MRC's cryobiology closure evokes protests

- Reviewers' recommendations over-ruled
- Lack of clinical results cited

London

THE United Kingdom's Medical Research Council faced a storm of protest from British and international research communities last week over its decision to close a small cryobiology unit in Cambridge, the only group developing techniques for freezing human tissue and organs in Britain.

Condemned by leading biomedical researchers on both sides of the Atlantic and as far away as Australia, the decision will lead to the dispersal an internationally valued team of 10 researchers. All told, the group, led by David Pegg, currently receives £250,000 a year out of the MRC's budget of £180 million. At the heart of the furore over the closure is the accusation that the MRC wrongly overruled the opinion of a panel of expert referees who were unanimous in recommending continued funding of the unit. One of them, Professor Felix Franks of the University of Nottingham, has even denounced the MRC decision as "a corruption of the peer review system".

Appointed last year by the MRC to conduct a routine review of the Cryobiology Unit's work, the referees all submitted highly favourable reports. But earlier this year the council's Cell Board — one of several committees that are responsible for making funding decisions — acting on a report from its own subcommittee, gave the unit only a 'beta' rating, a verdict that, with many 'alpha'-rated projects currently failing to win funds, guaranteed the unit's closure.

The Cell Board judged the unit's work to fall below the "competitive standard" in the current financial climate, says Nick Winterton, head of the secretariat of the MRC. That judgement, while apparently at odds with the views of specialists, reflects the board's "wider scientific representation", he adds. Effectively, the unit's fate was sealed by a concluding remark in the subcommittee report that, despite 10 years of funding, clinically useful applications seem to be "still around the corner".

Be that as it may, the most outspoken critics of the decision are transplant surgeons and clinicians. In a letter of protest, Sir Roy Calne, Professor of Surgery at Cambridge, said he was "amazed" at the decision and that he "earnestly requested the council to reconsider". The MRC, says Calne, does not appreciate the enormity of the problem being tackled by the group — how to keep tissue at sub-zero temperatures without it being damaged by ice crystals — which is "probably as difficult a thing to crack as the immune system in organ rejection". At least 70 other clinicians and scientists have also lodged protests.

These might have proved easier for the MRC to deflect if the two cryobiologists invited to sit on the Cell Board's subcommittee had not already voiced dissent. One of them, Peter Mazur of Oak Ridge National Laboratory in Tennessee, complained to the Cell Board's chairman saying that his positive views had been ignored and describing the report's emphasis on "clinical isolation" as "a distortion". In a letter to Dai Rees, head of the MRC, Mazur said that he had been "thunderstruck" to hear of the recommendation to close the unit. According to Winterton, the original report was not amended but the reservations of the two dissenting cryobiologists were communicated to the Cell Board before it made its final recommendation.

For some critics, news that a medical transfusion department currently being set up in Cambridge University had intended to incorporate the cryobiology unit as its main research arm made the council's decision even harder to swallow. Such a move would have answered the chief criticism of clinical isolation, says Calne. And concern over the closure rose further still when it emerged that plans to establish a new bank for human heart valves in Cambridge had been shelved because of the MRC's decision.

The planned closure is assumed by many critics to reflect on the need for a strategic reorganization of funding within the MRC rather than the quality of the unit's work. But regardless of any protest, it is unlikely that the MRC's decision will be reversed — the Cell Board has already had ample opportunity to review its original decision in the light of representation, says Winterton.

David Concar

DRUG APPROVAL

Fast track for AIDS and cancer drugs

Washington

NEW drugs for life-threatening diseases such as cancer and AIDS should be handled more quickly by the US Food and Drug Administration (FDA), concludes a report released last week by the President's Cancer Panel. The recommendations come from a committee, chaired by Louis Lasagna of Tufts University, asked by the Cancer Panel to determine whether the approval criteria for cancer or AIDS drugs should be modified, and to identify barriers that have impeded the access of cancer and AIDS patients to new treatments.

The committee concurs with a recent Government Accounting Office opinion that the FDA is under-financed and undermanned. But a substantial increase in federal funds for FDA is unlikely in the present fiscal climate, and the committee recommends that the FDA should reduce its burden by relying more heavily on outside reviewers. Phase I and II investigational new drug (IND) applications that are filed by academic "non-commercial" researchers, many of which involve new uses for approved drugs, should be reviewed by Institutional Review Boards, the committee says. The report also suggests that drug companies should be given the option of paying "user fees" to the FDA for an expedited review of a drug by experts outside the FDA who have no conflict of interest.

To hasten the approval process for cancer and AIDS drugs, the committee urges the FDA to make its criteria more flexible: for example, in assessing the therapeutic benefit of a drug for the treatment of life-threatening condition, proof that the drug will prolong life need not be a prerequisite for FDA approval. Instead, The report suggests that a drug that produces tumour regression in more than 20 to 30 percent of patients who have not responded to alternative therapies should be approved.

Similarly, the development of AIDS drugs could be facilitated by the approval of drugs that not only cause a rise in the T4 cell count but also improve a patient's quality of life.

The committee also believes that phase III cancer studies, designed to compare the efficacy of an experimental drug with that of a marketed drug, can delay the drug approval process and should not be a requirement for marketing approval.

The committee supports the rights of patients with life-threatening diseases to obtain accelerated access to experimental drugs, and although Lasagna accepts that making new drugs available for marketing at an earlier stage may increase the dangers of toxicity, he believes that "more good than harm" would come from implementing the committee's recommendations. The committee points out that patients with life-threatening conditions, for whom there are no alternative treatments, are often willing to accept the greater risks associated with new therapies.

Diane Gershon