Stanford hit by $1m fines over hazardous materials

San Francisco. Stanford University has agreed to pay almost $1 million in fines for mishandling hazardous waste materials, the largest fine ever levied on an educational institution in the United States. The university will pay $460,000 in penalties to the state, $235,000 in costs, and $300,000 to three local environmental groups.

The university has now warned its researchers that, in future, they could be personally liable for fines arising from any infringement of state regulations for which they are found to be responsible.

Stanford officials have admitted liability for 40 per cent of 1,600 violations of which they had been accused, thus avoiding a lengthy court battle. The violations concerned toxic spills, mislabelling of containers, and inadequate storage both in university laboratories and at its Environmental Health and Safety (EHS) facility on campus.

"The problems we saw at Stanford were as widespread and serious as any problems we had seen anywhere in the state," says Allan Hirsch, a spokesman for the California Department of Toxic Substances Control. Hirsch claims that toxic materials are just as serious "in an academic institution as in a factory", and that the settlement puts other educational institutions on notice that they will be held to the same standards as industry.

According to Hirsch, discussions are already taking place between his department and the University of California at Berkeley, and California State University campuses at Hayward and Sonoma, over possible violations.

But Lawrence Gibbs, director of EHS, disagrees with Hirsch on the severity of the problems at Stanford. "Regulations are needed, but the requirements must be appropriate for the environment," he says, arguing that regulations based on conditions in industry are not directly applicable to the laboratory. For example, says Gibbs, industrial chemical operations generate large quantities of relatively few different types of hazardous waste. This is in contrast to research universities such as Stanford, which has approximately 2,300 sites that generate or store approximately 5,000 different kinds of chemicals, but usually in very small quantities.

Barbara Barres, a researcher in the university's department of neurobiology, says that this itself can create problems when it comes to labelling. Regulations supplied in a volume "a foot thick" stipulate that every chemical must be labelled with its full name, with no abbreviations allowed. In some instances this is impossible, says Barres, given the very small containers routinely used.

The present settlement involves violations between 1988 and 1992. But Stanford has had problems with its handling of hazardous materials since 1986, when a whistle-blower complained of design flaws in the university's new $7 million EHS facility, including drains running in the wrong direction and an incinerator chimney that blew fumes back into the EHS offices.

In March 1992, the university told the state it had sorted out its problems. But an inspection one month later found hundreds of containers violating regulations; some were unlabelled or mislabelled, others were in a rusty condition, and many were improperly stored.

The state imposed 28 more citations on the university, saying that it had "intentionally or negligently falsified inspection records". More violations were uncovered in August and September 1993, and again in June this year.

A spokesman for the university claimed last week that the safety of both individuals and the environment "was not endangered". He said that three-quarters of the citations involved administrative processes, such as record-keeping, labelling, and reporting.

But some university researchers believe that the harshness of the fines which have been imposed on the institution may reflect the state's frustration with the way in which the university had attempted to deflect earlier criticism of its handling of hazardous materials.

Joel Shurkin

Genentech agrees to drop promotion of growth hormone

Washington. In response to pressure from Congress, the biotechnology company Genentech has withdrawn its support for controversial 'height screening' programmes and other promotional activity for the synthetic human growth hormone Protropin, one of the first pharmaceutical products of genetic engineering.

The California-based company announced its move in a letter to Ron Wyden (Democrat, Oregon), chairman of the House of Representatives small business regulation subcommittee. Wyden has been investigating allegations that the screenings led to the $20,000-a-year drug being prescribed for short children who are not hormone-deficient. Protropin, which earned $216 million for Genentech last year, has been approved for the treatment of hormone-deficient children only.

The drug's distributor, Caremark, has also promised to cut all financial links with doctors who prescribe the drug. Caremark and Genentech executives are facing charges in Minneapolis — which they deny — of making illegal payments of $1.1 million to a paediatrician who did so.

Wyden welcomed Genentech's move as "an effective step forward". But he added that it amounted to an admission that the promotional campaigns had gone too far, and promised to pursue tighter national standards to control the promotional activities of the pharmaceutical industry.

Colin Macilwain

France boosts gene therapy centres

Paris. **France is considering taking steps to simplify the regulatory procedures for gene therapy and to encourage the wider use of the technique in its public hospitals, according to Philippe Douste-Blazy, the country's junior health minister.**

Gene-therapy trials were first approved by the government in 1990, when the national bioethics advisory committee concluded that somatic gene therapy posed no special ethical problems. But as protocols for gene therapy are handled under existing legislation, their approval falls under the jurisdiction of four different committees.

In practice, this bureaucractic labyrinth has been less difficult to negotiate than it might appear. A coordinated processing system, reinforced by the fact that the same individuals often sit on the different committees, has meant that more than half of the 16 protocols examined so far have been approved, all within less than six months.

With demand expected to increase, the government is now considering ways of streamlining the process. But rather than taking the long route of passing new legislation specifically aimed at gene therapy, it is considering creating an inter-ministerial commission that would take over the work of the existing committees.

The government also intends to attach small gene-therapy centres to hospitals across the country, in a bid to shift gene therapy techniques from the laboratory to the hospital ward.

Another longer-term proposition aimed at speeding up clinical trials and encouraging greater industrial investment in gene therapy is that the country should establish the equivalent of the US Orphan Drug Act. Under this act, which was passed in 1983, companies that develop drugs for rare diseases — defined as those that affect fewer than 200,000 people — are granted certain commercial and legal privileges.

Declan Butler