Comments to the U.S. Environmental Protection Agency on the Proposed Rule for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide

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Summary of Comments

The American Lung Association, Earthjustice, the Environmental Defense Fund, and the Natural Resources Defense Council offer these comments on EPA's review of the primary National Ambient Air Quality Standards (NAAQS) for nitrogen dioxide (NO_2).

Since 1971, the U.S. has had one standard for nitrogen dioxide: an annual average concentration of 53 parts per billion (ppb). We are pleased that EPA has now proposed a second standard to protect against shorter, peak exposures—a standard that would limit 1-hour episodes.

This important addition moves in the right direction. We need both an annual and a short-term standard.

However, we believe that EPA is underestimating what is needed to protect the health of the public, especially those 48 million people who attend school, live near, commute, or work on or near transportation routes.

We recommend that EPA:

- adopt a 1-hour standard of not more than 50 parts per billion set at the 99th percentile;
- set a stronger annual standard for NO_2, similar to the level that California adopted in 2007, 30 parts per billion; [1] and
- establish a comprehensive roadside air pollution monitoring network, while retaining the current area wide NO2 network.

We applaud EPA's proposal for a national network of nitrogen dioxide monitors located near highways. This must be only the beginning of a comprehensive monitoring program for the other transportation-related pollutants, including particulate matter, diesel emissions, ultrafines, carbon monoxide, aldehydes, other toxics, and NO_x. However, we are concerned that EPA would retain only 52 (of over 400) monitors to measure area-wide concentrations for the entire United States. This is clearly inadequate to measure compliance with the standards.

We disagree with EPA's alternative proposal that would trade off the roadside monitoring program in return for setting the standard at a more protective level.

[1] California Environmental Protection Agency, Air Resources Board, "Air Board Approves Stronger Nitrogen Dioxide Standards," News Release, February 23, 2007. http://www.arb.ca.gov/newsrel/nr022307.htm.

We need much tighter standards. We need a transportation monitoring network to enforce compliance with the standards. We need EPA to take both steps to protect the health of those most at risk. We do not believe that the level of a national ambient air quality standard should depend on the extent of the monitoring.

EPA has Statutory Obligations for Reviewing Standards Under the Clean Air Act

The Clean Air Act Amendments of 1970 first introduced the requirement to establish enforceable national ambient air quality standards ("NAAQS"). The amendments were intended to be "a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution." *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976). The 1970 amendments "carrie[d] 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).

The NAAQS drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes a NAAQS, states and EPA identify those geographic areas that fail to meet the standards. CAA§ 107(d). Each state must prepare an "implementation plan" designed to control pollutant emissions in order to reduce the ambient concentrations of regulated pollutants to levels compatible with the attainment and maintenance of the NAAQS.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step in establishing a NAAQS involves identifying those pollutants, the "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 . . . ." CAA § 108(a)(1)(A) and (B). Once EPA identifies a pollutant, it must select 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.* § 108(a)(2).

Primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety." CAA § 109(b)(1). Any standards that EPA promulgates under these provisions must be adequate to (1) protect public health and (2) provide an adequate margin of safety, in order to (3) 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 for the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and 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.). The D.C. Circuit summed up EPA's mandate succinctly:

> 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 Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464-71 (2001). Each of these requirements is discussed in more detail below.

NAAQS Must Protect Public Health with an Adequate Margin of Safety

In setting or revising a NAAQS, section 109 of the Clean Air Act requires that the EPA achieve one thing at minimum: protect public health with an adequate margin of safety. This 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).[2] As a result:

[2] *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.").

> Standards 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 (Feb. 8, 1979).

Thus, as EPA has acknowledged, it 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.

Likewise, in implementing this mandate, EPA cannot deny protection against adverse health and welfare effects merely because those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. 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. As a result, opponents of protective NAAQS sometimes 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, 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 individuals at levels allowed by the current NAAQS, risks are by definition "significant" enough to require protection under the Act's protective and precautionary approach. *See* H. Rep. No. 294, 95th Cong., 1st Sess., at 43-51 (1977); *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 id.* at 18 ("the public health may properly be found endangered ... by a lesser risk of a greater harm").

EPA Must Err on the Side of Protecting Public Health

Courts have properly characterized the NAAQS as "preventative in nature." *Ethyl Corp.*, 541 F.2d at 15; *see also* H. Rep. No. 294, 95th Cong., 1st Sess., at 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 has held, "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 Ass'ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002).

NAAQS Must Guard Against Potential Health Effects of NO2

In keeping with the precautionary and preventative nature of NAAQS, EPA must set a standard that protects against potential health effects—not just those impacts that have been well established by science. *See Am. Trucking Ass'ns*, 283 F.3d at 369 (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")).

In the seminal case on the NAAQS, the D.C. Circuit found 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." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, "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." *Id.* at 1154-55.

In another case dealing with the "margin of safety" requirement of section 109, the D.C. Circuit rejected industry's argument that EPA was required to document "proof of actual harm" as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is "a significant risk of harm." *Ethyl Corp.*, 541 F.2d at 12-13. Noting the newness of many human alterations of the environment, the court found:

> Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, 'reasonable medical concerns' and theory long precede certainty. Yet the statute — and common sense — demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Id. at 25. *Accord*, *Industrial Union Dept. v. American Petroleum Inst.*, 448 U.S. 607, 655-56 (1980) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some

leeway where its findings must be made on the frontiers of scientific knowledge," and "is free to use conservative assumptions in interpreting the data," "risking error on the side of overprotection rather than underprotection").

NAAQS Must Protect Vulnerable Subpopulations

The 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. In fact, courts have repeatedly found that if a certain level of a pollutant "adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *American Lung Ass'n*, 134 F.3d at 390 (citations omitted); *see also American Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009).

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of Americans subject to respiratory ailments are entitled to the protection of the NAAQS: "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 1196, 91st Cong., 2d Sess., at 10 (1970). As the D.C. Circuit has explained:

> 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.

American Lung Ass'n, 134 F.3d at 390 (citations omitted). Stated another way, NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n,* 647 F.2d at 1153.

Twenty-two million Americans have been diagnosed with heart disease, nine million with chronic bronchitis, three million with emphysema, while twenty million adults and twelve million children have chronic asthma. The standards must set at a level that protects these and other populations with an adequate margin of safety.

EPA Cannot Consider the Economic Cost of Meeting NAAQS

In setting or revising a NAAQS, EPA cannot consider the economic impact of the standard—only the impact on public health. Lower courts had long held that costs

could not be considered in setting NAAQS, and in 2001, the Supreme Court affirmed this position. Justice Scalia, writing for a unanimous Court, found that the plain language of the statute makes clear that economic costs cannot be considered: "Were it not for the hundreds of pages of briefing respondents have submitted on the issue, one would have thought it fairly clear that this text does not permit the EPA to consider costs in setting the standards." *Whitman*, 531 U.S. at 465.

The Current Standard Fails to Protect Public Health

Our groups concur with EPA's conclusion that the current annual average standard fails to protect public health with an adequate margin of safety. We urge EPA to retain an annual standard and to add a short-term 1-hour standard. However, we urge EPA to strengthen both the annual standard and the proposed 1-hour standard to provide the necessary public health protection.

The current primary standard for NO_2 is an annual average standard of 53 ppb, established in 1971. EPA reviewed the NO_2 standard in 1985 and 1996, but took no action to update it in light of more recent health studies.

In this review, EPA has accepted the compelling evidence that the current standard is inadequate to protect public health. 74 *Fed. Reg*. 34426. This conclusion is fully supported by the Clean Air Scientific Advisory Committee (CASAC).[3]

Evidence Exists of Harm to Human Health from Nitrogen Dioxide

We agree with EPA's conclusions that nitrogen dioxide causes a range of harmful effects on the lungs:

- Increased inflammation of the airways;
- Worsened cough and wheezing;
- Reduced lung function;
- Increased asthma attacks;
- Greater likelihood of emergency department and hospital admissions; and
- Increased susceptibility to respiratory infection, such as influenza.[4]

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[3] Samet J. Letter to EPA Administrator Stephen Johnson: "Clean Air Scientific Advisory Committee's (CASAC) Peer Review of *EPA's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft*." EPA-CASAC-08-021, September 24, 2008.

[4] U.S. EPA. Integrated Science Assessment for Oxides of Nitrogen -- Health Criteria. EPA/600/R-08/071. July 2008. (Hereinafter ISA) Table 5.3-1. p. 5-5. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=194645

Children, older adults, and people with asthma or other lung disease and people with cardiovascular disease are at greatest risk. These include millions of people. For example, there are an estimated 22.9 million people, including 6.7 million children, with asthma in the U.S.[5] In addition, people who work, live or attend school along major highways also face increased risk, especially those living within 300 feet of a 4-lane or larger highway, railroad or airport.[6] EPA cites the most current assessment of that population at 47.8 million people, based on the 2007 American Housing Survey. 60 Fed. Reg. 134.

Strong evidence of the need for a short-term standard comes from a new meta-analysis of the human chamber studies as well as from new epidemiological research.

Over 50 new epidemiological studies of NO_2 health effects have been assessed since EPA's last review. The Integrated Science Assessment concludes:

> "The strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED [emergency department] visits and hospital admissions. These new findings were based on numerous studies, including panel and field studies, multipollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-hour average NO_2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average). The effect estimates from the U.S. and Canadian studies generally indicate a 2-20% increase in risks for ED [emergency department] visits and hospital admissions. Risks associated with respiratory symptoms were generally higher." [7]

[5] Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey Raw Data, 2007. Analysis performed by American Lung Association Research and Program Services using SPSS and SUDAAN software.
[6] U.S. EPA, ISA, Chapter 4, Section 4.3. The updated estimate was included in "Primary National Ambient Air Quality Standards for Nitrogen Dioxide, Proposed Rule." 60 *Fed. Reg*. 134 (15 July 2009).
[7] U.S. EPA. ISA. p. 5-15.

The Proposed Range for the Hourly Standard is Insufficient to Protect Public Health

We strongly support establishment of a new hourly standard to protect the public from short-term peak exposures to nitrogen dioxide. We support the focus on 1-hour daily maximum concentrations.

Nonetheless, the evidence is strong in support of an hourly standard at a level much lower than EPA has proposed. As we will discuss in the following, the meta-analysis of clinical studies provides clear evidence of harm for adults with mild asthma breathing NO_2 at levels within the proposed range. To protect against harm to these adults—much less to children, seniors or anyone with more severe asthma or other lung disease—requires a much lower level. Further, the epidemiological studies point to more serious health effects, occurring at much lower concentrations of NO_2 than were used in the chamber studies. They reflect adverse health effects resulting from contemporary exposures to NO_2 concentrations in the real world.

EPA has proposed a range of 80 to 100 ppb for the 1-hour maximum daily NO_2 standard. We believe that an hourly standard of 50 ppb is necessary to protect public health, including the health of sensitive populations, with an adequate margin of safety, as required by the Clean Air Act. EPA discussed such a standard in the *Risk and Exposure Assessment* (REA)[8]

Repeatedly, the EPA cites arguments based on the issues of uncertainty in scientific evidence, arguments used to extend the proposed range to 100 ppb and to request comments on levels to 150 ppb. Our comments will discuss some of those "uncertainties" and their implications for the standard.

However, we remind the EPA that the Clean Air Act mandates incorporating that margin of safety in the standard precisely because of the recognized limitation of knowledge. EPA should address any uncertainties remaining by further strengthening the standard.

Short-Term Epidemiological Evidence Documents Harm at Lower Levels

Epidemiological studies provide convincing evidence that short-term NO_2 concentrations affect respiratory symptoms and increase the likelihood of emergency and hospital admissions for respiratory diseases at levels below the current standard.

[8] U.S. EPA, Office of Air Quality Planning and Standards. Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard, EPA-452/R-08-008a, November 2008 (Hereinafter REA).

We agree with EPA's findings that such short-term exposure likely causes respiratory harm at levels shown in these studies. Yet, we believe the studies provide strong evidence of the need to provide protection from NO_2 levels in these lower ranges. Further, we show evidence from these studies that a stronger form of the standard is needed and that the 98th percentile allows too many days to have NO_2 levels above the standard to protect public health.

Epidemiological studies reported associations with adverse respiratory effects at mean 24-hour concentrations in the range of 3 to 50 ppb for emergency department and hospital admission studies.[9] EPA finds the epidemiological evidence for respiratory effects to be consistent and coherent. Based on these epidemiological studies, with supporting evidence from human and animal experimental studies, the ISA concludes that there is a "likely causal relationship" between short-term NO_2 exposure and adverse effects on respiratory symptoms.[10]

For respiratory symptoms, studies found positive associations where median 24-hour average concentrations ranged from 18-26 ppb,[11] and where the mean NO_2 level was 32 ppb for a 4-hour average.[12] These concentrations are well below the range being proposed by EPA. Additionally, the Mortimer et al., (2002) study of asthma exacerbations in inner-city children provides strong evidence of the inadequacy of the proposed short-term standard.

EPA relies on the Delfino et al., (2002) study to define a lower end of the range, focusing on the 98th and 99th percentile 1-hour daily maximum NO_2 concentrations in this study.[13] This study in southern California provided evidence of an association between NO_2 and asthma symptoms with 98th percentile 1-hour daily maximum NO_2 concentrations of 50 ppb, and mean concentrations of 24 ppb.[14]

We note that the respiratory morbidity observed in this study did not just occur at the high end of the distribution. The adverse effects reported in this study occurred at the mean concentration, as well as above and below the mean. A more

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[9] U.S. EPA ISA, p. 5-11.
[10] ISA a p. 5-6.
[11] Schildcrout JS, Sheppard L, Lumley T, Slaughter JC, Koenig JQ, Shapiro GG. Ambient air pollution and asthma exacerbations in children: an eight-city analysis. *Am J Epidemiol* 2006; 164: 505-517.
[12] Mortimer KM, Neas LM, Dockery DW, Redline S, Tager IB. The effect of air pollution on inner-city children with asthma. *Eur Respir J* 2002; 19: 699-705.
[13] Delfino RJ, Zeiger RS, Seltzer JM, Street DH, McLaren CE. Association of asthma symptoms with peak particulate air pollution and effect modification by anti-inflammatory medication use. *Environ Health Perspect* 2002; 110: 607-A617.
[14] Delfino RJ, Zeiger RS, Seltzer JM, Street DH, McLaren CE. Association of asthma symptoms with peak particulate air pollution and effect modification by anti-inflammatory medication use. *Environ Health Perspect* 2002; 110: A607-A617; and Thompson R, Jenkins S. Memo to the NO_2 NAAQS Review Docket, "Air Quality Statistics for Cities Referenced in Key U.S. Nitrogen Dioxide Epidemiology Papers."

appropriate basis is the mean 1-hour daily maximum concentration of 23.7 ppb. Rather than look to the highest concentrations during the study period, EPA should look at the mean concentrations at which effects occurred (as well as 1 standard deviation below the mean) and set a standard below this level that incorporates a margin of safety to protect against the adverse effects. Given that harm occurred at much lower concentrations, a standard based on the highest levels only cannot possibly protect public health.

Similar evidence shows up in other key epidemiological studies identified in the REA. Table 1 below notes the mean 1-hour daily maximum NO_2 concentrations for these additional studies identified in Chapter 10. These studies clearly identify adverse health effects such as emergency room visits and hospital admissions for respiratory causes at concentrations currently occurring in the U.S. Mean concentrations for all but two of these studies are about or below 50 ppb, suggesting that the standard must be set below this level to allow for a margin of safety.

Table 1: Mean 1-hr Daily Max NO_2 Concentrations Compared to 98th Percentile

Study	Mean 1-hr Daily Max (ppb)	98th Percentile (ppb)
Delfino	23.7	50
Peel (study period 1)	45.9	87
Peel (study period 2)	43.2	85
Jaffee	51	86
Ito	52	94
Ostro	71-75	180 -170
Linn	72	178
NYC - Manhattan	50	86
NYC - Bronx	49	88

Source: Thompson R, Jenkins S. Memo to NO_2 NAAQS Review Docket, "Air Quality Statistics for Cities Referenced in Key U.S. Dioxide Epidemiology Papers."

Further, the highest mean 1-hour daily maximum concentration reported in this set of studies is 75 ppb, providing further evidence that these studies cannot be used to justify a range of 80-100 ppb.

We note that there is no data to suggest that a uniform relationship exists between mean and 98th percentile concentrations in regions throughout the United States.

Considering the Delfino study alone on EPA's terms, that is, focusing on the 98th percentile of the 1-hour daily maximum concentrations, EPA reports a concentration of 50 ppb where asthma symptoms were observed. Based primarily on this study, EPA concluded in the REA that it was appropriate to set the lower end of the range at 50 ppb, which corresponded to the lowest-observed effects level of airway hyperresponsiveness in asthmatics. To provide the strongest public health protection, we therefore urge the level of the standard be set at 50 ppb.

During the CASAC teleconference on August 10, 2009, some CASAC members argued that the epidemiological studies that relied on area wide monitors to characterize exposure to NO_2 could not be extrapolated to set standards for exposures to NO_2 near roadways.[15] We disagree. The epidemiological studies typically considered multiple air pollutants and found consistent positive relationships with NO_2 after controlling for other pollutants. Unlike particulates, which may vary in composition from place to place, NO_2 is NO_2. The NO_2 occurring in and measured at roadside environments is likely to trigger similar health effects to NO_2 occurring in inland locations. We find the epidemiological studies in toto provide a strong basis for setting a strong 1-hour standard for NO_2 that would apply in all airsheds including the roadside environment.

The EPA argues that the roadside concentrations should only be factored in as they permeate to and impact area-wide exposures. With this argument, the EPA estimates that a standard level of as much as 150 ppb would only be reached near the roadways and that those roadside concentrations of NO_2 would disperse in the atmosphere to reach area wide levels as low as 90 ppb, or that roadside exposures of 100 or 80 would create area-wide exposures as low as 50 ppb or lower.

We disagree with the inclusion of roadway concentrations in this manner. According to the proposal, roadway concentrations are estimated to be 30 to 100 percent higher than area-wide concentrations. The EPA acknowledges that over 47 million people live adjacent to these roadways, railroads, and airports. Millions more commute to work daily on them or spend their workdays driving. For these people, the roadway concentrations provide their primary exposure and they deserve the direct protection of a tighter standard. If the standard is set where our groups argue it should be, those millions of people would have the protection they deserve,

[15] Samet J, Chair, Chean Air Scientific Advisory Committee, letter to The Honorable Lisa P. Jackson, Administrator, U.S. EPA, re: Comments and Recommendations Concerning EPA's Proposed Rule for the Revision of the National Ambient Air Quality Standards (NAAQS) for Nitrogen Dioxide. EAP-CASAC-09-014, September 9, 2009.

as would the millions who do not live or work along these roadways. However, we do not support a standard that would require them to continue to breathe NO_2 levels demonstrated to harm mild asthmatics in the assumption that area levels will reach lower levels.

The need to protect the health of the public includes the 47 million people who live near these roadways. We must establish a standard that will protect them. So if the assumption is that the area monitors will register 30 to 100 percent lower levels than roadside exposures, the basis for the calculations must be roadside exposures no higher than 50 ppb.

Clinical Studies Show that the Proposed Range Fails to Provide a Margin of Safety

Clinical studies provide clear evidence of harm to people with asthma who breathed NO_2 for 30 minutes to one hour while they were exercising. NO_2 enhances the responsiveness of the airways to allergens. This airway hyperresponsiveness—a narrowing of the airways in response to various stimuli —is a hallmark of asthma.

The meta-analysis of the clinical studies using individual level data from 19 clinical studies reported that 66 percent of subjects experienced an increase in airway responsiveness following 1-hour exposures to 100 ppb NO_2, the lowest level studied.[16] This provides strong evidence that the upper end of the proposed range—100 ppb—cannot possibly provide the requisite protection of public health. Clinical studies typically include only mildly asthmatic adults. These controlled human exposure studies serve as a warning of the greater harm likely to severe asthmatics or young children, who are generally not studied in such tests.

It is well established that children are more sensitive to air pollution than adults, for several reasons.[17] Infants and children have higher exposure to pollutants due to their greater ventilation rate. Children who spend time playing outside have greater exposures than adults who often do not. Children's lungs and immune systems are still developing, making them more susceptible to the effects of air pollution. Also, children with asthma have a higher degree of airway responsiveness compared with adult asthmatics.

[16] U.S. EPA ISA, Table 3.1-3.

[17] American Academy of Pediatrics Committee on Environmental Health, Ambient Air Pollution: health hazards to children. *Pediatrics* 2004; 114: 1699-1707. World Health Organization: The Effects of Air Pollution on Children's Health and Development: a review of the evidence E86575. 2005. Available at http://www.euro.who.int/document/E86575.pdf

In setting standards, safety factors must be incorporated to account for potential effects on infants, children, and those with moderate or severe asthma or other respiratory disease. In addition, adjustments must be made to compensate for the longer exposures allowed by a one hour standard, as compared to a clinical study of 30-minute exposures.

A standard of 100 ppb clearly cannot include any margin of safety. The millions of children and individuals with moderate or severe asthma face a likelihood of risk at levels well below 100 ppb. Therefore, based on the clinical studies alone, we consider that the proposed standard of 80 ppb likely fails to protect these sensitive populations and certainly lacks a sufficient margin of safety.

Health and Environmental Groups Support 1-hour Standard of 50 ppb

Despite the suggestion that the EPA will take comments on levels only as low as 65 ppb, we will go farther. We support a 1-hour standard for NO_2 set at 50 ppb, not to be exceeded. That level unquestionably provides greater protection than the proposal of 80 to 100 ppb based on the demonstrated harm to health and provides a more supportable margin of safety. The "no exceedance" form provides more coherence in the protection for a standard that targets peak exposures than a form based in the 98^{th} or 99^{th} percentile. However, if the EPA is unwilling to accept a "no exceedances" form, we support a 99^{th} percentile form of the standard.

We note that the American Thoracic Society's Environmental Health Policy Committee has supported a new short-term NO_2 standard in the range of 50 to 75 ppb.[18] The American Thoracic Society is the professional medical organization that represents researchers studying the effect of air pollution on lung health. An editorial in the Society's respected journal, the *American Journal of Respiratory and Critical Care Medicine*, states:

> "The science tells us that NO_2 in outdoor air, at levels that are within the current 'safe' standard, is worsening respiratory illness in susceptible people. It is time to create a short-term NO_2 standard that is protective and then work together to meet it."

The editorial cites "convincing evidence" that NO_2, at ambient concentrations, worsens asthma. Specifically, epidemiology studies link increases in NO_2

[18] Frampton MW and Greaves IA. on Behalf of the ATS Environmental Health Policy Committee. NOx - NOx: Who's There? *Am J Respir Crit Care Med* 2009; 179: 1077-1078.

concentrations with reduced lung function,[19] increased asthma symptoms[20], and increased emergency hospital visits[21]. These studies were conducted in cities that demonstrate compliance with the current annual NO_2 NAAQS of 53 ppb.

EPA Assessments Point to Improvements in Public Health at 50 ppb

The exposure assessment, risk assessment, and air quality analysis all demonstrate that of the options considered, only an hourly standard of no more than 50 ppb would protect against harm from peak exposures.

Table 1 in the proposal highlights the results of several of the analyses undertaken by EPA in support of the review of the NAAQS for nitrogen dioxide. The first analysis compares alternative standards to the number of days associated with the current annual standard (with a 100 ppb benchmark). 74 Fed. Reg. 34434. In this comparison, only a 99th percentile 1-hour standard of 50 ppb substantially reduces the mean estimated number of days per year with 1-hour NO_2 concentrations on or near roads greater than or equal to benchmark levels.

By comparison, the 150 ppb standard would show no real reduction in the number of days over the existing weak standard. Even a 100 ppb standard would leave 229 days in excess of the benchmark levels. While 229 days are roughly one-third fewer than the benchmark of 338 days, this nonetheless represents the equivalent of 8 months of days in excess of demonstrably unhealthy concentrations of NO_2. Only the 50 ppb standard would substantially reduce the exposure.

In the analysis of the impact on people with asthma in Atlanta, the table results further show the clear benefits of a 50 ppb standard. Only the 50 ppb standard reduced the mean percentage estimated to experience 6 or more days per year with 1-hour NO_2 exposures concentrations greater than or equal to benchmark levels of 100 ppb, relative to the current standard.[22] Of the options evaluated, only the 50 ppb 99th percentile option substantially reduced the number of respiratory emergency visits in asthmatics compared to the current annual standard.[23]

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[19] Linn WS, Shamoo DA, Anderson KR, Peng RC, Avol EL, Hackney JD, Gong H Jr. Short-term air pollution exposures and responses in Los Angeles area school children. *J Expo Anal Environ Epidemiol* 1996; 6:449-472.

[20] Schildcrout JS, Sheppard L, Lumley T, Slaughter JC, Koenig JQ, Shapiro GG. Ambient air pollution and asthma exacerbations in children: An eight-city analysis. *Am J Epidemiol* 2006; 164:505-517.

[21] Lin M, Chen Y, Burnett RT, Villeneuve PJ, Krewski D. Effect of short-term exposure to gaseous pollution on asthma hospitalization in children: A bi-directional case-crossover analysis. *J Epidemiol Community Health* 2003; 57:50-55.

[22] Table 1, 74 Fed. Reg. 34434.

[23] REA p. 274.

EPA's proposed *Regulatory Impact Assessment* (RIA) focuses on analyses of the 1-hour NAAQS at the 50 ppb level, because the projections indicated that by 2020, no counties in the analysis would have ambient 1-hour peak levels as high as the 80 to 100 ppb proposed range. The analysis assumes a baseline of no additional controls beyond the controls expected from rules that are already in place.[24]

Form of the Standard Should Allow Fewer Exceedances

EPA seems overly focused on the "stability" of the standard at the expense of precautionary protection of health. To address concerns of areas that may move in and out of nonattainment, the Agency is suggesting not one, but two fixes.

First, the Agency proposes that nonattainment be measured based on three years of monitoring data. This approach accounts for meteorological variation from year to year that can affect attainment determinations. We agree that this is reasonable to assure that attainment is not the product of favorable meteorological or other conditions that do not demonstrate permanent and enforceable reductions in the emissions that lead to elevated concentrations. *See* CAA § 107(d)(3)(E)(iii).

But the Agency goes one step further in pursuit of stability by proposing a 99th percentile form of the standard that would permit multiple exceedances—up to 4 days—each year. Alternatively, EPA proposes a 4th highest daily maximum hourly concentration for determining attainment.

Our groups favor a no exceedance form of the hourly standard, such as used in determining compliance with the California ambient air quality standards. However, we would strongly support the proposed 99th percentile form over a 98th percentile form. EPA has not presented analysis to differentiate between the health impacts of the 99th percentile form and the 4th highest daily maximum form of the standard.

We oppose use of the 98th percentile form. Given that a short-term standard is set to protect against short-term exposures, this form fails to provide that protection. The 98th percentile form allows for as many as 21 exceedances in a three-year period. Those exceedances can come in at any level and are not calculated until all exceptional events are discounted. We fail to see how a standard can protect against short-term exposures when three weeks of unlimited, unhealthy exposures are deemed acceptable.

[24] EPA/OAQPS/HEID/ABCG. Proposed NO2 NAAQS Regulatory Impact Analysis (RIA). July 2, 2009. Hereinafter RIA.

Alternative Proposal Offers Unacceptable Tradeoff

We disagree with EPA's alternative proposal that would trade off the roadside monitoring program in return for setting the hourly standard at a more protective level of 50-75 ppb. We need the tighter standards of 50 ppb. However, we also need a transportation monitoring network to enforce compliance with the standards. EPA must take both steps to protect the health of those most at risk.

The level of a national ambient air quality standard should not depend on the extent of the monitoring. However, the monitoring requirements are one of the essential elements of the proposal, because absent adequate monitoring, the standards cannot protect public health. EPA has acknowledged that the highest concentrations of NO_2 are likely to occur near heavily trafficked roadways where millions of people are exposed. EPA must protect these most exposed individuals with an appropriate standard backed up by a monitoring strategy to enforce the standards.

The EPA's proposal repeatedly calculates area-wide exposures based on expected concentrations near roadways that are projected to occur at lower levels near existing monitors. We continue to be baffled by this. The level of harm at or near roadways needs to be independently protective of public health for the tens of millions who live near or work on or near those roadways. If levels there meet the standards, then area-wide concentrations should as well.

Instead of using the estimated roadway concentrations to set a much higher standard, the Agency should require both tighter standards and roadside monitoring. With that combination, the health of those who face the greatest expected exposure to NO_2 and those farther away will both be protected.

The EPA Must Strengthen the Annual Average Standard

CASAC has consistently supported the need for retention of the annual average standard.[25]

Our groups urge EPA to strengthen the annual standard for NO_2. The use of an annual average form to the standard is critical to protect against long-term exposures. However, the current annual standard is inadequate. We urge the EPA to adopt an annual average standard of 30 ppb, as the State of California has done.

EPA's review of the scientific evidence in the ISA concludes that there is "suggestive" evidence of respiratory morbidity, specifically decrements in lung function growth associated with long-term exposure to NO_2. We note that based on a review of the same evidence considered by EPA, in 2008, California decided to establish for the first time a new annual average standard for NO_2, at 30 ppb, a far lower concentration than the current NAAQS.

In support of its action to establish an annual average standard in 2007, the California Air Resources Board cited evidence from epidemiological studies that showed that long-term exposures (one or more years) to NO_2 may lead to changes in lung function growth in children, symptoms in asthmatic children, and preterm birth. The annual average NO_2 level in these studies was 30 to 44 ppb.[26]

Recent studies not included in the ISA have pointed to serious health effects from long-term NO_2 exposures.

- A large English cross-sectional study of 40,000 adults, Forbes et al. (2009) found long-term exposure to contemporary concentrations of NO_2 (1995, 1996, 1997, and 2001) were associated with a small reduction in lung function in adults.[27]

[25] Samet JM, Chair, Clean Air Scientific Advisory Committee Letter to EPA Administrator Stephen Johnson: "Clean Air Scientific Advisory Committee's (CASAC) Review Comments on *EPA's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard*." EPA-CASAC-09-003, December 16, 2008.

[26] Comments of the Office of Environmental Health Hazard Assessment on the Draft Integrated Science Assessment for Oxides of Nitrogen, submitted in April 30, 2008 letter from Bart Ostro, Ph.D., Chief, Air Pollution Epidemiology Section to The Honorable Stephen L. Johnson, U.S. EPA.

[27] Forbes LJL, Kapetanakis V, Rudnicka AR, Cook DG, Bush T, Stedman JR, Whincup PH, Strachan DP, Anderson HR. Chronic exposure to outdoor air pollution and lung function in adults. *Thorax* 2009; 64: 657-663.

- An in-press study in British Columbia reported that higher lifetime average daily exposures to NO_2 were associated with statistically significant yet modest increased risk of inpatient or outpatient clinical encounters for infant bronchiolitis, inflammation of the tiniest airways of the lungs.[28] Karr et al concluded that "this study provides further evidence that children, specifically very young children in their first months of life, may suffer respiratory health compromise even at levels of ambient air pollution that fall within regulatory limits."

Furthermore, we remind EPA that distance to roadway studies fundamentally measure long term exposures. High traffic counts typically occur at the same places day after day as anyone who commutes to work can attest. These high levels cease being solely peak exposures when they occur as the previously cited Table I in the proposal attests. Elevated exposures that occur daily for 338 days out of a year can no longer be considered just peak exposures.

Traffic studies have reported an array of serious adverse health effects ranging from adverse birth outcomes to premature mortality. EPA systematically excluded these traffic studies from its review of the health evidence.[29] If studies did not contain distinct measurements of NO_x concentrations, they were not included in the ISA.

Despite this abundant evidence of harm, EPA has also excluded the distance from roadway studies from its review of the particulate matter standard. Therefore most of the new evidence of health effects of traffic-related pollution has not been evaluated in the recent reviews of the NAAQS.

The Health Effects Institute (HEI) recently completed a review of over 1,200 recent publications of traffic-related air pollution, including 170 epidemiology studies and 340 toxicology studies.[30] The review concluded that the evidence was "sufficient" to infer a causal relationship between exposure to traffic related air pollution and exacerbation of asthma and "suggestive but not sufficient" to infer a causal relationship with onset of childhood asthma, non-asthma respiratory symptoms, impaired lung function, and total and cardiovascular mortality.

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[28] Karr CJ, Demers PA, Koehoorn MW, Lencar CC, Tamburic L, Brauer M. Influence of Ambient Air Pollutant Sources on Clinical Encounters for Infant Bronchiolitis. *Am J Respir Crit Care Med* 2009 Aug. 27. Epub ahead of print.

[29] ISA Annex AX1.1.2. Criteria for Selecting Epidemiology Studies, at Annex p. 1-3.

[30] HEI Panel on the Health Effects of Traffic-Related Air Pollution. May 2009. Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and

In 1995 the World Health Organization (WHO) conducted a review of their guidelines for air quality standards for the criteria air pollutants and recommended an annual average standard for NO_2 of 40 µg/m^3 (21 ppb).[31] The WHO recommendation to retain their guideline for an annual average standard of 21 ppb was also premised on the California Children's Health Study. This study found that long-term exposure to nitrogen dioxide was associated with stunted lung function growth in children.[32] According to the WHO report:

> "In summary, the Southern California Children's Health Study provides evidence of the effect of nitrogen dioxide on lung function growth, and suggests that lung function values below the 80% predicted might be as much as five times more likely in polluted communities than in communities with low pollution. Given the fact that lung function values persist throughout life, these decrements will have a lifelong impact on the health of those affected."

Improvements Needed in Monitoring

The current monitoring network is not sufficient to detect the maximum concentrations to NO_2 to which people may be exposed. The REA indicates that only 58 of 489 total NO_2 monitors are sited in areas of expected peak concentrations. Furthermore, requirements for these monitors were retracted a few years ago, and EPA is proposing to reinstitute requirements for just 52 area wide monitors for the whole country. It is critical that the network of 489 monitors currently collecting air quality data remain intact.

More critically, monitors are not routinely located near roadways where the REA indicates that the highest exposures are expected. Any revisions to the NAAQS must be accompanied to changes to the monitor siting criteria to ensure that attainment is measured against monitors that reflect peak exposures.

Furthermore, it is crucial that any monitoring data collected be used to ascertain compliance with the air quality standards for the entire metropolitan area.

Although the highest exposures to NO_2 are likely focused along highways and other transportation networks, those networks are integral components of the economy

[31] Forastiere F, Peters A, Kelly FJ, Holgate ST. World Health Organization . Air Quality Guidelines Global Update 2005, Chapter 12. Nitrogen Dioxide.
[32] 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: 1057-1067.

and population centers. The transportation routes do not exist in isolation. Were it not for those broader metropolitan areas, the heavily-used transportation routes and nodes would be elsewhere. EPA has already begun to calculate the impact the higher concentrations along these transportation routes have on the levels of area-wide pollutants.

We urge the EPA to expand the monitoring for criteria pollutants to include a comprehensive near-roadway network. Such monitors are essential to providing adequate protection to human health, given the growing evidence that we have failed to fully appreciate the harm from these near-roadway exposures.

Our comments that follow are based on our best current understanding of the concentrated exposures of roadside NO_2. We recognize that the specific geo-spatial arrangement for capturing the maximum level may vary with different terrain and with urban compared to suburban or rural settings. We urge that the EPA consult experience from existing near-roadway monitoring to develop the final plans for this network.

More information from the experience of these states that currently monitor roadside conditions can improve the new national network. However, we cannot allow the pursuit of ever-better information on the parameters of roadside monitoring to delay the installation of such monitors. The experience from decades of research shows us that monitoring networks can and do evolve. The proposed network is a bare-bones beginning. We urge EPA to make this only the first phase of a comprehensive near-roadway, multi-pollutant monitoring network.

Network Design

We strongly support the proposed two-tier monitoring network requirement capturing maximum 1-hour NO_2 concentrations in the near-road environment in addition to monitoring the highest expected concentrations at the neighborhood or area-wide scale. We are pleased to see EPA take seriously the public health threats that are posed to millions of residents and other sensitive receptors in the near-highway environment as well as other high-exposure areas.

While these requirements likely pose the need for new monitoring infrastructure in many metropolitan areas to meet near-roadway monitoring requirements, this pollutant data has sorely been lacking from the national monitoring network and is long overdue. In fact, we urge EPA to expand monitoring of near roadway sites to other pollutants of concern, in the near future, including carbon monoxide, ultrafine, fine, and coarse particulate matter, black carbon and air toxics as suggested at 74 Fed. Reg. 34442. At a minimum, EPA must ensure that the design

requirements for NO_2 monitors near major roadways are compatible with the monitoring of additional pollutants as listed above. As the requirements of the atmospheric chemistry permit, these monitors should also be established to physically facilitate the monitoring of these additional pollutants.

Rapid Deployment of Near-highway Monitors Needed

EPA has not offered a justification for the amount of time proposed for the deployment of near-highway monitors. All local air monitoring agencies should be directed to act expeditiously to begin collecting NO_2 monitoring data in accordance with the new NAAQS requirements. Further, local air monitoring agencies should begin the planning process—financial logistical and otherwise—for monitor deployment now, rather than waiting for this regulation to be finalized. We urge EPA to seek Congressional funding for an expanded network and to set a deadline for deployment of no later than January 1, 2012. We believe two years should be more than adequate time.

We encourage the immediate review of the monitoring research to determine the optimal locations in each community, given the proposed parameters. Furthermore, all state and local air monitoring agencies should be directed to act expeditiously to begin reporting NO_2 monitoring data in accordance with the new NAAQS requirements as quickly as possible, particularly in states which have existing NO_2 roadside monitoring.

Monitoring Needed in Areas of Expected Maximum Concentrations Near Major Roads

This provision is one of the most important elements of the regulatory proposal for NO_2. The significant populations impacted by pollution from highways bolster the need for additional monitoring. The burgeoning system of highways and roads provide economic and mobility benefits that, at the same time, can impose severe impacts on communities. We have already noted EPA's finding that "A considerable fraction of the population resides, works or attends school near major roadways and that these individuals are likely to have increased exposure to NO_2." (74 Fed. Reg. 34419). The estimate of that population has grown since completion of the ISA. The most current (2006) American Housing Survey showed a significant increase in the number of households living with 300 feet of highways, railroads or airports, totaling 15.6% of housing units and impacting almost 50 million people 74 Fed. Reg. 34419.

Many schools fall into the high-exposure zone near roadways as well. In California, Green et al (2004) report that over two percent of public grade schools sit within

150 meters of high traffic roads. In addition, they found that a disproportionately large percentage of students attending these schools are economically disadvantaged and nonwhite.[33] Kim et al (2004) surveying over 1,000 elementary school students in Northern California found higher rates of asthma and bronchitis symptoms in children attending schools near busy roads and freeways.[34] Many other studies show that children spend a significant amount of time at school, making exposure to pollution at school an important consideration; and that close proximity of schools to a freeway greatly increases risks of acute and chronic respiratory illnesses and many other adverse health impacts.[35] Similarly, living in close proximity to major roadways is widely recognized as significantly elevating cancer risks, mortality, respiratory disease and other adverse health outcomes.[36]

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[33] Green RS et. al., Proximity of California Public Schools to Busy Roads. *Environ Health Perspect* 2004; 112: 61-66.

[34] Kim, J. et al. Traffic-related air pollution and respiratory health: East Bay Children's Respiratory Health Study. *Am J Respir Crit Care Med* 2004; Vol. 170: 520-526.

[35] Speizer FE., Ferris BG Jr. Exposure to automobile exhaust. I. Prevalence of respiratory symptoms and disease. *Archives of Environmental Health* 1973; 26: 313-318. van Vliet, P., M. Knape, et al. Motor vehicle exhaust and chronic respiratory symptoms in children living near freeways. *Environmental Research* 1997; 74: 122-132.

Appatova AS, et al. Proximal exposure of public schools and students to major roadways: a nationwide US survey. *Journal of Environmental Planning and Management* 2008; 51: 631-646.

Duki MIZ, Sudarmadi S, Suzuki S, Kawada T, Tri-Tugaswati A. Effect of Air Pollution on Respiratory Health in Indonesia and its economic cost; *Arch Environmental Health* 2003; 58:135–143.

[36]Nicolai T, Carr D, Weiland SK, Duhme H, Von Ehrenstein O, Wagner C, Von Mutius. Urban traffic and pollutant exposure related to respiratory outcomes and atopy in a large sample of children*; Eur Respir J* 2003; 21: 956–963.

Brunekreef B, Janssen NA, de Hartog J, Harssema H, Knape M, van Vliet P. Air pollution from truck traffic and lung function in children living near motor-ways. *Epidemiology* 1997; 8: 298-303.

Duhme H, Weiland SK, et al. The association between self-reported symptoms of asthma and allergic rhinitis and self-reported traffic density on street of residence in adolescents. *Epidemiology* 1996; 7: 578-582.

Edwards J, Walters S, et al. Hospital admissions for asthma in preschool children: relationship to major roads in Birmingham, United Kingdom. *Archives of Environmental Health* 1994; 49: 223-227.

Gauderman WJ et al. Childhood Asthma and Exposure to Traffic and Nitrogen Dioxide. *Epidemiology* 2005; 16: 737-743. This study was confirmed by a separate Southern CA study finding an 85% higher likelihood for an asthma diagnosis among children living with 75 meters of a major road.

McConnell R, Berhane K, Yao L, Jerrett M, Lurmann F, Gilliland F, et al. Traffic, susceptibility, and childhood asthma. *Environ Health Perspect* 2006; 114: 766-772.

Gauderman WJ et al. Effect of exposure to traffic on lung development from 10 to 18 years of age: a cohort study. *Lancet* 2007; 369: 571-1.[

Wilhelm M, et al. Environmental Public Health Tracking of Childhood Asthma Using California Health Interview Survey, Traffic, and Outdoor Air Pollution Data. *Environ Health Perspect 2008*; 116: 1254-1260.

Require a second near-road monitor in the largest CBSAs

We strongly support EPA's proposal to require a second near-road monitor this requirement, given the population density, profusion of freeways and general diversity in the largest core-based statistical areas (CBSAs). We also support the inclusion of CBSAs with unusually high traffic volumes —250,000 annual average daily traffic (AADT) —in this requirement for two near-road monitors, since the roadways with the highest traffic levels likely correspond to the highest exposures to NO_2. Where two near-road monitors are called for in a single CBSA, care should be taken to ensure that the two monitors are located in areas with distinctly different meteorology, traffic characteristics (e.g. heavy truck route vs. high commuter traffic volume), geography (e.g. hilly vs. flat), and/or socio-economic characteristics.

Meng YY, et al. Are Frequent Asthma Symptoms Among Low-Income Individuals Related to Heavy Traffic Near Homes, Vulnerabilities, or Both? *Annals of Epidemiology* 2008; 18: 343-350.

Venn AJ, et al. Living Near A Main Road and the Risk of Wheezing Illness in Children. *American Journal of Respiratory and Critical Care Medicine* 2001; 164: 2177-2180.

Lin S, Munsie JP, Hwang S-A, Fitzgerald E, Cayo MR. Childhood Asthma Hospitalization and Residential Exposure to State Route Traffic. *Environmental Research* 2002; Section A, 88: 73-81. Similarly, A San Diego study found increased medical visits in children living within 550 feet of heavy traffic.

English P, Neutra R, Scalf R, Sullivan M, Waller L, Zhu L. Examining Associations Between Childhood Asthma and Traffic Flow Using a Geographic Information System. *Environ Health Perspect* 1999; 107: 761-767.

van Vliet P, et al. Motor exhaust and chronic respiratory symptoms in children living near freeways. *Environmental Research* 1997; 74: 12-132.

Brauer M, et al. Air pollution and development of asthma, allergy and infections in a birth cohort. *Eur Respir J* 2007; 29: 879-888.

Pearson RL, et al. Distance-weighted traffic density in proximity to a home is a risk factor for leukemia and other childhood cancers. *Journal of Air and Waste Management Association* 2000; 50: 175-180.

Raaschou-Nielsen O, Hertel O, Thomsen BL, Olsen JH. Air Pollution from traffic at the residence of children with cancer. *Am J Epidemiol* 2001; 153: 433–443.

Knox and Gilman. Hazard proximities of childhood cancers in Great Britain from 1953-1980. *Journal of Epidemiology and Community Health* 1997; 51: 151-159.

Wilherm M. et al. Local variations in CO and particulate air pollution and adverse birth outcomes in Los Angeles County, California, USA. *Environ Health Perspect* 2005; 113: 212-221.

Ritz B, et al. Ambient air pollution and risk of birth defects in Southern California. *Am J Epidemiol* 2002; 155: 17-25.

Hoek G, Brunekreef B, Goldbohn S, Fischer P, van den Brandt PA. Association between mortality and indicators of traffic-related air pollution in the Netherlands: a cohort study. *Lancet* 2002; 360: 1203-1209.

Finkelstein MM, et al. Traffic Air Pollution and Mortality Rate Advancement Periods. *Am J Epidemiol* 2004; 160: 173-177.

Base Monitor Site Selection on AADT and Diesel Volumes

Near-road monitor placement should be determined not only by the highest AADT volumes in a given CBSA, but also by the highest heavy-duty truck volumes, where this data is available. Heavy-duty diesel trucks are one of the largest sources of NO_2 and therefore should be considered in seeking sites with maximum NO_2 concentrations. Further, the requirements should clearly articulate that near-road monitors should be located along freeways segments with highest heavy-duty truck volumes that also have a additional diesel truck traffic due to a co-located source such as a rail yard, large distribution center, marine port terminal or other heavy-cargo related business. While it may be helpful in some instances for air monitoring agencies to have some level of discretion in monitor placement, in order to protect the most exposed and vulnerable populations and for the sake of consistency, it is important for EPA to give specific requirements to obtain maximum concentrations. Finally, where several sites in a single CBSA exhibit similarly high diesel truck traffic and co-located diesel freight sources, a site with higher population density should be favored.

Place Monitors to Capture the Highest Concentrations

We strongly support monitor placement where they can capture the highest concentrations of NO_2 emissions. Currently, the evidence indicates those are within 50 meters of the outside edge of traffic lanes and situated to avoid physical obstructions within that distance. While NO_2 levels tend to stay elevated with greater distances from freeways relative to other pollutants, such as ultrafine PM, the area closest to the freeway appears likely to exhibit the highest concentration and therefore to constitute the best location to monitor, given that many sensitive sites exist this close to freeways. Other parameters, including monitor height, must be established to support the capture of the highest NO_2 concentrations.

For those reasons, the lower end of the proposed height of 2 to 7 meters appears to capture the highest NO_2 concentrations, and more accurately represents human exposure at the breathing zone. Additional monitors at other relationships to these sources may be needed for research purposes, but they should be in addition to those designed to establish the peak exposures for NAAQS compliance purposes.

Despite evidence of elevated NO_2 levels within 50 meters upwind of freeways due to vehicle-induced turbulence or other reasons, it is still paramount to capture the highest concentrations of NO_2 in the near-roadway environment. Therefore allowance of monitors in predominantly upwind locations is ill-advised.

Area-Wide Monitoring at Neighborhood and Larger Spatial Scales

We oppose the proposed requirement to retain only 52 air monitors to measure area wide concentrations NO_2. In 2006, EPA finalized revisions to the "National Monitoring Strategy" dramatically rolling back requirements for monitoring criteria air pollutants. In the case of NO_2, monitoring requirements on the states were essentially eliminated, based on the fact that most areas met the annual average standard in effect at that time. This short-sighted revision did not acknowledge that the NO_2 standards were over 35 years old and in need of updating and strengthening. Fortunately, most states retained the more than 400 monitors in operation around the country. With the proposal to add a new hourly NO_2 standard, these areawide monitors are needed to determine compliance with the standards.

EPA should require states and local offices to review inventory data to identify any potential NO_2 hotspots outside of those large metropolitan areas. For instance, if a large power plant or any other source is creating elevated NO_2 levels in proximity to homes, schools or other sensitive sites, in an area of less than one million people, EPA should consider requiring a monitor. In particular, certain large agricultural facilities may emanate high concentrations of NO_2 under certain conditions, such as wet weather. Many of these facilities are directly upwind of rural communities, meriting an NO_2 monitor.

Implementation Requirements

Planning Deadlines Should Be No Later than 2015

We are concerned that EPA has proposed a schedule for addressing near-highway locations that allows States nearly 15 years to address the hotspots that EPA acknowledges are of primary concern for peak NO_2 concentrations. Such delay is unnecessary and undermines the health protection goals of this rulemaking.

EPA correctly acknowledges that the current monitoring network does not fully satisfy the near roadway-oriented NO_2 monitoring requirements proposed. 74 Fed. Reg. 34450. EPA says that it anticipates that it will require up to three years to get a new monitoring network in place and an additional three years of monitoring thereafter to determine compliance and allow designations. *Id.* As a result, EPA designations could be delayed until 2018, with attainment deferred until 2023.

We urge EPA to accelerate this schedule. First, EPA should insist on faster compliance with the new monitoring requirements. EPA does not provide any basis for allowing States three years to get a new monitoring network in place. Two

years should be adequate to adjust the location of monitors to satisfy the new requirements.

Second, EPA need not wait for three years of data to redesignate unclassifiable areas. EPA has broad discretion in section 107(d)(3) to redesignate the unclassifiable areas to nonattainment. EPA may consider "air quality data, planning and control considerations, *or any air quality-related considerations the Administrator deems appropriate* . . . ." CAA § 107(d)(3)(A) (emphasis added). Emissions and resulting ambient concentrations will be closely tied to the level and composition of vehicle traffic on the nearby roadway. EPA could formulate a rational basis for redesignation based on limited monitoring data and available information on mobile source emissions from the relevant roadways. We encourage EPA to explore such options and commit to designating near roadway areas no later than the end of 2013.

Following redesignation, EPA also has flexibility under the Act to expedite the planning and attainment deadlines allowed under the Act. Section 172(b) directs EPA to set a deadline for the submission of nonattainment plans that is "no later than 3 years from the date of the nonattainment designation . . . ." Given the targeted focus of these plans, we believe it is reasonable to accelerate this schedule by at least one year and promulgate a nonattainment SIP submittal deadline of no later than the end of 2015. This will afford reasonable time to assure the plan is working to attain the standard by the end of 2018.

Every year saved in addressing peak concentrations near roadways will result in significant reductions of suffering. Nine years should be more than enough time to take the necessary action. We hope that EPA will explore other options to accelerate these deadlines yet further and we look forward to working with EPA to achieve this goal.

Implementation of the Permitting Program

We agree with EPA's conclusion that the Act requires areas designated nonattainment for the NO2 NAAQS to submit for SIP approval a nonattainment new source review permitting program within 18 months of the designation. *See* CAA §§ 191(a) and 173. We also agree with EPA's conclusion that the Act requires States to submit PSD programs for attainment areas within 3 years of the promulgation of this revised NAAQS for NO2. *See id.* § 110(a)(2). EPA also correctly notes that "[p]rior to the adoption of the SIP revision addressing major source nonattainment NSR for NO2 nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply." 74 Fed. Reg. 34453. We encourage EPA to make it clear to state and local permitting agencies how these permitting

requirements must be implemented immediately upon a nonattainment designation. We also encourage EPA to clarify the permitting requirements in attainment areas pending adoption of revised PSD programs.

Communication of Public Health Information

The Air Quality Index (AQI) has become a vital tool for translating complicated information about air pollution. The AQI not only aids individuals to better understand air quality, but to take steps to reduce their exposure to dangerous pollution levels. We appreciate the EPA's commitment to keeping this tool up-to-date.

The EPA reminds us that the traditional pattern for setting the AQI has placed the level of 100 at the level of the short-term NAAQS. The American Lung Association notes, however, that the evidence consistently shows that the EPA's proposed range for the 1-hour NO_2 NAAQS fails to include adequate protection for "sensitive groups," especially children and people with asthma. That presents a problem for making recommendations about lower levels in the AQI. It is especially problematic when EPA's own estimates in Table 1 show that these levels would be exceeded over 200 days in a year.

The Lung Association therefore recommends that EPA change its tradition and set the 100 level of the AQI below the revised primary NO_2 NAAQS if the Administrator selects a NAAQS within the proposed range. At a minimum, we recommend the 100 level should be at set at 50 ppb NO_2 1-hour average, which corresponds with the level of the standard we support. Such a threshold would allow the recommendations for "unhealthy for sensitive groups" to apply more appropriately for that level, as sensitive groups include those with asthma, children, the elderly and others for whom harm at that level is either documented or predicted from epidemiological evidence. The level of "moderate" should be well below 50 ppb 1-hour average, such as 25 ppb.

We disagree with EPA's proposal to retain the "breakpoints at the higher end of the AQI scale (from 200 to 500), which would apply to state contingency plans or the Significant Harm Level (40 CFR 51.16)." 74 Fed. Reg. 34454.

We recognize that prior practice has been to set the AQI value of 100 at the level of the primary NAAQS, the 500 at the Significant Harm Level (SHL), and intermediate breakpoints presuming a generally linear relationship between increasing index values and increasing concentrations. There are challenges with this pattern.

First, the SHL for nitrogen dioxide [3.750 µg/m^3 (2000 ppb) 1-hour average; 938 µg/m^3 (500 ppb) 24-hour average] was last changed/set at least 22 years ago.[37] Unless EPA seeks to review this threshold and revise it, its use as a marker cannot reflect the current science.

Furthermore, we observe that there is a clear lack of proportion between how AQI breakpoints are set for different criteria pollutants. For example, for daily maximum 8-hour average ozone concentrations, the breakpoint currently in effect for the AQI value of 200, the breakpoint between unhealthy and very unhealthy, is 115 ppb, *only 53%* above the NAAQS for ozone of 75 ppb, while the proposed corresponding breakpoint for nitrogen dioxide is 640 ppb, as much as *eight times* the low end (80 ppb) of EPA's proposed range for the NO_2 NAAQS.

We therefore recommend that the breakpoints between AQI of 100 and 500 need to be consistent with the health evidence. It is likely that the science already collected and reviewed for the purpose of determining the proper level for the NAAQS would also be instructive for making distinctions among the three intermediate categories of unhealthy for sensitive groups, unhealthy, and very unhealthy (i.e., for determining breakpoints for the AQI at 150 and 200), than would an arbitrary linear mapping of the AQI scale from 100 to 500 onto the corresponding range of pollutant concentrations.

EPA should establish a meaningful and practical scale of levels of concern and graduated cautionary statements for both sensitive groups as well as the general population. This index is appropriate for nitrogen dioxide, just as the ozone and $PM_{2.5}$ they have already proven to be.

Conclusion

Millions of Americans are unprotected by the current air quality standards for nitrogen dioxide. Children and adults with asthma should be free to work outdoors or participate in outdoor recreation without fear that air pollution concentrations will trigger asthma attacks that send them to the hospital. Children who live near busy highways should not risk their future ability to breathe because the pollution kept their lungs from fully developing.

Reducing nitrogen dioxide exposures in response to stricter health standards will reduce health costs and reduce susceptibility to the flu virus, two of the looming issues of the day.

The scientific evidence presented in this review compels EPA to set an hourly standard for NO_2 of 50 ppb, 99^{th} percentile, and to strengthen the annual average standard to the level of 30 ppb. The standard must be enforceable through a comprehensive monitoring program that measures nitrogen dioxide concentration near roadways, downwind of major sources, and in other areas.