m^3$—well below the proposed standard of 15 $\mu g/m^3$. The interquartile range was 11.3 to 15.2 $\mu g/m^3$. Significant associations with excess cardiac and respiratory admissions persisted even after excluding all days above 35 $\mu g/m^3$ (the level of the proposed daily standard) from the study.[78] Even where $PM_{2.5}$ concentrations met *both* the proposed annual and 24-hour standards, serious health effects occurred. This study also reported pronounced cardiovascular effects in the Eastern half of the country, where $PM_{2.5}$ concentrations are dominated by sulfates generated by fossil fuel combustion at electric utilities and in industrial boilers.

The Southern California Children's Cohort study also provides important evidence that the standard must be set at 12 $\mu g/m^3$ or below. This well-conducted long-term study of children in the Los Angeles region reported a decline in lung function growth in children associated with long-term exposure to $PM_{2.5}$ with concentrations ranging from 7 to 32 $\mu g/m^3$. Long-term exposure to $PM_{2.5}$ in the study was significantly associated with clinically reduced lung function at age 18 years, which is likely to be an irreversible effect. The overall mean $PM_{2.5}$ level in that study was 15 $\mu g/m^3$ (Staff Paper p. 5-23). There was no evidence of a threshold for the effects of PM on lung function growth in children even at these low levels of exposure.[79] EPA's justification for failing to reduce the annual $PM_{2.5}$ standard makes no reference to children's health, despite ample evidence for harm to children at annual exposures at or below the current standard. [80]

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[76] Dominici F, Peng RD, Bell ML, Pham L, McDermott A, Zeger SL, Samet JM. Fine Particulate Air Pollution and Hospital Admission for Cardiovascular and Respiratory Diseases. *JAMA* 2006; 10:1127-1134.

[77] Letter from Francesca Dominici to U.S. EPA, March 23, 2006. Docket ID No. EPA-HQ-OAR-2001-0017-0988.

[78] Letter from Francesca Dominici to U.S. EPA, March 23, 2006. Docket ID No. EPA-HQ-OAR-2001-0017-0988.

[79] Gauderman WJ, Avol E, Gilliland F, Vora H, Thomas D, Berhane K, McConnell R, Kuenzli N, Lurmann F, Rappaport E, Margolis H, Bates D, Peters J. The effect of air pollution on lung development from 10 to 18 years of age. *N Engl J Med* 2004;351:1057-67.

[80] Again, NAAQS must be set a levels that are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, and people with heart and lung disease. As the U.S. Court of Appeals for the D.C. Circuit has stated, in its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also "sensitive citizens" – who are particularly vulnerable to air pollution. If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard. *American Lung Assn. v. EPA*, 134 F.3d 388, 390 (D.C. Cir. 1998) (citations omitted); *see also Lead Industries Assn, Inc. v. EPA,* 647 F.2d 1130, 1153 (D.C. Cir. 1980) (NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals"). EPA must adopt a precautionary approach to NAAQS standard-setting. *See American Trucking Ass'n v. Whitman*, 283 F.3d 355, 369 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree' . . . .") (quoting EPA's PM NAAQS Federal Register notice, 62 Fed. Reg. at 38653); *Lead Indus. Ass'n*, 647 F.2d at 1155 ("[R]equiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to human

$PM_{2.5}$ Concentrations in Long-Term Exposure Studies Show Effects at Low Concentrations

EPA solicits comments on alternative approaches to interpreting the scientific literature to identify an annual average standard that will protect public health with an adequate margin of safety. (71 Fed. Reg. 2652 - 2653). An objective way to approach the question of the appropriate level of the annual average standard is to look at the mean concentrations reported in the major long-term studies of $PM_{2.5}$ effects, ± one standard deviation (SD), as shown below in Table 2. As the Staff Paper points out, this approach "may reasonably be used to characterize the range over which the evidence of association is strongest." (Staff Paper p. 5-22). About 70 percent of the data are within the mean plus and minus one SD, and the regression results are driven by the bulk of the data. Therefore, it follows that the results demonstrating adverse health effects are driven by this range. The results are not just driven by concentrations at the mean and above. Effects are also triggered by concentrations below the mean. If the mean minus one SD is around 15 ug/m^3 or below, that is very clear evidence that there are important effects at these levels. As table 2 below shows, the mean minus one standard deviation in many of the long-term studies including the Six Cities Study and the ACS study as well as a number of more recent studies are around 15 μg/m^3 or well below. For instance, in the Pope et al. 2002, 2004 studies, the value is 11 μg/m^3, and in the Laden et al. 2006 study, the value is 10.6 μg/m^3. As expected, the concentrations are higher in the studies conducted solely in California, so these concentrations should not be generalized to the entire U.S. (Chen et al. 2005, Künzli et al. 2005). This presents compelling evidence for setting the annual average standard at least at 12 μg/m^3, and probably below.

This analysis also reinforces the staff scientists' conclusion that "a standard of 12 μg/m^3 would be consistent with a judgment that a more precautionary standard was warranted given the seriousness of the mortality effects for which there is strong evidence of likely causal relationships, and the suggestive evidence of possible links to effects on fetal and infant development and mortality" (Staff Paper p. 5-23).

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health before it acts is inconsistent with both the Act's precautionary and preventative orientation and the nature of the Administrator's statutory responsibilities.").

Table 2

$PM_{2.5}$ Concentrations in Long-term Exposure Studies (Mean ± 1 S.D.)

(concentrations in µg/m³)

- Dockery (1993): 18 ± 2.8 = **15.2** –20.8
- Pope (1995): 18.2 ± 5.1 = **13.1** – 23.3
- Krewski (2000): 20 ± 5.3 = **14.7** – 25.3
- Pope (2002, 2004): '79 -'83: 21.1 ± 4.6 = **16.5** - 25.7
- Pope (2002, 2004): '99 -'00: 14 ± 3.0 = **11** – 17
- Chen (2005): 29 ± 9.8 = **19.2** – 38.8
- Künzli[81] (2005): 20.3 ± 2.6 = **17.7** - 22.9
- Laden[82] (2006): '74 -'89: 17.8 ± 6.3 = **11.5** - 24.1
- Laden[83] (2006): '90 -'98: 14.8 ± 4.2 = **10.6** - 19.0
- Dominici[84] (2006): 13.4 ± 3.0 = **10.4** - 16.4

In summary, the rigorous, objective cohort studies performed in the last decade provide compelling evidence of severe health effects at annual exposure levels below 15 µg/m³. The Six Cities and ACS studies have been subjected to extremely rigorous auditing and reanalysis, and their results have remained robust. The evidence, as documented above, unquestionably demonstrates increased mortality from long-term exposures to $PM_{2.5}$ below 15 µg/m³. An objective review of the cumulative health effects data compels lowering the annual standard to 12 µg/m³, or below, in conjunction with a daily standard of at most 25 µg/m³. The scientific evidence clearly shows that less stringent standards will cause death, as well as other adverse effects.

Given EPA's statutory obligation to establish limits on ambient levels of air pollution sufficient to protect public health with an adequate margin of safety based exclusively on health-related considerations, no action that adopts standards more lenient than 12 µg and 25 µg/m³ (for annual and 24-hours, respectively) will satisfy the requirement of the Clean Air Act. This conclusion is compelled by the scientific studies reviewed in the Criteria Document and the Staff Paper, and is made even more clear by the results of subsequent research. EPA may not avoid this conclusion by ignoring or dismissing the relevant studies without dealing directly and legitimately with

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[81] Personal communication with Nino Kuenzli, April 5, 2006.
[82] Personal communication with Francine Laden, April 4, 2006.
[83] Personal communication with Francine Laden, April 4, 2006.
[84] Personal communication with Luu Pham, April 5, 2006. Average of the county means.

health impacts that are demonstrably associated with ambient PM levels below the levels of EPA's proposed standards.

Recent Toxicological and Clinical Studies Provide Evidence of Cardiovascular Mechanisms and Effects at Low Annual Average Concentrations

The findings of the epidemiological studies are further corroborated by recent toxicological and clinical studies. Given the plausible shared mechanism of inflammatory cascades being triggered by $PM_{2.5}$ for both acute myocardial infarction and chronic atherosclerosis, the demonstration of increased short-term myocardial infarction risks at daily levels below 15 μg/m^3 is a strong argument for promulgating an annual standard below that level.[85]

Sun et al. have published findings that may explain why people who live in polluted areas have a higher risk of heart disease. Test results with laboratory mice showed a direct cause-and-effect link between exposure to fine particle air pollution and development of atherosclerosis, commonly known as hardening of the arteries. Mice that were fed a high-fat diet and exposed to air with fine particles had 1.5 more times plaque production than mice fed the same diet and exposed to clean air. Plaque, a fatty deposit on the inner lining of the blood vessels, can predispose individuals to conditions such as heart attacks and strokes. The fine particle exposure also led to increased inflammation of the artery walls and reduced function of the artery wall's inner lining. These findings are particularly important because the fine particle concentrations used in the study were well within the range of concentrations found in the air in the Northeastern U.S.. The average particle concentration over the course of the study was below the current 24-hour standard of 65 μg/m^3 and close to the annual average standard of 15 μg/m^3. The equivalent annual average concentration to which mice were exposed in this study was 15.2 μg/m^3, to be precise.[86] The study authors conclude:

> "These results suggest that repeated periods of short-term (eg, several hours) exposures to high particulate matter levels, such that may occur during rush hour traffic, is potentially capable of promoting progression of atherosclerosis, although the mean daytime particulate matter exposure concentration is within national recommendations. This may potentially have implications for the relevance of both the 24-hour and annual average National Ambient Air Quality Standards.

Two large clinical trials in Southern California have been following the progression of atherosclerosis in participants by measuring the thickness of the carotid artery. Researchers compared this data with the subjects' annual ambient $PM_{2.5}$ exposures. After adjusting for age and other factors, as association was observed between a measure of hardening of the arteries

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[85] Peters A, Dockery DW, Muller JE, Mittleman MA. Increased Particulate Air Pollution and the Triggering of Myocardial Infarction. *Circulation* 2001; 103:2810-2815.

[86] Sun Q, Wang A, Jin X, Natanzon A, Duquaine D, Brook RD, Aguinaldo J-GS, Fayad ZA, Fuser V, Lippmann M, Chen LC, Rajagopalan S. Long-Term Air Pollution Exposure and Acceleration of Atherosclerosis and Vascular Inflammation in an Animal Model. *JAMA* 2005; 294: 3003-3010. http://jama.ama-assn.org/cgi/content/abstract/294/23/3003

and long-term $PM_{2.5}$ exposures, suggesting a biological pathway for the relationship between particle exposure and premature death from heart disease[87] Long-term concentrations in this study were 20.3 $\mu g/m^3 \pm 2.6$ (one SD).[88]

The EPA Risk Assessment Demonstrates that the Proposed Standard of 15 µg/m³ Will Not Protect Public Health with a Margin of Safety

As discussed above, the Clean Air Act requires that EPA set a standard that protects health with an adequate margin of safety. This affirmative duty requires that EPA adopt a precautionary approach to the standard setting process, and that it set standards in a manner that deals with uncertainty not by ignoring uncertain effects but rather by protecting against adverse health effects even where those effects may be uncertain.[89]

EPA's proposed annual standard of 15 $\mu g/m^3$ cannot fulfill EPA's obligation to protect health with an adequate margin of safety. It is clear from EPA's limited risk assessment that thousands of people are dying prematurely each year due to exposure to fine particulate matter at concentrations below the proposed standards. The methodology for EPA's risk assessment and two draft risk assessment reports were carefully reviewed and vetted by CASAC, and numerous changes were made in the methods, assumptions and sensitivity analyses as a result of these reviews. CASAC placed considerable emphasis on the risk analysis results in recommending a lowering of the annual average standard in the range of 13 to 14 $\mu g/m^3$. Yet the EPA Administrator chooses to totally disregard the results of the risk analysis in proposing revisions to the $PM_{2.5}$ NAAQS, claiming that the results are too uncertain (FR p. 2648).

The risk assessment results show, that under all reasonable assumptions, thousands of premature deaths will occur each year under the current standards. According to the EPA Staff Paper (p 5-14), the risk assessment indicates:

> "the likelihood that thousands of premature deaths per year would occur in urban areas across the U.S. even upon attainment of the current $PM_{2.5}$ standards. Beyond the estimated incidences of mortality discussed above, staff also recognizes that similarly substantial numbers of incidences of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms and increased cardiac-related risk are also likely in many urban areas."

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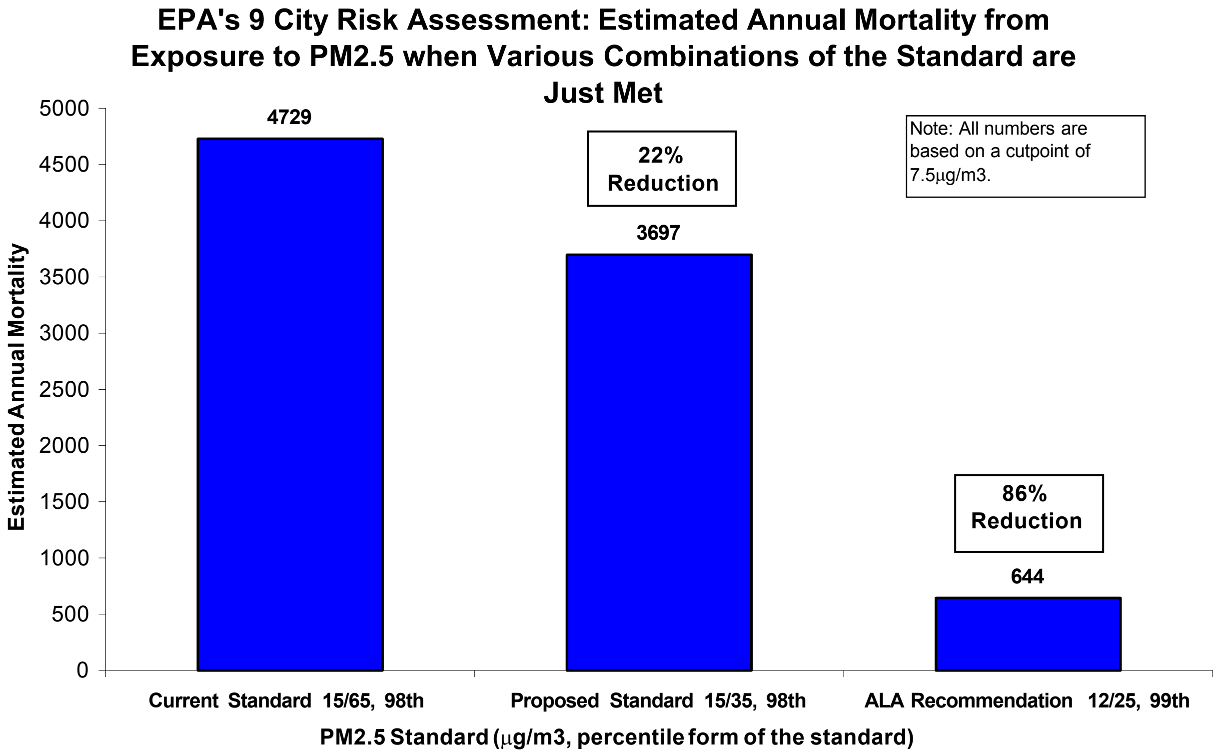
[87] Künzli N, Jerrett M, Mack WJ, Beckerman B, LaBree L, Gilliland F, Thomas D, Peters J, and Hodis HN. Ambient Air Pollution and Atherosclerosis in Los Angeles. *Environ Health Perspect* 2005; 113:201-206. http://ehp.niehs.nih.gov/members/2004/7523/7523.pdf

[88] Personal communication with Nino Kuenzli, April 5, 2006.

[89] *See American Trucking Ass'n v. Whitman*, 283 F.3d 355, 369 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree' . . . .") (quoting EPA's PM NAAQS Federal Register notice, 62 Fed. Reg. at 38653); *Lead Indus. Ass'n*, 647 F.2d at 1155 ("[R]equiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to human health before it acts is inconsistent with both the Act's precautionary and preventative orientation and the nature of the Administrator's statutory responsibilities.")

More specifically, EPA's limited risk assessment shows that more than 4,700 premature deaths attributable to $PM_{2.5}$ would occur each year in the nine cities analyzed even after these areas attain the current standards. Furthermore, there would be 3,700 premature deaths in these nine cities after attainment of the proposed standards. See Figure 4 below. Other cities were not studied. By extension, a national analysis, if available, would show that tens of thousands of premature deaths could be avoided with more stringent standards. In addition, substantially elevated numbers of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms, and increased cardiac-related risk associated with PM exposures will likely occur even if all urban areas meet the current standards.

Figure 4



U.S. Environmental Protection Agency. Particulate Matter Health Risk Assessment for Selected Urban Areas. December, 2005. Available at www.epa.gov/ttn/naaqs/standards/pm/data/PMrisk20051220.pdf. Accessed March 29, 2006.

What is obvious from EPA's risk assessment results is that the proposed suite of standards will not result in any reduction in long-term mortality risk in three of the nine cities analyzed, that is, Detroit, St. Louis, and Phoenix. See Figure 1 above. By extension, dozens of additional U.S. cities will not see any reduction in their PM-induced death rate or in the toll of respiratory and cardiovascular health effects as a result of the proposal.

However limited, EPA's analysis clearly adds significant value to the consideration of the health implications of PM pollution. Moreover, the results of the analysis go to the core of EPA's obligations under the Clean Air Act – to identify a safe level for ambient concentrations of PM, and to establish a limit for ambient concentrations of such pollutants that protects public health and welfare with an adequate margin of safety. The fact that EPA's risk analysis may incorporate some uncertainty can not justify EPA's decision to completely disregard that analysis.[90] EPA must directly confront the uncertainty and reconcile its decision on PM standards with the results of the risk analysis in light of both the strengths and weaknesses of the analysis. A failure to fully address and incorporate the findings of the risk analysis would render EPA's decision indefensible.

Additional Risk Assessments

Additional evidence of the potential benefits of an annual average standard of 12 $\mu g/m^3$ is provided by an independent analysis. Analysts used the BENMAP model developed for U.S. EPA to compare the impact of the current annual average $PM_{2.5}$ NAAQS of 15 $\mu g/m^3$ with a more stringent standard of 12 $\mu g/m^3$ in California. The study reported that approximately 2,000 additional fewer deaths would occur in California alone each year as a result of attainment of a 12 $\mu g/m^3$ standard, compared to a standard of 15$\mu g/m^3$.[91]

Particulate air pollution is not just shortening the lives of the elderly or infirm adults, but an increasing number of studies have shown that it is also a significant contributor to infant deaths in the U.S. An independent risk assessment estimated the risk of infant deaths attributable to particulate matter air pollution. Based on exposure-response functions from a U.S. cohort study, the team assessed postneonatal infant mortality in 23 U.S. metropolitan areas related to PM_{10} as a surrogate of total air pollution. According to a recent risk assessment, 24 percent of infant deaths from respiratory disease, and 16 percent of sudden infant death syndrome (SIDS) fatalities may be attributable to PM_{10}. The study used exposure-response functions from an earlier U.S. cohort study to estimate the risk of infant mortality attributable to PM_{10} in 23 U.S. metropolitan areas. The estimated number of air pollution related infant deaths was about 200 cases per year, in the 23 counties analyzed. An expert panel of the World Health Organization concluded in 2004 that the evidence is sufficient to infer a causal relationship between particulate air pollution and respiratory death in infants.[92]

Approximately 75 percent of the cases in the Kaiser et al. analysis were from areas where current pollution levels are estimated to be below the annual average NAAQS for $PM_{2.5}$. According to the authors, this suggests that "even if all counties would comply to the new $PM_{2.5}$ standard, the majority of the estimated burden would remain." The authors conclude:

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[90] *See* Public Citizen v. FMCSA, 374 F.3d 1209, 1219 (D.C. Cir. 2004).

[91] Davidson K, Hallberg A, McCubbin D, Hubbell B. Analysis of $PM_{2.5}$ Using the Environmental Benefits Mapping and Analysis Program (BENMAP). *Journal of Toxicology and Environmental Health* 2005; 203-205.

[92] Binková B, Bobak M., Chatterjee A, Chauhan AJ, Dejmek J, Dockery DW, Everard M, Forastiere F, Gilliland F, Holgate S, Johnston S, Krzyzanowski M, Kuna-Dibbert B, Maynard R, Raaschou-Nielsen O, Samet J, Schneider J, Skerrett PJ, Šrám RJ, Walters D, Weiland SK, Winneke G. WHO Monograph: The effects of air pollution on children's health and development: a review of the evidence. WHO Regional Office for Europe 2004.

> "Evidence for a causal effect of air pollution or morbidity and mortality is strong for adults, and evidence is building that air pollution has an effect on infants and young children and a potential impact during the fetal period."[93]

EPA raises unwarranted issues in the preamble, compromising the integrity of the rulemaking process

On the advice of OMB, EPA solicits comment on "a contrasting view" of the robustness of the ACS cohort study. FR p. 2652. Under this view, which is never attributed to any scientifically credible individual or organization, model sensitivity to sulfates, effect modification by socioeconomic status, and potential autocorrelation based on geographic proximity and pollution correlations potentially create sufficient uncertainty as to nullify the conclusions of the ACS cohort study as a basis for lowering the annual standard.[94] EPA never attributes this view to any scientifically credible individual or organization. Furthermore, this "alternative view" is completely out-of-step with mainstream scientific thinking and the conclusions of the Criteria Document and the Staff Paper, both of which were extensively vetted by CASAC. The use of specious arguments by the agency as a justification for retaining the annual standard is arbitrary and inconsistent with rigorous scientific standards.

Extensive previous deliberations have addressed the issue of the model's sensitivity to sulfates. While the extensive sensitivity analysis that the ACS cohort study underwent did demonstrate an effect of SO_2 on the model results, this effect is not biologically plausible. The most reasonable interpretation of the SO_2 results is that SO_2, a precursor to fine particle sulfates, serves as a surrogate for sulfates. Sulfates are a major component of fine particles, which are associated with cardiovascular mortality and other effects in a broad range of studies. The Health Effects Institute reanalysis clearly noted that "the absence of a plausible toxicological mechanisms by which sulfur dioxide could lead to increased mortality further suggest that it might be acting as a marker for other mortality-associated pollutants."[95] In contrast to SO_2, there is now extensive literature demonstrating the biological mechanism of particulate matter in causing cardiovascular damage. (CD p. 7-209-213). As Professor George Thurston has testified, "Based upon my own recent analysis, it is apparent that SO_2 is acting as a marker for coal combustion fine particle pollution in this $PM_{2.5}$ dataset."[96]

The preamble in several places alludes to the fact that various studies have shown greater impacts among populations with lower education (p. 2636, 2647). It is inappropriate to interpret the effect modification by education or socioeconomic status as invalidating the conclusions of

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[93] Reinhard Kaiser, R. Romieu,I., Medina, S., Schwartz, J., Krzyzanowski, M. and Künzli, N. Air Pollution Attributable Postneonatal Infant Mortality in U.S. Metropolitan Areas: A Risk Assessment Study. *Environ Health.* 2004; 3: 4

[94] Fax from OMB to Jason Burnett, Dec. 17, 2005.

[95] Krewski D, Burnett RT, Goldberg MS, Hoover K, Siemiatycki J, Jerrett M, Abrahamowicz M, White WH. *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality.* A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute Preprint, July 2000. p.235.

[96] Testimony of Dr. George D. Thurston, Sc.D. to the U.S. Environmental Protection Agency Public Hearings Regarding the Proposed Revisions to the $PM_{2.5}$ Ambient Air Quality Standards, March 8, 2006.

the ACS study. The Health Effects Institute report clearly notes: "the Reanalysis Team concludes that this modifying effect is not necessarily attributable to education per se, but could indicate that education is a marker for a more complex set of socioeconomic variables that impact upon the level of risk."[97] Recognition of factors that make some segments of the population more sensitive to the effects of air pollution and setting standards to protect those who are more sensitive is the mandate of the Clean Air Act. Effect modification by education in this study simply means that the dose response relationship is stronger among those with lower education than those with higher education. To use this observation as justification to discount the study findings and fail to lower chronic exposures to fine PM is arbitrary, non-scientific, and counter to our nation's principles of environmental justice.

The ACS study has been exquisitely reanalyzed, and results shown to be robust for a wide variety of analytic approaches. The undeniably correct interpretation of the ACS study is that long-term exposure to $PM_{2.5}$ increases the risk of premature death at levels well below the proposed annual standard.

EPA has Downplayed Environmental Justice Concerns

The scientific literature documents increased susceptibility among those with lower education, income, and those who live near roadways. Failure to lower the annual standard will perpetuate higher exposures in communities whose residents have the greatest susceptibility due to multiple factors, such as co-existing poverty, proximity to roadways, and higher rates of medical conditions (diabetes, heart disease, lung disease). The Office of Management and Budget (OMB) suggested, and EPA accepted, edits to the preamble that actively removed references to these populations and the issue of their susceptibility.[98] An adequate margin of safety for disadvantaged communities clearly requires lowering the annual standard below its current value.

EPA's removal of the reference to certain socioeconomic classes, in the face of clear evidence in the record that certain groups would suffer disproportionately from exposure to PM under EPA's

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97 Krewski D, Burnett RT, Goldberg MS, Hoover K, Siemiatycki J, Jerrett M, Abrahamowicz M, White WH. *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality.* A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute Preprint, July 2000.

98 Office of Management and Budget fax to EPA. 12/8/2005. Docket ID EPA-HQ-OAR-0017-0615, p. 39. The fax shows that OMB recommended striking the entirety of the following passage from the Nov. 23, 2005 version of the draft preamble:

"In considering population groups that might be more vulnerable to PM-related effects, there is some new evidence from epidemiologic studies that people from lower socioeconomic strata, or who have greater exposure to sources such as roadways, may be more vulnerable to PM exposure. Such population groups would be considered to be more vulnerable to potential effects on the basis of socioeconomic status or exposure conditions, as distinguished from susceptibility due to biologic or individual health characteristics (EPA, 2004, section 9.2.4.5)."

A close review of the final, published version of the preamble at 71 Fed. Reg. at 2637, column 1 shows that this entire passage regarding sensitive subgroups was in fact struck as urged by the White House OMB.

proposed rule, constitutes a gross dereliction of duty and violation of the public trust, and flies in the face of the President's Executive Order on Environmental Justice (E.O. 12898). EPA must specifically evaluate and discuss the implications of its proposal on low income and minority communities, and must establish standards that specifically address the impacts that these communities face. Failure to do so violates the Agency's obligations under applicable law, including the Clean Air Act (which requires that EPA establish standards that protect everyone), and federal Civil Rights statutes.[99]

Form of the Standard: EPA Must Eliminate Spatial Averaging

The current $PM_{2.5}$ annual average standard allows for the use of spatial averaging of monitors to assess compliance with the standard. This spatial averaging provision was introduced when EPA adopted the $PM_{2.5}$ standards in 1997. For most other criteria air pollutants, nonattainment is measured based on the highest reading monitor in the area. EPA has proposed to narrow the spatial averaging exemption based on concerns that it does not provide appropriate protection of public health, and may leaded to disproportionate impacts on vulnerable subpopulations within an area. In order to reduce the possibility of hotspots and the resulting environmental justice concerns, spatial averaging must be eliminated.

The proposed alternative is not acceptable because basing eligibility for spatial averaging on a correlation coefficient alone is not sufficient. As EPA acknowledges in the final Criteria Document, high correlations, "…do not imply uniformity in the $PM_{2.5}$ concentrations themselves."[100] The trouble with only evaluating the correlation coefficient is that a monitor representing a particular hot spot in an urban area could be overlooked due to a statistically high correlation between monitors in that area. Further, EPA's analysis shows that under the revised criteria, 1.2 million people could be left unprotected.[101]

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[99] Title VI Civil Rights Act of 1964 states that: "A recipient shall not use criteria or methods of administering its program which have the effect of subjecting individuals to discrimination because of their race." 42 U.S.C. § 2000d *et seq.* Executive Order 12,898 ("Executive Order"), issued in 1994, requires all federal agencies to develop and implement policies, strategies, programs, and activities to address environmental justice. Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, Exec. Order No. 12,898, 3 C.F.R. 859 (1995). Additionally, theU.S. House of Representatives and Senate passed amendments to EPA's appropriations bill directing the Agency to not spend any congressionally appropriated funds in a manner that contravenes the Executive Order or delays its implementation. Public Law No: 109-054; *See* also § 202 of H.R. 2361, Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006 ("None of the funds made available by this Act may be used in contravention of, or to delay the implementation of, Executive Order No. 12898 of February 11, 1994."). The President signed the bill into law on August 2nd, 2005. The amendment made clear that the House and Senate were dissatisfied with EPA's current attempts to ignore the Executive Order. EPA's actions in today's proposal, including both the proposed spatial averaging provisions and the efforts to purge the proposal of any reference to the serious and disproportionate impact that the rule will have on poor communities and communities of color, not only violate the above mentioned Civil Rights laws, the Executive Order, and the appropriations restriction, but collectively suggest an intent to discriminate and to cover up that discrimination by cleansing the proposal of any reference to protected classes of individuals.

[100] U.S. EPA, "Air Quality Criteria for Particulate Matter." October 2004, EPA/600/P-99/002aF. Volume I, p. 3-46.

[101] Schmidt M, Mintz D, Rao T, McCluney L., U.S. EPA Office of Air Quality Planning and Standards, Draft Analyses of Particulate Matter Data for the PM NAAQS Review, January 31, 2005. Output A-8. The commentary on the analysis states: "*Only* 1 million people live in those areas." The form of the standards must protect these 1,000,000 people.

The effect of spatial averaging is to allow an area to meet the national standards, even if particular portions of the area are especially polluted (hotspots), so long as other portions are sufficiently clean. Thus, spatial averaging allows exposure of people to unhealthy levels of pollution at specific locales even within an area meeting the standard. In order to ensure that people in all parts of the country are *equally safe* from unhealthy air, the agency must promulgate truly *national* ambient air quality standards. Were it not to do so, and instead let areas average their way out of cleanup requirements, EPA could allow particularly polluted areas to remain so, at an unacceptable threat to public health. The Clean Air Act does not permit EPA to create sacrifice zones where the health standard can be exceeded, but rather requires standards that apply "in all parts of the country, whether inhabited or uninhabited." [102] The Act requires EPA to base standards on a safe air quality level, not on estimating how many people are exposed to various air quality levels. 44 Fed. Reg. 8210 (February 8, 1979).

The Clean Air Act and its legislative history further confirm this premise that the NAAQS must protect *all* Americans. The Act's mandate could not be plainer: it requires that primary NAAQS be set at levels which, "allowing an adequate margin of safety, are requisite to protect the public health." [103] Part of the 1970 Clean Air Act Amendments, this mandate "carries the promise that *ambient air in all parts of the country* shall have no adverse effects upon any American's health." [104] *See also* 44 Fed. Reg. 8210 (February 8, 1979).

As discussed below, EPA has not provided adequate assurances that its proposed approach will prevent localized exposures that exceed the applicable limits and therefore place certain people at greater risk of harm. Thus, EPA's proposal to continue spatial averaging is in direct conflict with the Clean Air Act. Additionally, this provision conflicts with EPA's obligations under the President Executive Order on Environmental Justice and under federal civil rights statutes to provide low income and minority populations with equal protection under that nation's environmental laws. Moreover, the reasons for allowing spatial averaging are fundamentally at odds with EPA's obligations under the Clean Air Act, in that they relate directly to considerations of cost and feasibility and serve *no* purpose related to protecting public health.

EPA's staff conducted an analysis of spatial averaging under current requirements and under more stringent criteria as proposed. Their analysis shows that 32 metropolitan areas, with a combined population of almost 51 million, could use spatial averaging to meet an annual standard of 15 $\mu g/m^3$, while 45 areas, with a population of almost 64 million, could use spatial averaging to meet an annual standard of 14 $\mu g/m^3$. Out of these areas, 7 to 10 could potentially use spatial averaging to avoid cleanup obligations under the present standard (these areas would

[102] *Lead Industries Assn, Inc. v. EPA,* 647 F.2d 1130, 1180 (D.C. Cir. 1980).
[103] 42 U.S.C. § 7409(b)(1).
[104] 116 Cong. Rec. 42381 (December 18, 1970) (remarks of Senator Muskie, floor manager of the conference agreement). See also id. at 32901 (September 21, 1970) (remarks of Senator Muskie) ("This bill states that all Americans in *all parts of the Nation* should have clean air to breathe, air that will have no adverse effects on their health."); id. at 33114 (September 22, 1970) (remarks of Senator Nelson) ("This bill before us is a firm congressional statement that *all Americans in all parts of the Nation* should have clean air to breathe, air which does not attack their health." (emphasis added)).

attain the standard of 15 or 14 $\mu g/m^3$), leaving 9 to 14 million people unprotected.[105] The analysis also concluded that in most areas that could use spatial averaging (to meet either a 15 or a 14 $\mu g/m^3$ standard) the high site in these areas "is located in an area populated by lower income, higher percentage minority, and less educated people when compared to the overall metro area." The proposed alternative spatial averaging requirement was also analyzed with the results showing there would still be one million unprotected people in the one or two areas which could use spatial averaging to meet the annual standard, and 22 to 27 million people in 12 to 18 areas that could attain the standard faster, with less stringent requirements.[106]

A sensitivity analysis conducted for the risk analysis shows that a much smaller rollback in emissions is needed to meet a standard based on spatial averaging as compared to a standard using the maximum of monitor-specific annual averages. This analysis shows that in Detroit, Pittsburgh, and St. Louis, long-term mortality estimates for alternative suites of standards are 10 to 60 percent higher when spatial averaging is used to determine compliance. (Staff Paper p. 4-65.)

The preamble acknowledges that there is a large body of new health effects studies indicating further evidence of the serious adverse health effects of fine particulates. These studies include epidemiologic, toxicological, controlled human exposure, and dosimetry analyses. Because of the serious health effects caused by PM pollution, protecting individuals from potential hotspots of the pollutant is critical. There are numerous smaller areas within cities with elevated levels of $PM_{2.5}$; the people living and working in these areas who are exposed on a daily basis to high levels of fine particulates deserve to be protected. Further, an analysis described in the Staff Paper showed that, "the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels, and higher percentage minority levels." (Staff Paper p. 5-41). The following example is a case where this type of hotspot pollution is occurring.

El Paso/Ciudad Juárez $PM_{2.5}$ Hotspot

Although the El Paso area was not designated as a $PM_{2.5}$ nonattainment area in EPA's recent action, the monitoring data show violations of the annual $PM_{2.5}$ standard at the Sun Metro monitoring site in El Paso. While this is a result of micro-scale pollution problems, the high values recorded nonetheless pose serious human health harm for local residents. The $PM_{2.5}$ violations at this monitoring site, located on the U.S./Mexico border, are an indicator of the poor air quality experienced by communities in this area. There are two monitors at the Sun Metro site in El Paso; one is a continuous monitor and the other is a federal equivalent method monitor. Both monitors are violating the annual $PM_{2.5}$ standard.

[105] Schmidt M, Mintz D, Rao T, McCluney L., U.S. EPA Office of Air Quality Planning and Standards, Draft Analyses of Particulate Matter Data for the PM NAAQS Review, January 31, 2005. Output A-8
[106] Id.

In July 2003, the State of Texas sent a letter to EPA asking that the Sun Metro monitor only be considered for the 24-hour standard and not the annual standard because the site is a micro-scale site, representing a local hot spot area. The State cited 40 CFR Part 58 and EPA's April 1999, "Guideline for Data Handling Conventions for the PM NAAQS," where they allow for the exclusion of annual $PM_{2.5}$ data when a monitoring site is determined to represent a micro-scale, hotspot, or population oriented middle-scale area. In January 2004, EPA responded to the State's request granting this exclusion.

One monitor in this area is adjacent to highways, train tracks and bus facilities, and also very near to neighborhoods. People living in both El Paso and Ciudad Juárez are most likely heavily impacted by the elevated levels of fine particulates in this area. Because the Ciudad Juárez/El Paso area is a notoriously poor area, there are most likely environmental justice concerns for the people in this area who have no choice but to live near these high pollution sources. This situation is particularly relevant in the argument against the use of spatial averaging because it is a case where the entire area was overlooked as a $PM_{2.5}$ nonattainment area because only one monitor violated the annual standard.

Environmental Justice Considerations Demand that Spatial Averaging be Dropped

EPA has had an environmental justice office for over a decade. Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, signed in 1994 by President Clinton, directs federal agencies to develop strategies to protect minority and low-income populations from environmental health concerns. The interplay between EPA's Environmental Justice requirements (Executive Order 12898) and the Clean Air Act is critical. Regarding the $PM_{2.5}$ NAAQS, complying with those requirements dictates that EPA take actions to ensure that the form of this standard and its implementation protect minority and low-income populations. As demonstrated in the El Paso example above, the $PM_{2.5}$ hotspots that afflict many areas across the country must be addressed. It is inappropriate to develop a standard that allows spatial averaging across monitors in a certain area to downplay the importance of elevated fine particulates.

The Staff Paper acknowledges epidemiologic studies showing that increased effects of fine particulates on groups with lower education levels. The Staff Paper further notes that, "…people with lower socioeconomic status or who have greater exposure to sources such as roadways, may have increased vulnerability to the effects of PM exposure." (Staff Paper p. 5-42). This is further evidence that the annual $PM_{2.5}$ standard must not allow for spatial averaging across monitors. In order for EPA to meet its Environmental Justice and Clean Air Act requirements dictating that all Americans be protected from environmental health concerns, spatial averaging must be removed from the form of the annual average $PM_{2.5}$ standard.

EPA Must Lower the Level of the 24-Hour Average $PM_{2.5}$ Standard

The Administrator Disregarded the Recommendations of EPA Staff Scientists to Lower the 24-Hours $PM_{2.5}$ Standard

The EPA Administrator has chosen to ignore the EPA Staff Scientists' recommendations for the 24-hour $PM_{2.5}$ standard. The proposed standard falls outside the recommended range articulated in the final Staff Paper. More specifically, the staff articulated two options for standard setting. Under the first option, staff scientists recommended lowering the 24-hour standard to a range of 25 to 35 µg/m^3, while retaining the existing annual average standard. However, under this option, the Staff Paper made clear that the upper end of the range was recommended only in conjunction with a 99th percentile standard. (Staff Paper p. 5-46). EPA staff also suggested that a 99th percentile standard was appropriate for a standard at the middle end of the range. If EPA were to retain the 98th percentile form of the standard, the staff scientists recommended a standard in the middle or lower end of the range -- that is, at 25 or 30 µg/m^3. Yet EPA has proposed a 24-hour standard of 35 µg/m^3, 98th percentile, outside the range recommended by the EPA staff scientists as being protective of public health.

EPA Disregards CASAC Recommendations

CASAC recommended that EPA lower the 24-hour $PM_{2.5}$ standard in the range of 30-35 µg/m^3, in conjunction with a lowering of the annual average standard. Thus EPA's proposal (which would retain the annual average standard) is not in conformance with CASAC's recommendation, either.

As discussed previously, EPA must make decisions regarding the stringency of the NAAQS based on health-related considerations alone. Moreover, those decisions must be rational and supported by the available scientific data. Here, where EPA's Administrator fails to follow the recommendations of either the national health science community or his own staff science experts and advisory committee, that decision requires enhanced explanation and scrutiny to ensure that it meets the applicable statutory requirements and limitations. In this case, it is clear that the EPA's rationale for the lax standards included in the proposed rule, which does not adequately address why the more stringent standards recommended by numerous health experts are inappropriate, cannot withstand such scrutiny. As a result, EPA's proposed 24-hour standards for $PM_{2.5}$ are arbitrary and unreasonable.

Setting the 24-hour $PM_{2.5}$ Standard at 35 µg/m^3 Will Not Protect Public Health

EPA's proposed 24-hour $PM_{2.5}$ standard disregards important scientific findings and will not make a substantial dent in the epidemic of air quality-related illness and death. Hundreds of studies from around the world have now demonstrated that short-term exposure to fine particle pollution causes mortality from cardiopulmonary diseases, hospitalization and emergency room visits for cardiopulmonary diseases, increased respiratory symptoms, decreased lung function, and cardiac effects. That is, as air pollution rises, it is followed by an increase in adverse effects the next day, or over several days. New multi-city studies from Europe and the U.S. have documented increased morbidity and mortality from daily exposures at levels below the current standards. An annual standard alone is not sufficient to protect against these effects, nor the effects of more acute, sub-daily exposures. This is particularly true in areas that experience high daily concentrations relative to the annual average due to seasonal sources.

We concur with the assertion in the draft Staff Paper that:

> "Short-term exposure to $PM_{2.5}$ is likely causally associated with mortality from cardiopulmonary diseases, hospitalization and emergency department visits for cardiopulmonary diseases, increased respiratory symptoms, decreased lung function, and physiological changes or biomarkers for cardiac changes." (SP p. 3-66).

Studies Available to EPA and Summarized in the Staff Paper Show Excess Mortality at Levels Below 35 μg/m^3

The EPA Staff Paper and Federal Register notice summarized several studies that reported statistically significant associations with mortality in areas that met the current annual and 24-hour $PM_{2.5}$ standards.[107,108,109] In particular, the 98th percentile values for the 24-hour concentrations in these studies range down to 32 μg/m^3 (34 μg/m^3 99th percentile),[110] meaning that a standard set at (or above) this level is clearly within a range that is demonstrated to be associated with excess mortality. Based, therefore, on the evidence presented in the staff paper, the standard must be set well below 32 μg/m^3, 98th percentile, or below 34 μg/m^3, 99th percentile, in order to provide a margin of safety to protect against excess mortality.

Additionally, of the 10 short-term North American studies with annual mean $PM_{2.5}$ concentrations less than 15 μg/m^3 reviewed in the Ross & Langstaff memo, 95th percentile concentrations ranged from 20 - 43 μg/m^3, with most values in the upper-20's, and 98th percentiles ranged from 27 to 59 μg/m^3, with most values 35 μg/m^3 or less.[111] These data indicate that the 24-hour standard must be set at 25 μg/m^3 or below to accommodate a margin of safety. See Table 1, above.

Such a standard would be consistent with the recommendations of the World Health Organization working group which favored a 24-hour mean $PM_{2.5}$ standard of 25 μg/m^3, 99th percentile.[112]

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[107] Burnett RT, Brook J, et al. Association between particulate- and gas-phase components of urban air pollution and daily mortality in eight Canadian cities. *Inhal Toxicol* 2000; 12 Suppl 4:15-39.

[108] Mar TF, Norris GA, et al. Associations between air pollution and mortality in Phoenix, 1995-1997. *Environ Health Perspect* 2000;108(4):347-353.

[109] Fairley D. Daily mortality and air pollution in Santa Clara County, California 1989-1996. *Environ Health Perspect* 1999;107(8):637-641.

[110] Staff Paper pp. 5-34; 71 FR 2642 (January 17, 2006).

[111] Ross M, Langstaff J. Updated statistical information on air quality data from epidemiologic studies. Memorandum to PM NAAQS review docket OAR-2001-0017. January 31, 2005.

[112] World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005. WHOLIS number E87950.

A recent study of nine California counties, that included nearly two-thirds of the entire population of California, reported a significant association between daily $PM_{2.5}$ and mortality.[113] In that study, the mean $PM_{2.5}$ concentrations ranged from 14-29 μg/m^3, and the average 98th percentile concentrations were 68.75 μg/m^3, ranging from 37.8 μg/m^3 in San Diego County to 97 μg/m^3 in Fresno.[114] As expected, these values are high as California has the most polluted areas in the country. But the overall results of the study, that for every increase of 10 μg/m^3 in 2-day $PM_{2.5}$ concentrations, mortality increased by 0.6%, with greater increases among susceptible subgroups including diabetics, women, and people over age 65 years, reinforce the need for lower daily limits on fine particle pollution.

Studies Have Demonstrated Associations Between Short-term $PM_{2.5}$ Concentrations Below 35 μg/m^3 and Significant Morbidity

In setting the standards for $PM_{2.5}$, EPA must protect against a range of health effects, not just against mortality. A recent and very large study using hospital admission rates from the Medicare database in 204 urban counties in the U.S., found significant morbidity at daily levels below 35 μg/m^3.[115] The annual average $PM_{2.5}$ levels within these counties were generally at or below the current standard -- the average of the county means was 13.4 μg/m^3, and the interquartile range was 11.3-15.2 μg/m^3. The researchers found significant increases in hospital admissions for cerebrovascular disease, peripheral vascular disease, ischemic heart disease, cardiac arrhythmias, heart failure, chronic obstructive pulmonary disease (COPD), and respiratory tract infection with each 10 μg/m^3 daily increase in $PM_{2.5}$.

The principal investigator conducted additional analysis to restrict the data set to days with daily concentrations below 35 μg/m^3:

> "To provide more targeted evidence toward the adequacy of the proposed 24-hr $PM_{2.5}$ NAAQS standards as to whether they protect public health with an adequate margin of safety, we have conducted an additional analysis which was not included in the Journal of American Medical Association report. Specifically, we have re-estimated national average relative rates of hospitalization with the exclusion from the data set of days with 24-hour average levels of $PM_{2.5}$ exceeding 35 μg/m^3 (subset analysis). Table 3 [posted below] shows the results using the entire data set (same as Table 1 of Dominici et al. 2006) and the results from the subset analysis. In spite of the diminished statistical power due to the restriction of the analysis to a smaller number of days, we still find statistically significant associations between short-term exposure to $PM_{2.5}$ and hospital admissions for cerebrovascular disease, heart rhythm, heart failure, and respiratory infections."[116]

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113 Ostro B, Broadwin R, et al. Fine particulate air pollution and mortality in nine California counties: Results from CALFINE. *Environ Health Perspect* 2006; 114(1):29-33.
114 Personal Communication with Bart Ostro, April 4, 2006.
115 Dominici F, Peng RD, et al. Fine particulate matter air pollution and hospital admission for cardiovascular and respiratory diseases. *JAMA* 2006;295(10):1127-1134.
116 Letter from Francesca Dominici to U.S. EPA, March 23, 2006. Docket ID No. EPA-HQ-OAR-2001-0017-0988.

Table 3

Table 1. Percent change in hospitalization rate per $10\mu g/m^3$ increase in $PM_{2.5}$ on average across 204 counties*

Cause-specific admission	Lag (days)	National Average Relative rate	National Average Relative rate (Subset analysis)
Injury	0	-0.41 (-1.00,0.18)	-0.52 (-1.27,0.24)
Cerebro-vascular disease	0	0.81 (0.30,1.32)	0.84 (0.12,1.56)
Peripheral vascular disease	0	0.86 (-0.06,1.79)	0.39 (-0.81,1.59)
Ischemic heart disease	2	0.44 (0.02,0.86)	0.30 (-0.19,0.80)
Heart rhythm	0	0.57 (-0.01,1.15)	0.84 (0.10,1.57)
Heart failure	0	1.28 (0.78,1.78)	1.12 (0.51,1.74)
COPD	0	0.91 (0.18,1.64)	0.58 (-0.30,1.47)
Respiratory infection	2	0.92 (0.41,1.43)	0.68 (0.03,1.32)

This study shows increased hospital admissions in the elderly at daily concentrations below 35 $\mu g/m^3$ and is clearly indicative of the failure of EPA's proposed 24-hour standard to protect public health.

A large case-crossover study in the greater Boston area reported a significant increase in myocardial infarction associated with short-term exposures to $PM_{2.5}$.[117] The researchers divided the study group into quintiles of exposure, and found statistically significant increased odds of myocardial infarction in the fourth quintile OR=1.31 (CI = 1.01, 1.69). The 24-hour $PM_{2.5}$ concentrations in the fourth quintile ranged from 11.6-16.2 $\mu g/m^3$, well below the proposed 24-hour standard. In fact, the 95th percentile in this study was only 24.3 $\mu g/m^3$, meaning that this study indicates a need to seriously lower the 24-hour standard in order to protect against heart attacks.

A Vancouver study focusing on hospitalization for COPD also found effects at 24-hour concentrations significantly below 35 $\mu g/m^3$.[118] In this study, the 100th percentile 24-hour $PM_{2.5}$ concentration was 32 $\mu g/m^3$. Despite the fact that the concentrations of $PM_{2.5}$ in this study were all below the proposed EPA NAAQS, there was a statistically significant increase in hospitalizations for COPD within the pollution range of this study. Although the effect was not completely independent of NO_2 concentrations, the results should not be dismissed, because they occurred at conditions that are prevalent in many U.S. cities and would be expected to be present if the EPA finalizes the proposed 24-hour standard for $PM_{2.5}$.

[117] Peters A, Dockery DW, et al. Increased particulate air pollution and the triggering of myocardial infarction. *Circulation* 2001;103:2810-2815.
[118] Chen Y, Yang Q, et al. Influence of relatively low level of particulate air pollution on hospitalization for COPD in elderly people. *Inhal Toxicol* 2004;16:21-25.

A study in Montreal identified a significant association between emergency department visits among older adults and $PM_{2.5}$ at mean levels as low as 12.2 μg/m^3.[119] A different study of emergency room visits in Atlanta also reported significant associations between short-term $PM_{2.5}$ concentrations and visits for pneumonia among adults of all ages.[120] In this study, the 90th percentile concentration of $PM_{2.5}$ was 32.3 μg/m^3, and the mean was 19.2 μg/m^3.

Failure to adequately consider morbidity, in addition to mortality, renders EPA's decision on the 24-hour standard for $PM_{2.5}$ arbitrary and contrary to the statutory directives of the Clean Air Act. EPA must establish standards that protect the public health with an adequate margin of safety – protecting public health means protecting people from *non-fatal adverse health impacts* as well as fatal effects. To the extent that EPA has ignored, or inadequately assessed, the need to limit the concentration of $PM_{2.5}$ in order to address non-fatal effects, it has failed to fully implement the statutory mandate. Where an agency fails to address the full range of issues required by the controlling statutory provision, the resulting action cannot discharge the agency's legal obligations.[121] Here, EPA's inadequate consideration of short term $PM_{2.5}$ exposure on morbidity renders the analysis underlying the agency's proposed 24-hour PM standard critically incomplete.

California's Approach to Setting a 24-Hour $PM_{2.5}$ Standard

The entire spectrum of adverse health outcomes associated with ambient $PM_{2.5}$, including exacerbations of asthma, emergency room visits, hospitalizations, as well as mortality, occurs within the same general concentration range and is best described by a linear, non-threshold model. Consistent observations of health effects associated with low ambient concentrations of fine particles indicate that a short-term $PM_{2.5}$ standard is required to protect public health. Moreover, while attainment of an annual $PM_{2.5}$ standard does result in a reduction of $PM_{2.5}$ peak concentrations, some areas can attain the annual standard and still experience periods during which 24-hour $PM_{2.5}$ concentrations associated with increased morbidity and mortality can occur. This phenomenon also evidences the need for a protective short-term standard.

In order to address the lack of a threshold in the exposure-response curve, California EPA (CalEPA) scientists performed an analysis aimed at reducing the entire distribution of fine particles below the reported levels of distributions consistently associated with adverse health effects. CalEPA used statistical methods to examine the shape of the exposure-response relationships, tabulated the results of all time-series studies that explored associations between low levels of ambient $PM_{2.5}$ and daily mortality, and examined the upper tail of the $PM_{2.5}$ distribution in California consistent with an annual average of 12 μg/m^3. Based on the results of these analyses, CalEPA scientists recommended that the 24-hour $PM_{2.5}$ standard be established at a level of 25 μg/m^3, not to be exceeded. The level was chosen to help shift the entire $PM_{2.5}$ distribution to the left, and to influence peak concentrations.

[119] Delfino RJ, Murphy-Moulton AM, et al. Effects of air pollution on emergency room visits for respiratory illnesses in Montreal, Quebec. *Am J Respir Crit Care Med* 1997;155: 568-576.
[120] Peel JL, Tolbert PE, et al. Ambient air pollution and respiratory emergency department visits. *Epidemiology* 2005; 16:164-174.
[121] *See* Public Citizen v. FMCSA, 374 F.3d 1209, 1216 (D.C. Cir. 2004).

CalEPA staff obtained data from the authors of studies examining ambient $PM_{2.5}$ concentrations in relation to daily nonaccidental mortality. They constructed a table (Table 4 below) on the estimated percentage change in daily mortality associated with a 10 μg/m^3 change in $PM_{2.5}$. The analysis supports selection of a 24-hour standard well below the current standard of 65 μg/m^3, and in the range of 25 μg/m^3.

Table 4

Distributions and Associations of 24-hour $PM_{2.5}$ with Daily Total (T) and Cardiovascular (CV) Mortality in U.S. and Canadian Cities with Mean 24-hour $PM_{2.5}$ Concentrations < 25 µg/m^3

City	Time Period	Reference	Mean (µg/m^3)	98th Percentile %	Increase (95% CI) per 10 mg/m^3
Edmonton	1986-1996	Burnett et al., 2000	10	28	T:2.18(1.74, 6.10)
Calgary 1986	1986-1996	Burnett et al., 2000	10	29	T:0.63(3.58, 4.84)
Winnipeg	1986-1996	Burnett et al., 2000	10	29	T:0.38(3.15, 3.91)
Vancouver	1986-1996	Burnett et al., 2000	13	30	T:2.56(0.23, 4.89)
Topeka, KS	1979-1988	Schwartz et al., 1996	12	31	T:0.80(0.20, 3.60)
Phoenix, AZ	1995-1997	Mar et al., 2000	13	32	T:2.22(0.00, 5.56) CV:6.85(2.22, 11.48)
Portage, WI	1979-1987	Schwartz et al., 1996	11	34	T:1.20(0.30, 2.80)
Ottawa	1986-1996	Burnett et al., 2000	12	35	T:2.45(0.53, 5.43)
CoachellaValley, CA	1995-1998	Ostro et al., 2000	17	38	T:1.42(7.81, 4.97) CV:3.73(2.37, 9.84)
Toronto	1986-1996	Burnett et al., 2000	15	41	T:0.91(0.05, 1.87)
Boston, MA	1979-1986	Schwartz et al., 1996	16	42	T:2.20(1.50, 2.90)
Windsor	1986-1996	Burnett et al., 2000	18	43	T:5.20(2.24, 8.16)
Montreal	1984-1993	Goldberg et al., 2001a	18	43	T:1.93(1.16, 2.71)
Kingston	1980-1987	Schwartz et al., 1996	21	44	T:1.40(0.20, 2.60)
St. Louis, MO	1979-1987	Schwartz et al.,	19	46	T:1.10(0.40, 1.70)

		1996			
Santa Clara, CA	1990-1996	Fairley, 1999	13	51	T:3.26(1.27, 5.24) CV:2.48(0.35, 6.02)
Montreal	1986-1996	Burnett et al., 2000	15	51	T:1.23(0.11, 2.35)
Detroit, MI	1992-1994	Lippmann et al., 2000	18	55	T:1.24(0.26, 2.83) CV:1.28(0.91,3.65)

Source: CalEPA Staff Report, Public Hearing to Consider Amendments to the Ambient Air Quality Standards for Particulate Matter and Sulfates, May 3, 2002. p. 7-92 (Accessed at: http://www.arb.ca.gov/research/aaqs/std -rs/pm-final/pm-final.htm).

According to the CalEPA report:

> "(i) Multiple analyses of the exposure-response relationships between $PM_{2.5}$ and mortality indicate that the data can be fitted most parsimoniously with linear, nonthreshold models. Given the apparent linearity of the exposure-response relationships in the epidemiological data, it is difficult to determine at what concentrations within the $PM_{2.5}$ distributions in each study adverse health effects begin. Intuitively, one would expect greater biological responses and larger numbers of adverse events occurring at higher concentrations, everything else being equal. Nonetheless, in a linear exposure-response relationship, effects may be observed at lower levels as well (e.g., Schwartz et al., 1996).
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> The importance of the linear, nonthreshold exposure-response relationship cannot be overemphasized in light of legislation requiring that ambient air quality standards be "established at levels that adequately protect the health of the public, including infants and children, with an adequate margin of safety." (California Health & Safety Code section 39606(d)(2)). If a threshold in the exposure-response curve cannot be identified, then specification of an "adequate margin of safety" becomes challenging. The approach OEHHA [Office of Environmental Health Hazard Assessment] staff members have adopted in pursuit of this objective has therefore been to: (1) identify indicators of the distribution of $PM_{2.5}$ (specifically the means and 98th percentiles) in epidemiological studies that demonstrate the relationship of ambient fine particles with adverse health impacts, (2) recommend that the distribution of $PM_{2.5}$ in California be reduced below the levels of these distributions, and (3) incorporate a margin of safety in the form of a standard "not to be exceeded", which will assure that the extreme values of the $PM_{2.5}$ distribution in California will be lower (and in general substantially lower) than the 98^{th} percentiles of $PM_{2.5}$ distributions in published studies.
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> (ii) Without placing a short-term limitation on $PM_{2.5}$ concentrations, recent experience in California indicates that even attainment of the recommended annual standard of 12 $\mu g/m^3$ will allow for excursions well into the range in which adverse effects, including mortality, have been identified in epidemiological studies. Notably, the modified EPDC [Expected Peak Daily Concentration] analysis undertaken by the ARB [Air Resources

Board] staff indicates that for several large air basins, the estimated 98th percentile of the $PM_{2.5}$ distribution consistent with attainment of an annual standard of 12 $\mu g/m^3$ would be in excess of 40 $\mu g/m^3$. Thus, adoption of a 24-hour standard of 25 $\mu g/m^3$ would be intended to limit such excursions.

(iii) As with PM_{10}, morbidity and mortality outcomes appear to occur within the same $PM_{2.5}$ concentration ranges (see section 7.5). Therefore, we have focused on mortality as the most serious adverse health outcome. Changes in ambient air quality sufficient to protect against increases in mortality should, *a fortiori*, also protect against the occurrence of morbidity, in children as well as adults.

(iv) Among studies examining $PM_{2.5}$ and mortality, the long-term mean concentrations of those finding a significant association varied from 13 to 21 $\mu g/m^3$, while the 98th percentiles of the distributions ranged from 30 to 51 $\mu g/m^3$. Shifting the entire $PM_{2.5}$ distribution downwards and limiting short-term excursions should reduce the likelihood of fine particle associated mortality and morbidity. Recommending an annual average of 12 $\mu g/m^3$ addresses the issue of shifting the overall distribution downwards. By the same token, recommending a 24-hour $PM_{2.5}$ limit of 25 $\mu g/m^3$ would place the upper extreme of the distribution lower than the 98th percentile of those identified in studies finding significant associations with mortality, thereby incorporating a margin of safety. More specifically, except for the study of Vancouver (Burnett et al., 2000), all published investigations of $PM_{2.5}$ and mortality in which statistically significant effects were detected had 98th percentile $PM_{2.5}$ concentrations of 32 $\mu g/m^3$ or greater. Positioning the upper extreme of the $PM_{2.5}$ distribution in California at 25 $\mu g/m^3$ effectively incorporates a margin of safety into this recommendation, based on the best available scientific evidence."

Of course, this analysis is premised on pairing the 24-hour standard with an annual average standard of 12 $\mu g/m^3$.

The Administrator's Approach of Looking for Statistically Significant Associations at Various Levels is Fundamentally Flawed and Will Miss Important Health Effects

The Administrator's rationale for choosing a 24-hour standard based on an evaluation of the time-series studies for statistically significant effects is fundamentally flawed and insupportable.[122] In the Federal Register notice, the Administrator concludes:

"Within the range of 98^{th} percentile $PM_{2.5}$ concentrations of about 35 to 30 $\mu g/m^3$, this strong predominance of statistically significant results is no longer observed. Rather, within this range, some studies report statistically significant results (Mar et al., 2003; Ostro et al., 2003), other studies report mixed results in which some associations reported in the study are statistically significant and others are not (Delfino et al., 1997; Peters et

[122] 71 FR 2649 (January 17, 2006)

al., 2000), and another study reports associations in two of six cities that are not statistically significant (Klemm and Mason, 2003)."

It is astonishing that this statement is used to dismiss the positive findings in the range of 30-35 and instead justify choosing a 24-hour $PM_{2.5}$ proposed standard of 35 μg/m^3.

The Administrator's proposed approach is scientifically flawed because it relies unreasonably on point estimates of statistical significance at various concentrations,[123] rather than on trends, and because it completely fails to consider issues of statistical power. It is scientifically unavoidable that studies carried out at lower concentrations will have a narrower gradient of exposures over which exposure-response is assessed, making them less likely to have statistically significant effect estimates. In addition, many of the studies cited are single city studies, or are studies of only a handful of cities, meaning that they have limited statistical power due to the smaller sample sizes. It is clear that these smaller studies looking at lower concentrations have also shown elevated incidences of adverse health endpoints, and that they lack the power of the larger studies and the studies that have higher exposures. Dismissing the results of the smaller studies and the ones that have lower exposure concentrations is scientifically reckless, and especially unjustified where, like here, the results of these studies are fully consistent with the findings at higher exposure concentrations.

EPA may not select a level for the PM standard in a manner that is inconsistent with basic principles of scientific assessment. Here, as described above, EPA's justification for rejecting a 24-hour standard more stringent than the proposed limit of 35 μg/m^3 is simply irrational. It essentially fabricates uncertainty as a basis for avoiding a PM limit that the relevant data otherwise clearly indicates is necessary.[124] This is unreasonable, arbitrary, and inconsistent with EPA's obligations under the Clean Air Act. EPA must rely on a "weight-of-evidence" approach that takes into account all studies and asses their validity based on reasoned consideration of factors beyond just statistical significance. The Administrator must adopt a short-term standard at a level that is supported by a rational reading of the applicable science – that is, as discussed here, a level of no more than of 25 μg/m^3.

There is No Scientific Basis for Retaining the Current 24-hour $PM_{2.5}$ Standard or Lowering it Only Slightly

EPA solicits comment on the possibility of retaining the 24-hour $PM_{2.5}$ standard of 65 μg/m^3, or of setting the standard at a level within the range of 35-65 μg/m^3 (FR at 2653). The Agency offers no justification for its solicitation of comments on a level in this range, other than

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[123] *See also* Ethyl, 541 F.2d at 28 n.58 (Court rejects argument that EPA could rely only on studies whose "probability of error, by standard statistical measurement, is less than 5%," holding: "Agencies are not limited to scientific fact, to 95% certainties."), 18 ("the public health may properly be found endangered … by a lesser risk of a greater harm").

[124] As the D.C. Circuit has explained, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Lead Indus. Ass'n*, 647 F.2d at 1154-55.

"recognition of alternative views of the science and the appropriate policy response." EPA does not attribute these alternative views to anyone in particular. In fact, such views are completely outside the mainstream of scientific opinion, as evidenced by the fact that CASAC found no basis to recommend standards in this range.

The EPA Air Quality Index for $PM_{2.5}$ indicates that health problems for subgroups of the population occur at levels below the current standard and recommends avoiding activities such as hiking and other cardiovascular exercise when $PM_{2.5}$ levels are above 40 µg/m^3. EPA's consideration of weaker 24-hour standards than proposed is in conflict with this health advisory regulation.

For all the reasons cited above in support of a 24-hour standard of 25 µg/m^3, consideration of more lenient 24-hour standards than proposed as discussed in the preamble should be dropped from further consideration. Any other conclusion would be unreasonable.

The Benefits Assessment Makes Obvious that Lowering the 24-hour standards will Result in a Large Reduction in Premature Deaths Attributable to Particulate Air Pollution

EPA's draft Regulatory Impact Assessment (RIA) estimated reductions in incidence of $PM_{2.5}$ health effects due to urban area emissions reductions that would be triggered by various standards.[125] While the RIA is not a basis for decision-making on the standards, its limited health benefits assessment sheds some light on the public health implications of alternative suites of standards. In general, the final RIA needs to examine a broader range of policy options down to the level of 12 µg/m^3 annual and 25 µg/m^3 daily, and to estimate effects nationwide. Although factors relating to the costs of control measures cannot be part of the decision on the standard itself, it appears that the draft RIA inflates the estimates costs of controls by emphasizing local clean-up measures over regional strategies.

Only three alternative suites of standards were analyzed: 15/35, 15/30 and 14/35. EPA only examined health implications for five urban areas: Atlanta, Chicago, New York/Philadelphia, Seattle, and San Joaquin. The draft RIA examined a wide array of health endpoints: premature mortality due to long term exposure in adults and in infants; chronic bronchitis in adults; non-fatal heart attacks in adults; respiratory hospital admissions for all ages; cardiovascular hospital admissions for adults, emergency Room visits for asthma by children; acute bronchitis in children ages 8-12 ; lower respiratory symptoms in children, ages 7-14; upper respiratory symptoms in asthmatic children ages 9-18; asthma exacerbations in asthmatic children ages 6-18; work loss days in adults; and minor restricted activity days in adults.

The key conclusion of the draft benefits analysis is that the proposed suite of standards (15/35) provides zero incremental benefit across a broad range of health endpoints in two of the five cities: Atlanta and Chicago. (RIA p. A-47 and A-61). In Atlanta, the analysis shows substantially greater benefits for a standard of 15/30 compared to 14/35. In Chicago, the 15/30

[125] Office of Air Quality Planning and Standards, U.S. EPA. Draft Regulatory Impact Analysis for the $PM_{2.5}$ National Ambient Air Quality Standards. January 17, 2006.

and 14/35 options offer equivalent benefits. In New York/Philadelphia and Seattle, the 15/35 and 14/35 options offer equivalent benefits, with substantially greater benefits associated with a 15/30 suite of standards. In the San Joaquin area, all three options offer equivalent benefits. Thus in 4 of the 5 cities examined in the draft RIA, lowering the 24-hour standard to a level of 30 offers the greatest degree of health benefits.

Thresholds Are Not Evident in the Mortality Studies

One issue raised by the RIA and the risk assessment is the potential consideration of alternative "cutpoints" or thresholds below which the analysis assumes no adverse effects. There is no evidence to suggest that a threshold for PM health effects exists. The epidemiological studies fail to demonstrate any hint of a threshold, and the data fit a linear model.[126] An analysis in one city explicitly seeking any evidence of a threshold failed to find such a level, and concluded that if a threshold really existed, that it could probably be detected given the strength of the existing data.[127] A recent European study within the APHEA Multicity Project specifically assessed the hypothesis of thresholds in a very large dataset.[128] This study explored a variety of hypothetical thresholds in their data, including several explored in the Risk Assessment (20 and 10 $\mu g/m^3$), and discovered that in all cases the linear models gave a better fit. This large dataset, incorporating data from 30 cities across Europe, failed to give any support to the hypothesis that a threshold may exist.

Multi-city U.S. studies report similar results. Harvard University researchers applied a statistical method to examine the shape of the dose-response relationship between air pollution and daily deaths in ten U.S. cities. Simulation studies demonstrated that the method used can detect threshold and other nonlinear relationships in epidemiologic studies. But when used to analyze the association between PM_{10} and mortality, no evidence of a threshold was found, and the associations appeared to be linear down to the lowest levels studied.[129]

In an analysis of data for the 20 largest U.S. cites from 1987-1994 from the NMMAPS study, investigators used two different statistical models to try to identify a possible threshold concentration below which an effect of PM_{10} on mortality could not be detected. They reported that for total mortality and mortality from cardiovascular-respiratory causes, there was no evidence of a threshold down to daily ambient concentrations of PM_{10} as low as 10 $\mu g/m^3$. They concluded that linear models without a threshold are appropriate for assessing the effect of air pollution on daily mortality.

> "The present results give an indication that risk-free levels of PM_{10} are likely lower than the present NAAQS for PM_{10} . . . In fact, the continued demonstration of adverse effects

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[126] Pope CA, Burnett RT, et al. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. *JAMA* 2002;287:1132-1141.
[127] Cakmak S, Burnett R, Krewski D. Methods for detecting and estimating population threshold concentrations for air pollution-related mortality with exposure measurement error. *Risk Anal* 1999; 19:487-496.
[128] Samoli E, Analitis A, et al. Estimating the exposure-response relationships between particulate matter and mortality within the APHEA multicity project. *Environ Health Perspect* 2005;113;88-95
[129] Schwartz J, Zanobetti A. Using Meta-Smoothing to Estimate Dose-Response Trends across Multiple Studies, with Application to Air Pollution and Daily Death. *Epidemiology* 2000;11: 666-672.

> of air pollution over recent decades, even as concentrations of pollutants have declined, also suggests that exposures have not yet gone below no-effect thresholds, if such exist."[130]

Additionally, the long-term epidemiological studies such as the Harvard Six City Study and the American Cancer Society study found effects down to the lowest level studied -- which was lower than the levels of 10 and 12 $\mu g/m^3$ chosen by EPA for use in the sensitivity analysis. For lung cancer, the dose response relationship appears to be supra-linear, with a steeper linear slope at lower concentrations (Staff Paper p. 3-56). It is certainly plausible that robust individuals may be less susceptible to PM, but such a speculation is irrelevant to the question of whether there is a threshold in the population. In fact, the population contains large numbers of people with pre-existing cardiac or respiratory compromise. These people have already passed any threshold of resilience and would be predicted to respond with some incidence of adverse events at any level of exposure.

The staff appropriately concludes that "it is appropriate to focus on linear or log-linear concentration-response models reported in the studies for quantitative risk assessment." (Staff Paper p. 3-56). Nevertheless, the final Risk Assessment includes a series of cutpoints, including alternate cutpoints such as 10 $\mu g/m^3$ and 12 $\mu g/m^3$ that are especially implausible. The EPA Administrator must focus on the model that is supported by the data.

EPA Must Further Lower the Daily Standard to Protect Against Peak Exposures not Addressed by the Annual Standard

Another concern is that control strategies to reduce annual average concentrations will not target seasonal sources of emissions such as woodstoves or agricultural burning that can contribute to high daily concentrations. Thus EPA cannot rely solely on a "controlling" annual standard to reduce exposures due to these episodic emissions sources.

As illustrated by Figures 5 and 6 below, the importance of the highest concentrations can vary significantly from place to place. The data used to generate these figures were the "daily" values from monitoring sites that were reported on EPA's web site for the year 2000.[131] The pairs of cities in each figure had identical annual means, but as shown the distributions of daily values in the two California cities are much more skewed towards higher values. Given that the annual average concentration at each of the paired monitoring sites is the same, these figures illustrate clearly the importance of setting a tight 24-hour standard to protect against short-term health impacts. The situation for Sacramento is especially revealing: despite having an annual average concentration that is lower than the current $PM_{2.5}$ NAAQS, this city experienced numerous 24-hour concentrations at levels that are associated with severe health impacts from short-term exposure.

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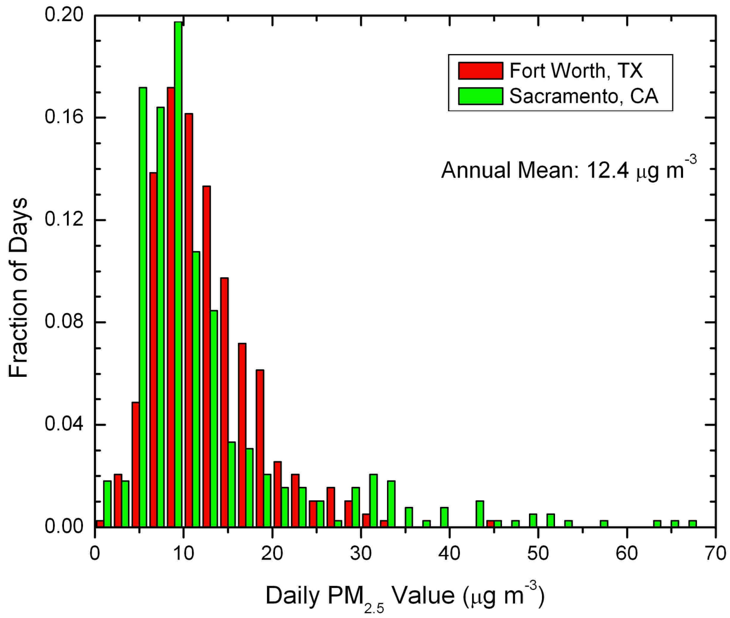
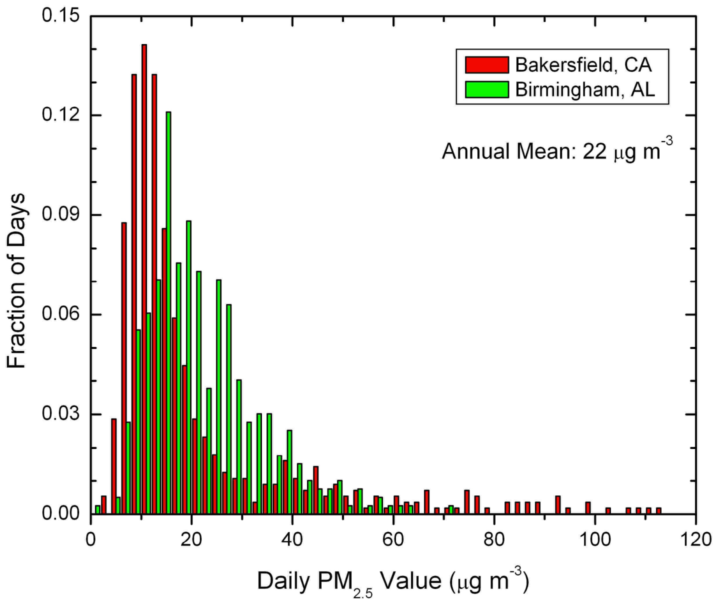
[130] Daniels MJ, Dominici F, Zeger SL, Samet JM. The National Morbidity, Mortality and Air Pollution Study. Part III: PM_{10} Concentration-Response Curves and Rhresholds for the 20 Largest US Cities. Health Effects Institute Research Report May 2004; Number 94, Part III.

[131] http://www.epa.gov/ttn/airs/airsaqs/detaildata/downloadaqsdata.htm

Figures 5 and 6





Distribution of 24-hour average $PM_{2.5}$ concentrations in each city for the year 2000. The cities are paired based on equivalent annual average values, but have sharply different distributions of daily $PM_{2.5}$ concentrations.

EPA Must Choose a 99th Percentile Form of the 24-hour Standard for $PM_{2.5}$

A “not to be exceeded” or single exceedance form of the 24-hour standard is warranted under the Act, because these forms provide the most protection for public health. However, of the options that have been analyzed by EPA in the Staff Paper and Risk Assessment, we recommend a 99th percentile form rather than the 98th percentile form chosen in the proposal. EPA staff scientists clearly recommended that a 99th percentile form would be appropriate in conjunction with the lax 35 $\mu g/m^3$ level of the standard proposed. Given this strong recommendation and the considerable analysis underlying it, EPA’s failure to even solicit comments on the 99th percentile form, or other more protective forms of the standard, is arbitrary and capricious.

The 98th percentile form of the standard allows for almost a week each year of dangerously unhealthy air. If the standard is averaged over three years, then eighteen days over a three year period could have significantly elevated 24-hour $PM_{2.5}$ concentrations even in an area that meets the EPA standard.[132] In comparison, the 99th percentile form still allows three exceedences per year, and up to 9 days over the three-year averaging period. Since we know from the science that every day with elevated levels of $PM_{2.5}$ will predictably result in excess morbidity, emergency room visits, hospitalizations, and deaths, it is not health-protective to allow for such a large number of exceedences to fall within the allowed range of the standard.[133]

Furthermore, with a 98th percentile form of the standard, there is no upper limit on how high pollution can rise on two percent of the days each year.

The EPA staff paper included a useful risk assessment comparing the estimated annual mortality reduction that would be achieved from the choice of the 98th vs. the 99th percentile form of the standard.[134] If the EPA chooses to finalize the current proposed combination of annual and 24-hour standards, and also chooses the 98th percentile form, the estimated annual mortality in the urban areas assessed in the EPA staff paper would be 3,700 excess deaths. This number would drop significantly, to 1,760 deaths per year, with a simple change from the 98th percentile form to the 99th (see Figure 7). Still greater reductions would be gained through lowering the daily standard and choosing the 99th percentile form.

The choice of a 99th percentile form of the standard will also send a less confusing message to the public. Many people are now using EPA’s Air Quality Index. It is confusing to people to learn that their area is in overall attainment with the EPA 24-hour standard, while also learning that the concentrations of $PM_{2.5}$ in their area frequently exceed the EPA standard. This dissonance would be lessened by the choice of a 99th percentile form.

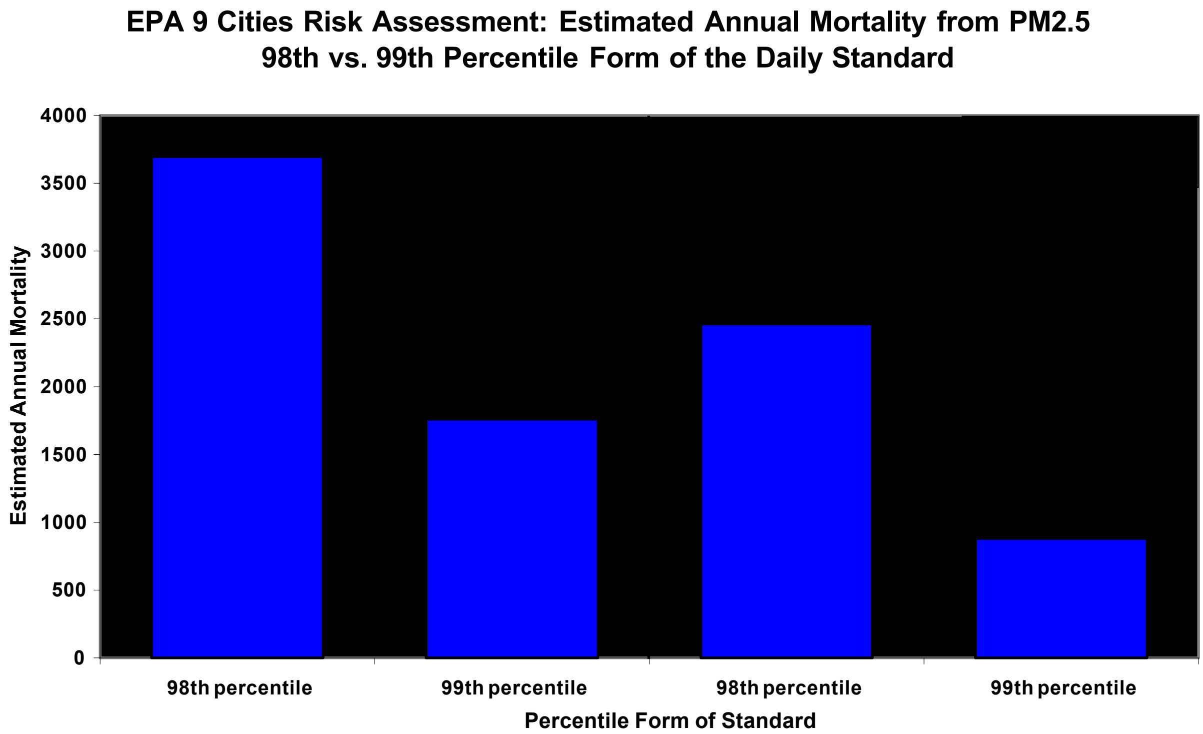
[132] EPA Staff Paper, p. 5-53.

[133] Again, it appears that EPA’s decision to propose a 98th percentile standard is motivated by considerations that are impermissible in the context of NAAQS standard setting, namely cost, and feasibility. NAAQS standards, including the form of the standard, must be established based on health effect considerations alone. EPA may not, as it proposes to do here, sacrifice public health in order to avoid the economic ramifications of setting a truly protecting standard.

[134] Summarized in EPA Staff Paper, p. 5-53.

EPA's current explanation for selecting the 98th percentile is inadequate – it fails to comprehensively address the added risk (and loss of life) associated with selecting the 98th instead of the 99th percentile. This determination, as with other decisions regarding selection of an appropriate PM standard, must be based on health-related consideration and not on other considerations (such as cost or technical feasibility). EPA has failed to demonstrate that there is a rational health-based reason for rejecting the 99th percentile – not to mention a justification important enough to sacrifice thousands of additional lives every year. EPA must revisit this arbitrary decision and must select the only reasonable option, a 99th percentile standard.

Figure 7



U.S. Environmental Protection Agency. Particulate Matter Health Risk Assessment for Selected Urban Areas. December, 2005. Available at www.epa.gov/ttn/naaqs/standards/pm/data/PMrisk20051220.pdf. Accessed March 29, 2006.

$PM_{2.5}$ Secondary Standards Must Protect Public Welfare

EPA has requested comment on whether to set a separate $PM_{2.5}$ standard, designed to address visibility, on potential levels for that standard within a range of 20 to 30 $\mu g/m^3$, and on averaging times for the standard within a range of four to eight daylight hours. As detailed below, we urge EPA to adopt a secondary $PM_{2.5}$ standard of 20 $\mu g/m^3$, with a 4-hour daylight averaging time, using a 98th percentile compliance level. We also recommend that the standard apply nationally, not simply in "urban" areas. This standard is the minimum necessary to protect urban, rural and Class I areas from the well-documented aesthetic, economic and environmental harm caused by fine particle pollution. While such a standard should and could not replace the regional haze program and congressionally declared national goal of preventing future and remedying existing impairment of visibility in Class I areas, it could also assist in advancing this goal.

A strong secondary NAAQS is essential to ensure restoration and protection of natural resources and the valuable outdoor experiences they provide. While the Regional Haze Rule provides a roadmap and requirements to improve visibility over the long term, in our National Parks and Wilderness Areas (Class I Areas), it does not provide timely relief for currently impaired ecological values. The adverse effects on public welfare from particulate matter pollution and its precursors are clear.

Visibility Impairment Remains a Serious Problem Nationwide

Nearly 30 years after Congress called for a return to natural visual air quality in America's premier parks and wilderness areas, many remain plagued by unsightly haze pollution. Regional haze has reduced annual average visibility to about one-third (west) to one-quarter (east) of natural conditions in our national parks. According to the National Park Service, "Air pollution currently impairs visibility to some degree in every national park."[135]

Views from scenic overlooks at Great Smoky Mountains National Park have been seriously degraded over the last 50 years by human-made pollution. Since 1948, based on regional airport records, average visibility in the southern Appalachians has decreased 40% in winter and 80% in summer.[136] Air pollutants at Grand Canyon National Park result in a reduction in clarity and brilliance of the natural features of the park and can eliminate distant views. Visibility in the park averages 106 miles, and can exceed 160 miles on the clearest days, but haze can reduce visibility to less than 50 miles.[137]

[135] National Park Service, *Air Quality in the National Parks*, Second Edition, September 2002.
[136] National Park Service, Great Smoky Mountains National Park, Nature and Science, Air Quality, http://www.nps.gov/grsm/pphtml/subenvironmentalfactors23.html .
[137] National Park Service, Grand Canyon National Park, Nature and Science, Air Quality, http://www.nps.gov/grca/pphtml/subenvironmentalfactors23.html .

According to the National Park Service, very small amounts of light-scattering pollutants can significantly reduce scenic views. In the Grand Canyon, for instance, visibility is often impaired by haze even though pollutant levels do not exceed the NAAQS.[138]

Visibility impairment in Class I areas in the eastern U.S. is due largely to $PM_{2.5}$, particularly sulfates, which account for 60-80% of the haziness.[139] Organics and elemental carbon play a greater role in some national parks in the west and Pacific northwest, with sulfates accounting for between 30 and 40 percent of visibility impairment in the western United States overall.

$PM_{2.5}$ is also the primary source of visibility impairment in urban areas, which include higher concentrations of organic carbon, elemental carbon, and particulate nitrate due to higher density of fuel combustion sources and diesel emissions.[140] Annual mean levels of 24-hour average $PM_{2.5}$ levels are generally higher in urban areas than those in Class I areas.[141]

Current Secondary $PM_{2.5}$ NAAQS Does Little to Protect Visibility

The current secondary $PM_{2.5}$ NAAQS is set at 65 $\mu g/m^3$, the same level as the 24-hour primary $PM_{2.5}$ NAAQS.

In 1997, in setting the current secondary standards, EPA found that "particulate matter can and does produce adverse effects on visibility in various locations" and that "impairment of visibility is an important effect of PM on public welfare" that is experienced throughout the United States.[142] EPA also acknowledged that attainment of secondary standards at the level of the primary standards would generally result in little or no change in visibility conditions in the western United States.[143]

Nevertheless, the Agency declined to set a tighter standard because of regional differences in PM levels and composition and because of generally higher levels of relative humidity in the East, which increases light scattering by sulfate and nitrate particles.[144] EPA found that its proposed secondary standard would help improve visual air quality in urban areas in the eastern U.S., but relied on the regional haze program for improvements in the West.

[138] NPS, Grand Canyon Air Quality.
[139] U.S. EPA, Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, June 2005, p. 6-4 (citing U.S. EPA, Air Quality Criteria for Particulate Matter, October 2004, p. 4-36), http://www.epa.gov/ttn/naaqs/standards/pm/data/pmstaffpaper_20050630.pdf .
[140] OAQPS Staff Paper, p. 6.5.
[141] OAQPS Staff Paper, p. 6-5.
[142] 62 Fed. Reg. 38652, 38680 (July 18, 1997).
[143] 62 Fed. Reg. 38681.
[144] 62 Fed. Reg. 38680.

CASAC and EPA Staff Findings Demonstrate That A National Secondary $PM_{2.5}$ NAAQS Is Necessary

The NAAQS must undergo review every five years to determine, based on the latest scientific evidence, whether stronger standards are needed. Section 109 of the 1970 Clean Air Act (42 U.S.C. 7409) directs EPA to set the NAAQS at a level necessary to protect public health (the primary standard) and welfare (the secondary standard). Welfare includes effects on visibility, vegetation and ecosystems.

EPA's independent Clean Air Scientific Advisory Committee (CASAC) sent a letter to EPA in June 2005 recommending a significant tightening of the secondary standard[145]. CASAC found that the current standard (65 $\mu g/m^3$, 24-hr. avg.) allows concentrations of $PM_{2.5}$ that significantly obscure scenic views. Furthermore they presented scientific evidence that strongly supports a sub-daily national secondary standard separate from the 24-hr primary standard. EPA staff accepted CASAC's findings and set out its recommended new secondary $PM_{2.5}$ NAAQS in the final Staff Paper.[146]

As EPA's Staff Paper demonstrates, concerns about regional differences raised in the 1997 NAAQS review are not apparent with regard to urban areas. Differences between east and west urban 24-hour $PM_{2.5}$ averages are much less than at rural sites (Figure 6-1 in Staff Paper)[147]. Moreover, the concern about relative humidity differences between the two regions was overstated especially during daylight hours. The Staff Paper discusses how average visibility impacts due to regional haze is minimized during daylight hours as regional haze is appreciably lower in both regions during the day than at night (See Figure 6.2 of Staff Paper)[148]. The Staff Paper goes on to demonstrate that during daylight hours, the correlation between reconstructed light extinction (accounting for relative humidity) and $PM_{2.5}$ is similar for urban areas in the East and West.[149] When EPA failed to propose a secondary standard in accordance with the CASAC recommendations the panel again wrote to EPA reiterating their support for a subdaily secondary standard below the level of the primary standard.[150]

Information presented in the Staff Paper and supporting documents demonstrates that it is both feasible and necessary to set a uniform national secondary standard to protect public welfare from adverse visibility impacts in urban areas across the country.

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[145] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, June 6, 2005. EPA-SAB-CASAC-05-007.
[146] EPA OAQPS Staff Paper, p. 7-13.
[147] EPA OAQPS Staff Paper, p. 6-7.
[148] EPA OAQPS Staff Paper, p. 6-8.
[149] EPA OAQPS Staff Paper, p. 6-13, figure 6-5.
[150] Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee letter to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, March 21, 2006, Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, EPA-CASAC-LTR-06-002.

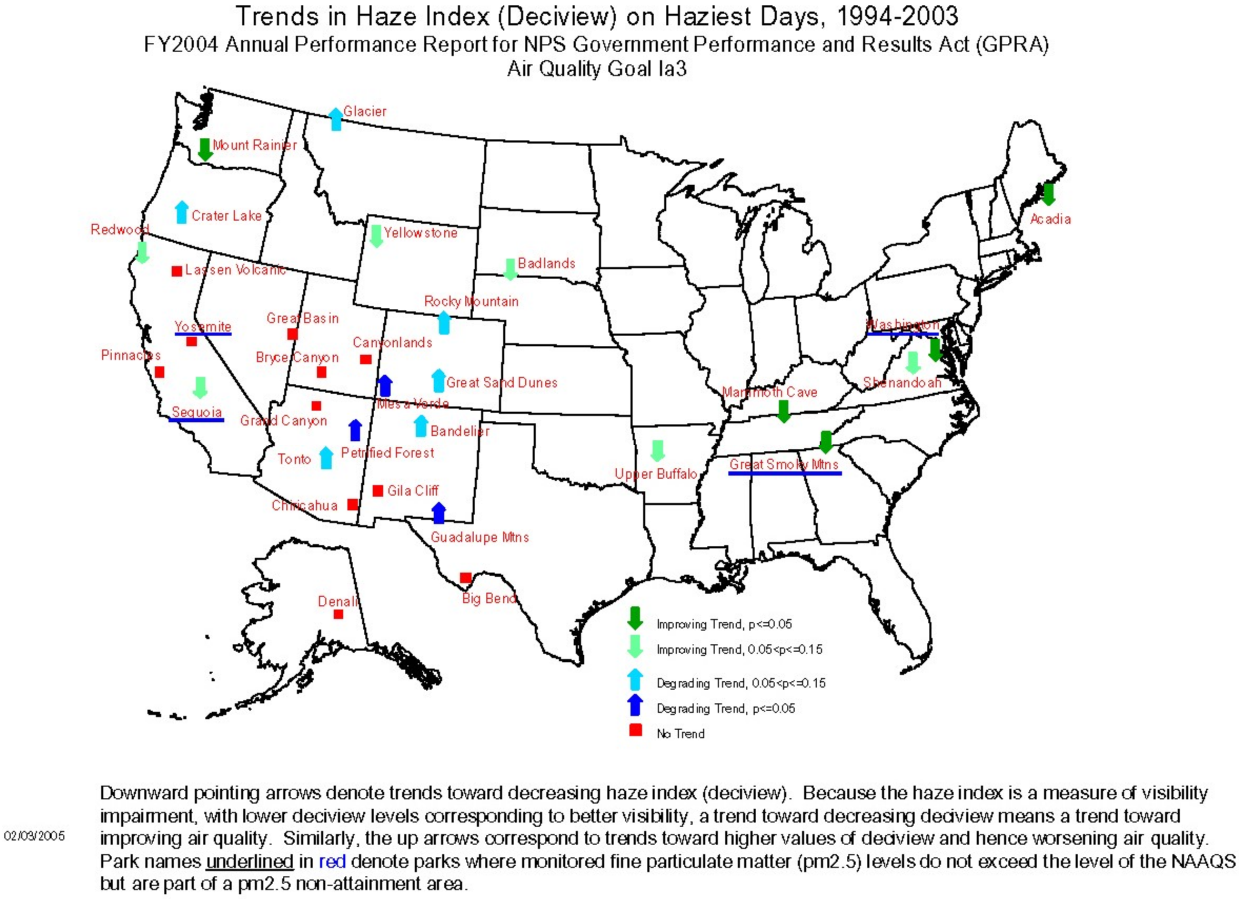
Furthermore, it is now apparent that the EPA's reliance on the regional haze program to improve urban visibility conditions in the western U.S. was misplaced. In Class I areas across the West, visibility on the 20% of the days with the poorest visibility has deteriorated over the past decade, indicating that haze in the West is worsening on the regional scale. Moreover, $PM_{2.5}$ concentrations in urban areas throughout the country are markedly higher than those in most Class I areas, showing the importance of local emissions in impairing urban visibility.[151]

As shown in the Criteria Document (Figure 4-39b, p. 4-181) and stated on page 6-5 of the draft Staff Paper, in Class I areas in the West, where most visibility monitoring is currently conducted, "aggregate trends showed little change during 1990 – 1999 for the 20% haziest days." In fact, however, this understates the problem.

Based on data from the IMPROVE network, Figure 8 shows trends over the period from 1994 – 2003 for haze on the 20% haziest days at monitoring sites in Class I National Parks across the country. While visibility on the haziest days is getting better at many sites in the eastern United States and at some sites on the West Coast, sites in the intermountain West show a stubborn trend toward degrading visibility

[151] U.S. EPA, Air Quality Data Analysis Technical Support Document for the Proposed Interstate Air Quality Rule, January 2004, p. 17.

Figure 8



The trends of worsening visibility on the haziest days are highly significant at Mesa Verde National Park, Guadalupe Mountains and Petrified Forest. Visibility deteriorated, although the trend was not as statistically significant, at Glacier, Crater Lake, Rocky Mountain, Great Sand Dunes, Bandelier, and Tonto. At Great Sand Dunes National Park, visibility deteriorated on the clearest 20% of the days as well. Trends could not be established at most other Class I areas in the region.

Finally, the secondary $PM_{2.5}$ standard should apply in all areas of the country, including Class I areas. While such a standard would not suffice to address impairment of visibility in scenic Class I areas, extending the standard to these areas as a supplement to regional haze efforts would help advance the goal of restoring visibility. EPA's Regional Haze Rule does not by itself sufficiently protect scenic views in our nation's parks and wilderness areas. There are a total of 156 Class I areas covered by the Regional Haze Rule. However there are 543 national park units and national forests, in addition to countless state and regional parks. The vast majority of these lands lack Class I protection and thus do not benefit from the Regional Haze Rule. Scenic views are a key feature of many of these unprotected lands, however many of these areas, like the National Mall, are currently plagued by unsightly haze (see Attachment A). Even for class I parks and wilderness areas, the regional haze rule will take six *decades* to be fully implemented.

All of our parks deserve clear air, and significantly strengthening the $PM_{2.5}$ NAAQS will help them get there sooner. A uniform national secondary $PM_{2.5}$ standard is therefore needed to ensure all areas of the country with significant visibility impairment experience improvements. Finally, EPA's reliance on the regional haze program to address adverse visibility impacts outside of Class I areas lacks any rational basis. The requirements of the regional haze program are focused on achieving visibility improvements within Class I areas, not elsewhere. Moreover, EPA has not shown that the regional haze program, either alone or in combination with other programs, will somehow provide sufficient incidental visibility benefits outside of Class I areas to protect public welfare throughout the nation, nor does the record support such a conclusion. Indeed, there are some states that do not have any Class I areas at all. 64 Fed. Reg. 35714, 25716 (1999). The Act requires EPA to adopt secondary NAAQS requisite to protect public welfare throughout the nation from *any* known or anticipated adverse effects from PM fine pollution. CAA §109(b)(2). EPA therefore cannot lawfully or rationally adopt a secondary $PM_{2.5}$ standard that fails to protect major parts of the nation from known and anticipated adverse visibility impacts associated with $PM_{2.5}$.

Increased Visibility Provides Significant Aesthetic and Economic Benefits Nationwide

EPA's Staff Paper cites numerous studies supporting the aesthetic and economic value of good visual air quality, including a "well recognized relationship between good air quality and economic benefits due to tourism."[152] Survey research on public awareness of visual air quality typically reveals that 80% or more of respondents are aware of poor visual air quality. The importance of visual air quality to pubic welfare across the country has been demonstrated by a number of studies demonstrating the public's willingness to pay for improvements in visibility. Benefits are estimated to be in the multi-billion dollar range annually.[153]

Good visibility is particularly important to visitors to our National Parks. National park visitors consistently rank "clean, clear air" as one of the most important features desired in visiting these areas. A June 2005 Zogby International Poll commissioned by National Parks Conservation Association concluded that more than three in five respondents, or 62% of those polled, said they would be unlikely to visit a national park clouded by haze or smog.

The National Park Service has conducted studies examining the relationship between visibility conditions and visitor experience as well as visitor attitudes toward clean, clear air in national parks. These studies have found that visitors are aware of visibility conditions and rated the visibility worse when the measured visibility was worse, and better when measured visibility was better.

NPS found that when visitors indicated that the view was very to extremely hazy, they enjoyed the view less, enjoyed the park less, and were less satisfied with visibility conditions than those who said they were not aware of haze or were aware of only slight to moderate haze. NPS also

[152] EPA OAQPS Staff Paper, p. 6-14.
[153] EPA OAQPS Staff Paper, p. 6-12.

found that visibility conditions affect the amount of time and money visitors are willing to spend at parks. Interviews of visitors indicated that they would be willing to spend more time and money if visibility conditions were better and less if visibility conditions were worse.[154]

Out of Sight: Haze in our National Parks, an Abt Associates study published in 2000 by the Clean Air Task Force, found that, given the degree to which air quality and visibility influence visitor experience in the national parks, declines in visibility of park vistas could reduce park visitation. The report also found "increases in visibility could raise park visitation by as much as 25 percent which could yield approximately $30 million in increased fee collection and $160 million in additional concession sales. This would in turn add nearly $700 million in retail sales to the economies around the park, $53 million in local tax revenues, and create 15,896 jobs."[155]

Improving visibility by reducing $PM_{2.5}$ provides economic benefits to urban areas as well. For instance, an analysis of the residential visibility benefits in the eastern U.S. due to reduced sulfur dioxide emissions under the acid rain program suggest an annual value of $2.3 billion (1994 dollars) in 2010.[156]

A Secondary $PM_{2.5}$ Standard Set at or Below 20 µg/m^3 is Necessary to Protect Against Adverse Visibility Impacts

EPA's $PM_{2.5}$ NAAQS proposal would set the secondary 24-hour standard at a level identical to the primary standard, 35 µg/m^3. The proposal is not supported by the thorough review and analysis by CASAC and EPA expert staff. Based on findings in CASAC's review, EPA's Staff Paper recommends a secondary $PM_{2.5}$ standard between 20-30 µg/m^3 averaged over 4-8 hours. EPA staff scientists found that the current secondary standard of 65 µg/m^3 was not protecting visibility in urban areas. Furthermore, EPA staff state that a national visibility standard should be considered in conjunction with the regional haze program to achieve protection in urban, non-urban and Class I areas.[157]

Concentration Level

The $PM_{2.5}$ NAAQS must be significantly strengthened to clean up haze pollution in our parks. We support the lowest end of the compromise standard recommended by EPA's expert staff – 20 µg/m^3 (4 hr. av.), 98^{th} percentile compliance level. While this standard is many times the level needed to restore natural visibility conditions (EPA's analysis suggests a standard of 2.5 µg/m^3

[154] National Park Service, Effects of Air Pollution on Visibility, http://www2.nature.nps. gov/air/AQBasics/visibility.cfm #types
[155] Abt Associates, Out of Sight: The Science and Economics of Visibility Impairment (August 2000) http://www.catf.us/publications/reports/Out_of _Sight2.pdf.
[156] OAQPS Staff Paper, p. 6-15, citing Chestnut, L. G.; Dennis, R. L. (1997) Economic benefits of improvements in visibility: acid rain provisions of the 1990 clean air act amendments. *J. Air Waste Manage. Assoc*. 47:395-402.
[157] EPA Staff Paper p 7-10.

would be needed[158]), it is a meaningful improvement over the current standard, and would help speed reductions in haze-causing pollutants.

As documented in the Staff Paper, a short term $PM_{2.5}$ standard set at 20 $\mu g/m^3$ or lower is needed to protect urban visibility, because this is the level below which study participants judged visual air quality to be satisfactory. The photographic images included with both the CASAC and EPA Staff Papers demonstrate that views with concentrations at the upper end of the proposed range (at 30 $\mu g/m^3$) are noticeably hazy and would not constitute a visibility protection standard. In contrast, a marked improvement in visual clarity is evident at and below the 20 $\mu g/m^3$ level. *See Attachment A.*

Based on studies in Denver, Phoenix and British Columbia, EPA's Staff Paper concludes that the public finds visual ranges within 40-60 km to be acceptable in urban and suburban areas. The state visibility standard in Denver, CO, which is based on citizens' perceptions of acceptable visual air quality, corresponds to a visual range of about 50 km. A 40-60 km visibility range would translate to a secondary $PM_{2.5}$ standard of around 10 $\mu g/m^3$ according to EPA's methodology.

Photographic images presented in *Attachment B* demonstrate that a short term $PM_{2.5}$ standard set at 20 $\mu g/m^3$ or lower is also needed to protect park visibility, especially in Eastern parks. As the photos illustrate, concentrations of $PM_{2.5}$ at 36 $\mu g/m^3$ are noticeably hazy, so a standard set at that level provides little in the way of restoring clear visibility conditions. We note that a short term standard set at 20 $\mu g/m^3$ would do very little to protect visibility in many Western parks where this concentration level would rarely be exceeded.

Appalachian Mountain Club conducted a visitor perception study using a view of Great Gulf Wilderness area in New Hampshire. Preliminary analysis of the data showed that half the survey respondents found a visual distance of less than 53 km not acceptable for a mountain vista approximately 5 miles away[159]. The authors note that the scene depth is a comparatively short range with respect to many other visibility monitoring sites in Class I areas and this may introduce a bias into the acceptability results. However this short range is more consistent with urban vistas and therefore we believe relevant to the urban standard. AMC members and the general public also have been submitting photographs from hikes to document visibility in a program called Visibility Volunteers. *Attachment C* shows some of those photographs at varying $PM_{2.5}$ levels. The photos, qualitatively demonstrate that $PM_{2.5}$ levels between 20-30 $\mu g/m^3$ can have significant impacts on visibility, degrading the outdoor experience.

EPA's proposed standard reflects a significantly lower acceptable visual range of only around 30-35 km. EPA's Staff Paper puts forth a number of justifications for selecting a visibility standard that is less protective than a standard deemed acceptable by the public survey research. For instance, EPA staff concluded that urban visibility appears to be "good" with $PM_{2.5}$

[158] EPA OAQPS Staff Paper, Attachment 6A.

[159] Hill et al., In Cole, David N, McCool, Stephen F. 2000. Proceedings: Wilderness Science in a Time of Change. Proc., RMRS-P-000. Ogden, UT: U.S. Department of Agriculture, Forest Service, Rocky Mountain Research Station.

concentrations between 20-30 μg/m^3 and significantly obscured with $PM_{2.5}$ concentrations above that level.

EPA's analysis includes photographs illustrating that visibility impairment is eliminated at very low $PM_{2.5}$ concentrations (2.5 μg/m^3).[160] Even the lowest end of EPA staff's recommended standard is significantly above that level, and allows a perceptible impairment to remain (see *Attachment D*).

A secondary standard of 35 μg/m^3 is clearly not protective of visual environments. As the photos presented in *Attachments A, B, C and D* demonstrate, visual air quality at this level is noticeably hazy. Indeed, as the EPA staff paper concludes, "appreciable improvement in visual clarity of the scenic views" analyzed by staff occurs only when $PM_{2.5}$ levels fall below 35 μg/m^3.[161]

Moreover, EPA articulates no rational basis, and none exists, for concluding that a 35 μg/m^3 secondary standard would be requisite to protect public welfare from any known or anticipated adverse impacts on public welfare due to visibility impairment. EPA proposes this level not on the basis of scientific analysis, survey results, and other data documenting levels at which adverse visibility impacts are experienced (as such information in fact shows the need for much more protective standard), but rather solely as a matter of administrative convenience. No where does EPA demonstrate that the primary standard is a valid or even passable surrogate for protection against adverse visibility impacts, and indeed the record shows precisely the opposite. Accordingly, the proposal is arbitrary and unlawful.

Averaging Time

Staff's recommendation that a 4-hour averaging time be used for the standard is appropriate, because it represents a practical compromise between the very short time periods over which visual air quality is experienced and the need for a reasonably stable averaging period. The availability of continuous PM monitors makes use of a 4-hour averaging time entirely practicable. The 4-hour averaging time must be applied on a rolling basis throughout the daylight hours, when visual air quality is most important. Coverage of the morning hours is particularly important, as reconstructed light extinction is usually highest in the morning, corresponding to the worst impairment.[162]

Form of the Standard

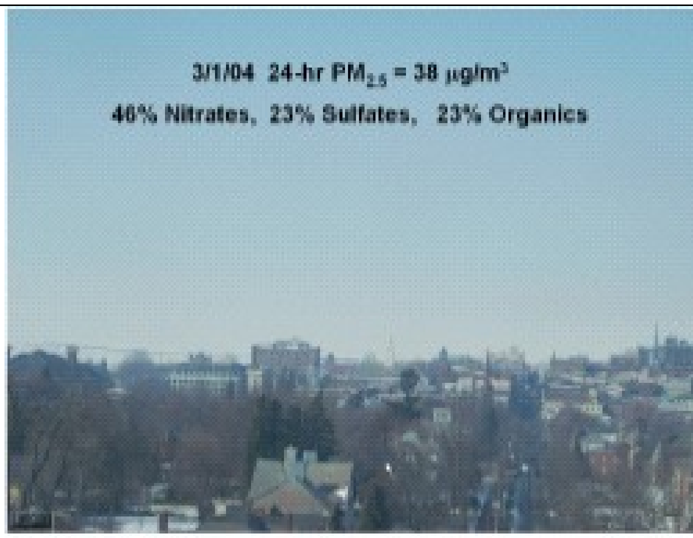
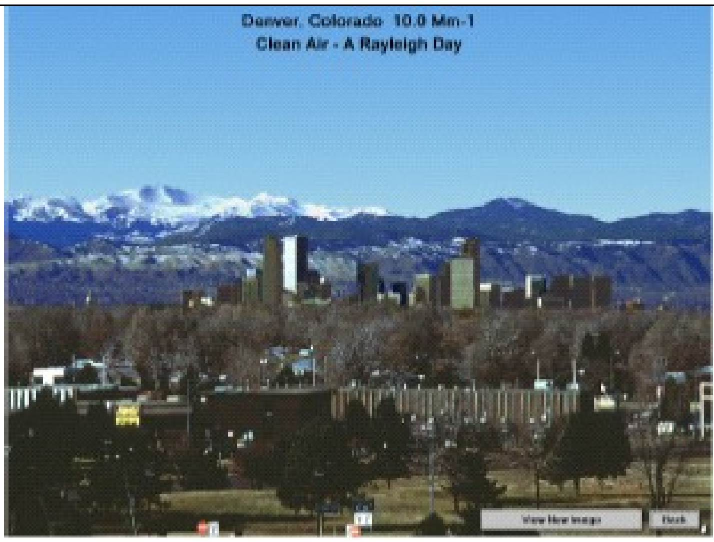
We further urge EPA to adopt a form for the standard that assesses violations based on the 98th percentile. A 90th percentile standard, for instance, would excuse 10 percent of the days – 36 days each year – from meeting any limit, and is therefore is too lax. EPA cannot lawfully or

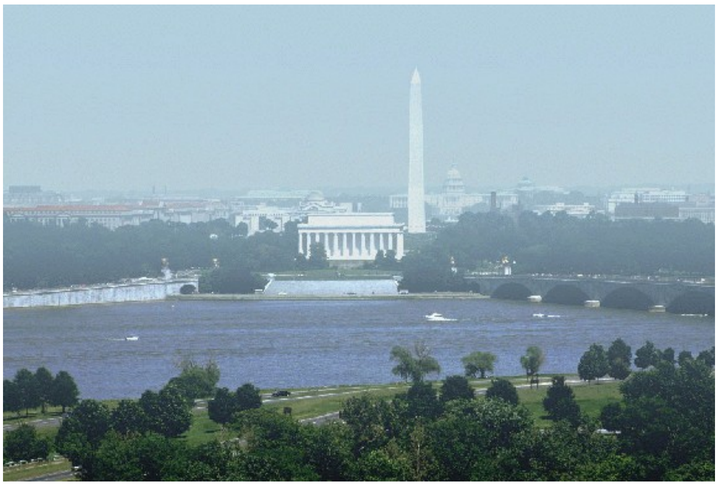
[160] EPA Staff Paper Attachment 6A
[161] OAQPS Staff Paper, p. 7-6.
[162] Schmidt et al. Draft analysis of PM ambient air quality data for the PM NAAQS review. Memorandum to PM NAAQS review docket OAR-2001-0017, January 31, 2005. See Output D.3 section.

rationally find that a standard allowing adverse visibility impacts on fully one out of ten days each year protects public welfare from "any" adverse welfare effects. To the extent EPA seeks to exclude violations that are due to natural conditions (e.g., concurrent precipitation or fog), its proposed method for doing so (arbitrarily excluding 10% of the days) has no rational relationship to that purpose.

EPA must allow use of continuous monitoring devices to provide equivalent measurements of fine particle concentrations. Continuous monitoring can provide additional data for compliance monitoring, health studies, and air quality forecasting, while reducing the workload required to operate the monitoring network.

ATTACHMENT A – Urban Visibility

Natural Visibility Conditions	EPA proposed standard PM2.5 = 35 µg/m^3
Burlington VT[1]	
	
Denver CO[1]	
	

Natural Visibility Conditions	EPA proposed standard PM2.5 = 35 $\mu g/m^3$
Washington DC[2]	
	
Chicago IL[3]	
	

1. Photographic illustrations of PM effects on visibility (R. Poirot, 2/2/06), http://www.epa.gov/sab/pdf/casac_pmrp_02-03-06_visibility_slides_rpoirot.pdf.
2. U.S. EPA, Second Draft of the PM Staff Paper, attachment 6A, http://www.epa.gov/ttn/naaqs/standards/pm/data/washdcimages-2005.doc.
3. U.S. EPA, Second Draft of the PM Staff Paper, attachment 6A, http://www.epa.gov/ttn/naaqs/standards/pm/_data/chicagoimages-2005.doc.

ATTACHMENT B – Park Visibility

All images generated using WinHaze 2.9.0

<table>
<tr><td>Clear Day Conditions
(10 Mm^{-1})</td><td>PM2.5 = 36 $\mu g/m^3$</td></tr>
<tr><td colspan="2">Acadia National Park</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">Shenandoah National Park</td></tr>
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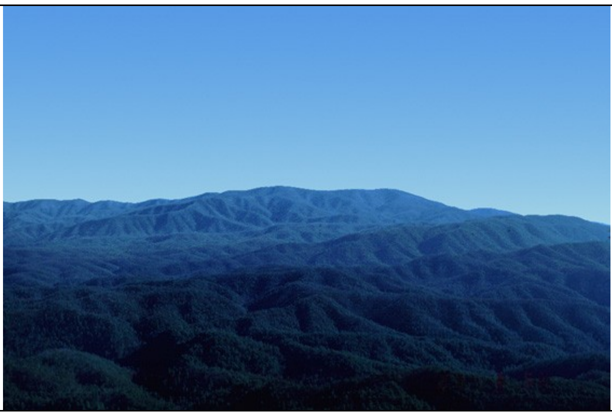
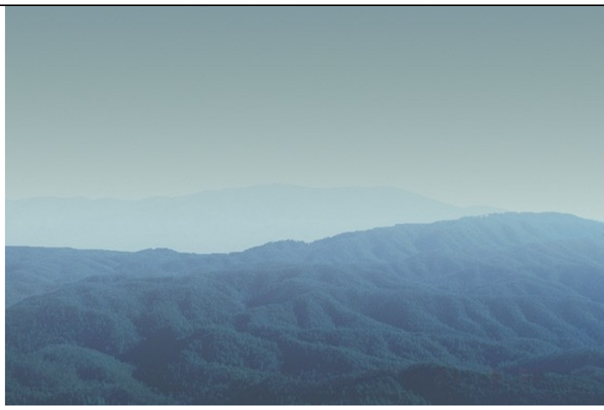
Clear Day Conditions (10 Mm^{-1})	PM2.5 = 36 $\mu g/m^3$
Great Smoky Mountains National Park	
	

ATTACHMENT C –AMC Visibility Volunteer Photos

Photos from hikers on the trail

In the summer of 2005 $PM_{2.5}$ hourly values ranged from 1-43 $\mu g/m^3$ during hikes and averaged 12 $\mu g/m^3$ (RH=Relative Humidity)

<table>
<tr><th>Hourly Conditions
$PM_{2.5}$ = < 10 $\mu g/m^3$</th><th>Hourly Conditions
$PM_{2.5}$ = 10-20 $\mu g/m^3$</th><th>Hourly Conditions
$PM_{2.5}$ = >20 $\mu g/m^3$</th></tr>
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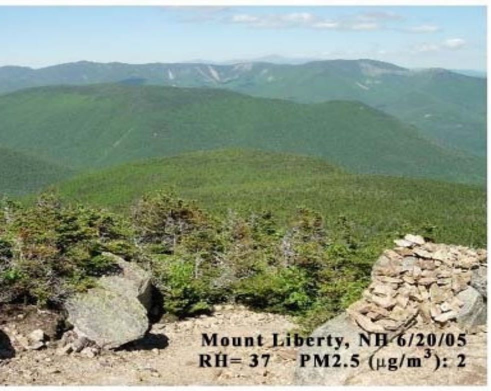
<td>
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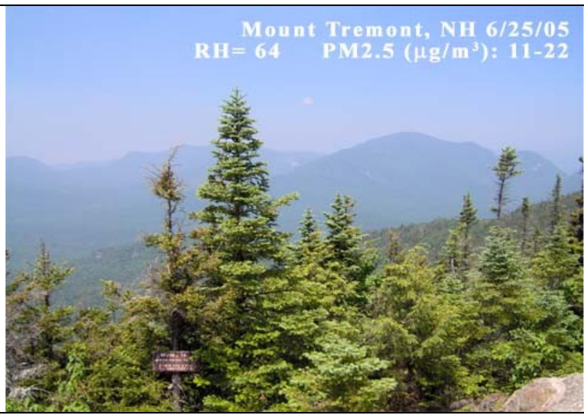
<td>
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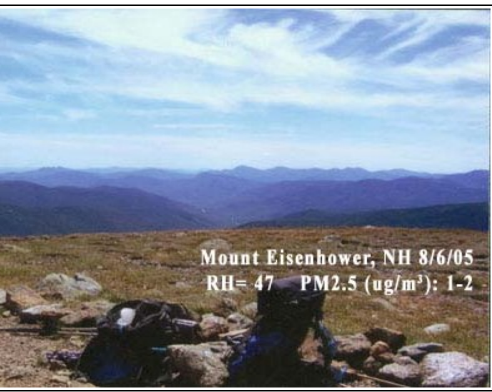
<td>
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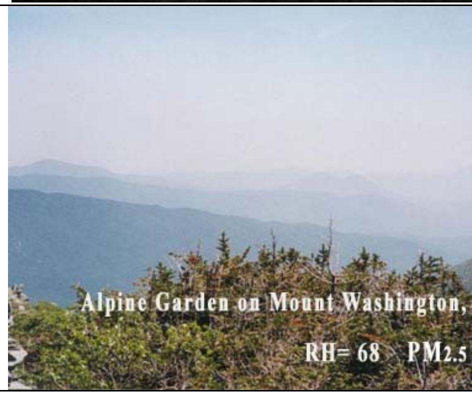
<td>
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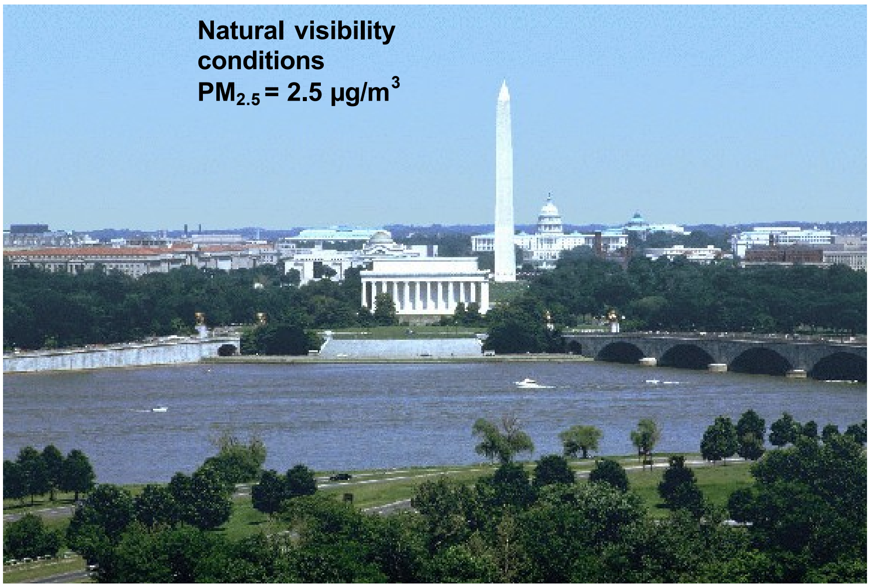
ATTACHMENT D – DC Mall Haze Photos from EPA Staff Paper




Current standard
PM2.5 = 65 µg/m3

Primary Coarse PM Standards

EPA must set a primary standard for thoracic coarse particles that protects all Americans

Clean Air Act section 109(b)(1)(1) provides that primary standards "shall be ambient 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." Thus EPA must set standards that (1) are requisite to protect public health and (2) provide an adequate margin of safety. Further, the statute makes clear that the Administrator's "judgment" in making these determinations is far from open-ended. In exercising such judgment, EPA (1) must err on the side of protecting public health, (2) must base decisions on the latest scientific knowledge giving due deference to the recommendations of the Clean Air Science Advisory Committee, and (3) may not consider cost, feasibility, or administrative convenience.

We strongly support the need for a coarse PM standard. We also support in principle the careful replacement of current PM_{10} standards with a new $PM_{10-2.5}$ standard to provide protection against the negative health effects of exposure to thoracic coarse particles. However, the coarse particle standard proposed by EPA is an egregious step backwards in protection of human health and welfare compared to the status quo. Based on the scientific evidence before it, in order to adhere to the requirements of the Clean Air Act, EPA must set a 24-hour average standard for thoracic coarse particles defined as $PM_{10-2.5}$ in the range of 25 to 30 $\mu g/m^3$, 99^{th} percentile, applicable to all areas of the United States and without exemptions for agriculture, mining, or other anthropogenic sources. EPA must set an annual average standard for coarse particles to protect against adverse health effects, including respiratory illness and impairment of lung function. EPA must also set secondary standards for coarse particles that extend to the whole United States and protect against ecosystem impacts and visibility degradation.

If EPA feels it lacks adequate data to undertake the change in the coarse PM indicator to a $PM_{10-2.5}$ standard, without reducing current protections by either inflating the level of the standard, discarding an excessive number of exceedances, omitting coverage for rural communities, and/or exempting agribusiness and mining from implementation measures, then the Agency must retain the existing PM_{10} NAAQS.

1.1 Clean Air Act Requirements for Coarse Particle standards

"Requisite" as used in section 109 of the Clean Air Act has been held to mean '"sufficient, but not more than necessary.'" *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 473 (2001) (quoting from transcript of Government's oral argument). In attempting to demonstrate that the proposed coarse particulate standard is "requisite" to protect public health, EPA focuses on the "not more than necessary" half of the definition without first showing that the proposed standard is "sufficient" to protect public health.

Courts have repeatedly noted that in order to show a standard is "sufficient" to protect public health, EPA must demonstrate that the standard is set at a level that ensures "an absence of adverse effect" on sensitive individuals. *See, e.g.*, *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980); *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). This is an affirmative obligation; it is not enough to demonstrate an <u>absence</u> of adverse effect by merely claiming that an adverse effect has not been definitively proven. *See American Trucking Ass'n v. Whitman*, 283 F.3d 355, 369 (D.C. Cir. 2002) ("The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree' . . . .") (quoting EPA's PM NAAQS Federal Register notice, 62 Fed. Reg. at 38653); *Lead Indus. Ass'n*, 647 F.2d at 1155 ("[R]equiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to human health before it acts is inconsistent with both the Act's precautionary and preventative orientation and the nature of the Administrator's statutory responsibilities.").

Limited data is not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, data limitations are relevant to ensuring that there is an adequate margin of safety beyond the level established as creating no adverse effects. As the D.C. Circuit has explained, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Lead Indus. Ass'n*, 647 F.2d at 1154-55. Not only does EPA have the authority to protect against uncertain harms, it is obligated to set standards to protect against likely adverse effects and then "allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Id.* at 1154.

EPA has made no attempt to show the proposed PM coarse standards ensure an absence of adverse effects, let alone that they include a margin of safety adequate to protect against effects that may yet be uncovered. This failure is manifest in numerous aspects of the proposal. First, EPA makes no finding that coarse particles cause no adverse effects to people in non-"urban" areas or areas that lack the other characteristics EPA proposes as prerequisites to applicability of the proposed coarse particle standards. Unless EPA can make such a finding, any standard that excludes these areas from protection is "insufficient" *per se*. Second, EPA makes no finding that there is an absence of health effects from coarse particles emitted from the agribusiness and mining industries. Again, the result is that EPA cannot say its proposed standard with these exemptions is "sufficient." Finally, and more fundamentally, EPA never shows that a 24-hour average standard of 70 $\mu g/m^3$, 98^{th} percentile, represents a concentration level that ensures an absence of adverse effects. Nor could it. Numerous peer-reviewed, scientific studies have found serious health impacts associated with exposure to concentrations well below this level. Each of these fundamental deficiencies is explained below in more detail.

1.2 <u>In exercising his discretion to set standards, the EPA Administrator must adhere to the precautionary directives of the Clean Air Act, must base the standards on the latest</u>

scientific knowledge, and may not consider cost, feasibility or administrative convenience

While section 109(a) provides for the Administrator to use his "judgment" in setting standards, it does not provide the wide-open discretion EPA presumes in this proposal. The judgment of the Administrator must be consistent with the precautionary directives of the Act, must be based on the latest scientific knowledge and may not consider cost, technological feasibility, or administrative convenience.

a. The proposal ignores the precautionary directives of the Act

Decisions must be consistent with the overarching purposes of the Act. In exercising his judgment, the Administrator must demonstrate that he is erring on the side of protecting public health. *See Lead Indus. Ass'n*, 647 F.2d at 1155; *American Trucking Ass'ns*, 283 F.3d at 378. Courts have long recognized the "precautionary" directives of the Act, emphasizing Congress' goal in preventing public health impacts. *See, e.g.*, *id.* at 1152 (*citing* H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 49 (1977)). As mentioned above and as discussed in more detail below, the level of EPA's proposed standard and the proposed restriction to urban areas and exemption of agriculture and mining industries manifestly fail to meet the precautionary directives of the Act. Promulgation of these standards as proposed would represent a clear abuse of the Administrator's limited policy discretion.

EPA repeatedly points to uncertainty as a basis for not setting a standard or not addressing certain types of coarse particles. This reasoning is the opposite of the precautionary presumption EPA must apply under the statute. In the face of uncertainty, EPA must err on the side of protecting public health and reducing ambient concentrations of these pollutants. One particularly egregious example of EPA's backwards approach is the decision to use 70 $\mu g/m^3$ as the standard for coarse particles on the ostensible ground that it provides protection that is "equivalent" to the current PM_{10} 24-hour standard. EPA points to the uncertainty surrounding population exposures in studies indicating the 24-hour standard should be set at 50 $\mu g/m^3$ and states that "a more cautious or restrained approach" would be to reject these conclusions because the uncertainties are too large. "Caution" and "uncertainty" are used to justify a standard that is less stringent than even the level EPA's own calculations show is truly "equivalent" to the current standards. See 70 Fed. Reg. at 2670 (citing EPA staff analyses showing that 98th percentile $PM_{10-2.5}$ standard of 60 $\mu g/m^3$ would be roughly equivalent on average to the current PM_{10} standard and that in the northeastern U.S., equivalency would necessitate a 98th percentile standard set at 40 $\mu g/m^3$). This is an abuse of discretion and ignores the statutory limits on EPA's judgment.

b. The proposal must be supported by the latest scientific knowledge

Clean Air Act section 109(b)(1) provides that the Administrator's judgment in selecting the standards shall be "based on [the CAA section 108] criteria." In turn, these criteria required under section 108 "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." CAA § 108(a)(2). EPA has no ability to set standards under 109(b)(1) that do not reflect objective scientific knowledge. *See American Trucking Ass'ns v. Whitman*, 175 F.3d 1027, 1058 (Tatel, J., dissenting) ("[I]n 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 qualities.'") (quoting CAA section 108(a)(2)).

EPA's proposed coarse particle standards fail to reflect the latest scientific knowledge. As detailed below, EPA has arbitrarily and capriciously ignored substantial evidence that demonstrates coarse PM found in rural areas contains harmful components, is not clearly distinguishable from coarse PM found in urban areas, and is associated with serious health impacts. EPA's standards also ignore a significant body of scientific knowledge demonstrating that coarse PM from mining and agriculture are harmful to human health. Finally, EPA's proposed level for the 24-hour standard disregards considerable scientific evidence of serious health impacts.

EPA's scientific discretion is further limited by section 109(d)(2) of the Clean Air Act, which establishes a scientific review committee to review the criteria and provide recommendations to the Administrator on revisions to the criteria and national standards. The recommendations of this committee are not merely another piece of the record that the Administrator can weigh along with other evidence in making his decisions. The Act requires specific explanations for any departures from the recommendations of this committee, CAA § 307(d)(3), and Courts have given heightened deference to decisions that follow these recommendations. *See, e.g.*, *American Trucking Ass'ns, Inc.*, 283 F.3d at 378-79. Where EPA departs from the recommendations of this independent scientific review committee, EPA's judgment is subject to heightened scrutiny because EPA can no longer point to the "objective justification" provided by the committee. *American Trucking Ass'ns*, 175 F.3d at 1059 (Tatel, J., dissenting).

EPA's proposal attempts to claim that it is consistent with the recommendations of CASAC. Since the proposal, however, CASAC has submitted an unprecedented letter to the Administrator, explaining that in fact EPA has misconstrued its findings and that the proposed rule is not consistent with the Committee's recommendations. Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Stephen L. Johnson, Administrator, U.S. EPA (March 21, 2006). Because EPA has falsely attempted to claim it was following the CASAC recommendations, the proposal includes none of the explanation required under section 307(d)(3) of the Act. As such, EPA must, at a minimum, supplement its proposal to provide the required explanations for the differences with the CASAC recommendations.[163] If, on reproposal, EPA continues to depart from the recommendations of CASAC, EPA must provide significant support to

[163] It is not enough for EPA to address the requirements of section 307(d)(3) in the final rulemaking. The Act is clear that the explanations must be part of the proposed rule, which must be open for public review and comment.

justify these departures because EPA can no longer claim that the proposal is based on the objective scientific analysis of its scientific advisory committee.

c. The Administrator has illegally considered cost, feasibility, and administrative convenience in exercising his judgment on the proposed standards

It is well established that the Administrator may not consider cost, feasibility or administrative convenience in exercising his judgment in setting a NAAQS. *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 471 (2001). Yet EPA has relied on these very factors in proposing to limit the PM coarse standard to urban areas and exempting agricultural and mining sources from regulation.

EPA's proposal to limit the standard and monitoring to "urban" areas with populations over 100,000 and population densities greater than 500 people per square mile is unsupported by health evidence in the record. Even if one were to accept EPA's claim that only coarse particles from industrial sources, construction and high-density traffic on paved roads are of concern, there is no rational basis for limiting the standards to certain urban areas. EPA makes no claim that these particles are only present in urban areas, nor could it. The same types of sources responsible for these toxic particles in urban areas are also present in non-urban and rural areas. EPA admits as much in requesting comment on whether the 24-hour PM_{10} standard should be retained in areas that do not meet the "urban" area criteria but "where the majority of the ambient mix of $PM_{10-2.5}$ is generated by high density traffic on paved roads, industrial sources, and construction activities . . . ." 71 Fed. Reg. at 2675. EPA's attempt to identify areas where ambient concentrations are "dominated" by these toxic particles is premised on an illegal consideration of cost, feasibility, and administrative convenience. EPA does not argue that these particles are somehow less toxic when ambient concentrations are dominated by rural dust. Nor does EPA provide any rational basis for finding that coarse PM from high density traffic, industrial sources, and construction activities in non-urban areas are somehow less harmful than coarse PM from the same activities in urban areas. The fallacy of EPA's logic is plain. Individuals in rural areas could be exposed to the exact same concentration of the so-called toxic particles as individuals in urban areas. Yet EPA claims there is no health concern because, in addition to this exposure, the individual is also exposed to an equal or greater concentration of "rural" particulates. Unless EPA can show that rural particulates counteract the toxicity of the toxic "urban" particles, it is clear that EPA's urban/rural distinction is not based on a health finding, nor does it have any rational basis at all.

EPA's only apparent rationale for limiting the standard to urban areas that meet arbitrary size and density criteria is one of cost and administrative convenience. Rather than establishing a uniform standard that limits the exposure to these toxic particles wherever they may be found, EPA is attempting to provide "targeted protection" in a world of limited resources. The Agency has expressly stated that it is limiting the areas where compliance monitoring is to be conducted in order to save money. 71 Fed. Reg. 2710, 2712 (Jan. 17, 2006). Moreover, the Agency's choice of size and population density thresholds to define areas in which the standard will apply is not based on health data establishing these thresholds based on adverse health impacts, but rather on administrative convenience (see discussion below on surrogates). These are the very kinds of considerations Congress and the courts have rejected.

Such improper considerations are just as transparent in EPA's proposed exemption for agriculture and mining sources. Again, EPA does not claim that coarse particles emitted by agricultural or mining sources are benign, or that they are any less harmful than coarse particles emitted by industrial sources, construction activity, or dense traffic. To the contrary, EPA notes that occupational exposure studies demonstrate the toxicity of these particles. *See* 71 Fed. Reg. at 2666. EPA instead asserts that ambient or community exposures are not sufficient to justify controls on these sources. *Id.* at 2668. Such determinations regarding whether ambient concentrations are sufficiently high to justify controls are classic cost-benefit decisions. EPA's job in setting the NAAQS is to specify an ambient concentration level that protects public health allowing an adequate margin of safety. It is not for EPA at this stage to assess whether concentrations in a given area are or are not elevated above this level or whether controls on specific sources are justified.[164]

1.3 EPA lacks authority to set an "urban-only" coarse PM standard

EPA attempts to claim that the proposed coarse particle standard is a national standard because "the indicator is not defined by nor limited to any specific geographic area, but includes the mix of $PM_{10-2.5}$ in any location that is dominated by these sources." 71 Fed. Reg. 2668. The incongruity of EPA's claims is made clear in the parallel proposed revisions to EPA's Ambient Air Monitoring Regulations, 71 Fed. Reg. 2710 (Jan. 17, 2006). EPA's proposed revisions to 40 CFR 58.30(b) explain that to be suitable for comparison to the $PM_{10-2.5}$ NAAQS, data must be from a monitoring site that meets "all five" of the specified conditions including that the site be within the boundaries of an urbanized area with a population of at least 100,000 and a density of 500 or more persons per square mile. Id. at 2782. Thus, even though EPA claims the proposed standard will apply in all areas, the only ambient data that can be compared to this standard are in urban areas. EPA's suggestion that it is setting a national standard is ludicrous. EPA must recognize that it has no authority to limit the geographic scope of a "national" standard, or else there is no reason for such a bizarre argument.

As noted above, EPA cannot justify limiting the standard only to urban areas because even those coarse particles it deems of greatest concern are present in many areas that are

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[164] EPA's attempt to hide such cost-benefit determinations under the banner of making a "public health" finding under section 108 is a tortured application of the Act. Section 108(a)(1)(A) directs EPA to establish NAAQS for pollutants the "emissions of which . . . cause or contribute to air pollution which may reasonably be anticipated to endanger public health . . . ." EPA attempts to argue (1) that emissions from agricultural and mining do not "cause" endangerment of public health because ambient concentrations from these emissions are too small and (2) that emissions from these sources do not "contribute" because the effects of these sources are not likely observed in the effects documented in urban epidemiological studies. The Act directs EPA to make the "cause or contribute" finding for the pollutant not the source. EPA acknowledges that the coarse particles emitted by these sources have been demonstrated to be toxic and that toxic coarse particles are the source of public health concerns. That is the end of the analysis.

rural or non-urbanized, and because the presence of these particles does not depend on whether ambient concentrations are dominated by other coarse particles or not. EPA's only justification is that concentrations of these "urban-type" particles may be lower outside urban areas. Whether ambient concentrations of the pollutant of concern are low in certain parts of the country, however, is not relevant to setting a national standard. The standards must apply to all areas, whether there is a public health concern in a given area or not. *See Whitman*, 531 U.S. at 473 ("We agree with the Solicitor General that the text of § 109(b)(1) of the CAA at a minimum requires that '. . . EPA must establish uniform national standards at a level that is requisite to protect public health from the adverse effects of the pollutant in the ambient air.'") (quoting from transcript of Government's oral argument) (emphasis added); *see also Lead Indus. Assn*, 647 F.2d at 1180 ("As EPA notes, the primary standard must be met in all parts of the country, whether inhabited or uninhabited."). EPA must eliminate any provisions, including those in the proposed monitoring rule, which have the effect of limiting the scope of the NAAQS to certain portions of the country.

1.4 EPA's urban/rural distinction is an illegal attempt to use population as a surrogate for defining the pollutant of concern

EPA claims that it "has sought to define the indicator in a way that more clearly focuses on the nature of the mix of thoracic coarse particles intended to be included and the sources that principally generate that mix, rather than just where they are found . . . ." 71 Fed. Reg. at 2667. As noted above, EPA's monitoring criteria in proposed 40 CFR § 58.30(b) rebuts any claims that the standard limits the concentration of toxic particles anywhere they are found in the country. Moreover, the criteria for monitoring amount to a narrowing of the pollutant's definition. Through the urban/rural distinction, EPA is defining the pollutant of concern as coarse particles found in urban areas meeting the specified criteria. EPA uses population as a surrogate for defining the toxic coarse particles of concern.

EPA, however, does not explain how population has any rational connection to the pollutant of concern. Even if we accepted EPA's claim that it is reasonable to target areas where the mix of coarse particles is dominated by resuspended dust from high-density traffic on paved roads, particles from industrial sources and particles from construction sources, EPA makes no connection between these areas and areas with specified populations. The arbitrariness of EPA's approach is further highlighted by the proposed attempt to look at populations as of the year 2000. Thus EPA must explain not just how "population" but how "population of an area in 2000" is somehow a rational surrogate for the pollutant of concern. EPA provides no explanation as to why population affects either the chemical composition of coarse particles in the air or the sources that emit these particles. In the proposed Monitoring Rule, EPA invites comment on whether a smaller population cutoff would be more appropriate, but gives no explanation as to how any line drawing based on population can help define the pollutant of concern. *See* 71 Fed. Reg. at 2733.

As EPA acknowledges, the D.C. Circuit has rejected similar attempts by EPA to use surrogates that have not been shown to be reliable and accurate indicators of the specific pollutants of concern. *American Trucking Ass'ns*, 175 F.3d 1027, 1055 (holding the "administrative convenience" of a given surrogate "cannot justify choosing an indicator poorly matched to the relevant pollution agent."). EPA asserts with no explanation that the use of population in siting monitors assures that toxic particles will not be over- or under-controlled. Such a conclusory statement, however, is simply inadequate to rationally justify the proposal and indeed defies common sense. The same toxic particles are present in areas that do not have the same "mix" of sources: the "mix" of sources is present in areas that do not meet EPA's criteria for being "urban." EPA must either regulate all coarse fraction particles or define the specific species of particles of concern. EPA cannot draw arbitrary lines based on factors that have no causal connection to the presence or composition of coarse particles in the air and rationally claim that the problems highlighted in *American Trucking* are resolved.

The same considerations require rejection of EPA's other mandatory benchmarks for treating coarse particles as "harmful": detection of the particles in an "urbanized area;" population density of more than 500 persons per square mile; measurement at a population-oriented site not located in a "source-influenced microenvironment;" and coarse particles dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial and construction sources. 71 Fed. Reg. at 2782/3. Nowhere does EPA provide evidence that any of these criteria provide accurate or reliable surrogates for distinguishing between "harmful" and "safe" coarse particles.[165] For example, nowhere does EPA identify evidence showing that coarse particles of concern occur only in areas with more than 500 persons per square mile, or at population-oriented sites. EPA borrows this density requirement, as well as the requirement that the violation occur in an "urbanized area," from Census Bureau conventions that have no health-based grounding whatsoever. Nor does EPA explain why coarse particles in a "source-influenced microenvironment" are somehow safe to breathe. There is no evidence in the record to support such a claim. Indeed, this exemption conflicts with EPA's own assertions that coarse particles from industrial sources do warrant limitation under the standard. Likewise, there is no health-based basis for excluding data from monitors that are not at "population-oriented" sites. Such an approach allows unlimited and profoundly unhealthful levels of coarse particles at such sites. The arbitrariness of this criterion is further shown by EPA's failure to articulate or justify any sort of health-related benchmark for the number of people who must live, visit, or pass through a site before it qualifies as "population based."[166]

EPA's proposed benchmarks are not based on any empirical evidence showing that they accurately or even passably establish the presence of unsafe pollution levels. At best, they serve merely as an administrative convenience, and at worst, as an arbitrary method of limiting the stringency of the rule. Indeed, as with the population test discussed above,

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[165] Note that the proposed monitoring rule requires *all* of these criteria to be met in order for monitored coarse particle levels to be considered in determining compliance with the NAAQS.
[166] EPA's proposed reliance on "population oriented" monitors for fine particles is equally problematic and must be rescinded.

EPA fails to even show a reliable connection between these surrogates and its stated basis for choosing them – namely, as an accurate predictor of areas where the coarse particle mix is dominated by resuspended dust from high-density traffic on paved roads,[167] particles from construction sources, and particles from industrial sources. The result is an approach that is not only arbitrary and capricious, but wholly indefensible under the only criteria relevant for purposes of setting the NAAQS – the protection of public health. As in *American Trucking*, the Agency cannot substitute arbitrary surrogates for standards that must be tailored to protection of health as mandated by the Act.

EPA's proposed approach is all the more arbitrary and unlawful because it would require a monitor to satisfy *all* of the above-referenced benchmarks before exceedances at that monitor would count toward a violation of the NAAQS. For example, a monitor could be located in an area that meets the population density requirement, but if not in an "Urbanized Area," EPA's proposal would deem coarse particle pollution there to be "safe," no matter how extreme the levels. The Agency has failed to demonstrate that requiring compliance with all of the benchmarks has any correlation at all, much less a reliable and consistent correlation, with the composition of the particles encountered in a given area or the toxicity of those particles.

1.5 EPA lacks authority to exempt agricultural and mining sources

Section 50.13(a)(ii) of EPA's proposed regulations provides, "Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard." This provision is arbitrary on it face. The regulations contain no definition of what constitutes an agricultural or a mining source, or what criteria will be used to show another source is "similar." EPA cannot defend such an open-ended exemption on the record because these terms have no connection to the specific findings EPA purports to have made. In fact, as shown in Appendix 3, the types of sources and activities included in the agricultural and mining sectors are widely disparate; EPA has not begun to show or even consider how coarse particles from beef cattle feedlots compare to those from melon farming, or how coarse particles from lead and zinc ore mining compare to those from lawn and garden services.

Equally glaring is the failure to provide any record support for equating emissions from agricultural and mining sources to emissions of "uncontaminated crustal material." Nowhere does EPA explain the leap by which it lumps together "uncontaminated crustal material" with the admittedly toxic particulate emissions from agricultural and mining sources. Thus, it is unclear what "similar" is intended to mean with respect to the emissions of crustal material. Without demonstrating that agricultural and mining sources emit uncontaminated crustal material, the language in section 50.13(a)(ii) is

[167] EPA's use of "high-density" traffic as a benchmark for harmful coarse particles is further arbitrary and unlawful because the term is completely undefined. The agency fails to articulate a dividing line (or for that matter any discernable distinction at all) between "high-density" traffic warranting attention under the standard, and other traffic densities that do not. EPA cannot rationally claim that such a vague and undefined term is anything but an arbitrary basis for limiting application of the coarse particle NAAQS.

nonsensical unless EPA intends also to exempt as "similar" other sources that emit particulates linked to adverse health impacts.

Likewise, EPA's invitation to other classes of sources to nominate themselves for exemptions is illegal and irrational. *See* 71 Fed. Reg. at 2668. Nowhere does EPA explain how this process will work or how, in expanding these exemptions, EPA will comply with the procedures for promulgating (or, in this case revising) a NAAQS. EPA cannot on the one hand try to justify the source-specific exemptions for agribusiness and mining as part of the standard itself and then allow further exemptions without treating these as revisions to the NAAQS. For example, how will such new exemptions be based on the criteria document as required by section 109(b)(1) of the Act? How will CASAC review and provide recommendations on these changes to the NAAQS? The open-ended exemption and invitation for other sources to join in is clearly inconsistent with the careful process required for promulgation of a NAAQS.

More fundamental, however, is the lack of authority for the proposed exemption. Never before, in more than three decades of promulgating NAAQS, has EPA even attempted to use an ambient air quality standard to exempt specific sources from control. The reason is because such an approach is squarely at odds with the language and structure of the Act. EPA can point to nothing in the Act that allows it to insulate sources from control when it sets National Ambient Air Quality Standards.[168]

Section 109 of the Act directs EPA to adopt standards for the "ambient air" – which of necessity contains pollutants emitted from all sources. EPA's own rules provide that the primary NAAQS required by §109 "define levels of air quality which the Administrator judges are necessary, with an adequate margin of safety, to protect the public health." 40 C.F.R. §50.2(b). Thus, NAAQS must be expressed in terms of levels of allowable ambient air quality, not in terms of emissions allowed or not allowed from specific industries.

EPA's proposal attempts an end run around of Congress' clear intention to preserve for the States the decision of which sources to control to meet the NAAQS. Clean Air Act section 101(a)(3) provides Congress' finding "that air pollution prevention (that is, the reduction or elimination, through any measures, of the amount of pollutants produced or created at the source) and air pollution control at its source is the primary responsibility of States and local governments." As the Supreme Court has explained, "The Agency is plainly charged by the Act with the responsibility for setting the national ambient air standards. Just as plainly, however, it is relegated by the Act to a secondary role in the process of determining and enforcing the specific, source-by-source emission limitations which are necessary if the national standards it has set are to be met." *Train v. NRDC*, 421 U.S. 60, 76 (1975). The Court added, "The Act gives the Agency no authority to

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[168] As noted above, the attempt to claim that this exemption somehow "defines" the particles of concern is absurd. There is no demonstration that these particles are less toxic than those emitted from the sources EPA deems to be of concern. Furthermore, EPA has proposed a blanket, unqualified exemption, which would place no limits whatsoever on coarse PM from agriculture and mining.

question the wisdom of a State's choices of emission limitations if they are part of a plan which satisfies the standards of § 110(a)(2) . . . ." *Id.*

To the extent EPA actually seeks to preempt state controls on agricultural and mining sources, EPA's proposal is flatly illegal. It is well established that the police powers of the States will not be preempted unless (1) "it is the clear and manifest purpose of Congress" that federal law preempt state law, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), (2) Congress intended federal law to occupy a field exclusively, *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990), or (3) state law conflicts with federal law by standing as an obstacle to the objectives of Congress. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). EPA can make none of these demonstrations. To the contrary, Congress expressly preserved State authority to formulate the plans for addressing air pollution. *See, e.g.*, CAA §§ 101, 107, 110. Thus there can be no claim that federal law includes express authority to preempt states in deciding which sources to control or that Congress implicitly intended the Act to "occupy the field" of air pollution control. Nor is there any basis for "conflict" preemption. Even if we assumed that emission reductions at mining and agricultural sources did little to reduce the pollutants of concern – an assumption that cannot be defended – a State's decision to regulate these sources does not prevent or in any way "stand as an obstacle" to reducing the emissions of concern. Under such an assumption, EPA might give a State little credit in its State implementation plan for such measures and might believe that the State's resources are being misplaced, but this is not a basis for preempting State controls as frustrating Congress' objectives. *See Train*, 421 U.S. at 76.

EPA must remove the language in 40 CFR 50.13(a)(ii) stating that agricultural, mining, and other "similar" sources of crustal material "shall not be subject to control in meeting this standard." EPA has no authority to include such restrictions on State controls and the record provides no support for this arbitrary exemption.

2. <u>The latest scientific knowledge indicates that coarse PM found in rural areas has adverse effects on human health</u>

2.1 <u>EPA has no rational basis for categorically discounting studies conducted in countries other than the U.S. and Canada</u>

EPA states in the proposal that "in its policy assessment of the evidence judged to be most relevant to making decisions on elements of the standards, EPA has placed greater weight on U.S. and Canadian epidemiological studies using thoracic coarse particles measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics. " 71 Fed. Reg. 2653. This decision has no rational basis. EPA has provided no evidence to indicate that the differences between Europe and the U.S., for example, are so great as to justify discounting European studies.[169]

[169] The Criteria Document simply states "Particular emphasis is focused in the text on those studies and analyses thought to provide information most directly applicable for United States standard setting purposes. Specifically, North American studies conducted in the U.S. or Canada are generally accorded

In contrast, the evidence suggests that the health effects are independent of national demographic or air pollution characteristics. The World Health Organization has reviewed studies from around the world and used them in developing its air quality guidelines. In a recent update, WHO's working group reported consistent health impacts in multiple city studies around the world:

> "Multi-city studies of 29 cities in Europe (Katsouyanni et al. 2001) and 20 cities in the United States (Samet et al. 2000) reported short-term mortality effects for PM_{10} of 0.62% and 0.46% per 10 $\mu g/m^3$ respectively. A meta-analysis of 29 cities from outside Western Europe and North America reported an effect of 0.5% (Cohen et al. 2004). A meta-analysis confined to Asian cities reported an effect of 0.49% (HEI International Oversight Committee 2004). This suggests that the health risks for PM_{10} are likely to be similar in cities in developed and underdeveloped countries at around 0.5%."[170]

The WHO finding demonstrates that EPA's decision was arbitrary. EPA cannot categorically dismiss studies cited herein or in the Criteria Document on the grounds that they are not from North America.

2.2 Rural coarse PM contains relatively toxic constituents**.**

Coarse particles consist of a wide range of materials, including factory exhausts; dust "kicked up" by cars, trucks, mining, construction and agricultural activities; and soot and ash released by the combustion of various materials. Although some generalizations can be made regarding the types of particles that can be found in various regions—like the expectation that concentrations of particles contaminated by automobile exhaust will generally be high in areas with heavy traffic—the content and character of coarse particles vary widely with the demographics, geology, climate, topography and history of events that have transpired at the particular location that is their source.

The sources EPA cites as producing harmful coarse PM – motor vehicles, suspended paved road dust, industry, and construction – are present and heavily impact rural as well as urban communities.[171] Additionally, there are numerous studies in the literature that

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more text discussion than those from other geographic regions. U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 8-4. No explanation is given of why studies from outside North American are not "directly applicable."

[170] World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005, WHOLIS number E87950, 11-12.

[171] The Staff Paper states "In most locations, a variety of activities contribute to ambient PM concentrations… Coarse particles are generally primary particles, meaning they are emitted from their source directly as particles. Most coarse particles result from mechanical disruption of large particles by crushing or grinding, from evaporation of sprays, or from dust resuspension. Specific sources include industrial process emissions, fugitive emissions from storage piles, traffic related emissions including tire and paving materials and grinding and resuspension of crustal, biological, industrial, and combustion materials that have settled on or near roadways, construction and demolition activities, agriculture, mining and mineral processing, sea spray, and wind-blown dust and biological materials….Some combustion-generated particles, such as fly ash, are also found as coarse particles." U.S. EPA, Review of National

demonstrate that coarse PM found in rural areas is commonly contaminated with the same toxic components as particles found in urban areas, as well as other toxic contaminants such as endotoxin and pesticides that are more prominently associated with "rural" sources.[172] The Criteria Document acknowledges this concern, stating "However, under some conditions, crustal particles may become sufficiently toxic to cause human health effects. For example, resuspended crustal particles may be contaminated with toxic trace elements and other components from previously deposited fine PM, e.g., metals from smelters (Phoenix) or steel mills (Steubenville, Utah Valley), PAHs from automobile exhaust, or pesticides from agricultural lands."[173]

As the Criteria Document notes, the premise that rural areas are not impacted by industrial emissions is a false one that can be refuted by referencing some of the very studies that EPA relies upon in attempting to formulate a rule that applies only to urban areas. For example, Steubenville is a small steel mill town in eastern Ohio with about 19,000 residents.[174] Studies of particulate matter concentrations in Steubenville have shown a statistically significant increase in death rates that are associated with increases in airborne concentrations of coarse PM.[175]

There are many sources of peer-reviewed, published literature identifying significant concentrations of harmful components in airborne coarse particulate matter. Moreover, many studies have specifically analyzed the composition of non-urban, or rural, coarse PM. Contrary to EPA assertions, benign crustal components are not the only coarse PM constituents found in rural areas. Even in remote lands there is a significant presence of contributions from anthropogenic sources, as many constituents are atmospherically transported over long distances. The composition of rural, coarse particulate matter may include organic and elemental carbon containing constituents including toxic polyaromatic hydrocarbons, potentially carcinogenic pesticides, harmful heavy metals and ionic species. Furthermore, airborne concentrations of even naturally-occurring crustal materials are known to harm human health. The review of some of this literature that follows is not exhaustive, but clearly demonstrates that many of the constituents of coarse PM that EPA contends are primarily found in "urban-type" coarse PM are also

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Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005. None of the anthropogenic generation mechanisms listed are restricted to urban areas.

[172] See for example: Eleftheriadis, K., Colbeck, I. (2001) Coarse atmospheric aerosol: size distributions of trace elements. *Atmos. Environ.* 35(31):5321-5330; Horvath, H., et al. (1996) The size distribution and composition of the atmospheric aerosol at a rural and nearby urban location. *J. Aerosol Sci.* 27(3):417-435; Milford, J.B., Davidson, C.I. (1985) The sizes of particulate trace elements in the atmosphere – a review. J. Air Pollution Control Assoc. 35(12)1249-1260; Offenberg, J.H., Baker, J.E. (2000) Aerosol size distributions of elemental and organic carbon in urban and over-water samples. *Atmos. Environ.* 34:1509-1517; Offenberg, J.H., Baker, J.E. (2000) Aerosol size distributions of polycyclic aromatic hydrocarbons in urban and over-water atmospheres. *Environ. Sci. Technol.* 33:3324-3331; Paode, R.D., Sofuoglu, S.C., Sivadechathep, J., Noll, K.E., Holsen, T.M., Keeler, G.J. (1998) Dry deposition fluxes and mass size distributions of Pb, Cu, and Zn measured in Southern Lake Michigan during AEOLOS. *Environ. Sci. Technol.*, 32(11): 1629-1635; Poster, D.L., Hoff, R.M., Baker, J.E. (1995) Measurement of the particle size distributions of semivolatile organic contaminants in the atmosphere. *Environ. Sci. Technol.* 29:1990-1997.

[173] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 8-344.

[174] *See* Wikipedia, at http://en.wikipedia.org/wiki/ Steubenville,_Ohio

[175] U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005. 3-14.

found in rural and remote areas. EPA has no basis for drawing a line between "urban" and "rural" areas.

In various studies, crustal components comprise only a fraction of coarse particulate mass. For instance, the chemical composition of $PM_{10-2.5}$ mass in non-urban areas of the southeastern U.S. indicated that crustal material, including Al and Fe, comprised 20-24% of $PM_{10-2.5}$ mass, while inorganic ions (i.e., SO_4^{2-}, NO_3^-, and NH_4^+) together contributed <14% of $PM_{10-2.5}$ mass. The "Other" category, largely considered to be organic matter, dominated the composition of $PM_{10-2.5}$, accounting for 63-66% of total mass.[176] Moreover, annual-average PM_{10} in non-urban, Calexico, California, was comprised not only of crustal components such as Al, Si, K, Ca, Ti, Fe (32%), but of organic carbon (16.3%) and ionic species such as nitrate, sulfate and ammonium (8-10%).[177] These results also coincide with findings from the Austrian Project on Health Effects of Particulates, where inorganic ions, organic carbon and "unidentified" components comprised the majority of PM_{10} composition in rural areas.[178] Although these latter studies examined PM_{10}, not $PM_{10-2.5}$, it is unlikely that all of the non-crustal constituents are found in the fine fraction. The more limited number of studies that have specifically examined $PM_{10-2.5}$ indicate they are not.

There are a number of investigations highlighting particular components of rural coarse particulate matter. The following discussion addresses three of those fractions: elemental and organic carbons, (including polycyclic aromatic hydrocarbons, or PAH), pesticides, and biological and elemental crustal material.

Carbonaceous components

Anthropogenically-produced elemental carbon and organic carbon compounds, including genotoxic and mutagenic polycyclic aromatic hydrocarbons (PAHs),[179] represent a significant fraction present in rural PM_{10} mass. While urban areas may sometimes experience greater PAH concentrations due to a higher density of incomplete combustion of organic matter, these sources are also present in rural areas, and may include vehicle exhaust, wood smoke, vegetative detritus, tire wear, and natural gas combustion.[180]

Exploring an over-water atmosphere downwind of Chicago, Offenberg *et al* (1999) found that while PAH size fractions reside mainly in the fine mode, (i.e., higher molecular

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[176] Edgerton, E.S., B.E. Hartsell, R.D. Saylor, J.J. Jansen, D.A. Hansen, and G.M. Hidy. The Southeastern Aerosol Research and Characterization Study: Part II. Filter-Based Measurements of Fine and Coarse Particulate Matter Mass and Composition. *J. Air & Waste Manage. Assoc.*, 55, pp 1527-1542, Oct 2005.
[177] Chow, J.C. and J.G. Watson, Zones of representation for PM_{10} measurements along the US/Mexico border, The Science of the Total Environment, 276, pp 49-68, 2001.
[178] Hauck, H., A. Berner, T. Frischer, B. Gomiscek, M. Kundi, M. Neuberger, H. Puxbaum, O. Preining, and AUPHEP-Team, AUPHEP – Austrian Project on Health Effects of Particulates – general overview, *Atmospheric Environment*, 38, pp 3905-3915, 2004.
[179] See U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 7-178 - 7-188.
[180] Manchester-Neesvig, J.B., J.J. Schauer, and G.R. Cass, The Distribution of Particle-Phase Organic Compounds in the Atmosphere and Their Use for Source Apportionment during the Southern California Children's Health Study, *J. Air & Waste Manage. Assoc.*, 53, pp 1063-1079, 2003.

weight PAHs), the more volatile PAHs (e.g., benzo[a]pyrene and benzo[ghi]perylene) are also associated with larger, coarser, particles.[181] The findings suggest that low molecular weight PAHs volatilize more rapidly from fine particulate then quickly adsorb to the coarse particles, distributing the more volatile PAH compounds on larger particles. Additionally, data from Massachusetts exhibited at least 50% of PAH associated with coarse rural aerosols at equilibrium, indicating that low and high molecular weight PAHs are coupled with both fine and coarse aerosols.[182] At non-urban (i.e., mountainous, rural coastal, rural inland) sites across Southern California, PAHs and other carbonaceous, organic compounds such as hopanes, steranes, levoglucosan, hexanedioic acid and 1,2-benzenedicarboxylic acid were found in PM_{10} mass (Manchester-Neesvig *et al* 2003). Results from a study conducted in rural Ontario indicate that semivolatile PAHs such as fluoranthene, pyrene and benzo[f]fluoranthene were detected in a coarse mode particle size range of 1.7–6 µm.[183] In rural China, mean normalized distributions of individual PAHs with particle size illustrated that low molecular weight PAH (including naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene) exhibited a multimode distribution, with major peaks in both the coarse mode (4.7-5.8 µm and 9.0-10.0 µm) and accumulation size range (0.43-2.1 µm) (Wu et al., 2006).[184] The abundance of evidence indicates that considerable amounts of dangerous carbonaceous compounds are present in rural coarse particulate matter.

<u>Chemical Pesticides</u>

Because rural areas have a smaller density of people and thus greater open spaces, such as crop fields, lawns and gardens, the use of chemical pesticides is widespread in rural areas. These substances volatilize and then associate with both fine and coarse aerosols. Application of fertilizers and pesticides are known to adsorb onto coarse particulate matter, then reside locally or, as is the case in the Saharan to Arctic connection, be atmospherically transported to distant lands.

Where agriculture is a primary source of semivolatile pollutants, drift from application of pesticides and volatilization of pesticides from soil contributes to the atmospheric loading. In the National Human Exposure Assessment Survey performed in rural and urban areas of Arizona, two organophosphate (OP) pesticides known to have toxic endpoints and potential carcinogenic endpoints, diazinon and chlorpyrifos, were detected in 21% and 10%, respectively, of outdoor air samples collected with a 10 µm inlet.[185]

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[181] Offenberg, J.H. and J.E. Baker, Aerosol Size Distributions of Polycyclic Aromatic Hydrocarbons in Urban and Over-Water Atmospheres, *Environ. Sci. Technol.*, 33, pp 3324-3331, 1999.
[182] Allen, J.O., N.M. Dookeran, K.A. Smith, A.F. Sarofim, K. Taghizadeh and A.L. Lafleur, Measurement of Polycyclic Aromatic Hydrocarbons Associated with Size-Segregated Aerosols in Massachusetts, *Environ. Sci. Technol.*, 30, pp 1023-1031, 1996.
[183] Poster, D.L., R.M. Hoff, and J.E. Baker, Measurement of the Particle-Size Distributions of Semivolatile Organic Contaminants in the Atmosphere, *Environ. Sci. Technol.*, 29, pp 1990-1997, 1995.
[184] Wu, S.P., S. Tao and W.X. Liu, Particle size distribution of polycyclic aromatic hydrocarbons in rural and urban atmosphere of Tianjin, China, *Chemosphere,* 62, pp 357-367, 2006.
[185] Gordon, S.M, P.J. Callahan, M.G. Nishioka, M.C. Brinkman, M.K. O'Rourke, M.D. Lebowitz and D.J. Moschandreas, Residential environmental measurements in the National Human Exposure Assessment

Among the most widely used and frequently detected pesticides in the U.S., the toxicity of these OP compounds is clearly established (Gordon *et al* 1999).

Furthermore, several pesticides commonly used in the agricultural areas of eastern North Dakota were detected by Hawthorne *et al* (1996) in air samples with a particle-size cut-off of <50 μm. Sampling sites were chosen as "islands" of nonfarmed land, located at least 0.4 km from the nearest farmed fields and known pesticide applications. Pesticides were collected on the polyurethane foam (PUF) sorbent and quartz fiber filters. Pesticides found on the filters included Atrazine, Trifluralin, Carbofuran, PCNB [pentachloronitrobenzene], Dicamba, MCPP [2-(4-chloro-2-methylphenoxy)propanoic acid], MCPA [(4-chloro-2-methylphenoxy)acetic acid], 2,4-D [(2,4-dichlorphenoxy)acetic acid], Chlorothanlonil, Cyanazine and 2,4-DB [4-(2,4-dichlorophenoxy)butanoic acid]), demonstrating that significant transport of pesticides occurs not only in the vapor-phase but on suspended matter such as soil and possibly pollen particulates as well.[186] Analysis of the filter samples by Hawthorne *et al* (1996) showed that the majority of particulates were crustal materials (quartz, clays, etc.) of <20 μm size, and therefore would have even longer atmospheric life-times. Moreover, as much as 50% of the particles consisted of pollen and spore grains, which were generally smaller than 15 μm.

It is well known that airborne pesticides and herbicides transported on toxin laden soils pose a threat to human health.[187] Griffin *et al* (2001) discuss the effects of heavily cultivated agricultural areas along the Aral Sea, where phosalone, an organophosphate pesticide, has been detected in airborne dust and beta-hexachlorocyclohexane has been found in breast milk. Dichloro-diphenyl-trichloroethane compounds (DDT) have also been detected in the blood of children. Furthermore, numerous authors have reviewed and discussed the long range atmospheric transport of pesticides and herbicides from desert dust originating in agricultural areas of Asia and Africa to the Arctic. These dust clouds have been calculated to carry as much as 4000 tons of dust per hour into the Arctic, remaining the major source of pesticide bioaccumulation in Arctic animals, also potentially impacting the health of Inuit infants.[188]

Crustal and Biological Material

Aside from additions of carbonaceous compounds and chemicals to rural coarse particulate matter, soil dust particles including toxic biological components, inorganic ions and heavy metals are also contributing factors. Activities such as mining, agriculture, dust storms and driving on unpaved roads will increase the contribution of

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Survey (NHEXAS) pilot study in Arizona: preliminary results for pesticides and VOCs, *Journal of Exposure Analysis and Environmental Epidemiology*, 9 pp 456-470, 1999.
[186] Hawthorne, S.B., D.J. Miller, P.K.K. Louie, R.D. Butler and G.G. Mayer, Vapor-phase and particulate-associated pesticides and PCB concentrations in eastern North Dakota air samples, *Journal of Environmental Quality*, 25 (3), pp 594-600, 1996.
[187] Griffin, D.W., C.A. Kellogg and E. A. Shinn, Dust in the wind: Long range transport of dust in the atmosphere and its implications for global public and ecosystem health, *Global Change & Human Health*, 2(1), pp 20-33, 2001.
[188] *Ibid.*

crustal materials to coarse airborne particulates. The arid, rural southwestern United States is particularly vulnerable to crustal loading because wind erosion of soils and resuspension of dusts contributes significantly to coarse PM.[189]

For instance, dust production from mining processes contributes to airborne particulate matter. Investigating a limestone quarry and nearby town in Wales, researchers found that a significant contribution of local PM_{10} mass was comprised of quartz, gypsum and clay from the quarry blasting site.[190] Also in local PM_{10}, Jones *et al* (2003) detected diesel soot, pyrite, halite, and in particular, phosphorus and sulfur –bearing particles, suggesting the influence of domestic pesticides and fertilizers used in the villagers' gardens. Furthermore, across rural England, opencast mining sites significantly added to the local PM_{10} load, particularly increasing the presence of shale.[191] Soot, flyash, carbon, biological, quartz, and other components were also detected in PM_{10} mass (Pless-Mulloli *et al* 2000).

Agricultural operations also disturb crustal materials, further amplifying the presence of soil particles in coarse particle mass. Silicates and the more respirable crystalline silica were found to dominate the mineral composition of California agricultural dusts, where local farmers exhibited a high correlation between respiratory symptoms and dust exposure.[192] Besides these inorganic components, Schenker *et al* (2005) also referred to the presence of organic components such as molds, fungi, pollen and endotoxin. In another California study, PM_{10} endotoxin concentrations were detected at moderate-to-high levels in not only rural communities, but urban, desert, and mountainous areas as well, stressing the importance of atmospheric endotoxin transport over long distances.[193]

Besides the detection of the above inorganic and organic substances in rural coarse PM, analysis of PM_{10} filters in non-urban areas of Maine identified the presence of heavy metals such as aluminum, copper and vanadium in particulate samples.[194] Comparing asthma hospitalization records, the heavy metals were also found to act as an environmental trigger for asthma episodes (Langley-Turnbaugh *et al* 2005). Heavy metals such as aluminum were also detected in particulate matter originating in soil dusts

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[189] Ellenson, W.D., S. Mukerjee, R.K. Stevens, R.D. Willis, D.S. Shadwick, M.C. Somerville, R.G. Lewis, An Environmental Scoping Study in the Lower Rio Grande Valley of Texas – II. Assessment of Transboundary Pollution Transport and Other Activities by Air Quality Monitoring, *Environment International*, 23 (5), pp 643-655, 1997.

[190] Jones, T., A. Morgan and R. Richards, Primary blasting in a limestone quarry: physicochemical characterization of the dust clouds, *Mineralogical Magazine*, 67(2), pp 153-162, Apr 2003.

[191] Pless-Mulloli, T., D. Howel, A. King, I. Stone, J. Merefield, J. Bessell, and R. Darnell, Living near opencast coal mining sites and children's respiratory health, *Occupational Environmental Medicine*, 57, pp 145-151, 2000.

[192] Schenker, M., J.A. Farrar, D.C. Mitchell, R.S. Green, S.J. Samuels, R.J. Lawson, and S.A. McCurdy, Agricultural Dust Exposure and Respiratory Symptoms Among California Farm Operators, *J. Occup. Environ. Med.*, 47(11), pp 1157-1166, Nov 2005.

[193] Mueller-Anneling, L., E. Avol, J.M. Peters and P.S. Thorne, Ambient Endotoxin Concentrations in PM_{10} from Southern California, Environmental Health Perspectives, 112(5), pp 583-588, Apr 2004.

[194] Langley-Turnbaugh, S.J., N.R. Gordon and T. Lambert, Airborne particulates and asthma: a Maine case study, *Toxicology and Industrial Health,* 21, pp 75-92, 2005.

from unpaved roads and desert lands across Texas, New Mexico and Utah, with other significant contributions from silicon, calcium and organic carbon.[195]

This review indicates there are many wide-ranging components of rural coarse particulate matter, aside from "uncontaminated crustal materials." First, not only are injurious carbonaceous compounds produced locally, but findings also indicate that long-range transport of carbonaceous primary combustion materials has a significant impact on coarse particulate matter,[196] therefore particularly affecting rural, down-wind areas. Secondly, chemical components have been found to adsorb onto dust and pollen grains, prevalent coarse particulate matter in rural areas and a vehicle by which pesticides travel and affect human health through air exposure or drinking water. Lastly, reflecting soil composition, crustal materials themselves may be harmful due to the presence of, for instance, ubiquitous silicaceous compounds, heavy metals, and harmful biological or chemical toxins. The presence of these elements in airborne PM is further exacerbated by disturbance of soils through rural industries such as mining and agriculture.

2.3 EPA's basis for exempting rural PM is unsupported by the evidence and logically flawed.

In its proposal for coarse PM, EPA unreasonably relies on limited conclusions about natural crustal material as grounds for disregarding all coarse PM found in rural areas. EPA's staff paper actually says nothing about toxicological studies of coarse PM found in most rural areas and small and mid-size communities. Rather, the staff paper states "Toxicologic studies, *although quite limited*, support the view that sources of coarse particles common in urban areas are of greater concern than *uncontaminated materials of geologic origin*."[197] EPA staff's conclusions about epidemiological studies were similarly limited: "Taken together, the epidemiologic studies that examine exposures to thoracic coarse particles generally found in urban environments and to natural crustal materials support the view that urban thoracic coarse particles are of concern to public health, *in contrast to uncontaminated natural crustal dusts*."[198] However, coarse particles in rural areas and in small and mid-size communities are not generally "uncontaminated materials of geologic origin" or "uncontaminated natural crustal dusts."

EPA's assertion that "natural" or "uncontaminated" crustal material is relatively benign (an assertion on which it unreasonably relies as a reason to limit the coarse PM NAAQS to urban areas) relies heavily on studies of Mount St. Helens ash. *See* 71 Fed. Reg. 2655, 2666. However, Mount St. Helens ash has a very specific composition, and is not representative of all volcanic ash, or of most "natural crustal material" or coarse PM

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195 Labban, R., J.M. Veranth, J.C. Chow, J.L.P. Engelbrecht and J.G. Watson, Size and Geographical Variation in PM_1, $PM_{2.5}$ and PM_{10}: Source Profiles from Soils in the Western United States, *Water, Air, and Soil Pollution*, 157, pp 13-31, 2004.

196 Turnbull, A.B. and R.M. Harrison, Major component contributions to PM_{10} composition in the UK atmosphere, *Atmospheric Environment*, 34, pp 3129-3137, 2000.

197 U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005, 5-55.

198 U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005, 5-56.

found in rural areas. Even in remote areas, with minimal anthropogenic influence, coarse PM typically contains organic matter, which is insignificant in volcanic ash. Whenever organic matter is present in coarse PM, there is also potential for semi-volatile organic compounds, including organic pesticides and polycyclic aromatic hydrocarbons to partition to the particle phase.[199] Furthermore, at least one recent study directly refutes the contention that even pure volcanic ash is benign with regard to respiratory health. Forbes et al. (2003) found an association between children's exposure to volcanic ash on the island of Montserrat with an increase in respiratory symptoms and clinic visits and with changes in spirometry.[200] Their results stand in contrast to epidemiological results reported after the Mount St. Helens eruption;[201] EPA has not explained the distinction or why the Montserrat results are not relevant.

EPA has also erred in overlooking toxicological evidence that indicates that "rural" dusts can be toxic. Toxicological studies available to EPA during the NAAQS review process have demonstrated cytotoxicity and in vitro cytokine release (indicative of inflammatory response) from mineral dust from stone quarries,[202] which are common in rural as well as urban areas. More recently, these responses have been observed with surface soils from rural as well as urban areas in the southwestern United States.[203] In rural as well as urban dusts, Veranth et al. (2005) found IL-6 release from human lung epithelial cells treated in vitro to be correlated with soil dust mass fractions of elemental carbon (EC), low volatility organic carbon (OC) and endotoxin, and IL-8 release to be correlated with mass fraction of EC and low volatility OC. Schins et al. (2004) found that coarse PM ($PM_{10-2.5}$) from a rural location in Germany induced the most potent inflammatory reaction upon intratracheal instillation in rat lungs, compared to coarse PM from an industrial location or fine PM.[204]

As the Criteria Document explains, "exposures to airborne dust containing elevated concentrations of a soil-dwelling fungus common to dry areas of central California and certain desert areas of the southwestern United States have been linked to outbreaks of "Valley Fever", a respiratory infection that can be potentially deadly."[205] The Criteria Document further states "During dry conditions encountered in desert or other endemic areas during drought periods, both natural dust storms and dust-generating human

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[199] Ramaswami, A., Milford, J.B., and Small, M.J., Integrated Environmental Modeling: *Pollutant Transport, Fate and Risk in the Environment*, John Wiley and Sons, 2005.
[200] Forbes, L., et al. (2003) Volcanic ash and respiratory symptoms in children on the island of Montserrat, British West Indies, *Occup. Environ. Med.* 60:207-211.
[201] Buist, A.S., et al. (1983) Acute effects of volcanic ash from Mount Saint Helens on lung function in children, *Am. Rev. Respir. Dis.*, 127:714-719 (finding no change in lung function in children attending a summer camp impacted by Mount Saint Helens' eruption.
[202] R.B. Hetland et al.,(2000) Mineral and/or metal content as critical determinants of particle-induced release of IL-6 and IL-8 from A549 cells, *J. Toxicol. Environ. Health*, A60:47-65; R. Becher et al., (2001) Rat lung inflammatory responses after in vivo and in vitro exposure to various stone particles, *Inhal. Toxicol.*, 13:789-805..
[203] J.M. Veranth, et al., (2006) Correlation of in Vitro Cytokine Responses with the Chemical Composition of Soil-Derived Particulate Matter, *Environ. Health Perspectives*, 114(3):341-349.
[204] Schins, R., et al. (2004) Inflammatory effects of coarse and fine particulate matter in relation to chemical and biological constitutents, Toxicology and Applied Pharmacology, 195:1-11.
[205] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 7B31-32.

agricultural activities and off-road vehicle use that disturbs the soil can reasonably be projected as being likely to increase *Coccidioides immitis* infection risk."[206]

In drawing conclusions about coarse crustal material, EPA is ignoring concerns about silica that it acknowledged in prior PM NAAQS reviews. The 1996 Staff Paper cites the 1982 Staff Paper as reporting that "some risk of long-term exposure to crustal dusts is suggested by autopsy studies of farm workers and residents in the Southwest (Sherwin et al., 1979), desert dwellers (Bar-Ziv and Goldberg, 1974), and zoo animals and humans exposed to various crustal dusts near or slightly above current ambient levels in the Southwest (Brambilla et al, 1979). These studies found evidence of a silicate pneumonoconiosis, which was related to local crustal materials. Responses ranged from the buildup of particles in macrophages with no clinical significance to possible pathological fibrotic lesions."[207] An American Thoracic Society review published in 1997 concluded that silica is a human carcinogen and can cause silicosis at relatively low levels in occupational settings, with chronic silicosis described after environmental exposures to silica in regions where soil silica content is high and dust storms common.[208]

EPA's primary epidemiological evidence for suggesting that crustal material is of limited health significance is a single study by Schwartz et al. (1999), who compared deaths on 17 dust storm days in Spokane with deaths on control days and found no elevated risk (RR = 1.00 (CI: 0.95 – 1.05) per 50 ug/m^3 change in PM_{10}.[209] This study is subject to several limitations. First, as EPA acknowledges, the PM_{10} levels may have been so high during the dust storms that Spokane residents took shelter indoors. Second, the study considered only mortality endpoints, not morbidity endpoints. EPA is not free to disregard the latter in setting standards for coarse PM. In contrast to Schwartz et al. (1999) more recent studies conducted in Asia have found epidemiological evidence of associations between PM from dust storms and premature death and serious illness. Chen et al. (2004) found an 8% increase in the incidence of death from respiratory disease in Taipei, Taiwan based on responses that followed 39 Asian dust storm events that occurred from 1995 to 2000.[210] Yang et al. (2005) found a statistically significant increase in primary intracerebral hemorrhagic stroke following 54 dust storm episodes that occurred over the period from 1996 to 2001 in Taipei, Taiwan.[211]

2.3 Studies Conducted in Rural Communities Link Death and Disease with Airborne Coarse Particles

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[206] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 7B21-22.
[207] 1996 SP, p. V-28. References in original.
[208] American Thoracic Society (1997) *Am J Resp Crit Care Med* 155:761-768.
[209] Schwartz, J. et al. (1999) Episodes of high coarse particle concentrations are not associated with increased mortality, *Environ. Health Perspectives*, 107(5):339-342.
[210] Chen, Y-S., et al., (2004) Effects of Asian dust storm events on daily mortality in Taipei, Taiwan, *Environ. Res.*, 95:151-155.
[211] Yang, C-Y, et al., (2005) Effects of Asian dust storm events on daily stroke admissions in Taipei, Taiwan, *Environ. Res.*, 99:79-84.

Although many of the studies linking coarse particles to death and disease have been conducted near urban areas, some have been conducted in rural ones as well. For example, Ostro et al. (2000) found statistically significant associations between concentrations of coarse particles in the air in Coachella Valley, California, and deaths due to heart disease.[212] EPA attempts to justify its decision to disregard this study by mischaracterizing and discrediting it, but these attacks are fundamentally flawed. First, EPA characterizes the Coachella Valley as an urban area, rather than a rural one. But the Coachella Valley consists principally of the communities of Palm Springs (population 42,800) and Indio (population 49,100).[213] Based on their populations, the two communities would be considered rural under EPA's proposed rule.

In its determination to carve out an exception for rural coarse particles, EPA also attacked the methods of Dr. Ostro's data collection and analysis.[214] Specifically, EPA challenged Dr. Ostro's use of statistical modeling to recreate 10 years of $PM_{10-2.5}$ data, using 10 years of PM_{10} data but only 2.5 years of $PM_{2.5}$ data. According to EPA, because the correlation used by Dr. Ostro to estimate $PM_{10-2.5}$ data during the 'missing years' was "effectively linear," the study confirms an association between PM_{10} and the observed cardiac deaths, but not necessarily between those effects and $PM_{10-2.5}$. However, this criticism has been rebutted by Dr. Ostro, who pointed out in his comments to the CASAC that because virtually all of the airborne PM in the Coachella Valley region is comprised of particles in the $PM_{10-2.5}$ range, it should not be surprising that there is a close correlation between PM_{10} and $PM_{10-2.5}$, or that there is a similar close correlation between observed deaths and the statistically derived values of $PM_{10-2.5}$.[215] In other words, because most of the daily variation in PM_{10} is due to variation in $PM_{10-2.5}$, one could conceivably relate either measure to cardiac mortality, since they are so closely related.

EPA also challenged Dr. Ostro's method of relating deaths occurring in Palm Springs with PM levels in the air derived from monitors roughly 20 miles away in the town of Indio.[216] Yet the climate and topography of the two towns are essentially the same; and as Dr. Ostro has pointed out to the CASAC, if differences in the characteristics of coarse particles in Indio and Palm Springs were so different as to break the association among particles and observed deaths, it would be reflected in parameters showing a statistically

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[212] Ostro, B. et al. (2000) Coarse and Fine Particles and Daily Mortality in the Coachella Valley, California: A Follow-Up Study, 10 *J. Exposure Analysis & Envtl. Epidemiology* 412.

[213] *See* http://www.answers.com/topic/palm-springs-california ; http://www.answers.com/topic/indio-california .

[214] According to EPA: Ostro et al. (2003) used a one-pollutant model to estimate the association between $PM_{10-2.5}$ on mortality using an effectively linear construct of PM_{10} (as observed in Indio, CA) to represent $PM_{10-2.5}$ for the entire study area. By using such a construct of PM_{10}, the estimated associations simply reflect a PM_{10} association (i.e., the construct does not provide additional information on the effect of PM10-2.5). 71 Fed. Reg. 2672.

[215] Dr. Bart Ostro, Presentation of the California EPA Office of Environmental Health Hazard Assessment Comments on EPA's PM NAAQS Proposal, to CASAC Particulate Matter (PM) Review Panel at the February 3, 2006 Public Teleconference, available at: http://www.epa.gov/sab/panels/casacpmpanel.html .

[216] According to EPA, roughly 75 percent of the cardiovascular mortality in this study occurred in or near Palm Springs, CA and PM characteristics differ significantly between Palm Springs and Indio . . . . Thus, the Ostro et al. (2003) study suggests a positive association between PM_{10} monitored in Indio and mortality in Palm Springs, but some view this study as offering little basis for attributing significant mortality association to $PM_{10-2.5}$ as observed in either city. *Id.*

non-significant association between the two. That is, if the $PM_{10-2.5}$ for the region is being poorly represented using Indio monitors, it would make it more difficult to find an effect that correlates statistically in the first place. EPA's argument is thus not sufficient to negate the positive association that has been found by the study.

A study of associations between mortality and airborne coarse particles conducted in Phoenix by Smith et al. (2000) similarly supports the fact of a relationship between observed deaths and the types of airborne particles that, according to EPA, are typical of rural environments. In that study, the authors separated the observed coarse-particle concentrations into "crustal" and "metal-enriched" components, where the crustal components, according to EPA's presumptions, would be characteristic of those types of particles found in rural areas. However, as pointed out by CASAC member Rich Poirot, the Phoenix study "noted strongest mortality associations during the spring and summer months when the metal-enriched particle concentrations were lowest (and the crustal component was the highest)."[217]

Taken together, the Phoenix and Coachella Valley studies provide ample evidence that rural and crustal particulates, presumed to be benign by EPA, are in fact associated with premature mortality. Additional studies, discussed elsewhere in these comments, indicate that "rural" particles are cytotoxic and that coarse PM found in rural areas is associated with respiratory symptoms and illness. The CASAC's findings do not refute such evidence; instead, there was a 'split' on the panel with respect to the question whether the new coarse particle standard should apply nationally or only in urban areas, with some members believing that "the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles," while others "recommended specifying a national $PM_{10-2.5}$ standard accompanied by monitoring and exceptional-events guidance that emphasized urban influences."[218]

2.4 <u>EPA's Proposed Rule Would Disproportionately Harm Minority and Low-Income Populations</u>

Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to consider the impact of programs, policies, and activities on minority populations and low-income populations. According to EPA guidance, agencies are to assess whether minority or low income populations face risks or a rate of exposure to hazards that are significant and that "appreciably exceed or is likely to appreciably exceed the risk or rate to the general population or to the appropriate comparison group."

Based on an EPA analysis of those areas of the country in which concentrations of $PM_{10-2.5}$ are expected to exceed 75 $\mu g/m^3$, a predominance of those areas lie in arid, rural regions of the desert Southwest. Those regions are inhabited by populations that are

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[217] Letter from Dr. Rogene Henderson, CASAC Chair, to Stephen Johnson, EPA Administrator, Sept. 15, 2005, at D-21 (comments of Mr. Rich Poirot).
[218] *Id.* at 4.

disproportionately poor and Hispanic. The Table 5 summarizes those demographics for four rural California, Arizona and New Mexico counties whose concentrations of $PM_{10-2.5}$ are expected to exceed the proposed standard by at least 5 $\mu g/m^3$:[219]

Table 5

		County		
	USA Avg.	Santa Cruz, AZ	Imperial, CA	Kings, CA
% Latino/Hispanic	12.5	80.8	72.2	43.6
% in poverty	12.4	24.5	22.6	19.5

Population statistics from U.S. Census (2000) http://quickfacts.census.gov/qfd/

Clearly, the rural populations in the Southwest that would be left unprotected under the proposed rule are characterized by people who are predominantly poor and Hispanic. Rather than recognize this fact and address it head-on, as Executive Order 12898 requires EPA to do, the EPA proposal ignores the harm this would proliferate within poor and minority populations of the American Southwest, and elsewhere.

3. EPA's proposal to exempt agriculture and mining sources from having to comply with the standard is not supported by scientific evidence

The Clean Air Act requires EPA to set standards that protect human health with an adequate margin of safety. EPA has clearly failed to meet this requirement in proposing to exempt agriculture and mining sources from regulations to meet the coarse PM standard,[220] because the Agency has provided no evidence that the copious quantities of coarse PM these sources produce is benign. In fact, EPA has ignored numerous studies that provide evidence that coarse PM from these sources poses a significant risk.

The studies EPA has arbitrarily chosen to ignore include numerous occupational health studies. EPA provides no real explanation for this choice. In its proposal, EPA notes that "In the 1987 review, EPA found that occupational and toxicological studies provided ample cause for concern related to higher levels of thoracic coarse particles. Such findings indicated that elevated levels of thoracic coarse particles were linked with effects such as aggravation of asthma and increases in upper respiratory illness, which was consistent with dosimetric evidence of enhanced deposition of thoracic coarse particles in the respiratory tract (61 FR 65649)." 71 Fed. Reg. 2654. As EPA notes, "the need for a standard for thoracic coarse particles" was upheld in the *American Trucking* case based

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[219] *See* U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005, fig. 2-13, at 2-35; 71 Fed. Reg. 2620 (proposing to set 24-hr. $PM_{10-2.5}$ standard at 70 $\mu g/m^3$.

[220] See 71 Fed. Reg. 2654, 2666-8.

upon this evidence. 71 Fed. Reg. 2665. EPA has not explained why occupational health evidence used to be, but no longer is, relevant to setting NAAQS for particulate matter.

The failure to consider occupational health studies is particularly egregious in this instance, because EPA is proposing complete exemptions – EPA's proposal would allow these sources to emit an unlimited amount of coarse PM, exposing nearby residents to concentrations of coarse PM that are unconstrained by ambient limits, and potentially placing them well within or even above the range of exposures seen in studies of occupationally exposed individuals. Under EPA's proposed regulation, ambient coarse PM levels could exceed levels found harmful in occupational settings and still state and local regulations would have no authority to take action under federal law.

In attempting to explain its exemptions for agricultural and mining sources, EPA dismisses occupational health data out of hand, claiming without support that "such studies do not provide relevant evidence for effects at much lower levels of community exposures." 71 Fed. Reg. 2666. Having dismissed the idea of even reviewing studies in occupational settings from the beginning of its process,[221] and hence not having examined the concentrations or mechanisms at issue in these studies, EPA cannot support its claims that exposure levels associated with adverse health impacts in occupational settings are irrelevant for community exposures. The likelihood of overlap between occupational exposures and community exposures is especially high for the agriculture and mining sectors, because the activities associated with production of PM from these sectors commonly take place in the open, often in close proximity to residences. Homes that are located on farms are an obvious case in point.

EPA asserts that "in the last review, EPA considered health evidence related to long-term silica exposures from mining activities, but found that there was a lack of evidence that such emissions contribute to effects linked with ambient PM exposures (EPA, 1996b, p. V-28)." 71 Fed. Reg. 2666. In fact, the section of the last review to which EPA points said something rather different. The 1996 Staff Paper says "There are limited data on ambient concentrations of silica, which is generally found in the coarse fraction. Based on analyses of the silica content of resuspended crustal material collected from several U.S. cities as part of the last review, staff concluded that the risk of silicosis at levels permitted by the current long-term PM NAAQS was low. This earlier conclusion is supported by the CD based on the integration of occupational and autopsy findings with ambient silica concentrations (CD, p. 13-79). … The 1982 staff paper (U.S. EPA, 1982b) reported that some risk of long-term exposure to crustal dusts is suggested by autopsy studies of farm workers and residents in the Southwest (Sherwin et al., 1979), desert dwellers (Bar-Ziv and Goldberg, 1974), and zoo animals and humans exposed to various crustal dusts near or slightly above current ambient levels in the Southwest (Brambilla et al, 1979). These studies found evidence of a silicate pneumonoconiosis, which was related to local crustal materials. Responses ranged from the buildup of particles in

[221] The introduction to the chapter on epidemiological studies in the Criteria Document says "Those epidemiologic studies that relate measures of ambient air PM to human health outcomes are assessed in this chapter, whereas studies of (typically much higher) occupational exposures are generally not considered here." U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004 8-3.

macrophages with no clinical significance to possible pathological fibrotic lesions. No inferences regarding quantitative exposures of concern could be drawn from these studies (U.S. EPA1982b)."[222] EPA has not explained how it makes the leap of logic that converts a finding that in several U.S. cities "the risk of silicosis at levels permitted by the current long-term PM NAAQS is low" to support for a complete exemption for mining and agricultural industries and a complete bypass of protection for rural areas.

Agricultural dust exposure has been recognized for centuries as cause of respiratory disease.[223] These diseases are attributable to both organic and mineral components of agricultural dusts. Likewise, exposure to mineral dusts from mining activities has been recognized for centuries as a cause of respiratory disease.[224]

Schenker et al. (1998) provide an extensive review of respiratory health hazards in agriculture, covering the effects of exposure to infectious and non-infectious bioaerosols, other organic dusts, and mineral dusts.[225] In occupational settings, field workers exposed to mineral dusts from agricultural sources experience enhanced prevalence of acute and chronic bronchitis, chronic obstructive airways disease and interstitial lung disease.[226] Intratracheal instillation of predominantly mineral dust from vineyards resulted in acute inflammatory changes in rats.[227] Organic dusts are associated with allergic reactions, asthma, hypersensitivity pneumonitis and organic dust toxic syndrome.[228] Increased prevalence of high-density and confined livestock feeding operations is enhancing exposure to organic dusts and gases from agriculture.[229] Animal confinement facilities are associated with occupational illness due to organic dust components including allergens, endotoxin, and infectious microorganisms.[230] The association of agricultural activities with elevated levels of endotoxin and lung function decrements, respiratory disease, and

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[222] 1996 SP, p. V-28.

[223] Schenker, M., et al. (1998) Respiratory Health Hazards in Agriculture, *Am. J. Resp. Crit. Care Med.*, 158:S1-S78; Kirkhorn S.R., Garry V.F. (2000) Agricultural lung diseases. *Environmental Health Perspectives Supplements,* 108:705-712; Linaker C., Smedley J. (2002) Respiratory illness in agricultural workers. *Occupational Medicine* 52:451-459.

[224] Fubini and Arean, 1999; Petavratzi, E., Kingman, S., Lowndes, I. (2005) Particulates from mining operations: a review of sources, effects and regulations, *Minerals Engineering*, 18:1183-1199.

[225] Schenker, M., et al. (1998) Respiratory Health Hazards in Agriculture, *Am. J. Resp. Crit. Care Med.*, 158:S1-S78.

[226] Schenker, M., (2000) Exposures and health effects from inorganic agricultural dusts, Environmental Health Perspectives Supplements, 108(S4):661-664.

[227] Rajini, P., Last, J.A., McCurdy, S.A., et al., (1995) Lung injury and fibrogenic response to dusts from citrus and grape harvests, Inhal. Tox. 7:363-376.

[228] Linaker C, Smedley J., (2002) Respiratory illness in agricultural workers. *Occupational Medicine* (52) 451-459.

[229] Kirkhorn S.R., Garry VF. (2000) Agricultural lung diseases. *Environmental Health Perspectives Supplements* (108) 705-712.

[230] Kirkhorn SR, Garry VF. (2000) Agricultural lung diseases. *Environmental Health Perspectives Supplements* (108) 705-712.

mediators of pulmonary toxicity is discussed in the Criteria Document.[231] There is evidence that these respiratory hazards extend to residents living near these facilities.[232]

Although more limited in number than studies of occupationally exposed individuals, studies of residents who live near mining and agricultural operations indicate risk associated with coarse PM from these sources. Pless-Mulloli et al. (2001) found that children living in rural and suburban communities with opencast coal mines were exposed to a small but significant amount of additional PM_{10}, compared to control communities with similar populations, and that children in the opencast mine communities made a significantly higher number of doctors visits for respiratory conditions than children in the control communities.[233] In support of a finding that children are susceptible to the harmful health effects from PM, the Criteria Document notes that "Pless-Mulloli et al. (2000) evaluated children's respiratory health and air pollution near opencast coal mining sites in a cohort of nearly 5,000 children aged 1 to 11 years in England. Mean PM levels were not high (mean < 20 $\mu g/m^3$ PM_{10}), but statistically significant PM_{10} associations were found with respiratory symptoms."[234] An important and tragic community health case study from American history that demonstrates the significant risk posed by suspended soil dust dates to April, 1935, when mortality rates for both infants and adults in the dust bowl of southwestern Kansas and the panhandle of Oklahoma were dramatically elevated. At the time, health professionals attributed the increased mortality rates observed in conjunction with the dust storms to "dust pneumonia."[235] While meteorological factors were also at play, human activities contributed significantly to this disaster. A Dust Bowl cloud that impacted Washington D.C. in 1934 was used by Dr. Hugh H. Bennett to help spur the United States Congress to pass the Soil Conservation Act of 1935. The purpose of the Act was to implement farming practices and other measures that would limit soil erosion by both winds and precipitation.[236]

As discussed above, EPA's primary toxicological evidence for the assertion that natural crustal material is relatively benign is studies of Mount St. Helens ash, which is not representative of all "natural crustal material" and may not even be representative of all volcanic ash. In fact there is a long list of natural crustal materials that are suspended in the atmosphere due to agriculture and mining that have been associated with human

[231] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 7B-24-29, Table 7B-3 at 7B-11.

[232] Thu K, Donham K, Ziegenhorn R, Thorne PS, Subramanian P, Whitten P, Stookesberry J. (1997) A control study of the physical and mental health of residents living near a large-scale swine operation. *J Agric Safety Health* 3(1):13-26 (1997). ; Wing and Wolf, 2000.

[233] Pless-Mulloli T, Howel D, Prince H. (2001) Prevalence of asthma and other respiratory symptoms in children living near and away from opencast coal mining sites. *International Journal of Epidemiology* (30) 556-563.

[234] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004 8-192, citing Pless-Mulloli T., et al. (2000) Living near opencast coal mining sites and children's respiratory health, Occupational Medicine, 57:145.

[235] Worster, D. Dust Bowl: The Southern Plains in the 1930s, Oxford University Press, 1979.

[236] Griffin, D.W., C.A. Kellogg and E. A. Shinn, Dust in the wind: Long range transport of dust in the atmosphere and its implications for global public and ecosystem health, *Global Change & Human Health*, 2(1), pp 20-33, 2001.

disease. The following Table 6, from Banks and Parker (1998)[237], provides a partial listing of inorganic compounds in this category. Additionally, coarse PM from agriculture and mining activities is not natural material, as EPA well knows. When minerals such as those listed in the table are entrained in the atmosphere due to agriculture and mining activities, they commonly end up in the coarse thoracic size range, allowing them to penetrate deep into the lungs of people who breathe them. As noted above, recent toxicological studies have demonstrated cytotoxicity and in vitro cytokine release (indicative of inflammatory response) from mineral dust from stone quarries.[238] Agricultural dusts are unlike volcanic ash in that they generally include significant fractions of both organic and inorganic material.[239] The inorganic fraction is primarily silicates, but may include crystalline silica.[240] As discussed above, clays found in resuspended agricultural dusts can carry organic materials and pesticides.[241]

Table 6

Table 1
Natural materials associated with human disease, (Banks and Parker, 1998)

Rock type/ore	Human health implications
Chrysotile, crocidolite, anthophyllite etc.	Used as asbestos. Asbestosis, lung cancer; cancer of the gastrointestinal tract; pleural, mesothelioma
Mica group minerals	Pulmonary fibrosis; silicosis; strong association with free silica, likely a major factor in producing fibrosis
Feldspar	Silicosis; often attributed to the included crystalline silica
Fullers earth—Bentonites	Pneumoconiosis without massive fibrosis and nodules; mottled X-ray appearance; some related silicosis
Granite, quartzite, sandstone, slate	Silicosis; silico-tuberculosis; nodular silicosis; fibrosis; enlarged and hardened lymph glands
Limestone, marble, dolomite	Bronchitis, emphysema, some scarring reported; calcinations increases toxicity; caustic burns; dermatitis
Silica, quartz, flint, crystobalite, tridymite	Silicosis; silicotic nodules in spleen; silico-tuberculosis; progressive pulmonary fibrosis; cristobalite-tridymite are more fibrogenic
Talc	Talcosis; talc pneumoconiosis
Bauxite ore; corundum	Aluminosis; lung scarring; pneumoconiosis; emphysema
Chromite	Lung cancer; ore may be associated with crhysotile asbestos
Iron ore (hematite, magnetite, taconite)	Siderosis; reports of increased lung cancer among taconite ore
Lead ore (galena, cerussite, anglesite)	Pneumoconiosis; diseases of the central nervous system; nephritis; anemia
Uranium, thorium and vanadium ores	Excess lung cancer
Tin, titanium	Severe X-ray changes in miners; tin pneumoconiosis; severe lung scarring; titaniosis

The deep illogic of EPA's proposal to exempt agriculture and mining sources from regulations designed to meet the NAAQS for coarse PM is demonstrated by the fact that

[237] Banks DE, Parker, JE. Occupational Lung Disease: An International Perspective. Lippincott Williams & Wilkins Publishers, 1998.

[238] R.B. Hetland et al., (2000) Mineral and/or metal content as critical determinants of particle-induced release of IL-6 and IL-8 from A549 cells, *J. Toxicol. Environ. Health*, A60:47-65; R. Becher et al., (2001) Rat lung inflammatory responses after in vivo and in vitro exposure to various stone particles, *Inhal. Toxicol*., 13:789-805..

[239] Schenker, M., (2000) Exposures and health effects from inorganic agricultural dusts, *Environmental Health Perspectives* Supplements, 108(S4):661-664.

[240] Green, F., Yoshida, K., et al. (1990) Characterization of airborne mineral dusts associated with farming activities in rural Alberta, Canada, *Int. Arch. Occup. Environ. Health*, 62:423-430.

[241] Giese, R., van Oss, C. (1993) The surface thermodynamic properties of silicates and their interactions with biologic materials, 327-346, In Health Effects of Mineral Dusts, G. Guthrie and B. Mossman, eds., Mineral Society of America.

this exemption would include urban areas, where "crustal" material suspended by agriculture and mining activities is likely to be commonly contaminated with material produced from heavy traffic and industrial activities.

4. EPA must set a 24-hour average standard for thoracic coarse particles in the range from 25-30 μg/m^3, 99th percentile, applicable to all areas of the United States and without exemptions for agriculture, mining, or other anthropogenic sources of this form of air pollution**.**

Even for areas where EPA has proposed that it would apply, the proposed coarse PM standard fails to protect human health with an adequate margin of safety. As we have commented throughout the NAAQS review and rulemaking process, this deficiency stems from a failure to adequately incorporate the results of numerous $PM_{10-2.5}$ studies into the proposed standard, especially studies with morbidity endpoints,[242] as well as failure to consider the hundreds of studies published since 1987 that indicate that the existing PM_{10} standard is inadequate to protect human health. As a consequence of these latter studies, the European Union and the state of California have both adopted 24-hour standards for PM_{10} of 50 μg/m^3.[243] The World Health Organization is also poised to issue air quality guidelines for PM_{10} set at 50 μg/m^3, 99th percentile.[244] For the new thoracic coarse particle standard to provide an adequate level of protection, EPA must narrow the proposed range for the 24-hour thoracic coarse particle standard to focus on concentrations of 25 to 30 μg/m^3, 99th percentile, reflecting the levels of $PM_{10-2.5}$ that are associated with harmful effects in the literature, as discussed below, while providing an adequate margin of safety. This would be more closely equivalent to the European Union and California 24-hour standards for PM_{10} of 50 μg/m^3.

The results of EPA's own risk assessment for coarse particles showed that even at the lower end of the range proposed in the Staff Paper (50 μg/m^3 98th percentile, or 60 μg/m^3 99th percentile) there would be zero reduction in risks of hospital admissions for asthma in Seattle, or in respiratory symptoms in children in St. Louis, the two cities analyzed, relative to "as is" concentrations.[245] Furthermore, the health studies EPA reviewed in setting the proposed standard found adverse health effects at levels as low as 30 μg/m^3. For example, studies of respiratory and/or cardiovascular hospitalization in Atlanta, Detroit, Seattle, and Toronto, and of respiratory symptoms in children in six U.S. cities reported significant associations with coarse particle concentrations of 30 to 40

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[242] See Comments Of American Lung Association, Environmental Defense, Natural Resources Defense Council, on U.S. EPA's Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information
OAQPS Staff Paper -- Second Draft (January 2005) and Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report January 2005, March 30, 2005, and references therein.
[243] http://europa.eu.int/comm/environment/air/pdf/pp_pm.pdf ; and http://www.arb.ca.gov/regact/aaqspm/aaqspm.htm
[244] World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005. WHOLIS number E87950.
[245] U.S. EPA, Office of Air Quality Planning and Standards. Particulate Matter Health Risk Assessment for Selected Urban Areas. June 2005. pp. F-5 and F-6.

μg/m^3, 98th percentile.[246] EPA states in its proposal that a standard of 70 μg/m^3 is justified because it is "below the 98th percentile $PM_{10-2.5}$ concentrations in the two mortality studies that reported statistically significant associations (i.e., Mar et al., 2003; Ostro et al., 2003). 71 Fed. Reg. 2671. Even if this is true, EPA is not free to disregard the studies showing that serious illness is associated with $PM_{10-2.5}$ at much lower concentrations. Basing the $PM_{10-2.5}$ standard largely on mortality studies is entirely insufficient to protect public health and ignores strong evidence of serious health impacts occurring at lower concentrations. The reported morbidity impacts have serious implications for the affected individuals and for public health, and EPA is not permitted to ignore them. EPA's proposed standard of 70 μg/m^3 is clearly inadequate to meet the requirements of the Clean Air Act.

As discussed in our March 30, 2005 comments on EPA's Second Draft Staff Paper, a number of recent studies indicate that coarse particle may have stronger effects than fine particles in susceptible populations. A recent study in Spokane, Washington found that even low concentrations of coarse particle air pollution may cause symptoms of respiratory distress in children with asthma. In children, a strong association between cough and $PM_{2.5}$, PM_1, PM_{10} and $PM_{10-2.5}$ was found. Stronger associations with cough were reported for coarse particles than for fine. Increased phlegm and runny nose were associated with PM_{10} and $PM_{10-2.5}$. The researchers concluded: "The association between asthma aggravation and coarse particles adds to the growing literature suggesting an association between this particle size and asthma aggravation. Such a finding is physiologically feasible since particles in this size range are known to deposit in the large bronchial airways."[247]

A study of daily deaths and hospital admissions of the elderly in the Detroit metropolitan area found that the relative risks for $PM_{10-2.5}$ were higher than those for $PM_{2.5}$ in the case of ischemic heart disease and stroke.[248] A study in Toronto, Canada reported a stronger effect of $PM_{10-2.5}$ on asthma hospitalization among children ages 6-12 compared with both $PM_{2.5}$ and PM_{10}. The stronger effect of $PM_{10-2.5}$ persisted, even after adjusting for

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[246] U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005, 5-64; Tolbert, P. E.; Klein, M.; Metzger, K. B.; Flanders, W. D.; Todd, K.; Mulholland, J. A.; Ryan, P. B.; Frumkin, H. (2000) Interim results of the study of particulates and health in Atlanta (SOPHIA). *J. Exposure Anal. Environ. Epidemiol.* 10: 446-460; Burnett, R. T.; Cakmak, S.; Brook, J. R.; Krewski, D. (1997) The role of particulate size and chemistry in the association between summertime ambient air pollution and hospitalization for cardiorespiratory diseases. *Environ. Health Perspect*. 105: 614-620. See also Comments Of American Lung Association, Environmental Defense, Natural Resources Defense Council, on U.S. EPA's Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper -- Second Draft (January 2005) and Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report (January 2005), March 30, 2005, and references therein.

[247] Mar TF, Larson TV, Stier RA, Claiborn C, Koenig JQ. An analysis of the association between respiratory symptoms in subjects with asthma and daily air pollution in Spokane, Washington. *Inhalation Toxicology* 2004;16:809 -815.

[248] Lippmann, M., Ito, K., Nádas, A., and Burnett, R.T. Association of Particulate Matter Components with Daily Mortality and Morbidity in Urban Populations. Health Effects Institute Research Report Number 95, August 2000.

the effects of gaseous air pollutants.[249] Recently, Chen et al. (2005) found $PM_{10-2.5}$ was significantly associated with second and overall admissions for respiratory disease in Vancouver, whereas there was no significant association with $PM_{2.5}$.[250] The mean ambient $PM_{10-2.5}$ concentration measured in the study was 5.6 μg/m^3.[251]

A number of toxicological studies have also reported greater effects of coarse than fine particles. These include: a study of in vitro cell injury and cytokine production (Pozzi et al. Toxicology 2003); oxidative DNA damage in vitro (Greenwell et al. 2002); inflammatory cytokine production, phagocytosis and other functional changes in alveolar macrophages, related to endotoxin content (Becker et al. Exp Lung Res 2003); and reduced alveolar macrophage function, not related to endotoxin (Kleinman et al. Toxicol Lett 2003).[252]

Very recent studies add to the growing body of evidence that coarse PM causes serious health impacts, including in children. Lin et al. (2005) reported a detrimental effect of relatively low levels of coarse particulate matter on hospitalizations for respiratory infections in children. This study used a case-crossover design to examine the relationship between various air pollutants and hospitalization for respiratory infections among children younger than 15 years in Toronto over a 4-year period. When PM and gaseous pollutants were both taken into account, the effect remained pronounced for $PM_{10-2.5}$ in both boys and girls. Mean $PM_{10-2.5}$ concentrations in this study were 10.85 μg/m^3.[253]

A multi-decade study reports that women who live in areas with greater coarse particle concentrations have a higher risk of developing and dying from coronary heart disease. In this long-term follow-up of the ASHMOG cohort, coarse particles were associated with increased risk of fatal heart disease in women, especially older women, but not in men, though the effect was stronger for fine particles. Long-term mean concentrations of $PM_{10-2.5}$ in this study were 25.4 μg/m^3.[254]

Becker et al. (2005) reported the results of laboratory toxicology study that exposed human alveolar macrophages and airway epithelial cells to particles in vitro and followed them for endpoints of inflammation and oxidant stress. These are the two

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[249] Lin, M., Chen, Y, Burnett, R.T., Villeneuve, P.J., and Krewski, D. The Influence of Ambient Coarse Particulate Matter on Asthma Hospitalization in Children: Case-Crossover and Time-Series Analyses. Environ. Health Perspect 2002;110:575 -581.

[250] Chen, Y., et al., (2005) The effect of coarse ambient particulate matter on first, second, and overall hospital admissions for respiratory disease among the elderly, Inhalation Toxicology, 17:649-655.

[251] Id.

[252] Lipsett M. No Particle Left Behind. Presentation at EPA Conference on "Meeting the Challenges of Particulate Matter Air Pollution: EPA's PM Research Centers, September 27, 2003. Available at: http://es.epa.gov/ncer/publications/meetings/9 -27-2004/pdf/lipsett.pdf.

[253] Lin M, Stieb DM, Chen Y (2005) Coarse Particulate Matter and Hospitalization for Respiratory Infections in Children Younger Than 15 Years in Toronto: A Case-Crossover Analysis. *Pediatrics* 116:235-240.

[254] Chen LH, Knutsen SF, Shavlik D, Beeson WL, Petersen F, Ghamsary M, Abbey D. The Association between Fatal Coronary Heart Disease and Ambient Particulate Air Pollution -- Are Females at Greater Risk? *Environ Health Perspect* 2005; 113:1723-1729.

main airway cell types likely to interact with inhaled particles. The study found that the proinflammatory response in alveolar macrophages was driven by material present in the coarse PM. Cultures of bronchial epithelial cells also responded to the coarse fraction with higher levels of certain markers of inflammation than induced by fine or ultrafine PM. These epithelial cells also showed evidence of oxidant stress in response to coarse particle exposure, as well as to other size fractions of PM.[255]

Brunekreef and Forsberg (2005) provided a systematic review of more than 30 studies (many published prior to 2003) that evaluated both fine and coarse PM. Their review reinforces many of the conclusions of the EPA staff scientists in the final Staff Paper. This review article examined studies that have investigated the effects of both fine and coarse particles, and concluded that for some health endpoints, the effects are even stronger for coarse particles than for fine particles. Specifically, the paper finds that "in studies of chronic obstructive pulmonary disease, asthma and respiratory admissions, coarse PM has a stronger or as strong short-term effect as fine PM, suggesting that coarse PM may lead to adverse responses in the lungs triggering processes leading to hospital admissions." The review also found support for an association between coarse PM and cardiovascular hospital admissions. With respect to the toxicology of coarse particles, the review concluded that "studies clearly show that coarse PM exerts toxic effects in laboratory experiments, and that such effects are at least as potent as those observed in experiments using fine PM, when expressed on a mass basis," while cautioning that fine particles may deliver a higher dose of toxic material to the lungs. Researchers concluded that the coarse particle fraction is of importance in the regulatory process as well as for control measures.[256] In an accompanying editorial, Swedish, German, and Dutch researchers argued that systematic review offers evidence for the separate regulation of the coarse particle fraction.[257]

EPA seeks to justify a weak $PM_{10-2.5}$ standard by asserting that coarse PM studies are undercut by "uncertainty related to exposure measurement error." 71 Fed. Reg. 2669. At best, the Agency is speculating on this point, and in relying on this speculation it manifestly fails to take the required precautionary perspective or providing any margin of safety in the standards. EPA identifies possible exposure errors in two studies: possible underestimation of exposure in the Detroit study by Ito et al. (2003) and possible overestimation of exposure in the Coachella Valley study by Ostro et al. (2003). The proposal goes on to state that "On the other hand, a close examination of the air quality data used in the other studies discussed above generally shows less disparity between air quality levels at the monitoring sites used in the studies and the broader pattern of air quality levels across the study areas than that described above in the Detroit and Coachella Valley studies." 71 Fed. Reg. 2670. Thus even accepting EPA's assertion that the Detroit study overestimated the relevant exposure, EPA is left with studies of

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[255] Becker S, Mundandhara S, Devlin RB, Madden M. Regulation of Cytokine Production in Human Alveolar Macrophages and Airway Epithelial Cells in Response to Ambient Air Pollution Particles: Further Mechanistic Studies. *Toxicol Appl Pharmacol* 2005; 207(2 Suppl):269-275.

[256] Brunekreef, B., Forsberg, B. Epidemiological Evidence of Effects of Coarse Airborne Particles on Health, *Eur Respir J 2005;* 26:309-318.

[257] Sandström T, Nowak D, and van Bree L. Health Effects of Coarse Particles in Ambient Air: Messages for Research and Decision-Making. *Eur Respir J* 2005; 26:187-188.

respiratory and/or cardiovascular hospitalization in Atlanta, Seattle, and Toronto, and studies of respiratory symptoms in children in six U.S. cities, that reported significant associations with 98th percentile coarse particle concentrations in the range of 30 to 40 $\mu g/m^3$.[258]

What EPA's analysis thus suggests is that (a) in the two cases where uncertainties were may have been an issue, the uncertainty cut in both directions and (b) the exposure estimates in most of the key studies EPA reviewed are not subject to much "uncertainty related to exposure measurement error." Instead of acknowledging this and moving forward to set protective standards with an adequate margin of safety, below the level of observed adverse health impacts, EPA punts and adopts what it claims is a "more cautious" approach, which is "to judge that the uncertainties in this whole group of studies as to population exposures that are associated with the observed effects are too large to use the reported air quality levels directly as a basis for setting a specific standard level." 71 Fed. Reg. 2670. This is a bizarre interpretation, and directly contradicts EPA's earlier conclusion that with the possible exception of the Detroit and Coachella Valley studies, the monitoring sites represent "the broader pattern of air quality levels" reasonably well. EPA is clearly trying to dodge the problem it finds itself in, that if the scientific evidence is taken at face value, there is no way it could show that the 70 $\mu g/m^3$ standard is requisite to protect human health with an adequate margin of safety. It bears repeating that "(t)he Clean Air Act requires EPA to promulgate protective primary NAAQS" even where, as here, the pollutant's risks cannot be quantified or "precisely identified as to nature or degree," American Trucking Assn v. EPA, 283 F.3d 355, 369 (D.C. Cir. 2002) (citations omitted).

4.2 EPA's qualitative approach of setting the $PM_{10\text{-}2.5}$ standard so it is "equivalent" to existing PM_{10} standard has no rational basis**.**

As discussed above, setting a $PM_{10\text{-}2.5}$ standard so it is "equivalent" to the existing PM_{10} standard is clearly not sufficient to protect human health when the PM_{10} standard itself is not adequate. Beyond that, EPA's own analysis shows that the proposed $PM_{10\text{-}2.5}$ standard is actually not equivalent to the current PM_{10} standard, but is less protective. As EPA notes in its proposal,[259] Schmidt et al. (2005)[260] found that a 98th percentile $PM_{10\text{-}2.5}$

[258] U.S. EPA, Review of National Ambient Air Quality Standards for Particulate Matter, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-05-005, June 2005, 5-64; Tolbert, P. E.; Klein, M.; Metzger, K. B.; Flanders, W. D.; Todd, K.; Mulholland, J. A.; Ryan, P. B.; Frumkin, H. (2000) Interim results of the study of particulates and health in Atlanta (SOPHIA). *J. Exposure Anal. Environ. Epidemiol.* 10: 446-460; Burnett, R. T.; Cakmak, S.; Brook, J. R.; Krewski, D. (1997) The role of particulate size and chemistry in the association between summertime ambient air pollution and hospitalization for cardiorespiratory diseases. *Environ. Health Perspect*. 105: 614-620. See also Comments Of American Lung Association, Environmental Defense, Natural Resources Defense Council, on U.S. EPA's Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper -- Second Draft (January 2005) and Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report (January 2005), March 30, 2005, and references therein.

[259] 71 Fed. Reg. 2670.

[260] Schmidt, M. et al., Analyses of Particulate Matter (PM) Data for the PM NAAQS Review, U.S. EPA Office of Air Quality Planning and Standards, June 30, 2005.

standard of 60 μg/m^3 would be roughly equivalent on average to the current PM_{10} standard. Schmidt et al. (2005) further concluded that in the northeastern U.S., equivalency would necessitate a 98th percentile standard set at 40 μg/m^3.[261]

4.3 EPA must set a 99th percentile standard to prevent frequent short-term exposures to high levels of coarse particulate matter**.**

For a pollutant such as thoracic coarse particles that is associated with acute health effects, choice of design value has significant implications for public health protection. Specifically, under a 98th percentile standard, 18 days over a three-year period are permitted to exceed the standard designed to protect the public. A 99th percentile standard reduces the number of days by half to 9 days over a three year period while still allowing for statistical abnormalities. EPA's risk assessments demonstrate that in every case, a 99th percentile form offers greater protection than a 98th percentile form. EPA must lower its proposed standard for thoracic coarse particles to a 99th percentile standard of 25-30 μg/m^3 to achieve an adequate margin of safety for the public with respect to health effects associated with $PM_{10-2.5}$.

4.4 EPA must set an annual average standard for coarse PM

EPA proposes to revoke the annual PM_{10} standard and does not propose an annual $PM_{10-2.5}$ standard, on grounds that "there is no quantitative evidence that directly supports an annual standard."[262] In support of this proposal, EPA singles out the ACS cohort study, stating that "specifically, no association is found between long-term exposure to thoracic coarse particles and mortality in the reanalyses and extended analysis of the ACS cohort.[263] But in relying on this finding, EPA again makes the error of focusing on mortality, when in fact it is legally obligated to set standards that protect against all adverse health effects, not just death.

The second draft Staff Paper suggests that an annual average coarse particle standard may be warranted due to concerns about decreased lung function and long-term $PM_{10-2.5}$ exposures (p. 3-29).[264] As discussed in the Criteria Document, the Gauderman et al. (2000; 2002) cohort studies found significant decreases in lung function growth among southern California school children to be related to PM_{10} levels.[265] The Criteria Document also recognizes that the Avol et al. (2001) study found that children who moved to areas with lower PM_{10} concentrations showed increased growth in lung function while those who moved to areas with higher PM_{10} concentrations showed reduced growth.[266] Additionally, the Criteria Document reports that the cohort study

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[261] Id.
[262] 71 Fed. Reg. 2668.
[263] 71 Fed. Reg. 2664.
[264] Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper – Second Draft, 3-29, EPA-452/D-05-001, January 2005.
[265] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, at 8-214 – 8-215.
[266] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, Table 8-B8.

conducted by Horak et al. (2002) found growth in FVC and MEF to be significantly related to winter PM_{10} levels; Ackermann-Liebrich et al. (1997) found statistically significant and consistent effects on FVC and FEV associated with PM_{10}; Zemp et al. (1999) found respiratory symptoms to be associated with PM_{10} and TSP; Heinrich et al. (2002) found bronchitis and respiratory colds associated with TSP; and Kramer et al. (1999) found bronchitis to be associated with TSP. [267] The second draft Staff Paper summarizes these studies with the statement "A number of long-term studies of respiratory effects also have been conducted in non-North American countries, and many report significant associations between indicators of long-term PM exposure and either decreases in lung function or increased respiratory disease prevalence (Table 8-B8 of the CD)."[268] EPA's conclusion that an annual standard is not requisite to protect the public health with an adequate margin of safety is based on arbitrary dismissal of European studies and illegal disregard for adverse health impacts other than death.

In 2002, California lowered its annual average PM_{10} standard from 30 $\mu g/m^3$ to 20 $\mu g/m^3$ to protect against chronic effects of coarse particles.[269] The updated World Health Organization Air Quality Guidelines also set an annual average standard of 20 $\mu g/m^3$ for PM_{10}.[270]

4.5 Revoking the current PM_{10} standards without adopting protective thoracic coarse particle standards would be arbitrary and capricious and a clear violation of Clean Air Act requirements.

EPA solicits comment on revoking the current PM_{10} standards without adopting a protective thoracic coarse particle standards. 71 Fed. Reg. 2673. EPA has no legal or scientific basis for such an action. The Criteria Document, the EPA Staff Paper and administrative record provide voluminous evidence based on the latest scientific knowledge indicating that coarse particles cause adverse health impacts. Coarse particles penetrate to and deposit deep in the lungs, similar to fine particles ($PM_{2.5}$).[271] EPA has found that "associations between $PM_{10-2.5}$ and mortality are similar in magnitude, but less precise, than those for $PM_{2.5}$ or PM_{10}."[272] Studies reviewed by EPA also have found associations between short term exposure to $PM_{10-2.5}$ and respiratory- and cardiac-related hospital admissions,[273] associations between $PM_{10-2.5}$ exposure and respiratory symptoms

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267 U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, Table 8-B8.

268 Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper – Second Draft, 3-29, EPA-452/D-05-001, January 2005.

269 California Environmental Protection Agency News Release, "Air Board Passes Stronger Particulate Matter Standards," Release 02-28, June 20, 2002, available at: http://www.arb.ca.gov/newsrel/nr062002.htm

270 World Health Organization, WHO Air Quality Guidelines Global Update 2005, Report on a working group meeting, Bonn, Germany, 18-20 October 2005. WHOLIS number E87950.

271 U.S. EPA, Criteria Document, p. 6-16, October 2004. Available at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html.; U.S. EPA, Staff Paper, p. 5-48, June 2005. Available at http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html .

272 U.S. EPA, Staff Paper, p. 5-49, June 2005.

273 U.S. EPA, Staff Paper, p. 5-49, June 2005.

and hospital admissions for asthma in children,[274] and associations between coarse PM and respiratory symptoms in both asthmatic and non-asthmatic adults.[275]
CASAC and EPA staff have recommended adopting a short-term standard for this size fraction. As noted above, where EPA departs from the recommendations of the CASAC, EPA's judgment is subject to heightened scrutiny because EPA can no longer point to the "objective justification" provided by the committee. *American Trucking Ass'ns*, 175 F.3d at 1059 (Tatel, J., dissenting). EPA has provided and cannot provide justification for declining to set standards for coarse PM that would withstand this heightened scrutiny.

In introducing this request for comments on the option of not adopting any coarse particle standard, EPA notes that "some commenters hold the view that the uncertainties that exist at the present time are so great that no standards for thoracic coarse particles are warranted." 71 Fed. Reg. 2673. The proposal discusses in particular the "view" that "four key $PM_{10-2.5}$ studies" (Ito, 2003; Burnett et al., 1997; Mar et al., 2003; and Ostro et al., 2003) are subject to uncertainty due to confounding by co-pollutants, including gases and fine particles. 71 Fed. Reg. 2672. We note that the language in this section of EPA's proposal was provided to EPA in a fax from the Office of Management and Budget dated December 19, 2005.[276] This certainly begs the question of whether EPA's expert technical staff had adequate opportunity to review this section of the proposal and to respond to OMB's suggested language before it was inserted. In fact, the line of argument presented in OMB's inserted language directly contradicts EPA's statements earlier in the proposal. On p. 2660, EPA states that "Multi-pollutant models including $PM_{10-2.5}$ and gaseous co-pollutants are included in Figures 8-16 through 8-18 of the Criteria Document, where it can be seen that associations with $PM_{10-2.5}$ are largely unchanged when gaseous co-pollutants are added to the models."[277] Also on p. 2660 the proposal notes that Ostro et al. (2003) and Mar et al. (2003) reported stronger associations with $PM_{10-2.5}$ than $PM_{2.5}$. The same paragraph on p. 2660 concludes that "This limited body of evidence suggests that $PM_{10-2.5}$ and $PM_{2.5}$ have associations with health outcomes that are likely independent of one another." All of this contradicts the OMB-derived "view" presented on p. 2672. Dr. Ostro has also directly rebutted OMB's criticisms of his study, by pointing out that because most of the airborne PM in the Coachella Valley region is $PM_{10-2.5}$, it should not be surprising that there is a close correlation between PM_{10} and $PM_{10-2.5}$, or that there are similar correlations between observed deaths with PM_{10} as well as $PM_{10-2.5}$.[278] The section of the proposal that is derived from OMB's insert also seeks to discredit the results of Mar et al. (2003) by indicating that they "found $PM_{10-2.5}$ to be positively associated with adverse health effects in a one-pollutant model, but also found similar associations with a range of other air pollutants." 71 Fed. Reg. 2672. What this section fails to note is that the "other air pollutants" were components of PM, or factor scores derived from a factor analysis of

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[274] U.S. EPA, Staff Paper, p. 5-49, June 2005; U.S. EPA, Criteria Document, p. 8-186, October 2004.
[275] U.S. EPA, Criteria Document, p. 8-206, October 2004.
[276] Docket I.D. number EPA-HQ-OAR-2001-0017-0539.
[277] See U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, Figures 8-16, 8-17, and 8-18. Also note that the same general conclusion holds for PM10.
[278] Dr. Bart Ostro, Presentation of the California EPA Office of Environmental Health Hazard Assessment Comments on EPA's PM NAAQS Proposal, to CASAC Particulate Matter (PM) Review Panel at the February 3, 2006 Public Teleconference, available at: http://www.epa.gov/sab/panels/casacpmpanel.html .

PM components, so the "similar" associations actually reinforce, rather than undercut, the finding of a significant association.

5.1 EPA has no authority to revoke the PM_{10} standards or the specific pollution controls mandated in Subpart 4 for PM_{10} nonattainment areas**.**

EPA's proposal to revoke both the annual and 24-hour PM_{10} standards is contrary to the Clean Air Act's express terms. In the 1990 amendments to the Clean Air Act, Congress codified the PM_{10} standard, and therefore, the designations and classifications, in §107(d)(4)(B) and in Subpart 4 of Part D, Title I ("Subpart 4"). See *Whitman v. American Trucking Assns.*, 531 U.S. 457, 476, 481-85 (2001). Congress further set out in the statute detailed control requirements and deadlines for reducing PM_{10} pollution, and for attaining the PM_{10} standards. EPA is completely without authority to override or circumvent these explicit statutory terms by "revoking" the PM_{10} standards or by abolishing the nonattainment area designations established by Congress for those standards.

a. Section 107

In §107(d)(4)(B), Congress in 1990 designated PM_{10} nonattainment areas "[b]y operation of law," and further provided that those designations would remain in effect "until redesignation by the Administrator pursuant to paragraph (3) [§107(d)(3)]." See also § 107(d)(1)(B)(iv)(designations "shall remain in effect until the area … is redesignated" pursuant to §§107(d)(3) or (4)). Section 107(d)(3) makes no provision for revocation of the PM_{10} standards or of the designations made for that standard. For areas designated nonattainment for PM_{10}, the only redesignation provided for in §107(d)(3) is from "nonattainment" to "attainment." There is no authority to redesignate from "nonattainment" to "standard revoked." Moreover, redesignation of a PM_{10} nonattainment area to attainment is only allowed if the area has actually attained the PM_{10} standards and has met all pollution control obligations applicable to PM_{10} nonattainment areas (including those under Subpart 4). §§107(d)(1)(B)(iv), (d)(3)(E).

EPA has not made the findings required by §107(d)(3)(E) with respect to all PM_{10} nonattainment areas, nor could it. The Agency concedes that a number of these areas continue to violate PM_{10} standards, a fact that by itself would disqualify such areas from redesignation to attainment under §107(d)(3)(E). Congress provided no exemption in the case of revised NAAQS from its general proscriptions against changing nonattainment designations unless the requirements of CAA §107(d)(3) are met. And "when a statute limits a thing to be done in a particular mode, it includes the negative of any other mode." *American Methyl Corp. v. EPA,* 749 F.2d 826, 836 (D.C. Cir 1984), *citing National R.R. Passenger Corp. v. National Ass'n of R.R. Passengers,* 414 U.S. 453, 458 (1974).

b. Subpart 4

In Subpart 4, adopted in 1990, Congress explicitly classified PM_{10} nonattainment areas "by operation of law," and further mandated reclassification of moderate areas to serious "by operation of law" whenever a moderate area failed to timely attain. §188(a), (b)(2).

Subpart 4 further set out explicit and detailed planning and control requirements for progress toward, and attainment of the PM_{10} standards. §§188, 189. For example, moderate areas had to require reasonably available control measures (RACM) and serious ares had to require best available control measures (BACM) by deadlines set out in the statute. §§189(a)(1)(C), (b)(1)(B). Subpart 4 specifies attainment deadlines and potential extensions thereof extending to as late as 2006. CAA §§188(c), (d), (e). It further specifies requirements that apply after that outside attainment date. CAA §188(d). Subpart 4 also applies to areas designated nonattainment any time after 1990. *See, e.g.*, CAA §§ 188(a), (c), 189 (a)(1)(C), (a)(2)(B).

Thus, Congress itself mandated steps to attain and maintain the PM_{10} standards, in terms that applied far into the future. Congress further mandated controls, including those mandated by Subpart 4, remain in the SIP – at the very least as contingency measures - even after an area attained the PM_{10} standards. §175A(d). For all these reasons, EPA is completely without authority to override the explicit control requirements in Subpart 4 by revoking the PM_{10} standards. It cannot revoke or override PM_{10} classifications and associated control requirements set "by operation of law" under Subpart 4. Nor can EPA use "revocation" of the PM_{10} standards to render the other explicit subpart 4 requirements inoperative as to PM_{10}. See *Whitman*, 531 U.S. at 484-85. Such an approach would conflict directly with the Supreme Court's holding in *Whitman* that EPA cannot render the Act's detailed anti-pollution regimes "abruptly obsolete." 531 U.S. at 485.

5.2 Even if EPA could revoke the PM_{10} standards it cannot allow relaxation of control and planning requirements mandated by Congress

EPA's proposal to immediately revoke the PM_{10} standards without requiring continued compliance with Subpart 4 or providing any antibacksliding protection in the affected areas would violate the Act, flout Congressional intent, and conflict with EPA's own stated policies.

A. Subpart 4

Even if EPA could revoke the PM_{10} standards, it could not revoke or nullify the above-described mandates and deadlines in Subpart 4 for PM_{10} control. Congress established those requirements by operation of law, and gave EPA no discretion to dispense with them. Thus, EPA must require $PM_{2.5}$ nonattainment areas to continue to adhere to and implement the PM_{10} schedules and control requirements in Subpart 4. Those requirements include a mandate for attainment of the PM_{10} standards expeditiously as practicable, but no later than 6 years from designation for moderate areas, and 10 years for serious areas. 42 U.S.C. §7513(c). They also require implementation of RACM within 4 years, and implementation of BACM within 4 years of classification (or reclassification) to serious. Id. §7513a. Subpart 4 further mandates control of precursor emissions, and achievement of rate-of-progress milestones. Id. §7513a(c), (e). For areas that fail to timely attain by the serious area deadline, Subpart 4 requires measures to assure at least a 5% annual cut in emissions until attainment is achieved. Id. §7513a(d).

Congress explicitly mandated these and other measures in Subpart 4, and EPA has no authority to waive them, via revocation of the PM_{10} standard or otherwise.

B. Antibacksliding

As EPA itself has stated, Congress has made clear its intent that revision of a NAAQS does not provide an excuse for relaxing pre-existing antipollution mandates and progress requirements under the Act. See 69 Fed. Reg. 23951, 23972 (2004). In the PM_{10} context, Congress made this intent clear by establishing PM_{10} designations and classifications by operation of law, by setting out explicit PM_{10} control requirements and deadlines in Subpart 4, by requiring that mandated controls remain in SIPs even after a standard is attained, by requiring (in §172(e)) EPA to adopt antibacksliding rules upon NAAQS revisions, by prohibiting relaxation of pre-1990 control requirements (in §193), and by prohibiting approval of SIP revisions that would interfere with timely attainment, progress or any applicable requirement of the Act (in §110(l)). Further, the Act's central purpose of protecting public health dictates that EPA prevent backsliding from pre-existing protections.

EPA's proposal flouts these principles. The Agency proposes to immediately revoke the PM_{10} standards throughout most of the nation, without requiring any steps to sustain existing controls or ensure fulfillment of unmet control obligations. The result would be to leave millions of Americans completely unprotected from coarse particles, potentially for a decade or more, and to allow removal of current anti-pollution protections in communities with long histories of polluted air. Such an approach conflicts sharply with the antibacksliding principles cited above – principles that EPA itself purports to espouse, and that the Agency itself says reflect Congressional intent.

EPA's proposal also violates §172(e) of the Act, which requires EPA to adopt antibacksliding rules when it relaxes a NAAQS. Here, EPA is proposing to relax the PM_{10} NAAQS by revoking them all together. The proposed coarse particle standard would not correct this relaxation, as that proposed standard would not apply in all of the areas covered by the PM_{10} standard, and is grossly inadequate to protect health for reasons discussed elsewhere in these comments. Even if EPA's action could be deemed a strengthening of the standard, EPA itself has taken the position in the ozone implementation rule that §172(e) shows Congressional intent to bar backsliding when EPA strengthens a NAAQS as well as when it relaxes a NAAQS. Indeed, to read §172(e) otherwise would produce the absurd result of allowing states to relax controls when EPA is adopting a more stringent standard.

Section 172(e) requires EPA to adopt requirements applicable to "all areas which have not attained" the existing standard as of the date of revision of that standard. Those requirements "shall provide for controls which are not less stringent than the controls applicable to areas designated nonattainment before" the revision. Here, EPA is proposing to revoke the PM_{10} standards without adopting the rules required by

§172(e).[279] The Agency's proposal to continue the 24-hour PM_{10} standard in a few communities does not excuse this failure because that continuation is of limited duration (EPA indicates that it will likely expire when PM coarse designations are made), because it does not cover "all areas have not attained" the PM_{10} standard, and because it does not cover the annual PM_{10} standard.

EPA tries to justify its proposal to limit the continuation of the 24-hour PM_{10} standard to 15 specified areas by asserting that these 15 areas have characteristics that make them more likely to violate the proposed coarse particle standard. But §172(e) requires antibacksliding protection for "all" areas that have not attained the PM_{10} standard, not just areas predicted to violate revised standards. Moreover, other provisions of the Act that show Congressional intent to prevent backsliding are not tied to predictions of future nonattainment of a revised NAAQS. Rather, those provisions show that Congress meant to require steady progress toward cleaner air, and to prevent backtracking on any progress previously required or achieved in fact. See §§110(l), 175A, 188, 189, 193.

The arbitrariness of EPA's proposal to protect only 15 areas from backsliding (and only to a limited degree) is graphically shown by reviewing the data on areas currently violating the PM_{10} standards. See Table 7 below. EPA has determined that monitors in the following counties have recorded violations of the daily PM_{10} standard in recent years (not all of the areas have been designated nonattainment), but would revoke the standard rather than requiring compliance in the areas the monitors represent.[280] However, EPA has made no showing that the PM_{10} or $PM_{10-2.5}$ in these areas is any less harmful than that in the larger areas where it proposes to retain the standard. Some of these areas, such as Imperial County and Owens Valley California, have recorded extreme PM_{10} concentrations that sometimes exceed "significant harm" levels established by EPA. (We incorporate by reference EPA's Airdata database, which documents these points. http://www.epa.gov/oar/data/index.html). Yet EPA is proposing to immediately deny these areas any protection from coarse particle pollution without even considering the health and environmental consequences.

Table 7

County	Existing PM_{10} Nonattainment Area
Anchorage, AK	
Matanuska-Susitna, AK	
Cochise, AZ	Douglas (Cochise County), AZ
Maricopa, AZ*	
Pinal, AZ*	
Santa Cruz, AZ	Nogales, AZ

[279] Although §172(e) allows EPA up to 1 year after NAAQS revision to adopt anti-backsliding rules, the effect of EPA's immediate revocation in this case would be to allow the very backsliding that §172(e) is designed to prevent.

[280] http://www.epa.gov/air/particles/pdfs/memo20051220.pdf

Imperial, CA	Imperial Valley, CA
Inyo, CA	Owens Valley, CA; Coso Junction, CA
Kern, CA*	Indian Wells Valley, CA
Mono, CA	Mono Basin, CA
San Bernardino, CA	Trona, CA
San Diego, CA	
San Luis Obispo, CA	
Yolo, CA	
Nassau, FL	
Power, ID	
Kandiyohi, MN	
Jasper, MO	
Glacier, MT	
Dona Ana, NM	
Nye, NV	
Clark, NV*	
Scioto, OH	
Muskogee, OK	
Stevens, WA	
Albany, WY	
Campbell, WY	
Carbon, WY	
Lincoln, WY	
Natrona, WY	
Sweetwater, WY	

The PM_{10} standard will be retained in part of the county

EPA's proposed revocation of the PM_{10} standard will also have the effect of undermining existing protection of the above areas (and others) from *fine* particle pollution. None of the above areas has yet prepared a State Implementation Plan (SIP) to attain the existing (1997) $PM_{2.5}$ standards, much less obtain EPA approval for such a SIP. Thus, the PM_{10} SIPs in these areas and the Subpart 4 provisions mandating them provide the only current set of enforceable controls to limit both fine and coarse particle pollution. Yet EPA is proposing to undermine these SIPs by revoking the standards on which they are based.[281] There is no plausible or rational justification for such a result.

[281] To be sure, EPA could (and indeed, must) prevent relaxation of a PM10 SIP requirement where the relaxation would interfere with applicable requirements for the PM2.5 standards. But revocation of the PM10 standard will relax some SIP requirements without any opportunity for EPA review or disapproval: e.g. a SIP requirement for nonattainment new source review or reasonably available control technology that applies only in areas that are designated nonattainment for PM10.

EPA suggests that it will adopt guidance on transition issues at some point in the future. But the Agency is proposing to revoke the PM10 standards *immediately* upon adoption of the coarse particle standard. Thus, unless and until EPA chooses to adopt protective transition rules, the adverse public health and environmental impacts from revocation will (under the proposal) commence immediately. The mere possibility that EPA might adopt transition rules therefore provides no support for EPA's arbitrary proposal to revoke the PM_{10} standards at once.

Indeed, EPA fails to articulate any plausible rationale for immediate revocation of the PM_{10} standards. Even if the Agency had authority to revoke those standards, the Agency identifies no rational basis for rushing to do so before fine and coarse particle SIPs have even been drafted, much less approved by EPA. The PM_{10} standards undeniably provide some protection against both types of particles, and that protection is *currently* enforceable through SIPs and applicable provisions of the Act. In contrast, the first PM coarse SIPs would not likely be approved by EPA until years into the future – indeed, EPA's advance notice of proposed rulemaking suggests that PM coarse SIPs might not be due until as late as a decade from now. 71 Fed. Reg. 6718 (Feb. 9, 2006)

Likewise, SIPs for the 1997 $PM_{2.5}$ standards are not due until 2008, and EPA approval/disapproval action on those SIPs would not be required until approximately 18 months after submittal. If history is any guide, full EPA approval of these SIPs will likely be delayed even longer, due to inadequate state submittals and EPA foot dragging. SIPs for any revised $PM_{2.5}$ standards will be due even later. There is no rational basis for depriving communities throughout the nation of effective protection from particulate matter pollution for as long as a decade or more merely because of EPA's arbitrary haste to dispense with the PM_{10} standards. Indeed, such an approach flouts the Act's public health purposes and EPA's stated goal of providing greater – not less – protection from PM pollution.

Although we contend that EPA has no authority to revoke the PM_{10} standards at all, the Agency would do less violence to the statute and act more rationally by retaining the PM_{10} standards until – at the very least – SIPs for the revised PM fine and coarse standards have been fully approved for an area. That way the public would at least be assured of continued protection from currently enforceable requirements of the Act and currently enforceable SIPs, while new plans are being developed to address the separate fine and coarse components of PM_{10}.

6. EPA must promulgate a secondary standard for coarse PM that encompasses the whole country and protects against ecosystem impacts and visibility degradation**.**

The Clean Air Act requires the Administrator to set a secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued. The secondary standard must "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. §7409. EPA has proposed to make the secondary standard for coarse PM "identical in all respects" to the proposed primary $PM_{10-2.5}$ standard. 71 Fed. Reg. 2685. This proposal would thus limit the application of the secondary $PM_{10-2.5}$ standard to urban areas and exempt mining and agriculture from the standard. But EPA has not shown and cannot show that such a standard will protect the public welfare from "any known or anticipated adverse effects" of coarse PM. In fact, EPA's proposal ignores overwhelming evidence that coarse PM impairs visibility and damages ecosystems in rural as well as urban areas and that coarse PM from mining and agriculture are fully implicated in these harmful impacts.

The Criteria Document finds that coarse particles are an especially important vector for nitrate deposition,[282] and are also important for significant deposition of ammonium and sulfate ions. Nitrate and ammonium contribute to problems of eutrophication, excessive fertilization, and acidification of terrestrial and aquatic ecosystems that are located in what EPA has defined as rural areas. As the Criteria Document states, "The deposition of PM from the atmosphere has the potential to alter ecosystem structure and function by altering nutrient cycling and changing biodiversity."[283] The Criteria Document identifies direct effects of coating vegetation with coarse PM (dust) as including heat stress, reduced net photosynthesis, reduced respiration and transpiration, clogging of stomata, and leaf chlorosis, necrosis, and abscission.[284] The Criteria Document also documents harm to vegetation associated with sulfate, nitrate and metal components, which can be carried in the coarse as well as fine particle modes.[285] Coarse particles are also carriers for semi-volatile organics. As the Criteria Document notes, "Materials as diverse as DDT, polychlorinated biphenyls (PCBs), and polynuclear aromatic hydrocarbons (PAHs) are being deposited from the atmosphere on rural, as well as urban, landscapes (Kylin et al., 1994)."[286] The Criteria Document also discusses the harmful impacts of nitrogen deposition (from coarse and fine PM) on ecosystems, focusing almost exclusively on rural areas.[287] Concerns about acid deposition (from coarse and fine PM) focus primarily on rural areas.[288]

Although light scattering efficiencies for coarse particles are smaller than for fine particles, they are not negligible. The Criteria Document finds that "The scattering efficiency for particles has been reported by White et al. (1994) for dry particles < 2.5 μm (2.4 and 2.5 m^2/g) and coarse particles (0.34 to 0.45 m^2/g). Other reported values for coarse particles include 0.4 and 0.6 m^2/g (White and Macias, 1990; Trijonis et al., 1987)."[289] Coarse particles are estimated to be significant contributors to visibility degradation at Class I areas. For example, data from the IMPROVE network indicate that coarse PM contributes 14.5% of light extinction on the 20% worst visibility days at

[282] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-45.
[283] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-60.
[284] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4- 63 - 64.
[285] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-68 – 4-77.
[286] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-78.
[287] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-94 – 4-112.
[288] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-113 – 4-122.
[289] U.S. EPA, Air Quality Criteria for Particulate Matter, EPA 600/P-99/002bF, October 2004, 4-160.

Badlands National Park, 16% at Great Basin National Park, 17.4% at Canyonlands National Park, 21.6% at Great Sand Dunes National Park, and 27.9% at Mesa Verde National Park.[290] Although some of this coarse PM is natural windblown dust, controllable anthropogenic sources including agricultural activities, mining activities, road dust, oil and gas development and other industrial sources also contribute.

Based on the Criteria Document and other data in the record, EPA cannot lawfully or rationally conclude that its proposed secondary coarse particle standards – identical to its proposed primary standards – are requisite to protect public welfare from any known or anticipated adverse effects. The proposed standards apply only in a limited number of densely populated urbanized areas, and only at locations meeting all of the criteria in proposed 40 C.F.R. §58.30(b), none of which are tailored to reflect public welfare impacts such as effects on soils, water, crops, vegetation, animals, wildlife, weather, visibility, and climate, damage to property, and hazards to transportation, and other welfare impacts. The criteria in 40 C.F.R. §58.30(b) are based solely on EPA's stated claims (refuted above) related to identification of coarse particles that impact public health, not welfare. EPA has not even attempted to show that these criteria are adequate surrogates for any public welfare impacts, nor could it, for the reasons stated above.

7. EPA's proposal to limit monitoring requirements for coarse PM to MSAs with a population of at least 100,000 people is arbitrary and illegal. (2732-2733)

EPA is proposing that $PM_{10-2.5}$ would only be monitored in metropolitan statistical areas (MSAs) that contain all or part of an urbanized area with a population of at least 100,000 and where $PM_{10-2.5}$ from agriculture or mining is not the dominant influence.[291] EPA has estimated based on 2001-2003 data that 98th percentile daily $PM_{10-2.5}$ concentrations at one or more monitoring sites in the following counties would exceed 50 $\mu g/m^3$,[292] but is proposing that $PM_{10-2.5}$ concentrations would not even be monitored at these locations, and that if such monitoring did occur the results would not be eligible for comparison with the standard.[293] Table 8 indicates such areas that are proposed to be exempt from monitoring, and their estimated $PM_{10-2.5}$ 98th percentile concentrations. However, EPA has not shown that these monitors are not impacted by industrial sources, construction activities, or high density traffic, the sources it views as emitting "harmful" $PM_{10-2.5}$ in larger communities. EPA's proposal is all the more arbitrary because it would not "count" exceedances at monitors in these communities even if the exceedances are in fact occurring at monitors dominated by the coarse particles from the sources that EPA says are of health concern. Nor has EPA shown that adverse health effects do not occur as a consequence of breathing $PM_{10-2.5}$ from other sources impacting these areas, including agriculture and mining.

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[290] http://vista.cira.colostate.edu/dev/web/AnnualSummaryDev/Composition.aspx
[291] 71 Fed. Reg. 2710, 2736.
[292] Mark Schmidt, spreadsheet containing information used to generation Figure 2-13 of the June 2005 Staff Paper, personal communication, February 26, 2006.
[293] U.S. EPA, Spreadsheet showing areas where $PM_{10-2.5}$ monitors would be required, February 10, 2006, available at www.epa.gov/air/particles/actions.html.

Table 8

County	Estimated $PM_{10-2.5}$ 98th Percentile Concentrations* (µg/m³)	MSA
Matanuska-Susitna, AK	68	
Cochise, AZ	53	
Santa Cruz, AZ	93	Nogales, AZ
Imperial, CA	57, 126, 149	El Centro, CA
Inyo, CA	75, 208	Bishop, CA
Kings, CA	109	
Gunnison, CO	57	
Washington, GA	56	
Maui, HI	55	Kahului-Wailuku, HI
Canyon, ID	66	Boise City, ID
Power, ID	79	Pocatello, ID
Power	66	Pocatello, ID
Cerro Gordo, IA	103	Mason City, IA
Muscatine, IA	62	Muscatine, IA
Kennebec, ME	58	Augusta-Waterville, ME
Rosebud, MT	77	
Cass, NE	71	Omaha, NE-IA
Harney, NE	90	
Brookings, SD	62	Brookings, SD
Codington, SD	82	Watertown, SD
Pennington, SD	58, 85	Rapid City, SD
Lubbock, TX	85	Lubbock, TX
Asotin, WA	82	Lewiston, ID-WA
Hancock, WV	52	Steubenville-Weirton, OH-WV
Campbell, WY	79	Gillette, WY
Ponce, PR	65	Ponce, PR
St Croix, VI	63	
St Thomas, VI	66	

* Multiple entries reflect estimated $PM_{10-2.5}$ 98th percentile concentrations at multiple monitors within the county.

Source: Mark Schmidt, spreadsheet containing information used to generation Figure 2-13 of the June 2005 Staff Paper, personal communication, February 26, 2006.

7.1 EPA's proposed five-part test of whether a monitoring site is suitable for comparison with the NAAQS is arbitrary and thus is illegal

As discussed above, EPA must set uniform national standards that protect all Americans, regardless of the size of the community in which they live. EPA's monitoring requirements are effectively part of the definition of the standard, since no violation could be recorded in an unmonitored area. EPA has illegally and arbitrarily limited the application of the standard by the five-part test it proposes in the monitoring rule for eligibility to be compared against the $PM_{10-2.5}$ standard. While EPA asserts that the five-part test links monitoring to the "urban-type" coarse PM it considers of greatest concern, in fact the cutoffs employed in the test are arbitrarily drawn.

EPA's proposed population cutoff of 100,000 and population density cutoff of 500 persons per square mile are arbitrary, because high levels of $PM_{10-2.5}$ due to industrial sources, construction activities and high-density traffic, as well as industrial agriculture and mining, can occur in communities with smaller populations or population density. EPA has no legitimate scientific basis for selecting cutoffs of 100,000 for population or 500 for population density. The Agency appears to have selected the 100,000 population cutoff based on the proportion of the U.S. population that lives in these areas.[294] But that is not a valid consideration for a decision that effectively determines the scope of protection the coarse PM NAAQS will provide. The Clean Air Act requires that EPA set a standard to protect all Americans, and does not allow it to neglect the 50 million Americans who happen to live in smaller communities, regardless of whether they are exposed to harmful coarse PM or not.

EPA has not shown and cannot show that harmful $PM_{10-2.5}$ exposures would not risk the health of the 50 million Americans who live in communities where application of the $PM_{10-2.5}$ NAAQS would be precluded. EPA's own data show that although there is a correlation between traffic (measured by county vehicle miles traveled (VMT)) and population, there is substantial scatter in the relationship, with many low-population counties having relatively high VMT.[295] Likewise, there is substantial scatter in the relationship EPA shows between population density and VMT density.[296] This situation occurs, for example, in small communities situated along interstate highways across the country. Other examples where traffic impacts on air pollution have been disproportionate to population include resort towns in Colorado like Steamboat Springs that have been designated as PM_{10} nonattainment areas in the past, but have since attained the standard after adopting and implementing local control measures.

Furthermore, EPA has placed no information in the record to indicate that it has even considered whether industrial sources of $PM_{10-2.5}$ affect smaller communities. Of course the numerous cement plants, pulp and paper mills, and power plants that are located in

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[294] Schmidt et al., Analyses of Particulate Matter (PM) Data for the PM NAAQS Review, Output A.11, p. 2., June 30, 2005.
[295] Schmidt et al., Analyses of Particulate Matter (PM) Data for the PM NAAQS Review, Output A.11, p. 2., June 30, 2005.
[296] Id.

small communities across the country stand as clear evidence that they do. Likewise, EPA has placed no information in the record to indicate that it has examined the effect of construction sources on smaller communities. In any event, the existence of a correlation between community size and traffic, industry, or construction activity on a national scale has no logical bearing on EPA's decision. To support its proposal, EPA would need to show that there is some threshold community size below which $PM_{10-2.5}$ does not threaten health, not simply that smaller communities, in general, are impacted by fewer sources.

EPA compounds the arbitrariness of its $PM_{10-2.5}$ monitoring proposal by adding the requirement that a site-specific assessment show that the ambient mix of $PM_{10-2.5}$ would not be dominated by PM from agricultural and mining sources.[297] EPA's proposal presents this as an additional constraint, so that even if the monitor were in an area with population above 100,000 and even if the population density were greater than 500 people per square mile, the monitor would be ineligible for comparison against the standard if agriculture and mining sources accounted for most of the $PM_{10-2.5}$ at the site. This requirement is impractical, at best, because the Agency has offered no means of distinguishing between contributions from agriculture, mining and other PM sources at a particular receptor. In fact, in all but the most clear-cut cases, it would be extremely difficult to make this demonstration. The amount of $PM_{10-2.5}$ contributed by different source categories is apt to vary significantly from day-to-day. With regard to the chemical components present in the largest quantities and thus most susceptible of quantification, generally minerals and organic carbon, $PM_{10-2.5}$ from urban road dust, construction sites, agriculture and mining sources are similar, so chemical "fingerprinting" would be difficult. Additionally, emissions inventories for these sources are uncertain, making it difficult to determine which sources dominate using emissions inventory-based models.

In addition to being impractical, the requirement of a site-specific showing that agriculture and mining are not the dominant sources of $PM_{10-2.5}$ is also arbitrary, for two key reasons. First, EPA has no basis to support its proposed 50% contribution threshold as delimiting harmful versus benign particles. EPA has not shown and cannot show that $PM_{10-2.5}$ with a 51 percent contribution from agriculture and mining is benign, while coarse PM with a 49 percent contribution is deemed harmful.[298] Second, as discussed above, EPA has no legal or scientific basis for exempting agricultural and mining sources from regulation to help meet the $PM_{10-2.5}$ standards. As discussed above, agricultural and mining dusts are known to be toxic, even where they completely dominate the $PM_{10-2.5}$ mixture, as they do in occupational settings. The inferences EPA draws for $PM_{10-2.5}$ from agriculture and mining based on limited data on the health impacts and toxicity of natural crustal material are even more strained when these sources contribute to an "urban" mixture with other $PM_{10-2.5}$ constituents.

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[297] 71 Fed. Reg. 2738.
[298] The converse is true, in fact, for EPA's proposal to require that monitoring sites be dominated by emissions from such sources as high-density traffic on paved roads, construction, and industrial sources. No where has EPA shown that a 49% contribution from these sources makes monitored exceedances at a site benign.

Appendix 1

Additional New Studies of Potential Interest

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Appendix 2

Counties that would meet the proposed 24-hour $PM_{2.5}$ standard of $35\mu g/m^3$ with an average annual $PM_{2.5}$ concentration $< 15\mu g/m^3$ $\geq 12^{\perp}$

State	County	Annual Average PM2.5 Design Value*	24-Hour 98th Percentile PM2.5 Design Value*	Population
Georgia	Richmond	14.9	31	196,265
North Carolina	Mecklenburg	14.9	32	771,617
Georgia	Clarke	14.7	31	103,951
Missouri	St. Louis City	14.6	33	343,279
Alabama	DeKalb	14.5	32	66,935
Alabama	Talladega	14.5	32	80,277
Alabama	Etowah	14.5	33	103,250
Georgia	Muscogee	14.5	34	182,850
North Carolina	Cabarrus	14.5	32	146,135
Ohio	Lawrence	14.5	34	62,705
Georgia	Washington	14.4	29	21,061
Georgia	Hall	14.4	30	160,925
Georgia	Wilkinson	14.4	31	10,191
Indiana	Elkhart	14.4	34	191,768
Texas	Harris	14.4	30	3,644,285
Virginia	Salem City	14.4	34	24,347
Indiana	Floyd	14.3	34	71,543
Kentucky	Kenton	14.3	33	152,890
North Carolina	Forsyth	14.3	33	320,919
Kentucky	Bullitt	14.2	33	66,645
Ohio	Clark	14.2	32	142,613
Alabama	Montgomery	14.1	32	222,559
Alabama	Shelby	14.1	33	165,677
Kentucky	Fayette	14.1	33	266,358
Michigan	Washtenaw	14.1	34	339,191
Mississippi	Jones	14.1	31	65,662
North Carolina	Gaston	14.1	30	194,459
Indiana	Madison	14	33	130,602
Kentucky	Bell	14	29	29,672
Indiana	Howard	13.9	30	84,615
Kentucky	Daviess	13.9	31	92,587
North Carolina	McDowell	13.9	29	43,285
North Carolina	Cumberland	13.9	32	308,489
Tennessee	McMinn	13.9	30	50,981
Tennessee	Blount	13.9	32	113,744
Virginia	Bristol City	13.9	31	17,308
Georgia	Dougherty	13.8	31	95,681
Tennessee	Sullivan	13.8	31	152,498
Virginia	Roanoke City	13.8	33	92,352
Alabama	Madison	13.7	31	293,072
Indiana	Allen	13.7	33	342,168

Kentucky	Campbell	13.7	33	87,256
North Carolina	Alamance	13.7	30	138,462
North Carolina	Guilford	13.7	31	438,795
North Carolina	Durham	13.7	33	239,733
Virginia	Henrico	13.7	32	276,479
Georgia	Paulding	13.6	32	105,936
Indiana	Spencer	13.6	29	20,310
Indiana	Delaware	13.6	31	117,774
Indiana	St. Joseph	13.6	32	266,431
South Carolina	Richland	13.6	31	334,609
South Carolina	Spartanburg	13.6	31	264,230
South Carolina	Lexington	13.6	32	231,057
Tennessee	Roane	13.6	28	52,920
West Virginia	Harrison	13.6	34	68,303
Illinois	DuPage	13.5	33	928,718
Illinois	Peoria	13.5	33	182,418
Missouri	St. Louis	13.5	34	1,009,235
North Carolina	Wake	13.5	32	719,520
Tennessee	Shelby	13.5	34	908,175
Texas	Dallas	13.5	33	2,294,706
Virginia	Loudoun	13.5	34	239,156
Michigan	Kalamazoo	13.4	32	240,724
Virginia	Chesterfield	13.4	33	282,925
Georgia	Chatham	13.3	28	238,518
Illinois	Will	13.3	33	613,849
Kansas	Wyandotte	13.3	31	156,487
Missouri	St. Charles	13.3	34	320,734
Ohio	Lorain	13.3	33	294,324
Alabama	Clay	13.2	30	14,092
Arkansas	Pulaski	13.2	31	365,913
Georgia	Houston	13.2	29	123,753
Illinois	Macon	13.2	32	110,980
Indiana	Porter	13.2	32	154,961
Kentucky	Warren	13.2	30	97,168
Kentucky	Franklin	13.2	31	48,142
Kentucky	Hardin	13.2	31	96,066
Missouri	Ste. Genevieve	13.2	31	18,264
Ohio	Portage	13.2	33	154,764
Kentucky	Madison	13.1	30	76,208
New Jersey	Gloucester	13.1	33	271,806
North Carolina	Wayne	13.1	27	114,245
North Carolina	Caswell	13.1	30	23,673
Alabama	Morgan	13	30	113,211
Illinois	Kane	13	32	472,482
Indiana	Henry	13	29	47,809
Kentucky	Pike	13	29	67,080
Massachusetts	Suffolk	13	30	666,022
Michigan	Kent	13	34	593,898
Mississippi	Forrest	13	29	74,469

North Carolina	Orange	13	28	117,515
South Carolina	Greenwood	13	30	67,519
Tennessee	Sumner	13	29	141,611
Tennessee	Montgomery	13	32	142,204
Illinois	Winnebago	12.9	29	286,788
Indiana	La Porte	12.9	32	109,755
Kentucky	Christian	12.9	31	70,649
North Carolina	Haywood	12.9	27	56,256
North Carolina	Buncombe	12.9	29	215,680
Tennessee	Putnam	12.9	30	65,963
Illinois	Sangamon	12.8	32	192,042
Kentucky	Perry	12.8	26	29,762
North Carolina	Mitchell	12.8	28	15,850
Pennsylvania	Perry	12.8	33	44,652
Texas	Bowie	12.8	30	90,248
Wisconsin	Waukesha	12.8	34	377,193
Kentucky	McCracken	12.7	29	64,700
Louisiana	East Baton Rouge	12.7	27	412,633
Michigan	Macomb	12.7	33	822,660
Mississippi	Lowndes	12.7	31	60,487
Texas	Tarrant	12.7	31	1,588,088
Virginia	Norfolk City	12.7	29	237,835
Alabama	Mobile	12.6	29	400,526
Delaware	Kent	12.6	33	138,752
Florida	Leon	12.6	27	243,867
Illinois	Adams	12.6	28	66,916
Louisiana	West Baton Rouge	12.6	26	21,880
Mississippi	Rankin	12.6	28	128,380
North Carolina	Robeson	12.6	28	126,469
Rhode Island	Providence	12.6	33	641,883
Virginia	Page	12.6	32	23,730
West Virginia	Raleigh	12.6	32	79,175
Alabama	Colbert	12.5	31	54,824
Illinois	McLean	12.5	29	158,006
Maryland	Harford	12.5	32	235,594
Maryland	Montgomery	12.5	33	921,690
Michigan	Ingham	12.5	30	280,073
Michigan	Ottawa	12.5	33	252,351
South Carolina	Edgefield	12.5	32	24,794
Virginia	Virginia Beach City	12.5	29	440,098
Alabama	Escambia	12.4	28	38,336
North Carolina	Swain	12.4	26	13,146
Pennsylvania	Luzerne	12.4	31	313,431
South Carolina	Georgetown	12.4	27	59,790
Tennessee	Maury	12.4	29	74,692
Louisiana	Iberville	12.3	28	32,497
South Carolina	Florence	12.3	28	129,679

South Carolina	Chesterfield	12.3	29	43,289
Virginia	Charles City	12.3	31	7,120
Arkansas	Faulkner	12.2	28	95,113
Georgia	Lowndes	12.2	28	95,787
Kentucky	Laurel	12.2	26	55,993
Louisiana	Caddo	12.2	28	251,506
Mississippi	DeSoto	12.2	28	130,587
Mississippi	Bolivar	12.1	29	38,928
North Carolina	Montgomery	12.1	26	27,501
North Carolina	Pitt	12.1	28	140,587
Ohio	Athens	12.1	32	63,187
Texas	Gregg	12.1	31	115,035
Virginia	Hampton City	12.1	28	145,951
West Virginia	Mercer	12.1	32	62,070
Arkansas	Crittenden	12	31	51,488
Illinois	Randolph	12	28	33,360
Michigan	Allegan	12	34	112,477
Mississippi	Lee	12	27	78,102
North Carolina	Chatham	12	26	57,023
North Carolina	Jackson	12	26	34,975
U.S. Total				**36,429,949**

*Design values are in $\mu g/m^3$

⊥ Design values based on 2002-2004 air quality monitoring data

Source: Air quality data obtained from U.S. EPA

Appendix 3

Industry sectors that might be excluded from the coarse PM standards by EPA's exclusion of agriculture and mining sources, if defined by SIC codes below 1500[299]

Division	**Major Group**	**Industry Group**	**Industry Sector**
A: Agriculture, Forestry and Fishing			
	Major Group 01: Agricultural Production Crops		
		Industry Group 011 Cash Grains	
			0111 Wheat
			0112 Rice
			0115 Corn
			0116 Soybeans
			0119 Cash Grains, Not Elsewhere Classified
		Industry Group 013: Field Crops, Except Cash Grains	
			0131 Cotton
			0132 Tobacco
			0133 Sugarcane and Sugar Beets
			0134 Irish Potatoes
			0139 Field Crops, Except Cash Grains, Not Elsewhere Classified

[299] The equation of agricultural and mining sectors with SIC codes below 1500 is made in Tom Rosendahl, National Ambient Air Quality Standards for Particulate Matter: Proposed Decision Docket (EPA-HQ-OAR-2001-0017), December 20, 2005. The memo states "In a rough attempt to screen out agricultural and mining sources, we have defined "industrial source" to include all those sources which have SIC codes of 1500 or above. This would exclude sources in Division A: Agriculture, Forestry and Fishing (i.e. SIC codes 0111-0971 including agricultural production – crops, livestock and animal specialties, agricultural services, forestry and fishing, hunting and trapping) and Division B: Mining (i.e. SIC codes 1011-1499 including metal and coal mining, oil and gas extraction, mining and quarrying of non-metallic minerals, except fuels)."

	Industry Group 016: Vegetables And Melons	
		0161 Vegetables and Melons
	Industry Group 017: Fruits And Tree Nuts	
		0171 Berry Crops
		0172 Grapes
		0173 Tree Nuts
		0174 Citrus Fruits
		0175 Deciduous Tree Fruits
		0179 Fruits and Tree Nuts, Not Elsewhere Classified
	Industry Group 018: Horticultural Specialties	
		0181 Ornamental Floriculture and Nursery Products
		0182 Food Crops Grown Under Cover
	Industry Group 019: General Farms, Primarily Crop	
		0191 General Farms, Primarily Crop
Major Group 02: Agriculture production livestock and animal specialties		
	Industry Group 021: Livestock, Except Dairy And Poultry	
		0211 Beef Cattle Feedlots
		0212 Beef Cattle, Except Feedlots
		0213 Hogs
		0214 Sheep and Goats
		0219 General Livestock, Except Dairy and Poultry
	Industry Group 024: Dairy Farms	

		0241 Dairy Farms
	Industry Group 025: Poultry And Eggs	
		0251 Broiler, Fryer, and Roaster Chickens
		0252 Chicken Eggs
		0253 Turkeys and Turkey Eggs
		0254 Poultry Hatcheries
		0259 Poultry and Eggs, Not Elsewhere Classified
	Industry Group 027: Animal Specialties	
		0271 Fur-Bearing Animals and Rabbits
		0272 Horses and Other Equines
		0273 Animal Aquaculture
		0279 Animal Specialties, Not Elsewhere Classified
	Industry Group 029: General Farms, Primarily Livestock And Animal	
		0291 General Farms, Primarily Livestock and Animal Specialties
Major Group 07: Agricultural Services		
	Industry Group 071: Soil Preparation Services	
		0711 Soil Preparation Services
	Industry Group 072: Crop Services	
		0721 Crop Planting, Cultivating, and Protecting
		0722 Crop Harvesting, Primarily by Machine

- 0723 Crop Preparation Services for Market, Except Cotton Ginning
- 0724 Cotton Ginning

Industry Group 074: Veterinary Services

- 0741 Veterinary Services for Livestock
- 0742 Veterinary Services for Animal Specialties

Industry Group 075: Animal Services, Except Veterinary

- 0751 Livestock Services, Except Veterinary
- 0752 Animal Specialty Services, Except Veterinary

Industry Group 076: Farm Labor And Management Services

- 0761 Farm Labor Contractors and Crew Leaders
- 0762 Farm Management Services

Industry Group 078: Landscape And Horticultural Services

- 0781 Landscape Counseling and Planning
- 0782 Lawn and Garden Services
- 0783 Ornamental Shrub and Tree Services

Major Group 08: Forestry

Industry Group 081: Timber Tracts

- 0811 Timber Tracts

		Industry Group 083: Forest Nurseries And Gathering Of Forest	
			0831 Forest Nurseries and Gathering of Forest Products
		Industry Group 085: Forestry Services	
			0851 Forestry Services
	Major Group 09: Fishing, hunting, and trapping		
		Industry Group 091: Commercial Fishing	
			0912 Finfish
			0913 Shellfish
			0919 Miscellaneous Marine Products
		Industry Group 092: Fish Hatcheries And Preserves	
			0921 Fish Hatcheries and Preserves
		Industry Group 097: Hunting And Trapping, And Game Propagation	
			0971 Hunting and Trapping, and Game Propagation
Division B: Mining			
	Major Group 10: Metal Mining		
		Industry Group 101: Iron Ores	
			1011 Iron Ores
		Industry Group 102: Copper Ores	
			1021 Copper Ores

Industry Group 103: Lead And Zinc Ores

1031 Lead and Zinc Ores

Industry Group 104: Gold And Silver Ores

1041 Gold Ores

1044 Silver Ores

Industry Group 106: Ferroalloy Ores, Except Vanadium

1061 Ferroalloy Ores, Except Vanadium

Industry Group 108: Metal Mining Services

1081 Metal Mining Services

Industry Group 109: Miscellaneous Metal Ores

1094 Uranium-Radium-Vanadium Ores

1099 Miscellaneous Metal Ores, Not Elsewhere Classified

Major Group 12: Coal Mining

Industry Group 122: Bituminous Coal And Lignite Mining

1221 Bituminous Coal and Lignite Surface Mining

1222 Bituminous Coal Underground Mining

Industry Group 123: Anthracite Mining

1231 Anthracite Mining

Industry Group 124: Coal Mining Services

		1241 Coal Mining Services
Major Group 13: Oil and Gas Extraction		
	Industry Group 131: Crude Petroleum And Natural Gas	
		1311 Crude Petroleum and Natural Gas
	Industry Group 132: Natural Gas Liquids	
		1321 Natural Gas Liquids
	Industry Group 138: Oil And Gas Field Services	
		1381 Drilling Oil and Gas Wells
		1382 Oil and Gas Field Exploration Services
		1389 Oil and Gas Field Services, Not Elsewhere Classified
Major Group 14: Mining And Quarrying Of Nonmetallic Minerals, Except Fuels		
	Industry Group 141: Dimension Stone	
		1411 Dimension Stone
	Industry Group 142: Crushed And Broken Stone, Including Riprap	
		1422 Crushed and Broken Limestone
		1423 Crushed and Broken Granite
		1429 Crushed and Broken Stone, Not Elsewhere Classified
	Industry Group 144: Sand And Gravel	

	1442 Construction Sand and Gravel
	1446 Industrial Sand
Industry Group 145: Clay, Ceramic, And Refractory Minerals	
	1455 Kaolin and Ball Clay 1459 Clay, Ceramic, and Refractory Minerals, Not Elsewhere Classified
Industry Group 147: Chemical And Fertilizer Mineral Mining	
	1474 Potash, Soda, and Borate Minerals
	1475 Phosphate Rock 1479 Chemical and Fertilizer Mineral Mining, Not Elsewhere Classified
Industry Group 148: Nonmetallic Minerals Services, Except Fuels	
	1481 Nonmetallic Minerals Services, Except Fuels
Industry Group 149: Miscellaneous Nonmetallic Minerals, Except	
	1499 Miscellaneous Nonmetallic Minerals, Except Fuels