THE WHITE HOUSE

WASHINGTON

February 18, 1997

MEMORANDUM FOR GENE SPERLING

FROM: ELGIE HOLSTEIN EH

RE: **Particulate Matter/Ozone**

Attached for your information is some additional background reading material on the PM/OZ issue.

AITKEN_S @ A1
02/13/97 09:11:00 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Chafee Suggests Compromise For Air Rules, Supports Commitmen

Chafee Suggests Compromise For Air Rules, Supports Commitment To Fine PM
Sen. John Chafee (R-RI), chairman of the Senate Environment and Public Works Committee, Feb. 12 threw his weight behind a proposed new air quality standard to regulate fine particulates, but urged the Environmental Protection Agency to delay setting the standard until more data is gathered.
In what has been characterized as a ``compromise'' on proposals to tighten regulations on ozone and PM, Chafee said EPA and lawmakers should commit to setting a new standard regulating particles 2.5 microns or less in diameter.
The proposal would set an annual standard of 15 micrograms per cubic meter (lg/m3) and a 24-hour standard of 50 (lg/m3).
Following a congressional hearing on the matter, Chafee told BNA that it appears substantial benefits could be gained from regulating these particles, although more time is needed to determine exactly where to set the standard.
Ozone, however, is a different matter, he said. Citing hospital data used by EPA in its ozone proposal, Chafee noted that only 120 hospital admissions in the New York area, out of more than 28,000, would be avoided each year under EPA's proposal. He questioned whether the substantial costs of the proposal would be justified by these results.
Browner Testifies
An aide to Chafee told BNA the proposed compromise included changing the existing one-hour ozone standard to an eight-hour standard, and setting it at a concentration level equivalent to the current standard. This level would be about 0.09 parts per million. The current one-hour standard is set at 0.12 ppm, while EPA has proposed an 8-hour standard set at 0.08 ppm.
Members of the Environment and Public Works Committee grilled EPA Administrator Carol M. Browner on the proposals for three hours during the Feb. 12 oversight hearing. Among other things, they questioned Browner about the science on which EPA relied for proposing the standards, potential costs of the proposals, and why EPA has not conducted impact analyses required under the Regulatory Flexibility Act, the Unfunded Mandates Act, and other statutes.
The hearing was the second in a series of oversight hearings on the proposals in both chambers of Congress. During a Feb. 5 hearing, members of the Environment and Public Works subcommittee on clean air looked into the state of the science behind ozone and PM.
EPA proposed new standards for ozone and particulate matter Dec. 13.
Bears And Barbecues
Browner attempted to dispel arguments raised by opponents of the standards that they will crimp the American lifestyle by requiring states to take actions such as banning the use of outdoor barbecues, lawn mowers, and fireworks on the Fourth of July. She said these arguments are baseless scare tactics that are designed to steer debate away from the public health impacts of the pollutants in question.

``It is not about backyard barbecues or lawn mowers,'' Browner said. Rather, she added, the standards are about ``whether a child can go outside on the Fourth of July'' to observe the fireworks.

Sen. Christopher S. (Kit) Bond (R-Mo) asked why EPA has not conducted impact analyses required by the Small Business Regulatory Enforcement Fairness Act and the Unfunded Mandates Act.

``I believe you are ignoring the letter of the law,'' Bond said. He said he does not accept EPA's argument that setting the standards does not impact businesses and other small entities, but rather the implementation of measures to meet the standards does. This, he said, is akin to a hunter shooting a bear and declaring that the bullet alone killed the animal, with no influence by the hunter's decision to aim the gun and pull the trigger. ``EPA is simply wrong,'' he said.

Browner countered that EPA had in fact conducted an impact analysis of the standards. Furthermore, she said, the analysis showed it is impossible to tell, before the standards are implemented, what the cost impacts will be on different sources. ``The problem, quite frankly, now is we don't know which bear . . . we have to analyze bear by bear,'' she said.

Democrats Defend EPA

Democrats on the committee defended EPA's proposals for the most part. Sen. Joseph Lieberman (D-Conn) said EPA simply is doing the job Congress required it to do under the Clean Air Act by proposing standards based solely on protecting public health. The only question for Congress, he said, is whether EPA is fulfilling that responsibility ``in a reasonable manner.''

Sen. Max Baucus (D-Mont), ranking Democrat on the committee, urged the rest of the panel to ``keep an open mind'' about EPA's proposals. They are not final actions, he said, adding that Congress should attempt to answer remaining questions before arriving at any judgment.

On the other hand, Sen. James Inhofe (R-Okla) urged Browner to take more time to research the health impacts of ozone and PM-2.5 before proceeding with a final rule. He also questioned whether EPA is rushing to judgment in revising the standards as a result of a court-ordered deadline of July 19 for the final rules (American Lung Association v. EPA, DC Ariz, No. 93-643, 2/4/97).

Browner said the deadline was the result of a schedule worked out with the litigants over several years. ``In no way does our desire to abide by a federal judge's order imply that we did not do the kind of detailed analysis required by the Clean Air Act,'' she said.

OMB Review

The court-ordered deadline, however, has interfered with a full review of EPA's proposals by the White House Office of Management and Budget, according to Sally Katzen, administrator of OMB's Office of Information and Regulatory Affairs.

Katzen, the only other witness to testify before the committee, said OMB received the proposals Nov. 4 and had to release them before the Nov. 29 deadline set for their completion. She said the agency gave the proposals ``top priority'' over other responsibilities.

``We were able to identify a number of issues that require further work, and while the court-ordered deadline precluded full discussion and resolution of these issues with EPA, we have been advised by EPA that some of these issues will be analyzed as part of the economic analyses that will be provided to us as part of the package for our review of the final standards,'' Katzen said.

Chafee asked Katzen whether OMB conducted an assessment of the feasibility

of the standards. She responded that OMB only reviews EPA's assessments, but added it did look at cost/benefit analyses the agency conducted. These analyses were based on using existing technologies, as EPA cannot foresee what types of more effective technologies or control strategies might emerge in the future, Katzen said.

She said these estimates are not very reliable. Moreover, she noted, estimating costs before an implementation strategy is developed ``could be potentially very misleading to the public.''

Senators Spar Over Impact

Chafee drew scathing remarks from a Democratic colleague for suggesting that EPA proposals to tighten air quality standards for ozone and particulate matter may undermine the public's support for the Clean Air Act.

Chafee said he feared the proposals may weigh too heavily on the public's will to accept clean air regulations because of their stringency.

``I think it is appropriate to ask whether the proposed standards . . . are the right measures or if they go too far--if they overload the Clean Air Act,'' Chafee said. ``Surely, we can find a way to work together to address the important public health concerns that the newest science indicates might be caused by air pollution without providing fuel for another round of attacks on our environmental laws,'' he told fellow members of the committee.

Sen. Joseph Lieberman (D-Conn), noting that he was ``very disappointed'' with Chafee's comments, said the Republican's observations are not believable. ``A revolt [against the Clean Air Act] by the American people based on the fact that we're trying to find a rational basis for protecting their health?'' he asked. ``I don't see it.''

Chafee, however, pointed out that several states had repealed inspection and maintenance programs for automobiles after receiving a substantial outcry from the public. ``When we talk about revolt, there is a perfect example,'' he said. ``If you push this thing too far too fast, there are going to be steps taken by the American public.''

-- By Alec Zacaroli

Agriculture

Message Sent To:

Donald R. Arbuckle
Michael A. Fitzpatrick
Jefferson B. Hill
Christopher D. Wolz
Randall W. Lutter

AITKEN_S @ A1
02/11/97 09:13:00 AM

Record Type: Record

To: Donald R. Arbuckle, Michael A. Fitzpatrick, Jefferson B. Hill, Randall W. Lutter

cc:
Subject: Federal Court Grants 3-Week Extension To EPA For Completion

Federal Court Grants 3-Week Extension To EPA For Completion Of Ozone, PM
A federal appeals court Feb. 10 gave the Environmental Protection Agency an additional three weeks to release a final decision on whether to revise the existing air quality standards for ozone and particulate matter (American Lung Association v. EPA, DC Ariz, No. 93-643, 2/10/97 </cite>). Under the new schedule, EPA must release its final decisions by July 19. The schedule also allows for an extension of the public comment period for the proposals by three weeks, setting a new deadline of March 12.
The court's action falls far short of EPA's hopes, however. The agency sought a 60-day extension from the court Feb. 4 after facing pressure from state governors and others to provide more time to comment on the proposals.
``Although we would have preferred more time, we will obviously comply with the court's order and complete the public comment period for proposed ozone and PM standards by March 12,'' EPA said in a Feb. 10 statement. ``The decision underscores the importance the court has placed on moving ahead in a timely manner to ensure that public health is protected.''
EPA had been under a court-ordered deadline of July 1 to release a decision on whether to revise the existing standards for ozone and particulates. The agency has proposed changing the existing ozone rule from a standard that sets a one-hour average concentration limit of 0.12 parts per million to one that sets an 8-hour limit of 0.08 ppm. EPA also has proposed setting a new standard regulating fine particles, or particles that are 2.5 microns or less in diameter.
Republican Warns EPA
Meanwhile, a House Republican warned EPA that its proposals will face both vigorous congressional oversight and judicial review unless the agency takes steps to comply with certain procedural requirements contained in recently enacted legislation.
Rep. David M. Mcintosh (R-Ind) said Feb. 10 that EPA ``appears to have failed to comply'' with provisions of the Congressional Review Act and the Unfunded Mandates Act, which among other things require agencies to assess the economic impact of regulations on small businesses and state and local governments. As a result, he said, EPA Administrator Carol M. Browner is ``on a collision course with common sense and ultimately this Congress.''
McIntosh chairs the House Government Reform and Oversight Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs, which has launched an inquiry into EPA's proposals. He made his comments during a meeting on the ozone and PM proposals sponsored by the American Enterprise Institute.
McIntosh told BNA following the meeting that his subcommittee will hold oversight hearings on whether EPA has met the procedural requirements of the Unfunded Mandates Act and the Congressional Review Act, which he called

Lester Lave, an economics professor at Carnegie Mellon University, criticized EPA's preliminary regulatory impact analyses on the rules for failing to consider their ecological benefits more thoroughly. ``Mortality drives everything,'' he said. Even accounting for ecological benefits, however, Lave agreed with EPA's estimates that the costs of a revised ozone standard will exceed its benefits, while the benefits of a new fine particulate matter standard will far outweigh its costs.
-- By Alec Zacaroli
Economic Policy

``right-to-know measures.'' The latter law allows Congress to review and possibly overturn major regulatory actions through fast-track legislation, although that legislation still would be subject to a presidential veto.

In an earlier speech at the meeting, Browner reiterated EPA's stance that economic impact questions raised under these and other laws governing the regulatory process do not come into play in the setting of science-based health standards. EPA is required by the Clean Air Act to consider environmental and health impacts, not cost, when setting the standards, she said.

``But that doesn't mean that there is no role for the practicalities of attaining these protections,'' Browner said. ``There is such a role when it comes to implementing the standards. In that case, it certainly is appropriate to consider costs.''

Clean Air Act Trumped?

McIntosh characterized the argument that the Clean Air Act prevents EPA from considering costs in setting health-based air quality standards as ``disingenuous.'' He noted that the laws he and other Republicans are urging EPA to follow were passed subsequent to the Clean Air Act. ``A later statutory provision will trump the earlier one,'' he said, adding, ``I am convinced the law requires them to do these measures.''

There are a number of measures Congress can take to address concerns over the economic impact of the ozone and PM proposals, McIntosh said. For instance, Congress could address the rules through the appropriations process, or through riders on other legislation. The review provisions of the Congressional Review Act are another vehicle opponents of the rules can use to block them.

These opponents, however, will have to forge a broad-based, well-funded coalition if they want to see the rules addressed by Congress, McIntosh said. In addition, they must put forth ``serious, constructive, free-market alternatives'' to the rules, he said. Without broad public support for legislative answers to concerns about the ozone and PM standard-setting process, Congress is not likely to act on the matter, he warned.

The courts, meanwhile, may provide a more favorable forum for opponents of the rule, McIntosh told BNA. He said congressional oversight of the rule-making process is likely to reveal EPA's failure to meet the requirements of the Unfunded Mandates Act, the Congressional Review Act, and other procedural requirements EPA must meet. EPA runs a serious risk of facing challenges under the Administrative Procedure Act if it continues to ``defy the law,'' he said. ``The agency should be aware of that,'' he said.

Other speakers at the event, meanwhile, also took the opportunity to attack EPA's efforts to conduct regulatory impact analyses of its proposals. Among other things, EPA's analysis of the benefits of setting a PM-2.5 rule do not account for the length of lives that would presumably be saved by the regulation, said Robert W. Crandall, a senior fellow with the Brookings Institution, a public policy and research group. For instance, he said, the agency's valuation of $4.8 million for each premature death avoided by the standard does not consider whether the person affected is elderly and ill or young and healthy.

Further, he said, EPA needs to engage in a ``risk/ risk'' comparison, under which it weighs the relative risk avoided through setting tighter standards against the risk that can be avoided by spending money in other areas, such as improving health care. McIntosh noted that EPA's preliminary cost estimate for the PM standard is $6 billion to $8 billion per year, and triple the cancer research budget of the National Institutes of Health.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

JAN 15 1997

The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman:

This is in response to your letter of December 16, 1996, regarding the Office of Information and Regulatory Affairs' (OIRA) review of the Environmental Protection Agency's (EPA) recently proposed revisions of the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter.

You asked for my response to four specific questions:

Question 1: According to section 6(b)(2)(B) of the Executive Order, the Office of Information and Regulatory Affairs (OIRA) is supposed to have up to 90 days to review "significant regulatory actions." This period of time is generally believed to be necessary to analyze complex draft regulations. Yet, it appears that OIRA had only about three weeks to review these very important rules despite advance knowledge of a judicial deadline of November 29, 1996 for Agency action.

a) **Please explain why these draft proposed regulations were not submitted to OIRA at a substantially earlier date in order to provide OIRA with a 90-day review period as contemplated in the Executive Order.**

Questions about the timing of EPA's submission of the proposed rules to OIRA can best be responded to by EPA.

b) **Please explain what efforts you made to ensure the submission of these proposed rules to OMB in time for a normal regulatory review as envisioned in the Executive Order.**

We originally expected EPA to submit the proposals in early September. As it became apparent that submittal of the proposals would slip, I made a number of requests to EPA to submit these proposals as soon as possible so as to provide OMB and other Federal agencies with time to properly review them.

c) **Given the short amount of time available to OIRA for review prior to the judicial deadline, please explain the extent to which OIRA was kept informed**

by EPA prior to formal submission of the various draft rules for OMB review, particularly with respect to (i) data, assumptions, models and analytic methods which were to be the foundation of the regulatory analysis; and (ii) the alternative standards under consideration.

A number of meetings were held over an extended period of time with EPA explaining in general terms the methodology it was using in its analysis of these two rules (e.g., data, assumptions, models, etc.). In addition, EPA and OIRA staff hosted a number of interagency meetings with EPA staff briefing other Federal agencies on the general issues surrounding EPA's review of the ozone and particulate matter NAAQS.

d) **The presence of an inflexible judicial deadline appears to have substantially curtailed OIRA's review of these important rules. Please explain whether, and to what extent, you believe that the judicial deadline adversely affected OIRA's ability to perform its regulatory review responsibilities under the Executive Order.**

During our discussions with EPA staff before the agency submitted the proposals, we identified a number of issues that were not resolved in the draft proposals submitted to OMB for review in early November. The abbreviated period of review required an intensified effort on our part and on the part of other agencies and EPA, and several issues were not able to be fully analyzed prior to publication of the proposals. We have been advised by EPA that these issues will be analyzed as a part of the Economic Analyses for the final rules.

Question 2: **Section 1(b) of the Executive Order sets forth a number of analytic and decision making principles that the Administration uses to guide regulatory decision making. Please explain the extent to which, in your view, these proposed regulations satisfied each of the principles set forth in this subsection of the Executive Order.**

Executive Order No. 12866 establishes twelve general "Principles of Regulation" that agencies should follow. (See the attached list of principles from the Executive Order.) A discussion of these principles as they apply to these proposals follows. We note that EPA will be preparing final Economic Analyses in response to comments on the proposals from the public and from other Federal agencies. These final Analyses will be available for Congress to refer to during its review process after promulgation of the standards.

(#1, 2, 12) EPA clearly identified the problem that it intends to address and the significance of this problem. Ozone and particulate matter air pollution is a problem of "market failure." Private markets fail to achieve optimal levels of pollution control because the benefits of pollution control do not primarily accrue to those who must pay the costs to control pollution. This classic economic problem of "externalities" is described clearly in the Economic Analyses

This problem is not caused by existing regulations. EPA clearly defined and described the proposed standards.

(#1,4,7) The Clean Air Act (CAA) requires EPA to review NAAQS every five years to ensure that they are protective of human health and the environment. As part of this process, EPA has completed comprehensive assessments of the peer-reviewed scientific literature on the public health and welfare (e.g., visibility and vegetation damage) effects of concern associated with these pollutants. These assessments were reviewed by the Clean Air Scientific Advisory Committee (CASAC), an independent review panel established by statute, with an opportunity for public comment during the Committee's review. While CASAC was concerned about scientific uncertainties that exist with regard to these effects and the lack of adequate research on fine particles, it concluded that EPA's assessments provide an adequate scientific basis for the Administrator to make policy decisions regarding revisions to the existing standards.

(#3, 5, 8, 11) NAAQS are set to protect public health with an adequate margin of safety and to protect public welfare from the adverse effects of the pollutants of concern. Under the law, EPA is not allowed to consider costs and other economic factors in setting health-based NAAQS. EPA and OMB are, of course, very concerned about the economic impacts of meeting any new standards and agree that Congress and the public should be fully informed as to the estimated costs and benefits that may result from their implementation. EPA's Economic Analyses were prepared under Executive Order No.12866 in order to inform the public about the expected benefits and costs of these standards as well as to guide implementation efforts to attain these standards in a cost-effective manner.

EPA has not proposed any specific compliance strategy or a specific set of control measures for complying with the new standards at this time; instead, it has indicated that it intends to propose an implementation strategy at a later date that incorporates recommendations from a subcommittee of the Clean Air Act Advisory Committee. The specific purpose of this subcommittee is to advise EPA on ways to develop innovative, flexible, practical, and cost-effective implementation standards to attain the proposed standard. Regarding distributional impacts, EPA has tailored the proposed standards to provide additional protection for sensitive subpopulations (e.g., outdoor exercising children, asthmatics, and the elderly). The analyses for these proposals did not address the distributional and equity effects of the rule.

(#9) EPA states in the preambles to both rules that the proposed revisions to the standards "will not in themselves impose any new expenditures on [state and local] governments" and thus EPA has not performed any analysis of effects on such governments. EPA recognizes that any corresponding revisions to associated State Implementation Plan requirements and air quality surveillance requirements may require additional expenditures. EPA has advised us that these effects will be addressed at the time such revisions are proposed and consultations with State and local governments will be conducted at that time.

(=6, 10) EPA has found it difficult to assess fully the costs and benefits of the proposed rules. Application of all known control measures would be insufficient to achieve compliance with the current ozone NAAQS in four metropolitan areas, and in 50 counties for the current PM NAAQS. The number of such "residual nonattainment areas" would increase significantly under the proposed standards. The cost estimates EPA presents in its Economic Analyses represent this "partial attainment" scenario based on currently identified measures with known costs that EPA considers likely to be implemented. EPA believes that new, cost-effective measures for reducing emissions of fine particles, NO_x, and VOCs will be developed in the future and will ultimately allow the residual nonattainment areas to come into compliance, but it has not estimated the costs of these as yet unknown measures. EPA also calculated benefits for the partial attainment scenario and found monetized benefits to be greater than costs for the proposed PM standard and less than costs for the proposed ozone standard.

There is also a potential overlap between control strategies to address ozone and particulates. For this reason, EPA intends to combine the implementation of the two standards to allow for efficient measures to reduce both particulates and ozone precursors simultaneously. However, EPA has not analyzed the extent to which the adoption of one of the two standards might reduce the benefits and costs of the other standard.

Question 3: Section 6(a)(3)(C) of the Executive Order sets forth certain requirements for the analysis of costs and benefits of "significant regulatory actions." On January 11, 1996, OMB published a guidance document entitled "Economic Analysis of Regulations Under Executive Order 12866," to guide agencies' fulfillment of these analytic requirements. This document describes the elements that agencies should include and the economic methods and practices that agencies should use in performing economic analyses under the Executive Order.

a) Please explain whether, and to what extent, EPA's economic analysis meets or fails to meet each of the significant technical requirements for economic analysis set forth in OMB's guidance document, entitled "Economic Analysis of Federal Regulations Under Executive Order 12866."

b) Please identify any and all technical errors in EPA's economic analysis discovered during OIRA's review which had, or may yet have, a material effect on the public's complete and clear understanding of the risks, costs, and benefits of these proposed rules.

The "Economic Analysis of Federal Regulations Under Executive Order No. 12866" lists three basic components of the prepublication "Best Practices" analysis of Federal regulations: a statement of need for the proposed action, an examination of alternative approaches, and an analysis of benefits and costs. The document includes a number of general principles and technical suggestions for each of these components; it is not intended to serve as a formulistic checklist.

Statement of Need for the Proposed Action

The Best Practices document suggests two general topics that should be discussed: the market failure, if any, that the regulation is designed to correct, and the appropriateness of solutions other than federal regulation, such as market mechanisms or state and local regulation. As discussed in response to question 2 above, EPA provided a discussion of the market failure which gives rise to the need for air quality standards. The CAA mandates Federal standards to address this problem and sets specific health-based criteria for standard-setting.

Examination of Alternative Approaches

The Best Practices document lists several different types of alternatives which should be considered where appropriate, including performance oriented standards, alternative levels of stringency, alternative effective dates of compliance, and informational measures.

Air quality standards are by their very nature performance standards. The Economic Analyses considered several different levels of stringency for both the ozone and PM proposals, but they did not evaluate some of the other types of alternatives listed above. For example, the current proposals do not include implementation schedules for attainment of the new standards; OMB has been advised that this issue will be addressed at the implementation stage. Finally, in the ozone proposal, EPA discussed the communication of public health information as a complement to the NAAQS, but did not consider or evaluate such an approach as an alternative to progressively more stringent NAAQS.

Analysis of Benefits and Costs

The agency conducted extensive analyses of the costs and benefits of the proposed standards These included sophisticated modeling efforts based on inventories of known emissions sources in which the agency attempted to identify, locality by locality, the most efficient set of control measures to attain the standards, the costs of these measures, and the resulting air quality improvements. These projected improvements then served as the basis for an assessment of potential health benefits, which were monetized by assigning dollar values to each health outcome. While these analyses were consistent with the Best Practices document and produced much useful information, there were several areas where additional work would have been productive; EPA has advised us that these areas, noted below, will be addressed in the Economic Analyses accompanying the final rules.

EPA's analytic baseline is compliance with the current NAAQS in 2007. For the ozone NAAQS, EPA did not disaggregate the cost of the control measures to meet the baseline. For the particulate standard, the 2007 baseline control measures and the associated costs were not presented. Finally, neither standard included adoption of the other in its baseline, which could result in an overstatement of benefits and costs of both rules.

EPA evaluated several alternative standards of differing stringency in its analysis of both NAAQS. In its ozone analysis, however, EPA presented an analysis of two options that "bracket" its proposed option, but not the proposed option itself. EPA prepared no quantitative analysis of the projected costs and benefits of its proposed "SUM06" secondary standard.

EPA frankly acknowledged that there is substantial scientific uncertainty in the risk analyses on which the benefits estimates are based. However, the analyses did not fully reflect the ranges of uncertainties associated with various assumptions and ad hoc adjustments in the models. In the case of fine particles, for example, the uncertainty attributable to the lack of an identified biological mechanism for the health effects of concern and the possibility of a threshold concentration below which there are no adverse effects were not reflected in the range of estimated benefits. For analyses as complex as these, it is difficult to document fully all assumptions. Nevertheless, there are several areas where additional clarification and sensitivity analyses would be helpful. For example, a large share of the estimated benefits are due to -- and sensitive to -- assumptions about improvements in air quality during off-peak periods, the periods in which most cumulative low-level exposure occurs. For the ozone standard, the basis of this "rollback" assumption is not clear, nor has the agency performed a sensitivity analysis, as it did for the particulate matter rollback assumptions.

As suggested in the Best Practices document, the analyses discussed several categories of benefits that have not been quantified or monetized. These include prevention of various respiratory symptoms; benefits to ecosystems, including plants and sensitive water bodies; prevention of materials damage and visibility improvements. In addition to monetized costs, there were also costs that have not been monetized. These include the administrative costs to states and local governments to plan and implement air quality programs. Finally, the analyses were presented in terms of annual benefits and costs, and neither costs nor benefits are discounted.

Question 4: According to press accounts summarizing EPA's recent announcements, the proposed new standards will result in costs to society of approximately $6.5 to $8.5 billion per year and annual benefits to society of $120 billion. Others have suggested that these figures may not be reliable. Based on OIRA's independent and objective analysis, please provide OIRA's best professional estimate of the expected costs and benefits of each of these proposed regulations presuming that each is fully implemented as proposed.

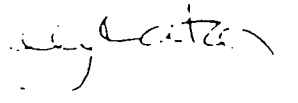
OIRA has not prepared its own estimate of the likely benefits and costs of attaining these proposals. We note, however, the following. As to costs, the estimate of approximately $6.5 to $8.5 billion per year is a combined estimate for both the ozone and particulate matter NAAQS. EPA estimated costs of $0.6 billion to $2.5 billion per year for the proposed ozone NAAQS and $6 billion per year for the proposed particulate matter NAAQS. Each of these estimates is for partial attainment. EPA did not estimate the costs of full attainment because it is not possible to estimate the costs of the as yet unknown measures that will be required to allow residual nonattainment areas to come into compliance.

As to benefits, the estimate of the benefits to society of $120 billion per year is a combined estimate for both the ozone and particulate matter NAAQS. EPA estimated benefits for partial attainment of the ozone NAAQS of approximately $30 million per year, with a range from $10 million to $1,200 million per year, and it estimated benefits for partial attainment of the particulate matter NAAQS of $60 billion to $120 billion per year.

As reported in the Economic Analyses for the proposals, there are a variety of ways in which these estimates may overstate or understate the benefits and costs of these proposals, including factoring in nonquantifiable costs and benefits, uncertainties, and efficiencies.

I hope that this fully responds to the questions you have on our review of EPA's ozone and particulate matter NAAQS.

Sincerely,



Sally Katzen

Enclosure

cc: The Honorable John Dingell

Principles of Regulation
Executive Order No. 12866

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the avail[illegible]

of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 21 1996

MEMORANDUM FOR DISTRIBUTION

FROM: EPA

SUBJECT: EPA's Proposed Ozone and Particulate Matter Public Health Standards

Issue for Consideration

Whether EPA should propose revisions to national air quality standards to ensure that these standards reflect the latest scientific knowledge and fully protect public health, most particularly for children and other at-risk individuals.

Overview

Under the Clean Air Act, EPA is required to set public health standards for certain fundamental air pollutants to assure the protection of public health with an adequate margin of safety. Pursuant to the law and court rulings, this public health decision is independent from any decisions regarding ultimate implementation strategies and costs. Once a public health standard is set, then a lengthy public process focuses on industry by industry, state by state, and city by city implementation mechanisms, taking into full account the cost of particular options.

An extensive, three-year, public scientific review, including multiple independent peer reviews, concluded that the current standards are not adequately protective of public health and that serious health risks arise -- particularly to children -- under the current ozone and particulate matter ("PM") standards. This scientific review process included both academic and industry scientists. The ozone external peer review panel found 185 relevant ozone health studies indicating that significant population groups were at risk under the current standard. The particulate matter scientific review panel found 67 of 86 relevant health studies indicated that the current standard was not protective.

Based on this extensive scientific review process, EPA recommends strengthening the ozone and particulate matter public health standards. This proposal, when culminated, will be a major and important step that will extend protections to 40 million children and help assure the health of some 133 million Americans. As with many EPA standards, its issuance is not without

controversy. Some will contend that we are acting precipitously and others will claim we are not being protective enough. We strongly believe, however, that the science is clear and results from an unprecedented independent process. Moreover, this unified proposal honors the requirement of the Clean Air Act to provide public health protections with a margin of safety.

In keeping with the reinvention goals of this Administration, in June of this year EPA delayed proposing the ozone standard until late November, allowing us thereby to merge the two proposals. This approach will allow us to speak to the common health effects, sources of pollution, and implementation strategies that arise from both standards.

It is important to note that the mere act of proposing -- or ultimately finalizing -- new health standards does not trigger any immediate regulatory requirements on any city, state, or business. Rather, these issues will be addressed in a lengthy, careful, and public process that can only occur once there is an indication of the precise level at which new standards will be set.

Public Health

Numerous peer-reviewed human health effect studies have found that the current standards are resulting in widespread adverse health effects in most large urban areas, including premature deaths, hospitalizations for respiratory illnesses, acute respiratory symptoms including severe chest pain, coughing and wheezing, aggravation of asthma, missed work and school days, and heightened susceptibility to other diseases. Since the standards were last revised, an increasingly large body of science points to particular risks to children, the elderly and people with respiratory problems. EPA believes that these health effects are unacceptable.

EPA's proposed new standards would result in:

- 20,000 lives saved annually;
- 450,000 - 650,000 fewer incidences annually of acute respiratory symptoms that can lead to missed work and school days, restricted activities and illness; and
- approximately 1.5 to 2 million fewer incidences annually of lung function decreases such as difficulty in breathing.

The ozone external peer review panel found 185 relevant ozone health studies indicating that significant population groups were at risk under the current standard. There was also consensus among the panel members that no bright line exists for ozone below which there will be no health effects. In other words, any ozone exposure above background has some health effects. The ozone standard consists of three interrelated variables; concentration, duration and form which determines the tolerance around the concentration. Merely altering any of those factors drastically changes the number of people at risk. While there was consensus among the panel members that the range of concentrations reviewed by EPA was appropriate, the panel concluded

inadequately characterized range of uncertainties of health risks at different standards

that selection of a specific level, to be measured on an eight hour basis, is a decision reserved to EPA based upon how many people to protect from what effects. Such policy judgment is ultimately driven by which subpopulations and what health effects EPA thought appropriate to address.

Policy judgment made in conjunction with risk assessment

Thus, pursuant to the Clean Air Act requirement of public health protection with an adequate margin of safety, EPA proposes a specific level of 0.08 ppm, which we believe is necessary to protect children and outdoor workers, particularly those with pre-existing respiratory disease.

While the panel members all agreed that the specific level was a policy judgment reserved to EPA, some, but not all, of the panel members did express their personal view to EPA. Of the eight of the sixteen who offered their personal views on the appropriate standard, they roughly split between .08 and .09 as appropriate. None at .07

In an effort to solicit public comment on this policy judgment, EPA's proposal to be published in the Federal Register does include a detailed discussion of what segments of the population would be protected and the degree to which health effects would be reduced at the .07, .08 and .09 levels. For example, the proposal details how many children and outdoor workers will be protected from increased severity of asthma attacks and other respiratory incidences at each level and solicits comment on the appropriateness of providing those protections.

— NOT IS FED REG NOTICE WE HAVE

Particulate: The particulate matter scientific review panel found that 67 of 86 relevant health studies -- some of which produced individual health data on hundreds of thousands of individuals -- indicated that the current standard was not protective. 19 of 21 members of this scientific advisory committee recommended setting a new standard to address finer particles than are presently addressed. 2.5 yes well/gen - no opinion

Litigation

Both the ozone and PM standard-setting processes have been subject to litigation brought by public health groups. During prior administrations, EPA scientists and other health experts had long believed that it was critical to conduct a thorough review of existing public health data on ozone and consider issuing tougher public health standards. Unfortunately, most recently the Bush-Quayle White House effectively prevented such a review.

When this Administration took over, it was under a court-imposed order to complete a review of the current ozone standard within three months. EPA had not, however, considered more than 2,000 potentially relevant peer-reviewed and published scientific studies regarding ozone. Recognizing that the Bush-Quayle Administration's review had been inadequate -- and

subject to litigation challenging EPA's failure to consider these studies -- EPA committed in a *Federal Register* notice (Attached as Appendix B), and subsequently in both the federal District Court and Court of Appeals for the D.C. Circuit, to undertake a thorough scientific review to be completed by mid-1996. While the Court of Appeals accepted EPA's proposed schedule, it also explicitly noted that the American Lung Association could file a motion for unreasonable delay if it became necessary in the future. The Lung Association has informed us of their intention to so proceed if EPA fails to act as promised by November 29th.

On particulate matter, the American Lung Association sued EPA to ensure prompt issuance of the standard. After litigation, the court in 1994 imposed a court-ordered deadline. In June 1996, EPA filed a notice in the *Federal Register* indicating that we would move forward with both the ozone and PM proposals together. This notice and the Court order specify November 29, 1996, for completing the scientific review and proposing and publishing any new standard, with a June 1997 deadline for final agency action.

In light of this history of aggressive litigation by public health groups on both the ozone and PM standards, it is absolutely clear that delay could lead to contempt or further litigation. Delay in issuing EPA's ozone proposal would almost certainly change the public perception from one where the Administration would have acted to propose strong public health protections, to one where we would be forced to do so in response to a lawsuit by the American Lung Association.

Implementation Strategies

Again, it is important to note that the mere proposal, or finalization, of new public health standards does not create, in and of itself, any new regulatory requirement. The mechanisms for achieving the public health standards will be developed over many years, with full public participation. EPA has already established and will expand its Clean Air Act Advisory Committee to facilitate dialogue and input from all. All individual implementation decisions will obviously be subject to full public comment. EPA is committed to working with other agencies, large and small businesses, state and local governments, and the public to develop a fair approach to implementing new standards. EPA is specifically committed to employing the assistance of a small business advisory panel in addressing implementation issues during the period between the proposal and finalization of new standards.

During the last four years, EPA -- working with industry and states -- has developed a number of new mechanisms for reducing air pollution. EPA believes the actions the Administration has accomplished and now has under development for other purposes will satisfy many of the new obligations that cities and industry may ultimately face. Important steps -- such as reducing toxic air emissions, controlling incineration, providing for cleaner gasoline and automobiles -- all will provide an important head start toward meeting new standards. We are

fully committed to continuing this outreach to develop successful common-sense and cost-effective strategies to implement new standards.

Furthermore, the history of clean air compliance in our nation has been a tribute to the ingenuity of industry to develop cost-effective strategies. As with the phaseout of choloroflourocarbons (CFCs) or the acid rain utility control provisions (where Congress contemplated allowances at $700-$1500 but at the latest auction they went for $70), initial industry estimates of pollution control costs were quickly disproven and cleaner air was achieved at much lower costs than initially predicted.

Cost/Benefit

While the Clean Air Act does not permit the consideration of costs during the health-based standard setting stage of the process, in keeping with EPA's desire to expand the use of cost/benefit as an important tool to assist in our work, EPA did conduct a regulatory impact analysis of these proposals.

Obviously such an analysis prior to finalization of specific standards and development of individual implementation strategies is speculative at best. While separate economic analyses were done for each standard, there will be significant overlap in implementation strategies by the joining of the standards leading to likely decreases in costs. Moreover, it is important to remember that historically, early cost estimates of compliance with the Clean Air Act have been far greater than reality. The regulatory impact analysis for both standards calculates combined costs of $6.6 billion to $8.5 billion and monetized benefits of $70 billion to $120 billion. Not included in the benefits estimates are health effects including premature aging of the lungs, lung function decreases, increased susceptibility to respiratory infection and environmental benefits such as improved visibility and ecosystem protection.

Conclusion

This Administration and this President have stood firm for, and prided themselves on, strong public health protections -- based on the best available science confirmed by peer review -- and employing reinvention to achieve common sense and cost-effective approaches that allow for sustained economic growth. This proposal will meet all of these commitments.

EPA's proposed health standards are about: extending protections to 40 million children; respecting thousands of hours of independent and scientific peer review; linking for the first time major pollution standards; and honoring the President's commitment to provide the public with the information to know about the health of its community.

EPA has worked hard during this Administration, in carrying out its extensive regulatory agenda, to make the OIRA review process and Executive Order 12866 a success. Some have suggested that allowing these proposals to move forward now will result in renewed Congressional interest in regulatory reform legislation. We firmly believe that whether or not this rule will spur regulatory reform efforts in Congress is far more likely to turn on the quality of the science and its attendant peer review and public comment processes -- which is unprecedented here -- than on whether OMB had a full review period at the conclusion of this three year rule development effort. Indeed, as Attachment C indicates, EPA has been consulting extensively with OMB and other agencies on review of these proposed standards since 1993, and we believe review could be accomplished during the current period.

We look forward to working with all in the Administration to honor the President's commitments to protect public health and the environment while ensuring strong economic progress for our nation.

PM — unprecedented
CASAC said too little review time

THE CLEAN AIR ACT SETS OUT A MODEL SCIENTIFIC PROCESS FOR REVIEWING AIR QUALITY STANDARDS

The Scientific Review for the NAAQS Proposal is Among the Most Thorough and Ambitious in EPA's History

- In reviewing the ozone and particulate matter standards, EPA started with a literature search of over 3,000 studies for each.
- Over a three-year process, the scientific process identified 185 human-health related studies of ozone, including controlled human studies, epidemiological studies and toxicological studies and 86 studies of links between particulate matter and human health, including epidemiological studies and toxicological studies
- These studies overwhelmingly indicated that neither the current ozone nor particulate matter standards adequately protect public health.

EPA Relies on Peer Reviewed Science and the Recommendation of Independent Scientists

- The Clean Air Act requires the Administrator of EPA to review and determine whether air quality standards are adequate to protect public health with an adequate margin of safety at least every five years.
- In reviewing the standards, the Act requires EPA to rely on the advice of an independent scientific review committee -- called the Clean Air Scientific Advisory Committee (CASAC).
- CASAC is made up of nationally recognized experts in many disciplines -- physicians, toxicologists, epidemiologists, atmospheric scientists -- from academia, industry and the states.
- EPA prepares two major documents for CASAC's consideration -- a criteria document that reviews the state of the science and a staff paper that attempts to interpret the science.
- The scientific review is extensively peer reviewed -- for a study to be considered for the criteria document, it must first appear in a peer review journal. National scientific experts peer review individual chapters of the criteria document before CASAC even considers them.
- CASAC peer reviews both the criteria document and the staff paper. Upon completion of its review, CASAC advises the Administrator as to whether the criteria document represents an adequate review of the available science and whether the staff paper constitutes an adequate basis for regulatory decisions.

The Scientific Review is a Public Process

- Drafts of the criteria document and the staff paper are made publicly available for review prior to the CASAC meetings where they are discussed.

- CASAC meetings are open to the public.

- EPA maintains a publicly available docket of all CASAC and standard-related proceedings. EPA also distributes this material through an extensive mailing list and over the Internet.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[FRL-4832-8]

Review of National Ambient Air Quality Standards for Ozone

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Notice of review.

SUMMARY: This notice announces the EPA's plans to review and revise the Air Quality Criteria for Ozone and Other Photochemical Oxidants (Criteria Document) as rapidly as possible and to complete review of the national ambient air quality standards (NAAQS) for ozone (O_3) as soon as possible thereafter.

The Clean Air Act (Act) requires periodic review and, if appropriate, revision of the NAAQS and of the air quality criteria on which they are based. The EPA completed its last formal review of the air quality criteria for O_3 in 1989. Based on that review, the EPA announced a final decision on March 9, 1993 not to revise the existing O_3 NAAQS.

Since early 1989, however, a substantial number of new studies on the health and environmental effects of O_3 have appeared in the peer-reviewed literature. The EPA is moving as rapidly as possible to review them, consistent with assuring a sound, scientifically-supportable decision.

The review process includes: (1) Reviewing and revising the Criteria Document; (2) reviewing the NAAQS through development of a Staff Paper based on the revised Criteria Document; (3) external review of Criteria Document and Staff Paper drafts by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board, an independent panel of scientific experts, and by the public; and (4) examining implementation ramifications of changes to the O_3 NAAQS. The EPA intends to adhere to strict schedules for external review of Criteria Document and Staff Paper drafts consistent with a full opportunity for thorough scientific and public review, and to deny any requests for extensions of the public comment periods specified in this notice.

During this NAAQS review, the EPA intends to continue implementing programs designed to meet the current standards and the requirements of the Clean Air Act Amendments of 1990 to ensure continued improvement in air quality. The EPA is also examining options for implementing alternative O_3 NAAQS to ensure a smooth transition if a decision is made to revise the existing NAAQS.

FOR FURTHER INFORMATION CONTACT: Dr. Karen Martin, Air Quality Management Division (MD-12), U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone (919) 541-5274.

SUPPLEMENTARY INFORMATION:

Background

Based on a Criteria Document issued by the Department of Health, Education and Welfare in 1970, the EPA promulgated the first NAAQS for photochemical oxidants under section 109 of the Act (36 FR 8186) in 1971. The primary and secondary NAAQS were both set at an hourly average of 0.08 parts per million (ppm) total photochemical oxidants not to be exceeded more than 1 hour per year.

In 1977, the EPA announced (42 FR 20493) the first review and updating of the 1970 Criteria Document in accordance with section 109(d)(1) of the Act. The EPA published a Criteria Document in 1978. Based on the revised Criteria Document and taking into account public comments on revisions proposed to the primary and secondary NAAQS in 1978 (43 FR 16962), the EPA announced revisions to the 1971 standards in 1979 (44 FR 8202). The primary standard was revised from 0.08 parts per million (ppm) to 0.12 ppm; the secondary standard was set identical to the primary standard; the chemical designation of the standards was changed from photochemical oxidants to O_3; and the form of the standards was revised from a deterministic form to a statistical form, which defines attainment of the standards as occurring when the expected number of days per calendar year with maximum hourly average concentrations greater than 0.12 ppm is equal to or less than one.

In 1982 (47 FR 11561), the EPA announced plans to revise the 1978 Criteria Document. In 1983, the EPA announced (48 FR 38009) that review of primary and secondary standards for O_3 had been initiated. The EPA subsequently provided a number of opportunities for public review and comment on drafts of the Criteria Document and associated Staff Paper (Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information—Office of Air Quality Planning and Standards Staff Paper). After reviewing the draft Criteria Document in 1985 and 1986, the CASAC sent the Administrator a "closure letter" outlining key issues and recommendations and indicating that it was satisfied with the final draft of the 1986 Criteria Document.

Following closure, a number of scientific articles and abstracts were published or accepted for publication that appeared to be of sufficient importance concerning potential health and welfare effects of O_3 to warrant preparation of a supplement to the Criteria Document (Supplement). The CASAC, having already reviewed two drafts of the Staff Paper in 1986 and 1987, concluded that sufficient new information existed to recommend incorporation of relevant new information into a third draft of the Staff Paper.

The CASAC held a public meeting in 1988 to review a draft Supplement and the third draft Staff Paper. Major issues included: The definition of adverse health effects of O_3; the significance of health studies suggesting that exercising individuals exposed for 6 to 8 hours to O_3 levels at or below 0.12 ppm may experience lung inflammation and transient decreases in pulmonary function; the possibility that chronic irreversible effects may result from long-term exposures to elevated levels of O_3; and, the importance of analyses indicating that agricultural crop damage may be better defined by a cumulative seasonal average than by a 1-hour peak level of O_3. In its "closure letter" of 1989, the CASAC indicated that the draft Supplement and draft Staff Paper "provide an adequate scientific basis for the EPA to retain or revise primary and secondary standards for ozone."

On October 22, 1991, the American Lung Association and other plaintiffs filed suit under section 304 of the Act to compel the EPA to complete its review of the criteria and standards for O_3 under section 109(d)(1) of the Act [*American Lung Association* v. *Reilly*, No. 91-cv-4114 (JRB) (E.D.N.Y.)]. The U.S. District Court for the Eastern District of New York subsequently issued an order requiring the EPA to sign a Federal Register notice announcing its proposed decision on whether to revise the standards for O_3 by August 1, 1992 and to sign a Federal Register notice announcing its final decision by March 1, 1993.

On August 10, 1992 (57 FR 35542), the EPA published a proposed decision under section 109(d)(1) that revisions to the existing primary and secondary standards were not appropriate at that time. The notice explained in some detail (see 57 FR 35546) that the proposed decision would complete the EPA's review of information on health and welfare effects of O_3 assembled over a 7-year period and contained in the 1986 Criteria Document and the 1989

Supplement. The notice made clear that the Administrator did not take into account more recent studies on the health and welfare effects of O_3 because these studies had not been assessed in the 1986–1989 Criteria Document/Supplement, nor had they collectively undergone the rigorous, integrative review process (including CASAC review) required to incorporate them into a new criteria document. The proposed decision, therefore, was based on an evaluation of key studies published through early 1989 as contained in the 1986–89 Criteria Document/Supplement, the 1989 Staff Paper assessment of the most relevant information in these documents, and the advice and recommendations of the CASAC as presented both in the discussion of these documents at public meetings and in the CASAC's 1986 and 1989 "closure letters."

In view of the large number of recent scientific papers and ongoing research on the health and welfare effects of O_3, the August 10, 1992 notice also announced the EPA's intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O_3. On March 9, 1993 (58 FR 13008) the EPA published its final decision not to revise the current primary and secondary NAAQS for O_3. Because of the scientific and technical complexity of such assessments, the EPA had estimated that 2 to 3 years would be necessary to rigorously assess more than 1,000 new studies and incorporate key information into a revised criteria document, to evaluate the significance of the key information for decision-making purposes, to develop staff recommendations for the Administrator, and to provide appropriate opportunities for CASAC review and public comment. Given the potential importance of the new studies and the EPA's continuing concern about the health and welfare effects of O_3, the March 9, 1993 notice also indicated the Administrator's intention to move the review process ahead as quickly as possible and, if appropriate, to propose revisions of the standards at the earliest possible date.

Current Review Process/Schedule

Following publication of the March 9, 1993 decision, the Agency, in consultation with the CASAC and the Science Advisory Board, undertook a rigorous examination of the NAAQS review process designed to identify all measures that could be taken to accelerate its review of the criteria and standards for O_3 consistent with assuring a sound and scientifically-credible decision. As a result, the EPA has adopted a number of measures intended to accelerate the O_3 NAAQS review. These measures include: (1) Conducting review and revision of the Criteria Document and development of the Staff Paper and associated analyses (e.g., exposure analysis and health risk assessments) in a more concurrent fashion than in the previous NAAQS reviews; (2) adhering to strict schedules for external review of Criteria Document and Staff Paper drafts consistent with a full opportunity for thorough scientific and public review; (3) establishing a highly-expedited Agency review process with senior level management oversight and involvement throughout the process, as well as early discussion of possible options with other Federal agencies, including the Office of Management and Budget; and (4) reducing the volume of information included in the revised Criteria Document by focusing on the most important new studies and setting a date beyond which new studies will not be included.

The EPA's current O_3 NAAQS review schedule incorporates the measures cited above. The Agency's target date for completion of the Criteria Document and Staff Paper is mid-1995, with proposal of changes to the O_3 NAAQS, if appropriate, in mid-1996 and promulgation in mid-1997. Table 1 outlines key milestone dates for this accelerated schedule.

As indicated in Table 1, there are a number of opportunities for public comment throughout the process. The EPA encourages involvement of interested parties and is providing this advance notice to alert potential participants in the review that adhering to the schedule will require some departures from past practices.

TABLE 1

Major milestones	Tentative dates
CASAC Subcommittee Meeting on Exposure Assessment Methods.	December 1993.
CASAC and Public Comment Period for Criteria Document (CD) (90 days).	February to May 1994.[1]
CASAC Subcommittee Meeting on Risk Assessment Methods.	March 1994.
CASAC Meeting on CD.	July 1994.
Comment Period on Staff Paper (SP) (60 days).	September to October 1994.
CASAC Meeting on SP.	October 1994.
Public Comment Period on Revised CD and SP (90 days).	Early 1995.
CASAC Meeting on Revised CD and SP.	Mid-1995.
Agency Development of Regulatory Decision/Proposal Package Draft.	Mid-1995 to late 1995.
Office of Management and Budget Review of Proposal Package.	Early 1996.
Publication of Proposal in Federal Register.	Mid-1996.
Public Comment Period on Proposal (90 days).	Mid-1996.
CASAC Meeting to Review Proposal.	Late 1996.
Regulatory Decisions and Final Package Draft Completed.	Early 1997.
Office of Management and Budget Review of Promulgation Package.	Early 1997 to mid-1997.
Publication of Promulgation Notice in Federal Register.	Mid-1997.

[1] For a notice of availability of external review draft, see 59 FR 4278, January 31, 1994.

In particular, the EPA has often granted requests for extensions of public comment periods in previous reviews; in order to meet the accelerated schedule for the O_3 NAAQS review, however, the EPA intends not to grant such extensions during this review. Accordingly, potential participants in the review should take note of the process outlined in this notice and be prepared to respond promptly when opportunities to comment are offered.

Given the scientific and technical complexity of the issues likely to be involved in the O_3 review, the diversity of scientific opinion that has characterized previous reviews of the criteria and standards for O_3, and the need to ensure that its ultimate decision is soundly based, the EPA cannot, of course, provide any absolute assurance that it will meet all of the interim milestone dates indicated in Table 1. Completion of the necessary steps in a timely manner is also predicated upon the availability of adequate resources during the review process. However, the Administrator has emphasized a high priority on meeting the accelerated schedule outlined in this notice.

To that end, the review process is well under way. The EPA initiated action to update the air quality criteria for O_3 in August 1992 (57 FR 38832). It

held two peer-review workshops on draft health effects chapters of a revised Criteria Document (58 FR 35454) in July 1993. Additional workshops on draft air quality and ecological effects chapters (58 FR 48063) were held in September 1993. Since then, the EPA has discussed the schedule and process outlined in this notice with the CASAC (58 FR 59034). The EPA is also conducting exposure and risk analyses. A subcommittee of the CASAC met on December 16, 1993 to review methodologies (58 FR 63345). A further subcommittee meeting on risk analysis is planned for spring 1994.

Implementation

It is important to stress that while conducting this review, the EPA remains committed to implementing the existing O_3 NAAQS in accordance with the Clean Air Act Amendments of 1990 (CAAA). During the review, the EPA will continue to work with States to implement emission control strategies required by the CAAA to meet the existing O_3 NAAQS. These efforts include State and Federal actions to reduce emissions of volatile organic compounds and nitrogen oxides, which act as precursors to O_3 formation in the troposphere. The EPA will make every effort to maintain implementation schedules consistent with requirements of the CAAA to ensure continued improvement in air quality.

As part of the review, the EPA is examining the ramifications of any changes to the NAAQS on current implementation efforts. If appropriate, new implementation rules and guidelines will be considered for alternative NAAQS. The EPA also is reviewing options to ensure a smooth transition for implementation of any new O_3 NAAQS in the event a decision is made to revise the current O_3 NAAQS.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: January 27, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94-2487 Filed 2-2-94; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 68

[CC Docket No. 93-268, RM-7815, RM-6147; FCC 93-484]

Connection of Customer-Provided Terminal Equipment to the Telephone Network

AGENCY: Federal Communications Commission.

ACTION: Proposed rules.

SUMMARY: This Notice of Proposed Rulemaking (NPRM) proposes to amend rules which regulate the terms and conditions under which customer-provided terminal equipment may be connected to the telephone network. The proceeding was initiated by petitions for rulemaking filed by Southwestern Bell Telephone Company (SWB) and Ameritech Operating Companies (Ameritech) who ask that regulations governing switched digital services be added. The effect of the proposed rules would be to promote rapid exploitation of switched digital technology. We propose also to provide for a registration revocation procedure which should greatly enhance our ability to enforce applicable rules as well as the Telecommunications Trade Act of 1988; and we take this opportunity to propose clarifications to other rules.

DATES: Comments were to be submitted on or before January 13, 1994, and replies by January 28, 1994; however, those dates have been extended to February 10, 1994 for comments and February 25, 1994 for replies.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554, with copy to William H. von Alven, FCC, Mail Stop 1600B2, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: William H. von Alven, Domestic Services Branch, Domestic Facilities Division, Common Carrier Bureau, (202) 634-1833.

SUPPLEMENTARY INFORMATION: This summarizes the NPRM in CC Docket 93-268, RM-7815, and RM-6147 (FCC 93-484) adopted October 22, 1993 and released November 22, 1993, supplemented by an Errata, and Order Extending Comment Period released January 12, 1994 (DA 94-46). Persons affected by part 68 practice and procedure are urged to review the full texts of both the NPRM and Errata, and the supporting file, which are available for inspection and copying during the weekday hours of 9 a.m. to 4:30 p.m. in the FCC Reference Center, room 239, 1919 M St., NW., Washington, DC. Copies may be purchased from the Commission's duplicating contractor, ITS, Inc., 2100 M St., NW., suite 140, Washington, DC 20037, (202) 857-3800.

Paperwork Reduction Act

Reporting and recordkeeping activities needed to comply with the proposed rules are usual and customary.

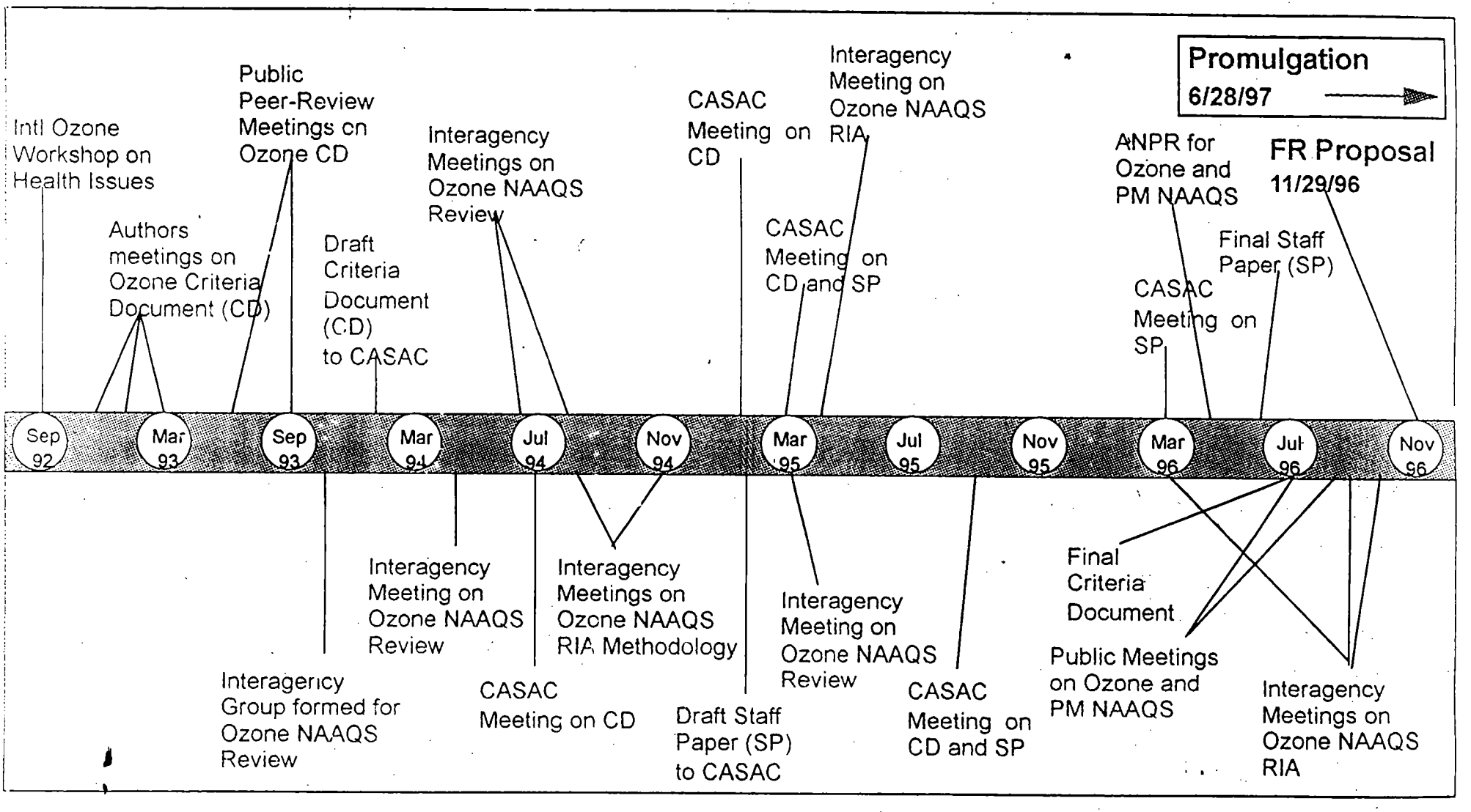
Analysis of Proceeding

1. By this NPRM we contemplate amending parts 2 and 68 of the rules, 47 CFR parts 2 and 68. A purpose of part 68 is to maintain uniform standards for the protection of the telephone network from harms caused by the connection of terminal equipment and associated wiring. This proceeding was initiated by two petitions for rulemaking, one filed by SWB (RM-7815) and the other by Ameritech (RM-6147).

2. SWB requests that part 68 be amended to include the regulation of terminal equipment connected to the two-wire Basic Rate Access (BRA) interface and to the Primary Rate Access (PRA) interface provided by Integrated Services Digital Network (ISDN) access technology. BRA consists of one or two 64 Kbps information channels with a 16 Kbps channel for dialing and network access information. The 1.544 Mbps PRA consists of 23 64 Kbps information channels and the 64 Kbps dialing and network access channel. ISDN is in a developmental phase, being deployed these last few years in an experimental mode. The Public Notice of SWB's petition elicited comments from eight parties and reply comments from three. There was overwhelming support for including this service in part 68 in order to promote, on a nationwide and worldwide basis, rapid exploitation of this technology with minimum mandatory criteria for connection of CPE (customer premises equipment). Thus, we propose for comment technical standards for including this service in part 68 in supplement to the existing standards for non-switched leased-line digital services which were added in 1985.

3. Commenting on SWB's petition, AT&T recommends (a) that part 68 rules covering PRA not be limited to the two-wire ISDN BRA service but also authorize terminal equipment connected to the 4-wire ISDN PRA (1.544 Mbps) interface pursuant to performance and compatibility standards adopted by ANSI (American National Standards Institute); (b) that amendments to part 68 provide equipment specifications for both PRA

History of Ozone NAAQS Review



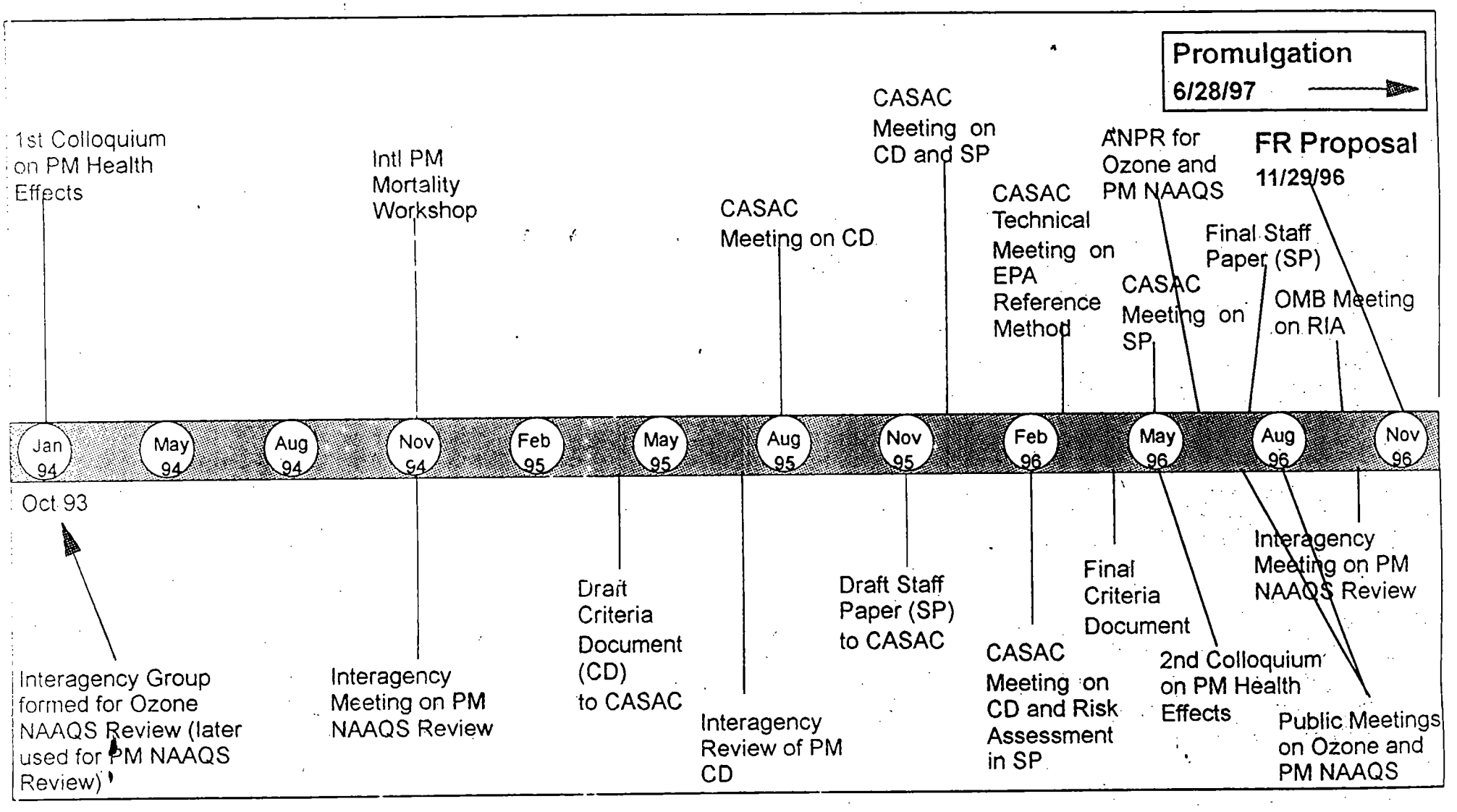
Blue Text: **Peer-review process with Clean Air Scientific Advisory Committee (CASAC)**

Red Text: Interagency Meetings

Black Text: Science Meetings

Green Text: **Public Meetings**

History of PM NAAQS Review



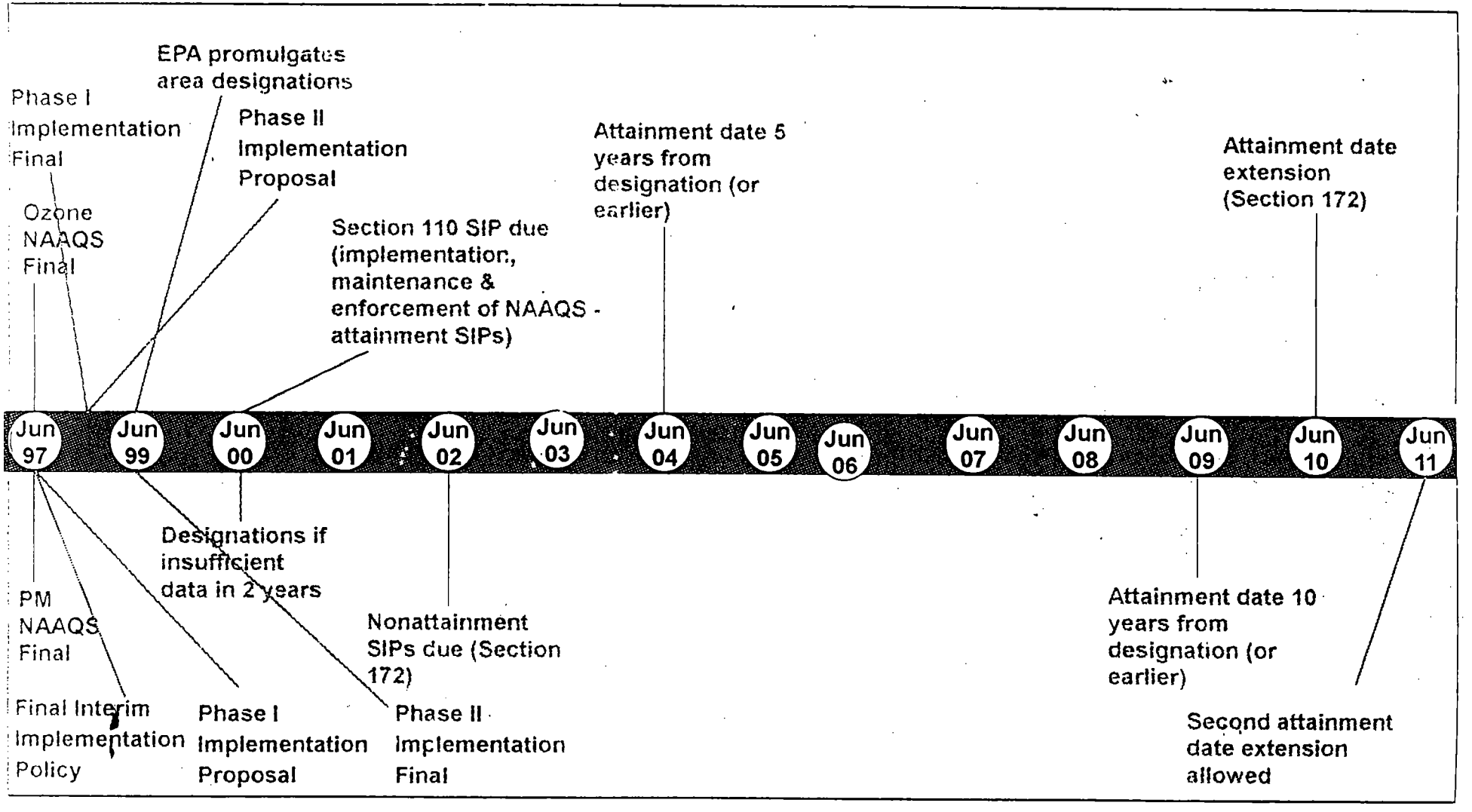
Blue Text: Peer-review process with Clean Air Scientific Advisory Committee (CASAC)

Red Text: Interagency Meetings

Black Text: Science Meetings

Green Text: **Public Meetings**

New NAAQS Timeline



Blue Text: EPA Policy or Rulemaking
Green Text: Statutory Requirements

Nov. 1996

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR THE PRESIDENT

THROUGH: Leon Panetta

FROM: Sally Katzen and Dan Tarullo

RE: EPA's Proposed Ozone and Particulate Matter Air Standards

This memorandum is to advise you that, after much debate, we are authorizing EPA to place in the Federal Register on Friday, November 29th, a notice proposing new rules under the Clean Air Act that would: (1) create a new, more stringent air quality standard for particulate matter (PM); and (2) improve and tighten the existing ozone air quality standard. The action-forcing event is a court-ordered deadline of this Friday for a review of the particulate matter standard. The American Lung Association and the Sierra Club have threatened to bring lawsuits to obtain a deadline for issuing the ozone proposal if it is not issued at the same time as the PM standard. Both proposals will be highly controversial.

Background

The PM proposal would create a new standard for fine particles (those measuring 2.5 microns or less; the width of a human hair is 100 microns). This decision reflects a consensus among EPA's science advisory committee that these small particles cause harm by lodging deep in human lung tissue. The current standard for larger particles (those measuring up to 10 microns) would remain in place. For ozone, the proposed rule expands the monitoring period from one to eight hours and lowers the allowable concentrations. The health effects of ozone are considerably less severe than those from small particles: while the PM proposal would reduce premature mortality, the ozone proposal is intended to address temporary (and reversible) reductions in lung function, and marginally reduce hospital admissions among sensitive populations.

The statutory standard under the Clean Air Act is to protect human health with "an adequate margin of safety." The courts have held that EPA is not to consider costs in setting the standard. But the costs of these proposals will be greater than any other EPA regulation issued during your first or second term. The annual compliance costs for the PM standard will be approximately $6 billion per year; and for the ozone air standard, $.6-$2.5 billion, or more, per year.

Assessment

EPA feels very strongly that its proposals are appropriate to protect children, the elderly, and other sensitive populations. Environmental and some public health groups feel likewise. Although these standards are only at the proposal stage -- the deadline for issuing final standards is June 1997 -- EPA's announcement will likely generate a strong reaction from industry and some state and local governments.

States and Locals. Changing these air standards will be particularly opposed by cities and counties that have, after many years of effort, recently come into attainment with the current standards and will now be required to go through the process of coming up with new control strategies for even tighter standards. Under the ozone proposal, hundreds of counties, with major populations, currently in attainment will be out of compliance, along with those that already cannot meet the current standard. EPA estimates similar effects under the proposed new PM standard.

Large and Small Business. Industry, particularly auto companies, oil companies, utilities, and many manufacturers, will oppose any revision to the current standards. They will be joined by numerous small businesses.

Congress. Members of Congress from existing and potential non-attainment areas can be expected to oppose the changes as well, and may renew efforts to push amendments to the Clean Air Act or comprehensive regulatory reform legislation to stop the proposed standards.

Recommendation

As we noted above, EPA is only announcing proposed new standards. The court deadline for the final PM rule is June 1997. There is no chance of interagency consensus on the ozone proposal in the near term. Also, EPA will be working on implementation rules that will affect the costs imposed. Its schedule for proposing those implementation rules is also June 1997.

Other agencies generally agree that the health benefits of the PM standard are substantial, and thus have agreed to it, notwithstanding the significant costs of compliance. With respect to ozone, however, many of the agencies believe that the beneficial effects of a moderately tightened standard are both less dramatic and harder to establish for any specific incremental tightening. Indeed, EPA's scientific advisory committee explicitly declined to identify a single standard and instead offered a range within which a "policy judgment" had to be made.

There has already been substantial public reporting of EPA's intention to publish the proposals. Any softening would be regarded by environmental and some public health groups as a retreat from the Administration's second-term commitment to health and the environment. At the same time, the proposed regulation will elicit very negative reaction.

As a result, we recommend the following course of action:

- Publishing the proposals in the Federal Register on Friday, November 29.

- Explicitly asking for comments on a variety of alternatives to the standards proposed by EPA, including taking no action at all, or improving the current standard while not significantly tightening it. This will indicate to affected interests the seriousness with which EPA and the Administration will review comments filed on the proposal.

EPA has agreed to the following suggested message to accompany the release of the proposals:

- The PM proposal is being issued to meet a court-ordered deadline. The agency is also issuing a proposal on ozone.

- The Clean Air Act requires regular review and revision, as needed, of these standards to respond to evolving scientific opinion about health effects from air pollution. EPA's science advisory committee has recommended changes to both standards.

- EPA will take comments on the need for any changes to the PM and ozone proposals in addition to soliciting views about its recommended approach. The purpose of the comment period is to reach out to all constituencies in order to obtain the best information available for determining the appropriate standards.

- EPA and the rest of the Administration recognize that these are significant and far-reaching proposals affecting the environment, public health, and the economy. Therefore, EPA is soliciting the broadest possible range of views on the appropriate standard.

FROM THE OFFICE OF THE CHIEF OF STAFF
Jason S. Goldberg

Doc Number

63

Author / Source

Cloherty, Patricia

Description

Personal letter and policy memo from Patricia M. Cloherty, President of Patricof & Co.

Send to 1	Send to 2	Send to 3	Send to 4	Send to 5
Sperling				

Send to Comments

EBB writes: "Ask Sperling's shop to review and respond."

Patricof & Co

January 21, 1997

Hon. Erskine Bowles
Chief of Staff
White House
Washington, DC 20500

Patricof & Co.
Ventures, Inc.
445 Park Avenue
New York, NY 10022
Tel 212-753-6300
Fax 212-319-6155

Dear Erskine:

First of all, congratulations on your new post. I can see that you are a glutton for punishment. But I also thought you were excellent and refreshingly direct on "Meet the Press" on Sunday morning.

Second, I thought you might be interested in the attached. It is a paper I prepared for the Center for Entrepreneurial Leadership, the major activity of the Kauffman Foundation of Kansas City, endowed by Ewing Kauffman, the now deceased founder of Marion Labs. The CEL Board is carrying out the entrepreneurial legacy of Mr. Kauffman in the non-profit environment, and as indicated herein, the BOD members asked me to set down my views of the policymaking process with respect of entrepreneurial business at the federal level.

I know you will be swamped, but if you or your staff have a chance to give me a reality check, I would appreciate it.

May I wish you every success in 1997.

Sincerely yours,

Pat

Patricia M. Cloherty
President

ANATOMY OF FEDERAL POLICY-MAKING RELATED TO ENTREPRENEURIAL BUSINESS

October 3, 1996
Kansas City
C.E.L. Board Meeting

By Patricia M. Cloherty

I was asked by my colleagues on the Board of the Center for Entrepreneurial Leadership to prepare a short briefing on how and through what organizations federal policies affecting entrepreneurial businesses in the United States are made.

Herewith that synopsis. Please note that this is intended as a thought paper based on my own and other colleagues' observations and experiences over several years in the policy process. It is not based on the sort of historical research and analysis one might do, given time, for example for publication.

"Entrepreneurial business" refers herein to that subset of 3% or 4% or less of the total universe of small companies in the country that seek rapid, sometimes explosive growth, based most frequently on achieving technological or other innovations aimed at producing substantial competitive advantage in an industry, often worldwide. It does not refer to the estimated 15 million small businesses, "the backbone of the economy", that may grow at around the rate of the economy generally and which tend to serve local or regional markets only.

"Federal policy-making" refers to the process at the federal level whereby the many

statutes and regulations that affect the formation and growth of entrepreneurial enterprises and capital flows to them is shaped. It embraces the Executive and Legislative branches of Government, plus policy appendages related thereto.

My basic contentions in this paper are the following:

1) There presently is no "port of call" -- institutional or personal -- in the Federal Government empowered to establish or maintain a policy framework suitable for entrepreneurial growth.

2) Such policy framework as does exist is scattered throughout Executive Agencies and Congressional Committees and Sub-Committees whose primary missions and authorities focus tangentially, if at all, on the entrepreneurial sector of the economy.

3) Relevant policies and regulations thus end up being largely accidental, the consequence generally of negative reactions of trade groups to policies launched to address other, generally larger, issues and constituencies. It is the Law of Unintended Consequences at work.

4) The Small Business Administration, often assumed because of its name to address issues of the high-growth enterprise, in reality does not do so due to its particular

origins, statutory mandates, history, and political support. Nor, as a corollary, do the Small Business Committees of the House and Senate. However, Federal agencies presently tend to think of entrepreneurial business as being part of what SBA has responsibility for.

To individuals involved in founding, growing and financing dynamic companies, this lack in our policy-shaping apparatus seems anomalous, even stunning, especially in the midst of the 1996 general election in which both major candidates are touting economic growth. But in truth, it isn't strange. For one thing, the political constituency supporting entrepreneurial activities is both tiny and impotent in the scheme of things. Second, since politics fundamentally is "the art of who gets what, when, where and how," larger established interests and their political representatives are unwilling to cede ground to newcomers. (To this day, the Small Business Innovation Research Program, begun experimentally in 1975, is bitterly resisted by many academic researchers and public policymakers.) Finally, a central conundrum exists: how can the American public arrange for timely consideration of policies affecting the fastest-growing and most-rapidly changing segment of the economy within structures that are (for lots of good reasons) fundamentally slow-moving and bureaucratic?

Even the Standard Industrial Classifications (SIC Codes) used to describe and measure the U.S. economy is always five to ten years out-of-date due to its publication cycle. Thus it fails to capture emerging industries that are growing or may grow substantially more rapidly than the economy generally. Where is the Internet code, for example?

For public policy purposes, the emerging growth companies have traditionally been lumped into the category of "small business" and consequently also, into the programs of the SBA. This is partly out of lack of knowledge on the part of both the public and of public servants. Like all of us, they need a "pocket" to put things into, to organize their acts. But it is also out of lack of interest in the growth sector by elected officials due to the nominal political dividends it yields to its champions. "Small business", with the 500-600,000 member National Federation of Independent Business as its principal constituency, is simply more productive politically than is "growth enterprise", supported by such as the National Venture Capital Association (300 members), BIO (membership in the hundreds), and the American Entrepreneurs for Economic Growth (10,000 maximum).

In fairness, also, it should be noted that the political constituency comprised of venture capitalists and actual or aspiring entrepreneurs is largely uninformed, and therefore inactive, on issues affecting it. California's ballot initiative, Proposition 211, relating to securities fraud lawsuits, has momentarily galvanized this group into a level of political activity not seen since the capital gains tax debates of 1978-79. But this is rare. The Venture Capital Journal commented in October, 1996,

> ... Venture capitalists, not known for their political savvy or for leveraging their industry as a potent political machine, are entering new territory these days. Galvanized by a single issue -- a local one at that -- that has inspired a real and profound fear, the venture industry has been driven to mobilize itself... Proposition 211 is the ultimate price the venture industry could pay for not being better informed of political and other special interest issues.

Proposal: It may be timely for the C.E.L., pursuant to its educational mission, to launch a serious study of the federal policy framework that gives rise to an entrepreneurial economy in the U.S. As noted herein, such an effort would capitalize on emerging trends, both in the economy and in political circles. The mere elucidation of such issues would represent original work and could make a major contribution to citizens' thinking about, and shaping, policies conducive to economic growth.

To clarify today's policy "players", SBA's historical role and political base of support are described below. This is followed by a (contrasting) outline of the types of issues presently important to growth companies, together with a roadmap of governmental responsibility for those issues. Finally, I've recommended an action program that C.E.L. might consider to fill the "knowledge gap" in the policy framework relating to entrepreneurial business.

Small Business and SBA

Small business came on the federal radarscope in the early forties when Congressman Wright Patman used the war effort to push the Executive Branch under President Roosevelt, then President Truman, to form the Smaller War Plants Corporation. Its main purpose was to assure that the defense contracting efforts did not put small businesses out of business in the rush to mobilize using contracts to Big Auto, Big Steel and other "Bigs". A far lesser theme was technological innovation, though then, to a greater extent than now, universities were viewed as the true and probably only, producers of important intellectual property.

Congress set up Small Business Committees as Sub-Committees of the Banking Committees in the House and Senate, but without legislative authority, i.e. they could hold hearings and give speeches, but 'til the late 60's, they could not legislate.

The tools of the SWPC were three: government contracts, loans and loan guarantees, and materials supply. The first two have remained mainstays to this day.

The SWPC was abolished post-war and its authorities dispersed among other agencies ... until the Korean War re-mobilization effort came along. Again under Congressional fire, PresidentTruman established by Executive Order (not statute) the Small Defense Plants Administration.

President Eisenhower made the Agency permanent in 1953 after an experimental period, for political and other reasons. Politically, NFIB had organized small businesses (barber shops, retailers, restaurants, gas stations, and others) in large numbers in a group whose conservative views merged into those of the Republican Party at that time. Also, however, one of his advisers, Wendell Barnes, an Oklahoman with Wall Street experience, was seeing the beginnings of a new issues market and of a nascent venture capital business. He recommended that such an agency might be a way of putting a mammoth federal bureaucracy in touch with changes in the economy, which thinking eventually produced the Small Business Investment Company Act of 1958, supported by a Federal Reserve Board report on the lack of long-term capital, mainly debt, available to small enterprise.

Essentially each Administration since that of Eisenhower has tried either to abolish SBA or to move its authorities to other Agencies represented on the Cabinet, usually to Commerce. For most officials in the Executive Agencies, such as Defense and Commerce, small business is a nuisance that requires that they set aside contracts, R&D funds and other resources from their Agency budgets.

But Congress, whose Members fraternize with (and raise funds from) small businesspeople, has been adamant in maintaining it. Though it is in the Executive Branch, the Agency is really a creature of Congress, which, over time, has loaded various programs on the Agency, from disaster relief loans to crop loans. Because the Agency has a power unique to it, namely the ability to make loans directly to citizens, rather than going through States or Municipalities, it has had political potency.

In fact, in 1978, as a measure of the inter-branch conflict over small business jurisdiction, Congress created the post of Chief Counsel for Advocacy, reporting directly to it, while reporting also to the Agency Administrator appointed by the President ... a formula for continued conflict.

The Kennedy Administration had no interest in small business, growth-oriented or otherwise, so nothing happened. The Johnson Administration, however, joined the small business issue with the Great Society program when in 1968, under the War Powers Act, the same tools of sole-sourced contracts and loan guarantees were applied to re-building riot-torn Watts. President Nixon subsequently based his Black Capitalism Program on the Agency's ability to sole source

contracts and to make loans directly to companies.

Social issues came to play a big role in Agency affairs, based on programs for "socially and economically disadvantaged" -- women, minorities, Indians, Aleuts, Eskimos, and Vietnam veterans -- a constituency that was quite distinct from the Agency's traditional small business base.

Through all this, little was able to emerge having to do with the Agency's attaining greater policy authority in any area, much less on the growth company issues, since it was always beset with claims from conflicting constituencies. As a further constituency matter, support groups of small business people have always been glad to be termed "entrepreneurs". The high growth entrepreneurial managers, however, resist the "small businessperson" designation:.

Two programmatic accomplishments over this time have affected growth companies positively -- the Small Business Investment Company (SBIC) program and the Small Business Innovation Research (SBIR) program. The first provided a "starter kit" to many of today's venture capitalists at a time when private capital was difficult to raise, and also today, when pension funds routinely don't back "first funds". The second program continues to provide seed capital for high risk technological projects of venture-backed and other companies. Both programs have had episodic political travails and related efforts, mainly from the Executive Branch, to dismantle. The National Institutes of Health, in particular, has never accepted unambiguously the "commercialization" goal embodied in the SBIR awards, and tends to lean

therefore toward academic research.

That's the SBA story in a nutshell from my point of view. It serves the "smalls", which as one observer says, comprises "a spooky constituency that wakes up seldom, but when it does, and usually negatively, Congress listens." Certainly NFIB had a big hand in arresting the progress of the Clinton health care program. That battle, at the time, distracted an otherwise knowledgeable and able Administrator (who, for the first time, had a seat on the Council of Economic Advisors) from focusing on growth companies.

As for the Executive Branch broadly, there have been three White House Conferences on Small Business --- under Presidents Carter, Reagan and Clinton. The first ended up with a small number of recommendations, some of which were implemented. The second deteriorated into a dogfight about SBA's existence. The report from the third, whose convenors tried to introduce growth company policies as an agenda item, ultimately got "Christmas-treed" and diffused, though some follow-up is ongoing. Basically, though, these conferences have served as ventilators for views of interested parties that result in a re-allocation of resources of existing programs, rather than as producers of fresh policy approaches.

Assorted non-SBA efforts to assist growth companies at the policy level have taken place over the years. The White House occasionally appoints a "Technology Czar", but generally in connection with flirtations with an Industrial Policy, which generally raises ideological opposition from the high growth constituency. In the 1970's, Treasury created the post of Deputy Assistant

Secretary for Capital Markets to manage equity capital availability issues. But the post was filled once, then forgotten.

Finally, of course, the economy and the capital markets as relate to growth companies have changed and gained critical mass in recent years. The newly formed coalition among BIO, the NVCA, the AEEG, the Software Publishers Association, NASDAQ and The Council of Growing Companies is a political reflection of this shift in reality. Their Entrepreneurs' Agenda for 1996-1997, could be the political basis for fresh initiatives as relevant issues are elucidated and understood.

Conclusion: The issues that have faced or are facing growth companies are not ones in which SBA is generally either involved or asked to opine, certainly not within any formal delegations of authority among Executive agencies.

So what are the issues? And how might they be addressed?

Growth Company Issues / Authorities

A broad set of government policies, laws and regulations influence the growth of entrepreneurial enterprise and risk capital flows to it. In a profound way, when taken altogether, these policies, laws and regulations tend to express our view of ourselves as a nation, our attitudes toward such things as risk-taking, social mobility, and willingness to absorb economic newcomers among the already established interests. The "rags-to-riches" theme is embedded in

our mythology. We admire the Bill Gates (Microsoft) and Fred Smiths (Federal Express) of the world. We write books on their economic feats. They're on TV ... and so forth.

As a consequence, our legal conventions tend generally to be enabling to entrepreneurship and risk capital across a broad, if uncodified, spectrum.

These policies range from those affecting pension fund investing, to securities laws and regulations, intellectual property rights, bankruptcy laws, tax matters, among others.

- Pension fund rules provide that a small fraction of these otherwise conservatively-managed, large pools of savings can be put at venture risk.

- Securities laws and regulation provide for the kinds of disclosures that give confidence to investors in buying shares of young companies in public markets.

- Tax laws provide for transparent treatment of venture capital partnerships so they're not taxed twice and provide, at present, a very narrow capital gains tax advantage for investors in small companies.

- Intellectual property laws afford protection for knowledge-based ventures through the patent and trademark systems and related court rulings.

- Bankruptcy laws provide a second chance for failed entrepreneurs through Chapter 11 proceeding, a rarity in the world.

Various reports in recent years have attempted to lay the groundwork for a broader view of the entrepreneurial policy issues and processes. Though nothing has come of these reports, the fact of their even being done signals an emerging sea change from historical patterns.

The most interesting of these, in my view, is a General Accounting Office report dated August 12, 1982, requested by Senator Lloyd Bentsen when he chaired the Joint Economic Committee. Entitled "Government-Industry Cooperation Can Enhance the Venture Capital Process", the report concludes that,

> ... Within the Government, many offices can potentially affect the venture capital process through their actions. Actions that affect the process can be the result of executive or congressional initiatives... Yet, no central point of coordination exists for [such] Government actions...

The report cites a series of tax, pension fund and labor promulgations that caught the venture industry by surprise, negatively.

A report published in 1986 is more typical of its genre, but also broke some new ground. Pursuant to the formation in 1985 of a bipartisan National Commission on Jobs and Small Business, a study team was formed, funded by the Charles Stewart Mott Foundation of Flint, Michigan, to recommend policies that would result in the formation of ten million new jobs. After 15 months of research and hearings from the various constituencies, the Commission came

up with "soup-to-nuts" recommendations on small business that skirt most of the central issues affecting the growth companies, in particular. According to at least one participant in the study, its breadth plus its admittedly bipartisan, but still political, roots, defeated efforts to get beyond the current institutional framework of policies and programs.

Finally, in the early 1990s, the White House Office of Science and Technology Policy staff wrote a report entitled "A Profile of Small High Technology Business in the United States". The report is the first high-level analysis of how efficient the sector is in creating new jobs, new technologies, and consequently, productivity gains.

While it was never published, the central thrust of the White House report today has become widely known, i.e., that high growth, high tech companies are engines of economic growth, due primarily to press coverage of the sector in the recent years of large corporate downsizing. The policy underpinning of that growth, though, remains fuzzy and unarticulated.

As a "reality check" on what some of the detailed issues are, and on their scattered jurisdictional responsibility, I looked at the NVCA's issue list for the past few years. It is most notable that virtually all of the issues pursued by NVCA arose as a result of legislation or regulations that were proposed or passed to address matters having nothing to do with entrepreneurial business. The sector simply got caught in "the wake of the ship." It also is notable that the policy swath cuts very broadly across government, with no one unit having any central responsibility for growth companies.

Herewith the issues and jurisdictions.

1) **Tax Policy**

Executive Branch

Treasury
Council of Economic Advisors

Legislative Branch

House Ways and Means
Senate Finance

(Tax generally operates at full committee level.)

Recent Issues:

- Capital gains tax rate.
- Section 1202. Targeted capital gains, passed in 1993.
- Section 212. Deductibility of investment expenses in computing the AMT.
- Section 382. Loss of net operating losses on change of control.
- Anti abuse partnership tax regulations.
- Proposed tax on distributions in kind to partnerships at time of distribution.
- Proposed tax on foreign investors in U.S. venture capital partnerships.
- Proposed triggering of unrelated Business Taxable Income (UBTI) on foreign venture investments.
- Investment Company Act Revisions

2) **Securities Laws**

Executive Branch

Securities and Exchange Commission
Financial Accounting Standards Board (Independent)

Legislative Branch

House Commerce Committee,
Subcommittee on Telecommunications and Finance
Senate Banking Committee,
Securities Subcommittee

Recent Issues:

- Accounting treatment of stock options
- "Free rider" regulations
- Regulation D revisions
- Securities litigation reform
- Investment Company Act Revisions

3) **Pension Funds (ERISA)**

Executive Branch

Department of Labor

Legislative Branch

House Economic and Educational Opportunities Committee,
Subcommittee on Employer and Employee Relations
Senate Labor and Human Resources Committee (full committee)

Recent Issues:

- Change in prudent man rule to permit pension funds to invest in venture capital
- Definition of a "venture capital operating company"

- Emergence of 401(k)s and their possible ability to invest in private equity, i.e., defined benefit versus defined contribution plans

4) Health Care Policy

Executive Branch

Health and Human Services,
Food and Drug Administration,
National Institutes of Health

Legislative Branch

House Commerce Committee,
Subcommittees on Health and Environment
Senate Labor and Human Resources Committee (full committee)

Recent Issues:

- Health care reform in general
- Proposed price controls on breakthrough drugs
- FDA reform
- FDA user fees
- NIH conflict of interest regulations
- CRADA pricing clause
- FDA financial disclosure regulations

5) Intellectual Property

Executive Branch

Patent and Trademark Office
U.S. Trade Representative

Legislative Branch

House Judiciary Committee,
Subcommittee on Courts and Intellectual Property
Senate Judiciary
Subcommittee on Anti-trust, Business Rights and Competition

N.B. Treaty-related matters go to full Senate.

Recent Issues:

- Patent policy changes contained in the General Agreement on Tariffs and Trade (GATT)
- Medical and biotechnology patent restrictions to assist doctors sued for product liability

Admittedly somewhat mind-numbing, this list still only partially reflects the pertinent policy matrix, from the capital provision side of the entrepreneurial equation only.

Conclusion and Recommendation

For a range of historical, political and economic reasons, there exists an important gap in our general understanding of which policies contribute to a flourishing entrepreneurial economy. That lack of understanding is matched by total lack of political institutional focus on the subject. Further, as the U.S. economy has matured, and growth companies have taken center stage, we at best have been lurching toward a clearer understanding of it, mainly through an accidental process whereby laws and statutes are proposed that affect the sector negatively, thereby galvanizing it episodically to defeat the challenge, to emerge scarred but somewhat wiser.

The few study efforts in recent years meant to elaborate this policy framework have served to signal direction, but they have not gotten far, due mainly to lack of political muscle behind them. In the end, it's self-fulfilling: they were all conceived and executed within a political environment that requires support of existing constituencies to propel forward motion. But constituencies don't form around inchoate ideas. It's a form of policy gridlock.

C.E.L. is in a unique position to take the bull by the horns and launch an independent effort to elucidate the policy underpinning of our entrepreneurial economy in the U.S. The very identification of such a "policy toolbox" would constitute important and original work, apart from any specific policy consequences the effort might have.

The study could take the form of a National Commission of finite life (X years) whose purpose would be to answer systematically the question "What public policies give rise to an entrepreneurial economy?" and to disseminate its finding appropriately. At a minimum, knowing such policies, the Commission could develop an annual scorecard for the federal government around the Mayor Koch-type question, "How're we doin'?". At a maximum, it could generate an important work on a par with those of the likes of Schumpeter, Veblen or Weber, that captures and explains a reality we know but never bothered to express, thus changing how people think and act.

THE WHITE HOUSE

WASHINGTON

SCHEDULING ADVICE MEMORANDUM FOR: Lorrie McHugh, Cheri Carter, Gene Sperling

FROM: **STEPHANIE STREETT AND ANNE HAWLEY**
DATE: February 13, 1997
SUBJECT: **SEE BELOW**

Invites the President to address an audience at *Financial World's* annual CEO-of-the-Year awards dinner in New York City on March 20, 1997.

PLEASE MARK ONE OF THE FOLLOWING AND WRITE ANY ADDITIONAL COMMENTS/RECOMMENDATIONS BELOW:

1) ___ The President does not need to accept/attend.

2) The President does not need to accept/attend but we STRONGLY recommend an Administration surrogate attend on his behalf:

___ Our office will arrange for a surrogate.

___ Our office will work with Cabinet Affairs to arrange for a surrogate.

3) ___ **THE PRESIDENT SHOULD ACCEPT -- PLEASE SUBMIT A SCHEDULING PROPOSAL WITH THE INVITATION ATTACHED TO THE WEST WING SCHEDULING OFFICE ASAP!**

COMMENTS/RECOMMENDATIONS:

IF YOU ARE NOT SUBMITTING A PROPOSAL, PLEASE RETURN THIS MEMO TO PETE SELFRIDGE IN ROOM 184 BY: ASAP

FINANCIALWORLD
MAGAZINE
America's Oldest Business Magazine • Founded 1902

BARRY L. RUPP
CHAIRMAN *and* CHIEF EXECUTIVE OFFICER

February 3, 1997

President Bill Clinton
The White House
1500 Pennsylvania Ave.
Washington, DC 20500

Dear Mr. President:

In the event that you might deem it timely to address an open forum of America's business leaders, I hope that **FINANCIALWORLD'S** annual CEO-of-the-Year awards dinner, to be held this year on March 20th at the Pierre Hotel in New York, might present an ideal opportunity.

The award, now 23 years old, is based upon balloting by the CEOs of America's largest corporations. Last year it was won by Arthur Martinez of Sears; Don Fites of Caterpillar returned to present the medal to his successor. We do not know yet who the 1997 winner will be, as the ballots are just now being returned; but Mr. Martinez has volunteered to come back to make the presentation.

In addition, we present Career Achievement Awards to distinguished executives who have just retired. This year the recipients will be Ed Artzt of Procter & Gamble, John Clendenin of BellSouth, Oz Nelson of UPS and Helen Gurley Brown of Cosmopolitan. Governor Michael Leavitt of Utah will accept an award as chief executive of the state that **FINANCIALWORLD** rates as the best in the country in which to do business; and Rick Goings of Tupperware will accept the check for the proceeds of the dinner, on behalf of the Boys & Girls Clubs of America, which has been selected as our charity beneficiary this year.

Previous speakers include Presidents Ford, Reagan and Bush; both Doles, Henry Kissinger and Daniel Patrick Moynihan.

The audience itself makes the occasion unique in American business, in its great good nature and camaraderie among people who know each other well, in a setting of recognition of high achievement. Typically, more than 300 will attend, with the winners often inviting members of their boards, or heads of corporations on whose boards they sit, to join in the celebration.

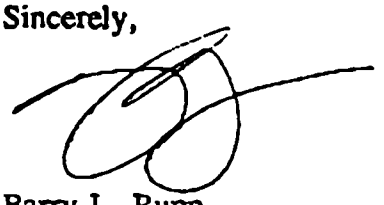
It is unique among business functions in its liveliness and warmth -- and an ideal setting for the frank discussion of serious issues affecting the country's business and finance, before an audience of the people who bear maximum responsibility for making the system work.

President Bill Clinton

You would add immeasurably to their appreciation of how they can make the greatest possible contribution to the tasks ahead, for which they will be enormously grateful -- as, of course, will we at **FINANCIALWORLD**.

With all good wishes,

Sincerely,



Barry L. Rupp
Chairman & Chief Executive Officer