EPA Administrator Stephen L. Johnson Air and Radiation Docket and Information Center U.S. Environmental Protection Agency Mailcode: 6102T 1200 Pennsylvania Avenue, NW Washington, DC 20460

RE: *Proposed* National Ambient Air Quality Standards (NAAQS) for Ozone—DOCKET ID NUMBER EPA-HO-OAR-2005-0172

#### **Dear Administrator Johnson:**

As leading medical, nursing, public health, disease and patient advocacy organizations, we are highly concerned that EPA's recently proposed revision to the primary National Ambient Air Quality Standard (NAAQS) for ozone does not adequately protect the health of the American public. While more stringent than the current standard, EPA's proposal to lower the standard to within the range of 0.070 parts per million (ppm) to 0.075 ppm does not go far enough to safeguard public health. Therefore, we ask you to finalize a stronger ozone standard of 0.060 ppm.

# **EPA Must Protect Public Health, Including Sensitive Populations**

Section 109(b)(1) of the Clean Air Act directs the Administrator of the EPA to promulgate a primary NAAQS for ozone that is "requisite to protect public health" with "an adequate margin of safety." As stated by the U.S. Court of Appeals for the D.C. Circuit, the federal court with primary jurisdiction for the Clean Air Act, the "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." Further, the D.C. Circuit Court has asserted unequivocally that "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." In sum, EPA must err on the side of protecting public health, including that of sensitive individuals, when exercising its discretion in setting national air quality standards.

By citing "scientific uncertainty" as a primary justification for not proposing a more stringent ozone standard, <sup>1</sup> EPA's current proposal disregards the precautionary nature inherent to the NAAQS promulgation process and fails to meet the statutory requirements of the Clean Air Act. As the science shows, a stronger standard is warranted to better protect public health.

#### **Current Standard Fails to Protect Public Health**

Our scientific and medical understanding of the mechanisms by which exposure to ambient ozone pollution impacts human health has grown considerably stronger during the last ten years. Since EPA last revised the ozone NAAQS in 1997, more than 1,700 peer-reviewed studies examining the health effects of ozone have been published.<sup>5</sup> Extensive reviews of this new body of evidence by EPA staff scientists<sup>6</sup> and by EPA's Clean Air Scientific Advisory Committee<sup>7,8</sup> (CASAC) have confirmed that the current primary ozone standard is set at a level that is not sufficient to protect public health with an adequate margin of safety.

## Respiratory Health Effects

Recent epidemiologic studies have demonstrated a range of adverse respiratory health effects at levels below the current 8-hour standard of 0.08 ppm, including increased hospital admissions<sup>9</sup> and emergency room visits, <sup>10</sup> respiratory symptoms in infants and children, <sup>11</sup> asthma exacerbations, <sup>12</sup> and school absenteeism. <sup>13</sup> This epidemiologic evidence is further supported by a number of controlled human exposure studies that have shown that some healthy adults experience reductions in lung function, increased respiratory symptoms, heightened susceptibility to respiratory infection and lung inflammation following just 6.6 hours of exposure to ozone at concentrations of 0.08 ppm. <sup>14,15,16,17</sup> It is important to note that the respiratory effects observed in these chamber studies occurred in healthy adult subjects and would likely be more severe among sensitive groups, such as asthmatics.

# Cardiovascular Health Effects

New evidence is beginning to emerge about the potential cardiovascular effects of ozone. Numerous recent studies point to adverse associations between ozone exposure and various cardiovascular health endpoints, including alterations in heart rate variability in older adults, <sup>18</sup> cardiac arrhythmias, <sup>19</sup> strokes, <sup>20</sup> heart attacks, <sup>21</sup> and hospital admissions for cardiovascular diseases. <sup>22</sup>

### Mortality Effects

Research published over the last ten years also has provided more robust, consistent evidence linking increases in daily ozone exposures to increased deaths from cardiovascular and respiratory causes. A series of recent meta-analyses and multi-city studies has documented an increase in premature death following ozone exposures below 0.08 ppm, particularly among the elderly. Furthermore, new research has focused on controlling for weather variables in assessing the effect of ozone on mortality. A case-crossover study of over one million deaths in 14 U.S. cities found that "the association between ozone and mortality risk is unlikely to be caused by confounding by temperature."

## Sensitive Groups

Factors such as age, preexisting disease and genetics can influence individual susceptibility to ozone pollution, whereas vulnerability is determined by one's likelihood of exposure while at heightened breathing rates. After reviewing groups known to be susceptible with those considered to be vulnerable, EPA has identified a number of groups as sensitive or "at risk" to ozone exposure. EPA is obligated under the Clean Air Act to set the ozone NAAQS at a level appropriate to protect the health of these sensitive groups.

Children are acutely vulnerable to the hazardous effects of air pollution.<sup>27</sup> Relative to adults, they tend to spend more time out of doors, they are often more physically active, they breathe more rapidly, their airways are narrower and they inhale relatively more pollutants in proportion to their body weight.<sup>27,28</sup> Additionally, lung growth continues long after birth, with as much as 80% of the aveoli developing during childhood and adolescence.<sup>29</sup> Epidemiologic evidence indicates that children face additional health risks beyond the adverse effects observed in the general population. Children experience acute effects such as difficulty breathing,<sup>11</sup> increased hospitalizations<sup>30</sup> and emergency room visits<sup>31</sup> from ozone exposure at concentrations below the current standard and may suffer long-lasting effects such as stunted lung function in young adulthood.<sup>32</sup> Ozone exposure can impact prenatal health, with recent research finding that in-utero exposure to ozone is associated with lower birth weight and intrauterine growth retardation.<sup>33</sup>

Several other groups have shown above-average susceptibility. Based upon a number of recent studies investigating age-related differences in the mortality effect of ozone, <sup>23,34</sup> the Criteria Document concludes that the elderly are at increased risk of ozone-related mortality. <sup>35</sup> Individuals with preexisting lung disease comprise another susceptible population group, and studies show that low level ozone exposure exacerbates respiratory symptoms in child asthmatics <sup>36</sup> and increases hospitalization among adults suffering from chronic obstructive pulmonary disease. <sup>9</sup> Outdoor workers <sup>37</sup> as well as active adults who exercise outdoors <sup>38</sup> are particularly vulnerable to ozone exposure due to greater levels of exposure.

## **EPA Proposal Falls Short, Departs from Recommended Standards**

EPA's current proposal would lower the ozone NAAQS from 0.08 ppm (effectively enforced at 0.084 ppm due to rounding) to within 0.070 ppm to 0.075 ppm (specified to the nearest thousandth ppm). While this tighter standard would help improve air quality in many areas of the country, it falls short of the action needed to adequately protect public health. Both controlled human exposure studies and epidemiologic research document adverse effects, including respiratory symptoms<sup>39</sup> and increased risk of premature death, from ozone exposure at concentrations as low as 0.06 ppm.

EPA's proposal ignores the widespread support for more health-protective standards within the medical, science, public health and environmental communities. <sup>41</sup> EPA's own Clean Air Scientific Advisory committee unanimously recommended the eight-hour

primary ozone standard be set within a range of 0.060 ppm to 0.070 ppm,<sup>7</sup> while EPA's Children's Health Protection Advisory Committee has asked the Agency to set the primary standard at the low end of this range (0.060 ppm) "in order to be more protective of the respiratory health of susceptible children." In a letter sent to EPA Administrator Johnson last April, more than 100 distinguished air pollution researchers and physicians called for the primary ozone standard to be set at a level lower than that currently proposed by the Agency. As Chapter 5 of the Final Ozone Staff Paper demonstrates, significant reductions in adverse health effects due to ozone exposure can be achieved by strengthening the standard beyond the 0.070-0.075 ppm range put forward in the current ozone NAAQS proposal.

### Conclusion

EPA's decision to solicit public comment on retaining the current ozone standard is indefensible. As the expert CASAC ozone panel concluded, "there is no scientific justification for retaining the current primary 8-hr NAAQS of 0.08 parts per million (ppm)." Moreover, the range of 0.070 ppm to 0.075 offered in EPA's proposed revision to the primary ozone NAAQS remains inadequate to protect public health with an adequate margin of safety.

Based upon the compelling scientific evidence of the adverse health effects of ozone air pollution at levels below the proposed range, we recommend that the EPA set the eighthour primary ozone standard at 0.060 ppm. EPA's own risk assessment shows that issuing this more stringent standard would produce significant public health benefits in the form of decreased incidence of respiratory symptoms in children, fewer hospital admissions and reduced ozone-related mortality. To satisfy the requirements of the Clean Air Act and to protect the health of children, the elderly, people with lung disease and other susceptible groups, EPA must strengthen the primary ozone standard to 0.060 ppm.

Thank you for your consideration of our concerns.

## **SIGNING ORGANIZATIONS**

American Heart Association
American Lung Association
American Nurses Association
American Public Health Association
Health Care Without Harm
Institute for Children's Environmental Health
National Association of County and City Health Officials
Physicians for Social Responsibility
Science and Environmental Health Network
Trust for America's Health

<sup>1</sup> U.S. Environmental Protection Agency (EPA). National Ambient Air Quality Standards for Ozone. 72 Fed. Reg. 132 (July 11, 2007).

<sup>2</sup> 42 U.S.C. § 7409 (b)(1).

<sup>3</sup> Lead Industries Assn. v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980)

<sup>4</sup> American Ling Association v. EPA, 134 F.3d 388, 390 (D.C. Cir. 1998). See also: Lead Industries Assn Inc. v. EPA, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

<sup>5</sup> Testimony of Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency before the U.S. Senate Environment and Public Works Committee, Subcommittee on Clean Air and Nuclear Safety, July 11, 2007.

<sup>6</sup> U.S. EPA, OAQPS Staff Paper: Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information (January 2007).

<sup>7</sup> Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency re Clean Air Scientific Advisory Committee's (CASAC) Review of the Agency's 2<sup>nd</sup> Draft Ozone Staff Paper; October 24, 2006; EPA-CASAC-07-001.

<sup>8</sup> Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency re Clean Air Scientific Advisory Committee's (CASAC) Review of the Agency's Final Ozone Staff Paper; March 26, 2007; EPA-CASAC-07-002.

<sup>9</sup> Medina-Ramon M, Zanobetti A, Schwartz J. The effect of ozone and PM10 on hospital admissions for pneumonia and chronic obstructive pulmonary disease: a national multi-city study. *Am J of Epidemiol* 2006; 163: 579-588.

<sup>10</sup> Peel JL, Tolbert PE, Klein M, Metzger KB, Flanders WD, Knox T, Mulholland JA, Ryan PB, Frumkin H. Ambient air pollution and respiratory emergency department visits. *Epidemiology* 2005; 16: 164-174.

<sup>11</sup> Triche EW, Gent JF, Holford TR, Belanger K, Bracken MB, Beckett WS, Laeher L, McSharry J-E, Leaderer BP. Low-Level Ozone Exposure and Respiratory Symptoms in Infants. *Environ Health Perspect*. Published online 29 December 2005.

<sup>12</sup> Gent JF, Triche EW, Holford TR, Belanger K, Bracken MB, Beckett WS, Leaderer BP. Association of low-level ozone and fine particles with respiratory symptoms in children with asthma. *JAMA* 2003; 290: 1859–1867.

<sup>13</sup> Gilliland FD, Berhane K, Rappaport EB, Thomas DC, Avol E, Gauderman WJ, London SJ, Margolis HG, McConnell R, Islam KT, and Peters JM. The Effects of Ambient Air Pollution on School Absenteeism due to Respiratory Illnesses. *Epidemiology* 2001; 12(1):43-54.

<sup>14</sup> Mudway IS, Kelly FJ. An investigation of inhaled ozone dose and the magnitude of airway inflammation in healthy adults. *Am J Respir Crit Car* Med 2004; 169: 1089-1095.

<sup>15</sup> Adams WC. Comparison of chamber and face mask 6.6-hr exposure to ozone on pulmonary function and symptoms responses. *Inhalation Toxicol* 2002; 14: 745-764.

Devlin RB, McDonnell WF, Mann R, Becker S, House DE, Schreinemachers D, Koren HS. Exposure of humans to ambient levels of ozone for 6.6 hrs causes cellular and biochemical changes in the lung. *Am J Respir Cell Mol Biol* 1991; 4: 72-81.

<sup>17</sup> Horstman DH, Folinsbee LJ, Ives PJ, Abdul-Salaam S, McDonnell WF. Ozone concentration and pulmonary response relationships for 6.6-hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis* 1990; 142(5):1158-1163.

<sup>18</sup> Park SK, O'Neill MS, Vokonas PS, Sparrow D, and Schwartz J. Effects of Air Pollution on Heart Rate Variability: The VA Normative Aging Study. *Environ Health Perspec* 2005; 113: 304-309.

<sup>19</sup> Rich DQ, Mittleman MA, Link MS, Schwartz J, Luttmann-Gibson H, Catalano PJ, Speizer FE, Gold DR, and Dockery DW. Increased Risk of Paroxysmal Atrial Fibrillation Episodes Associated with Acute Increases in Ambient Air Pollution. *Environ Health Perspec 2006*; 114: 120-123.

<sup>20</sup> Henrotin JB, Besancenot JP, Bejot Y, Giroud M. Short-term effects of ozone air pollution on ischaemic stroke occurrence: a case-crossover analysis form a 10-year population-based study in Dijon, France. *Occup Environ Med* 2007; 64: 4439-445.

<sup>21</sup> Ruidavets J-B, Cournot M, Cassadou S, Giroux M, Meybeck M, Ferrières J. Ozone Air Pollution is Associated with Acute Myocardial Infarction. *Circulation* 2005; 111: 563-569.

<sup>22</sup> Koken PJ, Piver WT, Ye F, Elixhauser A, Olsen LM, Portier CJ. Temperature, air pollution, and hospitalization for cardiovascular diseases among elderly people in Denver. Environ Health Perspec 2003; 111: 1312-1317

<sup>23</sup> Bell ML, Dominici F, Samet JM. A meta-analysis of time-series ozone and mortality with comparison to the national morbidity, mortality, and air pollution study. Epidemiology 2005; 16: 436-445.

<sup>24</sup> Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F. Ozone and short-term mortality in 95 U.S. urban communities, 1987-2000. JAMA 2004; 292: 2372-2378.

<sup>25</sup> Ito K, DeLeon SF, Lippmann M. Associations between ozone and daily mortality: analysis and metaanalysis. *Epidemiology* 2005; 16: 446-457.

<sup>26</sup> Schwartz J. How sensitive is the association between ozone and daily deaths to control for temperature?

Am J Respir Crit Care Med 2005; 171: 627-631.

27 Committee on Environmental Health, American Academy of Pediatrics. Ambient air pollution: health hazards to children. Pediatrics 2004; 114: 1699-1707.

<sup>28</sup> Pediatric Environmental Health, 2<sup>nd</sup> Ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003; 74-75.

<sup>29</sup> Diertert RR, Etzel RA, Chen D, Halonen M, Holladay SD, Jarabek AM, Landreth K, Peden DC, Pinkerton K, Smialowicz RJ, Zoetis T. Workshop to identify critical window of exposure for children's health: immune and respiratory systems work group summary. Environ Health Perspect 2000; Suppl 108(3): 483-490.

<sup>30</sup> Burnett RT, Smith-Doiron M, Stieb D, Raizenne ME, Brook JR, Dales RE, Leech JA, Cakmak S, Krewski D. Association between ozone and hospitalization for acute respiratory diseases in children less than 2 years of age. *Am J Epidemiol* 2001; 153: 444-452.

Tolbert PE, Mulholland JA, MacIntosh DL, Xu F, Daniels D, Devine OJ, Carlin BP, Klein M, Dorley J,

Butler AJ, Nordenberg DF, Frumkin H, Ryan PB, White MC. Air quality and pediatric emergency room visits for asthma in Atlanta, Georigia, USA. Am J Epidemiol 2000; 151: 798-810.

<sup>32</sup> Tager IB, Balmes J, Lurmann F, Ngo L, Alcorn S, Kunzli N. Chronic exposure to ambient ozone and lung function in young adults. *Epidemiology* 2005; 16: 751-759.

<sup>33</sup> Salam MT, Millstein J, Li Y-F, Lurmann FW, Margolis HG, Gilliland FD. Birth outcomes and prenatal exposure to ozone, carbon monoxide, and particulate matter: results from the children's health study. Environ Health Perspec 2005: 113: 1638-1644.

<sup>34</sup> 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.

<sup>35</sup> U.S. EPA. Air Quality Criteria for Ozone and Related Photochemical Oxidants (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/004aF-cF, 2006.

<sup>36</sup> 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.

<sup>37</sup> Brauer M, Brumm J, Vedal S, Petkau AJ. Effect of ambient ozone exposure on lung function in farm workers. Am J Respir Crit Care Med 1996; 154: 981-987.

<sup>38</sup> Korrick SA, Neas LM, Dockery DW, Gold DR, Allen GA, Hill LB, Kimball KD, Rosner BA, Speizer FE. Effects of ozone and other pollutants on the pulmonary function of adult hikers. Environ Health Perspect 1998; 106: 93-99.

<sup>39</sup> Adams WC. Comparison of chamber 6.6h exposures to 0.04-0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhal Toxicol* 2006; 18: 127-136.

<sup>40</sup> Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F, Ozone and short-term mortality in 95 U.S. urban communities, 1987-2000. JAMA 2004; 292: 2372-2378.

<sup>41</sup> Letter from the American Lung Association, American Academy of Pediatrics, American Public Health Association, et al. to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency re Science Review Compels Stricter NAAQS for Ozone; April 16, 2007.

<sup>42</sup> Letter from Dr. Melanie A. Marty, Chair, Children's Health Protection Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency re Review of the NAAQS for Ozone: Policy Assessment of Scientific and Technical Information; March 23, 2007.

<sup>43</sup> Letter from Jonathan I. Levy, ScD, Kent Pinkerton, PhD, William Rom, MD, MPH, et al. to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency re Broad Scientific Consensus to Lower Ozone Air Quality Standard and Close the Rounding Loophole: April 4, 2007.