Japan turns to US for help in launching gene therapy

Tokyo. Japan's dependence on the United States and other Western countries for expertise in the whole field of gene therapy has been highlighted by the process of government screening and approval of Japan's first proposed use of gene therapy.

Some Japanese researchers now fear that the application of gene therapy in Japan may give rise to renewed US criticism that the country is taking a 'free ride' on the basic science and technology of Western nations.

Last week, a newly established gene-therapy screening committee of the Ministry of Education, Science and Culture (MESC) met to discuss a proposal by a group at Hokkaido University to apply gene therapy to a 3-year-old boy suffering from adenosine deaminase (ADA) deficiency, an enzyme deficiency that can cause a breakdown in the immune system. The meeting of the MESC committee followed a meeting a week earlier by a similar committee of the Ministry of Health and Welfare.

Both committees, which have some overlapping members, decided to form a working group comprised of the seven members they have in common to examine the safety and efficacy of the proposed technique, a modification of the world's first gene-therapy treatment carried out by French Anderson and Steven Rosenberg at the US National Institutes of Health in 1990.

The retroviral vector to be used by Hokkaido University will be imported from the United States, and the working group will be entirely dependent on US data for assessing its safety.

Takehiko Oura, head of the university's hospital, told a press conference last month that the university has been in frequent contact with officials in the United States since June in order to obtain the necessary documentation to establish the safety of the technique.

At the end of August, when the university applied simultaneously to both ministries for approval of its proposed treatment, three published papers were submitted to substantiate the efficacy and safety of the technique. But this material was apparently not considered to be sufficient by the Ministry of Health and Welfare, and more documentation is now being sought.

The US Food and Drug Administration (FDA) has large amounts of data on the vector, which was developed by Gene Therapy Inc., a US company established by French Anderson. But the university has not yet been able to obtain all the FDA documentation.

The case has drawn attention to Japan's lack of an infrastructure either for developing vectors for gene therapy, or for assessing their safety. Seven leading Japanese pharmaceutical companies, with financial support from the Ministry of Health and Welfare, are planning to set up a joint venture to develop vectors, says Mitsuru Miyata, with widely-respected editor of the newsletter *Nikkei Biotechnology*. By developing its own vectors, Japan should be able to reduce its payments of royalties to US companies.

It was originally planned that the joint venture would also assess the safety of vectors. But it has now been decided to contract out such work to the US company Microbiology Associates, which performs this role in the United States under FDA guidelines, says Miyata.

In addition, the Ministry of Health and Welfare is planning to provide a small grant of about ¥10 million (US$100,000) to Japan's National Institute of Health to assess the safety of viral vectors.

One fundamental problem facing Japan is the lack of chimpanzee colonies to test the safety of vectors. There are only two colonies in Japan, one run by the government in Tsukuba science city and the other private. Both are preoccupied with testing the safety of treatments for AIDS and viral hepatitis, and, given the limited government funding for research in Japan, it is unlikely that this situation will be improved in the near future.

David Swinbanks

Committees split over opening up proceedings

Tokyo. Japan's two gene-therapy screening committees may serve parallel roles (see left), but they have adopted a very different attitude towards coverage of their proceedings by the Japanese media.

Television cameras and the press were allowed into the meeting two weeks ago of the screening committee of the Ministry of Health and Welfare, creating an atmosphere reminiscent of the open meetings of the Recombinant DNA Committee in the United States.

In contrast, the more conservative Ministry of Education, Science and Culture refused to let the press into its meeting.

Education ministry officials argue that, while the health and welfare ministry committee has to cover medical issues of social importance (and therefore requiring press coverage), their committee will focus more on research.

But the fact that the two committees have formed a working group on the safety and efficacy of proposed gene therapy comprised of the same seven members effectively belies any difference between the two committees. Furthermore, it is well known in Japan that government subcommittees, rather than their parent committees, are the more important decision-making bodies. **D. S.**

UK charity cuts research funds

London. Britain's largest medical charity, the Imperial Cancer Research Fund (ICRF), announced last week that financial pressures have forced it to reduce overall spending on research by more than 10 per cent next year. The decision will result in the closure of several ICRF laboratories, and substantial cuts in recruitment and support for research fellows.

Sir Walter Bodmer, the director-general of the ICRF, says that the fund has decided to give a stronger focus to its support for basic research — in particular in its central laboratories in London and at Clare Hall, in Potters Bar, Hertfordshire — and on clinical research.

Research units to be closed in London include the Tumour Immunology Unit at University College and oncology groups at the Royal London Hospital and the Institute of Child Health. Funding for the ICRF's Molecular Pharmacology Unit in Dundee and its laboratory at the Institute of Molecular Medicine in Oxford will also be cut back.

Bodmer says that the work of some of the groups being closed may be continued in ICRF's main laboratories. At the same time, about 30 of the fund's 1,600 posts may disappear.

The reduction in the ICRF's operating budget — almost 90 per cent of which is spent on research — from a planned £60.5 million (US$95 million) to £54 million next year has been made necessary largely by a drop in income from legacies. These represent almost three-quarters of the ICRF's voluntary income, and grew by about 15 per cent a year during the 1970s and 1980s.

Anticipating (wrongly) that this trend would continue, ICRF has been operating at a deficit of several million pounds a year for the past few years. "We had hoped that increases in income would meet our additional expenditure, but there came a point at which we felt this approach was no longer viable," says Bodmer.

According to Bodmer, ICRF's financial difficulties highlight the importance of the recommendation of a recent working group on research in the National Health Service that charities be relieved of covering the basic health-care costs of patients in hospitals where they fund clinical research units (see *Nature* **371,** 275; 1994). **D. D.**