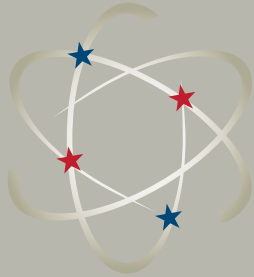




Improving the Use of Science in Regulatory Policy





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Executive Summary

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has been a political flashpoint in recent decades.¹ Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

The question is not whether scientific results should be used in developing regulatory policy, but how they should be used. This report is structured around three sets of questions that are at the heart of the debate over the use of science in regulatory policy. Those questions are:

- What kinds of activities or decision-making amount to “politicizing” science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?
- When and how should Federal agencies empanel advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees’ deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

Implementing our panel’s answers to these questions would result, we believe, in a more candid, transparent, and rigorous use of science in regulatory policy making and a more honest and thoughtful debate about regulatory proposals.²

¹ In this report, “science” refers to the natural and physical sciences and engineering.

² The primary focus of this report is the systemic problems affecting the role of science in regulatory policymaking, such as conflating science questions and policy questions, as they are fundamental, longstanding and often overlooked. Other forms of misuse or abuse of science in government are also unacceptable, as reflected by this panel’s clear admonition in Chapter 1 that “political decision-makers should never dictate what scientific studies should conclude.” However, those issues have been discussed elsewhere, and are not the primary subject of this report. Even if every potential abuse of science were avoided, regulatory policy would still get mired in avoidable debates unless the issues discussed in this report were addressed.



Recommendations

Each chapter of the report makes an overarching recommendation (those numbered below) and then elaborates on how to implement it. Those more detailed recommendations, listed below, are generally in bold in the text of the report.

- **RECOMMENDATION ONE: The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.**

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the “politicization” of science actually arise over differences about policy choices that science can inform, but not determine.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. At a minimum, the Administration should require that a section of the *Federal Register* notice for any proposed guidance or rule that is informed by scientific studies describe the primary scientific questions and the primary policy questions that needed to be answered in drafting the rule.

An additional approach to clarifying this distinction would be to also require the *Federal Register* notice to include answers to such questions as: What additional science would change the debate over a proposed regulatory policy and in what ways would the debate change? Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule.

The first impulse of those concerned with regulatory policy should not be to claim “the science made me do it” or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.

- **RECOMMENDATION TWO: *The Administration should promulgate guidelines (through executive orders or other instruments) directing agencies to follow the policies described below on: when to consult advisory panels on scientific questions, how to appoint them (including how to deal with conflicts of interest and biases), and how they should operate. Congress should pass, and the President should sign into law, any statutory changes needed to implement these policies.***

Federal agencies should use scientific advisory committees to the maximum extent possible to review the science behind regulatory policies.

TYPES OF ADVISORY PANELS

Advisory committees that are to exclusively address science questions (referred to in this report as “scientific advisory committees”) should generally consist only of members with relevant scientific expertise.

All non-government members of scientific advisory committees should be appointed as Special Government Employees.

In general, scientific advisory panels should not be asked to recommend specific regulatory policies.

*The remainder of the recommendations are concerned exclusively with procedures related to **scientific advisory panels**.*

TRANSPARENCY IN THE SELECTION PROCESS

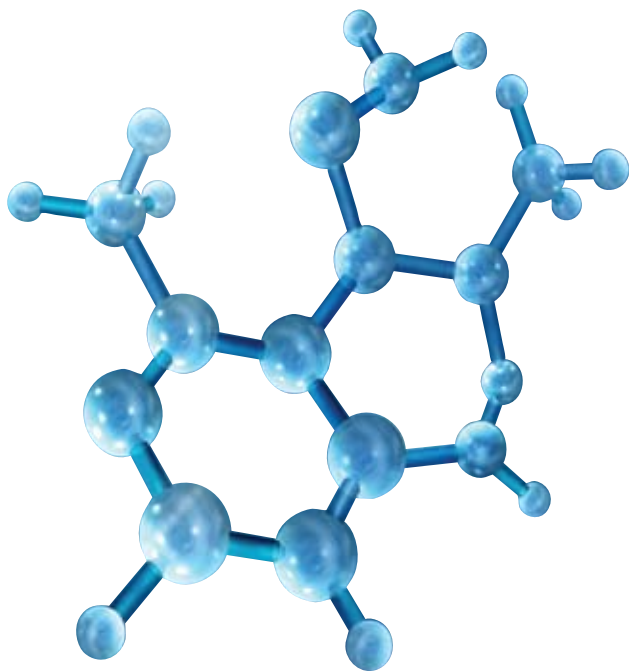
The process of naming advisory committee members should be made more transparent. Options for achieving greater transparency include: seeking recommendations for members on the Web and/or through contacts with relevant groups; publicly announcing on the Web the criteria for membership (such as the range of scientific disciplines that need to be included); and announcing proposed members on the Web to solicit public comment.

FACTORS IN SELECTING ADVISORY COMMITTEE MEMBERS

The primary purpose in appointing a committee is to gather a group of eminently qualified individuals who can have an open, engaged and comprehensive discussion of the issues before them. Appointing a committee capable of comprehensive discussion involves, among other things, achieving balance among the applicable scientific disciplines. Moreover, agencies should avoid turning repeatedly to the same scientists for service on advisory committees. And agencies should periodically turn over the staff that is assigned to select panelists.

DISCLOSURE OF QUALIFICATIONS, FINANCES AND ACTIVITIES

Members of federal scientific advisory committees should be required to disclose to the government information on relevant financial relationships and professional activities (such as giving talks at conferences and testifying in court) going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service.



Federal agency disclosure forms should be as clear and uniform as possible. Developing a single form that draws on the different forms used now by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) would be a good start.

For financial disclosure, the categories of information the National Academy of Sciences views as relevant for its panelists are also appropriate for federal agencies.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case. One possibility would be for federal agencies to make publicly available all the information on a panelist's disclosure form *except* the precise dollar amounts of their stock holdings or compensation and any information on the finances of their spouse or dependent children. At the same time, the agency would disclose the member's educational background and scientific credentials.

DETERMINING CONFLICTS OF INTEREST

For conflict of interest, there must be a clearer federal policy with bright lines that leaves as little doubt as possible as to who would be considered to have a conflict if they served on a particular advisory committee. The definition should be as uniform across agencies as possible and, at the very least, should set a minimum standard for all agencies. The general principles that the National Academy of Sciences uses to define conflict of interest apply equally well to the government. The question to be asked in defining a conflict of interest is whether a particular financial relationship would tend to constrain a generic individual's point of view. Such relationships need to be defined as conflicts regardless of the source of the funding.

When considering whether a conflict of interest exists, federal agencies should look back two years rather than just considering current relationships as is now the case. *Two members of our panel dissented from the recommendation in this paragraph for reasons described on page 22.*

DEALING WITH CONFLICTS OF INTEREST

The desired norm for federal agencies should be to appoint advisory committees whose members are free of conflicts of interest. There will be instances, though, when scientists with conflicts of interest may be needed for a panel because of their expertise.

The standard for allowing someone with a conflict of interest to serve on an advisory committee should be changed to the clearer and arguably more stringent policy of the National Academy of Sciences under which a conflicted expert can serve only in a situation where having a conflicted panel member is "unavoidable." (The current standard is whether the need for the conflicted member's services "outweighs the potential for a conflict of interest posed by the financial interest involved.")

Appointment of an individual with a conflict of interest should require a formal waiver from the appointing official. When a waiver is granted, the agency should publicly state that the appointee has a conflict and should provide enough information that the public and the other committee members understand what kinds of efforts were made to find a non-conflicted individual, how and why the appointed individual was considered to be conflicted, and why the individual was appointed nonetheless, as well as disclosing who signed off on the waiver.

Agencies should not appoint anyone with a conflict to serve as the chair or co-chair of a committee. And agencies should limit the issuance of conflict waivers.

DETERMINING AND DEALING WITH BIAS

The federal government should follow the National Academy's lead and distinguish clearly between conflict of interest and bias.

The goal should generally be to assemble committees of individuals who are as impartial (i.e., fair-minded) as possible and to ensure that the overall committee is balanced. Agencies should not shy away from including scientists on a panel who are considered "outliers" on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream.

MANAGING ADVISORY COMMITTEES

Once the final members of a committee have been named, federal agencies need to defend their choices of appointees and stand by their panel if it comes under attack.

Committee members need to know of each other's financial relationships and viewpoints. Moreover, the appropriate agency official needs to take an active role in supporting the committee's work, which includes managing any conflicts for the duration of the panel.

Federal agencies should not be able to circumvent the processes discussed above by contracting out the appointment or operation of advisory committees.

The Administration and the Congress should carefully think through the benefits and disadvantages of requiring all meetings to be open. It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above).

The recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. In the *Federal Register* notice for any rule for which a scientific advisory committee was convened, the federal agency should be required to state whether it differed with any conclusions of a scientific advisory committee and if so, why, and should be required to explain how the new regulatory policy is consistent with the conclusions that were accepted.

- **RECOMMENDATION THREE: *Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent.***

TRANSPARENCY

The process of conducting literature reviews should become more transparent. Agencies and their scientific advisory committees should be explicit about the criteria they are using to determine which scientific papers to review and how those papers are being evaluated. Once an agency has opened a docket on a rule or guidance that will draw on scientific studies, it should make available on the Web a list of the studies it is reviewing and should regularly update the list.

CRITERIA

In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism. But agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality. Conversely, studies that have not been peer reviewed should not be summarily rejected if they appear to contribute to the inquiry.

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of interest.

Agencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.

In fields where a public registry of studies exists (such as the registry established by the Food and Drug Administration Modernization Act of 1997), agencies and scientific advisory committees should consider the relevant registered studies and should be wary of studies that met the criteria for the registry, but were not registered.

DATA AVAILABILITY

Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular regardless of who funded the study.

Confidential Business Information (CBI) is a legitimate and needed designation for information submitted to the federal government, but it appears to be overused today. The Administration and the Congress should gather data on the extent and nature of CBI claims. The Administration and Congress should consider requiring each new CBI claim to include a brief, but substantive justification for the claim.

ADDITIONAL STUDIES

Agencies should experiment with a variety of additional approaches that would enable them to commission studies and literature reviews related to pending regulatory decisions that would be widely seen as unbiased.

PRESENTING CONCLUSIONS

In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty. Policy makers should be wary of conclusions about risk that are expressed as a single number.



- **RECOMMENDATION FOUR: The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.**

PEER REVIEW

Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review, particularly peer review of draft manuscripts. Universities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career. Scientific journals should improve the quality control of peer review and should experiment with different ways of conducting peer reviews. *The report lists a number of specific approaches that could be tried by the government, universities and journals.*

INFORMATION ON SCIENTIFIC STUDIES

Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies.

Federal agencies should determine whether the idea of research registries, which today is focused on research related to pharmaceuticals, can be expanded to other fields.

CONFLICT OF INTEREST

Journals should have clear, publicly accessible conflict-of-interest policies and should require full disclosure of how studies were funded and of any and all conflicts of interest they determine an author has. Editors should also disclose any of their own conflicts of interest. In addition, journals should consider requiring authors to certify that they had ultimate control over the design and publication of the study being described in a paper.

Federal agencies need to consider promulgating rules that would sanction scientists who run afoul of federal, university or journal requirements concerning disclosure, conflict of interest or ultimate sponsor control.



Introduction

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has been a political flashpoint in recent decades.¹ Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

These problems are largely systemic; they will not magically vanish with a change of Administrations or a shift in the composition of the Congress.² But the advent of a new Administration and a new Congress is an opportune time to take stock of the situation and to try to devise ways to get beyond the predictable battles that would otherwise lie ahead. The use of science in regulatory policy is another area in which government needs to get beyond the stale debates

and false dichotomies of the past. The question is not whether scientific results should be used in developing regulatory policy, but how they should be used.

New governmental processes are needed – approaches that will be seen as legitimate by stakeholders on all sides of issues and that will make policy making more transparent. A critical goal of any new procedures for establishing regulatory policy must be to clarify which

A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.

aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethics). A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.

To come up with new approaches, the Bipartisan Policy Center established the Science for Policy Project. To carry out the project, the Center assembled a diverse panel of experts to develop recommendations for both the Executive Branch and the Congress on how to improve the way science is used in making regulatory policy

¹ In this report, “science” refers to the natural and physical sciences and engineering.

² The primary focus of this report is the systemic problems affecting the role of science in regulatory policymaking, such as conflating science questions and policy questions, as they are fundamental, longstanding and often overlooked. Other forms of misuse or abuse of science in government are also unacceptable, as reflected by this panel’s clear admonition in Chapter 1 that “political decision-makers should never dictate what scientific studies should conclude.” However, those issues have been discussed elsewhere, and are not the primary subject of this report. Even if every potential abuse of science were avoided, regulatory policy would still get mired in avoidable debates unless the issues discussed in this report were addressed.

across the government's areas of responsibility. The panel includes liberals and conservatives, Republicans and Democrats, scientists and policy experts, and leaders with experience in government, industry, academia and non-governmental organizations.

This report is structured around three sets of questions that are at the heart of the debate over the use of science in regulatory policy. (By "regulatory policy," we mean not only specific rules, but all regulatory statements and guidance issued by Administration officials, and statements, hearings and legislation from the Congress.) Those questions are:

- What kinds of activities or decision-making amount to "politicizing" science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?
- When and how should Federal agencies empanel advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees' deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

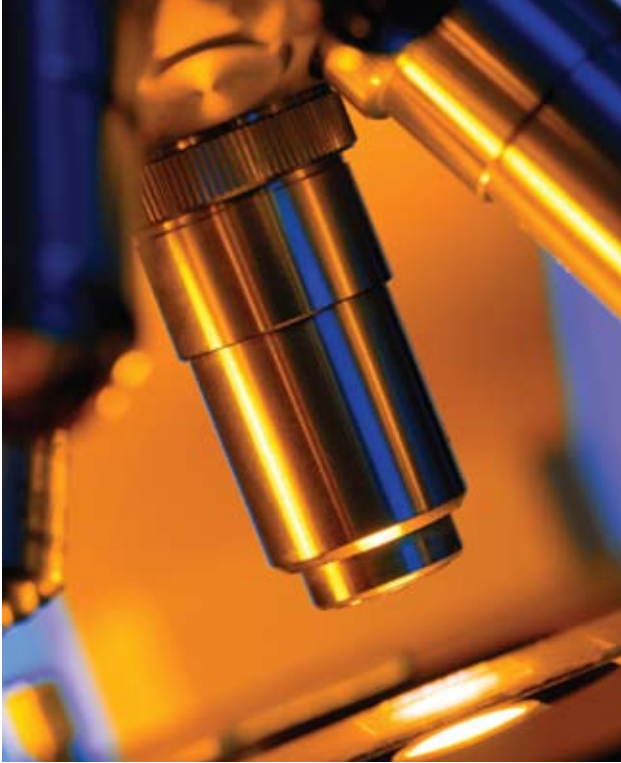
Implementing our panel's answers to these questions would result, we believe, in a more candid, transparent, and rigorous use of science in regulatory policy making and a more honest and thoughtful debate about regulatory proposals.

With those results in mind, our hope is that this report will help shape, among other things, the implementation of the President's scientific integrity memorandum, which raises questions similar to those above.³

Like the Presidential memorandum, this report does not focus on any particular area of regulatory policy. Instead, we recommend principles and procedures that we believe should improve regulatory policymaking and debate across the board. Our recommendations are focused on the procedures used by the regulatory agencies.

But while our only specific recommendation for Congress is to make any statutory changes needed to implement our proposals regarding scientific advisory committees (see Chapter 2), this report has additional implications for the Legislative Branch. Like the Executive Branch, Congress needs to take to heart, and find ways to implement, the principles and processes the report recommends. More specifically, Congress needs to find ways to distinguish the aspects of regulatory policy that involve scientific judgments from those that involve making policy recommendations in its debates, in the questioning of its witnesses, and in its parsing of the arguments brought to it by the Administration and lobbyists on all sides of regulatory issues. In addition, Congress should consider codifying the principles and procedures recommended in this report to make them less likely to change from Administration to Administration. Congress could consider passing general legislation on the issues in this report and/or including provisions in legislation as relevant

³ Memorandum for the Heads of Executive Departments and Agencies, March 9, 2009. <http://edocket.access.gpo.gov/2009/pdf/E9-5443.pdf>. It should be noted that our study was initiated in the spring of 2008 – in the midst of the Presidential primary season – so it was not created to inform the Memorandum.



programs are reauthorized. In doing so, however, Congress should avoid becoming overly prescriptive.

Again, our firmest and most fervent hope is that this report will help point the Administration, the Congress, the media, interest groups and the courts to think more carefully and to speak more precisely about what is truly at issue when regulatory proposals are being debated.

This report proposes specific procedures that we believe can inaugurate a new era – an era in which the science behind regulatory proposals will emerge

from a more transparent and credible process that fully acknowledges the complexities of reaching scientific conclusions; and in which the disagreements over political ideology, economics and values that are at the heart of many regulatory disputes will be debated openly and fully, not transmogrified into a political battle waged through science.

This new era will not come into being, and certainly will not be sustained, merely by public officials claiming to mean well or trying to do their best. Change requires institutionalizing specific procedures that will inculcate and direct this new way of thinking. This report recommends just such procedures.

If our recommendations are implemented and succeed as we hope, science will be better protected and political values will be more fully debated, enhancing the process of regulatory policy making, and ultimately, democracy itself. The result should be better regulatory policy that protects the public both from needless regulations and from needless dangers.



1

Chapter One

RECOMMENDATION ONE: The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the “politicization” of science actually arise over differences about policy choices that science can inform, but not determine.

For example, decisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science.

It would also help policy makers determine which experts to turn to for advice on regulatory questions, and what kinds of questions they should be expected to answer.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. That distinction also needs to be spelled out in regulatory documents. At a minimum, **the Administration should require that a section of the *Federal Register* notice for any proposed guidance or rule that is informed by scientific studies describe the primary scientific questions and the primary policy questions that needed to be answered in drafting the rule.** For example, for a clean air rule, the scientific questions might include how many excess deaths or hospital admissions would be expected to result from different atmospheric concentrations of the pollutant. The policy questions would include how to decide what level of concentration to allow, given the scientific information. The *Federal Register* notice would go on to describe

the answers to the listed questions and their rationale. (Chapters 2 and 3 discuss how federal agencies should obtain and characterize answers to scientific questions.)

One approach that could help clarify the often problematic distinction would be to also **require the *Federal Register* notice to include answers to such questions as: What additional science would change**

Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long.

the debate over a proposed regulatory policy and in what ways would the debate change? This both would help pinpoint the nature and extent of scientific uncertainty and would highlight which aspects of a regulatory issue are not primarily about science.

Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule. Although this approach is embodied in some federal decision processes (e.g., those under the National Environmental Policy Act), the approach is not uniformly applied, and the alternatives proposed can be less than genuine. The idea would be to make clear the range of policy options that were available, given the science and the requirements of law. For example, agencies could be required to describe alternatives of different levels of stringency (or cost, when allowed by statute) that would be in keeping with the science and would comply with statutory mandates.

Many additional options for implementing Recommendation One might be developed, but the goal should be to change the conversation about regulation and to inculcate new habits of thought. **The first impulse of those concerned with regulatory policy should not be to claim “the science made me do it” or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.**

No system for clarifying the roles of science and policy questions in regulatory decision making will be air tight or completely immune from abuse. But that is not a reason to adhere to the status quo. Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long. In short, there must be clarity and transparency about the roles of policy and science in regulatory decisions for science to be appropriately integrated in regulatory policy.

Chapter Two

RECOMMENDATION TWO: The Administration should promulgate guidelines (through executive orders or other instruments) directing agencies to follow the policies described below on: when to consult advisory panels on scientific questions, how to appoint them (including how to deal with conflicts of interest and biases), and how they should operate. Congress should pass, and the President should sign into law, any statutory changes needed to implement these policies.

Federal agencies should use scientific advisory committees to the maximum extent possible to review the science behind regulatory policies. (At the same time, agencies should be working to strengthen the internal capabilities of their staffs, including their scientists.¹) Public officials should not delegate their ultimate responsibility to set policy to advisory committees. But scientific advisory committees can help ensure that policies are based on a range of scientific knowledge and perspectives, and they can make the regulatory process more transparent. As a result, the proper use of advisory committees can make it easier to adopt and more difficult to overturn good regulations.

Types of advisory panels

The first question for an agency establishing an advisory committee should be whether the committee's charge will be to handle science questions or policy questions (or perhaps both). Agencies should ensure that science and policy questions are distinguished as clearly as

possible in charges to advisory panels. **Advisory committees that are to exclusively address science questions (referred to in this report as "scientific advisory committees") should generally consist only of members with relevant scientific expertise.** Advisory committees that are to address policy questions that are informed by science should include members with relevant scientific expertise along with policy specialists and stakeholders.

All non-government members of scientific advisory committees should be appointed as Special Government Employees to ensure they comply with the appropriate ethics guidelines and requirements.

In general, scientific advisory panels should not be asked to recommend specific regulatory policies.²

¹ Agencies may want to empanel advisory committees to provide recommendations on how to strengthen their internal expertise, but this report deals only with advisory committees charged with answering questions pertaining to regulatory policy.

² Our panel is not arguing that scientists should never be consulted on policy questions. As noted above, scientists should be included on policy panels when regulations that are informed by science are being considered. And agencies should always feel free to create avenues for individual scientists to give their views on regulatory policy. When scientists use such avenues, they should make clear they are talking about matters of policy, not science. But for the reasons described in Chapter 1, scientific advisory committees should not recommend specific regulatory policies. For example, a scientific advisory committee might draw conclusions about the cancer risks posed by a particular substance, but should not recommend what an agency should do in response.

Rather, they should be empaneled to reach conclusions about the science that would help guide a regulatory policy decision. They might also be charged with evaluating a regulatory option or options developed by federal officials in light of current scientific understanding. For example, a scientific advisory committee might be asked to determine if a proposed standard was consistent with achieving a level of risk prescribed by federal officials.³

*PLEASE NOTE: the remainder of this chapter is concerned exclusively with procedures related to **scientific advisory panels**.*

Transparency in the selection process

The process of naming advisory committees should be made more transparent. Options for achieving greater transparency include: seeking recommendations for members on the Web and/or through contacts with relevant groups;⁴ publicly announcing on the Web the criteria for membership (such as the range of scientific disciplines that need to be included); and announcing proposed members on the Web (along with their disclosure forms, to the extent discussed below) to solicit public comment. Agencies would then respond to the comments

³ There are some cases in which a scientific determination automatically triggers a policy outcome under a statute. Examples include whether a plant or animal is an endangered species under the Endangered Species Act and whether a substance endangers public health under the Clean Air Act. In such instances, agencies need to take special care to distinguish science and policy questions. On a panel concerning an endangered species designation, for example, arguments over whether to designate a species (i.e., applying the Act) should be distinguished from arguments about whether the Act is needed or whether the current state of the law imposes the correct standards for designation. And in both the Endangered Species and Clean Air Act examples, the determination that a species or substance requires regulation still leaves open questions about how the species or substance should be regulated. Questions about *how* to regulate have scientific and policy aspects that often can be distinguished, and a separate scientific advisory committee could be empaneled to address the science questions involved.

⁴ Agencies need to ensure that they seek advice from a balanced selection of groups, not favoring groups on a particular side of an issue or with a specific area of expertise. Groups might include scientific societies or relevant departments in universities.

when the final panel was announced. While some agencies use some of these techniques some of the time today, greater transparency needs to become the norm, and the processes for assembling advisory committees need to become more standardized. Merely announcing committees in the *Federal Register* is not sufficient.

In addition, each time an advisory committee is appointed, an agency should publicly release the names of the key officials responsible for appointing the advisory committee and briefly describe the roles they played in the process.

Factors in selecting advisory committee members

The primary purpose in appointing a committee is to gather a group of eminently qualified individuals who can have an open, engaged and comprehensive discussion of the issues before them. As the National Academy of Sciences puts it in describing its own policy for selecting panels, “All [committee members] must be highly qualified in terms of knowledge, training and experience...to properly address the tasks assigned to the committee.”⁵

Appointing a committee capable of comprehensive discussion involves, among other things, achieving balance among the applicable scientific disciplines. This is more essential than is commonly understood. Such balance not only ensures that the full range of science will inform a decision, but also guards against advice being unconsciously biased by the

⁵ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 2. Available at: http://www.nationalacademies.org/coi/bi-coi_form-0.pdf. In this report, the term “National Academy of Sciences” is used to refer to the entire Academy complex: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine and their operating arm, the National Research Council.



perspectives, values, norms or techniques that may be inherent in particular fields.

Agencies should also strive to include on committees scientists at different points in their careers. Young, mid-career and senior scientists may have different perspectives and strengths to bring to a committee.

It is also critical to identify a chair who is widely respected, has a reputation for considering all perspectives, and can manage a committee so as to encourage debate and discussion yet produce results on schedule.

Moreover, agencies should avoid turning repeatedly to the same scientists for service on advisory committees. Instead, they should seek to continually expand the circle of relevant experts to whom they turn for advice. One way to do this is to think more broadly about what expertise is applicable to the question before the advisory committee. Someone whose work is focused on questions at the periphery of a field or subfield, for example, may have sufficient expertise to understand a question and could bring a fresh perspective to it.

Agencies should be alert to their own biases in selecting advisory committee members. For example, staff who work on an issue to be reviewed by an advisory committee should not select the members of that committee, although they should be permitted to recommend panelists' names to the official making the committee appointments. **And agencies should**

periodically turn over the staff that is assigned to select panelists.

Finally, agencies need to consider what conflicts of interest or biases potential committee members may bring to the table. To determine whether conflicts or biases (as defined below) exist and have been properly handled, both agencies and the public need to have more information than is currently available concerning the members of scientific advisory committees.

Disclosure of qualifications, finances and activities

Members of federal scientific advisory committees should be required to disclose to the government information on relevant financial relationships and professional activities (such as giving talks at conferences and testifying in court) going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service. Any reporting period is inherently arbitrary, but the current disclosure periods need to be extended to get a fuller picture of a member's experience and possible conflicts and biases.

Federal agency disclosure forms should be as clear and uniform as possible; panelists should have no doubts about what the government needs to know. Developing a single form that draws on the different forms used now by the Environmental Protection Agency (EPA)⁶ and the Food and Drug Administration (FDA)⁷ would be a good start. For example, the FDA form asks about speaking and writing, while the EPA form does not. The EPA form includes general questions on bias that are not on the FDA form. The

⁶ EPA Form 3110-48: Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees.

⁷ FDA Form 3410: Confidential Financial Disclosure Report for Special Government Employees.

EPA form asks solely about compensated testimony, but uncompensated testimony is also relevant in assessing bias; the FDA form is unclear about whether uncompensated testimony should be listed.⁸

For financial disclosure, the categories of information the National Academy of Sciences views as relevant for its panelists are also appropriate for federal agencies: “employment relationships

(including private and public sector employment and self-employment); consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships and serving as an expert witness in litigation); stocks, bonds and other financial instruments and investments including partnerships; real estate investments; patents, copyrights and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.”⁹ Also, like the Academy, financial disclosure should cover not only the individual committee member, but “the individual’s spouse and minor children, the individual’s employer, the individual’s business partners, and others with whom the individual has substantial common financial interests... and the interests of those for whom one is acting in a fiduciary or similar capacity.”¹⁰ As noted above, the government should require this information for the previous five

⁸ While agency disclosure requirements should be as uniform as possible, some agencies may need to add specific questions that reflect conflict concerns particular to a specific inquiry. One goal of uniformity is to make it easier for scientists to comply with disclosure requirements by enabling them to provide the same standard information for all advisory committee service. But there is no point in making the standard form longer or more complicated than need be to accommodate questions that would only be relevant to a few committees.

⁹ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 5.

¹⁰ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 4.

years. The Academy seeks only current information about finances.¹¹

Not only the government, but also the public needs more information to determine whether a conflict or bias exists and has been appropriately handled.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case.

To build public trust through transparency, much more information on federal advisory committee members needs to be available than is now the case.

Obviously, a balance must be struck between the value of public information and privacy concerns. And public disclosure must not be so extensive that it greatly reduces the number of scientists willing to serve on committees. Federal agencies should monitor whether new requirements are making it harder to attract committee members. But disclosure is becoming more routine – in scientific journals and at universities, for example – and the government should not be a last bastion of secrecy.

One possibility would be for federal agencies to make publicly available all the information on a panelist’s disclosure form *except* the precise dollar amounts of their stock holdings or compensation and any information on the finances of their spouse or dependent children. At the same time, the

¹¹ Committee members should also be expected to disclose any conflict that might not be covered by these standard categories. For example, they should disclose if they have an adult child in a position that they know could be materially affected by the conclusions of the committee.

agency would disclose the member's educational background and scientific credentials. Ideally, all of this information would be released when committee members' names were put up on the Web for public comment (per our recommendation above).

An eventual goal would be to make it standard practice for scientists to have a public curriculum vitae (CV) that included all their relevant employment, research support, publications, speaking, testimony, etc. Such a CV would provide much of the information sought on government disclosure forms. Many scientists already post their CV on their websites, and standardizing and expanding this practice would be part of creating a culture of disclosure that would be responsive to, and relevant for more than requirements for service on government committees.

Regardless of whether they have such a CV, scientists should be far more attentive to the need to disclose financial relationships and professional activities, including the need to disclose any that develop during service on an advisory committee. But federal agencies must also do their own research on potential committee members; they should not rely exclusively on self-disclosure.

Determining conflicts of interest

While it is the duty of a scientist to fully disclose the information needed to determine whether a conflict of interest or bias would impinge on service on an advisory committee, it is the government that must define conflict and bias and decide how they will be handled. (Bias is dealt with later in this chapter.) **For conflict of interest, there must be a clearer policy with bright lines that leaves as little doubt as possible as to who would be considered to have a conflict if they served on a particular advisory committee.** The definition should be as uniform across

agencies as possible and, at the very least, should set a minimum standard for all agencies. Differences among agencies lead, among other things, to public confusion, and can leave advisory committee members open to the charge that a different agency would have considered them to have had a conflict of interest. Differences among agencies may be acceptable if the agencies draw on different scientific fields with different norms for conflict, but in such cases agencies should be required to explain publicly any departures from the standard government definition. (As discussed below, defining a conflict is a separate matter from – if related to – deciding what to do when someone is determined to have a conflict.)

The general principles that the National Academy of Sciences uses to define conflict of interest apply equally well to the government: “The term ‘conflict of interest’ means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual’s objectivity or (2) could create an unfair competitive advantage for any person or organization....[Conflict] means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the committee. Conflict of interest requirements are objective and prophylactic. They are not an assessment of one’s actual behavior or character....[For regulatory issues], *the focus of the regulatory inquiry is on the identification...of any interests that may be directly affected by the use of such reports in the regulatory process.*”¹² (Italics in the original.)

Our panel did not reach agreement on a complete set of circumstances that should be considered to constitute a

¹² The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Pages 4, 9.

conflict of interest. This again underscores the need for clear definitions and illustrative cases in federal policy as the definition is not obvious. (See the Appendices of this chapter for a list of the circumstances our panel considered, and for a comparison of conflict policies used by a variety of institutions.)

Our panel did agree that certain relationships should be considered a conflict. For example, an employee of a company that has a product under review, or a scientist funded by that company to research or defend that particular product should be considered to have a conflict of interest vis-à-vis an advisory committee reviewing the environmental or health impacts of that product. The same would be true of someone with the same links to a competing product.

The panel also agreed that the question to be asked in defining a conflict of interest is whether a particular financial relationship would tend to constrain a generic individual's point of view. Such relationships need to be defined as conflicts regardless of the source of the funding. Definitions of conflict should not single out scientists based on their affiliation or funding source (i.e. industry, academia, government, non-governmental organization); rather, conflict policies should treat all paid work in an even-handed manner, that is, according to the same principles. An example would be a conflict policy that was defining situations in which a scientist could fear losing a job or funding if he or she reached a particular conclusion. In that case, the task in setting policy would be to examine whether each type of employment or funding could be construed to pose such a threat. In short, it is the relationship between the funding source and the scientist, not the funding source itself, that is critical.

Whatever the definition of conflict, **when considering whether a conflict of interest exists, federal agencies should look back two years rather than just considering current relationships as is now the case.**

Any time period is going to be arbitrary, but financial relationships in the immediate past can be a relevant consideration. *Two members of our panel dissent from this recommendation for reasons explained below.*¹³

Agencies should ensure that the theory they use to classify particular relationships as conflicts of interest (e.g., because such relationships could lead a panel member to fear losing future funding) is consistent with the notion of considering past, and not just current relationships.

Dealing with conflicts of interest

The desired norm for federal agencies should be to appoint advisory committees whose members are free of conflicts of interest. (Relevant experts who have conflicts could still make presentations to a panel.) There will be instances, though, when scientists with conflicts of interest may be needed for a panel because of their expertise. This may be especially true in novel

¹³ The text of the dissent is: Two members dissent from the two-year look-back period because they believe the Committee is confusing the two key concepts, conflict and bias. When a scientist is engaged in a current activity that creates a conflict (e.g., acting as a paid expert witness in an ongoing trial concerning issues closely related to the panel's work), the presumption is that the scientist may be compromised in reaching a determination during the panel's work that is inconsistent with his or her paid testimony. That is a conflict. However, if that testimony occurred 18 months prior to the panel's work and the relevant legal proceedings are finished, there is no conflict. By definition, a conflict cannot be historical. It is possible, however, that a scientist with a history of expert testimony on a key issue may be judged to have a bias (e.g., if he is perceived as inflexible in his views, even in the face of new evidence) and that is why it is essential to understand a scientist's history as an expert witness and his or her openness to new evidence and insights. In the presence of such a bias, the scientist might be excluded from the panel or might be counter-balanced with one or more other experts who possess differing views or biases. The best solution to the bias depends on the pool of available experts. The same distinction – between conflict and bias – is important when assessing whether commercial relationships create a conflict. If a scientist has a direct commercial interest (e.g., through stock holdings or an employment relationship) in the outcome of a panel's deliberations (e.g., the scientist owns an airbag supplier or is Chief Executive Officer of an airbag supplier when the panel's work concerns the future of airbags), there is a conflict. A commercial interest that existed 18 months ago, and no longer exists, cannot – by definition – be a conflict. A bias, however, may or may not exist. Given this line of reasoning, it should be apparent why the National Academy of Sciences and the federal government do not currently use a two-year look-back period when assessing whether science advisors have conflicts.



areas of technology in which most funding may come from those interested in producing new products.

Currently, experts with conflicts of interest can be appointed as Special Government Employees to serve on an advisory committee if the need for their services “outweighs the potential for a conflict of interest posed by the financial interest involved.”¹⁴ **The standard should be changed to the clearer and arguably more stringent policy of the National Academy of Sciences under which a conflicted expert can serve only in a situation where having a conflicted panel member is “unavoidable.”** The Academy considers a conflict to be unavoidable “if, for example, the individual’s qualifications, knowledge and experience are particularly valuable to the work of the committee and if the [Academy] is unable to identify another individual with comparable qualifications, knowledge and experience who does not also have a conflict of interest.”¹⁵ The Academy’s description of how to determine when a waiver is permissible, or one similar to it, could be adopted by the federal government even if the current statutory language remained unchanged.

Appointment of an individual with a conflict of interest should require a formal waiver from the appointing

official. **When a waiver is granted, the agency should publicly state that the appointee has a conflict and should provide enough information that the public and the other committee members understand what kinds of efforts were made to find a non-conflicted individual,¹⁶ how and why the appointed individual was considered to be conflicted, and why the individual was appointed nonetheless, as well as disclosing who signed off on the waiver.** (If the disclosure procedures proposed in this chapter were in place, the agency would still need to specify which aspect of the individual’s background was considered a conflict.) If proposed advisory committee membership were placed on the Web for public comment, as recommended earlier, that would be the point at which a waiver would be announced.

Agencies should not appoint anyone with a conflict to serve as the chair or co-chair of a committee. And agencies should limit the issuing of conflict waivers to ensure that individuals with conflicts do not generally constitute more than a small percentage of the membership of a committee.

Determining and dealing with bias

The federal government should follow the National Academy’s lead and distinguish clearly between conflict of interest and bias. The Academy’s view of bias should guide federal policymakers: “Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular

¹⁴ 18 U.S.C. § 208(b)(3)

¹⁵ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 8.

¹⁶ This does not require releasing the names of individuals who were considered for appointment or who were asked and declined, nor does it require releasing the name of every group that was consulted. But it does require describing the kinds of steps that were taken to seek non-conflicted individuals. Following the recommendations in this chapter for soliciting public comment on potential committee members should help agencies gather names of qualified, non-conflicted individuals.

group. Potential sources of bias are not necessarily disqualifying for purposes of committee service.¹⁷

Bias is an inherently murky concept, and every individual has biases. But **the goal should generally be to assemble committees of individuals who are as impartial (i.e., fair-minded) as possible.** This is not the same as saying that a committee should (or could) be made up of individuals with no views on the matter at hand; the goal is to pull together a committee that can act in good faith.

Agencies should not shy away from including scientists on a panel who are considered “outliers” on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream.

The approach to bias will depend on the precise question(s) being posed to the committee. Generally, strong biases in committee members should be avoided. But in some cases, an agency may want to appoint some members with strong and even fixed views on an issue because they need such individuals’ expertise or because they want to ensure that those scientific views are fully represented on the committee. In such instances, **the goal should be to ensure that the overall committee is balanced.**

¹⁷ The National Academies Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. May 12, 2003. Page 3.

Agencies should not shy away from including scientists on a panel who are considered “outliers” on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream. Minority reports should be allowed on advisory committees, although consensus should be the goal.¹⁸ Outliers who are willing to engage the issues can play a useful function by sharpening discussion within a committee, even if they decide not to sign on to the committee’s final report.

Unlike conflict of interest, there is no way to come up with a litmus test for bias or to establish clearly delineated categories. Rather, in handling bias, federal agencies need to carefully consider the full picture of an individual’s activities that emerges from his or her disclosure forms as well as getting a sense of the individual’s personality and reputation in the field. For example, for academic scientists, receiving funding from a variety of sources can be a sign of fair-mindedness. Similarly, responding to critics, publishing in a variety of journals, and speaking at a variety of invited conferences can be indicators of openness. On the other hand, testifying repeatedly on one side of an issue before Congress or in the courts can be taken as indications of a point of view that may need to be balanced in putting together a panel.

Managing advisory committees

Once the final members of a committee have been named, **federal agencies need to defend their**

¹⁸ “Consensus” itself can be a tricky word. A useful definition appears in [Building United Judgment: A Handbook for Consensus Decision Making](#): “The goal of consensus is a decision that is consented to by all group members. Of course, full consent does not mean that everyone must be completely satisfied with the final outcome – in fact, total satisfaction is rare. The decision must be acceptable enough, however, that all will agree to support the group in choosing it.” (M. Avery, B.J. Streibel, B. Avuine. Madison, WI: Center for Conflict Resolution, 1981.)



choices of appointees and stand by their panel if it comes under attack. (This assumes, of course, that no new information comes to light that should have been disclosed by a scientist or uncovered by an agency. Seeking public comment on committee members, as recommended earlier, should help prevent such situations.)

Committee members need to know of each other's financial relationships and viewpoints. At their first meeting, and periodically thereafter, National Academy panel members are expected to discuss their relationships and previously stated views with fellow panel members in a closed session. Federal agencies may want to adopt this practice (although under current law it would have to be in open session), or may want to experiment with other means of ensuring that a panel has a collective understanding of its membership's commitments and interests. At a minimum, advisory committee members should be given copies of all the members' public disclosure forms prior to the first meeting.

Moreover, the appropriate agency official needs to take an active role in supporting the committee's work, which includes managing any conflicts for the duration of the panel. An official may need to remind panel members of member interests. Also, an official may need to seek recusal of a member or otherwise manage conflicts, if they develop.¹⁹ New conflicts that

¹⁹ New conflicts can develop because the committee discussion takes an unanticipated turn, but they are far more likely to arise because of new activities undertaken by committee members.

develop or relevant new activities that are undertaken during service on a committee must be disclosed and handled in the same manner they would have been in advance of service on a panel.

Federal agencies should not be able to circumvent the processes discussed above by contracting out the appointment or operation of advisory committees. The Administration should limit the extent to which federal agencies can use outside contractors to establish advisory committees, and federal agencies should be alert to any conflicts of interest those firms may pose. Moreover, committees chosen by contractors should be subject to the same rules and procedures as a similar committee established directly by an agency, particularly on the matters of conflict, bias and disclosure discussed above.

It is also vital for the federal government to establish and maintain an internal tracking system on the process of recruiting scientific advisors, the numbers and types of conflicts and biases encountered and the degree to which increased disclosure inhibits the recruitment of a full range of qualified experts. In addition, the public database on advisory committees needs significant improvement. It should provide easy access to the names and backgrounds of all individuals serving on advisory committees and information on the conflict of interest waivers that have been granted.

The Administration and the Congress should carefully think through the benefits and disadvantages of requiring all meetings to be open. **It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above).** Transparency is an essential principle of democratic governance, but some deliberations can benefit from a modicum of private discussion to enable committee members to think and

speaking more freely and open-mindedly. Allowing the closure of meetings would require changes in statute, and any such changes should limit the use of closed meetings and be very specific about when closure is permissible.

The recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. In the *Federal Register* notice for any rule for which a scientific advisory committee was convened, the federal agency should be required to state whether it differed with any conclusions of a scientific

advisory committee and if so, why, and should be required to explain how the new regulatory policy is consistent with the conclusions that were accepted.

Finally, federal officials must give advisory committees clear, definite and realistic deadlines for reporting and clear information on when a committee report will be released and how it will be used.

One way the Administration might approach some of the issues raised here would be to review the guidance that the Office of Management and Budget and the Office of Science and Technology Policy issued in 2005 to see how it might be improved.²⁰

²⁰ Office of Management and Budget. January 14, 2005. Final Information Quality Bulletin for Peer Review. *Federal Register*, 70: 2664–2677.

APPENDIX 1

Hypotheticals for consideration in setting rules for conflict of interest

As noted in the text, our panel did not reach agreement on a complete set of circumstances that should be considered to constitute a conflict of interest. But we did have a detailed discussion about the circumstances that might constitute a conflict. To structure that discussion, we debated the hypothetical cases described below. (Some of the hypotheticals are based on actual cases.)

Our panel did not agree on whether to define these cases as examples of conflict of interest or bias, or on whether to exclude the individual described in the case. Notably, though, these were two separate questions. For example, there were a number of members of our group who would describe these cases as “bias” but would nonetheless generally exclude the person with the bias (rather than just balancing their presence). The cases are described below because they should be thought through by any official deciding how to define and handle conflict and bias.

- An individual is a board member, employee or significant stock holder of the company whose product is being reviewed by an advisory committee – or has a similar interest in a competing company. How should company be defined for these cases? Would the limitation be the same if the byproduct of a company’s production was being reviewed, esp. if that byproduct was produced by many companies or even industries?
- An individual has received funding from the company to study the particular product under review.
- An individual has received funding to study the particular product under review from a philanthropic entity set up by the company (and that maintains close ties with the company).
- An individual has received research funding from a company that has a direct interest in the results of an advisory committee, but on a different subject – maybe even from a different division of the company. Should that person be excluded? Should it depend on whether the individual has also received funding from the government or others? Should it depend on whether the individual’s work has generally or always supported the company’s point of view?
- An individual is a board member, employee or stockholder of a company that would be part of a general class of companies affected by a regulation – say, a clean air rule. Should the disqualification still be automatic? Should it matter what division of a company the person is associated with (if an employee)?
- An individual is an employee of a non-governmental organization (NGO) that has taken a position on the issue before the committee.
- An individual is president of a professional society that espouses a position on the issue that is under review.
- An individual is an unpaid board member of an NGO that has taken a position on the issue before the committee. What if the individual is a board member of an environmental group on an issue on which other environmental groups have weighed in?
- An individual is an employee of an NGO and that individual has publicly testified on the matter under review by the committee. Would it make a difference if that testimony occurred during service on the committee?

-
- An individual runs a university center that has received funding from a company with a direct interest in the matter under review. Would the same decision apply to someone who was a dean of a college or president of a university that received that funding? Would the same decision apply to a gift from an individual with a clearly held view – either on the specific issue or ideologically? [Do such items even require disclosure?]
 - An individual is affiliated with (but does not head) a university center that has received funding from a company with a direct interest in the matter under review. What if the person were a professor in a college or university that received such funding?
 - An individual received funding from a federal agency that has an interest in the outcome of a review (as a regulated entity).
 - An individual has consulted for a company that has a direct interest in the matter under review. How close does the consultation have to be related to the matter at hand? Does it matter if the consultation was arranged through a contractor that was helping to defend a company's product?
 - An individual has a consulting contract with a firm whose other clients include a company with a matter under review by an advisory committee.
 - An individual was paid for lectures by a company with a product under review. Does it matter how directly the lectures promoted the product?
 - An individual is a member of a political or policy advocacy group that has taken a strong stand on the issue in question.

Comparison of conflict of interest policies – selected institutions¹

	National Academies Panels (2003)	International Agency for Research on Cancer Monographs (2003)	Food and Drug Administration FACA Committees (2008)	Environmental Protection Agency FACA Committees (no single date)	National Institutes of Health Office of Extramural Research (2005)
Definition of conflict of interest	"Any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."	"Conflict of interest means that the expert... has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered."	Conflict is not explicitly defined; it is determined through use of an "algorithm", which works through determining whether there is a conflict, whether the conflict is disqualifying, and whether to provide a waiver. "The term 'financial interest' means the potential for gain or loss to the employee (or persons/ organizations whose interests are imputed to him) as a result of governmental action on the particular matter." Certain financial interests are generally considered too "remote" to be disqualifying, such as ownership of mutual funds.	"18 U.S.C. §208 prohibits all employees (including Special Government Employees; SGEs) from participating in any particular Government matter that will have a direct and predictable effect on their financial interests." This section of U.S. Code talks about acts affecting a personal financial interest. The definition reiterates what is in the Code section.	For PIs and institutions: "A Financial Conflict of Interest exists when the Institutional designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research." (See definition of "Significant Financial Interest" below under Types of financial conflicts.) For peer reviewers: "A Conflict Of Interest exists when a reviewer has an interest that is likely to bias his or her evaluation." "Real Conflict Of Interest means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal."
Apparent conflict of interest	"Conflict of interest requirements are objective and prophylactic. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest." <i>continued</i>	"An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported."	"In some cases, an employee will have a financial interest or relationship that, while not a disqualifying financial interest, may cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter. See 5 CFR 263.5.502. Such matters should be evaluated under this regulatory standard and, if appropriate, an impartiality determination should be requested."	"5 C.F.R. Part 2635, Subpart E contains provisions intended to ensure that an employee takes appropriate steps to avoid an appearance of a loss of impartiality in the performance of his/her official duties. Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his/her household, or knows that a person with whom he/she has a covered relationship is or represents a party to such a matter, and where the person determines that the circumstances would cause a reasonable person with <i>continued</i>	No additional language.

¹ This table was created by the project staff in January, 2009 to assist the panel in its discussions of disclosure, conflict of interest, and bias.

	National Academies Panels (2003)	International Agency for Research on Cancer Monographs (2003)	Food and Drug Administration FACA Committees (2008)	Environmental Protection Agency FACA Committees (no single date)	National Institutes of Health Office of Extramural Research (2005)
<p>Apparent conflict of interest (continued)</p>	<p>The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of such conflicting interests.”</p>	<p>No specific language, but see wording under Relevant non-financial interests and Disqualifying activities later on in this chart.</p>	<p>No specific language, but see wording under Relevant non-financial interests and Disqualifying activities later on in this chart.</p>	<p>knowledge of the relevant facts to question his/her impartiality in the matter, the employee should not participate in the matter unless he/she has informed the agency designee of the appearance of a problem and received authorization from the agency designee.”</p>	<p>No specific language, but see wording under Relevant non-financial interests and Disqualifying activities later on in this chart.</p>
<p>Distinction between conflict and bias?</p>	<p>“Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group. Potential sources of bias are not necessarily disqualifying for purposes of committee service. The term ‘conflict of interest’ means something more than individual bias. There must be an interest, ordinarily financial, that could be directly affected by the work of the committee.”</p>	<p>“Different types of financial or other interests, whether personal or with the administrative unit with which the expert envisaged and the following list, which is not exhaustive . . . For example, the following types of situations should be declared:</p> <ol style="list-style-type: none"> 1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in – or otherwise related to the subject-matter of – the meeting or work; 2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares); 3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in <p>continued</p>	<p>“Some examples of an employee’s personal financial interests would be stocks or investments that he owns, his primary employment relationship, his consulting work, patents/royalties/ trademarks owned by him, his work as an expert witness, and his teaching/speaking/ writing work.”</p>	<p>Employment or consulting, whether or not for compensation, for the last 2 years preceding the date of filing. Includes: employee, officer, director, trustee, general partner, proprietor, representative/ executor of any business, consulting firm, non-profit, labor organization, or educational institution. Any organization or person with whom you are negotiating or have an arrangement concerning prospective employment. Any positions held with professional societies. Any compensated expert testimony for the last 2 years preceding the date of filing. Any source of research or project funding (e.g., grants, contracts, or other mechanism) in the last 2 years preceding the date of filing from any source. continued</p>	<p>“Significant Financial Interest is defined by the regulation as anything of monetary value, including but not limited to:</p> <ul style="list-style-type: none"> • salary or other payments for services (e.g., consulting fees or honoraria); • equity interests (e.g., stocks, stock options, or other ownership interests); • intellectual property rights (e.g., patents, copyrights, and royalties from such rights). <p>Significant Financial Interest does not include:</p> <ul style="list-style-type: none"> • salary, royalties, or other remuneration from the Institution; • any ownership interests in the Institution, if the Institution is an applicant under the SBIR or STTR programs; • income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; <p>continued</p>
<p>Types of financial conflicts</p>	<p>Employment relationships; consulting relationships; stocks, bonds, and other financial instruments and investments including partnerships; real estate investments; patents, copyrights, and other intellectual property interests; commercial business ownership and investment interests; services provided in exchange for honorariums and travel expense reimbursements; research funding and other forms of research support.</p>	<p>continued</p>	<p>continued</p>	<p>continued</p>	<p>continued</p>

	National Academies Panels (2003)	International Agency for Research on Cancer Monographs (2003)	Food and Drug Administration FACA Committees (2008)	Environmental Protection Agency FACA Committees (no single date)	National Institutes of Health Office of Extramural Research (2005)
Types of financial conflicts (continued)		the subject-matter of the meeting/work or an ongoing negotiation concerning prospective employment or other association with such commercial entity; 4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject-matter of the meetings or work; 5. payment or other support covering a period within the past 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy. With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.		Any assets currently held for investment. Stocks, bonds, annuities, trust holdings, partnership interests, life insurance, investment real estate or a privately-held trade or business. Sector mutual funds, which are funds invested in a particular industry, business, or location. Individual holdings of retirement plans like 401(k)s or IRAs. Holdings of investment life insurance or variable annuities. Defined benefit pension plans. Language above from Form 3110-48.	<ul style="list-style-type: none"> income from service on advisory committees or review panels for public or nonprofit entities."
Look-back period for conflicts	"The term 'conflict of interest' applies only to current interest."	Varies; see above.	"Disqualifying financial interests include only financial interests that are currently held."	Varies; see above.	Current for financial conflicts: For reviewers, also includes professional associates ("any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities") over the past 3 years.
Monetary limits for disclosure	No threshold stated.	No threshold stated.	No threshold stated.	"Assets that are valued at more than \$1,000 or that generate more than \$200 per year in income must be reported."	No threshold stated.
Individuals included in policy	"Consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and minor children, the individual's employer, the individual's business partners, and others with whom the <i>continued</i>	Partner and employer.	"1) You, your spouse, minor child, general partner, director, trustee, general partner or employee, and/or 3) Entity with whom you are negotiating or have any arrangement concerning prospective employment."	Spouse; minor child; general partner; organization in which the individual serves as officer, director, trustee, general partner or employee; person or organization with which the employee is negotiating or has an arrangement concerning prospective employment.	For PIs: Spouses and dependent children. For reviewers: relatives (a parent, spouse, sibling, son or daughter or domestic partner) and professional associates.

	National Academies Panels (2003)	International Agency for Research on Cancer Monographs (2003)	Food and Drug Administration FACA Committees (2008)	Environmental Protection Agency FACA Committees (no single date)	National Institutes of Health Office of Extramural Research (2005)
Individuals included in policy <i>(continued)</i>	Individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee)."	Potential experts asked: "Do you have, or have you had during the past 4 years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of tobacco or any tobacco products, or directly representing the interests of any such entity?" "Is there anything else that could affect your objectivity or independence, or the perception by others of your objectivity and independence?"	Focus appears to be exclusively on financial conflicts.	"Any reason that you might be unable to provide impartial advice on the matter to come before the panel or any reason that your impartiality in the matter might be questioned; any previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions; service on previous advisory panels that have addressed the topic under consideration; any public statements on the issue that would indicate to an observer that you have taken a position."	For PIs and institutions: Not specified. For reviewers: Longstanding scientific or personal differences with an applicant.
Relevant non-financial activities	Access to confidential material; reviewing one's own work; public statements and positions; employees of sponsoring agencies.			Language above from Form 3110-48.	
Disclosure to institutions and to the public	Forms required. In addition, committees are asked to discuss the issues of committee composition and balance and conflict of interest, and the relevant circumstances of their individual members, at the first committee meeting and annually thereafter. Disclosure of relevant information is a continuing obligation for the duration of the committee activity. Information is held confidentially, except that under FACA, names and bios will be released and subject to public comment.	Declaration form required. Also required is disclosure of any change in circumstances. Information disclosed on the form may be made available to persons outside of World Health Organization only when the objectivity of the meeting or work has been questioned such that the Director-General considers disclosure to be in the best interests of the Organization, and then only after consultation with you.	Forms required. Potential committee members must fill out either OGE Form 450 or FDA Form 3410. This form will not be disclosed to any requesting person unless authorized by law.	SGEs are required to file a confidential financial disclosure report (EPA Form 3110-48) when first appointed to participate in an advisory activity, and then annually thereafter. Regular Government Employees are required to submit either an OGE Form 450 (Confidential Financial Disclosure Report) or an SF-278 form (Public Financial Disclosure Report) as appropriate under regulations promulgated by the Office of Government Ethics (OGE). Names and short lists of prospective panelists may be made available for public comment.	Forms required. The applications and proposals and associated materials made available to reviewers, as well as the discussions that take place during review meetings are strictly confidential and must not be disclosed to or discussed with any one who has not been officially designated to participate in the review process. Reviewers have to fill out both pre- and post-review certifying forms.
Disqualifying activities	"Except for those situations in which the institution determines that a conflict of interest is unavoidable and promptly and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a <i>continued</i>	"Conflict of interest will, depending on the situation, result in (i) you being asked not to take part in the portion of the discussion or work affecting that interest, (ii) being asked not to take part in the meeting or work altogether, or <i>continued</i>	"If an individual or her spouse or minor child has... financial interests whose combined value exceeds \$50,000, she generally would not participate in the meeting, regardless of the need for her expertise." <i>continued</i>	Presence of any conflict of interest directly with a "covered entity" is a disqualifying conflict. <i>continued</i>	For PIs: appears to be greater than \$10,000 for a given year. For reviewers: "A reviewer who has a real conflict of interest with an application or proposal may not participate in its review." <i>continued</i>

<p>Disqualifying activities <i>(continued)</i></p>	<p>National Academies Panels (2003)</p> <p>committee of the institution used in the development of reports if the individual has a conflict of interest that is relevant to the functions to be performed.”</p>	<p>International Agency for Research on Cancer Monographs (2003)</p> <p>(iii) if deemed by WHO to be appropriate to the particular circumstances, and with your agreement, you taking part in the meeting or work and your interest being publicly disclosed.”</p> <p>IARC assesses these interests to determine whether there is a conflict that warrants some limitation on participation. A difficulty arises when an expert with relevant knowledge and experience has a real or apparent conflict of interest. The selection of experts with real or apparent conflicts of interest can erode confidence in the integrity and impartiality of the results. This creates a tension between two competing ideals: evaluations developed by the best-qualified experts versus evaluations whose integrity and impartiality are above question. The new category of invited specialist allows the IARC Monographs to achieve both ideals. [Language quoted from different sections of IARC documents.]</p> <p>“An invited specialist is an expert with critical knowledge and experience who is recused from certain activities because of a real or apparent conflict of interests. These activities include serving as meeting chair or subgroup chair, drafting text that discusses cancer data or contributes to the evaluations, and participating in evaluations reached by either consensus or vote. Invited specialists are available during subgroup and plenary discussions to contribute the benefit of their knowledge and experience.</p> <p>Invited specialists also agree to serve in their individual capacities as scientists and not as representatives of any organization or interest. Their conflicting interests are fully disclosed to the meeting participants and in the IARC Monograph.”</p>	<p>Food and Drug Administration FACA Committees (2008)</p> <p>“The following list includes the . . . financial interests that are considered so significant that a waiver would not be issued:</p> <ul style="list-style-type: none"> -The SGE or his/her employing institution receives (or is negotiating) a contract, grant, or Cooperative Research and Development Agreement (CRADA) from a firm that is the sponsor of the product application that is the subject of the particular matter involving specific parties to be discussed at the advisory committee meeting, and the SGE is or will be the principal investigator or co-principal investigator on the same product/indication that is the subject of the meeting. -The SGE or his/her employing institution receives (or is negotiating) a contract, grant, or CRADA from a firm that is the sponsor of a product labeled for the same indication (or if an investigational product, that has the same indication for use) as the product that is the subject of the particular matter involving specific parties to be discussed at the advisory committee meeting, and the SGE is or will be the principal investigator or co-principal investigator on the competing product. -The SGE or his/her employing institution receives (or is negotiating) a contract, grant, or CRADA from a firm that is the sponsor of the product that is the subject of the particular matter involving specific parties to be discussed at the advisory committee meeting, and the SGE is or will be the principal investigator or co-principal investigator on the competing product. <ul style="list-style-type: none"> -Receives or will receive personnel or salary support; or -Designs/will design or advises/will advise on any aspect of the clinical trial(s); or -Reviews or will review data or reports from the clinical trial(s). <ul style="list-style-type: none"> -The SGE or his/her employing institution receives (or is negotiating) a contract, grant, or CRADA from a firm that is the sponsor of a product labeled for the same indication (or, if an investigational product, that has the same indication for use) as the product that is the subject of the particular matter involving specific parties to be discussed at the advisory committee meeting, and the SGE is the head of the department that is conducting or will conduct the studies on the same product/indication that is the subject of the meeting, and the SGE: <ul style="list-style-type: none"> -Receives or will receive personnel or salary support; or -Designs/will design or advises/will advise on any aspect of the clinical trial(s); or -Reviews or will review data or reports from the clinical trial(s). <ul style="list-style-type: none"> -The SGE or his/her employing institution receives (or is negotiating) a contract, grant, or CRADA from a firm that is the sponsor of a product labeled for the same indication (or, if an investigational product, that has the same indication for use) as the product that is the subject of the particular matter involving specific parties to be discussed at the advisory committee meeting, and the SGE is the head of the department that is conducting or will conduct the studies on the competing product, and the SGE: <p><i>continued</i></p>	<p>Environmental Protection Agency FACA Committees (no single date)</p> <p>“The term `covered entities` is used to refer to those types of entities whose activities or interests may be affected by EPA decisions. . . . in such a way that individuals having financial or other relationships with such entities may have a financial conflict of interest or an appearance of a lack of impartiality (including a lack of independence or bias). In particular, covered entities include companies or persons that manufacture or provide wholesale distribution of pesticide products registered by the EPA, are currently seeking a pesticide registration or other relevant regulatory or adjudicatory finding from EPA, or companies whose corporate parent, subsidiary, or affiliate engages in such activities. `Covered entities` also can include consulting firms, non-profit organizations, labor organizations, or educational institutions with financial interests in the entities listed above.”</p>	<p>National Institutes of Health Office of Extramural Research (2005)</p> <p>“A reviewer shall have a real conflict of interest if he/she (1) has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review; (2) has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year (for reviewers who are federal employees the amount is \$15,000 per year); this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer’s already existing stock holdings, apart from any direct financial benefit deriving from an application or proposal under review.”</p> <p>“If the reviewer feels unable to provide objective advice, he/she must recuse him/ herself from the review of the application or proposal at issue.”</p>
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<p>Disqualifying activities (continued)</p>	<p>National Academies Panels (2003)</p>	<p>International Agency for Research on Cancer Monographs (2003)</p>	<p>Food and Drug Administration FACA Committees (2008)</p>	<p>Environmental Protection Agency FACA Committees (no single date)</p>	<p>National Institutes of Health Office of Extramural Research (2005)</p>
<p>-Receives or will receive personnel or salary support; or -Designs/will design or advises/will advise on any aspect of the clinical trial(s); or -Reviews or will review data or reports from the clinical trial(s). The relevant part of 5 CFR 2635.502 says: "Where an employee's participation in a particular matter involving specific Parties . . . would raise a question in the mind of a reasonable person about his impartiality, the agency designee may authorize the employee to participate in the matter based on a determination, made in light of all relevant circumstances, that the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations. Factors which may be taken into consideration include: (1) The nature of the relationship involved; (2) The effect that resolution of the matter would have upon the financial interests of the person involved in the relationship; (3) The nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter; (4) The sensitivity of the matter; (5) The difficulty of reassigning the matter to another employee; and (6) Adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.</p>					

APPENDIX 3

Comparison of conflict of interest policies – selected journals* 1

	<i>Journal of Clinical Investigation</i> (2007)	<i>Journal of the American Medical Association (JAMA)</i>	<i>Science</i>	<i>New England Journal of Medicine</i> (2002)	<i>British Medical Journal (BMJ)</i> (1998)	<i>International Committee of Medical Journal Editors (ICMJE)</i> (2002)
Definition of conflict of interest	<p>For authors: "Financial relationships that could undermine the objectivity, integrity, or perceived value of a publication." Largely defined by a list of potential conflicts (enumerated below).</p>	<p>"A conflict of interest may exist when an author (or the author's institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work, or manuscript."</p>	<p>Defined by affiliations, funding sources, and financial holdings.</p>	<p>"Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions."</p>	<p>"A competing interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors (or reviewers) of a BMJ article when they have a financial interest that may influence – probably without their knowing – their interpretation of their results or those of others."</p>	<p>"Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such as financial gain or personal rivalry). It may arise for the authors (or reviewers) of a BMJ article when they have a financial interest that may influence – probably without their knowing – their interpretation of their results or those of others."</p>
Apparent conflict of interest	<p>Many factors termed "potential conflicts."</p>	<p>"All authors are required to disclose all potential conflicts of interest... relevant to the subject of their manuscript. Authors should err on the side of full disclosure and should contact the editorial office if they have questions or concerns."</p>	<p>"Before manuscript acceptance, therefore, authors will be asked to sign a statement of real or perceived conflicts of interest."</p>	<p>"The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment."</p>	<p>No specific language.</p>	<p>"The potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment."</p>
Distinction between conflict and bias?	<p>Not explicitly differentiated, though many factors termed "potential conflicts."</p>	<p>Not distinguished.</p>	<p>Appears to treat as synonymous: "To meet its responsibility to readers and to the public to provide clear and unbiased scientific results and analyses, Science believes that manuscripts should be accompanied by clear disclosures from all authors of their affiliations, funding sources, or financial holdings that might raise questions about possible sources of bias."</p>	<p>Appears to treat as synonymous: "The potential of such relationships (defined above) to create bias varies from negligible to extremely great; the existence of such relationships does not necessarily represent true conflict of interest, therefore. (Relationships that do not bias judgment are sometimes known as dual commitments, competing loyalties)."</p>	<p>"We used to ask authors about any competing interests, but we have decided to restrict our request to financial interests. This is largely a tactical move. We hope that it will increase the number of authors who disclose competing interests. Our experience, supported by some research data, was that authors often did not disclose them." See Relevant non-financial activities later in the chart.</p>	<p>"These relationships (defined above) vary from negligible to great potential for influencing judgment. Not all relationships represent true conflict of interest." See Relevant non-financial activities later in the chart.</p>
Who is Included?	<p>Authors, reviewers, editors.</p>	<p>Authors, reviewers, editors.</p>	<p>Authors.</p>	<p>Authors.</p>	<p>Authors, reviewers.</p>	<p>Authors, reviewers, editors.</p>

* The Journals participating in ICMJE include JAMA, BMJ, and New England Journal of Medicine.

1 This table was created by project staff in January, 2009 to assist the panel in its discussions of disclosure, conflict of interest, and bias.

Types of financial conflicts	<p>Journal of Clinical Investigation (2007)</p> <p>Editors: Two tiers of potential conflict.</p> <p>First Tier:</p> <ol style="list-style-type: none"> Ownership. Direct ownership of equity in a private or public company in the health care field of \$10,000 or more (including restricted stock; the market price of all options, vested or unvested; and warrants). Does not apply to ownership of mutual funds, where the editor does not directly control the purchase and sale of stocks. Income. \$10,000 or more per annum of income from any single private or public company in the health care field in the preceding calendar year. This includes any and all sources of financial benefit, including, but not limited to, consultancy, speaking fees, royalties, licensing fees, retainers, salary (including deferred compensation), honoraria, service on advisory boards, and providing testimony as an expert witness. Research support. \$50,000 or more per annum from a private or public company in the health care field in the preceding fiscal year, including funding for personnel working within the laboratory. <p>Second Tier:</p> <ul style="list-style-type: none"> Relationship with a company in the health care field wherein the editor received some compensation for services, but the total amount of income was between \$1,000 and \$9,999 for the preceding calendar year. This includes, but is not limited to, any compensation as detailed above in (2). Prospective employment leading to a significant financial relationship as defined in (1), (2), or (3) with a private or public company in the health care field. <p>Authors: Same as first-tier conflicts of editors.</p> <p>Reviewers: "We ask referees to use their judgment in responding to our request for full disclosure, basing their response to the editors on the same financial criteria applied to authors and editors, as described above."</p>	<p>Journal of the American Medical Association (JAMA)</p> <p>"All relevant financial interests and relationships or financial conflicts (e.g., employment/affiliation, grants or funding, consultancies, honoraria, speakers bureaus, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), particularly those present at the time the research was conducted and through publication, as well as other financial interests (such as patent applications in preparation), that represent potential future financial gain." If authors are uncertain about what constitutes a relevant financial interest or relationship, they should contact the editorial office.</p>	<p>Science</p> <ul style="list-style-type: none"> Significant financial interest (equity holdings or stock options) in any corporate entity dealing with the material or the subject matter of this contribution. Within the last 3 years, status as an officer, a member of the Board, or a member of an Advisory Committee of any entity engaged in activity related to the subject matter of this contribution (whether compensated or not). Within the last 3 years, receipt of consulting fees, honoraria, speaking fees, or expert testimony fees from entities that have a financial interest in the results and materials of this study. 	<p>New England Journal of Medicine (2002)</p> <p>Asks for listing of:</p> <ul style="list-style-type: none"> Consulting fees or paid advisory boards Equity ownership/stock options Lecture fees from speaking at the invitation of a commercial sponsor. <p>Asks whether authors have been paid by a commercial entity for writing the manuscript.</p> <p>Asks whether authors have grant support from industry. If yes, have to disclose current grant support and grant support concluding within the past 2 years, including nonprofit/ government entities. (If there is no industry support, evidently do not have to disclose any funding.)</p> <p>Asks whether authors have patents or royalties, have served as an expert witness, or perform other activities for an entity with a financial interest in this area.</p> <p>Asks whether authors are employed by a commercial entity that sponsored the study.</p> <p>Asks whether authors have received any other payment from a commercial entity that sponsored the study.</p>	<p>British Medical Journal (BMJ) (1998)</p> <p>Asks of both authors and reviewers:</p> <p>"1. Have you in the past 5 years accepted the following from an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter:</p> <ul style="list-style-type: none"> Reimbursement for attending a symposium? A fee for speaking? Funds for research? Funds for a member of staff? Fees for consulting? <p>2. Have you in the past 5 years been employed by an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter?</p> <p>3. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter?</p> <p>4. Have you acted as an expert witness on the subject of your study, review, editorial, or letter?</p> <p>5. Do you have any other competing financial interests? If so, please specify."</p> <p>Not specific on what level of detail needs to be disclosed. See Disclosure section later in this chart.</p>	<p>International Committee of Medical Journal Editors (ICMJE) (2002)</p> <p>"Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself."</p> <p>"To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist."</p> <p>"Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff."</p>
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	<i>Journal of Clinical Investigation</i> (2007)	<i>Journal of the American Medical Association (JAMA)</i>	<i>Science</i>	<i>New England Journal of Medicine</i> (2002)	<i>British Medical Journal (BMJ)</i> (1998)	<i>International Committee of Medical Journal Editors (ICMJE)</i> (2002)
Look-back period for conflicts	Varies: see above.	Past 5 years and the foreseeable future.	Varies: see above.	Varies: • Consulting fees or paid advisory boards: last 2 years and into the known future • Equity ownership/stock options: current • Lecture fees from speaking at the invitation of a commercial sponsor: last 2 years and into the known future.	Varies: see above.	Not specified.
Monetary limits for disclosure	Varies: see above.	"Although many universities and other institutions have established policies and thresholds for reporting financial interests and other conflicts of interest, JAMA requires complete disclosure of all relevant financial relationships and potential financial conflicts of interest, regardless of amount or value."	"Significant" interests must be disclosed. No further definition.	Authors of review articles, editorials, and perspectives must check off none, less than \$10,000, or more than \$10,000 for consulting fees and paid advisory boards; equity ownership/stock options; and lecture fees from commercial sponsors. Authors of other types of articles must disclose actual amounts.	Not specified.	Not specified.
Individuals included in policy	Editors (first tier): • Interests held by immediate family members (spouse or children) of the editor are included. • Income generated by immediate family members (spouse or children) of the editor are included. Editors (second tier): • Relatives. If an editor has a close relative other than a spouse or child (sibling or parent) employed by or with a significant financial interest in a private or public company in the health care field, a second-tier potential conflict must be declared. • Personal. Editors will be required to declare a second-tier potential conflict if a manuscript is submitted by a close personal contact (former student, fellow or mentor, for example) or a recent collaborator (over the last 3 years). Relevant collaborations may include co-authoring a research article or serving as co-investigators on a grant. Authors: same as first-tier requirements for editors.	Author's institution or employer.	Individuals only.	Individuals only.	Individuals only.	Not specified.

	<i>Journal of Clinical Investigation</i> (2007)	<i>Journal of the American Medical Association (JAMA)</i>	Science	<i>New England Journal of Medicine</i> (2002)	<i>British Medical Journal (BMJ)</i> (1998)	International Committee of Medical Journal Editors (ICMJE) (2002)
<p>Relevant non-financial activities</p>	<p>For editors: (second tier) -Competition. Editors will be required to declare a potential conflict if a submitted manuscript presents data that are highly relevant to a manuscript the Editor has under review or in press elsewhere. Editors are prohibited from using unpublished information from the manuscript's under consideration by the JCI to further their own research, nor can they use new information gained from unpublished manuscripts for financial gain. In order to avoid even the appearance of potential favoritism to institutional colleagues, manuscripts from the University of Pennsylvania (where the editors are located) will not be handled by the editorial board at large, but instead in a separate process.</p>	<p>Not specified.</p>	<p>Within the last 3 years, status as an officer, a member of the Board, or a member of an advisory committee of any entity engaged in activity related to the subject matter of this contribution (whether compensated or not). A planned, pending, or awarded patent on this work by any of the authors or their institutions.</p>	<p>"Do you have any other relationship, financial or nonfinancial (such as leadership in an advocacy group that stands to gain from your opinion), that, if not disclosed, could compromise the interpretation of the article?"</p>	<p>"We are restricting ourselves to asking directly about competing financial interests, but you might want to disclose another sort of competing interest that would embarrass you if it became generally known after publication. The following list gives some examples. •A close relationship with, or a strong antipathy to, a person whose interests may be affected by publication of your paper. •An academic link or rivalry with somebody whose interests may be affected by publication of your paper. •Membership of a political party or special interest group whose interests may be affected by publication of your paper. •A deep personal or religious conviction that may have affected what you wrote and that readers should be aware of when reading your paper. If you want to declare such a competing interest then please add it to your statement."</p>	<p>Conflicts can occur for other (nonfinancial) reasons, such as personal relationships, academic competition, and intellectual passion. Moreover, as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design, collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.</p>
<p>Disclosure to the publication and to the public</p>	<p>Editors: "are obliged to disclose any and all potential conflicts of interest" The editors will report changes to their potential conflicts as they occur. An annual formal review of all disclosures will be performed in the evaluation of compliance. If an editor declares a first-tier potential conflict relating to (1), (2), or (3), this information will be declared online. An editor will be considered to be in conflict if a manuscript is funded solely by an organization with which the editor has a potential conflict, regardless of whether a research institution employs the authors. Should a manuscript be submitted with ties to one of these companies, the editor with the conflict will be required to leave the Editorial Board meeting when the manuscript is</p> <p><i>continued</i></p>	<p>"All authors are required to disclose all potential conflicts of interest, including specific financial interests and relationships and affiliations (other than those affiliations listed in the title page of the manuscript) relevant to the subject of their full disclosure and should contact the editorial office if they have questions or concerns." "All such disclosures must be listed in the Acknowledgment section at the end of the manuscript. Authors without conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject of their manuscript, should include a statement of no such interests in the Acknowledgment section of the manuscript. As part of the author agreement form, authors have to certify that either they have no conflicts or that these conflicts are disclosed in the Acknowledgment section." <i>continued</i></p>	<p>"Disclosure is accomplished in three ways: first, by a complete listing of the current institutional affiliations of the authors; second, through the acknowledgment of all financial contributions to the work being reported, including contributions "in kind"; and third, through the execution of a statement disclosing to the Editors all financial holdings, professional affiliations, advisory positions, board memberships, patent holdings and the like that might bear a relationship to the subject matter of the contribution." <i>continued</i></p>	<p>Authors must fill out disclosure forms. There is one form for authors of review articles, editorials, and perspectives and a second form for all other article types. "We also ask that you prepare a financial disclosure statement for publication with the paper. The statement should describe the authors' relationships with companies that make products relevant to the paper. The statement should specify the type of relationships (e.g., consulting, paid speaking, grant support, equity, patents) EACH author has with EACH <i>continued</i></p>	<p>Authors must fill out disclosure forms. BMJ editors treat all submitted manuscripts as confidential documents, which means they will not divulge information about a manuscript to anyone without the author's permission. The only occasion when details about a manuscript might be passed to a third party without the author's permission is if the editor suspects serious research misconduct. Reviewers' identities are revealed to authors "if any author has answered 'yes' to any of the above five questions (listed under Financial conflicts portion of this chart, <i>continued</i></p>	<p>All participants in the peer review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Authors should identify Individuals who provided writing or other assistance and disclose the funding source for this assistance. Investigators must disclose potential conflicts to study participants and should state they have done so. Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it <i>continued</i></p>

Disclosure to the publication and to the public <i>(continued)</i>	<p><i>Journal of Clinical Investigation</i> (2007)</p> <p>discussed. The second tier of potential conflicts will necessitate only internal disclosure to the Editorial Board. These second-tier potential conflicts will not be published, but they will be known to the staff and other editors. The editor in potential conflict will not be required to leave the room during the discussion of the manuscript, but will recuse herself/himself from discussion and decisions related to the manuscript. Authors must disclose potential conflicts that correspond to the first tier of potential conflicts defined for editors and certify that these have been revealed to editors as part of the authorship agreement. Such potential conflicts will be published in a footnote if the manuscript is ultimately accepted. Reviewers: We ask that referees inform the editors of any potential conflicts that might be perceived as relevant as early as possible following invitation to participate in the review, and we will determine how to proceed. Disclosing a potential conflict does not invalidate the comments of a referee, it simply provides the editors with additional information relevant to the review.</p>	<p><i>Journal of the American Medical Association (JAMA)</i></p> <p>Authors and editors must sign the following disclosure statement: "I hereby disclose all of my conflicts of interest and other potentially conflicting interests, including specific financial interests and relationships and affiliations relevant to JAMA and Archives Journals (e.g., employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or stock options, expert testimony, royalties, or patents filed, received, or pending). This applies to the past 5 years and the foreseeable future. I also agree that I will promptly notify the Editor in Chief in writing about any additional potential conflicts of interests that occur." "I agree that I will disqualify myself from reviewing, editing, or participating in editorial decisions about any JAMA and Archives Journals submission that deals with a matter in which either I or a member of my immediate family (i.e., my spouse, domestic partner, or minor children) have direct financial interest or a competing financial interest (e.g., employment or affiliation, grants or funding, consultancies, honoraria, stock ownership or stock options, expert testimony, royalties, or patents filed, received, or pending). This also applies to the past 5 years and the foreseeable future." "I also agree that I will not use any confidential information obtained from my activities with JAMA and Archives Journals to further my own or others' financial interests."</p>	<p>Science</p> <p>A "Statement on Real or Perceived Conflicts of Interest for Authors" checklist is used for this third step. As the editors deem appropriate, author affiliations will be included with those printed in the manuscript. All funding sources will be listed in the published manuscript. The editors will determine whether the material disclosed to them should be published as part of the article.</p>	<p><i>New England Journal of Medicine</i> (2002)</p> <p>company. The information should be consistent with the author's signed financial disclosure forms. The statement should be located before the Acknowledgement section of the text and labeled "Disclosure."</p>	<p><i>British Medical Journal (BMJ)</i> (1998)</p> <p>above) we consider that to be a possible competing interest, which, in the spirit of openness, should be declared. Please draft a statement to publish with the article."</p>	<p><i>International Committee of Medical Journal Editors (ICMJE)</i> (2002)</p> <p>is best to err on the side of publication. Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should recuse themselves from reviewing specific manuscripts if the potential for bias exists. To prevent the information on potential conflicts of interest from being overlooked or misplaced, it needs to be part of the manuscript. However, it should also be included on a separate page or pages immediately following the title page. Individual journals may differ in where they include this information, and some journals do not send information on conflicts of interest to reviewers.</p>
Disqualifying activities	<p>Editors: "The editor must recuse himself/herself from discussion of a manuscript if he or she could benefit personally from its disposition." Reviewers: "Referees should exclude themselves in cases where there is a material potential conflict of interest, financial or otherwise." Not specified for authors.</p>	<p>See above for disqualifying criteria for editors and reviewers.</p>	<p>Not specified.</p>	<p>Not specified.</p>	<p>"We are not aiming at eradicating competing interests – they are almost inevitable. We will not reject papers simply because you have a competing interest, but we will make a declaration on whether or not you have competing interests."</p>	<p>Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.</p>



3

Chapter Three

RECOMMENDATION THREE: Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent.

It is a commonplace to argue that regulation should be based on the “best available science,” but determining what constitutes the best available science in any specific instance is no easy task. Assembling and evaluating the relevant scientific literature is a complex undertaking, not subject to any single, simple formula. That said, some basic principles should guide agencies and their scientific advisory committees as they sift the scientific literature. It should be Administration policy that agencies adhere to these principles.

Transparency

First, **the process of conducting literature reviews should become more transparent.** Agencies and their scientific advisory committees should be explicit about the criteria they are using to determine which scientific papers to review and how those papers are being evaluated. Those criteria should be open for public comment either as part of the comment period on a proposed rule or, when possible, earlier in the rulemaking process.

In addition, once an agency has opened a docket on a rule or guidance that will draw on scientific studies, it should make available on the Web a list of the studies it is reviewing and should regularly

update the list.¹ The list should be open for public comment both to help evaluate the studies on the list and to help identify any relevant studies that are being omitted. When a rule based on scientific studies is proposed, agencies should make clear in the *Federal Register* notice which studies were particularly influential and why.² Agencies should require their scientific advisory committees to do the same in their final reports.

Criteria

While the specific criteria an agency or scientific advisory committee uses to evaluate scientific studies may vary from issue to issue, the criteria should always be consistent with the principles below.

In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism. However, the quality of peer review varies widely, and journal rankings and impact factors do not guarantee that peer review of

¹ Agencies should monitor the impact of making this information available to see if it is improving the regulatory process.

² In some cases, the influential studies will be cited and discussed in a supporting technical document such as a risk assessment or an engineering study. Even in such instances, the *Federal Register* notice should cite the key studies.

a specific paper was performed adequately. **Agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality.**

That further inquiry might explore how the peer review was conducted, how the paper fits into the larger body of literature under review, and perhaps most important, the methodology behind the conclusions described in the paper (for example, how a cohort to study was chosen in an epidemiological study).

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of interest.

Conversely, studies that have not been peer reviewed should not be summarily rejected if they appear to contribute to the inquiry. Agencies and scientific advisory committees should be able to commission their own peer reviews (or in some cases, the scientific advisory committee itself might be assigned, or take on peer review of a study as a formal task). Agencies need sufficient funding and need to set realistic schedules to allow for such reviews.

(Chapter 4 discusses ways in which the federal government, as well as scientists and scientific journals could improve the peer review process.)

In general, agencies and scientific advisory committees should be wary of studies when it is unclear who funded the study or whether the principal investigator(s) had any conflicts of

interest.³ Agencies and scientific advisory committees can seek this information if it is not made public as part of the paper itself.⁴ Agencies and scientific advisory committees should consider sources of funding and any conflicts of interest as they review the reasons why a study may have been undertaken, the way a study was framed and carried out, and how the study results have been interpreted and discussed. In general, no studies should be excluded *a priori* because of the type of funding behind them.⁵ The focus should be on the study itself.

Beyond general concerns about funding and conflicts of interest, **agencies and scientific advisory committees should be extremely skeptical of a scientific study unless they are sure that the principal investigator(s) (as opposed to the sponsor or funder) had ultimate control over the design and publication of the study.**

In fields where a public registry of studies exists (such as the registry established by the Food and Drug Administration Modernization Act of 1997), agencies and scientific advisory committees should consider the relevant registered studies and should be wary of studies that met the criteria for the registry, but were not registered. Among the reasons to consult a registry is that a registry is more likely than the published literature to include reports of negative results (i.e., of instances where a study failed to confirm

³ Our panel did not discuss how to define “conflict of interest” for the authors of scientific papers. More thought needs to be given as to whether definitions of “conflict of interest” for service on scientific advisory committees (including those used by the National Academy of Sciences) would be fully relevant and complete if applied to authors of original scientific papers and review papers.

⁴ For studies performed years or decades in the past, it may be difficult to obtain information about the funding of a study and to discern whether conflicts existed. In the future, if the disclosure practices this report recommends become more widespread, agencies and scientific advisory committees will be better able to identify conflicts.

⁵ Eliminating whole categories of studies raises practical as well as philosophical issues. For example, for questions involving new types of technologies or materials (e.g., nanotechnology), most of the available studies are likely to have been funded by the industries that are developing new products.

an expected effect). Negative results need to be taken into account even when they are not peer reviewed (with the cautions mentioned above); they are less likely to be peer reviewed because journals are often reluctant to publish such studies.

There is no simple way to lay out generic rules for literature reviews – every body of literature and every field has its idiosyncrasies – but the principles above should offer some overarching guidance. In short, a good literature review strives to develop a sense of the entire body of relevant literature; evaluates the methods that were used in studies; digs, when necessary, beyond the published material, to get a better sense of methods and data; and is aware of the sources of funding and the extent of sponsor control over studies. Or, put another way, a good literature review is an exercise in comparing studies, looking first at the thrust of a body of literature and how broadly and well founded its conclusions are, then examining any well done studies that may be taking issue with the literature, and then reviewing what might be categorized as exploratory studies – studies that may relate to the question under consideration but were not carried out for that purpose.

Data availability

As noted above, literature reviews are enhanced when more information is available on the methods and data on which studies' conclusions are based. Scientists themselves and scientific journals could take steps to facilitate access to methods and data, as will be discussed in the next chapter. But the government also could increase the availability of information on methods and data.⁶

Studies used in the formulation of regulation should be subject to data access requirements

⁶ Our panel did not discuss the Information Quality Act (P.L. 106–554, Section 515) or the regulations issued pursuant to it.

equivalent to those under the Data Access Act (Shelby Amendment)⁷ and its implementing circular⁸ regardless of who funded the study. If a study is used by an agency to inform the development of a regulation, then the same kinds of information about that study should be available upon request, regardless of whether the study was funded by the federal government, industry, or some other entity.

Confidential Business Information (CBI) claims can also make it difficult for the interested public to evaluate studies that contribute to regulatory policy.

CBI is a legitimate and needed designation for information submitted to the federal government, but it appears to be overused today. There is great incentive for companies to claim CBI (i.e., why not err on the side of caution and secrecy?) even though that may be counter-balanced by a desire to earn the trust of regulators by being open about their scientific data. **The Administration and the Congress should gather data on the extent and nature of CBI claims. The Administration and Congress should consider requiring each new CBI claim to include a brief, but substantive justification for the claim.** Congress should also review the CBI provisions of specific statutes as they come up for reauthorization.

Additional studies

The recommendations in this report thus far, though, may not always be enough to resolve a regulatory question or to gain public faith in a regulatory process. Sometimes, a literature review will make clear the need for additional studies to address a dispute, but an agency will be seen as having too great a stake in the outcome to commission such work itself. Or sometimes an agency may not be trusted to appoint a balanced scientific

⁷ P.L. 105–277.

⁸ OMB Circular A-110.

advisory committee, or the complexity of doing so might strain its resources. In the latter case, an agency could turn to the National Academy of Sciences, but agencies may want to consider creating other avenues, especially if settling a controversy requires additional studies, not just a review of the existing literature.

In the area of clean air policy, the Health Effects Institute (HEI), established in 1980 and jointly funded by industry and government, has established a reputation as an honest broker with trusted scientific expertise to help the Environmental Protection Agency when it runs into the kinds of issues mentioned in the previous paragraph. HEI has clear and strict procedures for commissioning and reviewing studies that have enabled it to be seen by all sides in clean air disputes as an unbiased authority.⁹

Agencies should experiment with a variety of additional approaches that would enable them to commission studies and literature reviews related to pending regulatory decisions that would be widely seen as unbiased. For example, agencies might want to consider setting up their own equivalents of HEI, or they might want to consider giving either standing or *ad hoc* scientific advisory committees the ability (and the budget) to commission additional studies. They might also turn to another federal entity that would not be considered to have a stake in the outcome of the issue. Regulatory agencies have sometimes turned to the National Institute of Environmental Health Sciences for this purpose, for example.

⁹ More information on HEI can be seen at www.healtheffects.org. Daniel Greenbaum, the president of HEI, is a member of this panel, but did not originate the proposals concerning HEI. HEI is often cited in the policy literature as a model for resolving scientific issues related to regulatory policy. See, for example, John D. Graham (ed.), *Harnessing Science for Environmental Regulation* (Westport, NC: Praeger, 1991) and Sheila Jasanoff, *The Fifth Branch* (Cambridge: Harvard University Press, 1990).

Agencies should also encourage creative mechanisms by which scientists from industry, government, academia and non-governmental organizations can design experiments, collaborate on studies, and co-author scientific papers for publication in the open literature. In addition to advancing scientific knowledge, these multi-sector collaborations may work to build trust.

Presenting conclusions

In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty.

Deciding how much risk and what kinds of risk society should tolerate is a policy decision, as is determining whether and how to act in the face of scientific uncertainty. Those values questions need to be debated fully and openly. What agency scientists and scientific advisory committees need to do to inform that debate is provide clear scientific information about what the risks appear to be and how definitive the current scientific literature is about the existence and levels of those risks.

Policy makers should be wary of conclusions about risk that are expressed as a single number.

Rather, risk should be expressed as a range, with different scenarios and assumptions for different risk levels, including their relative likelihoods, spelled out. The population distribution of risks should be spelled out when such information is available and relevant. Also, terms that are applied to levels of risk (e.g., “probable” or “possible”) need to be defined precisely, i.e. quantitatively. Legal terms need to be translated into scientific ranges and vice-versa. The same is true for the terminology used to describe uncertainty.

If agency scientists or a scientific advisory panel concludes that a range of concentrations is safe for humans, animals or plants, it should be clear about the levels of uncertainty and risk at different levels within that range.

4

Chapter Four

RECOMMENDATION FOUR: The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.

This report has focused on steps the federal government needs to take to clarify and improve its own processes for injecting science into the regulatory process. But the federal regulatory process draws on the larger ecology (and economy) of the scientific enterprise and can only improve to the extent that the overall enterprise is functioning well. It will be more difficult for the federal government to achieve the improvements called for in our earlier chapters unless the other actors in the scientific enterprise also rise to the occasion.

Peer review

Peer review is the primary guarantor of integrity in the scientific system. It has inherent limitations, as do all human processes, but without it, the scientific enterprise would have diminished quality and credibility. In recent years, there has been growing concern that the peer review system may be eroding. Scientists may feel too burdened to review their colleagues' papers or may do so with insufficient care. Peer review is no longer assumed to be a professional obligation, and the institutions that rely on peer review mostly do too little to underscore its value. Moreover,

there has been little experimentation or empirical study about how to make it more effective.

Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review, particularly peer review of draft manuscripts. Possible steps that could be tried run the gamut from paying scientific advisory committee members a nominal fee to participate to requiring federal grantees to participate in a minimum number of peer reviews over the life of their grant to qualify for future funding. A middle-ground might be requiring grant applicants to list peer review service on their applications. The government could also encourage or require universities that receive federal grants to demonstrate that they were creating incentives for their faculty to participate as peer reviewers. It might help even just to have top federal science officials make clear in their speeches and writings that service as a peer reviewer is an expected aspect of a scientific career. Agencies should also ensure that their own scientists serve as peer reviewers. The Office of Science and Technology Policy could direct federal agencies to experiment with ways to increase participation in peer review, and then evaluate which experiments turn out to be most successful.

Universities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career. Faculty should be encouraged to participate in peer review by both their colleagues and administrators. Service as a peer reviewer should

Peer review is the primary guarantor of integrity in the scientific system.

be rewarded in tenure, promotion and salary decisions. Graduate students, post-doctoral researchers, and even faculty, particularly junior faculty, should be mentored on how to conduct a creditable peer review.

Scientific journals should improve the quality control of peer review and should experiment with different ways of conducting peer reviews. Journals should try to expand their circle of peer reviewers and should encourage more thorough peer reviews, perhaps by publicly acknowledging top-notch peer reviewers. Journals should give peer reviewers feedback (perhaps from the scientists whose work they reviewed) on the quality of their peer reviews. Journals should consider experiments to determine what produces the best (and in some cases, most transparent) peer reviews, such as publishing peer reviews (with or without the name of the peer reviewer) on the Web or along with the paper being reviewed, publishing lists of peer reviewers annually or in each issue, using open rather than anonymous peer reviews, or going in the other direction and using double-blind peer reviews. Journals should require their peer reviewers to disclose to the journal the information the editors need to determine whether any conflicts of interest exist, and the journal should consider disclosing that information to the article author

and/or the readership.¹ Also, journals could consider nominally compensating reviewers.

Information on scientific studies

As noted in Chapter 3, to evaluate a study fairly and completely, one needs a full sense of the data generated and the methods employed in the study. Yet this information is often difficult to obtain. That may have been understandable when paper journals were the basic means to communicate scientific information, but in the electronic age, the primary limitation on providing more information is a lack of will. **Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies.** The extent to which data and methods should be made public will vary by field, as each field has different standards as to what information a scientist can hold close to protect their intellectual property or future work. But enough information should be published on-line in conjunction with journal publication that an interested scientist could fairly evaluate the study results and replicate them, if so desired. Scientists need to understand that if they wish their studies to be relied upon by federal regulators, those studies must have a high degree of transparency about data and analytic methods.

Also as noted in Chapter 3, registries can help make information on a field of research more complete and accessible. **Federal agencies should determine whether the idea of research registries, which today is focused on research related to pharmaceuticals, can be expanded to other fields.** The nature of clinical trial research and its link to federal regulation may well be unique, but there may be other fields

¹ As noted in Chapter 3, more thought needs to be given to how conflict of interest should be defined for authors of papers.



with enough similarities to experiment with variations on registries. At the very least, agencies could make it easier to find the results of any study that was federally funded by, for example, having a searchable database of reports on what research was performed with grant money. A model might be the EPA STAR (Science to Achieve Results) grant program, which maintains on-line versions of the regularly submitted progress reports from projects it is funding, providing a broader inventory of the work underway than is available through the peer reviewed literature. Ideally, such a database would also include intramural research, that is, research that was carried out by federal agencies themselves rather than by grantees.

Conflict of interest

As noted in Chapter 3, the quality of literature reviews depends, in part, on having complete and accurate information on the funding of scientific studies and on any possible conflicts of interest that the scientists conducting a study may have had. Given the value placed on peer review and on the reputations of scientific journals, it is also vital that any conflicts editors may have be disclosed as well. Many journals have tightened their conflict of interest rules in recent years, and they have made some efforts to coordinate their policies. But more could be done. **Journals should have clear, publicly accessible conflict-of-interest policies and should require full disclosure of how studies were funded and of any and all conflicts of interest they determine an author has. Editors should also disclose any of their own conflicts of interest. In addition, journals should consider requiring authors to certify that they had ultimate**

control over the design and publication of the study being described in a paper.

As noted in Chapter 2, universities have also begun to put in place tighter and more consistent rules concerning conflict of interest. Universities need to help create a culture of transparency about funding and need to have clear, accessible and enforced policies on conflict of interest and on ultimate sponsor control. Violating university policies should have real consequences.

Similarly, **federal agencies need to consider promulgating rules that would sanction scientists who run afoul of federal, university or journal requirements concerning disclosure of conflict of interest or ultimate sponsor control.**

Scientists

The recommendations above are directed at institutions both to help create a culture of participation and transparency and to ensure that bad actors are discovered and reprimanded. But a truly healthy scientific enterprise relies on the individual actions and the decisions of each scientist. Scientists themselves, regardless of where they work, need to understand that the future health and credibility of the scientific enterprise depend on individual scientists addressing the concerns raised in this chapter. They need to ensure that they and their colleagues are participating as actively and openly as possible in the entire scientific process from research through publication and are open to involving themselves in the policy process. They should work as well to ensure that their professional societies regularly host sessions at their annual meetings on the importance and conduct of peer review, and consider the establishment of annual awards for particularly significant contributors to peer review in their fields. Scientists cannot expect regulatory policies to be based on the best available science unless they conduct, review, and evaluate that science in a way that garners public trust.



Afterword

Our report does not, and was not intended to deal with every issue that bedevils regulatory policy making, or even the use of science in it. Our panel focused on what we saw as perhaps the most fundamental and least discussed problems in regulatory policy making – the conflation of science and policy questions, and the need for greater transparency in analyzing the science behind policy making.

Among the many questions we did not discuss, but want to acknowledge are: how to strengthen the internal scientific capacity of federal agencies, how to protect whistleblowers, the extent to which the White House (and in particular, the Office of Information and Regulatory Affairs) should review specific regulatory decisions, and what kind of access individual federal scientists should have to the media. These and other questions are important, but other groups have weighed in on them, and we put these matters beyond the purview of our report.

There are two matters, though, that we want to point out that should draw attention from those both inside and outside the government who might wish to follow up on this report.

First, as noted in the report, there is remarkably little empirical data and relatively little discussion in the policy literature of the issues the report covers. Data and research are greatly needed on such questions as: Who is getting appointed to federal advisory committees and how? How many advisory committee members have conflicts of interest (however

defined) and what impact do those conflicts have on committee proceedings? What kinds of committees give the best advice? What kinds of literature reviews are most “successful”? How often do peer reviewed papers prove to have faulty methodologies and how can that be prevented? What peer review systems work best? And so on. More work is also needed on questions related to the central theme of this report – the need to distinguish between scientific and policy questions. How can that be done in specific cases? Where has it been done successfully? What is the impact? What other, broader changes to the political system might enhance the debate about science and regulation? Our panel drew on the considerable and varied personal experience of our members and the policy literature that does exist to develop recommendations that we believe will make a difference. But that old saw of scientific reports is especially valid here: more research is needed. In this case, the research should include monitoring the extent to which our recommendations are implemented and their impact.

Second, this report did not deal directly with one fundamental problem at the intersection of science and policy: the inherent disconnect between the pace at which scientific understanding changes and at which policy action takes place. Sometimes the policy apparatus cannot keep up with the speed of scientific change; in other cases, policy makers seek scientific answers before the research to provide them is ripe. Deeper thinking is needed on the question of how to

continually refresh the scientific understanding that underlies regulatory policy, and how to periodically update that policy as a result – without building in so much instability that industries cannot plan, or so much constant debate that the rulemaking apparatus simply seizes up entirely.

Science and politics are both dynamic systems, and this report will hardly be the last word on the intersection of science and regulatory policy. But we believe it is an important start. We look forward to working with the Administration and the Congress to implement our recommendations.

Bibliography

This bibliography provides a list of materials the project staff consulted to prepare for panel meetings. Inclusion does not imply any endorsement by the staff or the panel. The staff also consulted the conflict-of-interest policies used by journals, institutions, agencies and universities, some of which are encapsulated in Appendices 2 and 3 to Chapter 2. The staff also consulted news articles on issues related to the report, which are not included in the bibliography.

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Panel Member and Staff Biographies

Members

SHERWOOD BOEHLERT (CO-CHAIR)

Former Congressman Sherwood Boehlert (R-NY) represented Central New York State in the U.S. House of Representatives for 12 terms, ending in 2006. He served on the House Science Committee for his entire Congressional career and in 2001 was elected its Chairman. In addition, he was third-ranking member of the House Transportation and Infrastructure Committee. From 1995 to 2000 he served as Chairman of the Subcommittee on Water Resources and Environment. Boehlert was also a long-time member of the House Permanent Select Committee on Intelligence and a founding member of the House Select Committee on Homeland Security. *Congressional Quarterly* named him one of the 50 Most Effective Lawmakers on Capitol Hill; *National Journal* dubbed the long-time environmental leader “The Green Hornet,” and *Time* magazine cited him as a go-to “power center” in the House. In 2007, Boehlert joined The Accord Group, where he is Of Counsel. Additionally, the former lawmaker serves with former Rep. Martin Sabo, former Sen. Slade Gordon, and former Detroit Mayor Dennis Archer as Co-chair of the Bipartisan Policy Center’s Transportation Project for the 21st century. Boehlert is a Board Member of a number of national organizations, including the Alliance for Climate Protection; the Heinz Center for Science, Economics and the Environment; the League of Conservation Voters; the Health Effects Institute and the Natural Resources Defense Council Action Fund.

DONALD KENNEDY (CO-CHAIR)

Donald Kennedy is the former editor-in-chief of *Science*, the journal of the American Association for the Advancement of Science, and a senior fellow of the Woods Institute for the Environment at Stanford University. His present research program entails policy on such trans-boundary environmental problems as: major land-use changes; economically-driven alterations in agricultural practice; global climate change; and the development of regulatory policies. Dr. Kennedy has served on the faculty of Stanford University since 1960. From 1980 to 1992 he served as President of Stanford University. He was Commissioner of the U.S. Food and Drug Administration from 1977-79. Previously at Stanford, he was Director of the Program in Human Biology from 1973-77 and Chair of the Department of Biology from 1964-72. Kennedy is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, and the American Philosophical Society. He served on the National Commission for Public Service and the Carnegie Commission on Science, Technology and Government, and as a founding Director of the Health Effects Institute. He currently serves as a Director of the Carnegie Endowment for International Peace, and as Co-chair of the National Academies’ Project on Science, Technology and Law.

ARTHUR CAPLAN

Arthur Caplan is the Emanuel and Robert Hart Professor of Bioethics, Chair of the Department of Medical Ethics and the Director of the Center for Bioethics at the

University of Pennsylvania. Prior to coming to Penn in 1994, Dr. Caplan taught at the University of Minnesota, the University of Pittsburgh, and Columbia University. He was the Associate Director of the Hastings Center from 1984-87. Dr. Caplan is the author or editor of 25 books and over 500 papers in refereed journals of medicine, science, philosophy, bioethics and health policy. His most recent book is *Smart Mice Not So Smart People* (Rowman Littlefield, 2006). He has served on many national and international committees including as the Chair of the National Cancer Institute Biobanking Ethics Working Group, the Chair of the Advisory Committee to the United Nations on Human Cloning, the Chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability, and a member of the Presidential Advisory Committee on Gulf War Illnesses. He is a member of the Board of Directors of The Keystone Center, Tengion, the National Center for Policy Research on Women and Families, Octagon, the Iron Disorders Foundation, and the National Disease Research Interchange. He writes a regular column on bioethics for MSNBC.com. Dr. Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association, Person of the Year-2001 from *USA Today*, one of the 50 most influential people in American health care by *Modern Health Care* magazine, one of the 10 most influential people in America in biotechnology by the *National Journal* and one of the ten most influential people in the ethics of biotechnology over the past ten years by the editors of the journal *Nature Biotechnology*.

LINDA J. FISHER

Linda J. Fisher is Vice President and Chief Sustainability Officer at E. I. du Pont de Nemours and Company. She has responsibility for advancing DuPont's progress in achieving sustainable growth, DuPont's environmental and health programs, the company's product stewardship programs, global regulatory

affairs, and government affairs. She joined DuPont in 2004. Prior to that, Fisher served in a number of key leadership positions in government and industry including: Deputy Administrator of the Environmental Protection Agency (EPA) from 2001-03; EPA Assistant Administrator - Office of Prevention, Pesticides and Toxic Substances; EPA Assistant Administrator - Office of Policy, Planning and Evaluation; and Chief of Staff to the EPA Administrator. Fisher, an attorney, was also Vice President of Government Affairs for Monsanto and was Of Counsel with the law firm Latham & Watkins. She is a member of the DuPont Health Advisory Board and the DuPont Biotechnology Advisory Panel and serves as liaison to the Environmental Policy Committee of the DuPont Board of Directors. Fisher serves on the Board of Directors of the Environmental Law Institute, on the Board of Trustees of The National Parks Foundation, on the Board of Directors of Resources for the Future, and on the Board of Covanta Holdings.

LYNN R. GOLDMAN

Lynn R. Goldman, a pediatrician and epidemiologist, is Professor in the Department of Environmental Health Sciences at the Johns Hopkins University Bloomberg School of Public Health. Her areas of focus are public health practice, children's environmental health, disaster preparedness, and chemical and pesticide regulatory policy. Dr. Goldman is Principal Investigator for the Hopkins National Children's Study Center and co-PI of the Center for Preparedness and Catastrophic Event Response (PACER). As Assistant Administrator for Toxic Substances at EPA, she directed the Office of Prevention, Pesticides and Toxic Substances from 1993 through 1998. Prior to joining EPA, Dr. Goldman served as Chief of the Division of Environmental and Occupational Disease Control of the California Department of Health Services. Dr. Goldman has served on numerous boards and expert committees, including the Committee on Environmental Health of

the American Academy of Pediatrics and the Centers for Disease Control Lead Poisoning Prevention Advisory Committee. Dr. Goldman is a member of the Institute of Medicine, Vice Chairman of the Institute of Medicine Roundtable on Environmental Health Sciences, and a member of the National Academy of Sciences Standing Committee on Risk Analysis Issues and Reviews.

JOHN D. GRAHAM

John D. Graham is Dean of the Indiana University School of Public and Environmental Affairs (SPEA). His research interests include government reform, energy and the environment, and the future of the automobile in both developed and developing countries. He came to SPEA after serving as Dean of the Frederick Pardee RAND Graduate School at the RAND Corporation in California. Prior to joining RAND, Dr. Graham served in the White House Office of Management and Budget (OMB) from 2001-06. As the Senate-confirmed Administrator of the Office of Information and Regulatory Affairs, he led a staff of 50 career policy analysts who reviewed major regulatory proposals from Cabinet agencies. Prior to his role at OMB, Dr. Graham was a Professor of Policy and Decision Sciences at the Harvard School of Public Health. From 1990 to 2001, Dr. Graham founded and led the Harvard Center for Risk Analysis. In 1995, he was elected President of the Society for Risk Analysis, an international membership organization of 2,400 scientists and engineers.

DANIEL GREENBAUM

Dan Greenbaum joined the Health Effects Institute (HEI) as its President and Chief Executive Officer in 1994. In that role, Greenbaum leads HEI's efforts, supported jointly by the EPA and industry, with additional funding from the Department of Energy, Federal Highway Administration, U.S. Agency for International Development, the Asian Development

Bank, and foundations, to provide public and private decision makers with high quality, impartial, relevant and credible science about the health effects of air pollution. Greenbaum has focused HEI's efforts on providing timely and critical research and reanalysis on particulate matter, air toxics, diesel exhaust and alternative technologies and fuels. Greenbaum currently serves on the U.S. National Research Council (NRC) Committee on Health, Environmental, and Other External Costs and Benefits of Energy Production and Consumption. He has been a member of the NRC Board of Environmental Studies and Toxicology and Vice Chair of its Committee for Air Quality Management in the United States. Greenbaum also chaired the EPA Blue Ribbon Panel on Oxygenates in Gasoline, which issued the report "Achieving Clean Air and Clean Water" and EPA's Clean Diesel Independent Review Panel, which reviewed technology progress in implementing the 2007 Highway Diesel Rule. Before coming to HEI, he was Commissioner of Environmental Protection in Massachusetts.

MICHAEL P. HOLSAPPLE

Michael P. Holsapple is the Executive Director of the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) in Washington, D.C. Dr. Holsapple has published over 150 manuscripts and chapters. After completing two years of postdoctoral work at the Medical College of Virginia/Virginia Commonwealth University, he was appointed an Assistant Professor in the Department of Pharmacology and Toxicology. He was tenured and promoted to Associate Professor in 1989. Dr. Holsapple served as the Director of his department's graduate program from 1987 until 1991, and he received the "Professor of the Year Award" in his department in 1989. Dr. Holsapple joined the Toxicology, Environmental Research and Consulting Laboratories at the Dow Chemical Company in 1994 and was promoted to

Scientist in 2000. His responsibilities included serving as the Technical Leader of both the Immunotoxicology and the Respiratory Toxicology Groups. Dr. Holsapple left Dow in 2002 to join the HESI staff. Dr. Holsapple is currently an Adjunct Professor in the Department of Pharmacology and Toxicology at Michigan State University. He is a member of the American College of Toxicology and the Society of Toxicology (SOT). He is a charter member of the Immunotoxicology Specialty Section in the SOT. In recognition of his contributions to toxicology, Dr. Holsapple received the SOT Achievement Award in 1992. Dr. Holsapple became the Vice President-elect of SOT in 2008.

KEVIN KNOBLOCH

Kevin Knobloch is the President of the Union of Concerned Scientists (UCS). Knobloch first worked at UCS from 1989 to 1992 as Legislative Director for Arms Control and National Security. He returned in January 2000 and was named President in December 2003. He oversees the organization's research, public education, and legislative programs. Knobloch recently served as Chair of the Green Group, a coalition of the CEOs of 34 national environmental organizations, and currently serves as Co-chair of the Green Group Climate and Energy Committee. He led UCS delegations to the United Nations International Climate negotiations in Montreal in 2005 and in Bali in 2007. In addition to his positions at UCS, he served as Director of Conservation Programs for the Appalachian Mountain Club in Boston. During six years on Capitol Hill, he was the Legislative Director for U.S. Senator Timothy Wirth (D-CO) and Legislative Assistant and Press Secretary for U.S. Representative Ted Weiss (D-NY). He began his career as an award-winning newspaper journalist, writing for several Massachusetts publications. He recently completed eight years on the Board of Directors of the Coalition for Environmentally Responsible Economies and serves on the Environmental League of

Massachusetts Board of Directors. He is also co-founder and former President of the Arlington (MA) Land Trust.

KENNETH OLDEN

Kenneth Olden has been the Founding and Acting Dean of the proposed School of Public Health at the City University of New York since 2008. Dr. Olden is a cell biologist and biochemist by training, and has been active in cancer research for over three decades. From 1979 to 1991, Dr. Olden worked at Howard University in several roles, ultimately as Director of the Howard University Cancer Center and Chairman of the Department of Oncology. From 1991 to 2005, Dr. Olden was Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program, with a concurrent scientific post as Chief of the Metastasis Section of the NIEHS Environmental Carcinogenesis Program. Dr. Olden has maintained his research interests throughout his administrative career. Much of his work has focused on the role of glycoproteins in cancer. Working with Ken Yamada and others at the National Cancer Institute, he studied the glycoprotein fibronectin, and its possible role in inhibiting metastasis.

ROGER A. PIELKE, JR.

Roger A. Pielke, Jr. has been on the faculty of the University of Colorado since 2001 and is a Professor in the Environmental Studies Program and a Fellow of the Cooperative Institute for Research in Environmental Sciences (CIRES). At CIRES, Dr. Pielke served as the Director of the Center for Science and Technology Policy Research from 2001-07. His research focuses on the intersection of science and technology and decision making. In 2006, Dr. Pielke received the Eduard Brückner Prize in Munich, Germany for outstanding achievement in interdisciplinary climate research. Before joining the University of Colorado, from 1993-

2001, he was a Scientist at the National Center for Atmospheric Research. Dr. Pielke is an Associate Fellow of the James Martin Institute for Science and Civilization at Oxford University's Said Business School. He is also a 2008 Fellow of the Breakthrough Institute. He is also author, co-author or co-editor of five books. His most recent book is *The Honest Broker: Making Sense of Science in Policy and Politics*.

SHERRI K. STUEWER

Sherri Stuewer is Vice President – Safety, Health and Environment for Exxon Mobil Corporation. In that role she is responsible for developing, reviewing, and coordinating Exxon Mobil's worldwide efforts concerning the environment, safety, and health. Prior to her current position, Stuewer was Strategic Planning Manager for Exxon Mobil, General Manager of the Exxon Company U.S.A. supply department, and Manager of the Exxon refinery in Baytown, Texas. Over her 33-year career with Exxon Mobil, she has held a variety of technical and managerial positions in refining, planning, and logistics. Stuewer is a member of the Board of Trustees and the Engineering College Council at Cornell University. She is also a Board Member of the YMCA of Metropolitan Dallas and the Bermuda Institute of Ocean Sciences. She is a past Chair of the Industry Advisory Board to the International Energy Agency.

WENDY E. WAGNER

Wendy E. Wagner is the Joe A. Worsham Centennial Professor at the University of Texas School of Law and recently joined the Case Law School faculty as a Professor through a joint, half-time arrangement with the University of Texas. Prior to joining the University of Texas Law faculty, Wagner was a Professor at the Case Western Reserve University School of Law and School of Management, and was a Visiting Professor at the Columbia Law School and the Vanderbilt Law School.

She writes primarily in the area of environmental law and science, exploring the ways that science is used and misused in decision-making by the courts, Congress, and the agencies. Wagner has participated as an officer or committee member in a number of professional societies, including several sections of the American Bar Association, the Society for Risk Analysis, the National Conference of Lawyers and Scientists, and has served on several National Academy of Sciences committees. Wagner began her legal career in 1987, when she served as a law clerk for the Honorable Albert Engel, the Chief Judge of the U.S. Court of Appeals, Sixth Circuit, in Grand Rapids, Michigan. She then served as an Honors Attorney at the Environmental Enforcement Section of the Environment Division at the Department of Justice in Washington, D.C. Wagner then moved to the General Counsel Office of the Department of Agriculture (USDA) in 1991 where she served as the Pollution Control Coordinator and established a central office, with six satellite legal offices, to manage and advise USDA agencies on compliance under the pollution control laws.

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David Goldston served as Chief of Staff of the House Committee on Science from 2001 through 2006, the culmination of more than 20 years on Capitol Hill working primarily on science policy and environmental policy. Since retiring from the Congressional staff, Goldston has been a Visiting Lecturer at Princeton University's Woodrow Wilson School of Public and International Affairs and at the Harvard University Center for the Environment. He writes a monthly column for *Nature* on science policy titled "Party of One." He serves on the National Academy of Sciences' Aeronautics and Space Engineering Board and on a panel of the Academy's Committee on National

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BPC Science for Policy Interim Report: Improving the Use of Science in Regulatory Policy

March 10, 2009

The use of science in the formulation of regulatory policy – by both the Executive Branch and the Congress – has become a political flashpoint in recent decades. Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.

These problems are largely systemic; they will not magically vanish with a change of Administrations or a shift in the composition of the Congress. But the advent of a new Administration and a new Congress is an opportune time to take stock of the situation and to try to devise ways to get beyond the predictable battles that would otherwise lie ahead. The use of science in regulatory policy is another area in which government needs to get beyond the stale debates and false dichotomies of the past. The question is not whether scientific results should be used in developing regulatory policy, but how they should be used.

New processes are needed – approaches that will be seen as legitimate by most stakeholders on all sides of issues and that will make policy making more transparent. A critical goal of any new procedures for establishing regulatory policy must be to clarify which

aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethics). The tendency, on all sides, to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.

To come up with new approaches, the Bipartisan Policy Center assembled a diverse panel of experts to develop recommendations for both the Executive Branch and the Congress on how to improve the way science is used in making regulatory policy across the government’s areas of responsibility. The panel includes liberals and conservatives, Republicans and Democrats, scientists and policy experts, and leaders with experience in government, industry, academia and non-governmental organizations.

The goal of the panel is to issue a report this summer with specific recommendations for both the Executive Branch and Congress. That report will be designed to answer three sets of questions concerning regulatory policy. (By “regulatory policy,” we mean not only specific rules, but all regulatory statements and guidance issued by Administration officials, and statements, hearings and legislation from the Congress.) Those questions are:

- What kinds of activities or decision-making amount to “politicizing” science? How and to what extent can one differentiate between the aspects of regulatory policy that involve scientific judgments and those that involve making policy recommendations (which are inherently political)?

- When and how should Federal agencies empanel advisory committees? How should members be selected? How should conflicts of interest and biases of potential members be handled? What is scientific balance and how can it be achieved? How can the independence and integrity of committees' deliberations be assured?
- What studies should agencies and advisory committees review in formulating regulatory policy? How should they be weighed? What role should peer review play and how might peer review be modified and strengthened?

The panel met for the first time in January and therefore still has much work to do to formulate specific policies and procedures that respond to these questions. But the panel did get far enough to lay out some initial general guidance for the new Administration. (Again, the final report will provide recommendations for the Congress as well as expanding on suggestions for the Administration.) Note that in the recommendations below, "science" refers to the natural and physical sciences and engineering. The panel's ultimate recommendations may also deal with the social sciences.

- **RECOMMENDATION ONE: *The Administration needs to develop ways, when developing regulatory policies, to explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.***

Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the "politicization" of science actually arise over differences about policy choices that science can

inform, but not determine. For example, decisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science. It would also help policy makers determine which experts to turn to for advice on regulatory questions, and what kinds of questions they should be expected to answer.

The Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy. That distinction also needs to be spelled out in regulatory documents. One approach that could help clarify the often problematic distinction would be to require policymakers to answer questions such as: What additional science would change the debate over a proposed regulatory policy and in what ways would the debate change? This both would help to pinpoint the nature and extent of scientific uncertainty and would highlight which aspects of a regulatory issue are not primarily about science.

Another possible approach would be to require federal agencies to spell out genuine alternative regulatory policies when proposing guidance or a rule. The idea

would be to make clear the range of policy options that were available, given the science and the requirements of law. For example, agencies could be required to describe alternatives of different levels of stringency (or cost, when allowed by statute) that would be in keeping with the science and would comply with statutory mandates.

Many additional options for implementing Recommendation One might be developed, but the goal should be to change the conversation about regulation and to inculcate new habits of thought. The first impulse of those concerned with regulatory policy should not be to claim “the science made me do it” or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making.

No system for clarifying the roles of science and policy questions in regulatory decision making will be air tight or completely immune from abuse. But that is not a reason to adhere to the status quo. Unless clarifying science and policy issues becomes a central aspect of regulatory policy discussions, it will be very difficult to get beyond the finger-pointing and misleading debates that have been a barrier to sensible policy making for so long. In short, there must be clarity and transparency about the roles of policy and science in regulatory decisions for science to be appropriately integrated in regulatory policy.

- **RECOMMENDATION TWO: *The Administration needs to develop guidelines on when to consult advisory panels on scientific questions, how to appoint them, how they should operate, and how to deal with conflicts of interest.***

Federal agencies should use advisory committees to the maximum extent possible to review the science behind regulatory policies that are under consideration. (At the same time, agencies should be working to strengthen

the internal capabilities of their staffs, including their scientists.) Public officials should not delegate their ultimate responsibility to set policy. But scientific advisory committees can help ensure that policies are based on a range of knowledge and opinions, and they can make the regulatory process more transparent. As a result, the proper use of advisory committees can make it easier to adopt and more difficult to overturn good regulations once promulgated.

The first question in establishing an advisory committee should be whether the group will handle science questions or policy questions (or perhaps both). Science and policy questions should be as clearly distinguished as possible in charges to advisory panels. Advisory committees that are exclusively addressing science questions should generally consist only of members with relevant scientific expertise. Advisory committees that are addressing policy questions that are informed by science should include members with relevant scientific expertise among their members.

In general, scientific advisory panels should not be asked to recommend specific policies. Rather, they should be empanelled to reach conclusions about the science that would guide a policy decision. They might also be charged with evaluating a regulatory option or options developed by federal officials in light of scientific understanding. For example, a scientific advisory panel might be asked to determine if a proposed standard was consistent with achieving a level of risk prescribed by federal officials.

The remainder of this section is concerned exclusively with procedures related to scientific advisory panels.

The process of naming advisory committees should be made more transparent. Options for accomplishing this include: seeking recommendations for members on the Web or through contacts with relevant groups; publicly announcing on the Web the criteria for membership

(such as the range of scientific disciplines that need to be included); and announcing proposed members on the Web to allow for public comment. While some agencies use some of these techniques some of the time today, greater transparency needs to become the norm, and processes need to become more uniform.

Achieving balance among scientific disciplines is more essential than is commonly understood. Such balance not only ensures that the full range of science will inform a decision, but also guards against advice being unconsciously biased by the perspectives, values or techniques that may be inherent in particular fields. It is also critical to identify a chair who is widely respected, has a reputation for considering all perspectives, and can manage a committee so as to encourage debate and discussion yet produce results on schedule.

Publicizing proposed committee members is also a way to learn of possible conflicts of interest. Our panel is still considering how agencies should handle such conflicts. Views run the gamut from allowing anyone with a conflict to serve on an advisory panel as long as the conflict is disclosed to banning anyone with a conflict from an advisory panel (while allowing the panel to hear and evaluate that person's views). We hope our final report can offer more specific guidance on how to assess and handle conflicts.

Without question, though, the Administration should set a clear, rigorous, uniform government policy on conflict of interest and create a standard form for disclosure that could be used by all advisory committees and in all agencies (or that, at the very least, would set a minimum standard for all agencies). The Administration should examine the range of conflict policies used by federal agencies, scientific journals and international scientific bodies in developing its policy. Any policy should clearly define what constitutes a conflict of interest that must be disclosed (including the time period covered, any monetary thresholds, and what family

members and professional associates are included), what conflicts would be disclosed to the public as well as the government, and what conflicts, if any, would disqualify an individual from serving on an advisory committee.

Agencies need to check more effectively for conflicts on the part of advisory committee members. Scientists should be far more sensitive to the need to disclose conflicts, but federal agencies should not be relying exclusively on self-disclosure to ensure that federal guidelines on disclosure are being followed.

Federal officials who select members of scientific advisory committees should consider biases in addition to financial conflicts of interest. The policies of the National Academy of Sciences helpfully distinguish between conflicts and biases, which arise, for example, when a potential advisory committee member has a record of taking sides on an issue. Having published views on a matter should not, in and of itself, be a barrier to participating on a related advisory committee. Rather, advisory committees should have a diversity of perspectives, and members should be expected to be open-minded, regardless of their previous work.

The Administration should also carefully think through efforts to ensure open meetings of advisory committees. It might be worth considering, for example, whether some scientific advisory committees could be allowed to hold some closed meetings if the selection process for committee membership were more open than it generally is today (as recommended above). Transparency is an essential principle of democratic governance, but some deliberations can benefit from a modicum of private discussion to enable committee members to think and speak more freely and open-mindedly. Allowing the closure of meetings would require changes in statute, and any such changes should limit the use of closed meetings and be very specific about when closure is permissible.

The recommendations of a committee, though, must always be made public (assuming no classified information is involved), and indeed committees should be required to explain fully their methodology and the rationale for their conclusions. Federal officials should be required to explain how a committee's conclusions or recommendations are embodied in a new regulatory policy or why they are not.

Finally, federal officials must give advisory committees clear, definite and realistic deadlines for reporting and clear information on when a committee report will be released and how it will be used.

One way the Administration might approach some of the issues raised here is to review the guidance that the Office of Management and Budget and the Office of Science and Technology Policy issued in 2003 to see how it might be improved.

- **RECOMMENDATION THREE: Agencies and advisory committees should cast a wide net in reviewing studies relevant to regulatory policy and must improve their methods of filtering and evaluating those studies.**

Our panel is just beginning to discuss how to flesh out this recommendation. However, a few general principles have emerged.

Not all studies should be given equal weight in surveying a field. To the extent possible, agencies and advisory committees should set out criteria in advance for reviewing the quality and relevance of individual studies and then should apply those criteria systematically in evaluating and synthesizing the research. Among the factors that need to be considered are where a study was published, the quality of the peer review it underwent, any conflicts of interest the scientists conducting the study may have had and whether such conflicts were disclosed, and the extent

to which a study's findings are supported by other work, and whether such work was published in peer reviewed journals.

Policymakers should be wary of conclusions about risk that are expressed as a single number. Rather, risk should be expressed as a range, with different scenarios and assumptions for different risk levels spelled out. Reviews of a body of scientific literature should always express levels of uncertainty as clearly and fully as possible so that policymakers can then discuss their response to that uncertainty.



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