

Subj: tip for the anthrax investigation

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From: TRempfer

To: amerithrax@fbi.gov

To whom it may concern with the Amerithrax investigation:

As the article below points out, on Oct. 13th, 2001 the CEO of BioPort Corporation met with Sen. Daschle to lobby for their product. Sen. Daschle had previously written a letter to the DoD and the FDA questioning their anthrax vaccine.

The news reports about BioPort's intentions at that time included the fact that BioPort was due to file their expedited application for reapproval on the 15th of October. I chose that day to file the Citizen Petition, under title 21, with the FDA in order to follow a statutory process of questioning the propriety behind the anthrax vaccine and its licensure.

BioPort evidently moved up their filing as other reports indicate to the 12th of October. The 13th of October was a Saturday. The FBI should inquire from the manufacturer why they accelerated the filing of their application for reapproval...

As you are aware from my previous emails, I never had any communication from Sen. Daschle's staffer, Mr. Randy DeValk, after the October 15th attack. Why? Mr. DeValk was the individual who coordinated Sen. Daschle's letters to the DoD and the FDA after myself and LtCol Russell Dingle briefed him and Rep. Gephardt's staffer in Washington in the late spring of 2001. He provided me an electronic copy of the letter in the summer and kept me apprised of the status of their investigation of BioPort as of late August of 2001.

Respectfully,

Major Thomas L. Rempfer

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http://www.rollcall.com/issues/50_38/vested/7008-1.html

Roll Call

October 4, 2004 Monday

HEADLINE: Seeking a Shot In the Arm;
Makers of Anthrax Vaccines Joust Over Federal Contracts

BYLINE: By John McArdle Roll Call Staff

BODY:

On Oct. 13, 2001, Robert Myers traveled to Capitol Hill from his home in Michigan to brief the staff of then-Majority Leader Tom Daschle (D-S.D.) on a new anthrax vaccine developed by his company, a small bioengineering firm known as BioPort.

It had been just a month since the terror attacks on New York City and Washington, and public officials like Daschle worried that terrorists would continue their nontraditional war against the United States by planning a biological attack against Americans.

Turns out, the anthrax already was in the mail.

Just two days later, in an office steps away from where Myers sat that day, a Daschle mailroom assistant opened the first of several seemingly innocuous letters sent to Capitol Hill in the fall of 2001 that contained deadly anthrax spores.

That day also would signal the start of a more conventional war in Congress: one fought by lobbyists.

A high-stakes fight is under way over who will supply 25 million to 75 million anthrax vaccine units that are needed to fill a government bioterrorism stockpile created after the attacks of 2001. The combatants are a small group of lesser-known companies and their teams of Washington lobbyists.

Among other things, the lobbying battle shows how something as popular as protecting Americans against bioterrorism translates into big business for Washington's lobbying industry. The federal government, through President Bush's newly signed BioShield initiative, is expected to pay \$5.6 billion over the next 10 years to purchase the various vaccines needed to fill the Strategic National Stockpile.

"Washington is where the money is," Myers, the executive vice president of BioPort, said during a recent visit to Capitol Hill. "I'm certain that all the companies that have good ideas for developing countermeasures ... show a presence at one time or another in this town."

With anthrax remaining one of the likeliest biological threats against the United States, federal agencies charged with protecting the nation against bioterrorism - including the Departments of Homeland Security, Defense and Health and Human Services - are prepared to pay big money to accumulate massive amounts of vaccines as quickly as possible.

Marc Wolfson, a spokesman for the department of public health and emergency preparedness at HHS, said the contract for a minimum of 25 million and maximum of 75 million anthrax vaccination units is anticipated to be awarded within the next month. It is possible that the contract could be awarded to more than one company, Wolfson said.

"There's certainly an impressive amount of government funding available for improving the preparedness of our country against biological threats and for the development of countermeasures," Myers said.

Executives at BioPort and VaxGen, a competing biotech company, say a major component of anthrax-vaccine lobbying simply is bringing Members and staffers up-to-date on what is available and how their vaccines work.

BioPort, which currently is the only company with an anthrax vaccine licensed and approved by the Food and Drug Administration, perhaps has the largest lobbying presence of any anthrax-vaccine maker in Washington.

The company already employs several lobbying shops, including Washington-based Cassidy & Associates and longtime vaccine specialist Dack Dalrymple of Dalrymple and Associates. Dalrymple has been lobbying on vaccine issues since 1979, when he left the House Energy and Commerce Committee. He began working with BioPort in 1998. Cassidy & Associates is a more recent hire for BioPort.

In addition, the Lansing, Mich.-based company is looking into starting an in-house D.C. office, as a way of keeping a BioPort presence in Washington full time. BioPort also started its own PAC in 2002 and in the past year has been running ads in Capitol Hill newspapers, including Roll Call.

In the past four years, more than 4 million doses of BioPort's BioThrax anthrax vaccine have been given to more than a million American service members. The company says it has reversed problems it initially faced at the Lansing facility.

BioPort repeatedly was cited by the FDA for violations – including contamination problems and changes made to quality-insurance records - at its manufacturing plant after acquiring it from the Michigan Department of Public Health in 1998.

Vaccine production was held up by federal regulators for several years because of those concerns, but the company fixed the problems and received official FDA approval to produce the BioThrax vaccine in January 2002. In the wake of the 2001 anthrax attacks on Capitol Hill, the vaccine was offered to and taken by dozens of those who were exposed.

BioPort holds a contract with the Defense Department to supply more than 10 million units of the anthrax vaccine. Earlier this year, the company was under attack from three separate federal lawsuits brought by soldiers who claim that the vaccine made them ill. Two D.C. lawfirms that have been working to defend BioPort in those cases are Arent Fox and Thelen, Reid and Priest.

VaxGen, which is looking to pick up the enormous Strategic National Stockpile contract through HHS, is a California-based company that has developed a "next-generation" vaccine which has yet to be approved by the FDA.

The company bills its vaccine, called rPA102, as potentially more efficient in its dosage amounts and cheaper than previous vaccines. VaxGen has retained lobbyist Vicki Hart, a former special assistant to Sen. Trent Lott (R-Miss.) and then-Senate Majority Leader Bob Dole (R-Kan.) who founded the lobbying firm Hart Health Strategies. Hart has monitored biodefense issues for VaxGen since 2003.

Avecia, a British-based biotechnology company, also is developing a next-generation anthrax vaccine that it wants to sell to the U.S. government. It already has garnered a \$71 million vaccine contract through the National Institute of Allergy and Infectious Diseases.

VaxGen officials say they have come to Washington three or four times since January to visit Capitol Hill and work with their outside lobbyists. BioPort executives say they frequently travel to D.C. to meet with power brokers at various agencies around the city.

BioPort executives say that usual stops include members of the Michigan delegation, contacts at the Pentagon and staffers on various Appropriations committees. BioPort hopes to become even more of a regular presence on the Hill once its D.C. office opens.

"We feel it's appropriate to add boots on the ground in Washington on a full-time basis," said Kim Brennen Root, BioPort's director of communications and public affairs. "If you look at someone across the table whose card actually says BioPort on it, it's very meaningful for that staff person or that Member."

BioPort also is in the process of developing a next-generation vaccine, but officials said research and development often is tied to government funding.

"We are funding our business with funds from our DOD contract," said Brennen Root. "We recognize that many of the opportunities that exist for development ... are related to the government funding of those products. Our commitments are tied to the commitment of the government."

In the meantime, BioPort is pushing hard to make sure its BioThrax vaccine is chosen for the Strategic National Stockpile. Myers said he believes the new stockpile should be made up of a combination of both the current FDA-approved vaccine and next-generation vaccines.

"What we're saying now is that if Health and Human Services has established this need of 75 million doses for the SNS, what we think is appropriate is that they strike a balance between the next-generation vaccine and the licensed, proven vaccine," Brennen Root said. BioThrax "is tried and true and we have to make sure that while we're focusing on new vaccines we shouldn't overlook what we have."

But VaxGen officials say lobbying efforts for anthrax vaccines should not go beyond education.

"We feel our effort is to respond to the government's needs," said Lance Ignon, vice president of corporate affairs for VaxGen. Ignon added that VaxGen doesn't try to publicize its anthrax vaccine but created it with specific government guidelines in mind. "I do think it is somewhat misguided to try to convince the government to buy something else," he said.