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**Assessing Benefits of Ground-Level Ozone:  
What Role for Science in Setting National Air Quality  
Standards?**

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## **Executive Summary**

A key determinant of the fate of the Environmental Protection Agency's (EPA) 1997 ozone standard is how the Agency responds to a Court of Appeals' decision that it must consider not only harmful respiratory effects, but also ozone's beneficial ability to reduce exposure to harmful ultraviolet radiation (UV-B).

In January 2001, EPA Administrator Browner signed a proposed response to the Court of Appeals' decision, but it has several problems. EPA's Scientific Advisory Committee did not review the scientific basis for Browner's proposed response, although such review is required by statute and EPA's internal procedures. The proposed response also ignores earlier EPA analysis suggesting that the health benefits of ozone are not negligible. Finally, it has significant conceptual flaws that the Advisory Committee could have corrected.

The existence of a tradeoff between respiratory effects and UV-B related risks means that careful science is essential to ensure that air quality standards improve public health. Before publishing a proposed response to the Court's decision, EPA should submit its assessments of UV-B related risks to its Scientific Advisory Committee. It should also seek the Committee's advice about how to set standards.

## **Assessing Benefits of Ground-Level Ozone: What Role for Science in Setting National Air Quality Standards?**

**Randall Lutter and Howard Gruenspecht**

### **1. Introduction**

A key determinant of the fate of the Environmental Protection Agency's (EPA) 1997 ozone standard is how the Agency responds to a Court of Appeals' decision that it must consider not only harmful respiratory effects, but also ozone's beneficial ability to reduce exposure to ultraviolet radiation (UV-B), which causes skin cancers and cataracts.<sup>1</sup> While these benefits are smaller than the UV-B screening benefits of stratospheric ozone that have motivated stringent regulatory actions on a global scale, they may be significant relative to the modest respiratory benefits of EPA's 1997 ozone standard.<sup>2</sup>

On January 19, 2001, then-EPA Administrator Browner signed a proposed response to the Court of Appeals remand, hereinafter referred to as the Response.<sup>3</sup> The Response states that information linking changes in ground level ozone concentrations to changes in exposures to UV-B radiation is too uncertain to warrant relaxing the standard issued in 1997. It also says associated changes in UV-B radiation exposures would likely be very small from a public health perspective. It then embraces the seemingly inconsistent conclusions that the benefits of tropospheric ozone effects are both "unquantifiable" and "small."<sup>4</sup> Finally it repropose an ozone standard identical to the one promulgated in 1997.<sup>5</sup> The new Administration has prevented publication of the Response, and EPA Administrator Whitman has yet to decide how to proceed.<sup>6</sup>

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<sup>1</sup> See U. S. Court of Appeals for the District of Columbia Circuit (1999). In setting the original 1997 standard, EPA had taken the position that only adverse effects should be considered. See Lutter and Wolz (1997) and U.S. Department of Energy (1995) for a discussion of the evidence and further readings.

<sup>2</sup> See Lutter and Wolz (1997). See Graham and Weiner (1995) for a summary of other risk-risk tradeoffs and the government's management of risk in this context.

<sup>3</sup> See U.S. Environmental Protection Agency (2001).

<sup>4</sup> See U.S. Environmental Protection Agency (2001, p.100).

<sup>5</sup> See U.S. Environmental Protection Agency (2001).

<sup>6</sup> See U.S. Environmental Protection Agency (2001).

The Clean Air Act accords a key role to science and scientific advisory bodies in the development of air quality standards. The Act establishes a committee, EPA's Clean Air Scientific Advisory Committee (CASAC), to "assist in the development of air quality criteria."<sup>7</sup> This Committee reviews a "Criteria Document," which, according to the Clean Air Act, must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of *all identifiable effects* on public health or welfare which may be expected from the presence of such pollutant in the ambient air [emphasis added]."<sup>8</sup> The Clean Air Act directs EPA to issue air quality standards, 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 [emphasis added]."<sup>9</sup>

Historically, EPA has extended scientific review beyond the minimum legal requirements. For example, EPA asked CASAC to review a "Staff Paper," which translates the science in the Criteria Document into terms useful to policy makers.<sup>10</sup> To supplement CASAC's work, EPA asked the scientific community, interested parties and the general public to comment on both documents.<sup>11</sup>

We show here that the Response has an inadequate scientific basis that could expose the ozone standard to further legal challenges. The Response argues that reproposal of the 1997 standard is appropriate given the *existing* administrative record and that reopening the record to allow CASAC review of UV-B related health effects is unnecessary.<sup>12</sup> But EPA's 1996 air quality Criteria Document, on which the standard must be "based,"<sup>13</sup> has *no* discussion of UV-B related health effects.

We also identify several concerns that, in the absence of CASAC review, raise doubts about whether the respiratory health improvements outweigh UV-B related health effects. The Response states that UV-B related health effects are small without comparing estimates of such effects with the respiratory health benefits of the ozone standard. It dismisses UV-B related effects as unquantifiable without identifying a

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<sup>7</sup> See Clean Air Act Section 117 and also Section 109(d)(2).

<sup>8</sup> See Clean Air Act Section 108(a)(2).

<sup>9</sup> See Clean Air Act Section 109(b)(1).

<sup>10</sup> See Clean Air Scientific Advisory Committee (1995b and 1995c). See also Clean Air Scientific Advisory Committee (1995a).

<sup>11</sup> See U.S. Environmental Protection Agency (1997c).

<sup>12</sup> See U.S. Environmental Protection Agency (2001).

<sup>13</sup> See Clean Air Act Section 109(b)(1).

threshold level of uncertainty necessary for this conclusion. It also makes highly selective use of available information and analyses without providing any justification.

In sum, the Response sets an unwise precedent for EPA to act without assurances that its actions are based on a strong scientific foundation as recommended by the National Academies of Science.<sup>14</sup> This is particularly true given the increased importance of careful science apparent in the Supreme Court’s recent interpretation of the Act. The Court confirmed EPA’s longstanding contention that it could not consider costs in setting air quality standards. But it added that this section of the Act requires “EPA to set air quality standards at the level that is ‘requisite’—that is, not lower or higher than is necessary—to protect the public health with an adequate margin of safety.”<sup>15</sup> Even without tradeoffs between skin cancers and respiratory function, EPA will need a careful risk assessment in order to set a standard that meets this criterion.

The next two sections address issues of process and substance respectively. The final section outlines our recommendations.

## **2. Procedural Problems**

In its May 1999 *American Trucking Associations* decision, the U.S. Court of Appeals for the D.C. Circuit ruled that “EPA must consider positive identifiable effects of a pollutant’s presence in the ambient air *in formulating air quality criteria* under section 108 and national ambient air quality standards under section 109 [emphasis added].”<sup>16</sup>

EPA’s Response to this decision seems inconsistent with provisions of the Clean Air Act. A key question is whether EPA’s air quality criteria, on which standards must be “based,”<sup>17</sup> already “accurately reflect”<sup>18</sup> knowledge useful in indicating beneficial UV-B related effects of ozone. The Response argues that the existing criteria are sufficient and that reopening the administrative record is unnecessary because EPA recognized in 1997

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<sup>14</sup> See National Research Council (2000).

<sup>15</sup> See U.S. Supreme Court (2001, p. 15).

<sup>16</sup> See U.S. Court of Appeals (1999, p. 25). The Administration did not seek Supreme Court review of this ruling.

<sup>17</sup> See Clean Air Act Section 109(b)(1).

<sup>18</sup> See Clean Air Act Section 108(a)(2).

that tropospheric ozone absorbs UV-B radiation.<sup>19</sup> In support of this claim the Response cites a partial paragraph<sup>20</sup> in the three-volume Criteria Document. But the two sentences are silent about health effects. Obviously, the existing Criteria Document falls well short of the Act's mandate to "accurately reflect the latest scientific knowledge."<sup>21</sup>

The inadequacy of the Criteria Document results from CASAC's truncated review of the UV-B question. At a March 1995 public meeting, Dr. Marvin Frazier of the Department of Energy presented to CASAC an analysis suggesting that UV-B related health effects associated with a 10 parts-per-billion reduction in tropospheric ozone could total dozens of deaths, thousands of non-melanoma skin cancers, and tens of thousands of cataracts.<sup>22</sup> Following the presentation, one CASAC member asked about governmental mechanisms for looking at this issue in a comprehensive fashion and the argument for having this information factored into the Criteria Document, as perhaps distinct from having the information available in some other form. He then posed the key question: "Should this group [CASAC] take responsibility for this problem?"<sup>23</sup> EPA staff replied, "We do not think . . . that the health effects of UV-B have to be added to the Criteria Document."<sup>24</sup> EPA staff also noted that there was as yet no decision on the separate policy question of whether UV-B health effects should be used to set the standards.<sup>25</sup> Based on this advice from EPA staff, the 1996 Criteria Document excluded both Dr. Frazier's assessment of UV-related health risks and CASAC's views about how to incorporate such risk estimates into the standard-setting process.

A second major procedural problem with the Response is its complete neglect of an earlier EPA analysis. It does not cite a 1997 EPA assessment of UV-B related health effects that was given to the Office of Management and Budget and is available in its docket. This assessment states "Any decrease in atmospheric ozone causes an increase in

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<sup>19</sup> See U.S. Environmental Protection Agency (2001, p.21).

<sup>20</sup> See U.S. Environmental Protection Agency (1996a, p. 5-79). The entire discussion is "However, the intensity of UV-B radiation reaching the earth's surface may be attenuated by O<sub>3</sub>-pollution in the lower troposphere (Brühl and Crutzen, 1989). Differences in the degree of this attenuation probably contribute to the discrepancies between recently observed trends in surface-level UV-B intensities (Scotto et al., 1988; Blumenthaler and Ambach, 1990)."

<sup>21</sup> See Clean Air Act Section 108(a)(2).

<sup>22</sup> See Lutter and Wolz (1997) for a readily available summary of Dr. Frazier's estimates.

<sup>23</sup> See U.S. Environmental Protection Agency, (1995, p. p. 212).

<sup>24</sup> See U.S. Environmental Protection Agency, (1995, p. 217).

<sup>25</sup> See U.S. Environmental Protection Agency (1995, p. 217).



solar radiation incident at the Earth's surface and therefore an increase in the incidence of non-melanoma skin cancers under the assumption that all other pertinent factors are held constant. The methodology for estimating such increases (of both UV levels and skin cancer incidence) is well-established."<sup>26</sup> The study concludes that 696 cases of non-melanoma skin cancers would result each year from the changes in ozone concentration that it modeled, but the Response fails to mention this work.

The 1997 EPA assessment goes beyond earlier work by Cupitt (1994), Frazier (1995), and Lutter and Wolz (1997), who had assessed changes in UV-B and associated skin cancers and cataracts based on an assumed uniform decline of 10 parts per billion in seasonal average ozone concentrations. The 1997 research assessed health effects for a change in ozone concentrations between a state-specific baseline and full attainment of EPA's proposed standard including changes in UV-B exposure at one-hour intervals throughout daylight hours.<sup>27</sup>

EPA has not refined its 1997 assessment, although a quick review suggests three areas for improvements. First, the analysis assumes a "current baseline" which is likely to result in an overstatement of adverse UV-B related health effects resulting from the standard to the extent that ozone concentrations would decline even in the absence of the new standard as areas approach attainment with the pre-existing ozone standard. Second, the analysis assumes that the entire population of each state experiences changes in ozone concentration that reflect a state-wide average. Since most people reside in major metropolitan areas where ozone concentrations exceed the statewide average, this approach will understate the average change in ozone concentration experienced by U.S. residents under the new standard. Third, the study is silent on other UV-B related health effects, though these may collectively be more important. Making these improvements is important because they could either raise or lower estimated benefits.

Finally, the Response departs from established procedures in deciding not to quantify UV-B related health effects without first seeking CASAC's advice. Earlier, in assessing possible reductions in mortality risk from reduced ozone concentrations, EPA

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<sup>26</sup> See U.S. Environmental Protection Agency (1997a, p. 1).

<sup>27</sup> See U.S. Environmental Protection Agency (1997a).

based its decision not to develop quantitative estimates on advice from CASAC.<sup>28</sup> The 1996 Criteria Document concluded the association between ozone and mortality needed further investigation.<sup>29</sup> In contrast, the Response left UV-B related health risks unquantified without any advice from CASAC.

### **3. Substantive Problems**

There are substantive problems with the Response, in addition to the procedural concerns outlined above. First, there is an internal inconsistency in its determination that information linking tropospheric ozone to UV-B related health effects is too uncertain to warrant relaxation of the standard. The Response justifies this conclusion in part by stating, “associated changes in UV-B radiation exposures of concern would likely be very small from a public health perspective.”<sup>30</sup> Yet this conclusion appears inconsistent with its view that UV-B related effects on public health are unquantifiable. The Response even states at one point that UV-B related health effects are “are likely very small, albeit unquantifiable.”<sup>31</sup> The Response begs the question how one can conclude something is small without measuring it quantitatively.

Second, notwithstanding the statement in the 1997 paper that the methodology for quantification of health risks is “well established,” the Response concludes that UV-B related health effects are unquantifiable. It is impossible, however, to judge the scientific merit of that conclusion because the Response does not identify a threshold level of uncertainty above which effects would be unquantifiable. Moreover, it is unclear whether the uncertainty associated with UV-B related effects will be smaller than uncertainty associated with other effects that EPA has quantified. In other contexts EPA has quantified risks that are very uncertain. For example, in a recent drinking water regulation addressing cancer risks from disinfection byproducts, EPA reported that the

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<sup>28</sup> EPA did develop quantitative estimates of mortality effects of ozone for use in its benefit-cost analysis. It based these in part on research that became available after CASAC concluded its review of the Criteria Document. But these were on the other side of the firewall separating EPA’s economic analysis from its decision-making. See U.S. Environmental Protection Agency (1997b and 1997d).

<sup>29</sup> See U.S. Environmental Protection Agency (1996a, p. 7-161).

<sup>30</sup> See U.S. Environmental Protection Agency (2001, p. 2).

<sup>31</sup> See U.S. Environmental Protection Agency (2001, p. 100).

baseline risks varied from 1 to 10,000 cases of cancer per year.<sup>32</sup> The Response's conclusion that the benefits cannot be quantified is difficult to understand.

Third, EPA's conclusion that the benefits of ozone are small is not based on any comparison of these benefits with estimates of the respiratory health benefits from the 1997 standard. Yet from the perspective of protecting public health, this is the only sensible basis by which to judge size.

The Response acknowledges that many of the factors important in conducting an assessment of UV-B related effects in a given area are also important in the assessment of respiratory health effects.<sup>33</sup> These factors cannot therefore provide an explanation of why respiratory effects, but not UV-related effects, can be quantified. In search of such an explanation, the Response states: "While analogous to the respiratory-related factors, there are a number of important differences between these sets of factors that arise."<sup>34</sup> Yet for the four such differences that it lists, it provides no persuasive reasons why they are sufficient to prevent quantification of health effects related to UV-B but not to respiratory function. Two of these differences—whether the health effects are "direct" (related to respiration) or "indirect" (related to solar radiation) and whether they derive from dermal or inhalation exposures—are by themselves irrelevant to determining the magnitude and uncertainty of risks. Another—whether effects vary with skin color—is also irrelevant. Skin color is no different from other demographic variables like age, level of physical activity and health status that EPA already considers in its risk assessments. The fourth difference, that quantifiable respiratory health effects stem from short-term exposures while UV-B related health effects result from chronic exposures would affect the form of a health-based air quality standard, but not whether UV-B related health effects can be quantified.<sup>35</sup>

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<sup>32</sup> See U.S. Environmental Protection Agency (1998).

<sup>33</sup> See U.S. Environmental Protection Agency (2001, p. 76).

<sup>34</sup> See U.S. Environmental Protection Agency (2001, p. 77).

<sup>35</sup> Note that EPA's rationale for the standard includes concern about unquantified "possible long-term damage to the lungs." See U.S. Environmental Protection Agency (1997c, p. 38856). Estimates of chronic health effects depend on assumptions about how emissions-related declines in ozone concentrations vary with weather patterns and times of the day or season. In its assessments of respiratory risks EPA already addresses these variations by assuming ozone concentrations "rollback" as the standard becomes more stringent. See, for example, U.S. Environmental Protection Agency (1997c, p. 38867).

Almost all of the sources of uncertainty in UV-B related health effects mirror similar sources of uncertainty in respiratory health effects. For example, aerosols affect UV-B screening by low-level ozone, and air pollutants may also modify the effects of ozone on human respiration.<sup>36</sup> One exception, the effects of a more stringent standard on the column of ozone above the ground, is not the subject of serious discussion in the Response.<sup>37</sup> The Response seems to deviate from the D.C. Circuit's instructions that EPA evaluate health benefits using the "same approach" as it does for reviewing studies showing benefits from ozone reductions.<sup>38</sup> It imposes a higher hurdle for quantifying UV-B related effects than respiratory effects.

EPA's 1997 analysis, which the Response ignores, suggests that benefits of ozone may be significant relative to the respiratory health benefits of the ozone standard. To illustrate, we assume for simplicity that the ratio of non-melanoma skin cancer cases to other health effects is the same as they were in the estimates presented by Dr. Frazier of the Department of Energy. In this case, the total annual number of additional melanoma cases, melanoma fatalities, and cataracts would be 10, 3, and 1,800 respectively for a lower-bound estimate and 46, 9, and 4,600 respectively for an upper-bound estimate. This back-of-the-envelope calculation can in no way substitute for a thorough risk assessment, or for CASAC's assessment and review of air quality criteria. But it casts substantial doubt on the Response's finding that UV-B related health effects are negligible.

It is useful to compare these estimates of UV-B related health effects with the respiratory health effects estimated by EPA for the 1997 ozone standard. EPA reported that the ozone standard would avoid 40 hospital admissions in New York City among asthmatics.<sup>39</sup> For nine cities EPA estimated that the number of "outdoor" children experiencing temporary "moderate lung function decreases" would fall by 70,000 per year, while those experiencing temporary "large lung function decreases" would fall by about 40,000 per year.<sup>40</sup> In addition, it estimated that 14,000 children would avoid

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<sup>36</sup> See U.S. Environmental Protection Agency (1996a, vol III, p. 6-156).

<sup>37</sup> The Response discusses this issue without using any data other than unpublished internal staff analyses dating to 1994. See U.S. Environmental Protection Agency (2001, p. 88).

<sup>38</sup> See U. S. Court of Appeals for the District of Columbia Circuit. (1999, Section III.B.)

<sup>39</sup> See U.S. Environmental Protection Agency (2001, p. 53).

<sup>40</sup> See U.S. Environmental Protection Agency (1997d, p. 38865).

episodes of “moderate or severe pain on deep inspiration.”<sup>41</sup> EPA believes that these quantifiable respiratory health effects represent the measurable part of a pyramid of larger magnitude.<sup>42</sup> Notwithstanding the possibility of such a pyramid, we believe the available evidence suggests that the UV-B related health effects of reductions in ozone are large enough relative to these respiratory effects that they cannot be dismissed without further serious analysis.

#### **4. Conclusions and Recommendations**

While principled standard-setting requires more than science,<sup>43</sup> the Clean Air Act provides a significant role for science in establishing a sound basis for policy decisions. The Court’s decision that EPA must consider the benefits of ozone has left EPA with a Criteria Document that does not provide an adequate scientific basis for a new ozone standard. EPA’s Response to the Court’s decision creates an unwelcome precedent for curtailing scientific review prescribed by the Act.

EPA’s actions to limit the scope of scientific review should not be rewarded. No public good is served by steering CASAC away from reviewing and assessing the science of UV-B screening and related testimony presented in CASAC hearings. This is especially true given the statement by EPA staff to CASAC that no policy decision had yet been made on the issue of whether UV-B screening effects would be considered by the Administrator.

EPA’s actions since the Court of Appeals remand are equally troubling. In the twenty months after the Court’s decision, EPA made no effort to update its risk assessments, develop new information on UV-B screening, or seek CASAC’s advice.

The lack of scientific review means the Response may harm public health. Reductions in respiratory ailments from the Response may not outweigh the increased risk of skin cancers and cataracts. We therefore make the following recommendations:

- EPA should expeditiously update its 1997 risk assessment of UV-B screening effects, correcting for deficiencies that have already been identified. In

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<sup>41</sup> See U.S. Environmental Protection Agency (1997d, p. 38865). CASAC opinion generally held that single, short-term, and moderate health effects occurring in healthy individuals should not be considered adverse. See U.S. Environmental Protection Agency (1996b, Table V-5b).

<sup>42</sup> See U.S. Environmental Protection Agency (1997d, p. 38868).

<sup>43</sup> See Marchant et al. (2000).

accordance with the court remand, EPA should prepare a supplement to the 1997 Criteria Document that summarizes the literature on health effects from UV-B screening and the findings of all available risk assessments. EPA should also prepare an addendum to its staff paper addressing UV-B screening.

- EPA should seek scientific advice from CASAC about the magnitude of the beneficial effects of ozone and the most appropriate standard given such effects. To develop this advice, CASAC should convene an appropriate subcommittee that includes several experts in the scientific fields addressed in the supplement to the Criteria Document as well as experts familiar with the respiratory health fields addressed in the 1997 criteria document. This team should:
  - review the Criteria Document supplement that, together with the original criteria document, summarizes all identifiable effects;
  - review all draft risk assessments related to UV-B screening, including an updated version of EPA's 1997 assessment, other risk assessments in the record, and available published literature;
  - recommend whether EPA should quantify given health effects;
  - review revisions to EPA's staff paper.

Finally, CASAC should advise EPA about the appropriate form and level of the standard, taking account of both adverse and favorable effects of ozone.

- Using the CASAC reviews, EPA should propose a response to the remand and develop a final standard in light of public comment about its proposal.

These recommendations are unlikely to delay emissions controls because EPA already has to respond to the Supreme Court's decision on implementation.<sup>44</sup> In addition the Supreme Court said it remains for the Court of Appeals to dispose of other challenges, including, presumably questions about whether the revised air quality standards are arbitrary and capricious.<sup>45</sup>

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<sup>44</sup> See U.S. Supreme Court (2001).

<sup>45</sup> See U.S. Supreme Court (2001, p. 15).

If EPA followed these recommendations, it would honor its own prior commitments to transparent and consistent risk assessment and peer-review. EPA's recent policy on risk "calls for a transparent process and [risk characterization] products that are clear, consistent and reasonable."<sup>46</sup> The principle underlying EPA's new peer-review policy is that "all major scientific and technical work-products used in decision makings will be peer-reviewed."<sup>47</sup>

The potential tradeoff between UV-B screening and respiratory health effects presents the EPA Administrator with a novel challenge in setting the air quality standard for ozone. That decision needs to reflect the best possible science.

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<sup>46</sup> See U.S. Environmental Protection Agency (2000b, p. 1).

<sup>47</sup> See U.S. Environmental Protection Agency (2000a, p. 26).

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