

News & Comment

Science Advisers Need Advice

Charges that two scientists who served on an EPA advisory panel later broke conflict-of-interest laws raise some vexing questions

Ethics In Science

This article on conflict of interest in advisory committees is the first of three articles on scientific ethics. Conflicts of interest in biomedical research are discussed on page 23. Congressional hearings on scientific misconduct are reported on page 24.

WHEN THEY AGREED to sit on a federal science panel in 1982, Wendell Kilgore and Christopher Wilkinson never imagined their gesture of public service would end in public humiliation.

In May the two toxicologists—both of whom have long and distinguished university careers—were accused during a Senate press conference of violating U.S. standards on government ethics. They may have broken a “revolving door” rule that limits the kind of consulting jobs that can be accepted after leaving an advisory panel.

Their troubles offer a lesson to any scientist who sits on a federal committee: government service incurs ethical and legal obligations that extend for a lifetime. They also raise a vexing question: how much can the government limit its advisers’ involvement with industry without isolating itself from the expertise it seeks?

Floodlights hit the case of Wendell Kilgore and Christopher Wilkinson on 15 May when Senators Harry Reid (D-NV) and Joseph Lieberman (D-CT) charged that the pesticide program at the Environmental Protection Agency (EPA) is riddled with pro-industry bias. Lieberman said that seven out of eight members of EPA’s Scientific Advisory Panel, a pesticide review board, were consultants for the “chemical industry.” And he singled out two members—Kilgore and Wilkinson—as possible violators of the ethics code, asking EPA’s inspector general to investigate. At issue is the same revolving door section on which former White House adviser Lyn Nofziger was convicted. (Last week an appeals court overturned the conviction on grounds the prosecution failed to prove criminal intent.)

In the EPA case, only Kilgore’s file has been forwarded to the Justice Department for review at this time, although both scientists have been investigated. Kilgore’s attor-

ney predicts the case will be dropped.

But even if these cases fizzle out, the senatorial blast could mark the beginning of a new cycle of inquiry into advisory groups and their ethical conflicts. Officials at EPA and the National Academy of Sciences say they have already decided to update disclosure procedures. The potential impact, if it goes beyond EPA, is broad: the U.S. Office of Government Ethics says the government keeps confidential disclosure forms on more than 100,000 advisers, including those of scientists—physicists, chemists, and biologists—who deal with issues ranging from biomedicine to arms control.

Kilgore, an environmental toxicologist with 29 years’ tenure at the University of California at Davis, also chaired the scientific panel that guides California in implementing its new toxic chemical law Proposition 65. Wilkinson, another toxicologist, taught at Cornell University for 22 years before moving in 1988 to Versar, Inc., an environmental risk management firm.

Both men say they had trouble reading the ethics code (see box). Kilgore says he was given some official papers when he began work on the panel, but was not told about the lifetime prohibitions. “You really have to have an attorney to interpret the law,” he says.

Wilkinson says the public accusation this spring came as “a big shock.” “I feel that my personal and professional integrity have been impugned,” but “I don’t feel guilty at all.” He says “most scientists have consulting agreements, and if an issue came up [affecting a client during a panel meeting] we would simply excuse ourselves and leave the room.” But he claims, “we were not told” the ban applied permanently.

Ignorance of the law is no excuse, of course—at least in the eyes of the law. However, Donald Nantkes, a veteran ethics specialist on EPA’s legal staff, says that in his experience the rules “have been used more as a weapon than as a shield”—as a cudgel against adversaries rather than a screen to keep out bad consultants. Nantkes says all EPA employees receive a package on ethical responsibilities, but it is possible that no one spelled out the post-service rules to the scientific panel.

The ethics investigations were launched at a hearing in which Senator Lieberman, a member of the EPA oversight subcommittee, attacked EPA for its waffling on Alar, a Uniroyal chemical used to promote crispness in apples. EPA’s Office of Pesticide Programs wanted to ban the chemical in 1985 because a breakdown product called UDMH looked like a potential carcinogen.



Hunter and quarry: Senator Joseph Lieberman (left) fired a blast at EPA’s Science Advisory Panel for ethics code violations and hit, among others, toxicologist Wendell Kilgore (right).

However, the science panel, including Wilkinson and Kilgore, unanimously rejected the rationale for doing so. "The data were terrible," says Wilkinson. Higher-ups at EPA sided with the scientific panel, to the staff's chagrin. The ban was called off and new studies were ordered.

Meanwhile, EPA permitted Uniroyal to continue selling Alar. Then, early this year, CBS's *60 Minutes* reported on the Natural Resources Defense Council's findings that Alar might cause cancer in children (*Science* 17 March, p. 1430). The Senate threatened to pass a law banning the chemical. Uniroyal retreated. Although the company still insists it is safe to use Alar, product manager Christopher Exton says, "We decided to withdraw it from sale in the United States because the apple growers [who were hurt by the publicity] begged us to."

But that didn't end the story for the two toxicologists. Wilkinson says the furor—and the attack on Kilgore and himself—is part of a tough political fight over the degree of muscle EPA should use in controlling pesticides. One casualty, he fears, will be the good name of EPA's scientific advisers, and another may be its ability to recruit good advisers in the future.

Wilkinson's personal troubles began, he recalls, in February 1987, about 5 months after he left the EPA panel, when Uniroyal called him asking if he would review some data from a 90-day feeding study on UDMH. He agreed. The company had launched a series of "chronic" 2-year studies with rodents as required by EPA to determine whether hints of carcinogenicity seen in 1985 were real. The lab running the test told Uniroyal that, based on a 90-day study, the maximum doses of UDMH for mice should be 10 parts per million (ppm) for males and 20 ppm for females. Higher doses could swamp the animals' metabolic systems and destroy their livers, leading to early deaths and unreliable tumor data. Uniroyal followed the lab's recommendation, but after the study had begun, EPA asked that the maximum doses be raised to 40 ppm and 80 ppm. Uniroyal tried to appeal EPA's demand in 1987. Exton says, "We called on Chris [Wilkinson] because we thought of him as a senior toxicologist, someone having credibility with EPA."

Wilkinson looked at the data and agreed to go with Uniroyal representatives to meet the EPA toxicologist who had insisted on the high doses and try to dissuade him. Wilkinson says: "We went along to tell EPA that it was crazy to do this because you'd be exceeding the maximum tolerable dose and the animals would die." But EPA took "not one whit of notice," he claims. EPA's high doses were used. Uniroyal now says that the

Ethics by the Book

The rules that apply to advisory panels are part of a dense structure of thou-shalt-nots assembled since 8 May 1965 when President Lyndon Johnson issued Executive Order 11222. Its aim was to prevent self-dealing by government employees and to avoid even the appearance of financially motivated bias or trading on personal acquaintance. Additional rules were added by the Ethics in Government Act of 1978 and by revisions of the Freedom of Information and Privacy Acts in 1985. Other executive decrees have affected the law, the most recent coming from George Bush on 12 April 1989. But the only one for which regulations have been written is the 1965 order. A more up-to-date code has been in the works for years.

When it comes to advisory groups, the key to the matter, says Donald Campbell, deputy director of the U.S. Office of Government Ethics, is to know whether the panel is made up of "representatives" or "special government employees." The sponsoring agency determines this important issue and is supposed to let its panelists know which type they are and what rules apply. Representatives are often members of a particular industry from whom the government wants advice—for example, timber company executives, for international negotiations on lumber trade rules—and such people are exempt from the law. Advisers who represent the public interest (and this applies to many scientific advisors) are considered U.S. employees and are not exempt. At EPA, all scientific advisers are special government employees, bound by the ethics law, which carries a maximum penalty for violators of a \$10,000 fine and 2 years in prison.

Some basic rules are as follows:

- Special federal employees may not be directly involved in "particular matters" (such as a decision to release a drug to the market) that affect their own or their employers' financial interests (stock or consulting income from the company that makes the drug). Personal interests include such things as stocks held by a spouse or children and consulting agreements.

- Ex-employees are permanently barred from representing a client before a federal agency on a "particular matter" they handled while in government service. This means that a scientist who served on, say, an advisory committee determining the safety of a pesticide can never represent the manufacturer of that pesticide in future government deliberations on the matter. Consulting privately on the matter is not ruled out, nor is it wrong to represent a client on that matter in state or private proceedings.

- Business partners of a federal employee or ex-employee are permanently barred from representing a client in federal proceedings on a "particular matter" handled by the employee during government service.

- Special government employees must file a confidential statement of assets and sources of income. Public interest groups suing to get access to the documents hope to persuade the court that much of the data on these forms should be released.

■ E.M.

mice are dying off because of severe liver damage, as predicted, months before the study's end in January 1990.

Using risk estimates based on preliminary data from these high-dose mice, EPA is recommending once again that Alar be banned. Pesticide office chief Victor Kimm says EPA is confident about the decision because the blood vessel tumors in the mice are uncommon; they are the same kind that appeared in earlier studies, and other tumors are showing up in rat data.

Meanwhile, Wilkinson got word this spring that he was being investigated by the EPA's inspector general for violating the ethics law. It puts a lifetime bar on "special government employees"—including advisory panel members—representing a client on a "particular matter" in dealings with the

federal government if they dealt with the same matter during government service.

Kilgore ran into trouble because he agreed to testify in 1988 as an expert witness for the Northwest Food Processors Association, which was suing EPA to get an exemption from EPA's ban on Dinoseb, a fungicide made by Uniroyal. Kilgore had served on the science panel when it reviewed Dinoseb and so, according to EPA, should not have accepted the job. He is "amazed" by the consequences, but says "I would have followed the rules had I known them."

Senator Lieberman doesn't accept their protestations. He finds it "outlandish" that scientists who served as guardians of the public interest would sign up as industry agents within months after leaving EPA's panel. The issues are "pretty basic," he

thinks, and don't require a close reading. Although he has not probed further, he said in a telephone interview, "I suspect there is a broader problem," since he found that "seven of the eight members [of the scientific advisory panel] were consulting for the chemical industry."

When Lieberman speaks of industry conflicts, he uses the term broadly. Included in his list of questionable consulting ties are those with the Chemical Industry Institute of Toxicology (CIIT), presided over by Roger McClellan, who also chairs EPA's Clean Air Scientific Advisory Committee. In addition, McClellan is president of the Society of Toxicology, the top professional society for both academe and industry.

"It's a small world," comments Sarah Walzer, an aide to Lieberman. While consulting for a nonprofit, generic research outfit like CIIT may not present any "specific conflict," she says, it creates an appearance of bias. Even though CIIT researchers may be insulated from the companies who support the work, she notes, "they know where their money comes from." In this case, "We're not saying these folks shouldn't be on the panel, but it may mean the American consumer should be getting other perspectives" as well. Lieberman and Reid want more pediatricians and public health experts on EPA's panel.

McClellan sees no basis for suspicion about CIIT, which is governed by an independent board and does no business-oriented research. He points out that in 1979 it disclosed that rats in a formaldehyde study had developed nasal tumors, a fact it made public even before completing the study. The announcement caused some CIIT sponsors to "take a deep breath," McClellan says, but "it was the right thing to do" and set a standard for future studies.

This sign of bona fides was not enough for EPA. It recently sought a ruling from its legal office, which reported back that experts could consult for both CIIT and EPA without facing a conflict. The reason for EPA's concern was that even if consulting ties pose no direct conflict, federal employees must avoid the appearance of conflict, which can be an elusive goal. It is a "murky" business, says Donald Barnes, executive director of EPA's Science Advisory Board. "If somebody wants to find something that they can blow up out of proportion, they can."

Barnes says that advisory groups try to



Pop Tox. After the controversy over Alar in apples hit the headlines, attention was drawn to who had been advising EPA on the toxicology.

avoid problems through disclosure and voluntary recusance. When panel members come on board, they fill out a confidential financial form listing assets and income, including past and present consulting agreements. In a new approach, members also state their interests as each new matter is taken up by the panel and, if it seems right, excuse themselves from the proceedings. Only in "the most egregious instances" is someone asked to step aside, which has happened once in Barnes' tenure.

But political advocacy groups often see companies playing a more sinister role, and they want to know more about consultants' backgrounds. Ellen Silbergeld, a toxicologist at the Environmental Defense Fund who also sits on EPA's Science Advisory Board, says she has not noticed more frank disclosures recently. She thinks EPA still has a long way to go. She adds that the poorest handling of bias she has encountered was at the Food and Drug Administration, where she briefly sat on a panel reviewing the use of a pesticide in shampoo. She learned that two members of the panel were consultants to the shampoo company and were being allowed to vote.

Asking experts to make confidential disclosure relies too much on self-enforcement, argues Patti Goldman of Ralph Nader's Public Citizen organization. Outsiders "don't get enough information to police these panels." Public Citizen and the Natural Resources Defense Council have petitioned EPA to release advisers' personal data with the dollar amounts blocked out to preserve some privacy.

More of this kind of information may be made public if the *Washington Post* is success-

ful in a legal battle it has been waging with the federal government. For 10 years, the *Post* has been trying to get copies of disclosure forms filed by advisers to the National Cancer Institute. The case has been in and out of the court of appeals several times, and, according to the *Post's* attorney Paul Mogin, a critical hearing will be held in the U.S. District Court for the District of Columbia on 27 September. The burden is on the government to show that releasing the forms would significantly limit its ability to collect such data in the future.

It may become harder not only to collect information, some U.S. officials say, but also to recruit experts. One EPA spokesman, for example, says that the agency is already trying

to make headway against a 50% refusal rate, a situation that is likely to worsen. The facts of life, says Bruce Jaeger, executive director of EPA's pesticide panel, are that the agency is allowed to pay a flat consulting rate of no more than \$230 to \$270 a day. This is not a huge attraction for the nation's best toxicologists, who command \$1000 a day from industry. They serve on federal panels for the prestige, not for the money, and certainly not for the privilege of being denounced as flunkies.

However, critics are not impressed by the shortage-of-talent argument. "In my view," says Goldman, "if someone is going to be deterred because the public will learn that they have this nexus with the industry, then the world is better off." Ironically, Kilgore and Wilkinson themselves agree that asking for public disclosure is the best way to avoid misunderstandings, and both say they would not object to making public a list of consulting agreements.

Joshua Lederberg, president of Rockefeller University, says that in recent weeks he has become a de facto "conflict-of-interest task force" consulting with a number of scientists about ethics requirements. He thinks the present standards are "reasonable," but believes they would work better if it became standard practice to make full public disclosure of all consulting arrangements.

It is not clear how EPA and other agencies that rely on free lance expertise will cope with new demands for ethical purity. But a reasonable guess is that they will be pushed toward disclosing more than in the past about those who serve on their top policy committees. ■ ELIOT MARSHALL