"They sat at the Agency and said, 'what can we do to reimagine authority under the statutes to regulate an area that we are unsure that we can but we're going to do so anyway?"

When he said those words, Scott Pruitt was <u>talking</u> about the Obama Administration. But it seems to be a pretty accurate description of the "transparency" proposal he issued last week.

Everyone agrees that it would be good to increase the public availability of scientific information for independent validation. But Pruitt's proposal is designed to provide EPA with a license to ignore studies that it views as insufficiently transparent – for example, when it cannot agree with investigators over how to protect patient confidentiality if health data is made public. This would allow it to ignore inconvenient evidence about the dangers of various forms of pollution. The proposal cites a string of congressional enactments as its basis, with no explanation of their relevance. But then it asks the public for suggestions about whether there are additional or different provisions it should be citing. Obviously, EPA is not at all confident that it has found the right legal peg on which to hang the proposal.

In my view, the federal statutes not only fail to support the proposal but instead require consideration of *all* relevant scientific evidence. The provisions cited by the EPA proposal provide flimsy support – thus the plaintive cry for legal assistance from public commenters. More importantly, the proposal flies in the face of EPA's primary responsibility to base its decisions on consideration of all relevant scientific evidence.

It would be tedious to discuss the statutes in each of the different areas that EPA regulates, and not very useful, since the provisions cited by EPA in each area are similar. Air pollution is probably the most important area covered by the proposal in public health terms, so I'll use that as an example.

As legal support, the proposal cites two provisions of the Clean Air Act. The first is § 103 of the Clean Air Act, which is entitled "Research and development program for prevention and control of air pollution." The provision goes into some detail about the research and development program in subsection (a), while subsection (b) gives a list of authorized activities. Excluding relevant information from rulemaking proceedings is not on the list of authorized activities. In fact, in this proposal, EPA cites no specific language in § 103 nor does it explain how the provision supports the action it is planning to take.

The proposal also cites § 301(a), which gives EPA authority "to prescribe such regulations as are necessary to carry out its functions under this chapter." Pruitt's EPA doesn't cite any

judicial authority or agency precedent for using this provision to impose limits on using reliable evidence in rulemaking proceedings. Since EPA is asking for suggestions about other sources of statutory authority, it is apparently unsure that its proposal is within the scope of § 301 or similar generic rulemaking provisions in other environmental statutes.

EPA rather conspicuously fails to cite the provision that you might think was most relevant, § 307(d). Section 307 is entitled "Administrative proceedings and judicial review," and subsection (d) is called, simply enough, "Rulemaking." Subsection (d) speaks directly to the issue of data disclosure (§ 307(d)(3)(A)), but of course EPA has never interpreted it to mean it should disregard studies if the data isn't confidential, and apparently still is not willing to embrace that view.

In fact, courts have rejected industry claims that § 307 bars reliance on studies based on nonpublic data. That's because the courts have construed the § 307 contrary to the proposal that EPA is now putting forward. In <u>American Trucking Associations</u>, <u>Inc. v. EPA</u>, 283 F.3d 355, 372 (D.C. Cir. 2002), the court said, "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." The court then quoted what it called a persuasive EPA argument:

'If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.... [S]uch data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].'"

Similarly, in <u>Coalition of Battery Recyclers Ass'n v. EPA</u>, 604 F.3d 613, 623 (D.C. Cir. 2010), the court reaffirmed its view that "raw data often is unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants" and that EPA is entitled to rely on published study results instead. In fact, Pruitt's proposal does not interpret *any* provision of the Clean Air Act to require exclusion of studies based on confidential information.

The problem is not just that the Clean Air Act fails to provide clear authority for EPA's proposed exclusionary rule. There are also provisions in the Act that cut strongly against the

proposal.

Section 109 is probably the most important single provision in the Clean Air Act. It sets air quality standards that are pivotal to many other provisions. Section 109 covers air pollutants such as particulates and ozone that cause widespread impacts on public health. In some cases, Pruitt's proposal would require EPA to ignore evidence of the seriousness of health risks as a penalty for failure to make the underlying data available. Section 109 cannot be squared with such a ban on considering relevant scientific evidence. In setting standards, § 109 mandates that EPA allow "an adequate margin of safety," ensuring that the air quality level would be safe even if the scientific evidence is not completely clear. How can EPA do that if it completely ignores available evidence about risk? Erring on the side of safety doesn't mean ignoring genuine evidence for procedural reasons. Imagine that a company said that, although there were peer-reviewed studies that one of its chemicals was harmful, it refused to even consider that evidence because scientists refused to give it access to the raw data due to privacy concerns. Would you think the company was serious about pursuing safety?

Moreover, EPA must base § 109 air quality standards on "air quality criteria." Under § 108, those air quality criteria must "accurately reflect the latest scientific knowledge useful in indicating the kind of and extent of all identifiable effects on public health or welfare." (§108(a)(2)). It doesn't say "latest scientific information except what EPA chooses not to consider." Instead, § 108 plainly requires that EPA consider *all* useful scientific information. Surely, in setting the air quality standards, EPA is not authorized to ignore the latest useful scientific information.

For obvious reasons, EPA's transparency proposal does not cite § 108 or§ 109, or any of the other statutory provisions that call for margins of safety or dictate use of the best available science. Like many recent EPA actions, the "transparency" proposal is an effort to elevate the concerns of regulated businesses at the expense of EPA's primary mission: protecting public health and safety. Transparency is a worthy goal, but it shouldn't serve as an excuse to ignore inconvenient evidence or to compromise public safety.