## NIH's summer of scandal

Officials at the US National Institutes of Health (NIH) are going through tough times. In a letter to NIH director Elias Zerhouni last month, a congressional committee accused the agency's researchers—including Richard Klausner, former director of the National Cancer Institute—of violating federal criminal and ethics laws by accepting 'lecture awards' from NIH grantees. The letter asks the NIH for a list of all awards and prizes received by its employees since 1998, saying the committee is investigating "management and ethics concerns" at the institute.

The committee alleges that as a presidential appointee, Klausner should not have accepted any outside income. Klausner, now director of the global health program at the Bill and Melinda Gates Foundation in Seattle, says he got permission for each award and filled out the required disclosure forms. NIH officials, who maintain that they are "not aware of any ethics rules violations," turned over all relevant documentation by 11 July, the deadline set by committee members.

The agency faced more bad publicity this month when Edward McSweegan, a researcher at the National Institute of Allergy and Infectious Diseases, gave media interviews saying he was being paid an annual salary of $100,000 to do trivial tasks fit for an intern. *AM*

## Europe to donate a billion dollars to Global Fund

European leaders have pledged to donate $1 billion to the Global Fund to Fight AIDS, Tuberculosis and Malaria by 2004. Speaking in Paris at an international conference assessing the fund's progress, European Commission president Romano Prodi cautioned the 250 attending delegates that the 15 European Union member states might encounter difficulties agreeing on the amount.

French President Jacques Chirac also committed to Europe's monetary support and called on the US to match Europe's contribution. The US in March doubled its donation to $200 million per year.

The fledgling program, set up last year to finance intervention programs, has been struggling for adequate funding since its inception. In May, federal investigators reported that the fund held just $300 million, even as officials approved grants cumulatively worth $1.5 billion. (*Nat. Med.* **9**, 632; 2003).

A number of other countries at the conference reconfirmed their support, which totals $2.6 billion through 2004 and $2.1 billion for 2005–2008. However, the fund still lacks the $3 billion it needs to cover the next three granting cycles. *PB*

News briefs written by Paroma Basu and Apoorva Mandavilli

## Europe to label GM foods

The decision in July by the European Parliament to label and strictly monitor all genetically modified (GM) foods prompted criticism from US industry groups and praise from environmental advocates. The new regulations require the labeling of all foods containing more than 0.9% of a GM organism. GM crops are to be rigorously traced through their passage from field to marketplace.

The Bush administration and several US farm and trade groups criticized the new legislation, condemning it as a barrier to commerce and a biased manipulation of consumers. The European Commission has noted it will lift the GM-banning moratorium of the past five years once the new rules take effect. However, it is unclear whether the Bush administration will drop the antimoratorium lawsuit it filed with the World Trade Organization in May.

Meanwhile, environmental groups praised the new labeling and traceability regulations. They maintain, however, that the 0.9% threshold is too high and that biotechnology companies should be strictly liable for GM-related environmental contamination.

The new rules will permit each of the 15 European Union (EU) member states to enforce their own laws to prevent genetically altered seeds from contaminating adjoining farms. The Council of EU Agricultural Ministers is expected to vote on the proposed regulations in late July. If approved, the rules will take effect in September, with a six-month compliance period. *PB*

## Massive cancer study set to probe epidemiologic trends

The US National Cancer Institute (NCI) announced funding in July for a large-scale, $17 million epidemiologic study to assess the combined effects of genes and the environment on breast and prostate cancers. The four-year international study will for the first time pool data from 10 diverse study populations—totaling 8,850 prostate cancer patients and 6,160 breast cancer patients—to boost researchers' chances of detecting significant epidemiological trends.

The study is the first research project of the Consortium of Cohorts, a group established by the institute in 2000. The consortium aims to increase large-scale collaborations on the genetics and molecular epidemiology of cancers, and currently comprises 23 cohorts in the US and Europe.

By pooling data from different cohorts, scientists can reach conclusions faster, with much lower cost and far greater certainty, says Edward Trapido, associate director of the NCI's Epidemiology and Genetics Research Program. Current large-scale studies follow up to tens of thousands of subjects, but pooling cohorts together could push sample sizes up to 100,000, Trapido adds. *PB*

## US to speed up drug review

The US Food and Drug Administration (FDA) plans to cut the average time for drug reviews by 10%, Commissioner Mark McClellan announced at the Biotechnology Industry Organization's annual conference in June. The initiative will unfold over five years and may accelerate the current drug approval process by as much as one month, McClellan said.

The FDA originally announced the initiative in January, soon after McClellan came to office last November. A drug review cycle now takes 6–10 months. The agency approved only 12 drugs last year, compared with 25 in 1993. Shorter review cycles will trim the cost of assessing new medications by more than $12 million, McClellan says.

As part of the new program, FDA officials will have early contact with drug companies to ensure they understand the application process. The agency also plans to institute controls such as a real-time electronic monitoring system that promptly alerts the organization about potential negative side effects of approved remedies.

The FDA is also planning new regulations to bring cheap generic drugs to the market more quickly. Drug companies holding patents will be limited to one 30-month extension of exclusivity—rather than a series of such extensions—when they sue manufacturers of generics. *PB*