From: Alan Morrison
Sent: Tuesday, April 02, 2013 5:34 PM
To: Reeve Bull
Subject: Re: Documents for April 2 Meeting

I do not have a word document and so I will make my few comments about each draft in this email.

Science: Page 1, 1st para line 3: I think "issued" is not best word choice. How about "made"?

Page 2, shaded area, para beginning Despite, line beginning "effectuating a regulatory decision and": I think you need something like "explaining the" policies for reopening etc.

Page 3, first line, I think requirements is too strong - I suggest "norms". Same line, I would change "furnish" to "submit or rely on".

Page 3, rec 2, next to last line: change "if" to "where" or perhaps "when"

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Science in the Administrative Process

DRAFT March 18, 2013

For the last three decades, many have criticized federal agencies for being insufficiently transparent in their use of science[1] in agency decisionmaking.[2] 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."[3] "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."[4] John Holdren, the Director of the Office ~~and~~of Science and Technology Policy (OSTP), elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections."[5]

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 ~~use of science~~ policy decision comports with the authorizing law, the larger scientific record, and political preferences. This transparent

Comment [A1]: Gretchen/Susan: Do you have any notes on what change was contemplated here?

Comment [A2]: My concern here was that the language suggested that "science" needs to "comport with… political preferences." We can't say that. 2 possible edits. Change science to "policy decision" OR delete "political preferences." I prefer the 1st and think that's what you intended, but could live with the 2nd. (The 2nd still suggests that science comports with authorizing law, which troubles me.)

[1] For purposes of this recommendation, the term "science" refers only to "natural sciences" (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields rather than "social sciences" (e.g., economics, psychology, sociology, etc.).

[2] *See e.g.* NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); 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); BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16, 41-42 (2009) [hereinafter "BPC REPORT"]; *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).

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

[4] *Id.*

[5] Memorandum from John P. Holdren for the Heads of Executive Departments & Agencies on Scientific Integrity (Dec. 17, 2010), *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 on the actions taken to develop and implement their scientific integrity policies by April 2011.

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~~misuse of science for political ends.[6]

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, the recommendation highlights a number of innovative practices undertaken by different federal agencies in enhancing the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information and set forth a systematic approach both for identifying relevant literature and devising new studies. Agencies should identify scientific research upon which they relied as well as the underlying data to the extent practicable and permitted by law.[7] Agencies should establish checkpoints for closing off consideration of additional research prior to effectuating a regulatory decision and policies for identifying future studies. Agencies should also consider extending authorship rights to staff that participate in the preparation of scientific reports in order to promote robust debate amongst agency scientists.[8] Finally, agencies should share "best practices with other agencies and should recommend the removal of any legal impediments to promoting transparency in scientific decisionmaking.[9]

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it recommends

Comment [A3]: Richard/Henry: You had mentioned the need to clarify the precise type of document we're referencing here. Do you have any suggested language for imparting the idea of "documents prepared by agency staff scientists in support of scientific decisionmaking"?

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Comment [A4]: **

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[6] BPC REPORT, *supra* note 2, at 3.

[7] As a general matter, the agency should make publicly available any scientific literature it considered, including literature it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, literature that an agency "considered" includes any study an agency official relied upon or reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). If any agency official merely had access to a study but did not specifically analyze it to determine its relevance, the agency has not "considered" it within the meaning of the recommendation for purposes of making such literature publicly available.

[8] In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note 3, a number of agencies have promulgated integrity policies to promote open debate amongst agency scientists. *See, e.g.*, 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; NAT'L OCEANIC AND ATMOSPHERIC ADMIN., SCIENTIFIC INTEGRITY (Dec. 7, 2011), *available at* http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; NUCLEAR REGULATORY COMM'N, COLLABORATIVE WORK ENVIRONMENT PROGRAM, http://www.nrc.gov/about-nrc/values.html#open (last updated May 4, 2012); *see also* Francesca T. Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf.

[9] *See* Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches 135–38 (Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

extending data disclosure requirements applicable to agency-funded research to privately funded research upon which an agency relies (to the extent practicable and permitted by law). Similarly, it recommends extending financial disclosure requirements to private parties who furnish studies used by an agency.

Practices ~~Worth~~Suggested for Agency Consider~~ing~~gation

1. *Explaining Agency Scientific Decisionmaking*: Agencies should explain in ~~the~~proposed and final ~~rule~~decision documents how they ensured rigorous review of the scientific ~~research~~information underlying each science-intensive regulatory project. This includes a statement of how the agencies evaluate the scientific information used in their analysis; how the agencies make that information available to reviewers and the public; how the analysis is reviewed by experts and interested parties; and how the agencies ensure that the final decision ~~can be compared against~~is supported by the scientific record.

2. ~~*Design*~~*Assuring Transparent ~~Risk~~ Assessments*: At an early stage in their regulatory processes, agencies should articulate the specific policy questions that may be informed by science; describe the study design, in the case of new research, or the criteria to be used in reviewing and weighing existing studies; identify other analytical choices; provide a synthesis of the available evidence and relevant literature guided by the study design; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the resulting policy decision. If possible, agencies should also explain the relationship between science and policy choices. [10]

3. *Disclosing Underlying Studies and Data*: In light of 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,~~have access to the information necessary to reproduce or verify the agency's analytical results within the time limits provided for public comment. This generally requires that the agency identify and make publicly available the scientific literature, underlying data, and models that it reviewed as well as its research results, including the results it obtained but on which it did not rely. To the extent practicable and permitted by law, the agency should identify and make publicly available (on the agency website or some other widely available forum) ~~a list of~~ the scientific literature it considered (including the literature ~~it rejected~~on which it did not rely when it is material to the scientific analysis, as well as the literature upon which it relied). [11]

[10] NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 7 (1983).

[11] *See* Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011); *see also* Memorandum from John P. Holdren, Director

4. *Checkpoints and Explanations*: Agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors. To the extent permitted by statute, agencies should consider establishing explicit checkpoints for regulatory projects, particularly in cases when they are not bound by judicially enforceable deadlines. These checkpoints should address both the conditions under which agencies will close their consideration of research or debate in order to reach a decision and when they might reopen that consideration. ~~In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.~~

5. *Identifying Future Research Projects*: For science-intensive rules, agencies should ~~use the results of uncertainty analysis to~~ identify specific types of future research projects ~~that~~ needed to reduce the most significant uncertainties in order to ~~will~~ best advance understanding of the regulatory ~~options~~issues. This identification of research questions and assignment of priorities should influence the agencies' research agendas as well as provide a basis for establishing future checkpoints.

6. *Agency Staff Authorship Rights*: Agency staff members 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~~ If appropriate, 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~~ could also be identified by name and general contribution.

7. *Encouraging Debate*: Agencies should encourage vigorous debate among scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Employees should be allowed and encouraged to publish their scientific work in the peer reviewed literature, provided that they follow applicable agency procedures and confidential governmental deliberations are not compromised. ~~In all cases and r~~Regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

8. *Sharing of Agency Best Practices through Central Executive Branch Coordinator*: OSTP, an interagency group headed by OSTP, or another body should be responsible for

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of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies re Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to fully or partially federally funded research papers twelve months after publication).

Comment [A5]: My notes indicate we moved the last 2 sentences to the top.

Comment [A6]: Agency people objected to the reference to "uncertainty analysis" which has a specific meaning and may not always be appropriate. I offered this edit to articulate what we had in mind and think the committee thought it solved the problem.

Comment [A7]: My notes say we deleted this sentence, but I don't recall why (and it was not my suggestion).

Comment [A8]: These 2 sentences say "should" in contrast to 2nd sentence, which says "should consider." These edits are to conform the idea that they should consider. Instead of adding "If appropriate," to 3rd sentence, we could substitute could fro should.

Comment [A9]: EPA edits (CAS)

Comment [A10]: May want to work with NIST on this one.

identifying and publicizing the innovations developed by agencies for transparently incorporating science into their regulatory decisions.

9. *Eliminating Legal Barriers to Transparent Decisionmaking*: Agencies should identify legal ~~barriers~~ obstacles that may 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 [A11]: My notes say Carol Ann had a concern or edit here

Agency Disclosures to Enhance the Transparency of Research

10. *Data Disclosure*: To the maximum extent practicable and in compliance with appropriate legal restrictions (e.g., protections for personal privacy, trade secrets, and confidential business information (CBI)), agencies should voluntarily comply with the Shelby Amendment[12] and OMB Circular A-110[13] in circumstances to which they do not literally apply. In addition, agencies should seek to provide disclosure of data underlying federally-funded or non-federally funded research, including from government contracts. Agencies should review their CBI policies to ensure that they include appropriate mechanisms to prevent over-claiming. Where the owners of such data will not provide such access, agencies should note that fact, explain why they used the results if they choose to do so, and may assign less weight to such research.

Comment [A12]: NIST points to a potential timing issue: It may be difficult to retroactively apply a disclosure requirement to privately funded research upon which an agency relies. In those instances, they suggest it might be more appropriate simply to state that the agency should base its decision to rely upon a particular study partly on whether the underlying data have been disclosed.

11. *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.[14] 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.

[12] Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681, 2681–495 (1998). (tasking the director of the Office of Management and Budget with amending Circular A-110 "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.")

[13] 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). ("[I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.")

[14] *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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Science in the Administrative Process

DRAFT March 18, 2013

For the last three decades, ~~many have criticized federal agencies for being insufficiently transparent in their use of science~~[1] ~~in agency decisionmaking~~several authorities have made recommendations for improving transparency in the use of science.[2] Partially in response to these ~~criticisms~~recommendations, the Executive Branch and Congress have ~~issued~~made a number of reforms ~~of~~to 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."[3] "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."[4] John Holdren, the Director of the Office ~~and~~of Science and Technology Policy (OSTP), elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections."[5]

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 identifies ~~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 ~~use of science~~policy decision comports with the authorizing law, and the larger scientific record~~, and political preferences~~. This transparent decision process also advances other institutional and scientific

Comment [A1]: NIST proposes revisions to the document to distinguish between those provisions that apply to non-regulatory agencies as well as regulatory agencies.

Comment [A2]: Carol Ann Siciliano's note: Let's consider rephrasing this opening sentence to focus on three decades of recommendations (rather than criticisms). This rephrasing sets the stage for the ACUS recommendations to come, which pluck the best of these ideas and recommend them directly to the agencies.

Comment [A3]: Carol Ann Siciliano's suggestion.

Comment [A4]: Carol Ann Sicilano's note: this concept seems out of place here.

[1] For purposes of this recommendation, the term "science" refers only to "natural sciences" (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields rather than "social sciences" (e.g., economics, psychology, sociology, etc.).

[2] *See e.g.* NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); 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); BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16, 41-42 (2009) [hereinafter "BPC REPORT"]; *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).

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

[4] *Id.*

[5] Memorandum from John P. Holdren for the Heads of Executive Departments & Agencies on Scientific Integrity (Dec. 17, 2010), *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 on the actions taken to develop and implement their scientific integrity policies by April 2011.

goals, such as identifying promising areas for future research and serving as a bulwark against ~~the politicization~~misuse of science for political ends.[6]

Despite these important ~~innovations~~initiatives, ~~agency decision-making processes would benefit from further improvements, and this recommendation offers several recommendations for enhancing the transparency of agencies' use of science~~a study commissioned by the Administrative Conference[7] and conferences held to consider questions it raised have revealed that agency decisionmaking processes would benefit from further improvements. Drawing on this learning, the recommendation offers several proposals for enhancing the transparency of agencies' use of science. At the same time, ACUS recognizes that agencies' abilities to implement this recommendation may be affected by resource limitations.

First, the recommendation highlights a number of innovative practices undertaken by different federal agencies ~~in~~to enhanc~~ing~~e the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information and specify study designs for new research and criteria for weighing existing ~~set forth a systematic approach both for identifying relevant literature and devising new~~ studies.[8] Agencies should identify scientific reports or data ~~research~~ upon which they relied ~~(as well as the underlying data)~~, and material literature that they considered but rejected, to the extent practicable and permitted by law.[9] Agencies should establish checkpoints for closing off consideration of additional research or debate prior to effectuating a regulatory decision and policies for reopening that consideration ~~identifying future studies~~. Agencies should also consider extending authorship ~~rights~~ attributions to staff ~~that~~who participate in the preparation of scientific reports ~~in order~~and taking other steps to promote robust debate amongst agency scientists.[10] Finally, agencies should share ~~"~~best practices with other agencies and should

Comment [A5]: Carol Ann Siciliano's suggestion.

Comment [A6]: Carol Ann Siciliano's suggestion. As noted in Wendy Wagner's report at p. 137, agencies' resource limitations may be a significant obstacle to implementation.

Comment [A7]: Carol Ann Siciliano's suggestion (because there is not necessarily a distinction between "research" and "data").

Comment [A8]: Carol Ann Siciliano's suggestion to conform to recent revisions to paragraph 6.

Comment [A9]: Richard/Henry: You had mentioned the need to clarify the precise type of document we're referencing here. Do you have any suggested language for imparting the idea of "documents prepared by agency staff scientists in support of scientific decisionmaking"?

[6] BPC REPORT, *supra* note 2, at 3.

[7] Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches (Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf.

[8] In so doing, agencies should endeavor to explain the relationship between scientific research and the policy decisions it supports. NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 7 (1983).

[9] *See* Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011); *see also* Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies re Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to fully or partially federally funded research papers ~~twelve months~~beginning one year after publication). As a general matter, the agency should make publicly available any scientific literature it considered, including literature it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, literature that an agency "considered" includes any study an agency official relied upon or reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). If any agency official merely had access to a study but did not specifically analyze it to determine its relevance, the agency has not "considered" it within the meaning of the recommendation for purposes of making such literature publicly available.

[10] In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note ~~3333~~, a number of agencies have promulgated integrity policies to promote open debate amongst agency scientists. *See, e.g.*, FOOD AND DRUG

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recommend the removal of any legal impediments to promoting transparency in scientific decisionmaking.[11]

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it recommends extending data disclosure requirements applicable to agency-funded research to privately funded research upon which an agency relies (to the extent practicable and permitted by law). Similarly, it recommends extending financial disclosure ~~requirement~~norms to private parties who ~~furnish~~submit studies used by an agency.

Comment [A10]: Carol Ann Siciliano 's note: This paragraph of the preamble will need conforming edits after the final paragraphs of the recommendation are discussed by the Committee.

RECOMMENDATION

Practices ~~Worth~~Suggested for Agency Consider~~ing~~ation

1. *Explaining Agency Scientific Decisionmaking*: Agencies should explain in ~~the~~proposed and final ~~rule~~decision documents how they ensured rigorous review of the scientific ~~research~~information underlying each science-intensive regulatory project. This includes a statement of how the agencies evaluated the scientific information used in their analysis; how the agencies ma~~k~~de that information available to reviewers and the public; how the analysis ~~i~~was reviewed by experts and interested parties; and how the agencies ensured that the final decision ~~can be compared against~~was supported by the scientific record.

Comment [A11]: Jeff Lubbers proposes consolidating recommendations 1-9 into a single recommendation with 9 sub-parts.

2. *~~Design~~Assuring Transparent ~~Risk~~ Assessments*: At an early stage in their regulatory development processes, agencies should ~~articulate~~ identify the specific policy questions that may be informed by science; describe the attributes of assessments needed to characterize risks and inform policy decisions; and describe ~~study design, in the case of new research, or~~ the criteria to be used in reviewing and weighing existing studies.~~;~~ Completed assessments should identify other appropriate analytical choices; provide a synthesis of the available evidence and relevant literature guided by the assessment ~~study~~ design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the ~~resulting~~

Comment [A12]: Carol Ann Siciliano note: I propose several clarifying edits to this paragraph to implement the Committee's views from the 4/2 meeting. All of the suggestions in this paragraph are mine, with the exception of edits to the title, the addition of "or criteria" and the edits to the last sentence.

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; NAT'L OCEANIC AND ATMOSPHERIC ADMIN., SCIENTIFIC INTEGRITY (Dec. 7, 2011), *available at* http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; NUCLEAR REGULATORY COMM'N, COLLABORATIVE WORK ENVIRONMENT PROGRAM, http://www.nrc.gov/about-nrc/values.html#open (last updated May 4, 2012); *see also* Francesca T. Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf.

[11] *See* ~~Wendy~~ Wagner, ~~Science in Regulation: A Study of Agency Decisionmaking Approaches~~*supra* note 7, at 135–38 ~~(Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation-Final%20Report_2_18_13_0.pdf~~ (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

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~~policy decision~~results of the assessment. ~~If~~Where possible, agencies should also explain the relationship between their scien~~ce~~tific conclusions and policy choices. [12]

3. *Disclosing Underlying Studies and Data*: ~~In light of~~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,~~have access to the information necessary to reproduce or verify the agency's analytical results within the time limits provided for public comment. ~~This generally requires that the agency~~To the extent practicable and permitted by law ~~or~~and applicable policies, agencies should identify and make publicly available the scientific literature, underlying data, and models that it reviewed as well as its research results, including the results it obtained but on which it did not rely. To the extent practicable and permitted by law, the agency should identify and make publicly available (on the agency website or some other widely available forum) ~~a list of~~ the scientific literature it considered (including the literature ~~it rejected~~on which it did not rely when it is material to the scientific analysis, as well as the literature that was used in the assessment ~~upon which it relied~~). [13]

4. *Checkpoints and Explanations*: ~~To the extent permitted by statute, a~~Agencies should consider establishing explicit checkpoints for regulatory projects, defining both the conditions under which they intend to close their consideration of research or debate in order to reach a decision and when they might reopen that consideration ~~for regulatory projects~~, particularly in cases when they are not bound by judicially enforceable deadlines. ~~These checkpoints should address both the conditions under which agencies will close their consideration of research or debate in order to reach a decision and when they might reopen that consideration.~~ In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

5. *Identifying Future Research Projects*: For science-intensive r~~ules~~egulatory projects, agencies should ~~use the results of uncertainty analysis to~~ identify specific types of future research projects needed to reduce significant uncertainties ~~that will best~~in order to advance understanding of the regulatory ~~options~~issues. ~~This identification of research questions and assignment of priorities should influence the agencies' research agendas as well as provide a basis for establishing future checkpoints.~~

Comment [A13]: Carol Ann Siciliano's suggestion.

Comment [A14]: Carol Ann Siciliano's note: I am very concerned about adding the phrase "reproduce or" to this sentence. An agency may not be able to provide all of the information necessary to replicate analytical results because of limitations relating to private information (and other legal restrictions) and funding.

Comment [A15]: Carol Ann Siciliano's suggestion.

Comment [A16]: Carol Ann Siciliano's suggestion.

[12] ~~Nat'l Research Council, Comm. on the Institutional Means for Assessment of Risks to Public Health, Risk Assessment in the Federal Government: Managing the Process 7 (1983).~~

[13] ~~*See* Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011); *see also* Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies re Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to fully or partially federally-funded research papers twelve months after publication).~~

6. *Agency Staff Authorship ~~Rights~~*: Agency staff members play an important role in producing their respective agencies' scientific analyses. ~~Agency managers should consider providing staff~~Agencies should consider providing their personnel with some form of consensual ~~authorship right or~~ attribution for reports or analyses to which they contribute in a significant way. If appropriate, ~~S~~such ~~rights~~attributions should be ~~acknowledged~~made for ~~all~~ staff authors who contributed in a significant way to a technical or scientific report, including not only scientists but also economists, lawyers, and other ~~nonscientists~~contributors. In a similar vein, reviewers and other contributors ~~sh~~could also be identified by name and general contribution.

7. *Encouraging Debate*: Agencies should encourage vigorous debate among scientists and should explore ways of incorporating the diversity of that debate in any resulting work product. Employees should be ~~allowed and~~ encouraged to publish their scientific work in the peer reviewed literature, provided that they follow applicable agency procedures and that confidential governmental deliberations are not compromised. ~~In all cases and r~~Regardless of the public availability of these discussions, dissenting staff members should be protected from reprisals.

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

9. *Eliminating Legal Obstacles ~~Barriers~~ to Transparent Decisionmaking*: Agencies should identify legal ~~barrier~~obstacles that may impede public access to the scientific information underlying agency analyses or otherwise ~~block~~may prevent the agencies' development of scientifically robust decision-making processes. Agencies should recommend appropriate actions, including 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~~.

Agency Disclosures to Enhance the Transparency of Research

10. *Data Disclosure*: To the ~~maximum~~ extent practicable and in compliance with appropriate legal restrictions and authorities ~~(e.g., protections for personal privacy, trade secrets, and confidential business information (CBI)), agencies should voluntarily comply with the Shelby Amendment[14] and OMB Circular A-110[15] in circumstances to which they do not literally~~

~~[14] Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681, 2681-495 (1998). (tasking the director of the Office of Management and Budget with amending Circular A-110 "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.")~~

~~[15] 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). ("[I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under~~

Comment [A17]: NOAA recommends strengthening this recommendation by striking the word "consider."

Comment [A18]: Henry/Richard: We had briefly discussed the need to distinguish Scientific Integrity and Research Misconduct in this recommendation. Do you have any proposed language that would resolve this issue (or do the existing edits at least partially fix the problem)?

Comment [A19]: Carol Ann Siciliano's suggestion.

Comment [A20]: Henry/Richard: You raised two concerns here: (1) the fact that peer review is typically anonymous (and this is not) and (2) it is unclear what sort of document is being contemplated. Do you have any suggested edits to fix the former issue? As to the latter issue, I think the idea is to include any formal report that an agency prepares based on its scientific research—do you have any suggested language to capture that concept?

Comment [A21]: Remington will provide language stating that OSTP will encourage agencies to publicize innovations in scientific transparency.

Comment [A22]: Carol Ann Siciliano's conforming edit.

Comment [A23]: Carol Ann Siciliano's suggestion: striking "in law" makes this concept broader and more in line with the earlier addition of "actions."

Comment [A24]: Jeff Lubbers proposes consolidating recommendations 10 and 11 into a single recommendation with two sub-parts on agency disclosures.

Comment [A25]: Carol Ann Siciliano's suggestion.

Comment [A26]: Carol Ann Siciliano's suggestion.

~~apply. In addition~~, agencies should seek to provide disclosure of data underlying ~~federally-funded or non-federally funded~~scientific research, including ~~from government contracts~~privately funded research being considered. Where such data are ~~is~~ not subject to legal or other protections and ~~the~~its owners ~~of such data~~nonetheless will not provide such access, agencies should note that fact, explain why they used the results if they choose to do so, and may assign less weight to such research. Agencies should review their CBI policies to ensure that they include appropriate mechanisms to prevent over-claiming. ~~Where the owners of such data will not provide such access, agencies 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. ~~*Financial* *Conflict of*~~ *Interests Disclosure*: Agencies should require ~~financial~~ conflict of interest disclosures on all scientific research submitted to inform an agency's licensing, regulatory, or other decision-making process. This disclosure should be similar to the ~~financial~~ conflict of interest disclosure required by some scientific journals.[16] The regulatory ~~financial~~ conflict of 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 or full dataset (to the extent permitted by law) without approval of the sponsor of the research. Finally, agencies ~~and scientific advisory committees~~ should ~~be skeptical of those~~evaluate studies to identify those 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 [A27]: NIST points to a potential timing issue: It may be difficult to retroactively apply a disclosure requirement to privately funded research upon which an agency relies. In those instances, they suggest it might be more appropriate simply to state that the agency should base its decision to rely upon a particular study partly on whether the underlying data have been disclosed.

Comment [A28]: Carol Ann Siciliano's suggestion.

Comment [A29]: Carol Ann Siciliano's suggestion.

Comment [A30]: Carol Ann Siciliano's note: This recommendation and the report seem to deal more with (broader) conflict of interest disclosure issues rather than being limited solely to (narrower) financial disclosure issues. I suggest several edits to reflect this idea. With the exception of the addition of "scientific" in the first sentence, the addition of "some" in the second sentence, and the deletion of FN17, all edits here are mine.

Comment [A31]: Carol Ann Siciliano's note: This is the first mention of scientific advisory committee in the recommendation. I suggest deleting it: advisory committees simply provide advice; the agencies are the ones that conduct the administrative process.

Comment [A32]: NIST recommends re-phrasing this so that it does not implicate "round-robin" studies designed by others in which agencies participate.

~~an award that was used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.")~~

[16] ~~*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.~~

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Science in the Administrative Process

DRAFT March 18, 2013

For the last three decades, many have criticized federal agencies for being insufficiently transparent in their use of science[1] in agency decisionmaking.[2] Partially in response to these criticisms, the Executive Branch and Congress have ~~issued~~made a number of reforms ~~of~~to 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."[3] "Each agency should [also] have appropriate rules and procedures to ensure the integrity of the scientific process within the agency."[4] John Holdren, the Director of the Office ~~and~~of Science and Technology Policy (OSTP), elaborated upon this memorandum in 2010, instructing agencies to "communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections."[5]

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 ~~use of science~~policy decision 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

Comment [A1]: NIST proposes revisions to the document to distinguish between those provisions that apply to non-regulatory agencies as well as regulatory agencies.

[1] For purposes of this recommendation, the term "science" refers only to "natural sciences" (e.g., chemistry, physics, medical science, geology, etc.), mathematics, statistics, computer science, and other allied fields rather than "social sciences" (e.g., economics, psychology, sociology, etc.).

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[2] *See e.g.* NAT'L RESEARCH COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011); 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); BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 16, 41-42 (2009) [hereinafter "BPC REPORT"]; *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).

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

[4] *Id.*

[5] Memorandum from John P. Holdren for the Heads of Executive Departments & Agencies on Scientific Integrity (Dec. 17, 2010), *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 on the actions taken to develop and implement their scientific integrity policies by April 2011.

promising areas for future research and serving as a bulwark against ~~the politicization~~misuse of science for political ends.[6]

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~~a study commissioned by the Administrative Conference[7] and conferences held to consider questions it raised have revealed that agency decisionmaking processes would benefit from further improvements. Drawing on this learning, the recommendation offers several proposals for enhancing the transparency of agencies' use of science. ~~–~~First, the recommendation highlights a number of innovative practices undertaken by different federal agencies ~~in~~to enhanc~~inge~~ the transparency of their scientific decisionmaking processes. As a general matter, agencies should articulate the specific questions to be informed by scientific information and specify study designs for new research and criteria for weighing existing ~~set forth a systematic approach both for identifying relevant literature and devising new~~ studies.[8] Agencies should identify scientific research upon which they relied (as well as the underlying data), and material literature that they considered but rejected, to the extent practicable and permitted by law.[9] Agencies should establish checkpoints for closing off consideration of additional research or debate prior to effectuating a regulatory decision and policies for reopening that consideration ~~identifying future studies~~. Agencies should also consider extending authorship rights to staff ~~that~~who participate in the preparation of scientific reports ~~in order~~and taking other steps to promote robust debate amongst agency scientists.[10] Finally, agencies should share ~~"~~best practices with other agencies and should

[6] BPC REPORT, *supra* note 2, at 3.

[7] Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches (Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf.

[8] In so doing, agencies should endeavor to explain the relationship between scientific research and the policy decisions it supports. NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 7 (1983).

[9] *See* Administrative Conference of the United States, Recommendation 2011-1, *Legal Considerations in E-Rulemaking*, ¶ 4, 76 Fed. Reg. 48789, 48789 (Aug. 9, 2011); *see also* Memorandum from John P. Holdren, Director of the Office of Science and Technology Policy, to the Heads of Executive Departments and Agencies re Increasing Access to the Results of Federally Funded Research (Feb. 22, 2013) (requiring agencies to permit public access to fully or partially federally funded research papers ~~twelve months~~beginning one year after publication). As a general matter, the agency should make publicly available any scientific literature it considered, including literature it reviewed but upon which it ultimately did not rely. For purposes of the recommendation, literature that an agency "considered" includes any study an agency official relied upon or reviewed but ultimately determined not to rely upon (because it was deemed to be outside the scope of the scientific study at hand, was not considered sufficiently reliable, or was otherwise rejected by the agency official). If any agency official merely had access to a study but did not specifically analyze it to determine its relevance, the agency has not "considered" it within the meaning of the recommendation for purposes of making such literature publicly available.

[10] In response to President Obama's call for agencies to develop "appropriate rules and procedures to ensure the integrity of the scientific process," Obama Scientific Integrity Memo, *supra* note 3, a number of agencies have promulgated integrity policies to promote open debate amongst agency scientists. *See, e.g.*, 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; NAT'L OCEANIC AND ATMOSPHERIC ADMIN., SCIENTIFIC INTEGRITY (Dec. 7, 2011), *available at* http://www.corporateservices.noaa.gov/ames/administrative_orders/chapter_202/202-735-D.pdf; NUCLEAR

Comment [A2]: Richard/Henry: You had mentioned the need to clarify the precise type of document we're referencing here. Do you have any suggested language for imparting the idea of "documents prepared by agency staff scientists in support of scientific decisionmaking"?

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recommend the removal of any legal impediments to promoting transparency in scientific decisionmaking.[11]

Second, the recommendation offers a series of proposals to bring greater congruity to the treatment of publicly and privately funded scientific research. Specifically, it recommends extending data disclosure requirements applicable to agency-funded research to privately funded research upon which an agency relies (to the extent practicable and permitted by law). Similarly, it recommends extending financial disclosure ~~requirement~~norms to private parties who ~~furnish~~submit studies used by an agency.

RECOMMENDATION

Practices ~~Worth~~Suggested for Agency Consider~~ing~~ation

1. *Explaining Agency Scientific Decisionmaking*: Agencies should explain in ~~the~~proposed and final ~~rule~~decision documents how they ensured rigorous review of the scientific ~~research~~information underlying each science-intensive regulatory project. This includes a statement of how the agencies evaluated the scientific information used in their analysis; how the agencies ma~~k~~de that information available to reviewers and the public; how the analysis ~~i~~was reviewed by experts and interested parties; and how the agencies ensured that the final decision ~~can be compared against~~was supported by the scientific record.

2. ~~*Design*~~*Assuring Transparent ~~Risk~~ Assessments*: At an early stage in their regulatory processes, agencies should articulate the specific policy questions that may be informed by science; describe the study design, in the case of new research, or the criteria to be used in reviewing and weighing existing studies; identify other analytical choices; provide a synthesis of the available evidence and relevant literature guided by the study design or criteria; identify significant assumptions and choices of analytical techniques; provide a statement of remaining uncertainties; and discuss how different plausible choices might change the resulting policy decision. ~~If~~Where possible, agencies should also explain the relationship between their scien~~ce~~tific conclusions and policy choices. [12]

REGULATORY COMM'N, COLLABORATIVE WORK ENVIRONMENT PROGRAM, http://www.nrc.gov/about-nrc/values.html#open (last updated May 4, 2012); *see also* Francesca T. Grifo, Federal Agency Scientific Integrity Policies: A Comparative Analysis (Mar. 2013), http://www.ucsusa.org/assets/documents/scientific_integrity/SI-policies-comparative-analysis.pdf.

[11] *See* ~~Wendy~~ Wagner, ~~Science in Regulation: A Study of Agency Decisionmaking Approaches~~*supra* note 7, at 135–38 ~~(Feb. 18, 2013), *available at* http://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation-Final%20Report-2-18-13-0.pdf~~ (identifying a number of external legal impediments to promoting transparency, including short statutory deadlines, limits on dissemination of scientific studies, resource limitations, and caps on the number of discretionary advisory committees agencies can constitute).

[12] ~~NAT'L RESEARCH COUNCIL, COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 7 (1983).~~

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Comment [A3]: Jeff Lubbers proposes consolidating recommendations 1-9 into a single recommendation with 9 sub-parts.

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3. *Disclosing Underlying Studies and Data*: In light of 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,~~have access to the information necessary to reproduce or verify the agency's analytical results within the time limits provided for public comment. This generally requires that the agency identify and make publicly available the scientific literature, underlying data, and models that it reviewed as well as its research results, including the results it obtained but on which it did not rely. To the extent practicable and permitted by law, the agency should identify and make publicly available (on the agency website or some other widely available forum) ~~a list of~~ the scientific literature it considered (including the literature ~~it rejected~~on which it did not rely when it is material to the scientific analysis, as well as the literature upon which it relied).[~~13~~]

4. *Checkpoints and Explanations*: ~~To the extent permitted by statute, a~~Agencies should consider establishing explicit checkpoints for regulatory projects, defining both the conditions under which they intend to close their consideration of research or debate in order to reach a decision and when they might reopen that consideration ~~for regulatory projects~~, particularly in cases when they are not bound by judicially enforceable deadlines. ~~These checkpoints should address both the conditions under which agencies will close their consideration of research or debate in order to reach a decision and when they might reopen that consideration.~~ In any case, agencies should explain their decisions to initiate, stop, or reopen consideration of research or debate. Such explanations should reference significant relevant ongoing research or other relevant factors.

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Comment [A4]: NOAA recommends strengthening this recommendation by striking the word "consider."

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scientists but also economists, lawyers, and other ~~nonscientists~~contributors. In a similar vein, reviewers and other contributors ~~sh~~could also be identified by name and general contribution.

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8. *Sharing of Agency Best Practices ~~through Central Executive Branch Coordinator~~*: ~~OSTP, an interagency group headed by OSTP, or another body~~Agencies should be responsible for identifying and publicizing the innovations they develop~~ed by agencies~~ for transparently incorporating science into their regulatory decisions. OSTP, an interagency group headed by OSTP, or another body should consider occasionally convening agency representatives to discuss and share best practices.

9. *~~Addressing~~~~Eliminating~~ Legal Barriers to Transparent Decisionmaking*: Agencies should identify legal ~~barrier~~obstacles that may impede otherwise appropriate public access to the scientific information underlying agency analyses or that ~~otherwise block~~may prevent the agencies' development of scientifically robust decision-making processes. Agencies should recommend appropriate actions, including revisions in existing law, to eliminate such impediments, to the Executive Office of the President, which may convene others for discussion as appropriate. ~~OSTP or another centralized entity should serve as a forum for identifying concerns affecting multiple agencies and urging appropriate changes in law.~~

Agency Disclosures to Enhance the Transparency of Research

10. *Data Disclosure*: To the maximum extent practicable and in compliance with appropriate legal restrictions ~~(e.g., protections for personal privacy, trade secrets, and confidential business information (CBI)), agencies should voluntarily comply with the Shelby Amendment[14] and OMB Circular A-110[15] in circumstances to which they do not literally apply. In addition~~, agencies should seek to provide disclosure of data underlying ~~federally-funded or~~

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