Human growth hormone

Approval for synthetic products in US, Britain

Washington

HUMAN growth hormone for treating hypopituitary dwarfism last week became the second pharmaceutical product manufactured by recombinant DNA techniques to be approved for use in human beings. In the United States, the Food and Drug Administration (FDA) finally gave Genentech Inc. approval to market its own brand of recombinant growth hormone, called Protropin, while in Britain, the Department of Health and Social Security approved KabiVitrum's Somatonorm, an almost identical product manufactured under licence from Genentech.

The approvals are a coup for Genentech, which also developed the previous single recombinant human pharmaceutical, insulin, which is manufactured under licence by Eli Lilley and Co. In both countries, the product is likely to be used immediately by virtually all young people needing growth hormone supplements: use of the only alternative, growth hormone derived from human pituitary glands, was halted in May because of fears that it could be responsible for transmitting a rare and fatal viral neurological disease known as Creutzfeldt–Jakob disease (CJD).

In the United States, there have been at least three suspected cases of CJD among young adults who received human pituitary growth hormone injections as adults, and one in Britain: the disease is rare enough for this to be a suspiciously high incidence in a small group. Intensive investigations are now under way to establish whether the pituitary product has indeed been contaminated with the infectious agent of CJD, but conclusive animal tests of infectivity take at least a year. In the meantime, it is not clear whether the suspected cases (of whom one now appears unlikely to have had the disease) presage further cases of CJD or whether those now known are likely to represent all cases caused by contaminated pituitary extracts.

Dr Albert Parlow of the University of California at Los Angeles, who has supplied pituitary products to the National Institutes of Health since 1977, claims that purification techniques he initiated then make it very unlikely that virus particles in an infected individual could still contaminate pituitary extracts; nevertheless, his laboratory is now taking extraordinary measures to eliminate virus particles, including filtration through filters with pore sizes as small as 25 nanometres.

Parlow says the ban on the use of pituitary products will represent "the genocide of pituitary research" unless FDA takes immediate steps to show convincingly that pituitary products can be made safe. Such a demonstration might be difficult: in a recent paper published in *New England Journal of Medicine*, physicians at the National Institutes of Health noted that it is prudent to assume "no amount of (chemical) processing can be guaranteed to result in a fully sterile end product".

The Genentech synthetic growth hormone is not identical with the human version, having an extra methionine residue at one end of the protein chain. Perhaps as a consequence, 30 per cent of patents develop antibodies to the product. Last year, FDA expressed concern about the immune reactions and asked for another year of follow-up data on trial patients: that period will not end until early 1986 but, doubtless impressed by the urgent need of treatment for adolescents of short stature, FDA decided after six months that its requirements had been met.

Since use of the human product was halted in May, one hundred or so hypopituitary patients in the United States who suffer from the serious complication of hypoglycaemia have been permitted to use Protropin under a special compassionate exemption; some adolescents have also been permitted to continue using human-derived growth hormone from the same production batch that they had used previously.

Genentech will soon face competition from several other manufacturers of recombinant growth hormone for the $40 million US market. (The market may even grow if, as hoped, the recombinant product proves effective against other forms of dwarfism.)

In the United States, Eli Lilly has a product in clinical trials and, in Europe, Serono Laboratories is in trials in Dublin with a product manufactured by Celltech, the British biotechnology company. The Celltech product is made in mammalian cells and so lacks the troublesome extra methionine, while a Danish company, Nordisk, has found an alternative solution to the problem of producing natural sequence growth hormone.

When natural sequence products are shown to be safe and effective, they can be expected to replace the early versions, but Genentech is not planning to be left behind and is working on a natural sequence growth hormone of its own.

Tim Beardsley

Soviet offer on AIDS

SOVIET doctors are prepared to cooperate with their colleagues in the United States in the fight against AIDS (acquired immune deficiency syndrome) according to Professor A. I. Vorob'ev, head of the haematological department of the Central Institute for Improving the Skills of Physicians. Writing in the newspaper *Sovetskaya Rossiya*, Vorob'ev noted that not a single case of AIDS "with the epidemiological features described by the Americans" had yet been reported in the Soviet Union.

The AIDS threat, however, is coming uncomfortably close. Poland's screening programme, launched last month (see *Nature* 12 September, p.100) has already found four instances of AIDS antibodies among the first 1,679 people screened. Only blood donors and people at special risk are being screened; the four AIDS suspects are two homosexuals (out of 52 screened) and two (out of 49) haemophiliacs who had been treated with imported clotting agents. Vera Rich

Shuttle contract for Aérospatiale

Paris

HERMES, the French miniature version of the US space shuttle designed to be launched on the European rocket Ariane, is to be built under the leadership of Aérospatiale, the company that builds French nuclear missiles, it was announced last Friday (18 October).

This at last brings to an end speculation over whether Aérospatiale or the aircraft company Marcel Dassault would be prime contractor on the FF14,000 million (£1,100 million) project (see *Nature* 10 October, p.469), and will be a relief to those who suspected that a Dassault victory would compromise European collaboration on Hermes. (It was said to be pressure from Dassault that caused France to withdraw from the European advanced fighter project a few months ago.)

Dassault will not, however, go unrewarded. As makes sense, the company, partnered by another aircraft manufacturer Breuget Aviation, will be subcontractor for the whole aeronautical system of Hermes — the components necessary for its flight in the atmosphere, as opposed to its flight in space.

The French space agency CNES which first conceived of Hermes will, alongside Aérospatiale, lead negotiations with other potential European partipants, and will, according to CNES, take account of the specializations now available in the European space industry through the development of Ariane, Spacelab, and Columbus (the European contribution to the US space station). Eight countries are said to be interested in participation, but they do not include West Germany, which apparently considers its space spending on Ariane 5 and Columbus quite enough for the time being. Robert Walgate