

starts" are now expected to present their case in a standard written format, answering a number of general questions. The entire committee then debates the merits of the proposal and votes on where to place the new project within a 5-year strategic plan.

At the academy meeting, Dutton and his panel handed out a sample 27-page questionnaire that advocates of new ideas would be asked to complete before seeking entry to the

list of approved projects. The proposal did not get a warm welcome, and the advice from the floor of the auditorium was to simplify it drastically, if it's to be used at all.

Whether space scientists will take the time—or accept the responsibility—for priority setting is not yet known. If they don't, the consequences could be destructive, according to Representative George Brown (D-CA), chairman of the House science

committee. Brown pointed out at the academy meeting that unless scientists make a forceful case for their own preferences, Congress will fall back on political methods—and that could be disastrous. Said Brown: "If scientists fail" to exercise discipline within their own ranks, "science funding may be increasingly decided by 'political pork' awarded to localities based on political rather than scientific goals." ■ ELIOT MARSHALL

## Anti-Cancer Drug IL-2 May Finally Be Approved

Is there life after death in biotech? Suppose the Food and Drug Administration (FDA) accepts a recommendation from one of its own advisory committees, widely publicized last week, to approve the drug IL-2 for treating kidney cancer. Could the Cetus Corp. recover from its strategically disastrous error in betting heavily on the experimental anti-cancer drug, only to be shot down 18 months ago when the FDA sent the company back to the drawing board to reorganize their data and expand their studies? Not really. Because that ruling triggered a humiliating takeover of Cetus, the grand old man of biotech startups, by an upstart competitor, Chiron Corp. And in its present incarnation Cetus exists only as the cancer-products division of Chiron.

So it's too late for Cetus to make a comeback as a corporation. But it isn't too late for IL-2. And the reason the FDA changed its mind about the drug is that, in the words of Jay Siegel, chairman of the license application review committee that is expected to take up the advisory group's recommendation soon, "a great deal has happened here. The picture looks considerably different than it did in July 1990."

In that month the picture was fatally flawed by several weaknesses in the Cetus trials: their small size, the concentration of positive results at one research center, and the failure to remove concerns about the drug's toxicity. Now some of those complaints have been met head-on, says Siegel.

To meet the FDA's concerns, the clinical trials were expanded to include more subjects and more institutions. In 2 years the number of patients given IL-2 alone or in combination with compounds such as lymphokine-activated killer (LAK) cells increased from 106 to 255. Furthermore, the objection that a majority (10 of 16) of the patients who responded favorably to treatment were at one lab (Stephen Rosenberg's laboratory at the National Cancer Institute) has been met by expanding the number of centers—and in the process including other centers where patients are showing favorable responses.

Side effects, however, remain a serious problem. IL-2 "causes severe toxicity in almost everybody," says Siegel—including circulatory problems that can be as severe as heart attacks and strokes. But Siegel adds that until now there had been considerable uncertainty about just how toxic the drug is; now, he says, there is "more certainty" about toxicity. He adds that there are now also improved treatments available for some side effects, such as staphylococcal infections.

In the end, the lack of other effective treatments for kidney cancer overshadowed concerns about IL-2's toxicity, and the advisory committee voted 7 to 1 to recommend approval—a vote that all but guarantees a positive response by the FDA. And that, in turn, should be good for the health

of Cetus, in its current, less-mighty form. "It's a key product in their long-term strategy," says James McCamant, editor of *Medical Technology Stock Letter*.

Still, it may never be the product once envisioned. For one thing, it's not likely to be used on its own: McCamant predicts IL-2 will be most marketable as a drug used in combination with chemotherapy or with other biological response modifiers. What's more, the market for the drug—once seen by optimistic Cetus strategists as being in the range of hundreds of millions of dollars per year—is now seen as being a far more modest tens of millions. And if this reduced view is correct, it looks as if those who chastised Cetus for pinning all their hopes on IL-2 were largely right. ■ RICHARD STONE

## Roche Eases PCR Restrictions

When the powerful gene amplification technique known as the polymerase chain reaction (PCR) was developed in 1983, scientists anticipated that it would spawn a lucrative new genetic testing industry. The technique can copy minute amounts of specific gene sequences, yielding sufficient DNA to diagnose genetic and viral diseases, determine a child's paternity, or help identify a rapist from the DNA in his sperm. But development of the industry has been hampered, say some, by restrictive licensing and royalty regulations. Until now.

Hoffmann-LaRoche Inc., the pharmaceutical company that acquired the full patent rights to PCR in December from Cetus Corp. of Emeryville, California, where the technology was originally invented, announced that it will relax the restrictions and reduce the royalties paid by laboratories using PCR for diagnostic and other tests. The company is still working out the details of the new regulations but hopes to have them ready sometime in February, says Douglas McQuilkin, vice president for business development of Roche Molecular

Systems Inc., a Roche subsidiary recently formed to develop PCR products.

Roche's new policy has already come as a relief to leaders in the biotech industry, who learned about it when McQuilkin mentioned it at a meeting on the commercialization of biology held at the Banbury Center at Cold Spring Harbor Laboratory on Long Island. Thomas Reed, chairman and chief executive officer of Vivigen, a company in Santa Fe, New Mexico, which currently uses PCR for genetic screening, told *Science* that the current fees had discouraged many laboratories from even seeking a license. Commercial laboratories have had to make a down payment of \$15,000 against royalties, which are supposed to amount to at least 15% of the cost of each test performed. The old licensing agreement also discouraged the development of new tests, Reed says, because the licensee "had to go hat in hand to Roche" to get permission for every new application. The expected removal of these restrictions should amplify the diagnostic uses of PCR—and perhaps Roche's royalties as well. ■ MICHELLE HOFFMAN