NIH Misconduct Probes Draw Legal Complaints

Attorneys for the accused say their clients are being denied due process. Should investigations be less academic?

WHEN THE NATIONAL INSTITUTES OF HEALTH received allegations that vision researcher David Bridges had stolen a rival's research plan from a manuscript a journal had sent him to review, the NIH fraud office convened a panel of scientists expert in the field to look into the case. The panel met one day at O'Hare Airport in Chicago to talk to witnesses. No transcript of the panel's meeting was kept. Bridges, a Baylor University faculty member at the time, was not allowed to hear the testimony or cross-examine witnesses who testified against him.

Nevertheless, based on that testimony and separate interviews with Bridges, who still wasn't told precisely what his accusers had said, NIH issued an official report declaring Bridges guilty as charged. The verdict came in 1989 (*Science*, 14 July, p. 120). Now, Bridges has appealed.

The Bridges case began in 1987 when the NIH's fraud division was in transition from a small one-person shop to the new Office of Scientific Integrity (OSI), with a professional staff nearing a dozen and an avowed commitment to establishing fair rules. To those who would argue that Bridges may not have been afforded the due process U.S. citizens have come to expect, NIH's defenders might argue that the office was just learning how to operate in a new and highly contentious arena. Indeed, since Bridges' first encounter with an NIH investigation, the rules have changed somewhat. His lawyer received an offer from the NIH to reopen the case this year. "This time, they said they would keep a transcript of the proceedings," Bridges told *Science*.

However, Bridges wasn't satisfied by that nod to due process. They still "wouldn't let me read it," he says. So, Bridges took the next step, available to him only because the verdict against him included a recommendation that he be debarred from receiving federal research funds. Bridges demanded a "trial-like" appeal before a hearing officer in the Department of Health and Human Services (HHS). It was the only way to get to see the evidence. Because the HHS hearing is governed by rules of administrative law, NIH was compelled to turn over the evidence on which its case rested.

The whole process really baffles Leslie Ribnik, Bridges' Houston attorney, who thinks the current system violates the Fifth Amendment's guarantee of due process. "They can debar you without even granting a hearing," he says. "We had no automatic right to a hearing. We had to convince HHS it was justified. It's terrible."

Welcome to the latest bone of contention in the research community's continuing struggle to devise rules for investigating allegations of scientific fraud and misconduct: the due process fight. Is it constitutional to deny someone due process when his or her livelihood as a scientist is at stake?

To attorneys representing the accused, these rights seem basic, but they are anathema to what NIH and some universities think of as the more informal, scholarly processes that govern their inquiries into fraud. High on their list is a pledge to protect whistleblowers from retribution—a pledge that is often interpreted as a promise to keep a whistle-blower's identity a secret.

A series of interviews with NIH and university officials, congressional staff, and several defense attorneys taken together reveal that even now there are two ways of looking at fraud—ways that are fundamentally different from each other. The academic school of thought treats misconduct essentially as an internal matter that is best resolved within institutions in the tradition of peer review—albeit peer review dressed up with procedural safeguards.

The alternative view is that people should behave right from the start as if the case were headed for court. One Boston attorney who has been close to fraud inquiries says it is a "fiction" to think of them as mere academic proceedings. Others tend to agree.

Barbara Mishkin is a Washington attorney with years of experience in the field of biomedical research ethics and misconduct. She has a client, a scientist formerly with an HHS agency, who wanted for his defense a copy of a memo he had written while in government. Says Mishkin, "When we asked OSI for a copy of his own memo, they said we couldn't have it because it was evidence in an ongoing investigation." Further, she adds, "OSI still doesn't have written procedures. It's impossible to know what your client's rights are."

In another case that has brought the due process issue to the fore, NIH earlier this year suspended its grants to Tufts University researcher Thereza Imanishi-Kari (*Science*, 29 June, p. 1598). Imanishi-Kari has been accused of fabricating data in a paper that has gained notoriety because it was coauthored by Nobel laureate David Baltimore.

A Decade of Discussion

The current controversy over due process in scientific misconduct comes at the end of a decade that has been devoted to writing guidelines for handling investigations. There have been workshops and seminars; a real "fraud circuit" has sprung up for scholars in the field. There have been reports galore.

In 1982, the Association of American Medical Colleges was the first out with guidelines for handling allegations of fraud (*Science*, 16 July 1982, p. 226).

A year later, the Association of American Universities (AAU) came forth with another set of procedural guidelines and urged their adoption.

In 1985 and 1986 and again in 1988 and 1989, NIH published a first draft, then final rules for handling allegations.

The Institute of Medicine convened a blue-ribbon committee in 1988 that not only recommended procedures for handling allegations but also talked about deterring fraud in the first place. About the same time, the AAU, joined by some ten other scientific societies, issued a "framework for institutional policies and procedures to deal with fraud in research."

Add to this the American Association for the Advancement of Science, which sponsored a series of professional workshops in conjunction with the American Bar Association (*Science*, 30 September 1988, p. 1748). The fruits of their labors have gone into a second printing.

For all of this, the matter is still contentious. Legal due process is expensive, time consuming, and, as one attorney puts it, antithetical to the idea that "the good old boys can still handle fraud like gentlemen." ■ B.J.C.

At a hearing in May before Representative John D. Dingell (D–MI), Suzanne Hadley, the deputy director of OSI, said that NIH was terminating one of Imanishi-Kari's grants because of a "mounting body of evidence" against her. But Singal told *Science*: "We don't know what that 'mounting body' is. And until we do I'm not permitting OSI to meet with my client. My job is to see to it that her rights are protected."

In part because of such cases, due process is becoming an issue on Capitol Hill. Representative Robert A. Roe (R–NJ), chairman of the House Committee on Science, Space, and Technology, is poised to introduce a bill that will grant universities and scientific publications immunity from suit in fraud cases on the condition that the accused have all the rights that adhere to due process—like the right to see evidence and cross-examine witnesses (see box below).

Science recently had a conversation about these issues with Jules V. Hallum, a microbiologist newly recruited from the University of Oregon to head NIH's Office of Scientific Integrity, and Hadley, who has spent the past year imbuing the office with previously lacking investigatory professionalism.

"In science, the burden of proof is on the person whose data are challenged," Hallum

The NIH fraud squad. *OSI head Jules Hallum and his deputy, Suzanne Hadley.*

believes. Says Hadley, "The person who made the allegation is irrelevant. It is not a case of Dr. X *v.* Dr. Y, but of OSI, as an institution, *v.* Dr. Y. We try to depersonalize things, to institutionalize them."

That approach is consistent with the idea of filtering evidence through the hands of OSI, and of sometimes withholding evidence until the last minute. "We've learned it is not always wise to give people a week or two to respond to specific evidence, especially not for the initial cut. It leaves too much time to concoct an excuse," says Hadley in defense of what one attorney called OSI's predilection for the "pop quiz." Hadley believes that OSI must guard itself against variations of the old "the dog ate my homework" excuse. However, Hadley says, "We never cut off the opportunity to revise or amplify a response. If someone wants to send in an amended response a couple of weeks or more after an interview with us, that's fine. We accept that." Furthermore, she argues that, in the end, the accused will be made aware of all the essential evidence. Take the Imanishi-Kari case.

Acknowledging that Imanishi-Kari had not been told the substance of that mounting body of evidence when she revealed its existence to Dingell, Hadley says it is sufficient that the evidence will be contained in OSI's final report—a report to which Imanishi-Kari will be able to reply. That, Hadley believes, goes a long way to fulfilling OSI's duty to provide due process.

Says Hallum, "We do provide due process despite the fact that we do not allow confrontation" between the parties. According to Hallum, newly instituted due process measures include taping and transcribing all interviews with the accused and accusers, and permitting all witnesses to bring a lawyer to the interview if they wish. In addition, the accused is allowed to comment on the

Immunity in Return for Due Process

A year ago, when Representative Robert A. Roe (D–NJ) held hearings on scientific fraud, he was impressed by testimony calling on Congress to grant immunity from lawsuits to universities that investigate—and journals that report—fraud cases in good faith.

Washington attorney Barbara Mishkin told Roe, for instance, that "there is considerable anecdotal evidence that academic institutions often fail to report confirmed or admitted cases of misconduct because they fear litigation." Mishkin then argued for immunity (*Science*, 7 July 1989, p. 24).

Last week, Roe's staff, headed by Gregory Simon, produced the second draft of a bill that would do what Mishkin wants. Called the "Science research protection act of 1990," Roe's bill holds that "research institutions should be free to protect the integrity of research by investigating fully allegations of misconduct and publishing the results of their investigation." Further, it says that scientific journals should be free to publish the results of those investigations.

Although some attorneys argue that special protection for journals is unnecessary because of existing First Amendment guarantees, Mishkin notes that many small publications could not afford to defend a lawsuit even if they could win it. "I think it is a good idea to include journals," she says.

Institutions too might be expected to like the Roe bill—but for one set of provisions. Roe staffer Simon reports that the bill's requirements for legal due process are surprisingly controversial. "Several scientific associations were having a fit over the first draft," Simon told *Science*. As Carol Scheman of the Association of American Universities explains it, "We're just putting guidelines in place. This is not the time to add new rules."

The solution? Roe's bill was redrafted to make immunity optional. Says Simon, "No one is required to accept the immunity provisions of our bill. But if you want immunity, you have to follow due process."

The provisions included in the bill are these:

- The accused must be given adequate notice and a fair hearing, within 3 weeks of the start of an investigation.
- A list of witnesses must be given to the accused.
- The accused should have the right to call witnesses and cross-examine them.
- Transcripts of proceedings must be kept. The accused has a right to get copies for a "reasonable" fee.

As for journals, special immunity would be granted only for the reporting of conclusions of due process investigations.

Roe's bill may be introduced in the House within the next couple of weeks. ■ **B.J.C.**

OSI's draft report and to request a formal appeal hearing if OSI recommends sanctions, such as debarment from receiving federal research funds.

However, says Hadley, "We do not give the accused access to someone else's testimony." And that has become the rub.

Hallum and Hadley report, with some justification, that OSI is making great strides in the way it does business. One attorney who has seen things from the defendant's position sees things differently. "It's a Star Chamber," he says, recalling the secret British tribunals that were abolished in the 17th century.

Others would not go that far, but do take issue with OSI's way of conducting an initial inquiry, an investigatory phase that is meant to quickly determine whether a full investigation is warranted. The NIH's ongoing inquiry in the case of AIDS scientist Robert C. Gallo (*Science*, 22 June, p. 1494) illustrates the point. For 6 months, NIH has been conducting what it insists is nothing more than a "fact-finding inquiry" into questions about the discovery of the virus that causes AIDS. Even though Gallo has been "interviewed" by an NIH panel on a dozen occasions so far, with three or four more scheduled, the NIH's position is that it is engaged in a preliminary inquiry.

Gallo has not complained, but others worry about the impression OSI conveys. Attorney Barbara Mishkin, viewing the case as an outsider, says the notion of an "interview" is "nonsense. They're really holding quasi-legal hearings," she believes. And therein lies the dilemma. Although institutions want to maintain the position that their inquiries and investigations are a far cry from civil or criminal court proceedings, there are many similarities—except due process.

Would the accused be better off if formal legal charges were brought against them? *Science* found no consensus among defense attorneys on this point but Mishkin did note that "once the Justice Department or the courts are involved, you can have all the due process you want." However, another, who declined to be quoted, says, "Absolutely, yes. Then you'd be confined to matters that are plainly illegal, and you'd only be able to hear from witnesses who have firsthand knowledge of a case."

The current debate may become moot if Congressman Roe's due process bill is approved by the House and Senate. Then, institutions that want to take advantage of congressional immunity will have to amend their procedures to include due process—even if the ink is barely dry on policies recently put in place.

■ BARBARA J. CULLITON

Hubble: It Could Have Been Worse

As good news goes, it seems a bit like learning that your tumor hasn't metastasized. But to scientists still trying to come to grips with the devastating optical flaw in NASA's $1.6-billion Hubble Space Telescope, the test results that arrived in early July were about the best they could hope for: "With a fair degree of confidence," says optics specialist Christopher Burrows of the Space Telescope Science Institute in Baltimore, "the error appears to us now to be on the primary mirror"—the 2.4-meter-wide disk of lovingly polished glass that NASA once called its Crown Jewel.

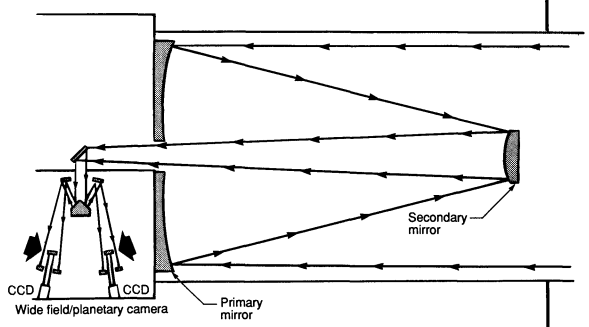
This is *good*? Indeed it is, says Burrows. Had the error been in Hubble's 0.3-meter secondary mirror, which takes the starlight collected by the primary and bounces it down into the scientific instruments, it would have given observers far more trouble than they have already and would have been considerably more difficult to fix.

Back when Hubble's optical imperfections were first recognized in late June, he explains, most astronomers hardly cared which mirror was at fault. Either way, the telescope's images were going to be contaminated with severe spherical aberration, a distortion that gives every star a fuzzy halo; more than half of their planned observations were going to be hampered or destroyed (*Science*, 13 July, p. 112).

However, Burrows and other opticians quickly realized that pinpointing the error was critical. If the flaw lay in the secondary mirror instead of the primary, he says, many observations would also suffer from a type of aberration known as coma, in which some star images acquire little tails that make them look like comets.

No such problem has yet showed up in Hubble's Wide Field/Planetary Camera (WF/PC), the instrument that first revealed the spherical aberration, says Burrows. But the WF/PC is located at the center of the telescope's field of view, where the coma would be close to zero in any case. Only about halfway out, at the location of the telescope's "off-axis" instruments—its two spectrographs, its photometer, and its Faint Object Camera—would the coma start to become serious. And at the very edge of the field of view, where Hubble's three Fine Guidance Sensors look for ultraprecise star images to keep the telescope pointed accurately, the coma would be crippling.

So Burrows and everyone else on the Space Telescope project were greatly relieved when several days of tests beginning on 6 July revealed no obvious sign of coma anywhere. In particular, trial images from the Faint Object Camera showed plenty of spherical aberration, but no comet tails. And the Fine Guidance Sensors locked onto their guide stars and steered the telescope quite happily. Thus, the error is almost certainly in the curvature of the primary mirror.



An easy fix? *The new camera can bring Hubble into focus with one new mirror per CCD detector (arrows).*

Scientists and engineers at NASA's Jet Propulsion Laboratory in Pasadena, California, are also relieved. They are currently in a rush to devise corrective optics for a second generation WF/PC scheduled to replace the first one when space shuttle astronauts revisit the telescope in 1993. And, as WF/PC II principal investigator John Trauger points out, a curvature error in the primary mirror turns out to be much easier to compensate for than one in the secondary mirror.

In either case, he says, the fix would consist of replacing certain nickel-sized relay mirrors inside the WF/PC II with new mirrors, each one having just enough curvature to restore the aberrated starlight and bring it to a perfect focus on the camera's eight detectors. But since the error is on Hubble's primary mirror, says Trauger, WF/PC II will only need eight new relay mirrors, one for each detector. If the error had been on Hubble's secondary mirror, WF/PC II would have needed 16 new relays—and the compensating curves on each one would have been much more complex.

"What we need now is to know exactly how big and what shape the error is," he says. To put it mildly, "we want to be 100% sure we have the correct solution."

■ M. MITCHELL WALDROP