

How a company cashed in on anthrax

The vaccine maker's frequent cries for help brought it millions of additional tax dollars - even when it could not deliver a product that troops could use.

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In a two-year span, the nation's only licensed anthrax vaccine maker went from pleading poverty to announcing \$100 million in acquisitions, including other pharmaceutical companies and a new manufacturing plant near Washington, D.C.

It's a pattern that's worked well for BioPort Corp.: Tell the Pentagon or Congress that it doesn't have the money to keep going, negotiate a new deal, then count the extra cash rolling in.

During the past seven years, it's transformed an initial investment of less than \$4.5 million into an international biotech firm, with contracts worth more than \$450 million. During that time, the company has capitalized on its monopoly over the vaccine and on fears that opposing armies and terrorists will unleash tiny anthrax spores somewhere.

BioPort is an example of how a sole-source government contract can become a gold mine - especially if you spend wisely on the right lobbyists and public relations professionals.

BioPort counts a former Cabinet member and assistant secretary of health and human services among those it pays to gain favor with government agencies.

"You always pay a higher price when you're stuck with a sole-source," says Philip Coyle, a former assistant secretary of defense for procurement. "The government has nowhere else to go if it wants what you have to sell."

He says Pentagon officials talked about taking over the anthrax vaccine plant and operations - especially after the government held the license for the vaccine as collateral for a series of loans and payments that kept the company afloat.

"What I never heard in those discussions was why nothing ever came of it," he says.

The Pentagon isn't telling that story, and neither is BioPort.

MOST BIOPORT FINANCES AREN'T OPEN TO PUBLIC



Troops and veterans who've been asked to put BioPort's products in their bodies often point to the company's problems getting a clean bill of health for its manufacturing plant, as well as to the company's ability to always get its way with government officials. They wonder whether BioPort's connections - not its scientific and medical prowess - are behind the company's success.

BioPort is a privately held company that doesn't make its stock available for public sale. As a result, most aspects of its finances and management aren't open to public scrutiny.

The company declined to provide its officers for interviews with the Daily Press. Six weeks after receiving a list of detailed questions - and promising answers - it sent a box containing two books and some news releases. None of the questions was answered.

BioPort's approach to veterans is similar: It sends substitutes to speak for it, often without disclosing that those sources were paid by the company. Those surrogates disregard evidence of deaths or severe health problems from the vaccine, and they provide testimony to government regulators and the public.

Meanwhile, the veterans who think that they've been harmed by the vaccine live on disability payments or suffer in silence.

No government grants support research into their questions about the shot.

EX-JOINT CHIEFS HEAD WAS NAMED DIRECTOR

Until 1998, the nation's only manufacturing plant for anthrax vaccine was owned and operated by the state of Michigan. The state agency that ran the plant was losing money, so the state put the operation and its license for making the anthrax vaccine up for bid.

Fuad El-Hibri, a 40-year-old German businessman with a Yale University management degree, formed a team of investors to buy the business, which included a \$100 million contract with the Pentagon.

His bid faced a problem, though: He and his father, Ibrahim El-Hibri, a wealthy international financier from Lebanon, dominated ownership of the company, which they named BioPort.

Both were considered friendly to the United States. Father and son had directed a company involved in Britain's anthrax vaccine program and they had worldwide interests in cell phone networks and other ventures.

But the U.S. government was not keen on letting a foreign-owned company control its anthrax vaccine. The only other bidder was also based overseas.

So Fuad El-Hibri played a trump card: A family friend, former Chairman of the Joint Chiefs of Staff Adm. William Crowe, was made a director.

Crowe put no money into BioPort but got about 10 percent of the stock, government records show. El-

Hibri says Crowe immediately advised him to apply for U.S. citizenship.

Crowe's advice was good, El-Hibri said. But Crowe's connections were better: He was the military's top officer during the Reagan administration, then endorsed Bill Clinton for president in 1992. Clinton made him U.S. ambassador to the United Kingdom, and while serving there, Crowe was close to the El-Hibri family, congressional testimony shows.

Crowe has persistently declined comment on his investment or role with the company, except for congressional testimony in 1999, when BioPort was seeking its second government bailout. During that testimony, he was asked whether he'd lobbied Pentagon officials for BioPort. Crowe vehemently denied it.

At that point, BioPort had all the leverage over the Pentagon that it needed - if the military wanted to continue its year-old program of inoculating every service member against anthrax.

Even though the Pentagon gave Michigan more than \$20 million for new equipment and repairs and \$100 million in guaranteed contracts the previous decade, the plant had several problems. It was shut for renovations in March 1998, six months before BioPort bought all operations and licenses in a \$25 million package of cash, loans and promises of future payments.

Food and Drug Administration inspections found repeated problems before and after BioPort took over. BioPort brought in more, and better-paid, consultants and employees to fix things up - even though its minor partners included managers who had run the plant that provided millions of doses of vaccine to U.S. troops, congressional records show.

As part of the sale, BioPort assumed the right to sell about \$7.9 million of vaccines already made and promised to the U.S. military. Within weeks, it signed a new contract with the Pentagon providing for \$45.1 million more, including \$16 million in immediate cash for plant renovations. The deal required the government to pay for vaccine even if the drugs weren't licensed for use.

MONEY FLOWED DESPITE

QUESTIONS ON EXPENSES

That wasn't enough for BioPort: Nine months later, in June 1999, it was still struggling to get FDA approval of its manufacturing plant. The company said it was running out of money and needed more help.

Pentagon auditors looked at BioPort's books and concluded that millions of dollars were unaccounted for. BioPort didn't even know the cost of making a dose of vaccine, the auditors reported.

It was clear that \$1 million had been spent to renovate and furnish offices, as well as \$1.28 million more on bonuses for "senior management."

One unnamed former manager got \$10,000 a month for as much as 40 months - whether he worked or

not, records show.

And \$1 million more had been spent on items unrelated to anthrax production, the auditors said.

They concluded that BioPort's request for extra money didn't meet legal requirements.

But Pentagon contract officers, citing "the interests of national security," overruled them and approved a \$24.1 million bailout in September 1999.

The contract addition that they blessed paid all the company's debts and provided a 144 percent increase in payment for each anthrax vaccine dose, from \$4.36 to \$10.64.

It was \$2 million less than BioPort sought. Pentagon officers wrote that by chopping the amount, they didn't have to notify Congress about the new deal.

Congress found out anyway, but did nothing to stop the deal.

Hearings were held, including one by Sen. John Warner, R-Va., chairman of the Senate Armed Services Committee. His session involved only BioPort officials and others who supported the bailout.

A second hearing involving critics of the company and the renegotiated contract was promised but never held.

More aggressive questioning took place in the House of Representatives. It was determined that El-Hibri and his partners had invested only \$4.5 million of their own money, in cash and loan guarantees.

All that money and the cash the Pentagon had chipped in was gone, spent on renovations, consultants' fees and physical improvements, congressional investigators found.

Further, the original \$25 million deal with Michigan had become \$14.45 million.

"The message seems clear: If a company wants to make millions without providing a product or service, enter into a sole-source contract with the Department of Defense to produce vaccines," Rep. Walter Jones, R-N.C., said in a written statement. "BioPort appears to have the government over a barrel."

Louis J. Rodrigues of the Government Accountability Office - a congressional oversight agency that's frequently criticized BioPort and the Pentagon's management of the vaccine program - told Congress that it "had no option" but to pay up if it wanted anthrax vaccine.

The Pentagon contractors who made the original deal with BioPort should have known there was no way that the company could stay in business, Rodrigues said.

"We did nothing to force BioPort's hand and make them come up with a cost-control system," he said.

Or, he added, a realistic business model.

COMPANY TROUBLED BEFORE 9/11

Pentagon officials promised Congress that they'd do a better job - in part by assigning government employees to oversee the company's bookkeeping and quality-control systems.

They denied that they'd been patsies for the well-connected company.

"All I am trying to say is that this is not a sweetheart deal," David R. Oliver, then principal deputy undersecretary of defense for acquisition technologies, told Congress.

BioPort struggled for more than three years to get licensing for its plant and product. Meanwhile, batches of vaccine were made and the Pentagon paid for each - including money for storage of unusable vaccine.

Vaccine made before the plant renovation kept going into the arms of thousands of troops. Dozens of them came to Congress, complaining that the drug made them permanently ill, giving them headaches, joint pain, loss of memory and more severe symptoms.

By 2000, even the Pentagon had lost patience and told BioPort to stop making vaccine until the plant regained its license. But the military agreed to keep making payments anyway, to keep the company afloat.

Those payments meant that BioPort's owners didn't have to borrow money elsewhere and didn't have to risk their personal finances, a congressional auditor testified in 2000.

By January 2002 - when federal drug regulators finally agreed that the plant and company could resume licensed operations - the Pentagon had paid BioPort \$126 million for drugs that were stored and unlicensed, congressional records show. It also paid \$33.5 million during that time for vaccine given to 525,000 troops.

The months before the licensing approval were tumultuous for the company and the nation.

In August 2001, Congress and the Pentagon publicly said they were considering giving up on BioPort and its failures in getting operations up to snuff.

Meanwhile, BioPort brought in more business partners and consultants from established vaccine companies and government contractors to figure out how to regain its license.

Then came Sept. 11, 2001, followed the next month by deadly anthrax-laden letters to members of Congress and others in Washington, D.C.; Connecticut; and Florida.

Instead of asking questions about the vaccine's safety, many members of Congress began asking why more doses weren't available.

Tommy Thompson, then secretary of health and human services and the Bush administration official

responsible for vaccine and drug licensing, was caught between a Congress that wanted action and critics who feared political pressure would hasten licensure.

"I can assure you nobody is pressuring FDA to approve this," he said in October 2001.

Three months later, BioPort had its license back.

A few months after that, it was back to pleading poverty.

This time, BioPort was after a bigger prize: a contract to supply millions of doses of anthrax vaccine for use by civilians, postal workers, police, firefighters and others who might encounter domestic terrorism.

A \$1 billion contract was being waved in front of vaccine and pharmaceutical makers, the largest in government history.

BioPort responded as it had in the past.

In a series of interviews, company officials said their business was "at risk" and in financial jeopardy if the government did not quickly give it the contract for a domestic vaccine stockpile - or a new Pentagon deal.

If BioPort was on the ropes financially, its biggest stockholders didn't seem to feel it.

During the same week the president of BioPort pronounced it "at risk," the chairman of the board and biggest stockholders - El-Hibri and his wife, Nancy - were in the news because neighbors were complaining about their plans to build an 88-acre commercial equestrian and polo center near their home in Gaithersburg, Md., near Washington, D.C.

The El-Hibris had never moved to Michigan to oversee the daily struggle over licensing at the vaccine plant there.

BIOPORT FOCUSES ON WASHINGTON, D.C.

Washington, D.C., was the focus of much of BioPort's attention anyway.

In 2002, records show, the company increased spending for lobbyists in Congress, from \$30,000 to \$110,000. The amount doubled the following year.

BioPort also hired Ruder Finn and Fleishman-Hillard, high-powered public relations firms staffed by many former government officials.

BioPort, still the nation's only licensed anthrax vaccine manufacturer, began sponsoring "public education seminars" and studies to build support for a bigger government stockpile of the drug.

On the first anniversary of the Sept. 11 attacks, six doctors, scientists and former military officers - described as a "panel of bioterrorism experts" by BioPort - announced the need for preparedness. Their

primary recommendation was to not rely on a new anthrax vaccine but to purchase millions of doses of BioPort's product.

BioPort paid several of the people on that panel to review and endorse the report, including former military officers who only a year before told Congress how safe and effective the company's vaccine was.

They included Marine Maj. Gen. Randy West and Lt. Gen. Ronald Blanck, a former Army surgeon general.

West said he was paid \$5,000 for reviewing the report, which was written by either BioPort or its public relations agent - not the experts on the panel.

Even though the ghost writing wasn't known at the time, a critic from the conservative Cato Institute publicly dismissed the panel's work as "just BioPort trying to make some money."

COMPANY CONNECTIONS WEREN'T PUBLICIZED

After that, the company's efforts became less obvious.

Muhiuddm Haider, an unpaid member of the panel and a professor in the school of public health at George Washington University, started operating a Web site for BioPort in support of the anthrax vaccine.

BioPort's name doesn't appear anywhere on the site, but the company supplies all the money to operate it, \$40,000 a year, Haider said.

The Web site says it's sponsored by the Partnership for Anthrax Vaccination Education, or P.A.V.E., a group of medical organizations that includes the prestigious American Medical Association.

Earlier this year, Haider and P.A.V.E. petitioned the FDA to license the anthrax vaccine for use against inhaled spores of the bacteria.

The ties to BioPort were not disclosed then, either.

P.A.V.E.'s Web site and the organization's publications extol the need for vaccine and say the vaccine is safe. They mention none of the side effects, even the minor ones that the Pentagon acknowledges are suffered by a third or more of those who get the shots.

"I am not marketing for BioPort," Haider says. "I am marketing for public safety."

P.A.V.E.'s public safety efforts began with a series of forums. Featured speakers were West, officials from BioPort, Haider and others connected to BioPort.

People who question the effectiveness and safety of the vaccine aren't on the agenda for those forums.

A frequent speaker is Jerome Hauer, former assistant secretary of health and human services for emergency preparedness. He was a leading proponent of stockpiling anthrax vaccine for civilian use while he was on the government payroll.

In his first few appearances at P.A.V.E. events, Hauer's connections to BioPort weren't disclosed. He'd become a paid consultant.

Later, he took over a new bioterrorism institute at Haider's university.

He was named to BioPort's board of directors in June and has been lobbying for the company's products.

As BioPort's board expanded, so did its business.

By September 2003, the Pentagon was paying \$22 a dose - more than double the price negotiated in the 1999 bailout.

Cash was coming in fast. The company could make a million more doses a year than the military demanded, El-Hibri told TWST, a Web site that runs verbatim interviews with business leaders.

"We are debt-free and profitable," he said.

VACCINE PROFITS FUEL BIG PURCHASES

BioPort was now a subsidiary of Emergent BioSolutions, led by El-Hibri and his business partners.

By the end of 2003, Emergent announced the purchase of a Maryland drug maker for more than \$3 million and signed a new contract with the Pentagon, worth from \$29.7 million to \$245 million, depending on the doses sold.

The following year, it began building a second, \$95 million, anthrax vaccine plant in Frederick, Md.

In January of this year, Emergent signed a deal with the British government to work cooperatively on toxoid and botulism vaccines, including a pledge to spend at least \$2 million during the next two years. Purchase of a British company working on five vaccines, including an oral anthrax vaccine, followed weeks later.

ONE CONTRACT LOST, BUT ANOTHER WAS WON

But BioPort and its parent still hadn't landed the big prize: supplying anthrax vaccine for the U.S. domestic stockpile.

BioPort and other companies received seed money to research a new-generation anthrax vaccine. But when the \$1 billion contract was awarded in November 2004, it went to VaxGen Inc., a California company without a licensed product and in trouble for misreporting financial results to Wall Street.

VaxGen's vaccine isn't ready for use yet and is in early trials, years away from licensing. Government

grants finance at least 11 other efforts to provide alternatives to BioPort's vaccine, aiming for a safer, more effective product.

When BioPort couldn't win in the lab, it doubled its efforts in Congress and other branches of government, adding more and better lobbyists.

It had hired Louis Sullivan, secretary of health and human services under President George H.W. Bush - the current president's father. But higher-powered help was needed.

TWO NEW LOBBYISTS

EQUALS ONE BIG DEAL

McKenna Long & Aldridge, a powerful Washington, D.C., law and lobbying firm also known as "MLA," was hired Jan. 1 of this year, U.S. Senate lobbying records show.

Within six months, it reported \$140,000 in lobbying fees and helped bring BioPort a \$122.7 million contract to supply 5 million doses of the vaccine to the Department of Health and Human Services, the second-largest award under BioShield, the federal law that created a domestic stockpile of antiterror vaccines.

The lobbyist's news release was headlined, "MLA Helps Client Secure BioShield Contract for AVA Anthrax Vaccine."

MLA had supplied several lawyers, including one who'd helped write the Homeland Security Act of 2002 and two who'd been tapped by Congress for help in creating the BioShield law.

But they couldn't do it alone.

Four days before the big contract award, BioPort added lobbyist John Hishta to the team. A few weeks later, he filed a U.S. Senate lobbyist report saying BioPort had paid him \$30,000 for "procuring a government contract for anthrax vaccine."

Hishta was executive director of the National Republican Congressional Campaign Committee during its successful 2002 election campaign. The committee is the main strategy and fund-raising organization for Republican candidates in the House of Representatives.

Hishta also managed a re-election campaign for Virginia Sen. John Warner. Warner is an important ally of the Pentagon in the anthrax vaccination program.

BioPort is still delivering those 5 million doses for the BioShield contract.

But the company didn't wait to resume its well-practiced, well-rewarded strategy for success: threatening to stop vaccine production, then reaping a new contract.

On July 14, BioPort President Robert Kramer told Congress that if the government didn't promise to buy

even more vaccine for the domestic stockpile, the company might have to stop producing anthrax vaccine altogether.

"We'll have to make a very simple business decision," he testified.

Whether it was the renewed threat - or just coincidence - BioPort once again got the desired result.

Last month, Health and Human Services posted a notice that it would enter private negotiations with BioPort to supply an additional 5 million doses of anthrax vaccine for the domestic stockpile.

The price to taxpayers hasn't been determined yet.

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