Tougher crackdown on fraud needed

Sir — An increasing number of scientific frauds in US universities are being reported in the media. But do university and federal authorities wish to resolve the problem quickly and effectively? I think not, and I think this is a matter of serious concern.

Fabrication of scientific data, malpractice and violations of federal regulations in university laboratories supported by the National Institutes of Health (NIH) are not only an outrage to all honest scientists, but are also serious federal felonies. Nevertheless, the NIH allows university authorities to carry out an administrative investigation when suspicion of fraud is reported.

University authorities have neither the apparatus nor the authority for a formal investigation: they cannot subpoena witnesses and evidence or seize relevant documents. University committees do not have the legal authority to prevent a defendant's attorneys from resorting to unethical pressure to discourage the whistle-blower and witnesses. Indeed, university authorities themselves are not protected from expensive lawsuits.

It is only at the end of the administrative investigation (which typically takes three to five years) that the university has to inform NIH whether federal grants are involved in the alleged fraud. If the university has decided there has been fraud, it has to pay back all the grants to NIH. This is an unfortunate conflict of interest.

Federal prosecutors inquire into scientific fraud only if the whistle-blower files a *qui tam*: an action aimed to formally involve the responsibility of federal authorities in the investigation. This usually happens after two to three years, when evidence has long since been contaminated or has disappeared. The federal prosecutor's office is not interested in considering the criminal aspect of the case (violations of federal laws and flagrant fraud in applications for federal grants) or in punishing the defendant. It does not even recommend a probation period during which the defendant cannot receive federal funds. It just collects sufficient evidence to reach a settlement with university attorneys, to recover part of the grants paid by the federal administration.

A recent case at the University of California at San Diego is a classic example (see *Nature* **385,** 566; 1997). In October 1993, the dean's office started an investigation against a professor of medicine for allegations of fabricated research results and violation of federal policies on human and animal experimentation and biosafety standards. In 1995, an *ad hoc* university committee found evidence of fabricated data in at least two articles reporting work supported by NIH grants, but this was not sufficient evidence for misuse of NIH funds: the university biosafety committee sanctioned the scientist for violation of biosafety regulations concerning the use of the AIDS virus. The scientist appealed to the academic senate and in December 1996 a panel of university scientists (colleagues of the defendant) cleared the scientist of all accusations of scientific fraud or violation of federal regulations.

Interestingly, just one week after the favourable conclusion of the academic senate, the US attorney's office decided to act against the defendant and the university, suggesting that the government was not convinced by the conclusion of the university investigation. About one year later, a settlement of only $135,000 was reached between the government and the University of California for the reimbursement of federal grants for work containing fabricated data. The defendant was released from any civil and criminal charges. Surely such a low settlement sends a conflicting message to scientists.

Federal legislators must re-examine the problem of scientific fraud — in particular the agreement between NIH and universities — and implement federal judiciary structures to handle from the beginning investigations of scientists accused of fraud (civil as well as criminal aspects), to protect whistle-blowers, and to apply an appropriate punishment in a timely fashion. Such a reform is needed to encourage some scientists to consider more carefully how taxpayers' money is used in their laboratories and to adopt higher standards of integrity.

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Modified animal feeds must be put to the test

Sir — One way to allay public concerns and to find out more about the effect of genetically modified organisms (GMOs) would be to investigate more fully their use in animal feeds. Much money is spent on determining the safety of GMOs as human foods, but would it not be cheaper, easier and more ethical to test animal feeds first?

Large quantities of plant materials, produced by genetic engineering, are destined as raw materials for animal feed: 85 per cent of maize, for example, is used as animal feed or as agro-industrial by-products. Most soya beans are used as protein-rich meal for animals; almost two-thirds of unginned cotton, and most rape seeds and tomato pomace are used as or in feedstuffs. These crops are among the first GMOs submitted for licensing, and will end up in the human food chain. It is obviously more convenient for research to be done on animal feeds rather than on human food.

The central concept in animal nutrition is 'nutritive value' which is influenced by the presence of undesirable substances, including the potential transfer of harmful factors introduced into the DNA of plants during their conversion into GMOs. Companies base their safety criteria on the principle of 'substantial equivalence' between the engineered and the corresponding conventional plants. To measure this, they generally use chemical, *in vitro* and *in vivo* analyses. Chemical methods compare the sequence of amino acids of the introduced protein with those of known allergenics; *in vivo* methods use small laboratory animals for acute oral toxicity tests of relatively short duration. Although these methods are useful tools, one cannot safely extrapolate between species. Biology is often unpredictable: for example the antibiotic cross-resistance to ampicillin in humans. In GMO plants resistant to herbicides, a complex is created between the 'factor introduced for resistance' and the 'herbicide'. The possibility cannot be ruled out that this complex could be broken down during digestion in the gut or during fermentation, resulting in release of the herbicide.

In addition to the need for labelling and an increased role for legislation and monitoring (guidelines), there is a strong need for research in 'evaluation'. Companies have to demonstrate that GMOs are both effective and non-toxic. Risk assessments are essential to ensure the latter. Study of feeds and farm-animal nutrition for at least one reproductive cycle is also needed. If the health of the animals is not harmed as a result of these tests (which should be done in government-funded institutions), the public is more likely to be reassured. Companies would be in a better position to convince the public of the safety of GMOs.

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