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