COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE ON THE ENVIRONMENTAL PROTECTION AGENCY'S PROPOSED RESPONSE TO REMAND REGARDING THE NATIONAL AMBIENT AIR QUALITY STANDARD FOR OZONE

Docket No. A-95-58, 66 Fed. Reg. 57,268 (November 14, 2001)

INTRODUCTION

The Competitive Enterprise Institute (CEI) is a non-profit public interest organization committed to advancing the principles of free markets and limited government. CEI has a long-standing interest in issues involving matters of public health and safety, with a particular interest in bringing to light the potentially deleterious consequences of regulations – consequences which are often neglected by federal agencies in their attempts to adopt a regulatory agenda.[1] CEI filed comments in 1997 during the initial rulemaking on the new National Ambient Air Quality Standard (NAAQS) for ozone.[2]

In 1999, the United States Court of Appeals struck down the new ozone NAAQS. Among other things, the Court faulted the agency for failing to take into account the potential adverse health consequences from the new NAAQS, and remanded the rule to

[1] *See, e.g. CEI v DOT*, 856 F.2d 1563 (D.C. Cir. 1988); *CEI v. NHTSA*, 956 F.3d 321 (D.C. Cir. 1992).

[2] "Comments of the Competitive Enterprise Institute on the Environmental Protection Agency's Proposed Rule Changing the National Ambient Air Quality Standards For Ozone," March 11, 1997.

the agency for further consideration. Nonetheless, EPA is now proposing to reaffirm the rule without change.

As the following comments demonstrate, the agency's proposed response to remand has done nothing to satisfy the concerns raised by the Court of Appeals, and the agency's ozone NAAQS remains in violation of the Clean Air Act (CAA).

BACKGROUND

In July of 1997, EPA issued a final rule tightening the existing NAAQS for ozone.[3] The rule was promulgated under sections 108 and 109 of the CAA, by which EPA sets and periodically revises standards for ozone and other so-called criteria pollutants. Section 108(a)(2) requires that EPA take into consideration "all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." Section 109(b)(1) requires that EPA set "ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."

Ozone is unusual among the pollutants addressed in that it has both harmful and beneficial effects on public health. Inhalation of ozone exacerbates respiratory conditions such as asthma, which was the primary focus of EPA's rulemaking. However, ozone also acts as a shield against potentially harmful ultraviolet-B radiation (UVB) from the sun, exposure to which has been linked to skin cancer. Although the plain meaning of "all identifiable effects on public health or welfare" in the CAA would indicate that both concerns must be taken into account when deciding whether to lower the existing

[3] 62 Fed. Reg. 38,856.

ozone NAAQS, EPA ignored the UVB effects in setting the stringent new standard. The agency asserted that it is precluded by the CAA from taking the beneficial effects of a pollutant into account, and added that such effects are nonetheless too speculative and trivial to justify changing the standard.[4]

These arguments failed when the final rule was challenged in the United States Court of Appeals.[5] There, the court flatly rejected the assertion that the positive effects of ozone in blocking UVB should be ignored, noting that "it seems bizarre that a statute intended to improve human health would, as EPA claimed at argument, lock the agency into looking at only one half of a substance's health effects in determining the maximum level for that substance."[6] The court directed that "EPA must consider positive identifiable effects of a pollutant's presence in the ambient air in formulating [the NAAQS]."[7]

With regard to EPA's claim that the UVB effects are uncertain and trivial, the court observed that the CAA "does not rigorously or uniformly demand either quantifiability . . . or any specific level of significance."[8] The court also objected to EPA's double standard regarding the UVB effects and respiratory effects, particularly the agency's decision to ignore the former based on evidentiary concerns conceded to also be

[4] EPA, "Regulatory Impact Analysis for Proposed Ozone National Ambient Air Quality Standard," November 1996; Letter from Ozone AQCD Team, EMAB, ECAO/RTP to Lester D. Grant, Director, ECAO/RTP, November 3, 1994; EPA, "Response to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Ozone," July 1997, pp 130-37.
[5] *American Trucking Associations, Inc., v. EPA*, 175 F.3d 175 (D.C. Cir. 1999).
[6] *Id.* at 1052.
[7] *Id.* at 1052.
[8] *Id.* at 1053.

applicable to the latter.[9] The court concluded that "we can see no reason for imposing a higher information threshold for beneficent effects than for maleficent ones. . . ."[10]

The court remanded the ozone NAAQS to EPA to incorporate into its final standard the beneficial effects of ozone in shielding UVB.[11] Upon rehearing, the Court of Appeals held that EPA "has given us no reason to doubt the correctness of our conclusion. . . ."[12]

On November 14, 2001, EPA published its proposed response to remand.[13] While purporting to comply with the Court of Appeals' order, the agency decided not to change the ozone standard. The agency has essentially repeated its earlier assertion that the UVB effects are too uncertain and too small to affect the NAAQS.

However, as will be shown below, EPA's response is completely at odds with the evidence, and fails to comply with the requirements of the CAA. In effect, the agency has done nothing on remand to rectify the deficiencies in its rule.

THE UVB FFECTS ARE SUBSTANTIAL, BUT ARE NOT ADEQUATELY ADDRESSED BY EPA IN ITS PROPOSED RESPONSE

1. EPA Has Ignored Its Own Evidence In Claiming No Clear Association Between Tropospheric Ozone and UVB.

Of all the health consequences associated with ambient ozone, its role as a shield against UVB's harmful effects is the most thoroughly documented. An extensive body of research on these effects has been conducted EPA and by other U.S. and international

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[9] *Id.* at 1052-53
[10] *Id.* at 1053.
[11] *Id.* at 1053.
[12] *American Trucking Associations, Inc., v. EPA*, 195 F.3d 4, 10 (D.C. Cir. 1999). Although EPA appealed to the Supreme Court on other grounds, the agency did not challenge the Court of Appeals' holding regarding the UVB effects.
[13] 66 Fed. Reg. 57, 268 (November 14, 2001)

agencies. Though highly relevant, EPA has ignored virtually all of this research, both in its original rulemaking and in its proposed response to remand

This work was conducted in the context of stratospheric ozone depletion (Title VI of the CAA and the Montreal Protocol on Substances That Deplete the Ozone Layer), and has been extensively relied upon by EPA in promulgating numerous rules placing restrictions on putative ozone depleting substances.

For example, on December 10, 1993, the EPA issued a final rule accelerating the phaseout deadline for chlorofluorocarbons (CFCs) from January 1, 2000 to January 1, 1996, and adding additional chemicals to the list of restricted substances believed to reduce ozone concentrations.[14] In the rule, the EPA cites studies conducted by the agency, the World Meteorological Organization (WMO), and the United Nations Environment Programme (UNEP), purporting to show an inverse relationship between atmospheric ozone and ground-level UVB and related health effects.[15] The rule was promulgated because of "the Agency's concern that significant ozone loss may occur over populated regions of the earth, exposing humans, plants, and animals to harmful levels of UV-B radiation. . . ."[16]

Most of this research is equally relevant to the current rule affecting ozone in the troposphere (the part of the atmosphere that extends from ground level up to the stratosphere). The evidence shows that UVB is attenuated by total column ozone in the atmosphere, both in the stratosphere and in the troposphere. "All other factors being

[14] 58 Fed. Reg 65,018 (December 10, 1993)
[15] EPA, "Assessing the Risks of Stratospheric Ozone," 1985; WMO and UNEP, "Scientific Assessment of Ozone Depletion," 1989 and 1991 editions; UNEP, "Health and Environmental Effects of Ozone Depletion," 1989 and 1991 editions; 58 Fed. Reg. 65, 019.
[16] 58 Fed. Reg. 15,015 March 18, 1993).

constant, there is no scientific doubt that such decreases in *total ozone* will increase ultraviolet-B (UVB) radiation at ground level." (emphasis added)[17] Although there is more ozone in the stratosphere than in the troposphere, the effect of tropospheric ozone and other gaseous pollutants in attenuating UVB is also significant and has been measured. For example, a 1994 UNEP study concludes that "tropospheric ozone and aerosols can reduce global irradiances appreciably."[18]

In fact, some research suggests that the changes in tropospheric ozone are as significant as the changes in stratospheric ozone. UNEP has concluded that "tropospheric ozone and aerosols may have masked the consequences of stratospheric ozone depletion for UV-B in some industrialized regions."[19]

EPA's own published measurements, which were excluded both from its rulemaking and proposed response to remand, demonstrate the considerable impact of tropospheric ozone in reducing UVB. For example, an EPA study, published in the *Journal of Geophysical Research* a few months before the ozone NAAQS was proposed, concluded that "summer haze [largely ozone] was found to attenuate UV-B radiation in the range of 5% to 23% when compared to a clear day in the autumn."[20]

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[17] UNEP, "Environmental Effects of Ozone Depletion: 1991 Update," November 1991, p. 1-1. (UNEP 1991).

[18] UNEP, "Environmental Effects of Ozone Depletion: 1994 Assessment," November 1994, p. 1-1 (UNEP 1994); See also, WMO, "Scientific Assessment of Ozone Depletion: 1994," p. 9-1 (WMO 1994). It should be noted that this research draws no qualitative distinction between ozone molecules in the troposphere and the stratosphere in attenuating UVB.

[19] UNEP 1991, Executive Summary.

[20] Jeral G. Estupinan et al., EPA National Exposure Research Laboratory, "Effects of Clouds and Haze on UV-B Radiation," *Journal of Geophysical Research*, Vol. 101, p. 16,807, July 20, 1996.

These and other studies, many of which have previously provided the basis of prior rulemakings under the CAA to protect the public from increases in UVB, show beyond question that a reduction in tropospheric ozone would result in an increase in ground-level UVB and related health effects. Once the Court of Appeals made clear that EPA is required to consider the UVB effects, the agency became obligated to consider all of its relevant research in the ozone NAAQS rulemaking process, but has failed to do so.[21]

2. EPA's Own Evidence Demonstrates the UVB Effects Are Substantial

EPA's unsupported assertions to the contrary, the effect of the new NAAQS on ozone and UVB is likely to be significant. EPA estimated that the new NAAQS would result in a reduction in tropospheric ozone of approximately 0.01 parts per million (ppm), constituting a decline in total column ozone of approximately 0.5 percent.[22] The agency now disputes this estimate, but declines to provide an alternative.

Based upon EPA's previous rulemakings, an ozone decrease of this magnitude can be expected to have substantial adverse health effects. Many studies have quantified the impact of ozone loss by estimating the increases in adverse health effects (largely skin cancers) expected for each percent decline in ozone. For example, a 1991 UNEP analysis concludes that "a 1% ozone depletion will result in a 2.3 ± 0.4% increase in the incidence

[21] The Clean Air Scientific Advisory Committee (CASAC) was never presented this evidence, as EPA made the decision that the UVB effects were to be excluded from its scientific review. Nor is there any indication that CASAC was consulted in formulating the response to the Court's remand.

[22] Larry T. Cupitt, "Calculations of the Impact of Tropospheric Ozone Changes on UV-B Flux and Potential Skin Cancers," AREAL, ORD, EPA (1994).

of skin cancer."[23] EPA relied on this and similar assumptions relating ozone loss to adverse health effects in numerous stratospheric ozone depletion rulemakings.[24]

Applying this work to the estimated decrease in total column ozone predicted to result from the new ozone NAAQS, EPA's internal research estimated that the annual increases in non-melanoma skin cancers would range from 3,000 - 4,000 cases.[25]

The Department of Energy, conducting a similar analysis, estimated 2,000 – 11,000 additional cases of non-melanoma skin cancer, 130 – 260 cases of melanoma, 25-50 melanoma deaths, and 13,000 – 28,000 new cases of cataracts annually.[26] In its response to remand, EPA speculates that this research may be inaccurate, but provides no alternative evidence.[27]

In its 1992 Regulatory Impact Analysis of the phaseout of ozone depleting compounds under Title VI of the CAA, EPA assigned monetary values to the health consequences of increased UVB.[28] The benefit for each non-melanoma skin cancer averted was estimated at $4,000 to $7,000.[29] Each case of melanoma was set at $15,000, and each skin cancer fatality at $3,000,000 to $12,000,000.[30] Each case of cataracts was

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[23] UNEP 1991, pp. 18-19.
[24] See, e.g., 58 Fed. Reg. 65,019.
[25] Cupitt, p. 16.
[26] Marvin Frazier, "The Department of Energy's Office of Health and Environmental Research's Comments on the US EPA Document, Air Quality Criteria and Related Photochemical Oxidants," 1995. (Frazier).
[27] 66 Fed. Reg. 57,284-86.
[28] EPA, "Regulatory Impact Analysis: Compliance With Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Compounds," July 1992, Chapter 6.
[29] *Id.* at 6-13. It is worth noting that the ozone NAAQS' UVB effects may result in fatalities, as skin cancers can be fatal. In contrast, EPA did not assert that the proposed change to the existing standard would save lives as a consequence of reduced respiratory effects.
[30] *Id.* at 6-13 to 6-15.

valued at $15,000.[31] If EPA were to apply these estimates to the range of predicted UVB effects here, the agency would not be able to claim that the public health impacts are trivial.

Another EPA analysis, conducted in 1997, concludes that "any decrease in atmospheric ozone (tropospheric or stratospheric) causes an increase in solar ultraviolet-B radiation incident at the Earth's surface, and therefore an increase in the incidence of non-melanoma skin cancers," and states that "the methodology for estimating such increases (of both UV levels and skin cancer incidence) is well established." [32] Focusing only on non-melanoma skin cancers, the study estimates an annual increase of nearly 700 cases resulting from the ozone NAAQS.[33] The proposed response to remand makes no reference to this study, instead suggesting that such an analysis is not possible.[34]

Even if, as EPA suggests, the resultant decline in total column ozone is considerably less than 0.5 percent, the health consequences will still be substantial, outweighing the admittedly small health benefits attributed to the new NAAQS. EPA's Regulatory Impact Analysis for the phaseout of ozone depleting compounds attributed health benefits ranging from 8 to 32 trillion dollars as a consequence of avoiding an approximately 10 percent decline in total column ozone.[35] A simple extrapolation of these estimates to the approximately 0.5 percent decrease in ozone from the new NAAQS would mean costs ranging from 160 to 640 billion dollars, largely attributable to skin

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[31] *Id.* at 6-14.
[32] EPA, "Improved Estimate of Non-Melanoma Skin Cancer Increases Associated with Proposed Tropospheric Ozone Reductions," draft memorandum, May 22, 1997, submitted to the Office of Management and Budget docket on the NAAQS for ozone.
[33] Id., Table 6.
[34] 66 Fed. Reg. 57,284-87.
[35] EPA, "Regulatory Impact Analysis: Compliance With Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals," July 1992 and 1994 Addendum.

cancers averted. This is far higher than EPA's estimated health benefits of only 0 to 1.5 billion dollars annually, due to a small marginal decline in respiratory and other problems associated with direct exposure to ozone.[36] Therefore, even if EPA is correct and the new NAAQS' effect on total column ozone is considerably smaller than initially estimated, the health costs would still be substantial compared to the health benefits.

3. EPA's Claim of Uncertainty Regarding the UVB Effects is Completely Inconsistent With Its Treatment of the Respiratory Effects and Contradicted by Its Own Evidence.

EPA's insistence that the association between reduced tropospheric ozone and increased UVB-related health effects is uncertain is completely refuted by its own evidence. But even if true, the agency's response to this uncertainty violates the CAA and is inconsistent with its treatment of uncertainties regarding the respiratory effects of ozone.

The CAA requires EPA to set primary standards that, "based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[37] Regarding the respiratory effects of ozone, EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that it is unclear whether the new standard is substantially more protective of public health than the existing standard.[38] EPA conceded that many CASAC members believed that "the differences in health protection may not be significant enough to justify a change from the current standard."[39] Despite these

[36] 62 Fed. Reg 65,746. These estimates were slightly increased after the final rule was announced.
[37] 42 U.S.C. § 7409(b)
[38] 61 Fed. Reg. 65,727-29.
[39] *Id.* at 65,729.

uncertainties, EPA decided that it *must* set a very stringent standard to protect the public against the respiratory effects of ozone exposure. In the agency's words:

> "the margin of safety requirement was intended to address *uncertainties associated with inconclusive scientific and technical information* available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, *even if the risk is not precisely identified as to nature or degree*."[40] (emphasis added).

In effect, EPA determined that the CAA required it to set NAAQS somewhere beyond the range of known health effects, and interpreted the "adequate margin of safety" language as preventing it from avoiding uncertainty.

In light of the Court of Appeals remand, EPA is required to deal with the UVB-effects no differently than the respiratory effects. Nonetheless, EPA now treats the putative uncertainties regarding the UVB effects, not as a reason to incorporate them with an adequate margin of safety (as it did with the respiratory effects), but as a reason to ignore them altogether. This astonishing double standard directly contradicts the basic thrust of the Court's decision; that the positive and negative effects of a pollutant have the same status under the CAA, and must be treated the same manner when setting NAAQS.

Further, EPA has not explained why it declined to deal with perceived uncertainties regarding the UVB-effects by establishing a range of predicted effects, which is what it does in most rulemakings and did here with regard to its analysis of the respiratory

[40] 61 Fed. Reg. 65,717.

effects. Indeed, the agency conceded in its notice of proposed rulemaking that "there are an unusually large number of limitations and uncertainties associated with the analyses and resulting cost impacts and benefit estimates," and finalized the rule despite recognizing "many uncertainties inherent in such an analysis. . . ."[41] EPA promulgated the new NAAQS based on a range of health benefits attributed to reduced respiratory effects. To now use the claim of uncertainty to avoid any attempt to quantify the UVB effects is entirely inconsistent with the agency's treatment of acknowledged uncertainty regarding the respiratory effects.

EPA's treatment of scientific uncertainty regarding the UVB effects here is at odds with its handling of these same uncertainties when the agency regulated ozone depleting substances. Indeed, the agency banned many alleged ozone-depleting compounds based on highly speculative evidence regarding public health benefits. For example, in its December 10, 1993 rule, EPA added methyl bromide and hydrobromfluorocarbons to the list of restricted chemicals, arguing that these changes are "necessary to protect human health and the environment. . . ."[42] Nonetheless, in the case of methyl bromide, EPA conceded that there are "areas of significant scientific uncertainty" regarding its impact on ozone.[43] With regard to hydrobromofluorocarbons, the agency admitted that only one such chemical is in production and that "the use of this chemical is extremely limited," yet still promulgated the restriction as necessary to protect human health.[44]

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[41] 61 Fed. Reg. 65,746; 62 Fed. Reg. 38,860.
[42] 58 Fed. Reg. 65,024. Unlike chlorofluorocarbons (CFCs), which were considered by EPA to be the primary anthropogenic ozone depleters, compounds like methyl bromide and hyrobromofluroocarbons were conceded to be relatively minor contributors.
[43] *Id.* at 65,034.
[44] *Id.* at 65,044.

In addition, EPA is claiming uncertainty over matters that it has treated with certainty elsewhere. For example, the agency asserts that the new NAAQS's ultimate effect on actual ambient ozone levels is too uncertain to quantify.[45] Specifically, the agency argues that "spatial and temporal variability" of ozone, as well as behavioral factors influencing actual human exposure levels, make any assessment of UVB effects impossible.[46] Yet the agency found no difficulty dealing with these very same factors with regard to ozone's respiratory effects, and in promulgating the new NAAQS based upon them. It is arbitrary and capricious to claim, as EPA does, that ambient ozone levels can be confidently predicted for purposes of calculating respiratory effects but not for the UVB effects.

Similarly, the agency insists that the inverse relationship between ozone and ground-level UVB is incalculably complex, and "cannot . . . be adequately viewed by reference to uniform assumptions applicable for specific sun angle, latitude, time of day, cloud cover, and the presence of other pollutants."[47] However, these are precisely the same simplifying assumptions used by the agency to promulgate the regulations restricting the use of putative ozone depleting compounds.[48] EPA goes so far as to claim that "a full risk assessment of UV-B radiation-related effects resulting from a moderate change in ground-level ozone would be an extremely challenging enterprise that appears to be

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[45] 66 Fed. Reg. 57,282-85.
[46] Id.
[47] 66 Fed. Reg. 57,282.
[48] Strangely, EPA also argues that behavioral factors ("the use of sunscreen, hats, sunglasses" as well as "sun-seeking or sun-avoidance behaviors") precludes any accurate estimate of UVB effects. 66 Fed. Reg. 57,282-84. However, these behavioral factors did not prevent the agency from promulgating rules based on the estimated public health effects of stratospheric ozone loss.

beyond current data and modeling capabilities."[49] Yet this is what EPA did in its Regulatory Impact Analysis for the phaseout of ozone depleting compounds.[50] There is no reason EPA could not have applied the same approach to the ozone NAAQS in order to assess the UVB effects.

Furthermore, the agency has advanced its claim of uncertainty with arguments it had previously rejected in other regulatory contexts. For example, EPA asserts that efforts to reduce certain ozone precursors in response to a tightened NAAQS may have the paradoxical effect of causing localized ozone increases.[51] However, EPA has explicitly rejected this argument in rulemakings addressing those ozone precursors, most recently in regard to the 1999 rules affecting motor vehicle emission standards and gasoline sulfur control requirements.[52]

CONCLUSION

The agency has used one set of facts regarding UVB effects in promulgating rules under Title VI of the CAA, and a contradictory set of facts in its proposed response to remand of the ozone NAAQS. Further, the agency has applied one standard of evidence for the UVB-effects of the ozone NAAQS, and quite another for the respiratory effects. In so doing, the agency has done nothing in its proposed response to remand to alleviate

[49] 66 Fed. Reg. 57,284.
[50] EPA, "Regulatory Impact Analysis: Compliance With Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals." July 1992, and 1994 Addendum. It should be noted that the Regulatory Impact Analysis assessed a number of phaseout scenarios varying only slightly from one another, indicating that EPA believes its approach has the sensitivity to deal with relatively small ozone changes. 1994 Addendum, Tables 7, 8, 9.
[51] 66 Fed. Reg. 57,285.
[52] EPA, "Tier 2 Motor Vehicle Emission Standards and Gasoline Sulfur Control Requirements: Response to Comments," December 1999, pp. 27-6 to 27-11.

the deficiencies in the ozone NAAQS identified by the Court of Appeals. The new standard remains in violation of the Clean Air Act, and the proposed response to remand should be withdrawn by EPA.

Respectfully Submitted,

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