John F. "Jack" Sutter
Chair

Terri E. Weaver, Ph.D.
Chair-elect

Charles A. Heinrich
Past-Chair

Robert A. Green, M.D.
Vice-Chair

James M. Anderson
Secretary

William Kowalewski
Treasurer

John L. Kirkwood
President &
Chief Executive Officer

NATIONAL HEADQUARTERS

61 Broadway
New York, NY 10006-2701
phone: (212) 315-8700
fax: (212) 315-8800

1150 18th Street, NW
Suite 900
Washington, DC 20036-3816
phone: (202) 785-3355
fax: (202) 452-1805

For over 100 years, the nationwide American Lung Association has worked in the fight against lung disease.

www.lungusa.org

1-800-LUNG-USA
(1-800-586-4872)

Improving Life,
One Breath at a Time

AMERICAN LUNG ASSOCIATION.

Testimony of Dr. John Balmes on Behalf of the American Lung Association and the American Thoracic Society

Before the Committee on Environment and Public Works, U.S. Senate

February 6, 2007

Testimony of Dr. John Balmes on Behalf of the American Lung Association and American Thoracic Society

February 6, 2007

Madame Chairman, members of the Committee, I am Dr. John Balmes. I am very pleased to be able to discuss with you today the most recent actions by the Environmental Protection Agency regarding the establishment of National Ambient Air Quality Standards (NAAQS) under the Clean Air Act. I am testifying today on behalf of the American Lung Association and the American Thoracic Society.

I speak to you today from the perspective of both a physician who treats patients with lung ailments and a researcher who studies the effects of air pollution on lung health. I understand the profound impact that air pollution can have on the health and lives of people. I also understand the importance of the review of scientific knowledge required by the Clean Air Act as to what limits to air pollution are necessary in order to protect public health with an adequate margin of safety.

I am here to express my alarm that the careful process for establishing and reviewing National Ambient Air Quality Standards (NAAQS) that EPA has developed to implement the Clean Air is being altered by this administration in ways that will weaken its effectiveness in the future. This process has proven to be enormously successful over the last three decades at achieving the goal of protecting the public health by improving our nation's air quality. In my view, the changes adopted under the guise of "streamlining" the NAAQS review process will weaken both the health protection the standards were intended to provide and diminish the scientific basis on which the standards were intended to rely.

The NAAQS Must be Based on Health

It is beyond dispute that the "primary" NAAQS standards are to be established exclusively to protect public health with an adequate margin of safety. The primary standard is to be set and revised without taking cost or achievability into account.[1] Further, the standards are to be reviewed and revised, as appropriate, every five years based on the latest scientific research and information available that are assembled in a Criteria Document for each criteria pollutant.

Why is this approach so important? Because the authors of the Clean Air Act knew that as our scientific understanding of air pollution evolved, the levels of protection initially established would be shown to be inadequate.[2] The only reliable and legitimate basis for tightening them would be where science, not cost or politics, found people were being harmed. Because the authors knew that scientific research would be uncertain as to what levels of pollutants would threaten public health, especially for sensitive subgroups like children or people with heart and lung disease, they required the standard protect the nation's populations with an adequate margin of safety. The concept was to err on the side of safety[3].

The approach enacted in the Clean Air Act has withstood the test of time. The Clean Air Act is considered by most people to be one of the most successful public health and environmental statutes enacted by Congress. Ambient levels of all criteria pollutants have been significantly reduced in spite of significant population and economic growth. Despite predictions, this progress has been achieved without unduly burdening the auto industry or any other sector of the

[1] Whitman v. American Trucking Association, 31 U.S. 457 (2001)

[2] In 1969 Dr. John Middleton, Director of the National Air Pollution Control Administration testified," We know from the criteria published for sulfur oxides, that at certain levels definite adverse effects occur in the lung. We also know that at a little lower level there are more subtle effects on the action of the lung…. But as science progresses, it is very likely we are going to find still other body chemical systems that are being affected, so the no-effect level always corresponds, you might say, to the limitations of scientific knowledge in this area…." Senate Committee on Public Works, *Legislative History of the Clean Air Act Amendments of 1970,* 93rd Cong., 2d Sess., 1974, p. 1185.

[3] The Senate Committee on Public Works Report states, "Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not identified.", *ibid,* p.410.

economy. Further, it is estimated that billions of dollars in health and other costs have been avoided as a result of lower levels of ambient air pollution

However, as predicted long ago, recent studies show that the health effects of particle pollution may be more far reaching than was previously understood. Particulate air pollution can affect the cardiovascular system as well as the lungs, triggering heart attacks and strokes. Lives are shortened not just by days or weeks, but by months or years. Air pollution targets not just the elderly, but also fetuses, infants, children and adolescents. People most at risk are not only those with asthma and other lung conditions, but also those with heart conditions and diabetes. Taken together, the people at risk represent a large fraction of the nation's population. Effects of ozone and particulate pollution are occurring at even lower concentrations than were previously believed to be harmful -- at levels below the current standards.

.

The Revised NAAQS Review Process Diminishes Scientific Input

Prior to the recent changes, the NAAQS process involved: development of a work plan for the review, establishment of review protocols, preparation of a draft criteria document which is subjected to multiple reviews by CASAC and the public, finalization of the Criteria Document, preparation of a risk assessment, also reviewed by CASAC, and finally the preparation and finalization of a staff paper which is also subject to CASAC and public review. All of this is done before a proposed standard is published and ultimately finalized.

Many regard the preparation and finalization of the Staff Paper, which is done by EPA's scientific staff, as the most crucial step. In this step, EPA's scientific staff synthesizes the

scientific information that has been reviewed in the Criteria Document in order to assess whether the existing standard meets the requirement of protecting public health with an adequate margin of safety, and, if not, to identify alternative standards that can. By tradition, if not by law, this step has been done by EPA scientific staff who are all civil servants, most with years of experience in interpreting the policy relevance of scientific studies of the health effects of air pollution. Traditionally, the Staff Paper is produced without the interference of politically appointed policy staff most of whom do not have extensive scientific backgrounds.

It is the elimination of the Staff Paper that we fear will lead to the diminishment of science in the standard setting process. The staff paper is to be replaced with a "Policy Assessment" which according to a memorandum by EPA's Deputy Administrator Peacock, "reflect the Agency's views, consistent with EPA's practice in other rulemakings."[4] However, the EPA does not set standards exclusively based on the protection of health using the latest scientific research in any other rulemaking. In sum, a unique standard demands a unique process, not EPA's "usual" practice. We believe the elimination of the Staff Paper is being done precisely because the science underlying protection of public health from air pollution is in conflict with what policy makers in EPA want to do in the implementation of the Clean Air Act. The elimination of the Staff Paper will make it easier for policy staff to fuzz the lines in public health protection and present the basis for alternative standards and the alternatives themselves in a way that favors the outcomes they are seeking rather than what the science says is needed. Substituting an Advanced Notice of Proposed Rulemaking for the Staff Paper will put policy makes at EPA and the White House in the driver' seat by enabling them to review and edit before it is reviewed by CASAC and the public.

[4] See www.epa.gov/ttn/naaqs/memo-process-for-reviewing-naaqs.pdf at p. 2.

It is no surprise that the American Petroleum Institute was the only organization to substantially attack the current Staff Paper and recommend its elimination and replacement with an Advanced Notice of Proposed Rulemaking in a letter the to the EPA NAAQS process Work Group.[5] Just one week later, this recommendation was included in the Work Group recommendation and subsequently adopted by Deputy Administrator Peacock.

The Science Shows That the NAAQS for Fine Particles and Ozone Must Be Tighter

The collision between the where the science is taking the NAAQS standards and where EPA's policy makers want to go could not be clearer when one considers the recently reviewed fine particle standard and the pending review of the ozone standard.

The EPA Administrator's decision regarding the fine particle NAAQS has been highly controversial because the ranges recommended by CASAC proposed tightening the annual NAAQS for PM 2.5 from 15 micrograms/ cubic meter to a level no higher than 14. One alternative included in the Staff Paper included a 12 microgram annual standard.[6] CASAC was so concerned that a failure to tighten the annual standard was outside the "scientifically" justifiable range that it took the unprecedented step of writing the Administrator to ask him to reconsider his decision.[7] While the Administrator has justified his decision based on the "uncertainty" of the scientific studies he considered, the American Lung Association and several states are challenging the decision in court.[8] In our view, given the need for protection of public health with an adequate margin of safety, the failure to tighten the annual standard for PM 2.5 is not based on the science and is not legal. We believe that the PM 2.5 Staff Paper's presentation

[5] Letter from Kyle B. Isakower to Lydia Wegman and Kevin Teichman, March 27, 2006.
[6] See www.epa.gov/ttn/naaqs/standards/pm/data/staffpaper_20051221.pdf.
[7] See www.epa.gov/sab.pdf/casac-ltr-06-03.pdf.
[8] American Lung Association *et al.* v. Environmental Protection Agency, U.S. Court of Appeals, D.C. Circuit, Docket No. 06-1411, December 22, 2006.

of a suite of alternatives all of which would tighten the fine particles standards was a major embarrassment to EPA policy staff and precipitated the review of the standard setting process culminating in the elimination of the Staff Paper.

The review of the NAAQS for ozone may, again, highlight a conflict between policy makers and the latest science. Recent research clearly shows that adverse effects are occurring at exposure levels below the current standard. This conclusion is clearly reflected in the closure letter issued by CASAC panel on which I serve. There was unanimous consensus that the original conclusion of the second draft Staff Paper that continuing the current standard could be considered a scientifically justifiable alternative was wrong. CASAC judged that there is scientific certainty that health effects of ozone at levels below the current standard occur and substantially impact public health. For example, thousands of people with asthma will have asthma attacks when ozone levels are at the current standard. These attacks can be prevented with a tighter standard. Therefore, I am pleased to see that the final Staff Paper on ozone, which was released last week, adopted most of the suggestions of CASAC and recommended that the ozone standard be tightened.[9] The dialogue between CASAC scientists and EPA scientists during the ozone review led to an improved Staff Paper that is based on scientific knowledge. We know, with certainty, that ozone harms public health at the current standard. We do not need to manufacture uncertainty. We await a final decision establishing an ozone NAAQS standard to see if, this time, sound science will prevail.

The Lead NAAQS Review Raises Additional Public Health Protection Concerns

As you may know, the review of the lead NAAQS is the first to be conducted under the new process established by Deputy Administrator Peacock. Because the new process was established

[9] See www.epa.gov/ttn/naaqs/standards/ozone/data/2007_01_ozone_staff_paper.pdf at p. 6-86.

after the Staff Paper for lead was already underway, the draft Staff Paper has been publicly released, but will not be revised. A Policy Assessment will be issued to replace it. However, a controversial proposal from the lead industry has already been inserted into the lead standard review. EPA has announced it is considering the alternative of eliminating lead as a criteria pollutant.[10] This action was first proposed by the lead battery industry to EPA during the review of the NAAQS setting process last summer.[11]

The lead Criteria Document found that lead is dangerous in much lower concentrations than was understood when EPA established the lead NAAQS in 1978. Indeed, the CD found that there is no lead level exposure that is considered safe.[12] Furthermore, the draft Staff Paper found that in 2002 over 13, 000 stationary sources were emitting 1,114 tons of lead per year into the air.[13] This included 50 battery production facilities located in 23 states emitting collectively 25 tons per year of lead. Finally, and most alarmingly, the draft Staff Paper found there appears to be "…significant 'under-monitoring' near known Pb emissions point sources."[14]

While no one disputes that the reduction of lead air pollution is one of the most significant accomplishments of the Clean Air Act, we do not see the scientific basis for eliminating lead as a criteria pollutant. It would be impossible to assess the impact of lead air pollution on health if lead were eliminated as a criteria pollutant with the attendant reduction in the already inadequate ambient air lead monitoring and the elimination of the periodic review of the scientific research on the health effects of lead air pollution required by the Clean Air Act.

The battery industry argues that alternative provisions of the Act provide for the continued regulation of lead emissions. Such an argument would substitute an outcome preferred by the

[10] See www.epa.gov/ttn/naaqs/standards/pb/data/pb_sp_1stdraft_120406.pdf at pp. 1-1 through 1-2.
[11] Letter from the Battery Council International to Lydia Wegman, Office of Planning and Standards, July 12, 2006.
[12] See www.epa.gov/ttn/naaqs/standards/pb/s_pb-cr-cd.html at p. E-16.
[13] See draft Staff Paper, p. 2-6.
[14] See draft Staff Paper, p. 2-47.

battery industry for the sound scientific review mandated by the Clean Air Act. We hope this is not the first of a succession of such efforts as EPA reviews other air quality standards in the future.

Restore the Role of Science to the NAAQS Process

As I have explained above, we believe that changes made in the NAAQS process diminish the role of science in the NAAQS review process. We believe restoring the Staff Paper and following science will help ensure that the public health will be protected from air pollution. Following the science is a central wisdom adopted into the Clean Air Act decades ago that has enormously benefited America's health.