AIDS FUNDING

Did Political Clout Win Vaccine Trial for MicroGeneSys?

Almost everyone agrees that developing an AIDS vaccine is a goal to which all possible resources should be devoted. Why, then, are so many AIDS researchers and policy makers gnashing their teeth over an amendment to the Department of Defense appropriations bill, passed this week, offering $20 million to the Army for testing an AIDS vaccine? The answer: They're outraged because, rather than letting scientists decide which vaccine to test, the amendment singles out a product of one company—Connecticut biotech firm MicroGeneSys. "It's really scary," says Bernadine Healy, director of the National Institutes of Heath (NIH). "If we're going to have legislators determining what drugs we test in people, I think that, as physicians and scientists, we're potentially facing as large a moral dilemma as we have ever faced in medical science."

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Healy says she knows of no precedent in which Congress has directed researchers to test a particular experimental preparation. And that's not the only reason scientists, activists, and public officials are disturbed. Another is a high-powered lobbying effort on behalf of the biotech company, an effort that included help from former Senator Russell Long of Louisiana. At a time when federal AIDS spending is essentially flat, that political muscle helped secure $20 million to test the MicroGeneSys vaccine, equal to more than half the $35.6 million that the National Institute of Allergy and Infectious Diseases spent on extramural AIDS vaccine research in fiscal 1991.

AIDS researchers, including virologist William Haseltine of Harvard's Dana-Farber Cancer Institute, had strong words for the amendment. "Not only is it bad precedent," says Haseltine, "it opens the door for a tremendous amount of lobbying abuses in the system. That group with the strongest lobbying can [ensure they] have their product tested." Ron Desrosiers of the New England Regional Primate Research Center, a leading AIDS vaccine researcher, used even harsher language: "This is the most ridiculous thing I've ever heard of. There are a lot of good products that deserve to be tested and to sneak one through is ridiculous."

One of the senators responsible for the amendment says he checked its scientific merits before introducing it. Senators Sam Nunn (D–GA) and John Warner (R–VA) introduced the amendment on 18 September. At the time, Nunn said: "According to Army medical experts, [a] Phase 2 [trial] has shown that the vaccine should go to Phase 3 as soon as possible." A Nunn spokesman said the senator's staffers had contacted the legislative affairs branch of the Office of the Secretary of Defense: "[W]e asked them about this specific measure and they said, 'We approve.'" The spokesman added that "if somebody's trying to draw a picture that Russell Long is cutting some deal for some organization for which he lobbies and that's the whole purpose of this, it's completely a false accusation. That's not how Senator Nunn works."

Although the amendment does not mention MicroGeneSys specifically, all involved agree the vaccine mentioned there is a MicroGeneSys product: gp160, a genetically engineered version of an HIV coat protein that is designed to be used as a form of therapy in infected people. The Walter Reed Army Institute of Research has been testing gp160 in infected volunteers since 1989. Currently, the institute is conducting a Phase 2 trial, a preliminary test of safety and efficacy, in more than 500 patients. Human tests of the MicroGeneSys vaccine are also being conducted by NIH and by a variety of researchers. None has yet shown that the vaccine keeps people healthy, though many believe early results are promising.

Although Nunn says the Office of the Secretary of Defense advised him it wanted trials of the MicroGeneSys vaccine to move ahead, the Army, which would have to carry out the trials, does not think the time is right. In response to questions from *Science*, a spokesman for the Army said in a written reply that the Army had never requested the $20 million appropriation and, in fact, was not aware of the amendment until it was introduced on the floor of the Senate. The "Army," says the statement, "feels that it is premature to initiate a large-scale trial until current studies of gp160 are completed and the data analyzed."

Regardless of whether the Army wanted the MicroGeneSys amendment, the measure got momentum from Long. When Warner and Nunn introduced the amendment, Warner took a moment to "commend" Long, who retired in 1986 after 38 years in the Senate: "[I]t should be noted that not only did our former colleague and friend bring it to our attention, but he was present on the floor of the Senate today...not in the capacity of lobbying, but indeed his presence connoted the importance of this amendment." Government records show that since 1991, Long's Louisiana law firm has been registered as a lobbying group on behalf of MicroGeneSys. Repeated telephone calls to Long and to MicroGeneSys were not returned.

The clout behind the amendment was sufficient to overcome last-minute opposition. Among letters to the chairman of the House appropriations subcommittee on defense, Representative John Murtha (D–PA), was one from scientific watchdog Representative John Dingell (D–MI), who wrote: "I believe that this Senate amendment is deeply flawed," since "these determinations should be left to scientific peer review and not made by the Congress in this manner." AIDS activist Mark Harrington, a leader of the Treatment Action Group, urged Murtha to remove the product-specific language. Says Harrington: "The idea that lobbyists are setting research agendas for the AIDS community is really chilling."

Although the amendment has been approved, its opponents have one hope: a stipulation in the bill that the vaccine trial not be carried out if the NIH director, the Food and Drug Administration commissioner, and the secretary of defense all submit "a written certification" within 6 months of enactment "that the large-scale Phase 3 clinical investigation should not proceed...." Warner, in a statement, said, "It is my intention to ensure that the secretary of defense, the National Institutes of Health, and the Food and Drug Administration thoroughly review the merits of this program in relation to other ongoing research."

Which seems to be just what Healy intends to do. "If the final language...gives me a coresponsibility of determining whether this vaccine should be tested," she says, "I will feel compelled as a physician and a clinical scientist to be guided by the ethical responsibility to patients, and that will include rigorous review of the product before it goes ahead." If the secretary of defense and the commissioner of the FDA agree with her, the $20 million won't be spent on the trial. But the sour taste will linger in the AIDS research community.

–Jon Cohen