

# The Politics of Alternative Medicine

The head of NIH's Office of Alternative Medicine has quit, charging that a powerful senator and advocates of unconventional therapies are shaping the office's research agenda

Devising a plan to study unconventional medicine, says one observer on Capitol Hill, is like "orchestrating a roomful of cats ... or setting the agenda for a convention of anarchists." The field is a smorgasbord of therapies—ranging from meditation and prayer to acupuncture, homeopathy, shark-cartilage enemas for cancer, biofeedback, massage, dosing with bee pollen to stop allergies, and many, many more. Each school is confident that its methods are the best. All distrust "the medical establishment." And most aren't skilled in collecting data. Yet for the past 3 years, the National Institutes of Health (NIH) has been struggling—under orders from the U.S. Senate—to rope these diverse schools into a coherent research program.

In the past month, that effort has been thrown into chaos, and even NIH Deputy Director Ruth Kirschstein admits that it "needs better management." The physician who has directed NIH's Office of Alternative Medicine (OAM) for the past 24 months, Joseph Jacobs, has quit—effective today. And Jacobs is leaving with a bang: In an interview with *Science* he blasted politicians—especially Senator Tom Harkin, the powerful Democrat from Iowa—and some advocates of alternative medicine for pressuring his office, promoting certain therapies, and, he says, attempting an end run around objective science.

He's not the only one speaking his mind. On 1 September, members of OAM's independent advisory council—most of them alternative medicine advocates—held their first official meeting, during which they attacked NIH for setting an agenda for OAM without their consent. The panel got OAM to make drastic, last-minute changes in a plan, drawn up 6 months ago, which called for spending \$1.8 million on up to four centers to examine alternative therapies, a plan that some activists deplored as pro-establishment. The number of centers will be halved, but because the money must be spent by 30

September—the end of the fiscal year—OAM is working slapdash to find a way of spending the full \$1.8 million.

And if this were not pressure enough, Congress has just turned up the heat. Led by Harkin, Congress has nearly doubled OAM's budget for 1995, which begins next week, increasing it from \$3.5 million to \$6 million. The amount may seem small—just 0.05% of NIH's total appropriation—but running OAM has suddenly become a major concern in the NIH director's office. The chiefs have snapped to attention in part because Harkin, who put a clause in the 1992 NIH appropriation creating the office of alternative medicine, chairs the appropriations subcommittee that approves the budget for the entire NIH.

Harkin and his assistant, Ed Long, place responsibility for the chaos squarely on NIH and Jacobs. Long claims Jacobs did a "good job of promoting alternative medicine," but "wasn't a good administrator," "couldn't run the office," and failed to establish good relations with the activists and the

NIH bureaucracy. Long says Harkin met personally with Kirschstein and NIH Director Harold Varmus early this year to tell them: "Make [OAM] run right, and we'll have no complaints."

Kirschstein has stepped in to try to straighten out the muddle. She agrees it will be "a challenge" to make good use of the 1995 funds Congress is providing. One problem will be to find enough staff to do the kind of studies requested by Harkin and the activists: "field investigations" in which staffers are sent out to examine and "validate" off-beat therapies. NIH, she notes, is supposed to cut 400 employees in the next year as part of a governmentwide cutback. Yet Kirschstein says she supports the congressional mandate for the office and says NIH will comply: She predicts that Jacobs' replacement will be recruited soon and will quickly arrange to spend OAM's doubled budget. To succeed, however, the new chief will have to heal wounds

and build bridges between the activist community and NIH, walking a tightrope, Jacobs says, between the enthusiasts and the entrenched skeptics.

## Rude awakening

When Jacobs arrived at OAM in October 1992 as its new full-time director, he was viewed as an easygoing "maverick," as *People* magazine put it—one "who does not see the orthodox and unorthodox as incompatible." The son of a Mohawk and a Cherokee, he had grown up with Native American medicine in upstate New York. After receiving an M.D. from Yale University, Jacobs had served as a pediatrician in the Indian Health Service. Later, with an M.B.A. from the Wharton School, he worked as a medical director at the Aetna Life Insurance Company. But Jacobs says that none of this prepared him for the "professionally insulting" experience of dancing to the tune of the alternative medicine lobby.

OAM had been in business for a year by the time Jacobs was appointed and had already spent the initial \$2 million provided by Harkin and Congress. One large chunk—about \$750,000—went to the National Cancer Institute (NCI) to investigate a topic of interest to Congress: "antineoplaston" therapy, a controversial cancer treatment (see box). The rest of the budget went to pay for salaries, travel, staff reports, and conferences. When Jacobs came aboard, he says he began working on a plan to search out "novel approaches" to clinical care, which he describes as "any modality that might help the patient get through the day." He was interested in setting up cooperative centers in academia to provide "outreach" to innovative therapists. But 8 months into the job, Jacobs says, he learned that he would not have much freedom to exercise his own judgment. He learned this, he says, at "The Hearing"—a special congressional review convened by Harkin on 24 June 1993.

Harkin began the session by telling how he had been cured of his allergies after his friend Berkeley Bedell—a former Iowa congressman and multimillionaire fishing-tackle manufacturer—persuaded him to take capsules of bee pollen. Later, Bedell himself appeared as a witness, plugging "a simple type of research" to test bee pollen and other therapies. He called it "outcomes research," a term he used interchangeably with "field studies."



PAUL MCGUIRE

**Out with a blast.** Joseph Jacobs says he resigned rather than carry out Congress's agenda for OAM.



## Shark Cartilage, Bee Pollen, and 'Antineoplastons'

The Office of Alternative Medicine (OAM) has generated lots of controversy (see main text) but, so far, has funded relatively little research. The projects approved so far, however, may be a preview of what's to come from the OAM as supporters in Congress boost its funding.

In its first year the OAM joined with the National Cancer Institute (NCI) to sponsor a three-site trial of "antineoplaston" therapy devised by Stanislaw Burzynski, a physician in Houston. OAM pays the Burzynski Institute to prepare batches of amino acid derivatives (phenylacetic acid, among others)—originally isolated from urine collected in a Texas park but now synthesized. Burzynski sends these antineoplastons to clinicians at NCI, the Mayo Clinic, and the Memorial Sloan-Kettering Cancer Center, where the therapy is tested in adults with recurrent brain tumors who have exhausted conventional therapy. So far, the clinics have accrued just three patients. It's been difficult to find more, clinicians say, because Burzynski has set very narrow criteria, limiting the trial to people with small tumors, no spinal involvement, and good neurological test scores. Burzynski, meanwhile, is defending himself against a fraud suit brought by an Oregon pension fund, which hopes to recover \$90,000 it paid Burzynski for treatment of a beneficiary. In July, a U.S. appeals court upheld a lower court's ruling against Burzynski.

In its second year, OAM gave out exploratory grants of \$30,000 each to 30 therapists to "identify promising areas of future research." These awards, selected by peer review from a pool of 452 applicants, cover the waterfront. They include acupuncture for depression, massage to stimulate AIDS patients' immune systems, hypnosis to speed bone healing, music therapy for patients with brain injury, dance for cystic fibrosis, macrobiotic diet to control cancer, yoga to control heroin addiction, biofeedback to treat pain, prayer to control drug abuse, and others. John Spencer, OAM's grants officer, says these grants may not yield published articles, but he plans to write up a report next January summarizing what investigators learned.

This week, OAM plans to fund another round of small explor-

atory grants and between \$1 million and \$1.8 million in collaborative grants to two research centers, one focused on alternative treatments for pain and the other on cancer. In addition, OAM staffers say the office is lending technical support for four "field studies." The aim is to share expertise in running clinical trials with alternative medicine practitioners and help them apply for Investigational New Drug permits. The studies include:

- Using bee pollen to control asthma. This therapy intrigues Senator Tom Harkin (D-IA), who claims it cured him of allergies. The pollen will be purchased from the family of the late Royden Brown, the man who gave Harkin his pollen capsules. The clinical research, according to OAM, may be conducted at the University of Texas, Galveston. Brown and his family recently paid a fine of \$200,000 to the Federal Trade Commission, which had filed a complaint against Brown for false advertising of bee pollen. Brown himself died in his bath this year, and NIH officials say this has slowed plans for the field study.

- Further research on Burzynski's antineoplastons—this time for control of pediatric brain tumors. Burzynski intends to recruit the patients, provide the drugs, and carry out the therapy.

- An examination of the use of shark cartilage and a healthy diet to stop cancer. Charles Simone, a former NCI oncologist who now runs his own center in Lawrenceville, New Jersey, hopes to learn whether shark-cartilage therapy is effective in reducing solid tumors. Preliminary data, he claims, show beneficial effects in 34% of his cases, although he agrees it's impossible to separate out the effects of the diet he also prescribes from those of the cartilage. The treatment does not seem to prolong life, however.

- A test of Revici therapy, a treatment for cancer devised by Emanuel Revici, a 96-year-old Romanian physician in New York City. An OAM official says the procedure is "complex" and difficult to describe, but involves giving patients a mixture of lipids and selenium compounds, adjusted specifically to suit the individual. NIH is still nailing down details, such as identifying a licensed practitioner to conduct the research.

—E.M.

NIH, Bedell said, should hire staffers to locate anyone who claims to have a successful therapy, search the files, and "just simply find out whether what he claims is correct."

Bedell also complained that NCI wasn't moving fast enough to validate antineoplaston therapy. Harkin responded that he would "get their attention real fast. I have been around here 18 years, and I have figured out how to use the purse strings."

But Bedell's idea for field studies wasn't the only concept presented at the hearing. David Eisenberg, an internist and instructor at Harvard Medical School, urged NIH to create a series of centers where people interested in alternative medicine could learn about biostatistics and data gathering. The goal, he said, would be to create a group of skilled investigators and sponsor "unbiased studies" by "people who have no vested interest" in the alternative therapies under study. Anyone with a new idea could turn to these centers to learn how to apply for peer-reviewed grants from NIH or experimental

permits from the Food and Drug Administration. NIH officials, including Kirschstein, liked the idea. But activists like Ralph Moss, publisher of the anti-establishment *Cancer Chronicles*, saw it as a scheme to fund "big-name universities."

When it was Jacobs' turn to testify, Harkin raked him over the coals for OAM's slow pace and small staff, stressing the need to "investigate and validate" therapies. When the session was over, Jacobs recently told *Science*, "it was clear to me that we had to do field investigations.... We had a senator who chairs the appropriations committee telling us: 'This is what you've got to do.'"

The problem with Harkin and Bedell's approach, Jacobs says, is that it is "very naive." While alternative therapists may be

eager to have the imprimatur of an NIH review, they may not want the rigor. Yet without well-controlled data collection, Jacobs

warns, field studies could degenerate into mere anecdote-gathering. "As a taxpayer, I wouldn't trust what comes out of my office under a system like that," says Jacobs.

In a telephone interview last week, Bedell brushed aside questions about how his field studies could be designed to avoid bias. This is a technical detail, Bedell said, and "I'm not a scientist." But he insisted at the hearing—and still insists—that field studies can be done quickly and easily, without fancy statistics or double-blinded

controls. Most patients, he says, don't care how a remedy works; they only want to know whether it works. He thinks it should be



**Alternative advocate.** Senator Harkin credits bee pollen with curing his allergies.



straightforward to get a yes or no answer.

But Jacobs says that, faced with the prospect of having to oversee such research, he informed Kirschstein that he would be leaving OAM the next year, in 1994. In the meantime, he says, OAM tried to foster some exploratory studies. The office solicited proposals for small pilot studies in alternative medicine. More than 450 came in. NIH's Division of Research Grants assembled ad hoc review panels, selected the best, and in October 1993, OAM awarded 30 grants at \$30,000 apiece. In addition, with "tacit support" from NIH Director Harold Varmus and the direct help of Kirschstein, Jacobs says, OAM in April 1994 solicited proposals for \$1.8 million to be spent on three or four centers in the Eisenberg model.

#### A final showdown

If the June 1993 hearing marked Jacobs' first major disappointment, he says the second came in January 1994, when NIH was considering candidates for an 18-member committee to advise the OAM. It became clear, says Jacobs, that the top NIH staff would go along with demands from Harkin's office and include on the list of candidate advisers four activists picked by Harkin. The four were Bedell; Moss; Gar Hildenbrand, president of the diet-oriented Gerson Research Organization of San Diego; and Frank Wiewel, former owner of a small recording studio who now runs an advisory and travel service for unconventional therapies, Patients Against Cancer of Otho, Iowa.

Jacobs had clashed often with these "Harkinities," as he calls them, when they served on an ad hoc advisory panel in 1993. He didn't want them on his permanent board. But he says the names he suggested "weren't looked on very favorably by Harkin's staffers." So he says NIH revised his list and sent it along to the Department of Health and Human Services (HHS). Varmus declined through a spokesperson to discuss the subject. Kirschstein said the list had been drawn up before she took over the office, but that "Senator Harkin was very interested in particular members being on the council." HHS revised the list further, for example, by removing the name of former surgeon general C. Everett Koop, whom both Jacobs and Harkin staffers had proposed. The letters of invitation went out in May 1994, and the board became official in August.

Meanwhile, Jacobs' fears that the office would be forced to conduct field studies have been borne out. "There's no paper trail," says Jacobs, but he claims that Harkin's staff "made a lot of threats." Long and Harkin's press secretary said that the senator had never spoken to Jacobs except in public meetings. Responding to a rumor among OAM staffers that the senator threatened NIH's budget, Long says, "We did not threaten to hold up the NIH

appropriation." Kirschstein, who says she is unaware of the alleged senatorial threat, confirms that OAM has begun four field studies.

The final confrontation between Jacobs and the advisory group came on 31 August and 1 September, during the board's first official meeting. At that point, Jacobs was a lame duck. Four vocal board members—Bedell, Hildenbrand, Moss, and Wiewel—were outraged that they had not been allowed to vote on the proposal to establish alternative medicine centers before NIH published the proposal and set up a review committee. They were especially enraged when they discovered that some of the panelists with conventional medical credentials—including Eisenberg—had seen the centers proposal in draft form and were candidates for a center award. Hildenbrand, Moss, and Wiewel proposed returning the \$1.8 million to the Treasury, but, realizing this would not help their cause, they abstained as the majority voted to allow two of the four centers to go forward. The unspent money will be used to increase support for the two centers and to fund a second round of small exploratory grants.

After the meeting, Hildenbrand fired off a letter to Harkin on 6 September. He charged that Kirschstein, by approving the decision

to go ahead with the centers, had "stiff-armed her way through with a scheme to divert the lion's share of OAM's discretionary budget to the universities." He also said NIH was plotting to "excommunicate" and ignore advisers like himself. He pleaded for "field investigations" and for Harkin's help.

No one knows how the contretemps will end, although Long insists the senator would be happy to support both field studies and centers, adding that he only wants projects of high scientific quality. Most important, says Long, is to "get a good administrator who can work with the council ... and get the office up and running."

Looking back on the experience, Jacobs says if there's any message he would like to convey, it is that political movements are right to set broad goals but shouldn't "screw around with how NIH or other large organizations do research.... It doesn't work, and it wastes money." Moreover, Jacobs is convinced that NIH, with its intense focus on fundamental science, is the wrong home for OAM. He thinks that alternative medical therapies would get a more sympathetic review in an agency whose heart is in the clinic, not the research lab.

—Eliot Marshall

#### ESPIONAGE

## Was U.S. Researcher a Double Agent?

KARLSRUHE, GERMANY—John Le Carré would be proud of American systems analyst Jeffrey Schevitz' account of his life in the shadowy world of Cold War intelligence. Schevitz was arrested 5 months ago by German police for allegedly passing sensitive information on technology and nuclear policy to the Stasi, the former East German intelligence agency, in the late 1970s and 1980s. Although he has not yet been formally charged, Schevitz admitted last week in an interview with *Science* and in a subsequent press conference that he did deliver information to the Stasi. But he claims he had good reason: He says he was working as a double agent for American intelligence services. "It was like living in a novel," Schevitz says.

German officials, however, dismiss Schevitz' claim to be a double agent, and U.S. sources have told *Science* that some aspects of his story seem implausible. "I am confident that the accused's claim can be disproved," says Rolf Hannich of the German federal prosecutor's office. Hannich says he expects the investigation will be wrapped up within a few weeks.

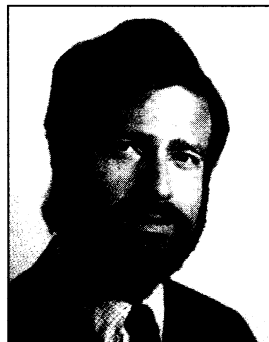
Shevitz, who worked for 14 years as a

systems analyst at the German government's Nuclear Research Center at Karlsruhe, is believed to be the only American arrested so far on suspicion of spying for the Stasi. He was arrested in May and released on 6 September after friends paid \$65,000 in bail. Under German law, he could have been held for up to 6 months without charges. If prosecutors choose to take the case to court, the charge

would be espionage, Hannich says, which carries a 5-year prison term or a fine.

Shevitz came to Germany in 1976 following an academic career that included stints at Princeton and the University of California, Berkeley, and teaching positions in sociology at other universities. He also had a long track record of activism, primarily in the free speech movement at Berkeley and in groups that opposed the Vietnam War.

Shevitz told *Science* that in 1975, while he was considering a teaching post at the John F. Kennedy Institute for North American Studies of the Free University in (then West) Berlin, he was contacted by Shepard Stone, a prominent U.S. diplomat and scholar who in 1974 founded the Aspen Institute Berlin, a public-



**Arrested.** Jeffrey Schevitz says he gave disinformation to the East German Stasi.