



60-70% of the Western population with genetic or malignant diseases do not have a matched donor in the family. Although there are about 1.5 million people in bone-marrow donor programmes, the search time is 6 to 8 months, because computer data banks cannot store a donor's complete HLA make-up, and the donation procedure has to fit in with the donor's personal schedule, a problem not associated with cord-blood transplants.

The Israeli bank is storing cord blood only from babies in families with siblings who already have cancers or genetic diseases-unless it can get financial support for expansion. Maintaining large volumes in deep freeze banks is costly. Part of the storage problem for whole blood could be solved now that the subpopulation of cells in cord blood expressing the stem-cell phenotype (CD34) can be separated (J Hematother 1993; 2: 243). Transfer of human umbilical cord blood genes to CD34 progenitor cells, the basis for future gene therapy using the CD34 cells in cord blood, has recently been reported (35th American Society of Hematology meeting, St Louis, Missouri, USA, Dec 1993, abstract 1191).

Rachelle H B Fishman

Drugs and environment in Europe

From Jan 1 next year applications to register medicines in the European Union will have to include an environmental risk assessment. For most products this will mean a simple verification procedure, but for live vaccines and biotechnology medicines, especially those containing live genetically modified organisms, the requirements will be much tougher. The EU's Committee for Proprietary Medicinal Products has just released five draft guidelines showing firms what factors they need to take into consideration when assessing their product's potential effect on the environment. National authorities and drug companies have been given until Oct 15 to comment on the drafts. Another guideline on environmental risk assessments for vaccines is also being drawn up.

Under the guidelines most products will need only a so-called phase I assessment, which is a preliminary check of environmental impact. Drug companies are advised to hire environmental experts to carry out the assessment and check the product's potential impact on soil, water, air, aquatic organisms, terrestrial vertebrates, and microroganisms. A phase II:

assessment would be needed for live products only if the expert found cause for concern during phase I.

Human medicines generally enter the environment through domestic sewage systems and consequent release into effluent waters or spreading on land as slurry. Phase I estimates of amount of product that would be released into the environment are based on information about the amount placed on the market per time unit, the use pattern, and the excretion and metabolite pattern in human beings. Other relevant information includes the expected extent of use, the substance's concentration in urine and faeces, the degradation process under typical conditions and during sewage handling, and disposal practices.

The environment risk assessment applies to the medicinal product as a whole, including adjuvants or excipients in the formulation, the immediate container and the packaging, as well as the active ingredient itself. It covers risks to the environment that could arise from the product's use, storage, and disposal rather than those arising from synthesis and manufacture of the drug and its active ingredient.

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On July 13, 1993, Dr Jean-Pierre Allain, formerly with the French blood transfusion service (CNTS) but then working in the UK for the University of Cambridge and the East Anglian blood transfusion service, was sentenced to a four-year prison term (two years suspended). The charge stemmed from a 1905 law on merchandise fraud aimed at, for example, those profiting from the sale of dangerous cheese. An appeal to the supreme court (Cours de Cassation) failed, as did a claim by some patients with haemophilia that the initial charge ought to have been one of wilful poisoning. The charges, against Allain, Dr Michel Garretta (also CNTS), and others, related to the distribution of blood and blood products contaminated with HIV. Allain worked in research, not manufacture or distribution; none of his own patients seroconverted; he was was one of those who strongly pressed for the acceleration of heat treatment of factor VIII, and he drew attention to the threat that AIDS posed for patients needing blood products.

The supreme court did not entirely rule out charges of wilful poisoning, and late last month that charge was brought against Garretta, accompanied by an immediate mandat depot (protective custody order). Allain was eligible for parole after about one year, and his request for a

hearing was set for July 27. A ruling was delayed until July 31 so that the judge (juge d'application de peine) could meet him. She decided in his favour on Aug 3 but the political head of the French Ministry of Justice had already announced in a radio interview that he would appeal if parole was granted, and the prosecutor did so immediately. That appeal was to be heard by magistrates at Evry (near the prison where Allain was held) on Aug 5. However, news of a result likely to be in Allain's favour had leaked out, and he was promptly arraigned before another judge (juge d'instruction) on a charge of wilful poisoning. The question of a mandat depot for him was held over until Aug 7. On Aug 5 the Evry court dismissed the Justice Minister's appeal and the next night a van from the blood bank near the prison was set fire to, presumably to create an artificial public disorder.

On Aug 7 Allain won his parole but he is not free to return to Cambridge, having had to surrender his passport; he will also have to report to a local police station twice a month. When I spoke to him he was at a secret address in Paris. His wife, Dr Helen Lee, while in London on Tuesday, told me horrific stories of anonymous threats, garbage in her letterbox, and similarities being drawn between her husband and the Nazi Klaus Barbie (the "butcher of Lyon"). It could take years before the new charge of poisoning comes to trial. Signs of hope have been a shift in opinion amongst French newspapers formerly hostile to Allain; vehement protests from jurists in France about a second charge for the same "offence"; and the continuing support for Allain from many haemophilic patients, colleagues in France and abroad, and institutions outside France, especially the University of Cambridge.

David Sharp

Haw River and other neurological diseases

An obscure inherited disease found in 5 generations of one family from the Haw River area of North Carolina may be able to shed light on the mutations associated with other diseases. The Haw River syndrome has many clinical and neuropathological similarities to Huntington's disease, spinocerebellar ataxia 1, and dentatorubropallidoluysian atrophy (DRPLA) found almost exclusively in Japan. The first symptoms are lack of coordination and ataxia, followed by personality changes, including paranoia, delusions, and hallucinations. Eventually chorea, generalised seizures, and dementia follow. As with Huntington's disease, Haw River syndrome manifests itself later in lifeusually between 15-30 years, with death occurring 15 to 20 years after the development of symptoms-such that many of the Haw River family were misdiagnosed