

Robert Windom announces a framework for industry and government collaboration on an AIDS vaccine.

collaborative program. These include: peptides isolated from or based on AIDS virus proteins that might be used in a potential vaccine, organisms such as vaccinia virus that can be genetically engineered to produce proteins normally made by the AIDS virus, methods for producing and dectecting the AIDS virus, isolation methods for proteins made by the AIDS virus, and molecular clones of the AIDS virus. The United States government owns the rights to these patents.

The PHS notice calls for collaborative plans from the private sector to be submitted by October 21, sixty days from the date of the notice. Each plan will be considered on a case-by-case basis, and final selection will be made by the agencies of the PHS including the National Institutes of Health and the Centers for Disease Control.

Harmison says that the concept for establishing a collaborative framework for AIDS vaccine development is not new. In 1984, the PHS issued an invitation for private industry to become involved in making test kits to detect AIDS virus antibodies in the blood (which were on the market by 1985), and the idea for vaccine development collaboration began then.

An AIDS vaccine is not likely to be available for general use until well into the 1990's. The primary reason for the expected delay in its development is the scientific complexity of the research problem, which necessitates large and equally complex research collaborations. Why did the PHS release its new notice now? Because the stage of scientific research warrants such collaborations at this point, says Harmison, and perhaps because the time is ripe for exercising some control over who has access to patent licenses.

DEBORAH M. BARNES

(A discussion of the different research strategies now being used to develop an AIDS vaccine will appear in the 12 September issue.)

Will an AIDS Vaccine Bankrupt the Company That Makes It?

In the present climate of richly rewarding lawsuits by individuals against manufacturers for product liability, U.S. pharmaceutical companies may be less than eager to invest large amounts of money and effort into producing a vaccine for AIDS. But an experimental AIDS vaccine should be available for initial clinical testing within the next decade, and individual scientists as well as drug companies recognize the need for legislation that will encourage rather than discourage vaccine production.

"The important legal issue is pretty clear," says Brian Cunningham, vice president and general counsel for Genentech in South San Francisco. "As the law stands today, manufacturers are held liable for injuries caused by a vaccine even though they were not negligent in designing it. In these circumstances, in my opinion, the legal system has simply run amuck. And for a small company like Genentech, we simply cannot take the financial risk." Genentech is now in the research phase of developing a potential AIDS vaccine, but the company has not decided whether it would move into full-scale vaccine development.

Currently, drug companies are subject to strict product liability, a legal term meaning that the manufacturer is liable for any injuries caused by the product, even though the product was made properly.

California is leading the legislative effort to lessen a manufacturer's liability for an AIDS vaccine with a bill, which is expected to pass before 1 September. Governor George Deukmejian has formally endorsed the vaccine legislation (as of this writing). His office projects that Californians will pay about \$3.5 billion in medical costs alone for AIDS patients in 1990, making the need for a vaccine a financial as well as a health care issue.

Due in part to persistent lobbying efforts by Genentech and other pharmaceutical firms, the new bill would relieve drug companies from strict product liability. Introduced by assemblyman John Vasconcellos, it is designed specifically to apply to an AIDS vaccine once it has been approved by the Food and Drug Administration (FDA). The bill offers not only protection from two classes of liability claims, but also provides incentives for drug companies to make a vaccine for AIDS.

The California bill has four essential features. First, it leaves intact a person's right to sue because of injury due to manufacturing defects in an AIDS vaccine. At the same

time, it eliminates strict product liability in a suit based on warning or design defects if the vaccine has been found to be "unavoidably dangerous" (defined on the basis of a California appellate court decision as a product with great public benefit that is unavailable in a less dangerous form). Second, it states that it is the intention of the state of California to purchase 750,000 doses of the vaccine for a maximum of \$20 a dose, if this number is not sold in the 3-year period following FDA approval of a vaccine. Third, it provides for \$6 million in grant money to be given to drug companies that do clinical testing of potential vaccines. And fourth, the bill guarantees compensation to individuals injured by an AIDS vaccine by paying their medical expenses, lost income, and a capped amount for pain and suffering. The money for this compensation fund will come primarily from a surcharge that the vaccine manufacturers will pay, with any future state appropriations to be decided later.

The California bill may prove to be model legislation for other states or perhaps for the federal government. The House of Representatives subcommittee on health and the environment has introduced bills that pertain to childhood vaccines. One of them, sponsored by subcommittee chairman Henry Waxman (D-CA), would protect pharmaceutical companies that make childhood vaccines which are already FDA-approved against strict product liability. It would also offer compensation to children who are injured by a properly made vaccine.

But any forthcoming vaccine for AIDS is admittedly experimental and will not have FDA approval until it is shown to be both safe and effective. Whether protective legislation will be introduced at the federal level for such an experimental vaccine is uncertain. Public Health Service scientists and representatives from private industry have been discussing these issues with congressional staff.

Deborah M. Barnes

NASA Council Sees Continued Erosion of Space Program

The advisory council of the National Aeronautics and Space Administration (NASA) has expressed "great concern" about the agency's ability to fulfill its mandate for national preeminence in space.

In a blunt letter to agency administrator James C. Fletcher, dated 14 August, council chairman Daniel J. Fink also says "that actions being taken by the U.S. to restore its

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space launch capability are neither adequate nor sufficiently rapid."

Fink's letter resulted from the council's annual summer meeting on 4 and 5 August. Breaking with its practice in previous meetings, which had concentrated on projects under consideration for the following fiscal year, the council this year focused on the overall state of the nation's space program. Fink, a Washington-based consultant and a former general manager of General Electric's space division, points to a number of factors that left the members deeply troubled:

- "The Nation has no long-range goals established to serve in a policy context as the framework for specific programs and missions." Currently, Fink adds, the council is putting together a task force to study two recent proposals for such goals: the report of the National Commission on Space (Science, 13 June, p. 1339), and the study of future directions being conducted by the National Research Council's Space Science Board.
- "The Nation has allowed its space technology base to erode, leaving it with little technological capability to move out in new directions should the need arise." NASA's present space technology program is essentially a Band-Aid effort, one council member later told *Science*. It is focused on fixing problems on the shuttle as they arise, instead of looking toward long-term innovation.
- The decision to replace the Challenger has been "inordinately delayed." (Fink's letter was dated 1 day before President Reagan in fact gave the go-ahead.)
- Even with a commitment to a new orbiter, "there is the likelihood that funds will be severely limited, leading to stretchout, inadequate spares, no excess capacity, and thus a repeat of a lengthy downtime should new problems arise."
- "There is no rational plan to make available expendable launch vehicles (ELV's) required for certain solar system exploration missions and to provide the mixed fleet necessary to avoid reliance on a single system. The prospects for purchasing the ELV service from the commercial sector have not been realistically assessed, and we found no plans for budgeting for ELV requirements whatever the source."

In summary, says Fink, unless actions are taken very soon to address these concerns, "the U.S. civil space program will continue to erode, to the Nation's great detriment."

Turning to more specific issues, he says, the council urges the earliest possible launch of the Hubble Space Telescope, and strongly supports a proposed initiative to reinvigorate the agency's program of space technology development. The council also urges that NASA continue or initiate development of several major science missions that are al-



ready well advanced: the TOPEX oceansensing satellite, the U.S. portion of the International Solar-Terrestrial Physics program, the Global Geospace Science project, the Comet Rendezvous/Asteroid Flyby mission, and the Advanced X-ray Astrophysics Facility. Given the uncertainty about launch availability, however, the council saw little point in considering any additional science missions for at least another fiscal year.

As for the space station project, says Fink, the council found it premature to comment. Not only is there a real possibility that the station will be scaled down and delayed beyond its scheduled 1994 launch date because of tight budgets—"our general feeling is that NASA has about \$1 to \$2 billion more program on its plate than it has money for," one participant later told Science—but the program itself is in disarray. Following the Challenger commission's recommendations on management (Science, 1 August, p. 512), Fletcher recently attempted to streamline the space station program by centralizing authority at headquarters and transferring some of the development work away from the Johnson Space Center in Houston; he was immediately bombarded with protests from the Texas congressional delegation, which feared a loss of jobs in the Houston area. Almost simultaneously, members of the astronaut corps questioned whether the station as currently designed could actually be built by people wearing space suits. On 31 July, Fletcher accordingly put the program on hold for 90 days pending a high-level review.

"Thus," says Fink, "we are not able to make constructive recommendations on the program and are left with considerable unease."

M. MITCHELL WALDROP

Soviet Union Suspends Plans to Divert Four Rivers

After a long and vigorous campaign of protest by leading members of the Russian scientific community, the Soviet government has agreed to suspend work on two ambitious schemes to divert the water of four rivers that currently flow toward the Arctic Ocean. The water would have been used to irrigate large agricultural areas in the south of the country.

Both schemes originated under Leonid Brezhnev 20 years ago. One would have involved diverting the Onega and Pechora rivers in western U.S.S.R. to flow southwards into the Volga, ultimately helping to top up the level of the Caspian Sea.

This project was strongly criticized at last December's meeting of the Soviet Writers Congress by intellectuals and scientists on the grounds that its construction would destroy vast areas of the heartland of "old Russia." A senior member of the Soviet Academy of Sciences wrote in the journal Sovetskaia Rossia at the time that if the project were carried through, 368 historic monuments would become submerged.

It was also pointed out that, in contrast to prevailing concerns at the time the project was first proposed in the mid-1960's, the level of the Caspian Sea has begun to rise again, increasing by more than 1 meter since 1978

The second scheme would have been even more ambitious, since it would involve reversing the flow of two of the largest rivers in central Russia—the Ob and the Irtysh—using a 1400-mile canal to deposit water from the rivers into the Kazakhstan region between the Caspian Sea and Mongolia.

Although work on this project has already commenced, the scientific community has been voicing increasing fear about its unknown impact on the environment. In particular, there has been concern about the impact on the global climate of shifting large amounts of water from the far north to the middle of central Asia, particularly since large stretches of the two rivers are frozen for much of the year.

A statement issued by the political bureau of the Communist Party in Moscow on 15 August said it had been decided to halt work on the project "in view of the need for more study of the ecological and economic aspects." It said that the decision had been made after close investigation of these problems by various research institutes—but admitted that the suspension of the projects had also been "advocated by wide bodies of public opinion."

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