

Conditional approval touted

Washington

AIDS patients in the United States, often with the approval of their doctors, are going to the black market to get drugs that have not been approved by the Food and Drug Administration (FDA). The solution, many argue, is for the FDA to offer a conditional approval, in which drugs could be marketed on the basis of preliminary safety and efficacy data on condition that they would be reassessed when the clinical trials usually required for FDA drug approval are complete.

Marcus Conant of the University of California in San Francisco points to experience with the anti-retroviral drug DDC. Combined therapy with DDC and zidovudine (AZT) retards the loss of CD4 cells — the key to the long-term survival of people infected with human immunodeficiency virus (HIV) — more than either drug alone, according to results of a clinical trial conducted by Margaret Fischl of the University of Miami. But DDC is not approved by the FDA, so a patient's only legal means of obtaining combined DDC/AZT therapy is to enrol in the appropriate clinical trial. Space is limited in these trials, however, and not all patients meet the entrance requirements, so many AIDS patients go to the black market for DDC. "If I were in their shoes I would be doing the same thing," Conant says.

Besides being illegal, buying DDC on the black market has another drawback: patients are not assured a continuous supply of the drug. The telephone of one black-market DDC outlet in San Francisco has a recorded message that the drug is unavailable until the middle of August; then it will be sold on a first-come, first-served basis.

NUCLEAR LABORATORIES

Radioactive frogs

Washington

FROGS' legs are definitely off the menu at the Oak Ridge National Laboratory, Tennessee. After a bumper breeding season, scores of leopard frogs, *Rana pipiens*, have started to migrate from two ponds at the site. The trouble is that, in the 1940s and 1950s, these ponds were used for the storage of intermediate-level liquid radioactive waste. After one frog was run over on the site and found to be contaminated, the laboratory's health physics staff closed a stretch of road near the ponds and are sampling other frogs on the site for contamination. Those that are clean are dropped into an uncontaminated creek; those that are not must go back to the contaminated ponds. Some staff at Oak Ridge became alarmed when one frog was found in the basement of a laboratory

Conant calls for the FDA to speed the approval process by instigating conditional approval, and the agency says it is currently evaluating various means to do just that. It is expected to release a preliminary report on the subject sometime in the next few weeks.

Last month, the FDA's Antiviral Drug Products Advisory Committee recommended that the agency approve for sale the anti-retroviral drug DDI on the basis of limited data from phase 1 (safety) and preliminary phase 2 (efficacy and side effects) clinical trials (see *Nature* 352, 269; 25 July 1991). Although the committee did not formally recommend conditional approval, it did ask the FDA to reassess the drug when the phase 2 trials are complete — a sort of *de facto* conditional approval.

■ Meanwhile, Conant reports a surprising clinical observation. Twelve AIDS patients have survived for between three months and two years with negligible numbers of the supposedly indispensable CD4 lymphocytes, he says.

Most people with AIDS die of opportunistic infections, such as *Pneumocystis carinii* pneumonia, within one year of their CD4 counts falling below 50 cells per cubic millimetre of blood. But the 12 patients' CD4 counts have hovered around zero for the past year, during which time they have never exceeded 10. A healthy person has a CD4 count of 800–1200. "A few years ago we would have said that life was incompatible with zero CD4 cells," Conant says.

The key to the survival of patients lacking CD4 cells is early diagnosis and aggressive preventive therapy against opportunistic infections, Conant says.

Rachel Nowak



office building, but Kornegay says there is little to worry about. The frogs are not contaminated externally, and could pose a threat to health only if eaten. The species is not edible.

P.A.

Science goes video

Washington

GARY Welz has an ambitious plan. By January 1993, he hopes to launch the world's first television network aimed specifically at working scientists. And last month he received a big boost towards that goal. After a year trudging the corridors of various US scientific societies and grant-making bodies with his proposal, the mathematician-turned-video producer received some financial backing to begin work on his project, in the shape of a \$30,000 grant from the Alfred P. Sloan Foundation.

The network would offer a mixture of news bulletins, televised scientific conferences and live interviews with researchers, Welz says, and it would be supported by income generated through advertising. It would be a service not dissimilar to that provided by the two leading multidisciplinary scientific journals, *Nature* and *Science*, except that it would be in video rather than printed form.

That parallel is not lost on Welz. When he explains his idea of raising additional funds by having some companies pay for feature-length programmes about their research activities, he notes that *Nature* has set the precedent, with the publication earlier this year of a supplement featuring the French oil and petrochemicals company Elf-Aquitaine.

Initially, Welz hopes to broadcast for a few hours a week, possibly via cable in centres of intense research activity, such as Cambridge, Massachusetts, and Palo Alto, California. But \$30,000 is only a small fraction of the funds needed to put a television network on the air, and Welz has yet to provide convincing proof that there really is a demand for his product. He believes there is a US audience of more than 500,000 — the 350,000 people who have earned science and engineering PhDs in the United States since 1960, some 120,000 current graduate students, as well as crossover interest from US physicians. But neither Welz nor anyone else can say just how many of these researchers — most of whom have difficulty keeping abreast of the literature in their fields — would be interested in adding a science television channel to their agendas.

Tom Wolzien, vice-president for cable projects at NBC television, says the initial problem for narrowly focused projects such as Welz's proposal is obtaining distribution. Before cable television operators will agree to distribute a new channel, he says, they need convincing that it will bring in advertising or subscription revenue. Welz, who is based at the City University of New York, is now busy writing further grant applications to secure funds for the all-important market research.

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