January 31, 2010

Roger O. McClellan, DVM, MMS, DSc (Honorary),
Diplomate-ABT, Diplomate-ABVT, Fellow-ATS
Advisor, Toxicology and Human Health Risk Analysis
13701 Quaking Aspen Place N.E.
Albuquerque, NM 87111-7168
Tel: 505-296-7083
E-mail: roger.o.mcclellan@att.net

Comments on
Proposed "Reconsideration" National Ambient Air Quality Standard for Ozone
for presentation at the
Public Meeting
U.S. Environmental Protection Agency
Arlington, VA

February 2, 2010

I am Roger McClellan, an advisor to private and public organizations on inhalation toxicology and human health risk analysis issues related to air quality. My entire career has been devoted to developing scientific information that will improve human health and will inform policy decisions that have positive impact on human health. I have served on numerous Clean Air Scientific Advisory Committee (CASAC) Panels including those dealing with ozone and I had the privilege of Chairing CASAC for 4 years. Thus, I understand the process by which the air quality standards are developed. I also appreciate the unique role of CASAC in advising the Administrator on the science that informs policy decisions on setting National Ambient Air Quality Standards (NAAQS).

The process by which standards are developed has two key phases. In the first phase, all of the relevant science is reviewed and integrated. In the second phase, the science is used to inform policy judgments that lead to a succinct policy outcome – the Standard (an indicator, an averaging time, a numerical concentration and a statistical form).

Decisions on the specific level and form of the Standard require that policy judgment be exercised since the level and form have associated health risks. The Clean Air Act does not compel the elimination of all risk.

Science provides a basis for estimating the health risks associated with a Standard set at a particular level and form. Scientific information alone cannot, and does not, establish whether

the health risks associated with a particular level and form are or are not acceptable – that is a policy decision.

I appreciate the opportunity to share with you my views on the proposed "reconsideration" standard (U.S. EPA, 2010). I am very familiar with the science that should inform this proposed rule having carefully followed EPA and CASAC activities leading to the 2008 Standards. Indeed, I offered comments (McClellan, 2007) in October 2007 on the proposed rule (U.S. EPA, 2007) that led to the March 2008 NAAQS for ozone (U.S.EPA, 2008). My comments were based in large measure on the discussions at a Conference held in Rochester, NY (June 5-6, 2007). A report on that Conference has been published (McClellan et al., 2009).

It is my understanding that Administrator Jackson will be relying on exactly the same scientific information in making her policy judgments on a "reconsideration" standard that Administrator Johnson considered in setting the 2008 Standard. In my opinion, the fact that a "reconsideration" proposal is even being considered relates to confusion over the unsolicited advice offered by CASAC to EPA Administrator Johnson after the 2008 Standard was finalized.

CASAC (Henderson, 2008) restated the Committee's preference for a primary health standard set in the range of 0.070 to 0.060 ppm ozone (8-hour average). Hereafter in this document reference will only be made to the 8-hour average concentration without repeating the indicator - ozone. The CASAC advice, while trumpeted as being scientific advice, was in reality a statement of the Committee preference for a policy outcome, i.e. a substantially lower standard, based on a blending of science and policy.

In arguing that the Standard should be set no higher than 0.070 ppm as contrasted with the 0.075 ppm level selected by Administrator Johnson, the CASAC moved beyond advising on the science. Indeed, CASAC did not clearly describe the science or the policy considerations that under-girded its policy preference outcome of 0.070 ppm or 0.060 ppm. Moreover, it offered no scientific or policy considerations as to why a higher level was unacceptable. The bright-line upper policy preference outcome, 0.070 ppm, interpreted as advice to the Administrator that the Standard should not be set higher, has the greatest significance. Presumably some members of the CASAC Panel found this level acceptable but would have preferred the lower level, 0.060 ppm. It is hard to conceive that the CASAC Panel was offering the lower level as a level the Administrator should not go below.

Administrator Jackson has repeatedly stated that the CASAC advice was the basis for proposing a "reconsideration" Standard in the range of 0.070 to 0.060 ppm. In doing so she apparently failed to recognize that the CASAC advice reflected a mixture of both scientific advice and policy judgment.

Supreme Court Justice Breyer (Breyer, 2010), in Whitman versus American Trucking Association used elegant language to emphasize the considerable flexibility the EPA Administrator has in setting the Standard. He clearly stated that the language of the Clean Air Act does not compel the elimination of all risk. He emphasized the flexibility the Administrator has in "deciding what risks are acceptable in the world in which we live." In his opinion, he noted the Administrator's considerable discretionary standard-setting authority. He specifically referred to the need "to take account of context when determining the acceptability of small risks to health."

Justice Breyer's opinion was based on his careful review and analysis of the Clean Air Act, specifically taking account of the role of the EPA Administrator. The discretionary authority the Clean Air Act accords the EPA Administrator, a Senior Administration official appointed by the President and confirmed by the U.S. Senate, is understandable. His opinion certainly gives no indication that such discretionary authority extends to CASAC whose members are appointed by the EPA Administrator. Likewise, it is difficult to envision that the authority to make discretionary policy judgments accorded the Administrator extends to CASAC Panels. These Panels consist of the CASAC members plus a dozen or so consultants selected on the basis of their scientific credentials, not their background and expertise for making policy judgments of substantial importance to Society.

It is interesting that while the 2007 proposal (EPA, 2007) quoted Justice Breyer's thoughtful opinion, these quotes are absent from the current proposal (EPA,2010). I submit that Justice Breyer's opinion is as relevant to the 2010 "reconsideration" proposal as it was to the 2007 proposal.

The EPA has previously acknowledged that the CASAC advice for a primary health standard in the range of 0.070 to 0.060 ppm was a blending of science and policy. Karen Martin, a career scientist with EPA's Office of Air Quality Planning and Standards gave a presentation on October 29, 2008 entitled, "Building on the Last Ozone NAAQS Review: Key Policy Relevant Issues" (Martin, 2008). That presentation was at a meeting initiating the next NAAQS

Ozone Review originally intended to be completed in 2013. In that presentation she related the following:

"**Primary standard: Evidence-based considerations in last review (cont'd.)**

Conclusions on level:

- **Primary consideration given to the body of scientific evidence.**

  Focused on proposed range of 0.070 to 0.075 ppm, recognizing that 0.075 ppm is above range recommended by CASAC (i.e., 0.070 to 0.060 ppm).

  While agreeing with CASAC's interpretation of the evidence, Administrator observed that recommendation "appears to be a mixture of scientific and policy considerations"

- **No evidence-based "bright line," such that choice is clearly a public health policy judgment, based on strengths and limitations of the evidence**

  Administrator placed less weight on Adams studies and on exposure/risk assessments than CASAC apparently did, and more weight on implications of uncertainties in assessments

  Not prepared to assume that continuum of risks extends "well below concentrations observed in key controlled human exposure studies" nor that "associations observed in epidemiological studies are, in fact, causally related to O_3 at those levels"

  Likelihood of obtaining benefits with a standard below 0.075 ppm decrease, while likelihood of requiring reductions that go beyond those needed to protect public health increases

EPA's awareness of the nature of the CASAC advice is formally documented in the "Reconsideration" NAAQS Ozone Proposal (EPA, 2010). In the discussion on the basis for a decision on the primary health standard the proposal states – "With respect to CASAC's recommended range of standard levels, EPA observed that the basis for CASAC's recommendation appeared to be a mixture of scientific and policy considerations."

It is clear that EPA recognized that the CASAC advice was a mixture of scientific and policy considerations. In calling attention to CASAC entering the policy arena, it is apparent that EPA appreciates that "policy judgments" are reserved to the Administrator. Thus, it is difficult to understand why EPA Administrator Jackson issued a "reconsideration" proposal and, moreover, stated that the decision to "reconsider" the Standard was driven by the science.

In my comments to then EPA Administrator Johnson on the proposed ozone rule (EPA, 2007), I emphasized that the scientific information in the record then (the same information that is being used in the "reconsideration" rule) was such that the Administrator could exercise his policy judgment prerogative in making decisions on the NAAQS "including continuation of the present Standard," which was then set at 0.08 ppm. Administrator Johnson made a policy judgment decision informed by the scientific information in the record to revise the standard to 0.075 ppm.

My advice to Administrator Jackson is that the "reconsideration" proposal be withdrawn. It is clear that CASAC's policy preference for a Standard lower than the 2008 Standard was a blend of scientific and policy considerations. It does not offer compelling scientific arguments that require "reconsideration" of the 2008 Standard at this time. In my opinion, the resources available to EPA could be better utilized in moving forward in an orderly manner with next scheduled ozone review, which is already underway and scheduled for completion in 2013.

If Administrator Jackson feels compelled to continue the "reconsideration" rule-making, I urge her to be mindful of the need to carefully consider the scientific information in the 2006 record and use the authority exclusively delegated to her under the Clean Air Act in making policy judgments required in setting the Standard. CASAC's stated policy preference outcome based on a blending of scientific and policy considerations should not be used as a basis for what should be the Administrator's independent policy judgments.

These judgments should take into account several key points.

(1) It is not necessary for her to include an "additional margin of safety" at the end of the Standard setting process as suggested by CASAC. This is the case since at each step in the scientific analysis and review process conservative approaches (more likely to over-state rather than under-state) were taken by the EPA staff and CASAC to characterize the health risks associated with ambient ozone.

(2) Background levels of ambient ozone vary markedly across the United States. For many locations background ozone levels were markedly under-estimated by the "Policy Relevant Background" approach that was introduced by the EPA staff as a statement of scientific fact in the review process when the statements clearly reflected policy judgments. Knowledge of background levels of ambient ozone is an important consideration in setting the level and form of the Standard, it is not merely an implementation consideration.

(3) There is substantial heterogeneity in short-term mortality, or the absence of mortality, associated with increases in ambient ozone across the U.S., the kind of increases targeted by an 8-hour standard. Indeed, the vast majority of cities, including many that would be in non-attainment for a standard set in the range of 0.070 to 0.060 ppm, show no statistically significant association between elevated ozone and short-term mortality. This includes my home town, Albuquerque, New Mexico (see attached figure). Only a very few cities show statistically significant associations between elevated ozone and short-term mortality. Moreover, those few cities are generally in non-attainment with the 0.075 ppm Standard set in 2008 and they were in non-attainment with the 0.08 ppm Standard set in 1997.

(4) Health effects attributed to ambient ozone in some of the epidemiological studies have not adequately considered the role of co-pollutants such as particulate matter. For example, when the association between short-term mortality and ozone reported by Bell et al. (2004) was re-evaluated with particulate matter (PM_{10}) included in the model, the average ozone effect was reduced by 22% to 33% (Smith et al., 2009).

(5) The clinical studies with controlled exposure of human volunteers to ozone do not provide convincing evidence of clinically significant effects with exposures below 0.080 ppm.

In closing, I wish to reiterate my opinion that scientific information should inform the setting of the ozone Standard. However, it is inappropriate to argue, as CASAC has, that the science compels policy judgments that lead to a particular policy outcome – a lower standard.

The views I have shared with you today are my own professional views. While I have been engaged by the American Petroleum Institute (API) to review EPA's proposed "reconsideration" ozone standard, the views I have expressed today are not necessarily those of the API.

Thank you for the opportunity to speak to you today.

References

Bell, M.L., McDermott, S. L. Zeger, J.M. Samet, F. Dominici. (2004) Ozone and Short-term Mortality in 95 US Urban Communities, 1987-2000. JAMA 292: 2372-2378.

Breyer J. (2001). Opinion in Whitman v. American Trucking Association. 531 U.S. 457, 494-495.

Henderson, R.F. (2008). Letter from CASAC Chair, Rogene Henderson, to EPA Administrator Stephen Johnson, April 7, 2008, EPA-CASAC-08-009.

Martin, K. (2008). Building on the Last Ozone NAAQS Review: Key Policy Relevant Issues. Presentation to CASAC OzonePanel, October 29, 2008.

McClellan, Roger O., Mark W. Frampton, Petros Koutrakis, William F. McDonnell, Suresh Moolgavkar, D. Warner North, Anne E. Smith, Richard L. Smith and Mark J. Utell. (2009) Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone: A Conference Report. Inhal. Toxicol. 21(S2): 1-36.

McClellan, R.O. (2007) Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172.

Smith, Richard L., Baowei Xu and Paul Switzer. (2009) Reassessing the Relationship Between Ozone and Short-Term Mortality in U.S. Urban Communities. Inhal. Toxicol. 29(S2): 37-61.

U.S. Environmental Protection Agency (2007). National Ambient Air Quality Standards for Ozone: Proposed Rule 40 CFR Part 50, Federal Register 72: 37818-37919 (July 11, 2007).

U.S. Environmental Protection Agency (2008). National Ambient Air Quality Standards: Final Rule. 40 CFR Parts 50 and58. Federal Register 73: 16436-16514.

U.S. Environmental Protection Agency (2010). National Ambient Air Quality Standard: Proosed Rule. 40 CFR Parts 50 and 58. Federal Register 75: 2938-3052.

Attachment

The figure shown on the next page is taken from Smith et al. (2009) and is a reanalysis of the data that were analyzed and reported by Bell et al. (2004). The Bell et al. (2004) paper was a key component of the science that informed the policy judgments that led to the 2008 Standard.

The substantial heterogenicity in the association between increases in short-term mortality and elevated ozone is very evident. It is noteworthy that when Smith et al. (2009) included particulate matter (PM_{10}) in the model the overall ozone-mortality coefficient was reduced by between 22% and 33%. The results of Smith were summarized in my comments submitted to the ozone docket in October 2007 (McClellan, 20o07). In my comments to the ozone docket, I also noted the results of a conference on critical considerations in evaluating the scientific evidence on the health effects of ambient ozone. Those conference proceedings have now been published (McClellan et al., 2009).

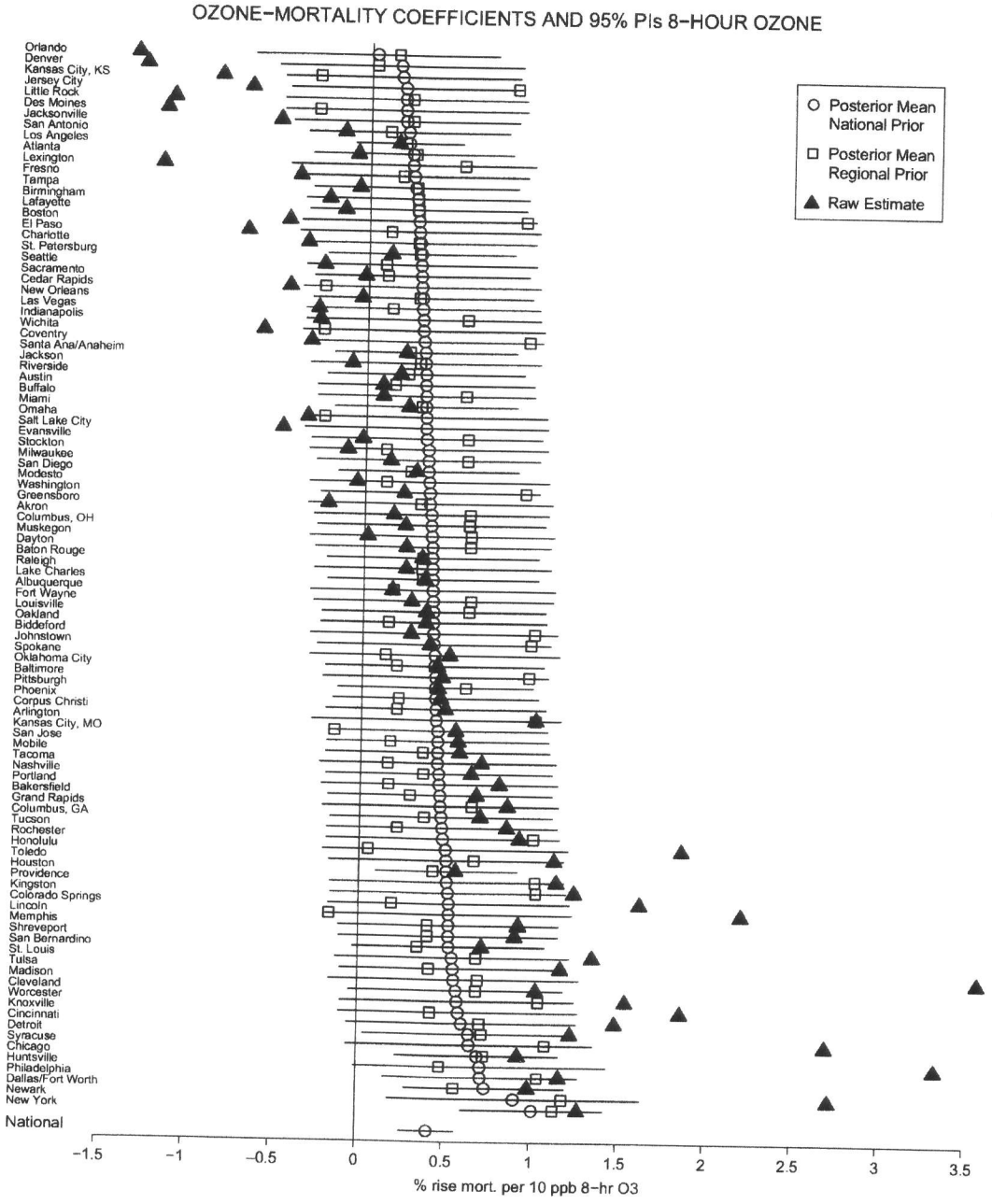


Figure 4. Ninety-five percent posterior intervals for the ozone-mortality coefficients, based on 8-h ozone, all-year data. The Bayesian posterior estimates under the "national prior" (circles) are shown alongside those for the "regional prior" (squares) and the raw maximum likelihood estimates (triangles).

Reconsideration of the 2008 Ozone NAAQS

EPA Public Hearing

February 2, 2010

Testimony of

Howard J. Feldman

American Petroleum Institute

Good morning. I am Howard J. Feldman, Director of Regulatory and Scientific Affairs at API. API is the primary trade association for the oil and gas industry, with about 400 members, and as you all know, we've been very active in the NAAQS process through the years.

Today, I will make three points. First, the oil and gas industry is helping make the air cleaner today and in the future. Second, there is actually far more debate on the science than EPA has represented. And third, the proposed new standards may impose real costs on real people without commensurate benefit.

Thanks to implementation of the Clean Air Act, our air quality has demonstrably improved. Since 1990, the oil and gas industry has invested more than $175 billion -- that's billion, with a capital "B," -- towards improving the environmental performance of its products, facilities, and operations. Approximately 57 percent of the industry's $14 billion environmental expenditures in 2007 targeted air pollution abatement, either meeting or surpassing the requirements of the Clean Air Act. We've put in place cleaner gasoline and cleaner diesel, and these fuels, along with cleaner equipment, cleaner cars, trucks, and buses, are leading to, and will continue to lead to, cleaner air. We've also worked with local and state governments to reduce the emissions from our facilities.

EPA's trends data (my Figure 1) show that the emissions from six criteria air pollutants dropped by 60 percent between 1970 and 2008, while vehicle miles traveled (VMT) went up 163 percent. This is an impressive accomplishment matched by progress in other areas. According to EPA's Toxics Release Inventory (TRI), since 1988 releases and transfers of toxic chemicals from the petroleum industry have decreased by 68 percent. Equally important, regulations and standards already in place will assure further progress. Refineries across the nation implemented new processes designed to dramatically

reduce the presence of sulfur in gasoline and diesel. These cleaner fuels, along with cleaner cars, buses, trucks, and non-road equipment will produce significant continuing air quality improvements. Amplifying this progress, cars and trucks will be 77-95% cleaner over the next decade than those produced before 2004. The annual emission reductions from the use of Ultra Low Sulfur Diesel with cleaner technology engines will be equivalent to removing the pollution from more than 90% of today's trucks and buses by 2030.

On to my second point -- there is actually far more debate on the science than EPA has represented, as previously acknowledged by Administrator Johnson. As the former chairman of the CASAC Dr. Roger McClellan indicated in his testimony earlier today, Administrator Johnson was justified in the **policy decisions** he reached regarding the setting of the NAAQS. And EPA has recently acknowledged that the newer studies on ozone 'do not materially change any of the broad scientific conclusions regarding the health effects of exposure'. **Therefore, this action lacks scientific justification.** API's written comments will include detailed comments on the science, including those studies that some are alleging provide new support for a tighter standard.

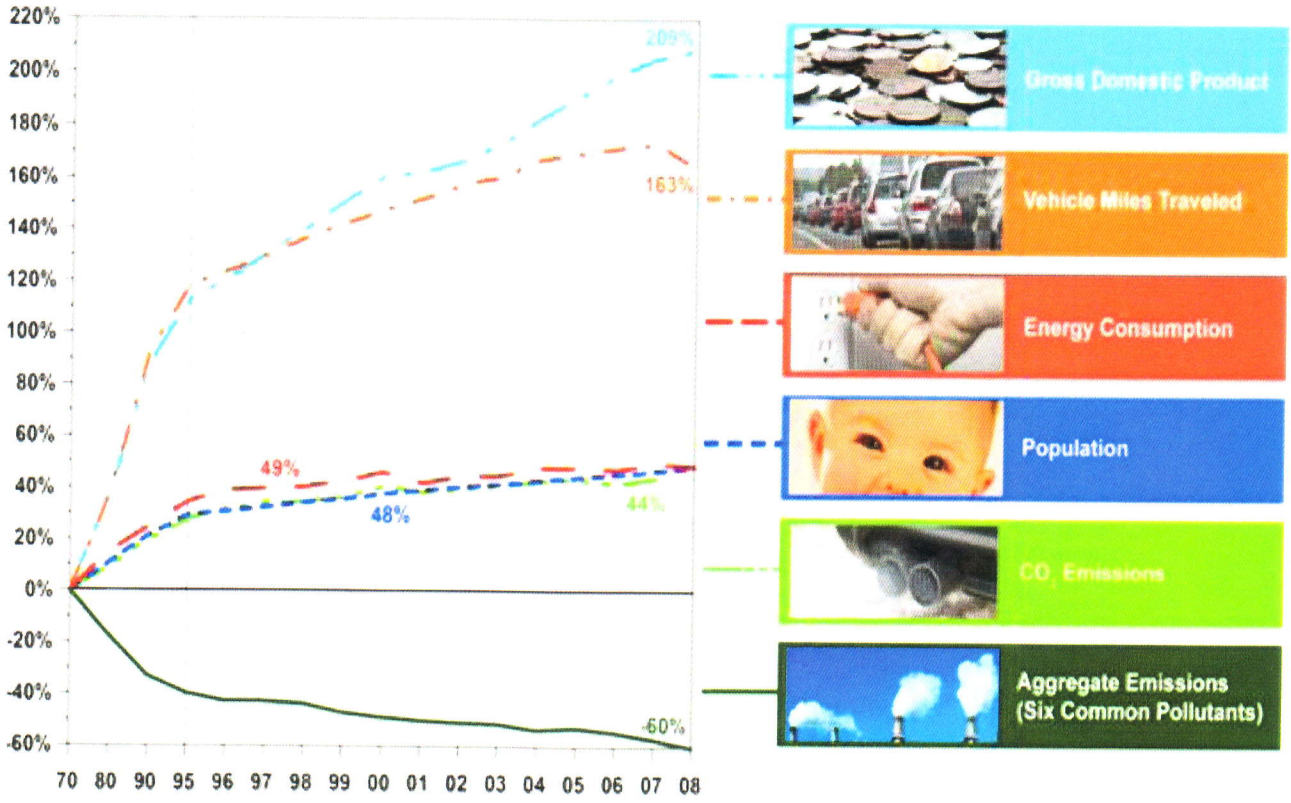
Moving to my third and last point, a more stringent ozone standard will burden the States with a new and more difficult target before they complete work and implement attainment plans for the current standard. To cite a football analogy, EPA is effectively proposing to move the goalposts in the middle of the game. Many local communities will be saddled with new costs that will hurt both large and small businesses and prevent expansion and growth. Even EPA estimates that **costs of this proposal could be as high as $90 Billion** and the standards still would not be achieved everywhere. Fuels that cost more to manufacture would be required in more areas. Jobs will unnecessarily be lost. **And EPA is proposing a**

range that is very close to setting the standard at peak background levels, so it will be incredibly difficult for states to attain the standard.

In summary, this proposal lacks scientific justification. There is absolutely no basis for EPA to propose changing the ozone standards promulgated by the EPA Administrator in 2008. To do so is an obvious politicization of the air quality standard setting process that could mean unnecessary energy cost increases, job losses and less domestic oil and natural gas development and energy security. This would impact citizens while they are still suffering from a severe recession, in the very communities where we need to be creating jobs.

Without a clear certain scientific basis for selecting a different numeric standard, the ozone standards should not be changed now. We urge the Administrator not to pursue this proposal.

Figure 1. Comparison of Growth Areas and Emissions, 1970-2008



January 31, 2010

Roger O. McClellan, DVM, MMS, DSc (Honorary),
Diplomate-ABT, Diplomate-ABVT, Fellow-ATS
Advisor, Toxicology and Human Health Risk Analysis
13701 Quaking Aspen Place N.E.
Albuquerque, NM 87111-7168
Tel: 505-296-7083
E-mail: roger.o.mcclellan@att.net

Comments on
Proposed "Reconsideration" National Ambient Air Quality Standard for Ozone
for presentation at the
Public Meeting
U.S. Environmental Protection Agency
Arlington, VA

February 2, 2010

I am Roger McClellan, an advisor to private and public organizations on inhalation toxicology and human health risk analysis issues related to air quality. My entire career has been devoted to developing scientific information that will improve human health and will inform policy decisions that have positive impact on human health. I have served on numerous Clean Air Scientific Advisory Committee (CASAC) Panels including those dealing with ozone and I had the privilege of Chairing CASAC for 4 years. Thus, I understand the process by which the air quality standards are developed. I also appreciate the unique role of CASAC in advising the Administrator on the science that informs policy decisions on setting National Ambient Air Quality Standards (NAAQS).

The process by which standards are developed has two key phases. In the first phase, all of the relevant science is reviewed and integrated. In the second phase, the science is used to inform policy judgments that lead to a succinct policy outcome – the Standard (an indicator, an averaging time, a numerical concentration and a statistical form).

Decisions on the specific level and form of the Standard require that policy judgment be exercised since the level and form have associated health risks. The Clean Air Act does not compel the elimination of all risk.

Science provides a basis for estimating the health risks associated with a Standard set at a particular level and form. Scientific information alone cannot, and does not, establish whether

the health risks associated with a particular level and form are or are not acceptable – that is a policy decision.

I appreciate the opportunity to share with you my views on the proposed "reconsideration" standard (U.S. EPA, 2010). I am very familiar with the science that should inform this proposed rule having carefully followed EPA and CASAC activities leading to the 2008 Standards. Indeed, I offered comments (McClellan, 2007) in October 2007 on the proposed rule (U.S. EPA, 2007) that led to the March 2008 NAAQS for ozone (U.S.EPA, 2008). My comments were based in large measure on the discussions at a Conference held in Rochester, NY (June 5-6, 2007). A report on that Conference has been published (McClellan et al., 2009).

It is my understanding that Administrator Jackson will be relying on exactly the same scientific information in making her policy judgments on a "reconsideration" standard that Administrator Johnson considered in setting the 2008 Standard. In my opinion, the fact that a "reconsideration" proposal is even being considered relates to confusion over the unsolicited advice offered by CASAC to EPA Administrator Johnson after the 2008 Standard was finalized.

CASAC (Henderson, 2008) restated the Committee's preference for a primary health standard set in the range of 0.070 to 0.060 ppm ozone (8-hour average). Hereafter in this document reference will only be made to the 8-hour average concentration without repeating the indicator - ozone. The CASAC advice, while trumpeted as being scientific advice, was in reality a statement of the Committee preference for a policy outcome, i.e. a substantially lower standard, based on a blending of science and policy.

In arguing that the Standard should be set no higher than 0.070 ppm as contrasted with the 0.075 ppm level selected by Administrator Johnson, the CASAC moved beyond advising on the science. Indeed, CASAC did not clearly describe the science or the policy considerations that under-girded its policy preference outcome of 0.070 ppm or 0.060 ppm. Moreover, it offered no scientific or policy considerations as to why a higher level was unacceptable. The bright-line upper policy preference outcome, 0.070 ppm, interpreted as advice to the Administrator that the Standard should not be set higher, has the greatest significance. Presumably some members of the CASAC Panel found this level acceptable but would have preferred the lower level, 0.060 ppm. It is hard to conceive that the CASAC Panel was offering the lower level as a level the Administrator should not go below.

Administrator Jackson has repeatedly stated that the CASAC advice was the basis for proposing a "reconsideration" Standard in the range of 0.070 to 0.060 ppm. In doing so she apparently failed to recognize that the CASAC advice reflected a mixture of both scientific advice and policy judgment.

Supreme Court Justice Breyer (Breyer, 2010), in Whitman versus American Trucking Association used elegant language to emphasize the considerable flexibility the EPA Administrator has in setting the Standard. He clearly stated that the language of the Clean Air Act does not compel the elimination of all risk. He emphasized the flexibility the Administrator has in "deciding what risks are acceptable in the world in which we live." In his opinion, he noted the Administrator's considerable discretionary standard-setting authority. He specifically referred to the need "to take account of context when determining the acceptability of small risks to health."

Justice Breyer's opinion was based on his careful review and analysis of the Clean Air Act, specifically taking account of the role of the EPA Administrator. The discretionary authority the Clean Air Act accords the EPA Administrator, a Senior Administration official appointed by the President and confirmed by the U.S. Senate, is understandable. His opinion certainly gives no indication that such discretionary authority extends to CASAC whose members are appointed by the EPA Administrator. Likewise, it is difficult to envision that the authority to make discretionary policy judgments accorded the Administrator extends to CASAC Panels. These Panels consist of the CASAC members plus a dozen or so consultants selected on the basis of their scientific credentials, not their background and expertise for making policy judgments of substantial importance to Society.

It is interesting that while the 2007 proposal (EPA, 2007) quoted Justice Breyer's thoughtful opinion, these quotes are absent from the current proposal (EPA,2010). I submit that Justice Breyer's opinion is as relevant to the 2010 "reconsideration" proposal as it was to the 2007 proposal.

The EPA has previously acknowledged that the CASAC advice for a primary health standard in the range of 0.070 to 0.060 ppm was a blending of science and policy. Karen Martin, a career scientist with EPA's Office of Air Quality Planning and Standards gave a presentation on October 29, 2008 entitled, "Building on the Last Ozone NAAQS Review: Key Policy Relevant Issues" (Martin, 2008). That presentation was at a meeting initiating the next NAAQS

Ozone Review originally intended to be completed in 2013. In that presentation she related the following:

"**Primary standard: Evidence-based considerations in last review (cont'd.)**

Conclusions on level:

- **Primary consideration given to the body of scientific evidence.**

  Focused on proposed range of 0.070 to 0.075 ppm, recognizing that 0.075 ppm is above range recommended by CASAC (i.e., 0.070 to 0.060 ppm).

  While agreeing with CASAC's interpretation of the evidence, Administrator observed that recommendation "appears to be a mixture of scientific and policy considerations"

- **No evidence-based "bright line," such that choice is clearly a public health policy judgment, based on strengths and limitations of the evidence**

  Administrator placed less weight on Adams studies and on exposure/risk assessments than CASAC apparently did, and more weight on implications of uncertainties in assessments

  Not prepared to assume that continuum of risks extends "well below concentrations observed in key controlled human exposure studies" nor that "associations observed in epidemiological studies are, in fact, causally related to O_3 at those levels"

  Likelihood of obtaining benefits with a standard below 0.075 ppm decrease, while likelihood of requiring reductions that go beyond those needed to protect public health increases

EPA's awareness of the nature of the CASAC advice is formally documented in the "Reconsideration" NAAQS Ozone Proposal (EPA, 2010). In the discussion on the basis for a decision on the primary health standard the proposal states – "With respect to CASAC's recommended range of standard levels, EPA observed that the basis for CASAC's recommendation appeared to be a mixture of scientific and policy considerations."

It is clear that EPA recognized that the CASAC advice was a mixture of scientific and policy considerations. In calling attention to CASAC entering the policy arena, it is apparent that EPA appreciates that "policy judgments" are reserved to the Administrator. Thus, it is difficult to understand why EPA Administrator Jackson issued a "reconsideration" proposal and, moreover, stated that the decision to "reconsider" the Standard was driven by the science.

In my comments to then EPA Administrator Johnson on the proposed ozone rule (EPA, 2007), I emphasized that the scientific information in the record then (the same information that is being used in the "reconsideration" rule) was such that the Administrator could exercise his policy judgment prerogative in making decisions on the NAAQS "including continuation of the present Standard," which was then set at 0.08 ppm. Administrator Johnson made a policy judgment decision informed by the scientific information in the record to revise the standard to 0.075 ppm.

My advice to Administrator Jackson is that the "reconsideration" proposal be withdrawn. It is clear that CASAC's policy preference for a Standard lower than the 2008 Standard was a blend of scientific and policy considerations. It does not offer compelling scientific arguments that require "reconsideration" of the 2008 Standard at this time. In my opinion, the resources available to EPA could be better utilized in moving forward in an orderly manner with next scheduled ozone review, which is already underway and scheduled for completion in 2013.

If Administrator Jackson feels compelled to continue the "reconsideration" rule-making, I urge her to be mindful of the need to carefully consider the scientific information in the 2006 record and use the authority exclusively delegated to her under the Clean Air Act in making policy judgments required in setting the Standard. CASAC's stated policy preference outcome based on a blending of scientific and policy considerations should not be used as a basis for what should be the Administrator's independent policy judgments.

These judgments should take into account several key points.

(1) It is not necessary for her to include an "additional margin of safety" at the end of the Standard setting process as suggested by CASAC. This is the case since at each step in the scientific analysis and review process conservative approaches (more likely to over-state rather than under-state) were taken by the EPA staff and CASAC to characterize the health risks associated with ambient ozone.

(2) Background levels of ambient ozone vary markedly across the United States. For many locations background ozone levels were markedly under-estimated by the "Policy Relevant Background" approach that was introduced by the EPA staff as a statement of scientific fact in the review process when the statements clearly reflected policy judgments. Knowledge of background levels of ambient ozone is an important consideration in setting the level and form of the Standard, it is not merely an implementation consideration.

(3) There is substantial heterogeneity in short-term mortality, or the absence of mortality, associated with increases in ambient ozone across the U.S., the kind of increases targeted by an 8-hour standard. Indeed, the vast majority of cities, including many that would be in non-attainment for a standard set in the range of 0.070 to 0.060 ppm, show no statistically significant association between elevated ozone and short-term mortality. This includes my home town, Albuquerque, New Mexico (see attached figure). Only a very few cities show statistically significant associations between elevated ozone and short-term mortality. Moreover, those few cities are generally in non-attainment with the 0.075 ppm Standard set in 2008 and they were in non-attainment with the 0.08 ppm Standard set in 1997.

(4) Health effects attributed to ambient ozone in some of the epidemiological studies have not adequately considered the role of co-pollutants such as particulate matter. For example, when the association between short-term mortality and ozone reported by Bell et al. (2004) was re-evaluated with particulate matter (PM_{10}) included in the model, the average ozone effect was reduced by 22% to 33% (Smith et al., 2009).

(5) The clinical studies with controlled exposure of human volunteers to ozone do not provide convincing evidence of clinically significant effects with exposures below 0.080 ppm.

In closing, I wish to reiterate my opinion that scientific information should inform the setting of the ozone Standard. However, it is inappropriate to argue, as CASAC has, that the science compels policy judgments that lead to a particular policy outcome – a lower standard.

The views I have shared with you today are my own professional views. While I have been engaged by the American Petroleum Institute (API) to review EPA's proposed "reconsideration" ozone standard, the views I have expressed today are not necessarily those of the API.

Thank you for the opportunity to speak to you today.

References

Bell, M.L., McDermott, S. L. Zeger, J.M. Samet, F. Dominici. (2004) Ozone and Short-term Mortality in 95 US Urban Communities, 1987-2000. JAMA 292: 2372-2378.

Breyer J. (2001). Opinion in Whitman v. American Trucking Association. 531 U.S. 457, 494-495.

Henderson, R.F. (2008). Letter from CASAC Chair, Rogene Henderson, to EPA Administrator Stephen Johnson, April 7, 2008, EPA-CASAC-08-009.

Martin, K. (2008). Building on the Last Ozone NAAQS Review: Key Policy Relevant Issues. Presentation to CASAC OzonePanel, October 29, 2008.

McClellan, Roger O., Mark W. Frampton, Petros Koutrakis, William F. McDonnell, Suresh Moolgavkar, D. Warner North, Anne E. Smith, Richard L. Smith and Mark J. Utell. (2009) Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone: A Conference Report. Inhal. Toxicol. 21(S2): 1-36.

McClellan, R.O. (2007) Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172.

Smith, Richard L., Baowei Xu and Paul Switzer. (2009) Reassessing the Relationship Between Ozone and Short-Term Mortality in U.S. Urban Communities. Inhal. Toxicol. 29(S2): 37-61.

U.S. Environmental Protection Agency (2007). National Ambient Air Quality Standards for Ozone: Proposed Rule 40 CFR Part 50, Federal Register 72: 37818-37919 (July 11, 2007).

U.S. Environmental Protection Agency (2008). National Ambient Air Quality Standards: Final Rule. 40 CFR Parts 50 and58. Federal Register 73: 16436-16514.

U.S. Environmental Protection Agency (2010). National Ambient Air Quality Standard: Proosed Rule. 40 CFR Parts 50 and 58. Federal Register 75: 2938-3052.

Attachment

The figure shown on the next page is taken from Smith et al. (2009) and is a reanalysis of the data that were analyzed and reported by Bell et al. (2004). The Bell et al. (2004) paper was a key component of the science that informed the policy judgments that led to the 2008 Standard.

The substantial heterogenicity in the association between increases in short-term mortality and elevated ozone is very evident. It is noteworthy that when Smith et al. (2009) included particulate matter (PM_{10}) in the model the overall ozone-mortality coefficient was reduced by between 22% and 33%. The results of Smith were summarized in my comments submitted to the ozone docket in October 2007 (McClellan, 20o07). In my comments to the ozone docket, I also noted the results of a conference on critical considerations in evaluating the scientific evidence on the health effects of ambient ozone. Those conference proceedings have now been published (McClellan et al., 2009).

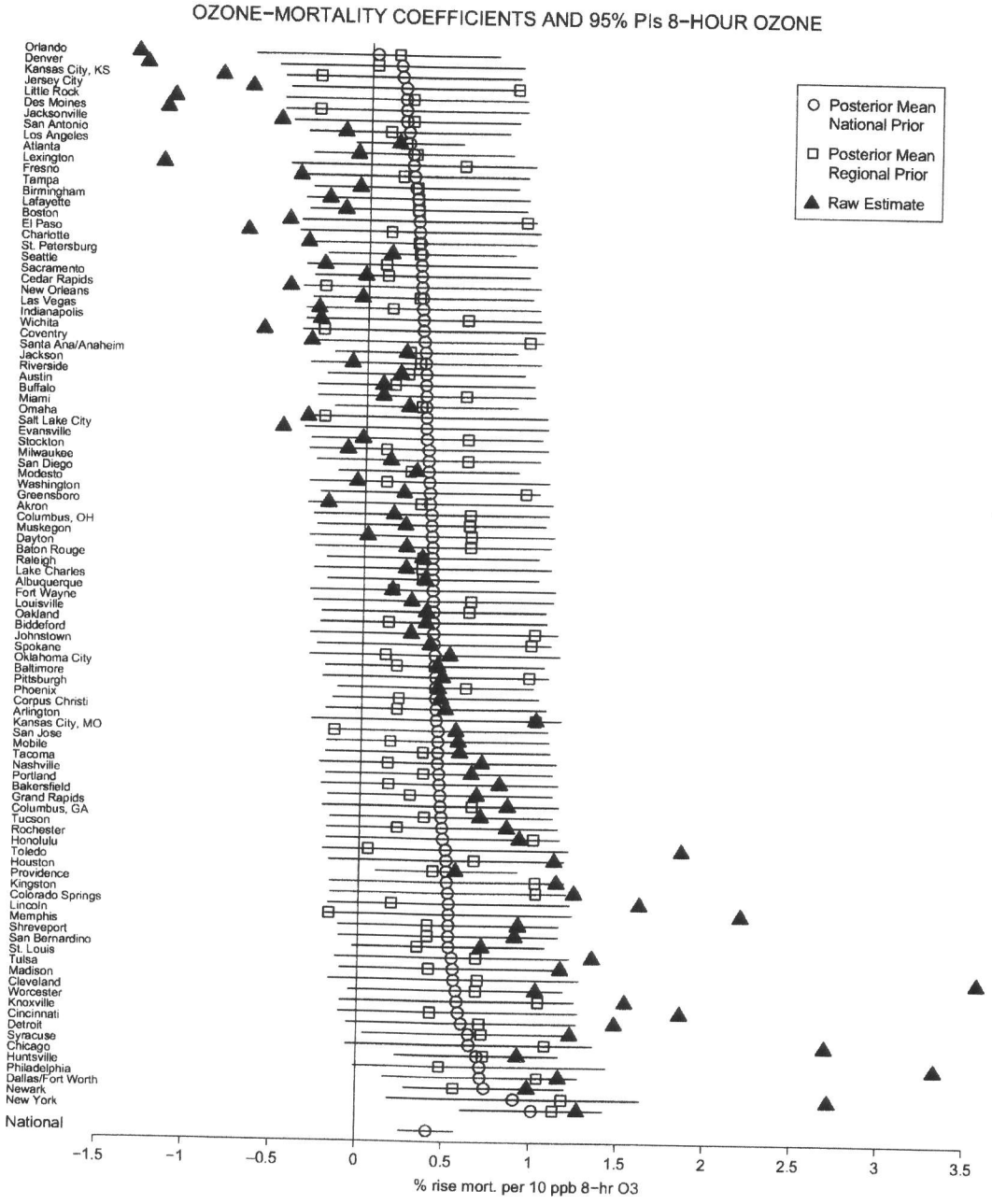


Figure 4. Ninety-five percent posterior intervals for the ozone-mortality coefficients, based on 8-h ozone, all-year data. The Bayesian posterior estimates under the "national prior" (circles) are shown alongside those for the "regional prior" (squares) and the raw maximum likelihood estimates (triangles).

FOR IMMEDIATE RELEASE **CONTACT: TERRY CLAWSON**
TUESDAY, FEBRUARY 2, 2010 **PHONE 512-239-0046 CELL: 512-657-0738**

TCEQ CHIEF TOXICOLOGIST DR. MICHAEL HONEYCUTT PROVIDES COMMENT ON EPA PROPOSED OZONE STANDARD

Oral testimony presented in Houston today

As EPA re-examines the ozone NAAQs, I, Dr. Michael Honeycutt, Director of the Toxicology Division would like to offer the following comments on behalf of the Texas Commission on Environmental Quality.

In developing the range for the new standard, EPA did not consider personal exposure to ozone. It is a scientific fact that outdoor ozone levels are not indicative of the ozone levels that people actually breathe. You do not have to take the word of the TCEQ on this. EPA's own CASAC ozone review panel wrote the following to EPA in a letter dated June 5, 2006:

> "The Ozone Staff Paper should consider the problem of exposure measurement error in ozone mortality time-series studies. It is known that personal exposure to ozone is not reflected adequately, and sometimes not at all, by ozone concentrations measured at central monitoring sites….Therefore, it seems unlikely that the observed associations between short-term ozone concentrations and daily mortality are due solely to ozone itself."

What this means is that the epidemiology studies used by EPA to set the health-based ozone standard are not scientifically rigorous enough to be used as the basis for this important policy decision. These studies are based on the supposition that the majority of people breathe outside air 8 to 24 hours each day while the scientific data clearly show this is not the case.

Many time-series studies have used patient medical records instead of patient histories to monitor exposure and assess health effects. Similar to ambient monitoring data, patient medical records are inadequate indices to associate ozone exposure and health effects.

EPA also used clinical studies published by Dr. William Adams as the basis for lowering the 0.08 ppm standard. EPA reanalyzed Dr. Adams' data inappropriately, as pointed out by Dr. Adams himself in his comments to EPA.

We hear anecdotally that hospital visits for asthma rise when ozone levels rise, but hospital admissions data show this is not the case. Texas Inpatient Hospital Discharge data on numbers of hospital visits for asthma between 1999 and 2001 actually show that fewer children in Texas visit the hospital for asthma during peak summer ozone season as compared to wintertime. Results from a 4-year (2000-2003) air quality study conducted by Texas A&M University and Driscoll Children's Hospital indicate hospital admissions to be weakly correlated with ambient daily maximum ozone levels. The Kaiser Permanente Report and the Gauderman study in 2004 found no increased hospital admissions in elderly patients and health effects in children due to ozone alone

Texas has spent significant state resources through multimillion dollar field studies on examining transport and background of ozone and precursors. The results of these studies confirm that background ozone and interstate transport are major factors in ambient ozone levels. We know that as the standard is lowered, transport and background will represent greater percentages of the problem for Texas cities.

The ozone standard proposal states that "The EPA recognizes the need in our CAIR replacement effort to address the reconsidered ozone standard, and we are currently assessing our options for the best way to accomplish this." We believe it will be extremely challenging for EPA to promulgate the replacement program in a timely manner or without additional legal challenges.

Some Texas areas may have to achieve the standard in as little as three to six years – before control strategies can take effect. Considering the magnitude of background ozone, we question if the necessary technology exists to reduce ozone precursors on sources within the state's control in such a short time. Your very own proposal acknowledges that "benefits from federal engine standards increase modestly each year…." In fact, within five to six years, mobile NOx emissions will start to increase unless vehicle standards are tightened further.

There is no indication from EPA of any studies to evaluate the social impact of tighter regulations. Texans and the EPA have both seen that programs that mandate changes to personal lifestyle were rejected. We witnessed it with the centralized vehicle Inspection and Maintenance program and the Employee Trip Reduction program. They proved to be unacceptable to the public. EPA has failed to

thoroughly examine the probability that individual citizens will simply choose to not comply with inconvenient or onerous rules.

In conclusion, a policy decision this important must be made not just by using good science, but understanding its limitations and using that science correctly. The exposure estimates from the epidemiology studies used to justify lowering the ozone standard do not account for personal exposure to ozone and are therefore faulty, as noted by EPA's own CASAC. EPA needs to address personal exposure before they implement such a costly and unobtainable standard.