

HEALTH POLICY REPORT

Science, Politics, and Federal Advisory Committees

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About 1000 committees advise the federal government. Many of them address scientific, technical, and medical issues. There is a continuing dispute about whether the administration of President George W. Bush has compromised the system of advisory committees by manipulating it for political and ideological reasons and seeking scientific advice that matches the administration's own views. In turn, administration officials have rejected these charges as politically motivated. They maintain that they are supporting a strong system, not subverting it by stacking the committees. The controversy comes at a time of exceptional partisanship in Washington, with major battles over many issues, including judicial nominees and Medicare reform.¹

The controversy received substantial national attention in February. The Union of Concerned Scientists, a nonprofit advocacy group, issued a critical report on "the Bush Administration's misuse of science" and released a statement signed by more than 60 leading scientists, including 20 Nobel laureates, calling for "regulatory and legislative action to restore scientific integrity to federal policymaking."^{2,3}

At the end of February, President Bush did not reappoint two members of the President's Council on Bioethics who had been outspoken in their support of research on human stem cells.⁴ In this issue of the *Journal*, Elizabeth Blackburn (pages 1379–1380), one of the members who was dismissed, discusses bioethics and the political distortion of biomedical science. Blackburn, a cell and molecular biologist at the University of California, San Francisco, argues that "scientific advice should and must be protected from the influence of politics."⁵ In an open letter to the President, many leaders in the fields of bioethics and medical ethics protested that he had "severely compromised" the council's credibility by "dismissing those two individuals and appointing new members whose views are likely to closely reflect those of the majority of the council and its chair."⁶ Dr. Leon Kass, who chairs the council, responded that the charges of political "stacking" were "unfounded and false."⁷ In this report, I examine this controversy and what might be

done to insulate the outside experts who advise the federal government from the effects of shifting political winds.

THE CONTROVERSY

Federal advisory committees are meant to provide independent, expert, and objective advice on policy, the funding of research, and other issues.⁸ Although their advice may be followed, or ignored, they do not make decisions. Consistent with federal law, the President and the heads of departments and agencies have the right to choose the advisers they want.

Some of the Bush administration's appointments, and its replacement of committee members and of entire committees, have inflamed passions in the scientific community.⁹ The areas affected include childhood lead poisoning, environmental health, genetic testing, reproductive health, the protection of research subjects, and workplace safety. The disputes are somewhat amorphous; generalizations may oversimplify nuanced situations. Nevertheless, there have been numerous instances in which candidates with views that were inconsistent with the President's core policies and positions have been eliminated.^{2,9-11}

Candidates have reportedly been asked to state their views on specific topics, such as abortion, stem-cell research, and human cloning. The newly appointed scientists include some with close ties to industries that are regulated by the federal government.¹² The administration replaced a majority of the members of an advisory committee to the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health. Some of these new appointees had industry ties.^{9,10,13} Similar concerns were voiced about new members of the CDC's Advisory Committee on Childhood Lead Poisoning Prevention. In an unusual move, nominees proposed by staff scientists at the CDC were rejected. A prominent committee member was not reappointed. Some of the new appointees had financial ties to the lead industry.² Critics contend that committee members who have connections

with industry might offer advice that would lead the government to weaken protections for children.^{10,14}

Secretary of Health and Human Services Tommy Thompson dissolved a committee that had been established two years earlier, during the Clinton administration, to advise the newly created Office for Human Research Protections. He replaced it with the Secretary's Advisory Committee on Human Research Protections, which is charged, according to the charter, with providing advice on research involving "pregnant women, embryos, and fetuses." Critics contend that the inclusion of "embryos and fetuses" was an ideological statement about equating embryos and fetuses with human subjects.^{10,15} Depending on one's point of view, the charter could lead to greater restrictions on the use of embryos in research or increased protection for pregnant women who are included in research, or it could have no effect.

A new Advisory Committee on Genetics, Health, and Society replaced the Secretary's Advisory Committee on Genetic Testing, which was also created during the Clinton administration.⁹ The Food and Drug Administration (FDA) considered appointing as the chair of its Advisory Committee for Reproductive Health Drugs an obstetrician-gynecologist who opposes abortion as well as the prescription of contraceptives for unmarried women. The physician also has strong views about Jesus' role in healing women.¹⁶ He was eventually appointed, but not as the chair.

The Safety and Occupational Health Study Section of the National Institute of Occupational Safety and Health differs from many other committees that review grants in that the office of secretary, not an institute director, has responsibility for appointments. The secretary rejected three of six candidates who had been proposed for permanent membership.^{2,17} According to Dana Loomis of the University of North Carolina, who was chair of the study section at the time, no reasons were given. The candidates were "all established scientists who had served as temporary members for some time and whose qualifications had been duly reviewed and approved at every other level. The reasoning nevertheless seems clear in at least one case. One of the rejected nominees is an expert in ergonomics who has publicly supported a workplace ergonomics standard."¹⁸ In 2001, congressional Republicans blocked the Clinton administration's efforts to establish such a standard. In consultation with the National Institute of Occupational Safety and Health, additional members were subsequently appointed.

THE FOGARTY INTERNATIONAL
CENTER ADVISORY BOARD

Dr. Gerald T. Keusch was associate director for international research at the National Institutes of Health (NIH) and director of the Fogarty International Center from October 1998 to December 2003. He is now assistant provost for global health at Boston University Medical Center and associate dean for global health at the Boston University School of Public Health. The Fogarty International Center Advisory Board is appointed by the secretary of health and human services and has about a dozen members. Keusch said in an interview that during the Clinton administration he proposed seven people for appointments to the board. All were approved by the director of the NIH and by Donna Shalala, the secretary, within a month. In 2001, during the first year of the Bush administration, Keusch proposed four people. After seven months, Thompson disapproved three of the candidates. The total time that elapsed between the initial nominations and the final approval of four candidates was nearly 14 months. "The function of the board was compromised during that period," Keusch said in an interview.

In total, during three years under the Bush administration, Keusch proposed 26 candidates, all of whom were approved by the director of the NIH. The secretary approved 7 of them, rejected 19, and also suggested alternative candidates, many of whom Keusch did not consider appropriate for the needs of the Fogarty International Center. According to Keusch, institute and center directors at the NIH are "in the absolutely best position to know their scientific needs and the scientific qualifications of the nominees for their advisory committees. Although the secretary makes the appointments, he or she is not in a position to judge the match between scientific needs and committee member capacity. Since these nominations are first reviewed by the NIH director's office, any further review at higher levels is unlikely to be scientific in nature."

VIEWS OF THE BUSH
ADMINISTRATION AND ITS CRITICS

Administration officials have vigorously defended their actions and denied that there is a "grand conspiracy" or a "litmus test."¹⁰ The office of the secretary has a responsibility to make appointments to federal advisory committees, according to Bill

Pierce, a spokesperson for the Department of Health and Human Services (DHHS). In an interview, Pierce said, "Here we are a year later or more after all these charges were made and yet none of the dire warnings, the 'sky is falling rhetoric' that was thrown around at the time, have come true. Are our children suffering more lead poisoning as a result of these appointments? Of course, the answer is no. Where is the problem? What is the bad advice? What is the catastrophe that is happening to our public health system? The facts are that nothing has happened. The advice continues to occur. Meetings go on. Where's the beef?"

Critics take a different view. Representative Henry A. Waxman, a California Democrat and a frequent leader of his party on scientific issues, established a Web site where his staff detailed the Bush administration's "political interference with science."¹⁹ He has charged that the administration has repeatedly manipulated the advisory committee process by appointing unqualified persons with industry ties or with ideological agendas, stacking advisory committees, and opposing the appointment of qualified experts.

In an editorial in *Science*, 10 prominent scientists wrote that "scientific advisory committees do not exist to tell the secretary what he wants to hear but to help the secretary, and the nation, address complex issues."²⁰ Donald Kennedy, the editor of *Science* and a commissioner of the FDA during the Carter administration, criticized "an epidemic of politics" in which "advisory committees are shut down and reassembled with new members, and candidates are subjected to loyalty tests." He wrote that "what's unusual about the current epidemic is not that the Bush administration examines candidates for compatibility with its 'values.' It's how deep the practice cuts, in particular, the way it now invades areas immune to this kind of manipulation."²¹ This view was amplified and extended in the recent report by the Union of Concerned Scientists.² The report noted that "there is a well-established pattern of suppression and distortions of scientific findings by high-ranking Bush administration political appointees across numerous federal agencies" and that "there is strong documentation of a wide-ranging effort to manipulate the government's scientific advisory system to prevent the appearance of advice that might run counter to the administration's political agenda." Bush administration officials have disputed these charges.

PRIOR CONTROVERSIES

Scientific advisory committees have played important roles throughout the nation's history, in particular during wars and other times of crisis. Through much of the 20th century, there was a general commitment to a rational, enlightenment view of the importance of science, according to Paul C. Light of the Brookings Institution and New York University's Wagner School of Public Service. Gradually, things changed. Light, who has extensively studied presidential appointments, said in an interview that "politics could play a role for sure but it was really inappropriate to staff these advisory boards with people with explicit political views about science."

According to a recent report on the NIH, between 1972 and 1974, when the Nixon administration was trying to gain control over the NIH budget, "there was conflict within the scientific community over the perceived politicization of the advisory committee appointment process; this issue re-emerges from time to time."²² For example, the Science Advisory Board, a committee that advises the Environmental Protection Agency, has frequently been mired in politics.²³⁻²⁵ In the 1980s, during the Reagan administration, there was a controversy about a "hit list" of scientific advisers to that agency who were allegedly targeted for exclusion from future appointments because of their liberal or pro-environment viewpoints.^{23,26} In addition, an ethics advisory board in the executive branch was disbanded because of disputes related to abortion.²⁷ In 1989, when President Bush's father was president, Louis W. Sullivan, the secretary of the DHHS, tried to end a controversy over political tests for scientific jobs. The controversy had begun after candidates for leading positions were questioned about their views on abortion and research with the use of fetal tissue. Sullivan drew a line at the level of assistant secretary for health and said that below that level there would be no ideological "litmus test."²⁸

THE FEDERAL ADVISORY
COMMITTEE SYSTEM

Congress enacted the Freedom of Information Act in 1966 and the Federal Advisory Committee Act in 1972. At the time, there were about 5000 federal advisory committees, many of which operated in secret. Some legislators and members of the public felt that the "unchecked proliferation of advisory

committees and their closed methods of operation were creating a ‘fifth arm of government’ standing outside the networks of democratic control,” according to Sheila Jasanoff, of Harvard University’s John F. Kennedy School of Government.²³ The Federal Advisory Committee Act established uniform procedures for committees and led to the elimination of many of the groups. All committees had to be specifically authorized by Congress, by the President, or by an agency head. All had to have written charters. Other provisions included open meetings with advance notice of the time and place, detailed transcripts, and some rights of public participation.

The act also required committee membership “to be fairly balanced in terms of the points of view represented and the functions to be performed.” The committees’ advice and recommendations are not to be “inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee’s independent judgment.”⁸ The present controversy centers on the meaning of this section in practice.

Each year, more than 50,000 people serve on federal advisory committees, including new members, those who are reappointed, and those whose terms are coming to an end. Depending on the specific committee, the President, a department or agency head, or other senior staff in the executive branch may appoint the members. Agency staff will often collect and propose names and have important roles in making the appointments, but they do not make the actual appointments. It takes about 1500 full-time equivalents of federal staff and \$281 million a year to run the system, including the costs of federal staff. Advisory committee members may receive a per diem fee or a stipend, depending on the agency, and are usually reimbursed for travel expenses. The General Services Administration administers the act and maintains a public data base that provides information about all the committees.²⁹ There is a committee management office at each agency.

Table 1 provides information about advisory committees at federal agencies that have responsibilities related to science and health. The DHHS has 247 advisory committees, many of which are appointed by the secretary. The NIH has 144 chartered advisory committees, the largest number of any executive-branch agency.³⁰ Many of the NIH committees are review groups, which evaluate applications for research funding. The NIH director

Table 1. Federal Advisory Committees.*

Total number of committees, 977
Active committees, 948
Inactive committees, 29
Type of active committee
Nonscientific, 315
Scientific and technical, 214
National policy and issues, 156
Grant review, 102
Other, 161
Agency committees
Department of Health and Human Services, 247†
National Institutes of Health, 144
Food and Drug Administration, 30
Centers for Disease Control and Prevention, 23
Department of the Interior, 115
Department of Agriculture, 54
Environmental Protection Agency, 26
National Aeronautics and Space Administration, 13

* Data are from the Federal Advisory Committee Act data base²⁹ and agency statistics for fiscal year 2003.

† Not all Department of Health and Human Services agencies are shown.

or the institute or center directors make these appointments. Advisory boards and councils perform the second level of peer review for research grants and advise the institutes about policies and programs. Recommendations of the FDA’s advisory committees about the approval of medications and medical devices or their advice on other topics is often pivotal.³¹ The FDA’s associate commissioner for external relations has responsibility for these appointments.

According to Pierce of the DHHS, the department takes into account many factors before making an appointment, starting with the person’s qualifications in the areas of the committee’s jurisdiction. It aims to balance members according to geographic region, sex, race or ethnic group, and diversity of opinion. “We want people with differences of opinion who represent different points of view,” Pierce said. “We want to bring new thinking and new people into the process.”

EVALUATING THE CONTROVERSY

It is difficult to draw an irrefutable connection between advice from a particular committee and a flawed policy or decision. Even if some of the members of a committee had been different, there is no way to be certain that the advice would have differed

PROPOSALS FOR REFORM

or that the government would have chosen a different course. In the case of a committee that reviews grants, recommendations can always be second-guessed. This does not necessarily mean that there is systematic bias. The counterargument is that it is wrong to focus mainly on outcomes. To maintain the integrity of federal advisory committees, advocates insist that the appointment process and subsequent committee deliberations should emphasize relevant scientific or clinical expertise and be free of ideological, political, and economic bias.

The controversy can also be viewed as part of a more general debate about the role of experts. Complex societies rely on experts “to have thought more carefully, and responsibly, than any of us, as individual citizens, could possibly hope to do” on many topics, according to Jasanoff of Harvard. When presidential administrations use science and scientists to further their political objectives and to make sure they get the results they want, they undermine the role of scientists as “ostensibly” neutral experts and of expertise as “almost the foundation stone on which the functioning of modern democracies has come to rest.”¹² Some, such as Sally Satel, a psychiatrist and a fellow at the American Enterprise Institute, argue that controversy is also more likely between scientists and a conservative Republican administration than between scientists and a liberal Democratic administration. The assumption is that scientists often share the views of Democratic political appointees rather than those of Republican appointees and that a shared ideology may reduce the potential for conflict about appointments to advisory committees.

Although separating appointments to federal advisory committees from politics and ideology has support among scientists and health professionals, many in government would not back it and, at a certain level, everyone has a point of view. “Insulating appointments to advisory committees from politics is just about an impossibility,” according to G. Calvin Mackenzie, a professor of government at Colby College and an expert on the presidential appointment process. In an interview, Mackenzie said, “This is not what the President wants, this is not what the President’s supporters want, and this is not what the members of Congress want. When scientific decisions interact with the moral values or the political concerns of their constituents they are going to apply a litmus test. They will never say that, but they will do that all the time.”

One approach to reform would be to publish the names of proposed appointees in the *Federal Register* and give the public a month to comment. The government could then consider these comments, and make changes, before a committee’s membership was made final. The national academies — the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council — are private organizations with a congressional charter. Like the federal advisory committees, they provide scientific and technological advice to the nation. They routinely use a procedure for public comment in determining whether a committee contains “the requisite expertise to address its task and whether the points of view of individual members are adequately balanced such that the committee as a whole can address its charge objectively.”³² The federal government already uses the mechanism of public comment for proposed regulations and other matters. This approach would probably require that Congress amend the Federal Advisory Committee Act.

A second approach, as outlined by Kennedy, of *Science*, would be a hierarchy of appointments.³³ For senior appointments, considerations of scientific merit as well as tests of political support for the President’s policies would be appropriate. For committees and panels advising scientific agencies, the primary criteria would be scientific merit, but policy considerations could have some role. For committees that evaluate research proposals or peer-review research findings, selection would be based solely on scientific merit. Even if an outside group were to monitor the process, this approach would in large part depend on an administration’s willingness to follow this hierarchy. A variant of this approach would be to eliminate situations in which presidential appointees such as the secretary of a federal department are responsible for appointments to scientific and technical advisory boards and delegate this authority to senior scientific officials.

A third approach would be greater use of non-partisan expert groups that are not part of the executive branch — groups that perhaps would be established by Congress or under the auspices of the national academies. For example, to improve the protection of human research subjects, the Institute of Medicine recently recommended that Congress establish an independent multidisciplinary expert

advisory group.³⁴ As an example of a successful model, it cited the Institute for Laboratory Animal Research. This standing committee of the National Research Council provides advice on the care and use of laboratory and other animals in research. The chair of the National Human Research Protections Advisory Committee, which was dissolved by the Bush administration, was an adviser to the Institute of Medicine committee that produced the recent report.³⁴ Committees of the national academies, however, are not immune to ideological, political, and industry pressures. Their committees are also not subject to the Federal Advisory Committee Act, although there are explicit requirements for public access. Another example is the Health Effects Institute, an independent, nonprofit corporation in Cambridge, Massachusetts, that is supported jointly by the Environmental Protection Agency and industry and that provides advice on environmental issues.

Congress would have to establish independent advisory groups and would then have to provide funds and the authority for them to continue to exist. A notable example of a now defunct group is the Office of Technology Assessment, a small congressional agency established in 1972 and often praised for providing impartial advice and analysis. In 1995, the Republican majority in Congress terminated the office, as part of a round of budget cutting that included reducing Congress's budget.³⁵ Another example is the Biomedical Ethics Advisory Committee, which Congress established in 1985. Owing to a political impasse on abortion and disagreements about who should be appointed, it took almost three years for the committee to meet for the first time. It met only once more before closing in 1989, a victim of abortion politics.²⁷

The integrity of the peer-review system at the NIH is of particular concern.³⁶ Although not perfect, this system "is the best guarantee we have overall that scientists will carry out research that is of high quality and high potential for scientific progress," according to Harold Shapiro, the former president of Princeton University and the chair of a committee of the National Academy of Sciences that recently evaluated the structure of the institutes.²² The committee reported that it is "essential that members be appointed to [NIH] advisory groups because of their ability to provide scientific or public health expertise to the review and approval of awards and policies. They should not be selected to advance political or ideological positions." It also recommended that the independence of advisory

councils be strengthened by appointing more members with research support from other institutes or from outside the NIH.²²

As a result of the controversy about federal advisory committees, two potentially influential reports are forthcoming. At the request of Congress, the General Accounting Office is examining the role of scientific advisory committees in the development of national policies and regulations and their size, scope, and authority. It is also evaluating the adequacy of the procedures used by agencies to ensure that the committees can provide scientifically sound, independent, and balanced advice. In addition to the DHHS, the review involves the Departments of Agriculture, Energy, and the Interior, the Environmental Protection Agency, and the National Aeronautics and Space Administration. A committee of the national academies is preparing a report on presidential appointments to top science and technology positions and the selection of members of federal committees providing advice on science-based policy and on the review of research proposals.

There is continuing concern over the injection of politics into science and the role of groups with economic and social agendas in influencing government regulations.^{37,38} Light, of the Brookings Institution, said that although the Bush administration is not the first one to appoint people to advisory committees who share its political views, the continuing "lowering of the threshold" makes it easier for future presidents, regardless of their party, to do the same thing. According to Mackenzie, of Colby College, "No one in America has any trouble sleeping at night because they are worried about members of federal advisory committees. Politicians are free to do whatever they want. What they want to do is to keep the status quo because there are political benefits in that for them, even though intellectually they can understand that this may not be the perfect system."

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