

Gene donors' rights at risk

Even those who treat other people's genomes as intellectual property concede that sample donors deserve some share of their genes' financial value. But those rights are already threatened in several ways — a situation that requires urgent attention.

FEW of the ethical dilemmas created by the growing commercial interest in human genetics are as complex — or as potentially explosive — as those relating to the 'ownership' of genetic data. So far, the most acute conflicts in this area have been provoked by applications from Western researchers for patents on genetic information derived from indigenous groups in developing countries. This is not surprising. Such instances stimulate passionate feelings about the way other resources belonging to such groups have been exploited in the past, and how little of the fruits of this exploitation made their way back. But it would be wrong either to dismiss the passion as being purely politically motivated, or to see the issue as restricted to indigenous populations.

Virtually all large pharmaceutical industries are now developing an intense interest in the genetic basis of disease, which many see as central to their future products. The increasing sophistication of the tools of genetic analysis means that this interest is no longer restricted to 'single-gene' diseases such as cystic fibrosis, but now extends to a wide spectrum of what are called 'complex disorders', from arthritis to cancer. Companies likely to achieve dominance are those that maintain a scientific lead over their competitors. And this is likely to be built partly on a combination of commercial secrecy and the exploitation of intellectual property.

All this means that the stakes involved in the quest for genetic information are high. Those already caught up in this new gold-rush include virtually any group considered sufficiently homogeneous to provide tissue or blood samples from which information leading to the eventual identification of a disease-related gene or genes can be identified (see Briefing, page 12). Such groups range from isolated populations distinguished by certain medical characteristics (which could be resistance to a particular disease) to sets of families suffering from a common illness, such as diabetes, who agree to assist researchers in the hope of developing improved treatment.

The dilemma raised can be expressed straightforwardly: if the knowledge about the gene or genes in question subsequently attains a significant commercial value, how much of that value should be returned to the group that provided the original samples, and in what form? In the past, the prospect of novel treatment resulting from a better understanding of disease has generally been seen as sufficient reward. This formula is no longer sufficient, chiefly because it does not provide any mechanism for ensuring that other potential benefits are made available to contributors. But finding a substitute mechanism for distributing the gains equitably is fraught with practical difficulties.

For example, the proposal that individuals contributing samples to a research project should each receive a slice of future royalty payments sounds attractive in principle. But imagine trying to negotiate such payment on behalf of 5,000 families, spread over three continents, involved in a study of a particular gene. There are also legitimate philosophical questions. The implications of part of an individual's genetic identity being something that can be bought and sold — that is, reduced to a commodity — flies in the face of many deeply held cultural beliefs about human value, even if it is already enshrined *de facto* in Western patent laws.

Three factors need to be recognized by all those engaged in such debates. First, informed-consent agreements should explicitly

acknowledge the possibility of commercial gains from research, and indicate how the issue is to be equitably addressed. Second, any agreement with commercial sponsors should not obstruct the development of research, for example by imposing excessively strict limitations on who should have access to family data, and under what conditions; legislation that already permits this should be re-examined to see whether the rights given to patent holders are so broad as to discourage healthy competition. Third, cultural diversity, as well as the political rights of indigenous populations, must be respected in international agreements on patent law — perhaps by introducing clauses that allow for both in the patenting of human genetic material in future revisions of GATT, the General Agreement of Trade and Tariffs. □

Budget clouds lift a little

Last week's US budget settlement leaves science in a stronger position than was feared, but this is no time to relax.

THE United States budget for the 1996 financial year has now been fixed, after seven months of unseemly haggling between the President and the Congress. It is a powerful tribute to the political skills of President Bill Clinton that he is widely perceived as emerging from this process as the victor. For its outcome is an unprecedented \$22 billion cut in non-defence spending at the discretion of the Congress. That is a 9 per cent reduction in one year — 12 per cent if inflation is allowed for.

Given such a context, science has not fared too badly (see pages 6–7). Non-defence research and development (R&D) spending has fallen, but technology, not science, has taken most of the cuts. The largest basic research agency, the National Institutes of Health, will enjoy a 6 per cent budget increase. The National Science Foundation and the National Aeronautics and Space Administration have cut back on money for new facilities, while their support for research has been frozen. Non-defence R&D at the Department of Energy is down by 10 per cent but most of the attrition has been in technology projects, not in pure science.

The picture is worse for small agencies, with the National Biological Survey and various activities related to global climate change falling victim to political micromanagement of the worst kind. But overall, the science lobby has done reasonably well. It is those without a lobby, such as public housing residents and people in need of legal aid, who bear the real brunt of this budget.

Now attention turns to 1997 and beyond. The Clinton administration helpfully suggests that we ignore its projections for 1998 onwards (see *Nature* 380, 657; 1996) although it cannot openly state the reason why: whether Clinton wins or loses in November, they will be history by Christmas. The Republicans in Congress are also clicking into election mode. In preparing their 1997 budget, the early signs are that they will talk less about spending cuts and more about tax cuts. The glory days of science funding may be gone for ever, but this year's budgetary environment should be somewhat gentler than that of the one just ended. Nevertheless, the need to lobby hard on all fronts persists. □