The fouling of air due to the burning of fuels has long plagued the inhabitants of populated areas. After the industrial revolution, the emissions from factory smokestacks were added to the pollution resulting from cooking and household heating. The increased use of coal combined with local meteorological conditions in London produced the dense, smoky, foggy condition first referred to as "smog" by Dr. H. A. Des Vouex in the early 1900s.

Dr. Des Vouex organized British smoke abatement societies. Despite the efforts of these organizations, the problem grew worse and spread to other industrial centers during the first half of the twentieth century. In December 1930 a dense smog in Belgium’s Meuse Valley resulted in 60 deaths and an estimated 6,000 illnesses due to the combined effect of the dust and sulfur oxides from coal combustion. This event, and a similar one in Donora, Pennsylvania, received public attention but little response. Serious smog control efforts did not begin until a disastrous “killer smog” in London in December 1952 resulted in approximately 4,000 deaths.

The first major air pollution control victory was the regulation of high-sulfur coal burning in populated areas. The last life-threatening London smog incidents were recorded in the mid-1960s. Unfortunately, a new smog problem, linked to the rush hour traffic in large cities such as Los Angeles, was fast developing. This highly irritating, smelly, smoky haze—now referred to as photochemical smog—is caused by sunlight acting on air laden with nitrogen oxides, unburned hydrocarbons from automotive exhausts, and other sources. The resulting chemical reactions produce a variety of exotic chemicals that are very irritating to lungs and nasal passages—even at very low levels.

The Clean Air Act of 1963 was the first comprehensive U.S. legislation aimed at controlling air pollution from both stationary sources (factories and power plants) and mobile sources (cars and trucks). Under this law and its early amendments, regulations have been issued to establish maximum levels for both ambient air concentrations and emissions from tailpipes and smokestacks for common pollutants, such as sulfur dioxide, suspended particulates (dust), carbon monoxide, nitrogen dioxide, ozone, and airborne lead.

After years of debate Congress finally passed the 1990 Clean Air Act amendments. This complex piece of legislation includes more stringent standards and extends controls to many additional sources of air emissions. It was designed to improve air quality by the end of the twentieth century and to reduce the incidence of acid precipitation that occurs when nitrogen- and sulfur-oxide emissions return to earth hundreds of miles from their sources in the form of rain, snow, or fog laden with sulfuric and nitric acids. The 1990 amendments did not respond to concerns, expressed by many environmental health experts, that the standards for the maximum allowed ambient air levels of ground-level ozone and suspended particulates are too high.

Based on a controversial series of research reports, demands have been made for these levels to be made more stringent to protect the health of sensitive segments of the population, including children, asthmatics, and the elderly. In July 1997, with the support of the Clinton administration, the EPA announced its decision to significantly lower permissible ozone levels and to phase in a new, more restrictive standard for suspended particulate matter aimed at controlling smaller, presumably more toxic particles.

The following selections are excerpts from statements by Carol M. Browner and Daniel B. Menzel, which were included in extensive, contentious testimony at the series of congressional hearings held prior to the implementation of the new standards.
Statement of Carol M. Browner

Mr. Chairman, members of the Committee, I want to thank you for inviting me to discuss the Environmental Protection Agency’s (EPA) proposed revisions to the national ambient air quality standards for particulate matter and ozone.

On these two pollutants, over the past three and a half years, EPA has conducted one of its most thorough and extensive scientific reviews ever. That review is the basis for the new, more stringent standards for particulate matter and ozone that we have proposed in order to fulfill the mandate of the Clean Air Act.

On average, an adult breathes in about 13,000 liters of air each day. Children breathe in 50 percent more air per pound of body weight than do adults. For 26 years, the Clean Air Act has promised American adults and American children that they will be protected from the harmful effects of dirty air—based on the best available science. Thus far, when you consider how the country has grown since the Act was first passed, it has been a tremendous success. Since 1970, while the U.S. population is up 28 percent, vehicle miles travelled are up 116 percent and the gross domestic product has expanded by 99 percent, emissions of the six major pollutants or their precursors have dropped by 29 percent.

The Clinton Administration views protecting public health and the environment as one of its highest priorities. We have prided ourselves on protecting the most vulnerable among us—especially our children—from the harmful effects of pollution. When it comes to the Clean Air Act, I take very seriously the responsibility the Congress gave me to set air quality standards that “protect public health with an adequate margin of safety”—based on the best science available.

Mr. Chairman, the best available, current science tells me that the current standards for particulate matter and ozone are not adequate, and I have therefore proposed new standards that I believe, based on our assessment of the science, are required to protect the health of the American people.

The standard-setting process includes extensive scientific peer review from experts outside of EPA and the Federal Government. Under the law, we are not to take costs into consideration when setting these standards. This has been the case through six Presidential administrations and 14 Congresses, and has been reviewed by the courts. We believe that approach remains appropriate. However, once we revise any given air quality standard, it is both appropriate and, indeed, critical that we work with states, local governments, industry and others to develop the most cost-effective, common-sense strategies and programs possible to meet those new standards... .

Background

The Clean Air Act directs EPA to identify and set national standards for certain air pollutants that cause adverse effects to public health and the environment. EPA has set national air quality standards for six common air pollutants—ground-level ozone (smog), particulate matter (measured as \( \text{PM}_{10} \), or particles 10 micrometers or smaller in size), carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide.

For each of these pollutants, EPA sets what are known as “primary standards” to protect public health and “secondary standards” to protect the public welfare, including the environment, crops, vegetation, wildlife, buildings and monuments, visibility, etc.

Under the Clean Air Act, Congress directed EPA to review these standards for each of the six pollutants every 5 years. The purpose of these reviews is to determine whether the scientific research available since the last review of a standard indicates a need to revise that standard. The ultimate purpose is to ensure that we are continuing to provide adequate protection of public health and the environment. Since EPA originally set the national air quality standards (most were set in 1971), only two of EPA’s reviews of these standards have resulted in revised primary standards—in 1979, EPA revised the ozone standard to be less stringent; and in 1987, EPA revised the particulate matter standard to focus on smaller particles (those less than 10 micrometers in diameter), instead of all sizes of suspended particles.

By the early 1990’s, thousands of new studies had been published on the effects of ozone and there was an emerging body of epidemiological studies showing significant health effects associated with particulate matter. EPA was sued by the American Lung Association to review and make decisions on both the ozone and particulate matter standards. I directed my staff to conduct accelerated reviews of both standards... .

Rationale for EPA’s Proposed Revision of the Ozone Standards

Since the mid-1980’s, there have been more than 3,000 scientific studies published that are relevant to our understanding of the health and environmental effects associated with ground-level ozone. These peer-reviewed studies were published in independent scientific journals and included controlled human exposure studies, epidemiological field studies involving millions of people (including studies tracking children in summer camps), and animal toxicological studies. Taken as a whole, the evidence indicates that, at levels below the
current standard, ozone affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. Indeed, one of the groups most exposed to ozone are children who play outdoors during the summer ozone season.

Certain key studies, for example, showed that some moderately exercising individuals exposed for 6 to 8 hours at levels as low as 0.08 parts per million (ppm) (the current ozone standard is set at 0.12 ppm and focuses on 1-hour exposures) experienced serious health effects such as decreased lung function, respiratory symptoms, and lung inflammation. Other recent studies also provide evidence of an association between elevated ozone levels and increases in hospital admissions. Animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to ozone over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

As a result of these and other studies, EPA's staff paper recommended that the current ozone standard be revised from the current 1-hour form (that focuses on the highest “peak” hour in a given day) to an 8-hour standard (that focuses on the highest 8 hours in a given day). It also recommended setting an 8-hour standard in the range of 0.07 ppm to 0.09 ppm, with multiple exceedances (between one and five per year).

The CASAC [Clean Air Scientific Advisory Committee] panel reviewed the scientific evidence and the EPA staff paper and was unanimous in its support of eliminating the 1-hour standard and replacing it with an 8-hour standard. While I do not base my decisions on the views of any individual CASAC member (as a group they bring a range of expertise to the process), it is instructive to note the views of the individual members on these matters. While ten of the 16 CASAC members who reviewed the ozone staff paper expressed their preferences as to the level of the standard, all believe it is ultimately a policy decision for EPA to make. All ten favored a multiple exceedance form. Three favored a level of 0.08 ppm; one favored a level of either 0.08 or 0.09 ppm; three favored the upper end of the range (0.09 ppm); one favored a 0.09-0.10 range with health advisories when a 0.07 level was forecast to be exceeded; and two just endorsed the range presented by EPA as appropriate.

Consistent with the advice of the CASAC scientists and the EPA staff paper, we proposed a new eight-hour standard at 0.08 ppm, with a form that allows for multiple exceedances, by taking the third highest reading each year and averaging those readings over three years. We are asking for comments on a number of alternative options, ranging from eight-hour levels of 0.07 to 0.09 ppm to an option that would retain the existing standard. Just as a point of reference, based on our most recent analysis of children outdoors, when measuring the exposures and risks of concern, as well as the number of areas of the country that would be in “nonattainment” status, the current 1-hour ozone standard of 0.17 ppm is roughly equivalent to a 0.09 ppm 8-hour standard with approximately two to three exceedances.

We considered a number of complex public health factors in reaching the decision on the level and form proposed. The quantitative risk assessments that we performed indicated differences in risk to the public among the various levels within the recommended ranges, but they did not by themselves provide a clear break point for a decision. The risk assessments did, however, point to clear differences among the various standard levels under consideration. These differences indicate that hundreds of thousands of children are not protected under the current standard but would be under EPA’s ozone proposal.

Also, consistent with EPA’s prior decisions over the years, it was my view that setting an appropriate air quality standard for a pollutant for which there is no discernible threshold means that factors such as the nature and severity of the health effects involved, and the nature and size of the sensitive populations exposed are very important. As a result, I paid particular attention to the health-based concerns reflected in the independent scientific advice and gave great weight to the advice of the health professionals on the CASAC. To me, this is particularly important given the fact that one of the key sensitive populations being protected would be children. The decision to propose at the 0.08 ppm level reflects this, because, though it is in the middle of the range recommended for consideration by CASAC and the EPA staff paper, as a policy choice it reflects the lowest level recommended by individual CASAC panel members and it is the lowest level tested and shown to cause effects in controlled human-exposure health studies.

Finally, air quality comparisons have indicated that meeting a 0.08 ppm, third highest concentration, 8-hour standard (as proposed by EPA) would also likely result in nearly all areas not experiencing days with peak 8-hour concentrations above the upper end of the range (0.09 ppm) referred to in the CASAC and the EPA staff paper. Given the uncertainties associated with this kind of complex health decision, we believe that an appropriate goal is to reduce the number of people exposed to ozone concentrations that are above the highest level recommended by any of the members of the CASAC panel. The form of the standard we proposed (third highest daily maximum 8-hour average) appears to do the best job of meeting that goal, while staying consistent with the advice of the CASAC as a group, as well as the personal views of individual members.

It is also important to note that ozone causes damage to vegetation including:

- interfering with the ability of plants to produce and store food, so that growth, reproduction and overall plant growth are compromised;
- weakening sensitive vegetation, making plants more susceptible to disease, pests, and environmental stresses; and
- reducing yields of economically important crops like soybeans, kidney beans, wheat and cotton.

Nitrogen oxides is one of the key pollutants that causes ozone. Controlling these pollutants also reduces the formation of nitrates that contribute to fish kills and algae blooms in sensitive waterways, such as the Chesapeake Bay.

As part of its review of the ozone science, the CASAC panel unanimously advised that EPA set a secondary standard more stringent than the current standard in order to protect vegetation from the effects of ozone. However, agreement on the level and form of the secondary standard was not reached.
Rationale for EPA’s Proposed Revision to the Particulate Matter Standards

For particulate matter standard review, EPA assessed hundreds of peer reviewed scientific research studies, including numerous community-based epidemiological studies. Many of these community-based health studies show associations between particulate matter (known as PM) and serious health effects. These include premature death of tens of thousands of elderly people or others with heart and/or respiratory problems each year. Other health effects associated with exposure to particles include aggravation of respiratory and cardiovascular disease, including more frequent and serious attacks of asthma in children. The results of these health effects have been significantly increased numbers of missed work and school days, as well as increased hospital visits, illnesses, and other respiratory problems.

The recent health studies and a large body of atmospheric chemistry and exposure data have focused attention on the need to address the two major subfractions of PM10—“fine” and “coarse” fraction particles—with separate programs to protect public health. The health studies have indicated a need to continue to stay focused on the relatively larger particles or “coarse” fraction that are a significant component of PM10 and are controlled under the current standards. We continue to see adverse health effects from exposures to such coarse particles above the levels of the current standards. As a result, CASAC scientists were unanimous that existing PM10 standards be maintained for the purpose of continuing to control the effects of exposure to coarse particles.

However, a number of the new health and atmospheric science studies have highlighted significant health concerns with regard to the smaller “fine” particles, those at or below 2.5 micrometers in diameter. These particles are so small that several thousand of them could fit on the type-written page at the end of a sentence. In the simplest of terms, fine particles are of health concern because they can remain in the air for long periods both indoors and outdoors contributing to exposures and can easily penetrate and be absorbed in the deepest recesses of the lungs. These fine particles can be formed in the air from sulfur or nitrogen gases that result from fuel combustion and can be transported many hundreds of miles. They can also be emitted directly into the air from sources such as diesel buses and some industrial processes. These fine particles not only cause serious health effects, but they also are a major reason for visibility impairment in the United States in places such as national parks that are valued for their scenic views and recreational opportunities. For example, visibility in the eastern United States should naturally be about 90 miles, but has been reduced to under 25 miles.

EPA analyzed peer-reviewed studies involving more than five and a half million people that directly related effects of “fine” particle concentrations to human health. For example, one study of premature mortality tracked almost 300,000 people over the age of 30 in 50 U.S. cities.

Based on the health evidence reviewed, the EPA staff paper recommended that EPA consider adding “fine particle” or PM2.5 standards, measured both annually and over 24 hours. The staff paper also recommended maintaining the current annual and/or 24-hour PM10 standards to protect against coarse fraction exposures, but in a more stable form for the 24-hour standard. This more stable form would be less sensitive to extreme weather conditions.

When CASAC reviewed the staff paper, 19 out of 21 panel members recommended establishment of new standards (daily and/or annual) for PM2.5. They also agreed with the retention of the current annual PM10 standards and consideration of retention of the 24-hour PM10 standard in a more stable form.

Regarding the appropriate levels for PM2.5, staff recommended consideration of a range for the 24-hour standard of between 20 and 65 micrograms per cubic meter (μg/m3) and an annual standard to range from 12.5 to 20 μg/m3. Individual members of CASAC expressed a range of opinions about the levels and averaging times for the standards based on a variety of reasons. Four panel members supported specific ranges or levels within or toward the lower end of the ranges recommended in the EPA staff paper. Seven panel members recommended ranges or levels near, at or above the upper end of the ranges specified in the EPA staff paper. Eight other panel members declined to select a specific range or level.

Consistent with the advice of the EPA staff paper and CASAC scientists, in November [1996] I proposed adding new standards for PM2.5. Specifically, based on public health considerations, I proposed an annual standard of 15 μg/m3 and a 24-hour standard of 50 μg/m3. In terms of the relative protection afforded, this proposal is approximately in the lower portion of the ranges or options recommended by those CASAC panel members who chose to express their opinions on specific levels. However, taking into account the form of the standard proposed by EPA, we understand that the proposal would fall into the lower to middle portion of the ranges or options. In order to ensure the broadest possible consideration of alternatives, I also asked for comment on options both more and less protective than the levels I proposed.

Also consistent with the advice of the EPA staff paper and CASAC scientists, I proposed to retain the current annual PM10 standard and to retain the current 24-hour PM10 standard, but with a more stable form. I also requested comment on whether the addition of a fine particle standard and the maintenance of an annual PM10 standard means that we should revoke the current 24-hour PM10 standard.

As has been the case throughout the 25-year history of environmental standard setting, uncertainty has played an important role in decisionmaking on the particulate matter standards. Specifically, the uncertainty about the exact mechanism causing the observed health effects has led some to argue that not enough is known to set new or revised standards. In this case, however, because of the strong consistency and coherence across the large number of epidemiological studies conducted in many different locations, the seriousness and magnitude of the health risks, and/or the fundamental differences between “fine” and “coarse” fraction particles, the CASAC scientists and the experts in my Agency clearly believed that “no action” was an inappropriate response. The question then became one of how best to deal with uncertainty—that is, how best to balance the uncertainties with the need to protect public health.
Given the nature and severity of the adverse health effects, I chose to meet the Congressional requirement of providing the public with an "adequate margin of safety," by proposing PM<sub>2.5</sub> standards within the ranges recommended in the EPA staff paper and commented upon in the CASAC closure letter. I believe the levels chosen reflect the independent, scientific advice given me about the relationship between the observed adverse health effects and high levels of fine particle pollution. That advice led to a proposed decision toward the lower end of the range of levels for the annual standard which is designed to address widespread exposures and toward the middle of the range for the 24-hour standard, which would serve as a backstop for seasonal or localized effects.

One final note on particulate matter. Some have suggested we need more research before decisions are made about these standards. I strongly support the need for continued scientific research on this and other air pollutants as a high priority. However, as we pursue this research, we must simultaneously take all appropriate steps to protect public health. We believe that tens of thousands of people each year are at risk from fine particles and I believe we need to move ahead with strategies to control these pollutants.

**Finding Common Sense, Cost-Effective Strategies for Implementing a Revised Ozone or PM Standard**

Throughout the 25-year history of the Clean Air Act and air quality management in the United States, national ambient air quality standards have been established based on an assessment of the science concerning the effects of air pollution on public health and welfare. Costs of meeting the standards and related factors have never been considered in setting the national ambient air quality standards themselves. As you can see from the description of the process I went through to choose a proposed level on ozone and particulate matter, the focus has been entirely on health, risk, exposure and damage to the environment.

I continue to believe that this is entirely appropriate. Sensitive populations like children, the elderly and asthmatics deserve to be protected from the harmful effects of air pollution. And the American public deserves to know whether the air in its cities and counties is unsafe or not; that question should never be confused with the separate issues of how long it may take or how much it may cost to reduce pollution to safe levels. Indeed, to allow costs and related factors to influence the determination of what levels protect public health would be to mislead the American public in a very fundamental way.

While cost-benefit analysis is a tool that can be helpful in developing strategies to implement our nation’s air quality standards, we believe it is inappropriate for use to set the standards themselves. In many cases, cost-benefit analysis has overstated costs. In addition, many kinds of benefits are virtually impossible to quantify—how do I put a dollar value on reductions in a child’s lung function or the premature aging of lungs or increased susceptibility to respiratory infection? Very often I cannot set a value and these types of health benefits are, in effect, counted as zero.

At the same time, both EPA and industry have historically tended to overstate costs of air pollution control programs. In many cases, industry finds cheaper, more innovative ways of meeting standards than anything EPA estimates. For example, during the 1990 debates on the Clean Air Act’s acid rain program, industry initially projected the costs of an emission allowance (the authorization to emit one ton of sulfur dioxide) to be approximately $1,500, while EPA projected those same costs to be $450 to $600. Today those allowances are selling for less than $100. . .

On the other hand, the Clean Air Act has always allowed that costs and feasibility of meeting standards be taken into account in devising effective emission control strategies and in setting deadlines for cities and counties to comply with air quality standards. This is certainly the case for any revision we might make to either the ozone or the particulate matter standards. This process has worked well. In fact, our preliminary studies indicate that from 1970 to 1990 implementation of the Act’s requirements has resulted in significant monetizable benefits many times the direct costs for that same period.

If we ultimately determine that public health is better served by revising one or both of these standards, the Clean Air Act gives us the responsibility to devise new strategies and deadlines for attaining the revised standards. In doing so, we are determined to develop the most cost-effective, innovative implementation strategies possible, and to ensure a smooth transition from current efforts.

To meet this goal, we have used the Federal Advisory Committee Act to establish a Subcommittee for Ozone, Particulate Matter and Regional Haze Implementation Programs. It is composed of almost sixty members of state and local agencies, industry, small business, environmental groups, other Federal agencies and other groups and includes five working groups comprised of another 100 or so members of these same kinds of organizations.

The Subcommittee and the various workgroups have been meeting regularly for well over a year working to hammer out innovative strategies for EPA to consider in implementing any revised standards. Members from industry, state governments and others are putting forward position papers advocating innovative ways to meet air quality standards. It is our belief that results from this Subcommittee process will lead us to propose innovative approaches for implementing any new standards. The Subcommittee will continue to meet over the next year to help develop cost-effective, common-sense implementation programs.

The issues being addressed by the Subcommittee include:

- What will be the new deadlines for meeting any new standards? [If EPA tightens a standard, it has the authority to establish deadlines of up to ten years—with the possibility of additional extensions—beyond the date an area is designated "nonattainment."]
- What will be the size of the area considered “nonattainment”? [If it revises an air quality standard, EPA has the ability to change the size
of the affected nonattainment areas and focus control efforts on those areas that are causing the pollution problems, not just the downwind areas that are monitoring unhealthy air.

- How do we address the problem of the pollutants that form ozone and/ or fine particles being transported hundreds of miles and contributing to nonattainment problems in downwind areas?
- What kinds of control strategies are appropriate for various nonattainment areas? Can we use the experience of the past several years to target those control strategies that are the most cost-effective?
- How can we promote innovative, market-based air pollution control strategies?

The implementation of these new standards is likely to focus on sources like trucks, buses, power plants and cleaner fuels. In some areas, as with the current standards, our analysis shows that reaching the standards will present substantial challenges. All of the air pollution control programs we are pursuing to meet the current ozone and particulate matter standards, as well as programs to implement other sections of the Clean Air Act, will help meet any revised standards. For example, the sulfur dioxide reductions achieved by the acid rain program will greatly help reduce levels of fine particles, particularly in the eastern United States. Cleaner technology in power plants would also greatly reduce the nitrogen oxides that help form ozone across the eastern United States. In fact, we believe that under certain comprehensive control strategies, more than 70 percent of the counties that could become nonattainment areas under a new ozone standard would be brought back into attainment as a result of a program to reduce nitrogen oxides from power plants and a large number of other sources. Programs underway to reduce emissions from cars, trucks, and buses will also help meet a revised particulate matter or ozone standard.

I intend to announce our proposals on implementation of the proposed new standards in phases that correspond to the Federal Advisory Committee Act Subcommittee’s schedule for deliberating on various aspects of the program. I expect to propose the first phase of that program at the same time that I announce our final decision on revisions to the ozone and particulate matter standards.

In announcing the proposed ozone and particulate matter standards last November, I directed my Office of Air and Radiation to further expand the membership of the Federal Advisory Subcommittee to include more representation from small business and local governments. Also, in conjunction with the Small Business Administration and the Office of Management and Budget, we are holding meetings with representatives of small businesses and small governments to obtain their input and views on our proposed standards.

There is one last point I would like to make on this matter. Critics of the proposals have been saying that meeting these proposed standards means widespread carpooling and the elimination of backyard barbecues, among other lifestyle changes. The broad national strategy is being developed by EPA, as I have described, with extensive input from industry, small business, state and local governments and others. While the ultimate decisions as to what programs are needed to meet air quality standards are up to the state and local governments, I would like to state categorically that there will not be any new federal mandates eliminating backyard barbecues or requiring carpooling. These kinds of claims are merely scare tactics designed to shift the debate away from the critical, complex public health issues we are attempting to address.

Conclusions

Mr. Chairman, I commend you for holding these hearings. The issues we are discussing today are critical to the state of the Nation’s public health and environment. It is imperative that the American public understand these important issues. In that regard, I am disappointed that some have chosen to distort this important discussion by raising distracting and misleading pseudo issues like “junk science” and “banning backyard barbecues.” I am hopeful that this and other hearings and public forums will help focus the national debate on the real health and environmental policy implications of these national air quality standards.

In the Clean Air Act, the Congress has given me the responsibility to review every 5 years the most recent science to determine whether revisions to national air quality standards are warranted. In doing so, the law tells me to protect the public health with an adequate margin of safety.

We are constantly reviewing the science associated with these standards, but we do not often propose revisions to them. I have done so in the case of ozone and particulate matter because of compelling new scientific evidence. For the past three and a half years we have targeted our resources to conduct a thorough, intensive review of this scientific evidence. The scope and depth of this review process has been based on unprecedented external peer review activities.

Given the sensitive populations affected by these pollutants—children, asthmatics, the elderly—as well as possible effects on outdoor workers and other healthy adults, it was my judgment that it was appropriate to propose standards that tended to fall in the lower end of the range of protection supported by my independent science advisors and recommended by experts in my technical offices. Based on the record before the Agency at the time of proposal, including the advice and recommendations of the CASAC panels, I concluded—subject to further consideration based on public comments—that the proposed standards were both necessary and sufficient to protect the public health, including sensitive populations, with an adequate margin of safety.

At the same time, I recognize that the proposed standards involve issues of great complexity and I look forward to receiving a broad range of comments from all affected and interested parties. As I have described, we have gone to unprecedented lengths to provide the public with opportunities to express their views on the proposed standards. We have also expressly requested comments on options (including alternative levels and forms of the
standards) that are both more protective and less protective than the levels we proposed.

Note

1. CASAC itself agreed that there are a continuum of effects—even down to background—and that there is no "bright line" distinguishing any of the proposed standards as being significantly more protective of public health.

Daniel B. Menzel

Statement of Daniel B. Menzel

My name is Daniel B. Menzel. I am Professor and Chair of the Department of Community and Environmental Medicine, University of California at Irvine, California. I have had more than 30 years' experience in research in air pollution and toxicology. My expertise centers in two areas: mechanisms of air pollution toxicity and mathematical modeling of toxicology, particularly deposition of air pollutants in the respiratory tract. I have served as a senior author on multiple EPA Criteria Documents and recently as a Consultant to the Clean Air Scientific Advisory Committee examining the Particulate Matter Criteria Document and proposed standard.

The Committee has requested that I provide my views on the ozone and particulate matter standards, which EPA has published in the Federal Register and intends to implement under the Clean Air Act. I am pleased to do that and would also like to extend my testimony to include the research effort of EPA because it directly affects the standard-setting process. I understand that the two standards present different problems in terms of the form of the standard, the scientific data supporting each standard and the process by which the standard was promulgated. In my view, however, there are similarities between the two standards that reflect a major deficiency in EPA's efforts. The common deficiency is the lack of solid scientific data. EPA is a grossly underfunded Agency given the scope of its responsibilities. EPA has not done well with its resources by not sustaining research to meet the long-term goals of the Agency. Thus, I hope that the committee will allow me to express my concerns about the research planning at EPA.

Air Pollution Is a Major Long Term Public Health Problem

Air pollution is a worldwide problem. In the United States air pollution is of such public health importance that it is critical that a national debate be undertaken on the future directions of air pollution research and regulation. This committee is providing a very valuable forum to the people so that they may learn more about the scientific controversy surrounding these two air pollutants and the alternative views that exist concerning the future of air pollution.
remediation efforts. I am at the moment writing a review of the toxicology of ozone.’ This will be the third review of ozone that I have written for the scientific literature. Almost ten years have elapsed since my last effort, and I was surprised and saddened to note on examining the literature that questions which we raised in the review in 1988 still remain unresolved. Much new human data has become available on ozone supporting a lower standard and shorter averaging time, but the book is far from closed on ozone. I also wrote the first part of the health section of the SO, (sulfur oxides) Particulate Matter Criteria Document for EPA in 1980. Many of the questions raised in that document also remain unanswered. As a consultant to the Clean Air Scientific Advisory Committee I assisted in the review of the current Particulate Matter Criteria Document. Not only were the fundamental questions raised in the original SO, Particulate Matter Criteria Document still existent, but new important questions arose for which we have no answer. All of these experiences suggest to me that a greatly enhanced and invigorated research effort in air pollution is needed if we are to make sound, reasonable and rational decisions on the implementation of clean air standards. If anything, air pollution research is now more important to the national public health than ever before.

Both the ozone and particulate matter standards have vast implications for the quality of life and the economy of the United States. It is my opinion that the vast majority of Americans support improving and enhancing the quality of their life by eliminating or decreasing air pollution. Americans are quite willing to shoulder the burden of cleaner air, cleaner water, and cleaner food if they can understand clearly the benefits to be gained by these activities. The confidence of the American people in the decisions being made on environmental issues is critical to the ability of this government to govern and implement these decisions. If ever the public loses confidence in the environmental strategies promulgated by the Federal Government then it will be impossible to carry out large national programs designed to eliminate or at least ameliorate the adverse effects of air pollution. I am very concerned that the Environmental Protection Agency and the Congress maintain the confidence of the U.S. public and demonstrate to the public their vigorous support for a better quality of life and clean air. Scientific truth is the only lasting commodity upon which decisions can be based.

Generic Issues

From my view the difficulties that we face with both the ozone and the particulate matter standard stem from generic issues in toxicology which must be addressed in a sound scientific manner. The first of these generic issues is a plausible biological mechanism of action for the particular pollutant. The second is the nature of the dose-response relationship. I will address each of these and give examples of how they-impinge upon the two standards that we are discussing today.

Plausible Biological Mechanisms

What is a plausible mechanism? We have learned a great deal about the quantitative nature of toxic reactions in the last 40 years. It is now possible to divide biological reactions to toxicants into several categories under which plausible mechanisms have been elucidated. A plausible mechanism of action for a toxin places the toxin within the context of our knowledge of disease processes. Having a plausible mechanism of action increases our confidence that health effects observed in animals will occur in humans. Understanding a mechanism of action also makes experiments more meaningful and relevant. In this forum it is not possible for me to elaborate in greater technical detail on how a plausible mechanism influences the experimental design and interpretation of the results of experiments. Experimental design and the concept of plausible mechanism of action are dealt with in standard textbooks of toxicology, such as "Casserett and Doull’s Fundamentals of Toxicology.”

A plausible mechanism of action is critically essential to controlled human exposure studies. The extrapolation from animal experiments to human exposures as they occur in nature, that is with free-living people, depends upon an intermediate link of controlled exposures of human volunteers to the toxin. We must have a clear idea of a plausible mechanism so that human studies can be developed with due care that no harm will ever result to the volunteers who courageously commit themselves to these kinds of experiments. In air pollution many of the human studies have been very limited because of the lack of a clear understanding of a plausible mechanism. Investigators have been very reluctant to engage in high level exposures of human subjects because they fear that some long-term harm will result from their experiments. Clearly, we cannot and will not tolerate human experimental studies that result in harm to the volunteer. This is simply not ethically acceptable.

Plausible Mechanism of Ozone Toxicity

One plausible mechanism of action of ozone is the production of free radicals by the reaction of ozone with cellular constituents. The free radical theory is that which we proposed in 1971. It is now clear that this mechanism of action is too naive and simplistic and clearly does not explain the consequences of chronic exposure to ozone. Studies with experimental animals clearly show that the results of a continuous or intermittent lifetime exposure to ozone are highly complex and are not predictable from the free radical hypothesis alone. Further experiments are needed with life-term exposures of experimental animals using the most modern molecular biology techniques. The complex pattern of lifetime ozone exposure must involve multiple signal transduction pathways. Simply put, the adverse health effects of chronic exposure to ozone are complex and beyond the free radical theory which we now recognize as accounting for the brief initial contact of ozone with the lung.

Chronic exposure is the critical issue in ozone exposure. EPA initiated and was carrying out an excellently conceived and implemented research program on the chronic effects of ozone in support of the current ozone standard. But
this research has stopped and support for ozone research by other Federal agencies has stalled. Basic research support for ozone by the National Institutes of Health and particularly the National Institute of Environmental Health Sciences (NIEHS), has fallen away. The scientific community is in error in allowing this to have happened.

Very compelling controlled human exposure experiments suggest that the current ozone standard (0.12 ppm) may be toxic. The short term exposures under which humans can be safely exposed do not allow us to study the chronic effects of ozone exposure. Epidemiologic studies are underway in the South Coast Air Basin, particularly those by Professor John Peters of the University of Southern California but this study is hampered because no quantitative biomarker of ozone health effects has been developed.

We would not be...engaging in this discussion if EPA's chronic ozone study in experimental animals had been carried out. Nor would we still have doubts about the ozone standard if ozone research had received a high priority in research support by the other Federal research agencies such as NIH and NSF.

In summary, there is a preliminary biologically plausible mechanism of action for ozone. The free radical theory is not comprehensive and does not explain all of the effects of chronic exposure to ozone. Much additional work is needed to understand the chronic effects of ozone.

**Particulate Matter**

In contrast to the ozone problem, no plausible biological mechanism of action has so far been proposed for particulate matter. It has been very difficult to demonstrate toxicity for particulate matter in experimental animals. In my laboratory and that of my colleagues at UCI we have not been able to show major toxicity with particulate matter at potencies approaching the levels reported from epidemiologic studies.

To place this problem in a more global context, urban particulate matter is a universal problem. Particulate matter seems to be a common result of human concentration in urban areas. To eliminate all of the particulate matter in our cities would, in my view, be only possible by the elimination of all human activity. Clearly this Draconian approach is not reasonable.

The studies of Schwartz and his colleagues have challenged our conclusions from experimental animal studies. These studies indicate that all particles regardless of their geographic origin have the same toxicity. It is well known that the chemical composition of the urban particles differ widely between geographic areas. For example, in the western US, especially in the South Coast Air Basin of Los Angeles and its environs, the chemical processes responsible for the formation of particulate matter depend on photochemical reactions. Nitric acid is the dominant end product. There are very few oxides of sulfur present because of the nature of the fossil fuels used in California. On the other hand, in the East Coast Corridor the consumption of sulfur-containing fuels is much greater, and the chemistry of the reactions leading to the formation of particulate matter is not as dependent upon photochemistry as it is upon chemical reactions. Sulfuric acid, not nitric acid, is the dominant end product present in particulate matter. The chemical nature of the particles formed in California are quite different from those of the East Coast Corridor. Yet the health effects measured by epidemiologic techniques suggest that all particles have the same effect despite the differences in chemical composition. This is a very troublesome problem. One of the basic tenets of toxicology is that the toxicity occurs via chemical reaction. How then can the same effect result from very different kinds of chemistries? We must conclude that there is no plausible mechanism now available for particulate matter which can account for the reported results.

**Particle Size and Site of Action of Respirable Urban Particles**

The toxicity of particles also depends on the site within the respiratory tract where they are deposited. A major advance has been the recognition of the dependence of toxicity on the site of deposition. The site of deposition in the respiratory tract depends, in turn, on the physical size of the particle. By measuring the amount of particles within the size range which can be deposited in the human lung, EPA adopted a biologically based criterion for its standard setting. This concept of defining particulate air pollution in terms of the size of particles most likely to be responsible for the adverse health effects is referred to as PM<sub>10</sub> where 10 refers to particles of 10 micrometers aerodynamic mass diameter or less. PM<sub>10</sub> is a fairly good surrogate measurement for the amount of material that would actually be inhaled and deposited in the human respiratory tract. Schwartz and his colleagues extrapolated from measured PM<sub>10</sub> values. PM<sub>10</sub> is a major advance in public health policy pioneered by EPA. The PM<sub>10</sub> concept shifts emphasis to particles of that size which are likely to be the most harmful to people. A network of PM<sub>10</sub> monitors has been constructed in the US and large amounts of data have been accumulated.

Schwartz and his colleagues went beyond PM<sub>10</sub> and extrapolated from a very limited set of measurements of PM<sub>2.5</sub> and PM<sub>10</sub> to estimate PM<sub>2.5</sub> values and to relate mortality and morbidity to particulate matter exposure smaller than PM<sub>10</sub> or particles less than 2.5 micrometers mass median aerodynamic diameter. Only a few data exist on the PM<sub>2.5</sub> exposure in our major cities. By shifting from PM<sub>10</sub> to PM<sub>2.5</sub> values, a major difference in the regional deposition within the lung of these particles is suggested as the site of action. The smaller the particle the more deposition occurs in the deeper parts of the lung. By assigning toxicity to particles in the PM<sub>2.5</sub> range the site of action is also assigned to the thoracic region of the lung. Because these PM<sub>2.5</sub> values are calculated and not measured, it is very difficult to place the heavy weight of evidence on this ultrafine particle range as EPA has done in its criteria document. Even with a shift in attention to particles of this size range, there is still no plausible mechanism for toxicity. Further, some of the CASAC members questioned the potency of the particles calculated from the mortality and morbidity data. All of this underscores the importance of the research program reviewed by CASAC as part of the particulate matter standard setting process.
Dose-Response Relationship

The dose-response relationship is a curve that relates the number of individuals responding with an adverse reaction (mortality, morbidity or the like) to a certain exposure concentration of the chemical. The shape of the dose-response curve is important when setting standards. All theories of the dose-response relationship so far indicate that these curves will be non-linear; that is, there will be a point at which the probability that a response would occur is very unlikely. To put it another way, all theories suggest that there is a concentration at which nothing will occur while above that concentration adverse effects will occur. The point at which there is nothing detectable is the threshold. The dose-response relationship is at the heart of the risk assessment. In both the particulate matter and ozone standard the dose-response relationship is only poorly understood. Consequently, estimates of risk are also uncertain. Examples for ozone and particulate matter follow.

The Particulate Matter Dose-Response Curve Is Linear Not Curved

The current assumption of epidemiologic studies is that the mortality or morbidity is a linear function passing through zero at zero concentration of particles. The dose-response function has no point at which no adverse effects occur. The linear dose-response curve is in opposition to all of the theories and experimental data derived for a host of chemicals acting by a variety of different mechanisms of action.

The epidemiologic basis for a linear relationship between effect and dose is very poor. The data are not supported by any kind of a generalized theory and are in many cases a default assumption coming about because the epidemiologic data are weak. It is very difficult for epidemiologists to relate exposure to effect. The methodologies of epidemiology at present are insensitive to the concentration or exposure effect. This is especially true in ecological studies where indirect evidence is used for adverse health effects.

For example, the epidemiologic studies of particulate matter health effects depend upon death certificates and the coincidence of an increase in death with an increase in particulate matter exposure. These studies again provide no indication of how a person might have died from the exposure to particulate matter. The studies only associate the death with the exposure to particulate matter. Nonetheless, the increases in mortality associated with particulate matter are troublesome. If the magnitude of mortality suggested by these studies is correct, then we are faced with a major public health problem that demands immediate attention.

Time and Intensity Relationships in Ozone Health Effects

EPA initiated a time and intensity study in cooperation with the USSR. This program was well thought out and attacked the question of which variable is most important in determining the health effects of ozone. From the data that were generated by this study it appears that the intensity is the most critical factor rather than the duration of exposure for ozone toxicity. These studies of the time and concentration effects on ozone toxicity led to the current hypothesis upon which the proposed ozone standard is based. If it is correct that the magnitude of the exposure is more important, then extremes of exposure should be reduced. One strategy to reduce exposure to extreme concentrations of ozone is to change the averaging time for the standard, making implementation plans stricter for short-term excursions. The US-USSR research program to study the time and concentration dependency of ozone adverse health effects was very productive and was progressing along a track which would, if continued, provide us a great deal of information at this time. Unfortunately, EPA chose to reduce and essentially eliminate this line of study. Extramural support for the program lagged and ozone in general has become an unpopular topic for support by other government agencies such as NIEHS.

Based on the fragmentary information that we have available, I feel that it is appropriate to support the EPA proposal of changing the averaging time for the ozone standard so that large excursions over short time periods will be eliminated or reduced. However, one should recognize that changing the averaging time will have a major impact on State implementation plans and will have major economic consequences. Clearly, understanding the nature of the dose-response relationship is very important and affects which alternatives we choose to reduce ozone health effects.

Time and Intensity Relationship for Particulate Matter Health Effects Are Unknown

As stated above, most time and intensity (dose and dose-rate) relationships for chemicals follow a simple relationship that the product of the dose rate and the time of exposure form a constant. This constant is arbitrary and unique for each chemical. Epidemiologic studies of the increases in mortality associated with increases in particulate matter are strictly linear with the amount of particulate matter. One reason why this assumption occurs is that a lag period has been assumed. The lag period means that the increases in mortality occurring 2 to 3 days after an exposure are related to the exposure to particulate matter, not earlier or later. The underlying hypothesis is that particulate matter toxicity is not immediately evident but occurs after this lag period. This very short acting time raises the question as to what happens when people are exposed to concentrations of particulate matter over the long term. We really have no data on the chronic effects in humans of exposure to particulate matter. Chronic exposure studies are very difficult to achieve using epidemiologic data.

To my knowledge there are no experimental animal data or controlled human studies which relate this kind of lag time to exposure to the toxicity of particulate matter. In my laboratory and that of my colleagues at UCI we have found that experimental animals such as the rat are very insensitive to particulate matter exposures. We have never observed potencies equivalent to that proposed for humans based on the epidemiologic data. This again raises the question of a plausible biological mechanism of action...
Conclusions

The Proposed Ozone Standard

It is my opinion that we will have achieved only marginal effects by decreasing the current ambient air quality standards for ozone from 120 parts per billion to 90 parts per billion. The nature of the dose-response relationship is such that it may still be at a linear range and thus reduction to much lower levels may be necessary to result in the abolition of detectable health effects from ozone. My colleague, Robert Wolpert, and I published a simple analysis of different kinds of dose-response relationships for ozone looking toward this very issue. How much would one have to reduce the ozone concentration in the air in order to be able to find a detectable advance in public health? Because the data are so sparse, a multitude of different kinds of theoretical treatments are possible. None of them, however, are sufficiently sensitive that one could lead to a clear prediction of a health benefit. On the other hand, as I mentioned above, a change in the time constant alone is going to have a great benefit. I endorse EPA's analysis of the time constant and think that EPA's proposal to a change in the averaging time for ozone is likely to be of benefit to the public health.

Still, I think that translating these changes into new State implementation plans may be very difficult. To translate both a change in the concentration, that is the amount of ozone that is permissible in the air and the duration over which it is permissible, will be a very difficult task indeed to implement. Continued research into the health effects of ozone are urgently needed. Further reductions in the ozone standard may be indicated in the near future. Because of the economic impact of ozone standards and strategies, the highest quality research is needed.

Particulate Matter Standard

As I have said previously, I do not doubt that the particulate matter problem is a very serious problem indeed. We need to place a very strong active and progressive research program into place in order for us to cope with this problem. It is my view that too little is known. In the report of the Clean Air Scientific Advisory Committee to Administrator Carol Browner, the committee pointed out that one of the areas in which additional research should be undertaken is chronic exposure.

I am not in favor of the use of a PM$_{2.5}$ standard. A viable network of monitoring instruments and sound research supports the PM$_{10}$ standard. The PM$_{2.5}$ standard has no background. There is no existing research quality PM$_{2.5}$ network. Without a research quality PM$_{2.5}$ network it is not likely that we will make much progress towards the goal of a new particulate matter standard. We lack information on the actual PM$_{2.5}$ in the atmosphere of our cities. We do not know the duration of exposure of people to PM$_{2.5}$. The chemical nature of the PM$_{2.5}$ fraction is poorly known. We lack a plausible biological mechanism for particulate matter. We do not know if regulation of PM$_{2.5}$ will be of benefit. A strong aggressive long-term research program is essential to address the current data deficiencies if we are to convince people that this is a major problem.

Notes

Is the Environmental Protection Agency’s Decision to Tighten Air Quality Standards for Ozone and Particulates Justified?

Analysis of the options that are available for reducing the health effects of air pollution is complex, and, like most technological problems related to environmental protection, it requires the use of many unprovable assumptions. The National Research Council’s Committee on Research Priorities for Airborne Particulate Matter, asked by Congress to assess research in this area, published Research Priorities for Airborne Particulate Matter I: Immediate Priorities and a Long-Range Research Portfolio (National Academy Press, 1998); Research Priorities for Airborne Particulate Matter II; Evaluating Research Progress and Updating the Portfolio (National Academy Press, 1999); and Research Priorities for Airborne Particulate Matter III: Early Research Progress (National Academy Press, 2001). A fourth volume updating the assessment is planned. A specific proposal for a new, costly set of regulatory standards requires a judgment about whether or not the analysis is based on an adequate set of valid research results and whether or not the interpretation of the results provides sufficient confidence that the benefits achieved will justify the expense. It is on this point—rather than the question of whether or not suspended particulate matter and ozone are serious health threats—that Browner, Menzel, and many other experts disagree. Menzel points out one serious problem with the proposal to base particulate matter standards on particles smaller than 2.5 microns rather than 10 microns: no system for monitoring the smaller particles exists. In announcing the actual schedule for implementing the new standards, the EPA acknowledged this problem and established a timetable associated with the development of the needed monitoring network.

One of the key research efforts that the EPA used in formulating the new particulate standard is the Harvard School of Public Health’s “Six Cities” study. For a report on epidemiologist Joel Schwartz’s role in directing that research, see Renée Skelton’s article “Clearing the Air” in the Summer 1997 issue of The Amicus Journal. Another debate about the new standards, featuring Lester B. Lave and Robert W. Crandall, was published in the Summer 1997 issue of The Brookings Review under the title “EPA’s Proposed Air Quality Standards.” For a lengthy denunciation of the new particulate and ozone standards and the scientific research on which they are based, see “Polluted Science,” by Michael Fumento, Reason (August/September 1997). For a summary of the Health Effects Institute study released in July 2000, see Jocelyn Kaiser, “Evidence Mounts That Tiny Particles Can Kill,” Science (July 7, 2000).

In “Who Will Be Protected by EPA’s New Ozone and Particulate Matter Standards?” Environmental Science and Technology (January 1, 1998), Feng Liu reports that some moderation would occur under the new regulations in the disproportionate effect of air pollution on Hispanics, Asians/Pacific Islanders, and African Americans. In the June 1, 1998, issue of the same journal, see Allen S. Lefohn, Douglas S. Shadwick, and Stephen D. Ziman, “The Difficult Challenge of Attaining EPA’s New Ozone Standard.”

On October 15, 1997, the EPA issued a report entitled The Benefits and Costs of the Clean Air Act, 1970 to 1990. On November 15, 1999, a second report was issued entitled The Benefits and Costs of the Clean Air Act, 1990 to 2010. Both concluded that the benefits of the programs and standards required by the 1990 Clean Air Act Amendments significantly exceed costs. See http://www.epa.gov/airlinks. However, on October 29, 1999, the U.S. Court of Appeals for the District of Columbia upheld a May 1999 court decision calling the EPA’s 1997 National Ambient Air Quality Standards (NAAQS) for ozone and particulates unconstitutional. See April Reese, “Bad Air Days,” E: The Environmental Magazine (November–December 1999) and Richard J. Pierce, Jr., “The Inherent Limits on Judicial Control of Agency Discretion: The D.C. Circuit and the Nondelegation Doctrine,” Administrative Law Review (Winter 2000) for criticism of the decision. In January 2000 New Jersey and Massachusetts asked the U.S. Supreme Court to review that decision. In February 2001 the Court “unanimously upheld the constitutionality of the Clean Air Act as EPA had interpreted it in setting health-protective air quality standards for ground-level ozone and particulates.” In March 2002 the D.C. Circuit Court rejected all remaining challenges to the EPA’s 1997 particulate and ozone standards, and the EPA declared its intent to “move forward with programs to protect Americans from the wide variety of health problems that these air pollutants can cause, such as respiratory illnesses and premature death.” Unfortunately, in June 2002 the discovery of a small error in the calculations of the risks of fine particulates threatened to reawaken the debate; see Jocelyn Kaiser, “Software Glitch Threw Off Mortality Estimates,” Science (June 14, 2002).

Much of the debate has centered on air quality standards, especially for particulates. Regulations to control downwind air pollution (mentioned by Browner) have also come under fire. Eastern states have demanded that the EPA enforce agreements that would reduce the amount of air pollutants emitted by Midwestern power plants, which travel on the wind and add to air quality problems in the East. Industry groups and states such as Michigan filed suits to block such reductions, but in June 2000 the U.S. Court of Appeals for the District of Columbia chose to allow the EPA to implement its plans. However, in June 2002 the EPA proposed to relax rules requiring old, high-emissions, coal-burning power plants to improve their emissions control systems when they undergo major upgrades. The announced rationale was to give utilities greater flexibility and to keep consumer electric bills down. Environmental groups immediately objected that the savings would not be worth the increased incidence of health problems.