Can OSI Withstand a Scientific Backlash?

Assailed by powerful critics on all sides, NIH's attempt to keep the investigation of scientific misconduct in the hands of scientists is in jeopardy

TO A VISITOR, THE HOME OF NIH'S OFFICE of Scientific Integrity (OSI) looks as if it's been on the receiving end of Hurricane Bob. Inside the office, which is identified only by a taped-up paper sign on its outer door, mismatched carpet strips line the floor, stacked boxes nearly fill the corridors, and piles of keyboards, computer monitors, and other paraphernalia are tucked haphazardly into offices and conference rooms. Paper is everywhere—filling boxes, spilling out of file folders, stacked in piles on the desks. It's hard to escape the impression that NIH's apparatus for investigating allegations of scientific misconduct is a mess.

Appearances, of course, can be deceptive: This chaos is the result of long-awaited renovations, not the "horrendous management failures" for which NIH director Bernadine Healy has repeatedly lashed OSI. Yet to the scientific community, the relative disarray of OSI's offices might stand as a metaphor for its operations as a whole. The office is under siege, accused by an array of critics—ranging from Healy to an imposing collection of prominent researchers and scientific societies—of "appalling" sloppiness and disregard for the constitutional rights of the scientists it investigates. Indeed, hostility to OSI has grown so overt that Representative John Dingell (D–MI), a frequent critic of NIH misconduct investigations, has come to the office's defense, suggesting that Congress might remove it from the NIH for its own protection.

The stakes in this acrimonious dispute are high—perhaps higher than many OSI critics realize. For behind a parade of familiar charges against the office—it takes too long to complete its investigations, confidential information has leaked to the press on several occasions, it doesn't afford accused scientists full due process—lie deeper questions. Can science satisfy legislators such as Dingell that it is capable of regulating its own conduct? Does an office such as OSI stand any chance of gaining the confidence of the community itself? And if OSI is dismantled or changed beyond recognition at the request of scientists, is the community ready to live with the consequences—a style of investigations more like a criminal proceeding?

Most of the tensions underlying the current debate stem from OSI's attempt to tread a fine line between investigating too hard—thus becoming the much-ballyhooed "science police"—and investigating too gently, thereby providing an excuse for Dingell and his colleagues to create a science police force outside NIH. OSI's origin reflects its quandary. Back in March 1989, as congressional investigations by Dingell and Representative Ted Weiss (D–NY) continued to turn up cases in which universities had whitewashed or ignored misconduct allegations, pressure mounted on NIH to create its own investigative office before Congress did so. As a way of keeping the investigations within the scientific community, OSI was set up as part of NIH and staffed with professional scientists newly trained as investigators.

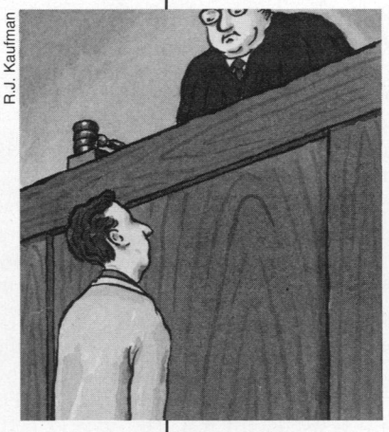
OSI at a Glance

Date created: March 1989
Location: Basement level of Building 31 on the NIH campus
Investigative staff: eight "caseworkers" from a variety of academic and bureaucratic backgrounds. Seven hold doctorates in fields ranging from immunology to cardiovascular physiology to statistics; one has no scientific background but is a former internal investigator for NIH.
Number of cases closed: roughly 200
Number of cases open: roughly 70
- **Cases being investigated by universities with oversight by OSI:** roughly 50
- **Cases being investigated by OSI itself:** 21

Number of OSI investigations involving forensic or statistical analysis: 7
Number of cases involving allegations brought in bad faith: 1
Average length of a full investigation: 6 months
In 1990, OSI findings of data fabrication: 6
- **OSI findings of plagiarism:** 5
- **OSI findings of other "deviant" practices:** 7
- **OSI findings of no misconduct:** 6

Types of "deviant" practices found by OSI: A journal referee's misuse of privileged information in a reviewed manuscript; fabrication of bibliography entries; selective reporting of primary data
Number of criminal actions pending against OSI-investigated scientists: 2
Number of research institutions required to send OSI annual reports describing any misconduct problems: 2400
Number of research institutions in 1990 reporting active misconduct inquiries or investigations: roughly 70
Percentage of OSI inquiries/investigations that find no misconduct: roughly 80%
Annual budget: $1.64 million

Source: OSIR annual report and OSI staff



R.J. Kaufman

How the system works

OSI also adopted an unusual strategy for conducting its investigations. Instead of collecting evidence for use in a public hearing before an administrative or criminal law judge—the type of procedure the Food and Drug Administration uses to investigate allegations of fraud in clinical trials, for instance—the office employs an approach that director Jules Hallum calls a "scientific dialogue," aimed at ferreting out the scientific truth behind an allegation of misconduct. The scientific dialogue is an ambitious attempt to keep the process of investigating misconduct out of the hands of lawyers by keeping the focus on the scientific issues in any given dispute.

To these ends, OSI conducts investigations in which the accused scientist has no right to confront his or her accusers or, during the investigation, to review potentially incriminating evidence amassed by OSI. Instead, assisted by an expert scientific panel usually composed of academic researchers, investigators "frame" the issues, collect evidence and testimony, and ask the accused to explain any discrepancies. OSI then weighs these explanations, writes a draft report of its findings and conclusions, and supplies it to the accused for comment. "We don't allow cross-examination of witnesses. We do allow cross-examination of the scientific issues in the draft report," says Hallum.

Any comments made by the researcher under investigation are incorporated into

the report and appended in their entirety. The resulting document is then sent up the chain of command, along with recommended sanctions, to the NIH director and then the Office of Scientific Integrity Review (OSIR), a sister office in the Public Health Service (PHS) that reviews OSI investigations for thoroughness and adherence to PHS guidelines. Eventually, OSI's conclusions make their way to the assistant secretary for health, who renders a final verdict of guilt or innocence and decides on appropriate punishment. Those found guilty can be forced to work under supervision, be suspended from NIH committees, or be "debarred" from receiving federal grants for a period of several years.

How the system doesn't work

The scientific dialogue model was expected to appeal to scientists, but instead it appears to infuriate them. Hallum argues that it is natural to place the "burden of proof" on the scientist whose data is challenged. Many scientists, however, complain that such procedures amount to little more than "star chamber" proceedings in which subjects are kept ignorant of the evidence against them. To ensure fairness, they argue, OSI must give its targets the kind of protection they would expect in a court of law. "The whole process is relative—it has no basis in a specific set of charges," says James Abbs, a University of Wisconsin neurologist who last year sued NIH over its misconduct procedures.

Critics of OSI were granted a window of opportunity last December, when a federal district court ruled in Abbs' suit that OSI's policies and procedures had been drawn up illegally because OSI had neglected to follow a formal rule-making process (*Science*, 11 January, p. 152). The PHS belatedly published them in the *Federal Register* 2 months ago for public comment. Seven Washington-based scientific and academic associations—including the Association of American Universities, the National Association of State Universities and Land-Grant Colleges (NASULGC), and the Association of American Medical Colleges—have already piled on, signing a joint letter critical of the way OSI conducts its investigations. "We thought it would be very, very valuable...if we could indicate that the whole community was together," says Jerry Roschwalb, NASULGC's director of federal relations.

Relying on a 25-page legal analysis prepared by Robert Charrow, a Washington attorney who has represented two scientists under investigation by OSI, these societies dispute the notion that OSI doesn't make judgments and call for a separation of investigation and adjudication into different offices; argue that targets of investigations should have access to "important and possibly exculpatory information" produced by the investigation; and complain that the definition of scientific misconduct in the guidelines is "too broad" because it encompasses "practices which seriously deviate" from those commonly accepted within the scientific community.

The Federation of American Societies for Experimental Biology (FASEB), acting independently, has gone even further, urging its members to "inundate" PHS with letters urging that the rules be withdrawn. And FASEB members appear to be responding: So far, PHS has received "about 1900" comments, some 1650 of which are derived from FASEB's draft letter, says PHS attorney Barbara Bulman.

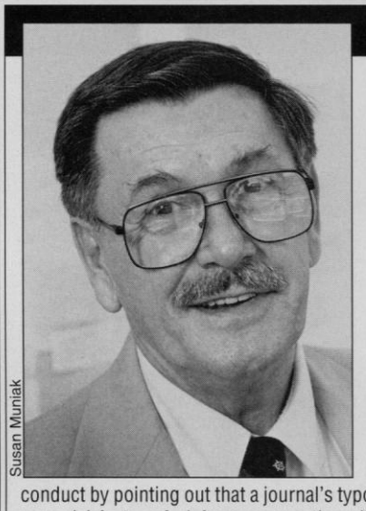
The attack from within

These objections have now received strong support from a powerful source: OSI's own boss, Bernadine Healy. For more than a month, Healy has been telling anyone who will listen that OSI has not only been mismanaged for years, it has operated with absolute disregard for its guidelines and fundamental fairness. "Here's an office that's had festering problems for as long as anyone can remember, recurring management problems, and unfair treatment of both accused and accusers," she said in a recent interview with *Science*.

Dingell has accused Healy of carrying out a vendetta against OSI, perhaps because OSI is investigating a case at her former institution, the Cleveland Clinic Foundation, where her husband Floyd Loop still serves as director. (Healy has recused herself from all matters involving OSI until that investigation is complete; she said in her *Science* interview that her statements reflect positions she had taken before her recusal.) Dingell was particularly exercised by what he saw as Healy's mistreatment of Suzanne Hadley, a former OSI deputy director and one of the founders of the office. Although Hadley left OSI last March, she had agreed to continue supervising its two most prominent investigations—those of intramural AIDS researcher Robert Gallo and Tufts immunologist Thereza Imanishi-Kari. Last June, however, Healy in rapid succession asked Hadley to rewrite the draft report in the Gallo case; sent NIH general counsel Robert Lanman to review Hadley's telephone notes in order to assure that she was not "too close" to Margot O'Toole, the whistle blower in the Imanishi-Kari investigation; and finally ordered Hadley to return her files to OSI and, Hadley says, to make no further decisions in the cases. (Healy denies removing Hadley from the investigations.) Hadley then resigned from the cases (*Science*, 26 July, p. 372).

Healy now says she was unaware of Hadley's agreement when she assumed the directorship. "No one said to me there was a bizarre situation going on here and that it might be a tar pit," she said. To Healy, what she calls Hadley's "rogue office" was symptomatic of the management ills afflicting OSI. In interviews, she sounds an overarching theme: OSI, through "lack of resolve," has failed on numerous occasions to follow its own rules. These failures were concentrated in two areas, she says: a frequently violated formal 120-day time limit for investigations, and OSI's inability to keep sensitive material confidential. She points, in particular, to the leak of two draft investigative reports to the press, the announcement of a new OSI investigation in another draft report, and one instance in which a confidential tape recording was mailed to the subject of an investigation.

Jules Hallum



Susan Muniak

Bespectacled and pleasantly rambling in the style of a beloved college professor, Jules Hallum seems at first glance an unlikely person to head an office devoted to rooting out scientific misbehavior. In unguarded moments, the former Oregon Health Sciences University virologist even sounds almost ambivalent about his new line of work. After describing a case in which an OSI scientific advisory panel had deflated an accusation of misconduct by pointing out that a journal's typographical error had omitted a crucial factor of -1 from an equation cited by a whistle blower, he sighed and said: "It's much more pleasant to find no misconduct. Everyone in the office gets depressed when we find misconduct." Yet some of Hallum's sharpest detractors, such as Bernard Davis, an emeritus professor of microbiology at Harvard and a frequent OSI critic, fault him for pursuing misconduct too hard. Hallum, says Davis, is too "zealous" about doing a "thorough" job. "He's perfectly honest in his intentions, but...good intentions can result in costly products," Davis says. Responds Hallum: "I could say the same thing about Bernie. Reason alone is not able to change his mind."

Healy is reluctant to specify exactly which OSI management practices led to the problems she has enunciated, however. When pressed, she changes the subject to larger issues, such as whether OSI treats accused scientists fairly. "I think one could make an argument that this is in fact a constitutional issue," she said. "If you believe that these people are accused, and that the accused in this country are entitled to the protections under the Fifth Amendment to the Constitution, then inherent in the principle of due process is that you give people a fair hearing."

OSI's reaction

While Hallum and his staff won't say so explicitly—and in fact are careful to say that Healy has been "very supportive" of OSI—they give the distinct impression they think she has exaggerated many of their problems. For instance, they say that confidentiality breaches such as the mismailed tape (they deny leaking any draft reports) are isolated flukes. "When we mentioned that to the U.S. Attorney's office, they burst out laughing and said, 'You've only done that once?' " said investigator Alan Price. And when told that Healy had accused them of a "lack of resolve" in completing their investigations on time, several staffers sighed and rolled their eyes. "That's just wrong," said Price. "Absolutely wrong," agreed acting OSI deputy director Clyde Watkins.

They are not denying that the 120-day rule is rarely followed, however. One problem, OSI staffers say, is that the office's rules and procedures make it virtually impossible to finish even the simplest cases in that time. Each step of an OSI investigation—forming a scientific panel, scheduling site visits and interviews, and distributing interview transcripts for verification and corrections—can take at least a month, says Price. "There's no way to do [an entire investigation] in less than 6 months," he says. More complicated cases, such as the Gallo and Imanishi-Kari investigations, require even more time because of the intricate details through which OSI investigators and scientific panelists must wend. Stanford immunologist Hugh McDevitt, one of the panelists in the Imanishi-Kari case, notes that delays in that investigation came about mainly because the panel insisted on seeing more forensic evidence before coming to a conclusion. "Several of us wanted something like a smoking gun," McDevitt says. "I said I wanted something that would convince me beyond a reasonable doubt."

Adding to the consternation of the OSI staff is the fact that, as Watkins points out, "nobody's accusing us of not conducting thorough investigations." Scientists who have participated in OSI advisory panels generally agree. "The whole staff was very conscientious about finding evidence for fraud," says McDevitt, who dissented from some of the OSI's conclusions in the Imanishi-Kari case. As for fairness, University of Texas immunopathologist Stewart Sell, who also worked on the Imanishi-Kari investigation, says: "All the important issues were raised before the committee....In that sense, [Imanishi-Kari] had the opportunity to confront all the incriminating evidence."

And one panel member in the Gallo investigation, who spoke on condition of anonymity, says that any procedural problems at OSI were minor in the context of the office's workload. Describing Hadley as a "person of tremendous integrity," the panel member says Healy's teatment of her "to me was a hatchet job....[Healy] acted in my opinion very precipitously. We only heard in her congressional testimony what her reasons were, after the fact."

What comes next

If OSI does crumble in the face of such assaults, what will replace it? One of the ironies of this controversy is that in complaining about OSI, the scientific community could end up bringing upon itself a federal investigative apparatus more similar to the "science police" than OSI. And scientists might be surprised to learn that Healy is more than a little sympathetic to ideas reminiscent of some researchers' worst nightmares. Saying that she finds the idea of training scientists as investigators "illogical," Healy suggested that misconduct should be handled by "professional investigators"—perhaps from the Health and Human Services inspector general's office. While scientists are important for scientific review, she said, "I would like to see investigators who can pursue document evaluations, ink chromatograms, or whatever." Healy has also suggested splitting OSI into two bodies—one for investigating, one for adjudicating.

Such ideas have a familiar ring to them. Hallum and Hadley coauthored a 1990 article defending the scientific dialogue in which they argued that a legalistic approach to misconduct investigations would reduce scientists to "expert witnesses" in the proceedings—a "serious loss to the interests of science." Some scientists agree. "I think that's entirely possible," says Stuart Bondurant, dean of the University of North Carolina medical school and a member of a new PHS advisory committee on scientific integrity. "Most examples [of misconduct] that I know of were resolved by the existing system....Whether it's wise to change the system to address the residual problems is open to question." OSI's Watkins puts it more starkly: "In a legal forum, you lose the ability to distinguish misconduct from honest error."

More than philosophical issues are at stake, too. Hallum points out that a fully adversarial system could end up costing much more than OSI's $1.64-million annual budget. "How many [grants] are scientists willing to give up in order to assure due process?" he asks.

In the end, however, such concerns may not count for much against the passions inflamed by OSI. "I honestly think that if the scientific community had experienced what I have experienced in terms of observing [OSI]...the scientific community would be on bended knee to say, 'Get it out of NIH, if that's the best you can do,' " Healy said. "I'm not saying get it out of NIH, by the way. I'm saying let the original system be put in place and given a chance." Whether or not OSI is to get that chance will next depend on PHS administrators and Congress—not to mention the scientific community itself. ■ **DAVID P. HAMILTON**

Suzanne Hadley

Susan Muniak

If one person deserves most of the credit—or blame—for the way OSI does its job, that person is Suzanne Hadley. Named deputy director in May 1989, she was the only staffer to serve continuously from OSI's creation in March 1989 through the completion of the draft report in the Baltimore case last March. And as acting director for 5 of those 24 months, she left an indelible fingerprint on just about every facet of OSI's operations. By all accounts, Hadley, a former psychologist at the National Institute of Mental Health, was a tireless investigator, regularly putting in 12- to 14-hour days in the office. One NIH source says Hadley left OSI last March because of friction with Hallum. According to this source, Hadley felt crowded by Hallum, who insisted on learning as much as possible about her day-to-day activities in running investigations. Hadley "didn't have time for that," the source says. These days, Hallum praises Hadley as a "superb writer and investigator," but adds that "too many decisions" were concentrated in Hadley's hands, creating an OSI "bottleneck" that slowed the completion of investigations.