Green light for gene therapy in Japan

Japan's first clinical gene therapy trial has finally been given government approval to go ahead. On 6 February a 15-member committee of senior Japanese scientists, social critics and legal experts assembled by the Ministry of Health and Welfare approved a proposal put forward by Yukio Sakiyama of Hokkaido University in northern Japan. A protocol pioneered in the United States will be used to treat a 4-year-old boy with adenosine deaminase deficiency, a genetic disorder that leads to impairment of the immune system (*Nature Medicine* **1**, 9; 1995).

The health ministry meeting was the final hurdle in a series that Sakiyama has had to leap since he first submitted his plans last summer. One of the reasons that approval has taken so long is that the Ministry of Education, Science and Culture has also demanded a say. A joint working group set up by both ministries approved Sakiyama's proposal last December. The education ministry's full committee, which met behind closed doors on 1 February, then rubber-stamped the plan, closely followed by the health ministry five days later.

The health ministry's meeting provided another landmark: it was the first time that such a government committee has been open to members of the public and press. This is a promising sign. The Japanese government and medical establishment seem to recognize that new forms of treatment such as gene therapy have broad ethical implications that deserve greater publicity and more open debate than is usual in Japan.

Most of the committee's discussion centred on the precise wording used in the document of informed consent, which has to be signed by the patient's parents. There was some debate, for example, over whether it would be raising false hopes to describe the procedure as a 'treatment' rather than 'experimental'. But after the wording was toned down, the proposal was given unanimous approval.

The initial response in Japan appears to be positive. The meeting was free from the disruption and controversy that has at times accompanied similar gatherings in Europe or the United States. The 30 or so onlookers, mostly journalists, sat in virtual silence as the committee carried out its sober deliberations. Reporting in the Japanese media has concentrated largely on the problems associated with informed consent but has also emphasized the hope that gene therapy might one day be extended to treatment of much more common conditions such as cancer and AIDS.

Sakiyama will not be able to start right away. The retroviral vector he plans to use to transfer the therapeutic gene into his patient's cells is produced in the United States and will require approval from the US Food and Drug Administration before it can be exported to Japan. How long this will take is unclear but Sakiyama says that he hopes to begin treating his patient next month.

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Dingell disavows 'Dingell' report on Gallo

The long-running inquiry into the work of Robert C. Gallo and his discovery of the first blood test for AIDS was supposed to culminate with a report from the US Congress. That report, being prepared under the auspices of Representative John Dingell (Democrat, Michigan), was widely rumoured to be the *coup de grâce* in a case in which inquiry after inquiry has failed to prove that Gallo or his colleagues at the US National Cancer Institute did anything illegal or fraudulent in their research on the human immunodeficiency virus (HIV). The Dingell report was supposed to change all that, proving once and for all that evil lurked in the hearts of scientists in Gallo's Laboratory of Tumor Cell Biology.

Dingell: It's not my report.

The report finally appeared in late January, when it was released via the Internet by Walter Stewart, a self-appointed fraud investigator employed by the National Institutes of Health and informally affiliated with Dingell's House of Representatives subcommittee on oversight and investigations. The central issue of dispute since 1984 has been the relative contribution to early HIV research of the Gallo laboratory versus that of Luc Montagnier of the Pasteur Institute in Paris.

The report not only criticized Gallo (as expected) but also alleged a massive cover-up by the United States government, which has patent rights on the blood test that is now used worldwide. Essentially, the report alleges that US officials who defended the Gallo laboratory's research *vis-à-vis* patent claims essentially lied, not only to protect Gallo but also to protect the US government itself against still unproved claims by the government of France that it deserves a greater share of the patent. The report contends that an agreement reached between the United States and France in 1987 amounts to a sham.

As with previous attempts to prove Gallo and the United States at fault, this latest report runs to hundreds of pages full of accusations that are not supported or have been previously rebutted. Each side in the dispute is playing its assigned role. But now, along comes congressman Dingell (often characterized as an anti-Gallo bully), distancing himself from the report. In fact, in a letter to Harold Varmus, director of the NIH, Dingell says of the report:

> We cannot vouch for the authenticity or accuracy of the papers provided to you. They were not reviewed, much less evaluated, by the staff director, the Chairman, or any other Member of the Subcommittee. While some staff time was spent developing a report, one early draft on the matter had been rejected several months ago. Because of the enormity of the editing and fact-checking tasks needed to assure that a report on this topic met the standards of the Subcommittee, no report was issued.

In short, neither Dingell nor full time members of his investigative staff stand behind this report which is essentially the work of Suzanne Hadley, a former member of NIH's former fraud office. As a result of the November political elections in the United States, which brought the Republican party to power, Dingell is no longer chairman of the House's investigations subcommittee. There is every reason to believe that the Republicans have other, better things to worry about and that the matter will now evaporate from the halls of Congress.

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