EPA recently issued a notice of proposed rulemaking entitled "Strengthening Transparency in Regulatory Science." The proposal would prohibit the agency from considering studies of health risks unless enough data is made publicly available to allow EPA or industry to validate the results. That sounds fine, but these studies often involve either confidential health records or trade secrets of a chemical manufacturer. One example would be the test results and medical files of patients with respiratory diseases who were included in a study of the health effects of air pollution. Scientists believe the proposal is simply an excuse to keep out important studies when conservatives like Pruitt don't like the findings.

This proposal raises a host of legal and policy issues, which Holly Doremus and I will be discussing in upcoming blog posts. Hopefully others will chip in too.

I wanted to kick off the conversation with a basic legal point: the document fails to meet the fundamental legal requirements for a valid rulemaking proposal. It is vague as to the actual parameters of the proposal, open-ended in terms of the alternatives under consideration, and utterly lacks the data transparency it purports to advocate. Any rule issued on the basis of this notice will be invalid, quite apart from its merits.

The courts have made the requirements for a valid proposal clear. For instance, according to U.S. Court of Appeals for the Third Circuit in Prometheus Radio Project v. F.C.C., 652 F.3d 431, 449 (3d Cir. 2011):

> "there must be an exchange of views, information, and criticism between interested persons and the agency.… Consequently, the notice required by the APA [Administrative Procedures Act]… must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based.… *[A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." Home Box Office, Inc. v. FCC,* 567 F.2d 9, 35–36 (D.C.Cir.1977) (emphasis added) (internal citations and footnotes omitted).

The *Prometheus Radio opinion* continues;

> "[A]n agency also "must 'describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making.'

> " *Horsehead Res. Dev. Co., Inc. v. Browner,* 16 F.3d 1246, 1268 (D.C.Cir.1994) (internal citations omitted)"

EPA's transparency proposal totally fails to satisfy these requirements. Consider EPA's explanation of what it proposes and what alternatives are on the table:

1. EPA is apparently unsure of what statutes actually authorize its proposed action. It provides a list and then remarks that it "solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed action." As I will discuss in a later post, the agency is right to question whether the statutes actually do allow this.
2. EPA says it "should collaborate" with other agencies to identify strategies to protect private information (such as patient health records) when it is making information publicly available. When will these procedures be developed and what happens in the meantime?
3. The agency "should be guided by this policy to the maximum extent practicable during ongoing regulatory action." What does that mean?
4. The EPA asks "whether other alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles on the programmatic or statutory level would be appropriate as alternative or additional steps."
5. The EPA also seeks additional comment on "which criteria the Agency should use to establish exceptions, including whether case-by-case exceptions may be appropriate." It also solicits comment on whether the proposal should apply to a broader or narrower set of regulatory proceedings, or whether certain categories should be exempt. And also on whether to add stronger data access requirements to the terms of research grants.

The list of EPA's queries goes on. But you get the picture: the agency has no clear idea of what alternatives should be considered and is looking for guidance on almost everything. So much for identifying alternatives with specificity!

The agency also makes no effort to identify the data supporting its proposal. It says that implementation of previous policies about public access to data has been spotty, but it cites no examples. It says that its proposals are generally consistent with a number of other policies or reports by scientific groups or scientific journals, but it does not explain the basis for those other policies and reports, nor does it specify in what respects those documents support its proposal. It assumes that patient privacy and trade secret issues can usually be

overcome, but provides no evidence except for a few quotes from other reports.

Finally, the proposal nowhere explains why EPA thinks otherwise probative evidence should be excluded from consideration when the models and data are not publicly available to the extent that EPA would prefer.It is easy to imagine that EPA might not be able to agree with outside scientists on whether privacy or trade secrets are sufficiently protected. Why is this disagreement a reason for disregarding the study entirely? Is the problem supposed to be that this evidence is entirely lacking in probative value? Scientists apparently do not think so, and EPA presents no argument for rejecting scientific practice. Or is this exclusionary rule intended as an incentive for greater disclosure by scientists? If so, EPA does not explain why the loss of probative evidence is outweighed by the need to provide an incentive for this public disclosure.

Another blatant gap: EPA fails to indicate the costs of the proposal or even the number of existing studies that will be subject to the rule. Obviously, this process will take resources and employee time, and by some estimates this might be quite expensive. Moreover, EPA says it will work with outside scientists in an endeavor to make data available – what about the time and resources of those scientists? And what about potential delays in proceedings and the loss of probative information? Not a word about how the agency appraises these costs or their relationship to the putative benefits. All the proposal says is: "EPA shall implement the provisions of this subchapter in a manner that minimizes costs." EPA could say pretty much the same thing about any proposed regulation. It also says that its requirements are consistent with recommendations of the National Academies, "which will help lower the costs of implementation" – but the proposal itself does not provide a safe harbor, under which compliance with current scientific proposals and recommendations would be sufficient to satisfy the proposed new EPA requirements. So we can't be sure that compliance with the disclosure requirements imposed by scientific journals will actually be enough.

In other words, this proposal provides no data to support its assertions, is open-ended about possible alternatives, fails to specify exactly what actions it will require by EPA, and fails to cover obvious questions like the actual costs and benefits of the proposal.

Really, the agency might just as well have said: "We want to do something about data transparency. Just spitballing, folks, but here's one idea. We're also open to doing something completely different. Let's just bat this around and see what we come up with." That might be fine for a brainstorming session over a few beers. But it's not what the courts expect from a notice of proposed rule-making.