

US protests about possible drugs for AIDS treatment

- Concern that treatment is withheld
- Drugs manufactured only in Japan

Washington & Tokyo

WHEN a group of demonstrators, chained together and wearing black T-shirts bearing the slogan "Silence=Death", poured into the office of a small Japanese company in Manhattan last week, the stunned company staff had at first no idea whether they were about to become the victims of a hijacking or a hoax.

It was a couple of hours before the demonstrators had put across their message. They were protesting that the company's parent organization, Kowa, a textile company based in Nagoya, was refusing to sell a drug called dextran sulphate to US visitors to Japan. Dextran sulphate may — or may not — have some effect against AIDS and is in wide demand for self-treatment by US AIDS patients. It is manufactured only in Japan.

The protesters, who said they repre-

MRC joins hands with Sumitomo

Tokyo

BRITAIN'S Medical Research Council has joined hands with Japan's Sumitomo Corporation to introduce to Japan inventions and drugs developed by the council's research organizations and to establish research links between the council and Japanese corporations.

Under an agreement signed last Thursday (30 June) Sumitomo will act as the council's sole agent in Japan to license technology and drugs to Japanese corporations and to arrange contract and joint research partnerships. The council has already arranged contracts with more than 100 companies in Europe and the United States but none is Japanese.

Christopher Hentschel, director of research programmes at the council's Collaborative Centre who visited Tokyo to sign the agreement, says that the council has a 'shopping list' of things to offer the Japanese but cannot disclose what at this stage. The council was introduced to Sumitomo by the UK company Celltech Ltd which has been represented by Sumitomo in Japan for several years. And the new agreement is expected to lead to an expanded transfer of British biotechnology and medicines to Japan and will also allow for a flow of information in the other direction, according to David Noble, administrative secretary of the council. David Swinbanks

sented the activist group ACTUP (AIDS Coalition To Unleash Power), may not have chosen their target too carefully. Kowa America's business is the import of ladies' shoes and clothing; it does not deal in pharmaceuticals in the United States and the company's executives were not even sure what dextran sulphate was.

But the protest does represent a real sense of concern amongst AIDS patients that new drugs — untested or still under test — that might have some therapeutic value are being withheld.

A week before the Kowa protest, the Food and Drug Administration (FDA) attempted to stop two companies selling AL-721, a lipid-enriched substance that is now taken by thousands of US AIDS patients. A small study conducted by National Cancer Institute scientist Robert Gallo in 1985 showed that AL-721 helped to inhibit invasion of cells by HIV (human immunodeficiency virus). But that was in a cell-culture experiment; there is no good evidence that it has any clinical effect. But there is also no evidence that AL-721 does harm and FDA's attempt to block its sale quickly ran aground. After lawyers from homosexual activist groups stepped in, FDA agreed to allow AL-721 to go on sale provided it was not labelled as a drug.

Dextran sulphate may have more potential as an anti-AIDS drug. A group in the laboratory of National Cancer Institute's Samuel Broder has published evidence that it inhibits virion binding to T lymphocytes (*Science* 240, 646; 1988). Broder suspects that the drug may also have other anti-viral effects. But he stresses that these encouraging results in tissue culture cannot be extrapolated to the treatment of AIDS patients.

Nobody knows what will happen to the drug when it is orally ingested, nor whether it may have unexpected side-effects.

Although the drug has been in use for 25 years in Japan to treat high blood-lipid levels, Japanese researchers point out that that does not mean it is free from problems. It is dangerous for haemophiliacs to take it and, as most of Japan's AIDS patients are haemophiliacs, there is little interest in testing it as an AIDS drug there. But clinical trials of dextran sulphate are under way in the laboratory of Don Abrams at San Francisco General Hospital. Successes in the laboratory have encouraged a flourishing underground market in dextran sulphate. The drug

comes only from Japan, where it is produced by at least 15 companies, including such giants as Meiji Seika and Takeda Chemical. Although primarily a textile company, Kowa also produces the drug.

According to a Kowa spokesman, dextran sulphate is not usually available in Japan without a prescription. But it has been on sale, in limited quantities, at the 'American Pharmacy', a well-known drug store with many foreign customers, located not far from Tokyo's Ginza central shopping district. A Kowa spokesman said the company will sell the drug directly only to "legitimate" customers and knows nothing of "underground" dealings.

AIDS activist groups stress that there is a case for allowing dextran sulphate's free sale in the United States. Tom Hannon, who helped to found the Community Research Initiative, a New York-based organization that sponsors clinical trials of AIDS treatments, argues that "we know a great deal about the action of dextran sulphate from its 25 years' use in Japan. We also know a lot about its potential from *in vitro* work. People should be allowed to make informed choices of whether they want to take it or not." Community Research Initiative is carrying out clinical trials of AL-721. Dextran sulphate is for sale in New York from People With AIDS, an organization that also markets AL-721. Many thousands of people with AIDS are believed to be self-administering the drug.

So far, FDA has not attempted to interfere with its sale and FDA commissioner Frank Young is generally credited with the view that the FDA should not be an obstacle to the availability of new drugs. But it has the power to stop the sale of dextran sulphate if it wished.

Many AIDS patients groups argue that there should be a general "right to access to unapproved drugs". AIDS researchers, many of whom Hannon characterizes as "arrogant", have argued that clinical trials will become impossible if AIDS sufferers are taking a whole range of underground treatments. But Hannon criticizes clinical trials that are "not looking from the perspective of the patient".

That AL-721 has not attracted the notice of any of the giant pharmaceutical companies is seen by many AIDS patients groups as evidence that the desire for profit dominates AIDS research. AL-721, like dextran sulphate, is already in production and could not now be patented, so big profits could not be made.

Not so, reply the pharmaceutical companies, because patents can be granted for new uses of a drug. And if the possible 'new use' is already widely known, making a patent impossible to grant, then there are always ingenious ways of patenting modified version of the drug. Alun Anderson & David Swinbanks