DRUGS TESTING

Parallel trial controversy

Washington

THROUGH a premature announcement of a new "parallel track" for the testing of AIDS drugs, Anthony Fauci, director of the US National Institute of Allergy and Infectious Diseases, has set off a chain reaction over how US drug approval procedures should be changed in the light of the AIDS pandemic. Fauci's announcement just over a month ago that the government may soon sanction the distribution of unapproved drugs to people with AIDS outside controlled drug trials triggered media reports and a congressional hearing. Congressional interest, in turn, has prompted James O. Mason, Assistant Secretary of Health, to instruct Food and Drug Administration (FDA) commissioner Frank Young to find out just how such a scheme would work.

The deluge of criticism from AIDS activists over the speed of drug testing by FDA has already brought about major changes in the drug-approval process in the past three years. The first new measure was the 'treatment IND' (investigational new drug) under which companies could sell drugs for serious and life-threatening diseases after the first two phases of tests — for safety and efficacy — are complete, but before the final phase of testing on a larger number of patients begins. Next came the '1AA' designation to streamline the FDA's processing of the paperwork for AIDS drugs. And last year, the FDA proposed dropping the expanded Phase III trials altogether for drugs for life-threatening diseases, in favour of a 'Phase IV' surveillance to study side-effects once the drug is on the market. The latest 'parallel-track' proposal would allow people with AIDS to receive 'safe and promising' drugs even earlier — after Phase I safety tests.

Young says he and Fauci have been discussing ways to make promising AIDS drugs more available for nearly two years, but that Fauci's public announcement came as a "surprise". He does not think a 'parallel track' would decrease the number of participants in controlled clinical trials: people get free treatment — not just the drug — in a clinical trial, and the 'parallel track' could be structured so that it opens up only once established clinical trials are filled. But Young would prefer to see the treatment IND improved instead.

Drugs companies are not expected to embrace another proposal for them to give drugs away free. A statement issued by the Pharmaceutical Manufacturers Association at the congressional hearing two weeks ago was ambivalent. But Bristol-Myers — the maker of dideoxyinosine (ddI), an AIDS drug less toxic than AZT — may lead the way. The company has announced it will give ddI to people with AIDS outside its Phase II clinical trials, set to begin in September, if the FDA permits.

Carol Ezzell

NUCLEAR ENERGY

Waste exports opposed

Munich

THE trend toward European cooperation in nuclear energy continued last week when West Germany signed an agreement to ship nuclear fuel to Britain for reprocessing. British Nuclear Fuels PLC (BNFL) agreed to reprocess 6,000 tonnes of fuel at its new Thorp plant beginning in 1999 for an estimated cost of DM5,000 million (about £1,600 million).

But the pro-nuclear West German government will not be able to export its political problems with nuclear power so easily. Opposition Social Democrats (SPD), who are in power in six of eleven *Länder* (states), have been threatening to bring the centre-right government before the federal constitution Court over the right to reprocess nuclear fuel outside West Germany.

The issue is safety. The West German Atomic Law requires the government to guarantee that used fuel elements will be disposed of in an environmentally safe manner; but it makes no prescription about whether or where the fuel should be reprocessed. Once the fuel leaves West Germany, the opposition claims, the government can no longer guarantee its safety. SPD politicians would like reprocessing to stop and the fuel to be brought directly to nuclear waste dumps.

Environment Minister Günther Jansen (SPD) of Schleswig-Holstein is prepared to shut down the three nuclear reactors in that *Land* if the government does not abandon reprocessing entirely.

West Germany signed a similar agreement with the French company Cogema in April to reprocess fuel at La Hague in northwestern France (see *Nature* **338**, 611; 1989). The agreements allow West German utilities to reprocess fuel at a much lower cost than would have been possible at the abandoned Wackersdorf plant.

The spokeswoman for the Federal Ministry of Environment and Reactor Safety, Marlene Mühe, said the government may try to force Schleswig-Holstein to accept the government view, which could lead to a court battle. SDP spokesman Michael Weidemann said Schleswig-Holstein would prefer further negotiations.

Steven Dickman

AIDS SURVEY

No sex please, we're American

Washington

WITH the blunt words "The Public Health Service is directed not to proceed with the study", the US House of Representatives Appropriations Committee last week scotched an $11 million budget item that would have provided funds for a survey of sexual behaviour in the United States. A $2-million pilot survey, for which funding has already been obtained, is awaiting approval by Louis Sullivan, Secretary of Health and Human Services (see *Nature* 340, 90; 1989).

Howard Silver, executive director of the lobbying group COSSA — the Consortium of Social Science Associations — suggests that Congress's peremptory dismissal of the survey was catalysed by recent agitation over the "Mapplethorpe affair". Washington's Corcoran Gallery cancelled a planned exhibit of works by the photographer Robert Mapplethorpe, who died of AIDS earlier this year, out of concern that the arguably "pornographic" nature of some of the photographs would jeopardize the Corcoran's support by the National Endowment for the Arts (NEA). The Mapplethorpe exhibit was put on privately instead.

With sex such a sensitive topic in Washington, the House decided that a survey of sexual behaviour was not "an appropriate use of public funds". Sullivan could now, according to Silver, use the cancellation of the full survey as a reason to abandon the pilot survey too, and avoid any further controversy. On the other hand, if the pilot survey were to proceed, and produce valuable insights into the future spread of AIDS, researchers would have ammunition with which to return to Congress and ask for the $11 million again.

David Lindley

AIDS RESEARCH

French group moves on two fronts

Paris

THE French national association for AIDS research (ANRS), which was officially inaugurated last month, has chosen its first two 'co-ordinated actions'. The first is an epidemiological study of the prevalence and incidence of infection by the human immunodeficiency virus (HIV) in France. The study, to be directed by Dr Jean-Baptiste Brunet, will report annually on the epidemic.

The second programme will work on anti-HIV vaccines. It is to be directed by Professor Marc Girard, scientific director of Pasteur-Vaccins. The programme will coordinate the work of laboratories currently working on candidate vaccines and will tie them in with with the two major French vaccine producers, Pasteur-Vaccins and Transgene.

Peter Coles