

Why Scott Pruitt's Decision to Ignore Certain Scientific Studies When EPA Sets Air Quality Standards is Illegal April 26, 2018

I. Introduction and Summary

EPA Administrator Scott Pruitt is seeking comment on a plan that would not allow EPA to consider scientific studies when EPA sets rules and other policies if the raw underlying data and the models used to analyze that data supporting the study is not available for public review.

This new policy would massively damage several EPA programs, including Superfund cleanups and the control of pesticides and toxic chemicals. It would probably most affect EPA's program to protect public health by setting national ambient air quality standards (NAAQS), since it would bar the Agency from considering a wide range of data on which it has historically relied.

Such a policy would be illegal. In brief summary:

- Congress required EPA to set NAAQS that protect public health with a safety margin added, and to base NAAQS on "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects [of air pollution] on public health." Scientific knowledge comes in many forms, and it would be impossible for EPA to perform this task without at least **considering** all of them. This has been EPA's unbroken practice for over 40 years. NAAQS, like all other EPA rules, must be set through a structured dialogue with the public. The agency issues a detailed proposal for action. Any member of the public can comment, submitting any information considered relevant to the decision. The Agency **must** respond when it takes final action. Accordingly, even if Administrator Pruitt were to initially not consider certain studies, he would have to consider them if the public submitted them. But then, if the study were widely known, it would make no sense not to consider it in framing the proposal.
- The Pruitt policy would, in effect, make in advance a critical part of the regulatory decision on all future NAAQS, namely the decision which studies to give weight to, and how much. But since the basic regulatory decisions thus being altered require scientific review and public notice and comment to be legally valid, this attempt to make it in advance would require the same procedures.
- The new policy rests entirely on the assertion that the studies it addresses are too lacking in scientific integrity to play **any** role in agency decision-making. But since Congress plainly intended for EPA to be guided by scientific practice in setting NAAQS, it is not the political leadership of EPA, but the scientific community world wide, that should decide that question. For this reason also, existing law requires EPA to solicit the views of the scientific community before making any such decision. Even in advance of such solicitation, however, it is clear that there is no support for the proposed Pruitt policy in any legal or regulatory requirements or standards designed to reflect good scientific practice.

Our discussion follows.

II. Discussion

A. NAAQS Must Protect Public Health Based on **All** the Scientific Evidence

Congress established the legal standards that NAAQS must meet almost 50 years ago in the 1970 Clean Air Act. That law requires NAAQS not just to “protect the public health,” but to do so “with an adequate **margin of safety** [emphasis added],” Clean Air Act (CAA) § 109(b)(1).

In setting these standards, EPA cannot consider the costs of meeting them, see *Whitman v. American Trucking*, 531 U.S. 457, 464-71 (2001) (Scalia, J.), but must instead comprehensively consider the state of scientific knowledge. To make sure this happens, Congress required NAAQS to be based on “air quality criteria,” CAA § 109 (b), which must “**accurately reflect** the latest scientific knowledge **useful in indicating** [emphasis added] 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,” CAA §108(a)(2). To make sure that EPA based its decisions on this latest, useful science, Congress also required EPA to appoint a scientific review committee to review the scientific information to be embodied in the air quality criteria and used to determine NAAQS. CAA § 109(d). The Supreme Court agrees that NAAQS must be based on “published air quality criteria that reflect the latest scientific knowledge” *Whitman*, supra, at 457. Accord, *State of Mississippi v. EPA* 744 F. 3d. 1344, 1346 (D.C. Cir. 2013).

These statutory provisions originated in the 1970 Senate version of the Clean Air Act. The Senate Report on them stated that: “Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against **hazards which research has not yet identified** [emphasis added]” The courts agree. See, e.g. *American Trucking Association v. EPA (ATA III)*, 283 F.3d. at 369 (D.C. Cir. 20002).

EPA could not obey these statutory commands unless it considered both (1) all knowledge that met the standards of quality observed by the scientific community to establish health effects of pollution and (2) knowledge that, though it might not meet these standards, was nevertheless “useful in indicating” these effects or pointing to “hazards which research has not yet identified.”

Since the NAAQS provisions were enacted in 1970, EPA has conducted many NAAQS rulemakings. Without exception, EPA has considered **all** scientific studies presented to it, without applying any up front barrier. In the one case in which the issue of access to underlying data was raised, EPA turned it down and the courts affirmed that denial, and endorsed EPA’s reasoning.¹

¹ Specifically, the court said: This brings us finally to Petitioners' argument that EPA "denied the public essential procedural rights" by failing to obtain and make public the data underlying certain "key studies" relating to the "confounder" issue. Claiming neither that they were unable to obtain the studies, nor that the studies were improperly published or peer reviewed, Petitioners instead urge us to impose a general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies. The Clean Air Act imposes no such obligation; it merely directs EPA to include in any notice of proposed rulemaking "data, information, and documents ... on which the proposed rule *relies* [emphasis added]," 42 U.S.C. § 7607(d)(3). Here, EPA explained that it "relied on

B. The Decision Making Procedures that EPA Must Observe Require EPA to Consider All Relevant Information

1. Rulemaking Procedures in General

The law requires EPA to set NAAQS through a structured dialogue with the public, CAA § 307(d)(3). First, EPA must issue a proposal setting out the “factual data” relied on, the “methodology used in obtaining the data and in analyzing the data,” and the major legal and policy considerations underlying the proposal. The public can then comment on every aspect of this proposal, and can submit its own data. When EPA takes final action, it must respond “to each of the significant comments, criticisms, or new data submitted” *id.*

2. The Necessary Effect of EPA’s New Policy Requires the Use of Rulemaking Procedures

If a commenter submitted a study that EPA would have declined to consider under the Pruitt policy, this framework would require EPA to evaluate on the merits the document it had tried to exclude. But if EPA knew the study would be submitted, wouldn’t it be far more efficient to assess it in the proposal? Only if EPA can disregard such studies without even examining them can it avoid this dilemma.

But in that case, the new policy would make in advance a critical part of the regulatory decision on all future NAAQS, by eliminating the need for any case by case consideration of excluded studies during any specific rulemaking - consideration that would otherwise have been required.

Since the regulatory decision on a NAAQS requires full scientific review and public comment, this attempt to make part of it in advance could only be valid if it were made through the same procedures.

3. The Substantive Justification for the New Policy Would Also Require the Use of Rulemaking Procedures

The asserted ground for Administrator Pruitt’s step is the need to protect the scientific validity of rulemaking studies. But neither Mr. Pruitt by himself or even EPA by itself is the arbiter of what constitutes scientific validity. That is a decision that rests on the consensus of the world wide scientific community.

For this reason as well, Mr. Pruitt can make such a decision only after soliciting the views of that community to determine whether in fact its proposed new approach would reflect such a consensus. Rulemaking procedures such as those used to set NAAQS are designed for such solicitation of views.

the scientific studies cited in the rulemaking record, rather than on the raw data underlying" those studies. Particulate Matter NAAQS, 62 Fed. Reg. at 38,689. In addition, Agency counsel advised us at oral argument that on those few occasions when EPA requested underlying data from an investigator, the Agency included those data in the record, Tr. of Oral Arg. at 74-75. More generally, we agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary." Particulate Matter NAAQS, 62 Fed. Reg. at 38,689. *ATA III* at 372

C. Even if Administrator Pruitt Used Proper Procedures, a Data Exclusion Rule would be Indefensible on the Merits.

The proposal is manifestly illegal on substantive as well as procedural grounds. It is clear that EPA's the new Pruitt policy would conflict with government-wide regulatory guidelines, with substantive Clean Air Act requirements, with other EPA laws on the proper use of data more enacted by Congress after passage of the Clean Air Act, and with the practices of other agencies.

Congress passed the Information Quality Act, 44 U.S.C. §3516, in 2001 to improve the "quality, objectivity, utility and integrity" of data released by the Federal Government. Both OMB and EPA guidelines to implement that act specifically find that safeguards such as peer review can assure that studies can meet these statutory standards even if the underlying data is not available. The OMB guidelines specifically reference the air quality standards study in which the courts upheld EPA's denial of a request for the underlying data.² Yet the Pruitt policy would automatically bar the use of studies where no underlying data was available no matter how many other controls for quality they incorporated, and no matter how compelling the ethical, feasibility, or confidentiality reasons why that data was unavailable.

This cannot be reconciled with the Clean Air Act's explicit requirement that air quality criteria "accurately reflect" the "latest scientific knowledge" which is "useful" in assessing "all identifiable effects on public health." Indeed, the policy's refusal to consider studies which are part of air quality criteria impermissibly amends those criteria without going through the mandated procedures for doing so (both the statutorily mandated peer review, and the broader public process) and, equally important, without satisfying the section 108 (b) substantive standard. Nor can the policy be reconciled with the precau-

² The Information Quality Act, 44 USC section 3516 note, Act requires agencies to issue guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency". OMB's implementing rules, in defining "objectivity" make clear that a study remains objective even when underlying data cannot be reproduced given "ethical, feasibility, or confidentiality constraints." OMB IQA Guidelines section V.3. b. ii. A (at 62 FR at 8460 (Feb. 22, 2002)). These Guidelines go on to state that 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error." The explanatory preamble indicates that the Harvard 6-City Study satisfies this criteria ("Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. See, e.g., "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000." 62 FR at 8456-57.) In addition, the Guidelines make clear that external peer review is generally sufficient to create a presumption of "objectivity." EPA's implementing Guidelines contain similar provisions, not necessitating replicability where there are proprietary or confidentiality issues, and finding that external peer review creates a presumption of objectivity. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA" (EPA/260 R-02- 008) at 6.3.A.3.5and 6.3.A.3.1.

tionary purposes of the Clean Air Act, which require the agency to consider a deliberately broad range of scientific information to make sure that its standards adequately protect public health, and, for the NAAQS, provide a margin of safety to guard against potential or imperfectly understood harms. When Congress more recently enacted the Safe Drinking Water Act - another statute calling on EPA to regulate to protect the public health – it identified peer review as the most central safeguard for the quality of information used to support regulations, and made clear that action to protect public health should not be delayed until scientific perfection arrives, calling on EPA to set regulations using both (1) “the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” and in addition (2) “data collected by accepted methods or best available methods.” 42 USC section 300g-1 (3)(A). See *City of Waukesha v. EPA*, 320 F. 3d at 247 (DC Cir 2003) (agency peer review satisfies requirement to use best, peer-reviewed science and supporting studies); *City of Portland v. EPA*, 507 F 3d 706, 716 (DC Cir, 2002) (same).

Finally, EPA is far from alone in its need to rely on this data in making decisions. Should EPA’s concerns be valid, why should they not be accepted across the government, for example, by the Food and Drug Administration as a standard for new drug approvals? Accordingly, no such policy should be adopted without considering its significance for government decisions across the board.

For Further information:

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