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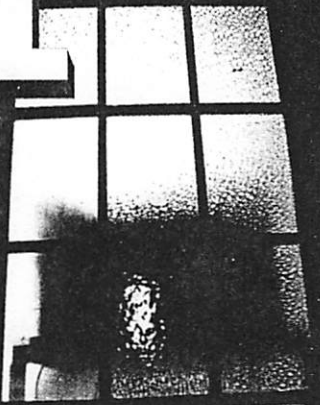
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FRAUD AND LOATHING IN THE LAB

By Leslie Alan Horvitz



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Can Scientists Police Themselves?

By Leslie Alan Horvitz

Sloppy science and falsified research may be more widespread than previously believed. While whistle-blowers have drawn attention to corruption in several recent cases, many feel abused by the very system intended to ferret out fraud.



Like politicians caught with their hands in the till, scientists accused of fraud and incompetence have learned the art of obfuscation. Take Roger Poisson, a researcher at St. Luc Hospital in Montreal, charged with falsifying data in a 1985 study of breast cancer conducted by the University of Pittsburgh. Explained the chastened scientist, "I always feel sorry for a nice case to be denied the right to enter a good protocol just on account of trivial details."

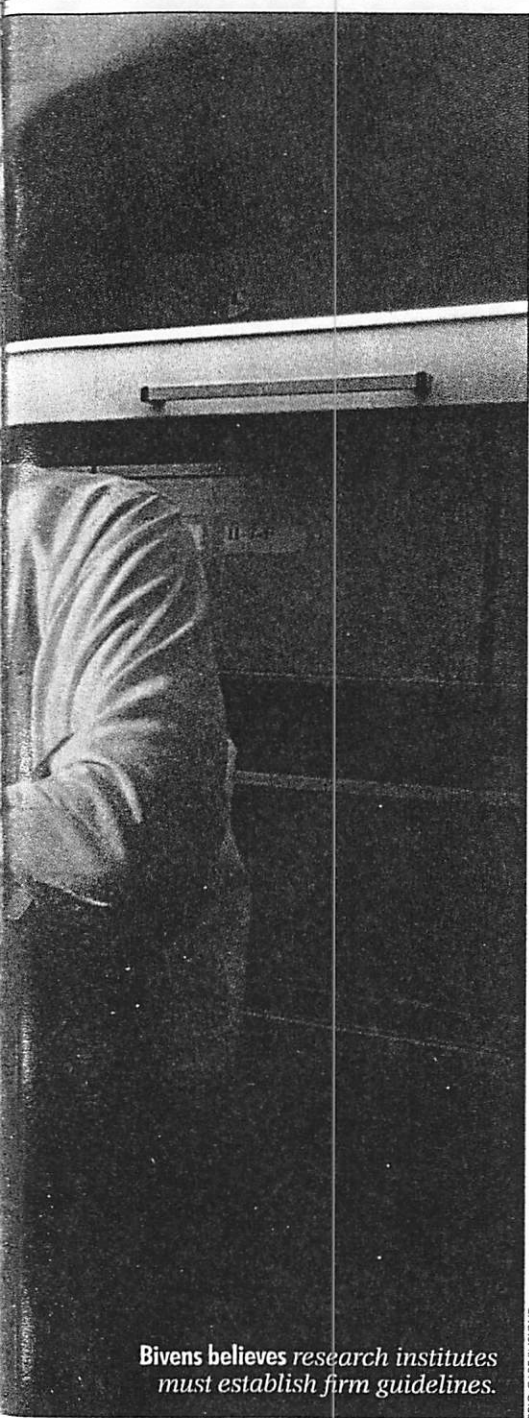
Trivial details? Thousands of wom-

en with breast cancer had relied on the results of this research to make life-or-death decisions — to have mastectomies or lumpectomies. After a second serious discrepancy in the data was found, the study's coordinator, Bernard Fisher, was put on administrative leave and the case was turned over to the Office of Research Integrity, or ORI, the federal agency that monitors misconduct at organizations receiving federal funds for scientific research.

According to a recent survey by the Acadia Institute, a nonprofit research center in Bar Harbor, Maine, 43 per-

cent of graduate students and 50 percent of faculty members have "direct knowledge" of some kind of misconduct in their laboratories. Misconduct usually refers to what Acadia's president, Judith Swazey, calls the FFP Trinity — fraud, falsification and plagiarism — but she cautions that her survey, said to be the largest and most reliable of its kind, measures perception and not verifiable incidence of wrongdoing.

Nevertheless, the survey and a slew of much-publicized investigations suggest there is a significant problem. The



Bivens believes research institutes must establish firm guidelines.

BING CARE/INSIGHT

question is, how significant? "Are we looking at the tip of an iceberg, or is it just a matter of a few rotten apples?" asks ORI director Lyle Bivens.

A great deal of funding will be affected by the answer to that question. The federal government doles out \$11 billion annually for biomedical research, distributing about \$1 billion to the National Institutes of Health and the rest to research foundations and universities. "American science has been largely supported by the government since after World War II. It's a sort of mini-socialism," says Charles

McCutchen, National Institutes of Health physicist and gadfly to the scientific establishment. "Once you get a really politicized atmosphere, then appearance is all important, and if you need a little fraud to maintain that appearance, you do it." American's biomedical research establishment is an entrenched and corrupted system, he believes, not unlike the defunct Soviet bureaucracy.

McCutchen and others point to a date when American science took a turn for the worst: Dec. 12, 1980, when Congress enacted a little-noticed piece of legislation called the Bayh-Dole bill. The measure, which created the Patent Reform Act, allowed universities to retain exclusive rights to patents generated by research in their labs even if the work had been subsidized by taxpayers. Before the legislation, American citizens held the patents, and as a result, private corporations had little incentive to enter into research partnerships with universities unable to protect their discoveries.

The Patent Reform Act "produced a gold rush," according to Leonard Minsky, chief of the National Coalition for Universities in the Public Interest, a Ralph Nader group. Universities were now full-time workers in a money-making business. "Everything we thought would happen did," he says.

Minsky offers a theoretical example: "I'm a scientist working on a new drug, and I want to know if the drug's effective. If I were just a pure scientist in the old days, I might publish my results even if they weren't conclusive." The goal was to contribute to general knowledge. Today, a scientist might be tempted to "massage" the data enough to make it appear as if the drug is effective, motivated by the prospect of a lucrative deal with a pharmaceutical company.

Just how many scientists succumb to the temptation is unknown. "There are still a lot of senior people in the scientific community who are saying that misconduct is so rare we're wasting our time on it," says Acadia's Swazey. "If we ignore all the noise it'll go away eventually, and we can go back to business as usual." Some scientists argue that misconduct isn't the community's most pressing issue. "I think that sloppy science is so much more dangerous than crooked science, since there is so much more of it," says Jules Hallum, a virologist and former director of the Office of Scientific Integrity, a forerunner of the ORI.

But the fact is that misconduct and incompetence increasingly remain undetected. Scientists no longer have

any reason to replicate the results of their colleagues. "If you're in the grant business, you're not going to get any funding for replication," says Robert Sprague, a professor of psychology at the University of Pittsburgh. "If you do it, you have to do it on your own time with your own money, or bootleg it." (Bootlegging means using money intended for one type of work for another.)

Some scientists wonder if instances of misconduct would ever come to light without whistle-blowers. According to a 1990 House Government Operations Committee report, the answer is clear: "Many cases of scientific misconduct would have gone undiscovered, and many of the scientists would have continued their fraudulent or misleading research, without the courageous and sometimes single-minded efforts of one or two individuals, many of whom are sharply criticized by the institutions involved as vindictive or jealous colleagues."

But most Americans regard whistle-blowers with ambivalence. "They tend to be looked at as more deviant than the ones on whom the whistle is blown," says Swazey. "There are strong norms in society about being loyal to a group."

When Sprague, for example, testified before Congress about a case involving a psychopharmacologist charged with data fraud, his university promptly threatened him with a libel action. Sprague wrote to the president of the university, reminding him that by law individuals are granted immunity for testifying before Congress. The university backed down. The psychopharmacologist was found guilty.

While ORI's Bivens agrees that universities have behaved badly in the past, he views the situation with guarded optimism. "Institutions are learning that if they try to ignore, cover up or head off these kinds of situations, they're going to blow up in their face," he says. "There are undoubtedly cases where universities push things under the rug, but I think it happens less than it might have happened 10 years ago." He believes that half of all misconduct disputes could be avoided if universities established firm guidelines to govern issues such as apportioning credit for research results and establishing ownership of intellectual property.

Whistle-blowers frustrated by an institution's internal investigation have the option of appealing to the ORI. Founded in June 1992, the ORI is a

hybrid of two former watchdog agencies, the Office of Scientific Integrity and the Office of Scientific Integrity Review. But it wasn't until the National Institutes of Health Revitalization Act in 1993 that ORI became a fully functioning agency under the Department of Health and Human Services. (The recent bureaucratic mutations have caused confusion even among people involved in misconduct cases.)

With 52 investigators, ORI automatically reviews all internal institutional investigations into misconduct. (ORI does not look into inquiries determining whether an investigation is warranted.) If ORI investigators conclude that unanswered questions remain, or if a whistle-blower is unsatisfied with the initial investigation, the agency conducts its own investigation. It is involved with about 50 investigations at any given time.

In 1991-92, however, ORI pursued only six of the 314 cases referred to it — some of them under either the scientific integrity review offices — passing queries on to other agencies or dismissing them because they failed to meet federal criteria defining misconduct. "We're obliged to protect federal research money," Bivens explains. "We're not dictators of ethics and science."

Others have a less sanguine opinion of ORI. Ernie Fitzgerald, an Air Force cost analyst, gained public attention when he exposed defense industry corruption. He is critical of the agency. "It's eye-wash for the public," he says. "They will occasionally concede what's going to come out anyway, but put the best possible face on it and assure the tax-paying public that whatever problems there are have been solved." Sprague calls the ORI "window dressing." McCutchen calls it "the black hole bureau — it vacuums up complaints and buries them."

Bivens admits that the ORI has had some rocky times, but he maintains that morale is high. "There are a lot of reasons why people are disgruntled no matter what we do," he says. "This office has no hidden agenda. I've always said that if we're catching hell from everybody we must be doing something right."

Rightly or wrongly, many whistle-blowers believe the agency to which they've turned for help has abused

Scientists Circle Their Wagons

If scientific fraud doesn't come to light as a result of replication — the attempt by one researcher to repeat the results of another — how does it become known? It's often the junior scientists — the people who "don't have much power in the system" — who detect and report misconduct, says Carolyn Phinney, a research psychologist who recently won an unprecedented \$1.13 million judgment in a case against the University of Michigan and senior researcher Marion Perlmuter.

Of course, there's an obvious conflict of interest in stepping forward, especially if the junior scientist depends upon the person he or she accuses for promotions

versity to behave like a family, and families usually would rather deny there is a problem than admit it publicly, whether the problem is alcoholism or scientific misconduct. Allegations by whistle-blowers are often explained as personal vendettas by the person accused of wrongdoing, and their friends and 'family' tend to believe it."

Investigations are hampered because most of the investigators "know the poor bloke who's accused," notes Walter Stewart, a National Institutes of Health researcher who has examined numerous fraud charges. Several members of the committees looking into Phinney's allegations, for example, were participating in grant work with the faculty member she'd accused of purloining her information. Scientists in the same field attend the same conferences, referee papers colleagues submit to medical journals and sit on National Institutes of Health committees which decide who receives federal grants.

When Phinney first talked to Stewart and mentioned that she had a problem with a senior researcher, he told her, "You're in the worst trouble you've ever been in in your whole life. Your career is destroyed, your reputation is destroyed, you're going to be out of a job soon." He predicted that in retaliation for speaking up, she would be charged with misconduct herself. And so she was.

While each whistle-blowing case may be different, the response by institutions is invariably the same, says Phil Green, an Ann Arbor, Mich., attorney who won the judgment for Phinney. He says the university tries to smear the name of the whistle-blower, then does what it can to get the person fired and prevented from finding employment elsewhere.

Phinney's conclusion: "If you stay inside the system, you get eaten alive. You get eaten alive at the university level and then you get eaten alive by the professional organizations; then if you go to the government, they won't do anything either. The only recourse available is court." — LAH

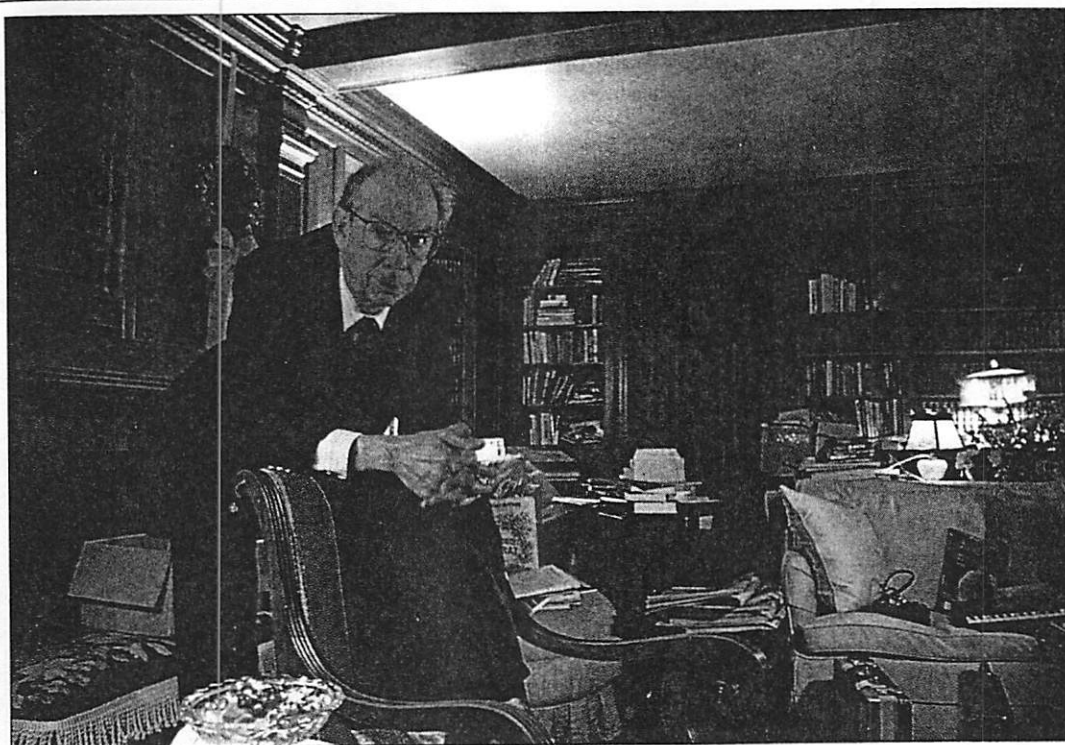


Phinney won, but at what cost?

and recommendations. If the junior researcher does bring a charge, Phinney says, "there's generally a circling of the wagons around the senior person. If their reputation is harmed, the university's reputation is harmed, and funding may be taken away."

In her own case — one which involved allegations of plagiarism, stolen data and cronyism — the university stands to lose \$11 million in funding, about 1 percent of its total annual budget.

A 1990 House Government Operations Committee report bluntly described the problem: "There is a tendency for the uni-



BRIG CABLE/INSIGHT

McCutchen says federal science funding and research grants have created a "mini-socialism."

them. (See sidebars, pages 8 and 10.) At the University of Pittsburgh — which has been involved in an unusually high number of misconduct cases — Professor Erdem Cantekin took his case to ORI after accusing principal researcher Charles Bluestone of falsifying data involving antibiotics in the treatment of a common childhood middle-ear infection called otitis media. Cantekin maintained that Bluestone had committed fraud on behalf of drug companies; in any case, Bluestone had received \$75,000 a year in travel expenses and honoraria from them. ORI conducted an inquiry but found no evidence of misconduct, concluding only that the data could be open to various interpretations. Not unexpectedly, Cantekin berates the agency. "Their position is to cover up," he complains. "They have no conscience about what is good for American people.... They're completely dishonest."

Even when ORI decides that someone is guilty, "they can't make it stick," says Walter Stewart, a researcher at NIH who has generated a great deal of controversy for his work (along with colleague Ned Feder) in examining fraud cases. One big reason: The agency's standards for determining misconduct are too stringent. The ORI not only must prove misconduct based on a preponderance of evidence but on intent to defraud as well. A congressional investigator agrees. "We get five [whistle-blower] complaints a week, we don't know what to do with them, we

ship them to the ORI, which has limited capabilities to take these on, and limited powers. ORI is 33 percent of the problem, but the appeals board is the majority of the problem."

According to ORI guidelines, any individual the agency finds guilty of scientific misconduct has the right to appeal to the Health and Human Services Departmental Appeals Board. But the board comprises lawyers and has even higher standards than ORI. It also guarantees legal protection for those found guilty of misconduct.

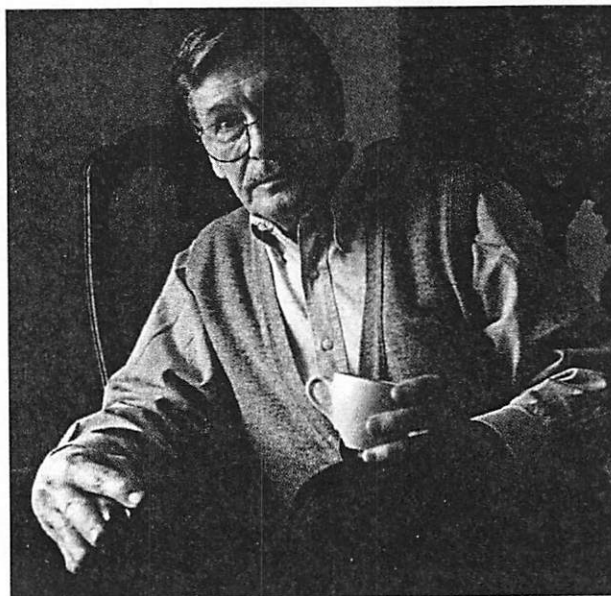
One of the most important cases that ORI has handled — some will say fumbled — involved celebrated virologist Robert Gallo and his collaborator, Mikulas Popovic. In 1984, Gallo's team at the National Institutes of Health announced that it found the HIV strain that causes AIDS, a discovery disputed by France's Pasteur Institute, which claimed to have isolated the virus first. The controversy involved money (patent rights to the blood test to detect HIV) and lives (the dispute could have ham-

pered the search for a cure). Gallo and Popovic denied wrongdoing.

The scientific integrity office's initial investigation found Gallo guilty only of permitting lapses and misrepresentation by his team. But a November 1989 *Chicago Tribune* article raised serious charges against Gallo and reawakened interest in the case. Rep. John Dingell, a Democrat from Michigan who heads the House Energy and Commerce subcommittee on oversight and investigations, had taken an interest in cases of scientific misconduct and called for a new investigation.

After three years of grappling with the case, ORI finally reversed the original findings and concluded that Gallo and Popovic were, in fact, guilty of "minor misconduct."

The ORI then argued the case before the Health and Human Services Departmental Appeals Board, starting with the charges against Popovic. But the board ruled that the agency failed to account for all possibility of error or to prove that the researchers deliberately intended to deceive. Realizing it would not fare better against Gallo, the ORI dropped



RICK KOZAK/INSIGHT

Hallum believes the ORI works at cross-purposes.

the case in November 1993.

"The board has upped the stakes considerably," complained Bivens after the decision. "They basically treat these cases now as criminal cases. This has led to a fundamental conflict between the legal and scientific cultures."

But according to former OSI director Hallum, the Gallo-Popovic case was muffed from the start. Hallum, who was in charge of the ORI investi-

gation into the cases, believes the ORI pursued it only because of pressure from Dingell. "Dingell wanted to get Gallo," says Hallum. "Bivens didn't do substantial investigating besides taking the word of Dingell's staff."

He continues, "The problem of ORI is that they're trying to deal with fraud, not science. We wanted to look at four science papers [of Gallo and Popovic's] and see if the data backed them up and if they were true. Now this ORI busi-

ness comes along, and they want something that isn't dealing with science."

Bivens, in turn, dismisses Hallum's scenario as hopelessly idealistic. "We're trying to get some model incorporating legal and scientific processes.... It's unfortunate that the first few cases [including Gallo and Popovic] were so difficult. Some of them were leftovers from the old ways of doing investigations when we didn't have the high standards."

A Whistle-blower Returns to the Scene of the Crime

Maureen Polsby, a former fellow at the National Institutes of Health, knew she was in trouble when she opened a local newspaper and read an account of her research — on an obscure neurological ailment known as spasmodic torticollis — and saw no mention of her name. Her worst fears were realized a short time later when her supervisor, Thomas Chase, took over her research and relegated her to an inactive project for the last six months of her fellowship.

To be sure, Polsby, who was working at the Institute of Neurological and Communicative Disorders and Stroke, had long since become disenchanted with NIH. Although NIH is one of the major centers of medical research sponsored by the federal government, she was stunned by the attitude of many of her colleagues. "I was there for two years," she says, "and I never heard anyone say 'How can we help sick people?' They were interested in getting papers published, they all wanted large labs with lots of equipment, they were building up their own fiefdoms — the research itself didn't matter to them."

She also maintains that she was unduly pressured by Chase after rebuffing his advances, a claim Chase has denied. When her fellowship ended, she filed a lawsuit in federal court against Health and Human Services for the theft of her data as well as for sex discrimination. "The next thing I knew," she says, "my career was ruined." The fraud charges were dismissed by a federal judge on the grounds that government employees can't be sued as individuals, and the discrimination suit later was thrown

out on a technicality.

In December 1989, four years after leaving NIH, Polsby received a call from a retired college English teacher who said he was a subject in her torticollis study, but he didn't remember undergoing clinical tests



Polsby has waited eight years for a hearing on her charges.

shown in the data. He'd just come across a paper ascribed to her. When Polsby read the paper, she suspected that its data were totally fabricated.

When confronted, Polsby's NIH supervisor, whom she had named in her original complaint charging sex discrimination, contended that the paper was accurate. Another coauthor was conveniently unavailable,

having returned to his home in Germany. But Polsby's allegations were considered substantive enough for the ORI to pursue her case.

At an inquiry conducted on November 17, 1993, at ORI headquarters, a few miles from NIH in Bethesda, Md., the following exchange ensued between Polsby and John Ferguson, a neurologist representing NIH:

Ferguson: This considerable proof that you don't want to go into, is that proof that these patients did not exist, or proof that —

Polsby: I'm not going to tell you what proof I have. Let me just say I can prove these allegations, and you ought to be able to prove them as well. I don't even know why you are talking to me at all. What I have said over and over again throughout this is why don't you just go to the authors of these papers? Why don't you go to [the authors] and ask them for the list of patients who were in the study? And then get these patients' charts and look at those charts and see if these things were done. Interview the patients. Ask them if they had these tests. It's not up to me to prove these allegations.... At least three-quarters of the data that is reported in this paper is fabricated."

Two months later Polsby learned that the ORI had recommended that the NIH conduct an inquiry into her charges of misconduct — eight years after she'd gone to NIH with her initial complaint about sex discrimination. "They're probably stewing," Polsby says, referring to NIH officials who now are obliged to revisit her case. "They're wondering what they can do about this. Running around, thinking: Damage control, damage control!" —LAH

When the ORI finds scientists guilty of misconduct, it can institute three forms of punishment: prohibit them from serving on Public Health Service advisory or review committees; bar them from applying for or receiving federal grants; and demand the return of grant money used to subsidize fraudulent work. If it's evident that someone is violating federal laws, ORI will refer the case to the inspector general's office for criminal prosecution. But Bivens acknowledges that it's rare for the government to take these cases. "Most of the time IG regards our cases as pretty labor intensive without much payoff."

Hallum says that whistle-blowers often were mistaken in bringing their charges. "I wanted the accuser to be the OSI [not the whistle-blower], to accuse on the basis of science, to make it an impersonal sort of thing." Perhaps more people would come forward with evidence of wrongdoing if they weren't so afraid of the consequences, says Hallum.

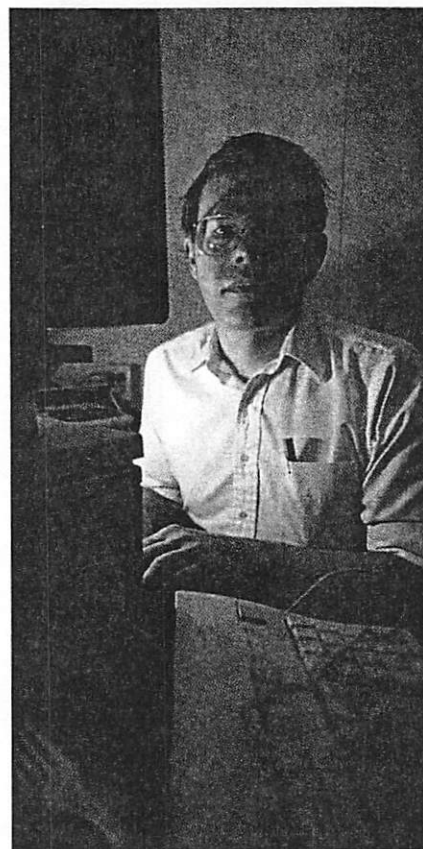
Bivens acknowledges that legal protections for whistle-blowers remain ineffectual. Protections for federal whistle-blowers do not apply to individuals who receive federal grants. The ORI, which is mandated to establish such protections, is conducting a study — still eight months from completion — to gather additional empirical data on the subject.

Obviously whistle-blowers aren't waiting for vague protections to become effective. Several have gone to court on their own to redress their grievances, although many judicial

system watchers admit that recourse often compounds problems. Trying such cases poses unique difficulties because the issues involved often are complex. Indeed, attorneys say that universities often try to complicate matters in hope of camouflaging the real issues involved, while also making the complainants appear vindictive. Cases can drag on for years.

The University of Pittsburgh's Cantekin chose to go to court, filing a *qui tam* action to establish a suit on behalf of himself and the state under the False Claims Act, which allows citizens to bring charges against recipients of federal funds who they believe are violating criminal law. Knowingly making a false statement on a federal grant application, for example, would fall into this category. So far, Cantekin has won one of his lawsuits: A court agreed that he had the right to publish his version of the disputed otitis media research results. He has other actions pending, including one against the university for persecution and prosecution.

Typically, one piece of litigation begets another. When Heidi Weissmann, a specialist in gall bladder disease then associated with Montefiore Medical Center (the teaching hospital for Yeshiva University's Albert Einstein College of Medicine), won a plagiarism suit in federal court against her mentor, Leonard Freeman, in February 1989, she thought she'd been vindicated. Not so. The same day the decision was handed down she underwent a humiliating search by hospital security, was barred from her office

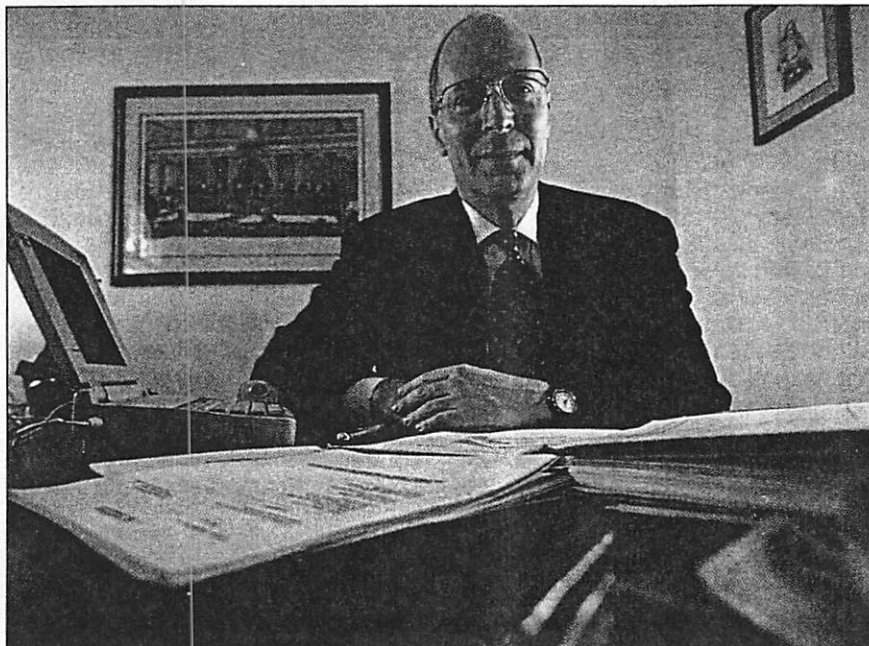


Stewart: Can't make charges stick.

and fired from her job. Ironically, the doctor who'd lost the case not only had his legal expenses covered by Yeshiva but also was promoted. Weissmann believed he had no other alternative but to file another motion against Yeshiva for sex discrimination. The university continues to insist that it was guilty of no wrongdoing, but reached a settlement with Weissmann for \$900,000 — a record amount for this type of case. In exchange, however, Weissmann had to agree not to seek employment at Yeshiva or any of its 29 affiliated institutions in the greater New York area.

Phil Green, an Ann Arbor, Mich., attorney who won a major fraud case against the University of Michigan, sees little hope that whistle-blowers will ever be free to expose misconduct and escape retribution. Litigation may offer the only means for whistle-blowers to achieve vindication. "We are essentially developing a whole new canon of law without setting about it systematically," says Paul Friedman, dean for academic affairs at the University of California at San Diego Medical School. "It's a very treacherous business. No one loves you for dealing with these cases."

When it comes to dealing with scientific misconduct, Friedman's statement is probably the only issue on which all sides can agree. •



Green believes that whistle-blowers may not be able to expose misconduct.