ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

To: **Committee on Regulation**
From: **Gretchen Jacobs**
Reeve T. Bull
Re: **Draft Recommendation for Science in the Administrative Process Project**

Science in the Administrative Process

DRAFT February 15, 2013

For the last three decades, many have criticized federal agencies for being insufficiently transparent in their use of science in agency decisionmaking.[1] Partially in response to these criticisms, the Executive Branch and Congress have issued a number of reforms of the scientific process undergirding agency decisionmaking. Most recently, in 2009 President Obama issued a memorandum to the agencies directing that, "[t]o the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."[2] "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."[3] John Holdren, the Director of Office and Science Technology Policy (OSTP), elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a

[1] *See e.g.* NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011) [hereinafter NAS, FORMALDEHYDE REPORT]; COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); NAT'L RESEARCH COUNCIL, ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter NAS, RISK ASSESSMENT]; BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16-16, 41-42 (2009); *see also* CTR. FOR EFFECTIVE GOV'T, ADVANCING THE PUBLIC INTEREST THROUGH REGULATORY REFORM: RECOMMENDATIONS FOR PRESIDENT-ELECT OBAMA AND THE 111TH CONGRESS 26, 34, 47 (2008).

[2] Memorandum from the Admin. of Barack H. Obama for the Heads of Executive Departments & Agencies on Scientific Integrity (Mar. 9, 2009) *available at* http://www/gpo/gov/fdsys/pkg/DCPD-200900137/pdf/DCPD-200900137.pdf.

[3] *Id.*

clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections."[4]

At base, these initiatives demand heightened transparency of agencies' use of science as a central means of ensuring the basic accountability of agency regulation. If an agency isolates the role that scientific information plays in its ultimate decision and explains how it ensured that its scientific analysis was rigorous, then the public has a basis against which it can evaluate both the scientific and policy judgments underlying the agency's decision. This transparency allows those outside the agency to assess whether the agency's policy decision informed by science comports with the authorizing law, the larger scientific record, and political preferences. This transparent decision process also advances other institutional and scientific goals, such as identifying promising areas for future research and serving as a bulwark against the politicization of science.[5]

Some agencies are developing innovative ways to communicate how science informs their policies in sophisticated, yet accessible ways. Agencies are also establishing processes that solicit both expert and internal review of their work and that document the changes made in response to this input. Integrity policies established by at least one agency allow staff to raise scientific differences with supervisors through various informal and formal mechanisms.[6] Finally, agencies increasingly have used the Internet to list the literature and other scientific evidence they relied on when making decisions.[7]

---

[4] Memorandum from John P. Holdren for the Heads of Executive Departments & Agencies on Scientific Integrity (Dec. 17, 2010) [hereinafter John Holdren Scientific Integrity Memo] *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf. To effectuate this and a number of other responsibilities, agencies were asked to report back to OSTP with a report on the actions taken to develop and implement their scientific integrity policies by April 2011.

[5] BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY, FINAL REPORT 3 (2009), *available at* http://www.bipartisanpolicy.org/sites/…/BPC%20Science%20Report%20fnl.pdf.

[6] *See* NUCLEAR REGULATORY COMMISSION, COLLABORATIVE WORK ENVIRONMENT PROGRAM, http://www.nrc.gov/about-nrc/values.html#open (last updated May 4, 2012); FOOD AND DRUG ADMIN., SCIENTIFIC INTEGRITY AT FDA, FDA STAFF MANUAL GUIDES, VOLUME IV-AGENCY PROGRAM DIRECTIVES 2 (2012) *available at* http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm.

[7] *See* THE HEALTH AND ENVIRONMENTAL RESEARCH ONLINE (HERO) DATABASE, http://hero.epa.gov/ (last updated Feb. 8, 2012).

Despite these important innovations, agency decision-making processes would benefit from further improvements, and this recommendation offers several recommendations for enhancing the transparency of agencies' use of science. First, it highlights a series of best practices designed to improve the transparency, accountability, and timeliness of agencies' use of science in policymaking. Second, the recommendation aims to bring greater parity to the treatment of agency-funded and externally-funded research. Finally, the recommendation offers a number of proposals for improving the rigor and transparency of peer review processes deployed by agencies in scientific investigations.

I. Best Practices

Comment [r1]: Morrison: Might consider a term other than "best practices," using another phrase that denotes "practices worth considering."

1. *Transparent Ex Ante Design of Risk Assessment*: At an early stage in their regulatory processes, agencies should articulate the specific policy questions that may be informed by science; specify how the risk assessment will integrate available information, including the criteria to be used in reviewing and weighing existing studies and approaches; identify other a priori analytical choices; assess the available evidence bearing on these policy-relevant questions; apply the evidence to the policy questions at issue (with robust statements of material uncertainties and assumptions); and identify plausible scientific approaches to inform policy alternatives. Agencies should maintain a clear distinction between assessment of risks and review of risk management alternatives.

Comment [r2]: Dudley: This should define the term "a priori" (Morrison concurs) and should define the criteria for inclusion and exclusion.

2. *Conducting Systematic Review*: In conducting the systematic review process, agencies should observe the following practices:

   (a) assemble a team of experts with the appropriate skills required to conduct the review;

(b) adopt standard protocols for evidence identification that contain clear and precise criteria for including or excluding studies on the basis of relevance and scientific merit[8];

(c) in interpreting and synthesizing different studies, should: (i) articulate one or more hypotheses about how a hazard causes, directly or indirectly, an endpoint of concern, including an explanation of related phenomena that are expected to be observable if the hypotheses are indeed true; (ii) review all relevant research studies for their implications regarding these hypotheses and summarize such evidence; (iii) evaluate evidence supporting the hypotheses; and (iv) infer, based on the weight of evidence, whether the potential hazard has a causal effect on the endpoint of concern, explaining why this conclusion is more likely than the alternative;

Comment [r3]: Jacobs: Some of these sub-sub-points seem to be covered in other sub-parts of this paragraph. In any event, I would make this a separate paragraph.

(d) use a database to capture study information and relevant quantitative data and prepare standardized evidence tables that will capture the key features of each study;

(e) determine whether the available information is adequate to address each problem statement, identify gaps where additional studies would be useful, and determine whether the agency's stakeholders or others can generate any missing data;

Comment [r4]: Morrison: We should provide additional clarification as to what this means.

(f) adopt uniform approaches to evaluate the weight of evidence of each study and thoroughly and transparently identify any weaknesses, uncertainties, or variability in the data or analysis; and

(g) evaluate the strength of contrary and negative evidence, in addition to the primary studies used by the agency, and consider the use of multiple studies in quantitative analysis.

[8] In this connection, agencies should consider using the standards articulated in the following sources: Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, PROCEEDINGS OF THE ROYAL SOC'Y OF MED., 58, 295-300 (1965); HJ Klimish & Andreae M. Tillman U., *A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data*, REGAL TOXICOL PHARMACOL 1-5 (1997).

Agencies should ensure transparency in designing and conducting systematic reviews. The agency should prepare an internal document describing its general process for conducting systematic reviews and should post that document on its website. In addition, in each instance in which it conducts such a review, the agency should catalogue its efforts to comply with the above steps in a publicly accessible document.

3. *Disclosure of Underlying Studies and Data*: Consistent with the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that qualified members of the public can, within the time limits provided for public comment, fully reproduce the agency's analytical results. This generally requires that agencies identify and make publicly available the scientific literature, raw data, models reviewed, and its research results, including the results it obtained but on which it did not rely. Scientific and technical literature, whether utilized or rejected, should be posted online to afford the public the opportunity to evaluate and comment on it,[9] unless subject to copyright, in which case clear instructions should be provided concerning how to obtain it consistent with copyright law.

4. *Checkpoints and Explanations*: Particularly in cases when they are not bound by judicially enforceable deadlines, agencies should generally establish explicit checkpoints for regulatory projects. These checkpoints should address both when agencies will close their consideration of research or debate in order to reach a decision and when they might reopen that consideration. External peer review bodies may be particularly useful to agencies in establishing scientifically credible checkpoints. In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should particularly reference any relevant ongoing research or external deliberations.

Comment [r5]: Dudley: It is not clear whether this refers to only science-based decisions or also policy decisions? Also, is it a time-based or information based deadline?

[9] Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011).

5. *Identification of Future Research Projects*: For science-intensive rules, agencies should use the results of uncertainty analysis to identify specific types of future research projects that will best advance understanding on the regulatory issue (for example, through the use of value of information analysis). This identification of research questions and priorities should influence the agencies' research agendas as well as provide a basis for establishing future checkpoints.

6. *Agency Staff Authorship Rights*: Agency staff play an important role in producing their respective agencies' scientific analyses. Agency managers should consider providing staff with some form of consensual authorship right or attribution for reports or analyses to which they contribute in a significant way. Such rights should be acknowledged for all staff authors who contributed in a significant way to a technical or scientific report, including economists, lawyers, and other nonscientists. In a similar vein, reviewers and other contributors should also be identified by name and general contribution.

7. *Dissent Rights*: Agencies should encourage vigorous debate among agency scientists, and should explore ways of incorporating the diversity of that debate in any resulting work product. One such policy would allow agency staff to dissent or express their non-concurrence on a technical issue in a document to which they contributed. In cases where written dissent or nonconcurrence is permitted, agency managers should take seriously a staff member's request to place a dissent or non-concurrence into the public record. Dissenting employees should also be allowed and encouraged to publish these dissenting positions in the peer reviewed literature, provided that confidential governmental deliberations are not compromised. In all cases and regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

Comment [r6]: Dudley: I would recommend deleting this recommendation: it is difficult to distinguish scientific disagreements from policy disagreements, and this could therefore prove problematic. If the recommendation is retained, however, it should not be limited to agency staff and should also include staff at other agencies.

8. *Transparency for External Review*: Agencies should comply with section 6(a)(3)(E) of Executive Order 12866,[10] or any successor Executive Order, and identify all substantive

Comment [r7]: Dudley: I would recommend deletion of this recommendation.

[10] Exec. Order No. 12,866, 3 C.F.R. 638 (1993), *reprinted as amended in* 5 U.S.C. § 601 (2006).

changes in regulations between the draft submitted to the Office of Information and Regulatory Affairs (OIRA) for review and the action subsequently announced.

Comment [r8]: Morrison: I would strengthen this recommendation to require agencies to indicate when changes were made and by whom they were suggested.

9. *Sharing of Agency Best Practices through Central Executive Branch Coordinator*: OSTP, an interagency group headed by OSTP, or another body designated by the President should be responsible for identifying and publicizing the innovations developed by agencies for transparently incorporating science into their regulatory decisions.

10. *Elimination of Legal Barriers to Transparent Decisionmaking*: Agencies should identify legal barriers that impede public access to the scientific information underlying agency analyses or otherwise block the agencies' development of scientifically robust decision-making processes. Agencies should recommend appropriate revisions in existing law to eliminate such impediments to the Executive Office of the President. OSTP or another centralized entity should serve as a forum for identifying concerns affecting multiple agencies and urging appropriate changes in law.

Comment [r9]: Dudley: Can we provide some examples?

II. Agency Disclosure to Enhance the Transparency of Research

11. *Data Disclosure*: To the maximum extent practicable, agencies should voluntarily comply with the Shelby Amendment[11] and OMB Circular A-110[12] in circumstances to which Circular A-110 does not literally apply. In particular, agencies should seek to provide disclosure of data underlying federally-funded or non-federally funded research, including from government contracts. Where the owners of such data will not provide such access, the agency should note that fact, explain why they used the results if they choose to do so, and may assign less weight to such research.

[11] Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 122 Stat. 2681, 2780, 3176 (1998).

[12] Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (OMB Circular A-110), 2 C.F.R. § 215 (2004).

12. *Legal Restrictions on Disclosure*: Public transparency of scientific information may not be possible because of legal restrictions. These may be based on personal privacy[13] or because the owner of information claims it to be protected from disclosure as trade secret or other confidential business information.[14] Agencies should explain these restrictions in the agency's individual analyses and indicate whether any such restricted information was relied upon and, if so, for what conclusions. Agencies should publish non-restricted summaries of such information and consider procedures to provide for the sharing of CBI with outside parties in ways that do not compromise confidentiality (e.g., user agreements).

13. *Financial Interests Disclosure*: Agencies should require financial interest disclosures on all research submitted to inform an agency's licensing, regulatory, or other decision-making process. This disclosure should be similar to the financial interest disclosure required by scientific journals.[15] The regulatory financial interest disclosure should also, where possible, identify whether the experimenter or author had the legal right to design the research, collect the data, interpret the data, and author, publish or otherwise disseminate the resulting report without approval of the sponsor of the research. Finally, agencies and scientific advisory committees should be skeptical of those studies wherein a party other than the principal investigator (e.g., the study sponsor or funder) had control over the design or publication of the study.

Comment [r10]: Dudley: We should run this by representatives from FDA and other affected agencies prior to adopting such a recommendation.

III. Use of Peer Review for Agency Science

14. *External Peer Review Panels*: Agencies should finalize the charge/questions submitted to a peer review committee before choosing reviewers. In constructing peer review panels

Comment [r11]: Dudley: This timing may not prove feasible; it takes time to choose the reviewers, and the process of deciding the charge can be informed by the process of choosing the reviewers.

[13] The Privacy Act of 1974, 5 U.S.C. § 552a (1974).

[14] Trade Secrets Act, 18 U.S.C. § 1905 (2012); Freedom of Information Act, 5 U.S.C. § 552(b)(4) (2012).

[15] *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Manuscript Preparation and Submission: Preparing a Manuscript for Submission to a Biomedical Journal*, INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, http://www.icjme.org/manuscript_1prepare.html.

consisting of outside experts, agencies should select panel members based primarily upon their expertise and experience as well as their ability to contribute to the panel's deliberations without conflict of interest or undue bias or pre-disposition. This applies to all potential members, whether hailing from government, academia, or the private or non-profit sectors. Agencies should carefully delineate the difference between financial conflicts of interest and bias or pre-disposition. Agencies should avoid financial conflicts of interest to the greatest extent feasible. Insofar as virtually all potential panel members possess certain general views or pre-dispositions based on background and training, agencies should select members that represent a range of respected perspectives and fields of expertise. Indeed, panels with a healthy range of perspectives are more likely to engage in a robust review of critical scientific issues.

In constructing peer review panels, agencies should observe the following principles:

(a) Agencies should develop guidelines for implementing peer review procedures, including identification of issues that warrant additional procedures and issues that warrant external review (rather than internal review).[16]

Comment [r12]: Morrison: We should provide some clarification of what procedures are contemplated here.

(b) For the most significant scientific work products, agencies should consider employing recognized third-party institutions (e.g., NAS) to conduct the relevant peer review.

(c) When agencies use contractors to organize peer review panels, they should require the contractors to apply to prospective and actual members of such panels the same ethics requirements that would apply if such individuals were special government employees.

(d) Agencies should provide a meaningful and timely opportunity for the public to provide input into the peer review process before the pre-review commences. This

[16] *See* OFFICE OF MGMT. AND BUDGET, PEER REVIEW BULLETIN 4-6 (2004), available at http://www.whitehouse.gov/sites/default/omb/memoranda/fy2005/m05-03.pdf.

normally would include an opportunity to comment on the scope of review (i.e., problem formulation), peer review charge/questions, and proposed peer reviewers. The public should have the opportunity to nominate proposed peer reviewers and needed areas of expertise and to submit oral and written comments in sufficient time for review by panel members.

(e) Agencies should permit public participation in at least some meetings of every panel, and such sessions should be conducted in a fair, balanced manner that gives adequate time to all views. For particularly significant peer reviews, agencies should encourage and provide sufficient time for the peer reviewers to engage in dialogue with public commenters.

Comment [r13]: Morrison: I would add a reference to FACA here and state that peer review meetings should generally be public, unless one of the FACA exceptions is met. More broadly, we might address whether the peer review process should involve public meetings or instead can simply entail an exchange of documents.
Bull: If the peer review members submit comments individually and do not interact as a group, then the "individual advice" exemption of FACA applies, and the meeting need not be conducted publicly. If, however, the members exchange views as a group, then I agree that FACA would apply and that we should make note of that.

(f) Where panel members draft comments for discussion at panel meetings, the comments should be disclosed prior to panel meetings, allowing a sufficient amount of time to ensure a robust discussion of the individual comments at the panel meeting and to allow adequate time for public review of the comments prior to the meeting.

(g) Agencies should consider establishing independent ombudsmen to ascertain whether the agencies have adequately responded to peer review and public comments.[17]

(h) Agencies should publish a response to significant peer review and public comments on the peer review process at the completion of the review, in order to allow responses from panel members or from the public prior to the publication of the final document under review.

(i) Agencies should draw an appropriate balance between the competing concerns of paperwork burdens on panel members, privacy, and transparency in their review for

[17] ENVT'L PROT. AGENCY, SCI. ADVISORY BD. & ORD BD. OF SCIENTIFIC COUNSELORS, IMPLEMENTATION OF ORD STRATEGIC RESEARCH PLANS: A JOINT REPORT OF THE SCIENCE ADVISORY BOARD AND ORD BOARD OF SCIENTIFIC COUNSELORS 36 (2012) *available at* http://www.epa.gov/osp/bosc/pdf/120928rpt.pdf.

possible conflicts or bias. Panel members should update their disclosures during the duration of the panel if there are material changes to the information presented.

(j) Agencies should make available electronic records of peer review meetings, including transcripts, within 30 days of such meetings on the appropriate agency website.

15. *Internal Review*: Consistent with President Obama's scientific integrity directive,[18] agencies should seek expert review of scientific analyses wherever possible, even if this review occurs wholly within the agency. Agencies should explain in the final rule how they ensured rigorous review of the scientific research underlying each regulatory project.

[18] *See supra* note 2.