To: Committee on Regulation

From: Wendy Wagner

Re: Plans for Revisions of the "Science in the Administrative Process" Report as a result of the NAS-ACUS Workshop

Date: Sept. 18, 2012

The following document identifies the best practice discussions/recommendations that I plan to revise or add in the wake of the NAS-ACUS workshop on September 10. There were a number of helpful suggestions at the workshop, and ultimately I hope to address virtually all of them. To that end, I provide below a preliminary list of recommendations that I plan to add, revise, expand or clarify in the report, listed roughly in order of their significance.[1] Please let me know if there are other issues that stand out or whether you think some of these issues should not be addressed:

- Recommendation 10 calls attention to the four step conceptual process pioneered in the NAAQS program as a means for enhancing the transparency of both science and policy judgments in agency decision-making. Panelists were uniformly supportive of these steps and suggested that this conceptual framework should be expanded to include a preliminary step that sets out a protocol or plan for the agency's decision-making process (e.g., a priori principles). While subsequent analysis and integration of science into the regulation may depart from this a priori plan, departures will need to be identified and explained by the agencies. Stopping rules could also be identified at this early juncture. Panelists pointed to complementary approaches in clinical medicine and also in the NAS Science and Judgment report that provide models for this expanded conceptual framework. The report will be revised and elaborated to incorporate this early step and to integrate the complementary literature.
- Recommendation 10 will also be broken out into sub-recommendations. In particular, the step that discusses the NAAQS process for conducting a literature review, or Integrated Scientific Assessment (ISA), deserves more elaboration in the report and recommendations. This discussion will also be linked with the supporting literature, which includes the Bipartisan Policy Center report and the NAS Formaldehyde Report.
- New Recommendations regarding the Transparency of Private Science. OSHA Administrator David Michaels suggested including a set of new recommendations that increase the ability of the public and the agencies to scrutinize the science submitted by regulated parties. These recommendations build on existing requirements in law and in the biomedical journal. (Note that this issue is already identified in the report as a

[1] Note: The report will likely exceed the 100 page maximum with these changes.

problem that deserves further study, see pages 115-17). Administrator Michaels cited both his own work (published with Wagner; see, e.g., attached comment in *Science*) and recommendations in the BiPartisan Policy Center Report as examples of potential recommendations that would provide for this enhanced transparency of the data and provenance of studies produced by regulated parties. For example, the BiPartisan Policy Center report recommends:

> Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular (OMB Circular A-110) regardless of who funded the study. If a study is used by an agency to inform the development of a regulation, then the same kinds of information about that study should be available upon request, regardless of whether the study was funded by the federal government, industry, or some other entity.[2]

The next iteration of the report will include a new set of recommendations that provide greater transparency for privately produced research that informs regulation.

- New Recommendation regarding the Identification of Important Gaps in Scientific Research. The agency should identify significant knowledge gaps and discuss what might be done to fill them. This recommendation could complement the recommendation for stopping rules; one panelist suggested these two concepts could be combined and called "checkpoints". This new recommendation will be included in the next iteration of the report.
- Recommendation 8. Several panelists suggested that in developing robust dissent policies, agency staff should be allowed and even encouraged to publish their dissents in the peer reviewed literature. By doing so, the dissent would not only be public, but would undergo external checks on reliability and ensuring that there is evidentiary support for the dissent. The Fish and Wildlife Service publication policies were highlighted as particularly strong in this regard. This suggestion will be explored in the next iteration of the report.
- Recommendation 9. While there is no one-size-fits-all approach to peer review, there are additional procedures that could be added to the report's existing recommendation that will further improve the agencies' use of external peer reviewers. Several suggestions to be considered in the next iteration of the report include: the use of stopping rules for peer review that limit the use of peer review when it is no longer necessary; soliciting letters or comments from individual peer reviewers in advance of their collective deliberations in science advisory boards; expecting agencies to provide a public response to significant peer review comments; and soliciting from peer review panels whether and how they

[2] BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 43 (Aug. 2009).

might view their charge as incomplete when compared with the agency's regulatory decision.

- Recommendation 7. Panelists were generally supportive of the encouragement of authorship and attribution for staff reports. The discussion at the workshop underscored how such policies not only provide important rewards for staff, but also provide external readers with the identity of those drafting the report. Indeed, if lawyers, economists, or others are involved in drafting staff technical reports, they should be identified either by name or attributed as part of the agency's interdisciplinary team. The discussion and recommendation concerning authorship and attribution in the report will be expanded to underscore the need to disclose the identity of *all* staff who contributed to staff technical reports in significant ways, even if they are not scientists.
- Recommendation 5. In March, the committee added a phrase to the report's recommendation #5 that directs agencies not only to list the literature they relied on in developing a regulation or policy, but also to identify the literature they rejected. Dr. Zeckhauser expressed a concern that this additional requirement is excessively costly in relation to the benefits gained from the added transparency. Further research will be dedicated to exploring this possibility so that the committee has full information about the implications of this amendment.
- New Recommendation regarding Creating an Infrastructure for Data used in Regulation. The report could include not only a suggestion that agencies develop a publicly available bibliography of references they relied on in developing a decision, but that they should also consider dedicating resources to the development of an infrastructure that makes all the underlying data available. This new recommendation will be explored in the next draft.
- Several important discussions already present in the report would benefit from additional emphasis. They include:
    - Reminding the reader that the line between science and policy is not clear and that it is not feasible or ultimately helpful to try to recommend drawing brighter lines as a way of reforming agency decision processes. Instead, the goal is to develop decision processes that make all judgments more explicit, including judgments that include a significant link to a large body of scientific literature (e.g., the literature search discussed above).
    - Making it clear, perhaps repeatedly, that the report is not advocating a one-size fits-all approach, or "cookie cutter" process for the integration of science into agency decisions.
    - Clarifying that stopping rules need not require "stopping" the collection and integration of science, but that they simply set default choices for when new literature will be considered at a given point in a regulatory decision.