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Agency Chief Spurs Bioterror Research -- And Controversy

As Dr. Fauci Pours NIH Funds
Into Makers of Vaccines,
Some Say He Oversteps

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BETHESDA, Md. -- Anthony S. Fauci has hundreds of millions of dollars at his disposal to bet on drug companies, hoping they will come up with the next hit vaccine or medicine.

Dr. Fauci isn't a venture capitalist. An AIDS-research pioneer, he runs the infectious-diseases institute within the National Institutes of Health. Since the terror attacks of 2001, he has been playing an unusual role for an NIH official by supporting start-up companies with NIH grants and contracts. His belief: Market forces alone won't provide the medicines Americans need for protection against bioterrorism.

The 64-year-old Dr. Fauci is drawing his share of controversy. Some entrepreneurs who haven't been showered with money talk of a "Fauci Club" of favored companies.

Others say he is overstepping his bounds by funding rival entities and pitting them against each other for government contracts. In one case, the NIH gave materials from a supplier of one company to help jump-start research at a rival. One of his biggest bets -- on a next-generation anthrax vaccine -- has yet to pay off.



Anthony S. Fauci

The most fundamental question is whether the government and Dr. Fauci should be trying to influence what drugs and vaccines the marketplace produces. "If you had to pick one person, he's a pretty good guy to pick," says J. Leighton Read, a partner at Alloy Ventures, a Palo Alto, Calif., venture-capital firm. "But I'm not sure Tony should be investing. His experience in products and manufacturing is very limited. Maybe they ought to pay more attention to the invisible hand."

The workings of the invisible hand, though, have been all but invisible. Publicly traded drug companies have tended to stay away from vaccines, antibiotics and related drugs. These products have low profit margins and are especially prone to liability suits. The government is often the main customer for them.

Dr. Fauci acknowledges that bankrolling product development in the private sector "is not our spécialité de la maison." Still, he argues that some entity has to be the investor of last resort if the marketplace isn't producing crucial medicine. "The industry wasn't going to make the investment when they had a choice between developing a new Viagra, a new Lipitor, versus the very risky procedure of doing advanced development in a product where there wasn't going to be a guaranteed payback for them," Dr. Fauci says.

Dr. Fauci is pumping about \$500 million to \$600 million in taxpayer money a year, or about a third of his biodefense budget, into product development. Much of that goes to companies. By comparison, biotechnology venture investments in the U.S. totaled \$4.06 billion in 2004, according to surveys by PricewaterhouseCoopers.

Dr. Fauci's goal is to get companies ready to bid on contracts under the BioShield program run by the NIH's parent, the Department of Health and Human Services. The department was authorized by Congress last year to spend \$5.6 billion over 10 years on biodefense drugs under BioShield.

A native of Brooklyn, N.Y., who joined the NIH in 1968 after graduating from Cornell University's medical school, Dr. Fauci already had achieved prominence as a scientist-bureaucrat before Sept. 11 set the stage for his new role. In the 1970s and 1980s, he did groundbreaking work on the immune system, and later gained recognition for helping decipher how the AIDS virus destroys the body's defenses. At a recent concert in Washington, D.C., the Irish rock star and activist Bono dedicated a song called "Miracle Drug," about his hopes for future disease treatments, to Dr. Fauci.

The scientist wows members of Congress with lucid briefings, all delivered in a rapid-fire New York accent. Discussing pandemic flu at a recent news conference, President Bush made a point of saying that he consults with Dr. Fauci.

After Sept. 11 and the anthrax attacks in the fall of 2001, Dr. Fauci and his agency, whose formal name is the National Institute of Allergy and Infectious Diseases, divided pathogens into three categories. They gave highest priority to Category A pathogens such as anthrax, smallpox and plague. Dr. Fauci argued that his agency was well-suited to receive new funds for biodefense.

Research Bets
Companies that have received major funding from Anthony S. Fauci's agency:

| COMPANY/ LOCATION | VACCINE TYPE | AWARD in millions |
|---|-----------------|----------------------|
| Bavarian Nordic, Kvistgard, Denmark | Smallpox | \$171* |
| Acambis, Cambridge, U.K., Cambridge, Mass. | Smallpox | \$141* |
| VaxGen, Brisbane, Calif. | Anthrax | \$100 |
| Avecia, Manchester, U.K. | Anthrax | \$80 |

*Full amounts if U.S. exercises options.
Sources: U.S. Department of Health and Human Services; company announcements

It was a persuasive argument. The agency's biodefense-related funding rose from \$42 million a year in 2001 to nearly \$1.2 billion in 2003 and nearly \$1.7 billion this year. Spurred by colleagues, Dr. Fauci says he decided to fund companies on a large scale. That was a radical role for the NIH, which mostly has funded academic or basic research.

While an anthrax vaccine already existed, Dr. Fauci and other experts worried that it was hard to make and might cause side effects such as fever and headache. Dr. Fauci's institute solicited bids for a better one. Among the responders was a company in Brisbane, Calif., called VaxGen Inc.

Dr. Fauci knew VaxGen because the company had a promising AIDS vaccine that his agency had funded over several years. In 2003, however, the AIDS vaccine failed important clinical trials. In the meantime, VaxGen was busy reinventing itself as a biodefense company with a next-generation anthrax vaccine candidate.

Demanding Schedule

NIH spelled out a demanding schedule for the anthrax-vaccine bidders, such as delivering early trial results by the end of 2003. A predecessor company of drug giant Sanofi-Aventis SA declared the timetable impossible and was disqualified. Dr. Fauci's agency awarded

\$100 million in two funding rounds to VaxGen and about \$80 million in two rounds to its main rival, Avecia Group PLC, a United Kingdom biotechnology company. The idea was to get them prepared to compete for a big federal contract to deliver a new anthrax vaccine to the national stockpile.

One of VaxGen's rivals, BioPort Corp., of Lansing, Mich., cried foul. The bidding specifically excluded any makers of the existing older-generation vaccine, of which there was just one, BioPort. The company swung into action, hiring publicists and lobbyists. Eventually, BioPort received a \$122 million contract to supply the older vaccine, which is approved by the Food and Drug Administration, to the U.S. stockpile.

In late 2004, the department awarded the entire \$877 million contract for a new anthrax vaccine to VaxGen under the BioShield program. Since then, though, VaxGen has stumbled and its vaccine is almost a year late. Its first deliveries now are slated for late 2006. The company won't get paid until it delivers. Meanwhile, Dr. Fauci finds himself on the spot.

At a House government reform committee hearing last month, Rep. Chris Cannon, a Utah Republican, grilled Dr. Fauci: "So now we've got a small company [VaxGen] failing to perform...We have an experimental technology to deal with a disease that we've already been attacked with...We don't have a stockpile, even though my understanding is, we have a company that has an FDA-approved vaccine for anthrax. Is that a fair statement of where we are?"

"Yes, it is a fair statement," Dr. Fauci replied. He added that the "experimental" technology has been used in other vaccines and an authoritative federal panel called for a transition to a new, safer vaccine.

In many ways, Dr. Fauci's description of his job makes him sound like a venture capitalist, although the NIH never takes ownership stakes in the companies it funds. He seeks to place bets on multiple companies in the hopes of hitting the jackpot and to dole out the NIH's money in multiple rounds, using milestones to gauge progress.

"When you put your eggs in one basket, even a totally unavoidable scientific slip-up can leave you with no eggs in your basket. You have to hedge your bets," Dr. Fauci says.

Nonetheless, the Silicon Valley comparison makes him cringe, and he dislikes the term "venture capital" applied to his new role. "It makes our grantees very nervous," he says, referring to the traditional recipients of NIH money who worry about competing with companies for funds.

There is another big difference between Dr. Fauci and a venture capitalist. If a company that gets NIH funding becomes a stock-market darling, U.S. taxpayers don't enjoy any financial windfall, even though their money was put at risk.

Dr. Fauci says he draws on the vast scientific expertise within NIH to come up with products and companies worthy of funding. In May, he hired Michael Kurilla, an infectious-disease specialist who has worked at the drug company Wyeth, to work on biodefense projects.

The NIH's bet-hedging strategy has at times seemed prudent. It gave money to both [Sanofi-Aventis](#) and Chiron Corp. to develop an effective vaccine against H5N1 influenza, the bird flu that has raised alarms around the world about a possible pandemic. In August, Dr. Fauci announced that the first human trials of the Sanofi-Aventis vaccine were effective. The company now is trying to scale up production.

Funding Rivals

Dr. Fauci's tactic of funding rivals with directly competing products also can create controversy. In 2001, Bavarian Nordic A/S, a Danish biotechnology company, brought an idea for a smallpox vaccine to Dr. Fauci's institute. This got his attention, since the new vaccine could be used on patients with AIDS or other conditions that compromised their immune system. The existing vaccine is considered highly risky for such patients.

Dr. Fauci began funding Bavarian's research and development of a new smallpox vaccine. He also started funding a rival, [Acambis](#) PLC. NIH awarded more than \$100 million to each company, with an eye toward making them competitors for a BioShield contract. That contract, for 20 million doses of the new smallpox vaccine, is expected to be awarded in 2006.

In a move that stunned Bavarian, the NIH gave Acambis samples of modified smallpox virus used by Bavarian. It had obtained the samples from Bavarian's own supplier, a professor in Germany.

Bavarian filed a civil lawsuit against Acambis in August at the U.S. District Court in Delaware. It filed a parallel complaint with the U.S. International Trade Commission in Washington, which has the power to bar imports of products that use stolen intellectual property. Bavarian said it has exclusive rights to the German professor's virus strains.

Bavarian didn't sue the NIH, though. It has been awarded \$130 million in NIH contracts and already has received \$45 million of that. "We do not believe it is good business practice to involve your customers in litigation," says Li Westerlund, director of intellectual-property rights at Bavarian.

The chief executive of Acambis, Gordon Cameron, says his company believes it received the virus strains without restrictions on their use. Dr. Fauci says he can't comment on the spat because it is in litigation.

When the government initially solicited bids for the smallpox-vaccine contract expected to be awarded next year, it required that all bidders have "unencumbered" intellectual property. After Acambis was sued, the government revised its bid solicitation to remove the word "unencumbered."

John Clerici, a partner at the law firm McKenna Long & Aldridge LLP in Washington who isn't involved in the Acambis case, says the revision shows how the government tends to deal with a few anointed companies. "I think this makes clear that NIH can and will do what it wants to ensure the game is being played by its rules, no matter what the rules have been in the past," says Mr. Clerici, who represents BioPort, the anthrax-vaccine maker. "This isn't exactly fair and open competition."

Dr. Fauci, while declining to discuss specific cases, says competing for the parent agency's big BioShield contracts is all a matter of competence and meeting milestones. The issue for BioShield bidders, he says, is: "Do you meet the criteria?"

In reality, several companies have been funded by NIH only to find themselves on the losing end of big contracts.

Nonetheless, some companies worry that without NIH funding, they can't get on the inside track for BioShield. "If the NIH is giving grants, they become the gatekeeper. They define what gets developed, and exclude all these other innovative ideas," says Richard Hollis, chief executive of [Hollis-Eden Pharmaceuticals](#) Inc., a San Diego biotechnology concern developing a radiation-sickness antidote.

Hollis-Eden's experimental medicine addresses two medical problems stemming from radiation exposure. A rival product, [Amgen](#) Inc.'s Neupogen, addresses only one. Dr. Fauci's agency is funding studies of Neupogen for this use. When the Department of

Health and Human Services recently put out draft bid requests and specified only one of the indications, it seemed to favor the Amgen product. Hollis-Eden's stock dropped 50% on the Nasdaq Stock Market over the next few days.

Hollis-Eden began urging members of Congress to complain to HHS Secretary Michael Leavitt. Rep. Tom Davis, Republican of Virginia, did so, writing that he is "very troubled" by the draft bid request. Stewart Simonson, an assistant HHS secretary, responded that the department was focusing on the most significant blood abnormality of radiation exposure. Dr. Fauci declined to comment on the Hollis-Eden protests.

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