

appeals or in courts of law as the fine points of conduct are contested.

Additional paragraphs in the misconduct definition deal with obstruction of an investigation and with non-compliance with research regulations. The idea, according to commission member C.K. Gunsalus, of the University of Illinois at Urbana-Champaign, is to have both a principle *a priori* to which scientists can refer and a definition that does not allow the exclusion of certain practices if a dispute results in legal proceedings.

The responsibility for adhering to the principles of the new definition remains, in the commission's view, with the institution where the scientists work.

The whistle-blowers' bill of rights is extensive and is intended to raise institutions' awareness of this responsibility, says ORI director Lyle Bivens (who is not a member of the commission). It deals with such issues as the timeliness and fairness of proceedings and draws attention to the whistle-blowers' responsibility to behave "honorably" given the serious consequences of their accusations. The report notes that it is a matter of public record that some "good-faith whistle-blowers" have experienced "harm or ruin to their professional careers."

Currently, regulations require institutions to provide 'assurances' that it has mechanisms in place to investigate allegations of misconduct. These must accompany grant applications submitted to branches of the Public Health Service. The commission recommends inclusion of an additional assurance that educational programmes are in place for continuing training in the ethics of research.

One area not covered, but which was raised during the commission's earlier discussions, is that common standards should be drawn up concerning issues such as authorship and data management. The commission concluded that this would be too difficult given the diversity in the nature and practice of science. This is where some commission members believe professional societies have a role to play.

The commission's final meeting will be this month. Before new regulations can be issued, its new proposals will have to be published in the *Federal Register* for public comment. Alternatively, Congress could enact legislation to encompass the commission's opinion about how misconduct should be defined. Either way, the process has a long way to go.

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Imanishi-Kari gains ground at hearing

A small, cramped hearing room five blocks from the US Capitol Building has been the setting this summer for what is probably history's most costly and complex science fraud 'trial'. The hearing is Thereza Imanishi-Kari's appeal of the US Office of Research Integrity's (ORI, Department of Health and Human Services) charges that she fabricated data for a 1986 paper in *Cell*.

So far, the ORI's scientific arguments have not fared well. The ORI, for example, has alleged that an antibody reagent known as BET-1 had never worked in her former Massachusetts Institute of Technology laboratory as the *Cell* paper claimed. Under cross-examination, ORI's lead investigator John Dahlberg admitted that he had not subtracted background counts from her BET-1 measurements and had omitted BET-1 data from all but the most extreme, and hence unreliable, dilutions. "Isn't it fact that if you had done some of these things, [if] you [had] included some of [these] data, your overall presentation would have been more accurate?" asked Joseph Onek, Imanishi-Kari's defence lawyer. "Yes," Dahlberg replied. Led through the corrected calculations, Dahlberg reversed his earlier claim that BET-1 had not worked. Experts have also testified that the laboratory's Moema Reis

and even Margot O'Toole, the original whistle-blower, had comparable BET-1 data.

This embarrassment was not for lack of notice. Immunologist Ursula Storb of the University of Chicago and an advisor to ORI, told the ORI last year that "focusing so strongly on the BET-1 problem makes one wonder whether the rest of the accusations may be false. Imanishi-Kari had no valid scientific reason to falsify the BET-1 data."

For the ORI, immunologist Joseph Davie, of the Massachusetts-based biotechnology company Biogen Corporation, has criticized what he sees as 'scientific misrepresentations' by Imanishi-Kari. Two other scientists, William McClure of Carnegie Mellon University and Nobel laureate Walter Gilbert of Harvard University, have also testified for the ORI. Significant parts of their testimony depend on the validity of forensic evidence slated for scrutiny in late August, after *Nature Medicine* went to press. Meanwhile, 12 immunologists and four *Cell* paper coauthors, including Nobelist David Baltimore, have testified for Imanishi-Kari.

Next month, a *Nature Medicine* special report will more fully examine the charges in this case.

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Orphan drug tax credit renewal

Legislation that would extend and make permanent a tax credit programme intended to benefit companies developing drugs to treat rare diseases could fall victim to the partisan politics that often precede a US presidential election.

Until last December, companies could claim a 50 per cent tax credit on costs incurred in clinical trials of so-called orphan drugs developed to treat diseases affecting fewer than 200,000 people. When Representative Nancy Johnson (Republican, Connecticut) noted that the bill had expired, she reintroduced the measure in May to the US House of Representatives, adding a clause that permits companies to carry the tax credit forward to a profitable year. The bill would also make the tax-law provision permanent. In July, Senator Orrin Hatch (Republican, Utah) introduced in the US Senate a companion bill, identical in nature to Johnson's proposed legislation.



Nancy Johnson and Orrin Hatch call for permanent tax credit for orphan drugs.

Introduced originally in 1983, the Orphan Drug Act provides special tax and marketing incentives to companies developing drugs to treat rare diseases like dwarfism and Gaucher's disease.

An aide to Johnson says that the best chance for the bill's passage is if the House Ways and Means Committee tags it onto its 1996 budget proposal, in which case it could be law by autumn.

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