DDI Approval Gets Uneasy Welcome

AIDS researchers expressed some doubts last week when a top advisory committee to the Food and Drug Administration (FDA) recommended that an experimental AIDS drug, dideoxyinosine (DDI), be conditionally approved though it is still in the early stages of clinical trials.

The committee proposed that DDI, which is produced by Bristol-Myers Squibb Co., should be available only to patients with advanced stages of HIV infection and who do not respond to AZT, the only AIDS drug currently approved. The final decision still rests in the hands of the FDA, but generally the agency follows the advice of the panel.

While the recommendation was widely welcomed by AIDS activists, some members of the committee were unsatisfied with the verdict. One reason: The decision was based on preliminary data. The only results available to date indicate that the drug has some toxic side-effects, but they do not clearly prove its efficacy.

In addition, there is concern about the impact of the decision on the clinical trial itself. Around 2400 patients are currently involved in the clinical studies, which are due to end next year. "We are concerned that some of our participants might drop out of the trial," says Daniel Hoth, director of the study, which is being conducted at the National Institute of Allergy and Infectious Diseases. "But still, we do support the decision of the panel to recommend the approval of DDI now," Hoth adds, because the urgent need for a new AIDS drug overrules any lingering doubts.

Does last week's decision set a precedent for the approval of other drugs prescribed for debilitating conditions such as cancer and Alzheimer's disease? That might become clear soon, as an application for yet another AIDS drug, DDC, is expected to be completed sometime this year.

David Scott/Savannah River Ecology

Croaking. *A tree frog hangs on.*

New Task Force on Declining Amphibians

In places as far apart as Brazil, the Rocky Mountains, Australia, and Europe, populations of frogs, toads, and other amphibians seem to be declining. But why? One proposed explanation is global change: increased ultraviolet radiation penetrating our thinning ozone layer harms fragile amphibian eggs. But not all investigators blame global environmental problems. They see the work of predators, natural population fluctuations, pollution, or acid rain.

Unfortunately, there isn't much good world data on amphibian populations to help researchers choose among these different possible causes. And even if there were such data, there isn't a single clearinghouse to compile and analyze it. As a first step toward remedying these shortcomings, the International Union for the Conservation of Nature (IUCN) has recently set up a "Task Force on Declining Amphibian Populations," located in Corvallis, Oregon.

"We are trying to set up a worldwide communication network and establish a database for all scientists involved in amphibian research," says task force coordinator James Vial, a retired ecologist from the University of Tulsa and expert on amphibians.

Because the problem seems to be global in scale, much of the task force's work will go on far from Corvallis. Most of the field studies and research will be carried out by independent working groups, some of which have already been established in various corners of the world.

But even before the task force really gets down to work, a group at Oregon State University that will participate just added another disturbing report to the growing body of data on amphibian decline.

When studying Western Toads at Lost Lake in central Oregon, they found that for 2 consecutive years nearly 100% of the toad eggs died in the early stages of development. Adult toads were normal, and eggs brought into the laboratory developed normally, suggesting that those in the wild were succumbing to unknown environmental factors. It will be up to the task force to determine these factors.

Bostonian Gene Transfer

Take a ride on the Boston Biosciences Line. If you pass GO, collect 200 genes. No, Monopoly didn't move its home from Atlantic City to Boston, but Boston bioengineering workers will soon advance from lab to lab more easily.

Mayor Raymond Flynn recently unveiled plans for a special mass transit line to link many of the biomedical research and clinical centers in and around Boston. According to Boston's transportation commissioner, Richard Dimino, the new transportation line will help the city "bioengineer its way out of a fiscal crisis." The Massachusetts economy has followed its computer industry into a severe slump, and Boston is counting on biotech to pull it out. Dimino cites a projected 40% job growth in biotech over the next decade, which for Boston translates into 42,000 new jobs (and 42,000 new commuters) by the year 2005. The city is now reviewing five different proposed lines, which will range in total cost from $800 million to $1 billion—but raising that kind of money will take a lot of cloning.

Panel Wavers on Roots of Cancer

Are scientists observing real increases in death from cancer throughout the industrialized world, as epidemiologists reported last year (*Science*, 16 November 1990, p. 900), or are they detecting something less alarming—perhaps a mere statistical shift resulting from improvements in health care for older people? And what should be done to discover the causes of the rise in cancer, if it is real?

These questions came before a special health policy review group on 21 July, a confidential panel called the Committee to Coordinate Environmental Health and Related Programs, which reports to the director of the Public Health Service, James Mason. The panel's verdict: Some increases are real and others are not, and there's no need to expand existing federal epidemiological programs.

The panel focused on a volume of studies written by 18 scientists and published last year by the New York Academy of Sciences. The book's authors found that cancers of the breast, brain, lung, kidney, non-Hodgkins lymphoma, melanoma, and multiple myeloma have increased in most of the 13 countries they examined, chiefly in people over age 55. But, says the review panel's chairman, Vernon Houk, director of the Center for Environmental Health and Injury Control: "There was no information in the New York Academy of Sciences report that would support the view that there are increasing [cancer] rates all over the place or that they are associated with environmental pollution." In declining to recommend new research, Houk says the panel felt that the National Cancer Institute already has sufficient relevant studies under way.