"Science in the Administrative Process"
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Wendy Wagner, University of Texas School of Law

General Description and Focus of the Study

Reform proposals offered over the last decade to redress perceived problems in regulatory science generally target one of two points in the agencies' decision-making process. One set of reforms seeks to shore up internal oversight of science within the agencies, including strengthening how agency staff and political officials assemble, weigh, and communicate the scientific information used in their regulatory decisions. A second set of reforms attempts to reinvigorate external checks on agency decisions that involve scientific information (e.g., greater White House review, less deferential judicial review, more points for interest group input, and greater congressional oversight).

This reconnaissance study focuses on the first set of reforms -- strengthening internal agency oversight processes -- rather than on bolstering external checks on regulatory science. It does so for several reasons. First, the external oversight mechanisms available to detect and repair problems with regulatory science are limited by the low salience of many science-based regulatory decisions, which necessarily involve technical and voluminous records for decision. Second, improvements in the agencies' internal procedures for using science not only facilitate better use of science from within the agency, but spill over to enhance external oversight mechanisms as well. If the agency does a better job explaining its work, for example, it will be easier for outside parties to ensure that the agencies' use of science comports with the authorizing law, the larger scientific record, and political preferences. Finally, virtually all of the reforms that have been formally established to address problems in regulatory science seek to strengthen internal oversight of decision-making processes (see III in outline below), and these reforms thus present a particularly rich area for retrospective study.

I. Background and Purpose of the Study

A. There appears to be potentially significant slippage between the ideal vision of the agencies' use of science in the administrative process and what is actually occurring in practice.

1. The Ideal: Scientific research that informs regulation should be reliable, transparent, and its incorporation into policy should be reasonable and comprehensible. Scientists inside the agencies should enjoy some independence to protect against politicization of the scientific information that informs regulation. Top scientists from outside the agencies should be tapped to contribute to the development of this science policy.
2. Allegations of Problems (mostly in the popular press or anecdotes)
    i. Politicization of science (top-down adjustments to the scientific record or regulatory process).
    ii. Poor explication of some of the agencies' science-based decisions.

iii. Errors in some of the agencies' science-based decisions that result from relying on unreliable research or inadequate peer review processes.
iv. Agency use of science lags far behind developments in the field.

B. Purpose: This study will investigate how agencies use and oversee science in the administrative process. The study is intended to evaluate the severity of the allegations of problems in I.A.2., identify potentially new problems that have gone unacknowledged, and prioritize areas in need of reform. The study will also attempt to understand what is going particularly well in the agencies' use of science and how agencies vary in their use and oversight of science.

II. Methods and Scope of the Study

A. Methods
1. Most of the findings will be drawn from a review of the general literature on science policy.
2. The general literature will be supplemented with closer (but not exhaustive) study of five agencies: EPA, OSHA/NIOSH, DOI, FDA, and USDA. Staff from these five agencies, as well as staff from OMB and OSTP, will be interviewed. Wagner will work with ACUS on finalizing the interview questions and contacting the agencies.

B. Outside the scope
1. The research will exclude issues related to agency funding of external research (e.g., NSF and NIH).
2. The focus of the study will be on internal agency processes governing the use and oversight of science. The role of the courts and congress in influencing regulatory science is outside the scope of this particular study, although it is unquestionably an important topic for further investigation.

III. The Evidence: How Agencies use Science

This section provides a general description of the internal processes agencies utilize for identifying, reviewing, and incorporating science in their regulatory decisions. The section provides a backdrop for evaluating the breadth and effectiveness of recent reforms discussed in Section IV and in identifying additional problems in need of reform in Section V.

A. The Independence of Agency Scientists
1. Size and hiring of scientific staff
2. Separation of scientific staff from other offices, particularly from policy and legal offices
    i. Office of Science Advisor(s) and how organized
    ii. Role(s) of staff scientists
3. Formal or informal protections for scientific independence of scientists
    i. Publication rights
    ii. External communications
    iii. Internal documentation of differences with administration

B. Transparency of Research that informs Regulation
1. Public Access
    i. Studies

ii. Data
2. Processes to Ensure Clear Explication of Role of Science in Regulation

C. Critical Review of Research
1. Peer Review (individual/written) and other Screening Processes for Research that Informs Regulation [including the usefulness of the notice and comment process]
i. to ensure comprehensive scientific information
ii. for evaluating research
iii. continuing review
2. Science Advisory Boards (and other collectives) that provide formal science advice
i. When they are used
ii. How they are employed (e.g., selection of scientists)

D. Areas in Need of Improvement as identified by the agencies themselves
E. Summary

IV. Assessing Recent Reforms

This section surveys recent reforms established to strengthen the agencies' internal use of science and evaluates their effectiveness. Effectiveness is measured by whether the reforms identify meaningful problems (using the findings in Section III as the backdrop); whether agencies have complied with these various reform/directives; and any other information that proves useful. The reforms are:

1. Obama and Holdren Memoranda on Scientific Integrity
2. OMB peer review guidance
3. OMB's draft risk assessment guidance
4. Data Quality Act and OMB's guidance on agency compliance with DQA
5. Data Access Act

V. Remaining Problems

This section identifies additional problems in need of reform. It is premature to provide a complete list of these remaining problems, but a preliminary literature review reveals the following:

A. Agencies face insufficient incentives to communicate the quality and role that science plays in their decisions in a way that is accessible to a broader audience (e.g., EPA).
B. The quality of agencies' use of science can be quite poor, at least in some situations when the science is subjected to limited oversight from affected stakeholders (e.g., FBI forensic evidence in criminal cases).
C. Agencies have incomplete or nonexistent policies for reviewing the quality of private science or for sharing that research with the public.
D. Agencies face impediments to revising the science underlying informal rules.
E. Agencies have insufficient authority and resources to direct funding to needed areas of research that informs regulation.

VI. **Reform recommendations**

This final section identifies additional reforms that appear to be needed in light of the prior analysis, particularly Sections IV and V, and offers suggestions for how the reforms might be designed. The reforms listed below are preliminary and are likely to change once the study is completed.

A. Highest priority reforms
    1. Additional protections to prevent the politicization of science advice (building on the Holdren memorandum).
    2. More rigorous review of all science used for regulation, particularly private science, and transparency of this research to the public (expansion of the Data Access Act).
    3. More accessible communication of the quality of the relevant science and the role it plays in regulatory decisions.

B. Medium priority reforms
    1. Additional procedural guidance on the deployment of science advisory boards.

C. Lower priority reforms
    1. The development of additional administrative mechanisms that enable agencies to respond to changing science.
    2. Greater authority and resources for agencies to identify and address research gaps in the available science.