

A final frenzy for landmark cases?

Washington

ANY new year resolution to say no more about misconduct and Robert Gallo, Thereza Imanishi-Kari or David Baltimore will almost certainly be broken. This may, however, be the last year in which that is the case. After years of heated rhetoric and conflicting claims, several landmark cases in the evolution of scientific misconduct policy are nearing their end.

Imanishi-Kari

The 1986 *Cell* paper has been retracted,

co-author David Baltimore has resigned as president of the Rockefeller University, a draft report from National Institutes of Health (NIH) investigators found evidence of misconduct, and yet the case of Thereza Imanishi-Kari and her immunology research could still have a few more scenes to play out.

The US attorney in Baltimore, Maryland, may seek an indictment on criminal charges as early as late January. But now that Suzanne Hadley, the principal investigator in the case, has been forced to

resign from NIH's Office of Scientific Integrity (OSI), the misconduct office is backpedalling as fast as it can from her damning draft report, which was leaked last year. (In fact, OSI no longer even calls it a draft report. Officials now refer to it as the "cross-examination report" and say that the final document in the case will probably bear little resemblance to what has been seen so far.)

But until Imanishi-Kari and her lawyer agree to cooperate, OSI is deadlocked. Imanishi-Kari has refused to comment on

Growing up in public

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If the modern era of scientific misconduct was born two and a half years ago when the National Institutes of Health (NIH) created the Office of Scientific Integrity (OSI), 1991 was its awkward adolescence. The year opened with a nation watching the investigations of AIDS pioneer Robert Gallo and immunologist Thereza Imanishi-Kari (and by extension, her co-author David Baltimore), as well as open warfare over the operation of the OSI. And, unfortunately, it closed just the same way.

In the intervening 12 months, Suzanne Hadley resigned as the deputy director of OSI, and Representative John Dingell (Democrat, Michigan) strongly criticized NIH for its bungled handling of the whole issue. Other than that, not much changed. Investigation of scientific misconduct was a mess last year, and it is a mess today.

However, 1992 may be the year in which misconduct grows up. For one thing, the investigations of Imanishi-Kari and Gallo — OSI's flagship cases — seem to be winding down, though slowly (see story this page). And although those cases have been long, ugly affairs, they have opened up the misconduct system as never before.

Through congressional hearings, a phenomenal amount of news coverage, and the attention of virtually every element of the scientific community, the pitfalls of misconduct investigating are now a matter of public record. Leaks are one problem. So are inconsistent procedures (for instance, prominent researchers got special review committees, although others did not). In both the Imanishi-Kari and the Gallo case, NIH investigators were often reduced to a role of following up allegations in the press, which made nearly everyone but Dingell uncomfortable. And an important debate over 'due process' in OSI investigations has, intentionally or not, essentially halted several cases.

Even OSI admits that some of its most prominent investigations were badly handled. But it has also learned some tricks on the job: to avoid leaks, sensitive drafts reports now go only to principal parties, and OSI is increasingly employing forensic and statistical analysis to add some quantitative rigour to what has often been a disquietingly subjective process. Investigations now focus on whether misconduct occurred, and no longer stumble on the question of a researcher's intent. As OSI discovered, claims of "unintentional" misconduct have flummoxed many university investigations, even when they turned out to be a red herrings that obscured clear abrogation of scientific responsibilities.

Other changes at OSI are coming from outside. After losing a lawsuit that challenged the way it developed its procedures, OSI published a set of proposed new rules last year. Public comments were generally scathing, mostly focused on the

proposed definition of misconduct, which included, together with the usual "fabrication, falsification and plagiarism", the category of "other practices that seriously deviate from those that are commonly accepted from the scientific community". An NIH advisory committee has recommended that the catch-all phrase be changed to "other fraudulent activities in proposing, conducting, reporting or reviewing research", a definition that OSI says it can live with.

The committee also proposed — and NIH agreed — that OSI's staff be increased from 19 to 28, including, for the first time, three lawyers (OSI investigators have traditionally been scientists). And the committee recommended open hearings, in which accused and accuser can face each other. OSI director Jules Hallum opposes that move, arguing that face-to-face confrontations "would destroy the willingness of whistle-blowers to come forward."

Even as it reconsiders its role, however, OSI languishes in a sort of bureaucratic limbo. Both Congress and some Administration officials are contemplating taking OSI away from NIH and placing it instead under the wing of the Department of Health and Human Services, NIH's parent agency. When Dingell held a hearing last summer accusing Bernadine Healy, the NIH director, of a conflict of interest in an OSI investigation of a case at the Cleveland Clinic, Healy's former institution, it only reinforced the concern that OSI — located on a campus full of scientists — is vulnerable to pressures from the scientific community. Dingell thinks OSI might be more independent if it operated like any other government investigative office — firmly entrenched in the bureaucracy. If the administration does not propose the move itself, congressional legislation to that effect may appear this year.

But the worst may be behind the misconduct controversy, if not OSI itself. Perhaps the most encouraging sign is the improving quality of university investigations. Whereas academic panels in the past often erred on the side of finding no misconduct, Hallum says that recent university investigations, such as two last year at the California Institute of Technology, have been more thorough and fair. "If they keep it up, they may put us out of business," he says. Nevertheless, until conspicuous mishandlings such as Imanishi-Kari's inquiry at the Massachusetts of Technology and that of whistle-blower Erdem Cantekin at the University of Pittsburgh (see story, next page) become a thing of the past, OSI wants to keep tight reins on the universities. The proposed new procedures would allow OSI to intercede earlier in an academic investigation if things seem to be going awry, and Hallum is hoping to have the rules clarified to give OSI explicit authorization to investigate the universities themselves, to explore the possibilities of cover-ups.

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