Gene therapy experiments put on "clinical hold"

James Ciment *New York*

The Food and Drug Administration (FDA) temporarily shut down a series of human gene therapy experiments at the University of Pennsylvania last month following the death of Jesse Gelsinger, an 18 year old man from Arizona who was being treated for a liver disorder.

The order to place the university's entire gene therapy programme on indefinite "clinical hold" came two days after inspectors issued a report noting 18 specific violations of government protocols.

The administration said that the hold would not be lifted until the university's Institute for Gene Therapy showed that it could follow procedures that protect volunteers from harm.

Among the evidence gathered by the administration was the institute's failure to consider Mr Gelsinger's eligibility for the treatment, in the light of reports of serious effects in other patients.

This violation was made public in a report issued during a December meeting of the recombinant DNA advisory committee, the National Institutes of Health's panel established to oversee gene therapy research.

But the final report included numerous other violations. The FDA said that the informed consent process "was not well documented" and thus it was difficult to determine who had conducted or attended the discussions on informed consent.

Meanwhile, Paul Gelsinger, Jesse's father, who supported the experiments even after last month's advisory committee report, has said that he has now changed his mind and hired a lawyer. So far no suit has been filed.

Jesse Gelsinger was undergoing treatment for ornithine transcarbamylase deficiency, a disorder that prevents the liver from effectively processing ammonia, a toxin produced in the breakdown of proteins. He died of multiple organ failure triggered by a severe immune reaction to an infusion of corrective genes.

Adding to the controversy was the fact that the inherited disorder is relatively mild and that the patient had previously kept the problem in check through diet modification and prescription drugs.

Mr Gelsinger's death is believed to be the first directly resulting from gene therapy. The episode—widely reported in the media—has sent shock waves through the gene therapy research establishment. □

The artist Alexa Wright collaborated with the dermatologist Professor Irene Leigh to create this image of a woman with vitiligo. The photograph is part of the Invisible Body exhibition at the Atrium Gallery, Whiteleys Shopping Centre, London, until 13 February.

Talks continue on UK juniors' pay

Linda Beecham *BMJ*

Junior doctors' negotiators were due to have a formal meeting with the Department of Health this week for the first time since 5 December.

At its meeting in December, the BMA's Junior Doctors Committee rejected the latest proposals for improving out of hours' pay, although it resolved that the concept of a banded contract, which recognised antisocial and intense working, was its "chosen option" (1 January, p 62). At the same time, it asked the BMA to put in place the mechanisms to conduct a ballot on industrial action if no progress was made.

At a meeting of the BMA's council executive last week the juniors did not ask for a ballot but spelt out the gaps that still existed between what officials have offered and what the juniors' committee has called for.

Mr Nizam Mamode, chairman of the negotiators, said that he anticipated that his out of hours pay would increase from 50% to 52.5% of basic pay. Doctors working shifts with antisocial hours would get little extra recognition.

The executive committee reaffirmed its support for the juniors' campaign, and the chairman of the Central Consultants and Specialists Committee, Dr Peter Hawker, said that he was impressed with the progress that had been made so far. But he believed that there was still room for manoeuvre.

After the meeting the chairman of council, Dr Ian Bogle, said, "It is important for all junior doctors to be fully involved in the decision making process. Once the negotiators have reached as far as they can, I believe that all 30 000 junior doctor members of the BMA should be asked whether the proposed deal is acceptable. □

Details of the campaign and related papers are on the BMA's website (www.bma.org.uk).

Patients, but not doctors, like mediation for settling claims

Clare Dyer *legal correspondent, BMJ*

Mediation may provide better redress for victims of medical negligence than pursuing claims through litigation, according to a three year study carried out for the Department of Health in England.

But the NHS and claimants' lawyers will need to be more willing to refer cases for mediation if the benefits are to be reaped.

The pilot study in two NHS regions—Anglia and Oxford, and Northern and Yorkshire—was launched in 1995 with the aim of analysing up to 40 mediations over two years. But the low referral rate meant the study had to be extended for a third year, and only 12 cases were completed by the end.

However, the research team, led by Linda Mulcahy, reader in law at Birkbeck College, University of London, also identified 44 "near miss" cases in which mediation had been suggested to the opposing side, 14 of which were ongoing referrals at the close of the scheme.

The study also included an analysis of nearly 4000 claims handled by traditional methods. The researchers interviewed claimants whose claims were settled in the standard way, parties who took part in the mediations, solicitors specialising in clinical negligence, and claims managers. Doctors who had been involved in a claim were also surveyed, but the response rate was only 14%.

Of all the groups involved in mediation, doctors were the least satisfied with the process. Doctors are more exposed through mediation than through traditional litigation. □

Full story in News Extra at www.bmj.com