

The anthrax vaccine scandal

Why did the Pentagon allow BioPort Corp. to remain the sole U.S. supplier of a crucial weapon against bioterror, despite years of failure to deliver the vaccine?

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With each new confirmed anthrax infection raising fears of a wider bioterror attack in the U.S., pressure is mounting on the Defense Department and the Food and Drug Administration (FDA) to give the green light to Michigan-based BioPort Corporation, the nation's lone anthrax-vaccine manufacturer, to ship new lots of the vaccine to the Pentagon.

Anthrax vaccine shipments from BioPort have been suspended by the FDA since 1998 because of questions about the facility's quality control, forcing the Pentagon to dramatically reduce its program to vaccinate all 2.4 million U.S. soldiers and reservists against anthrax. Now the lack of the vaccine threatens to become a scandal, as the U.S. is sending thousands of soldiers overseas and calling up reserves, and as the public is clamoring for access to protection from the deadly bacterium.

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After three years of getting bailed out by the Defense Department, BioPort could be poised to make a fortune -- as its CEO Fuad El-Hibri did working with the British seller of anthrax vaccine, Porton International, during the Gulf War a decade ago. But only if the FDA approves the company's renovated plant, as expected, sometime in the next week. The decision could open the door for BioPort to market the drug to a worried public, as new anthrax scares are reported daily.

The story of the troubled U.S. anthrax-vaccine program is a tangled saga of science, politics, private-sector deal-making and national security. There have been persistent questions about the vaccine's safety and effectiveness. Critics say Defense Department studies have never proven the vaccine works against the more dangerous inhaled form of anthrax, only against cutaneous, or skin anthrax. Some military personnel have complained of mysterious illnesses after taking the vaccine, and at least 400 have been disciplined for refusing the mandatory

inoculation. But the Pentagon insists the vaccine is both effective and safe. Even now, some researchers say the vaccine is seriously outdated, as BioPort gears up to ship more.

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Then there are questions about BioPort's role as the nation's only anthrax-vaccine maker. How did Fuad El-Hibri, 43, a German-born entrepreneur and former director of British vaccine-maker Porton Products, come to have so much control over the West's supply of anthrax vaccine? Why didn't the Pentagon turn to a larger, more established drug maker for the crucial anti-biowarfare weapon? And how could it let BioPort remain the sole maker of the vaccine after it failed repeatedly to gain FDA approval for its renovated facility?

"It speaks to DoD culture more than anything else," says a congressional staff aide who asked not to be named. "The Pentagon just does not have a corporate culture. Once they decided to go with this program (BioPort), they stuck with it, even though oversight indicated they had built their biodefense program on a foundation of sand, and they had an unreliable producer. The DoD is simply incapable of admitting a mistake. They genetically just can't back out."

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The Pentagon and BioPort deny they made a mistake, of course, and they believe their problems will be solved, perhaps next week. Government sources close to the process say as early as Monday, the FDA will approve BioPort's renovated facility, and enable it to resume shipments of the vaccine it has been stockpiling since 1999.

A government official who asked not to be named says while BioPort is "70 percent on the way there" in terms of improvements in quality control demanded by the FDA, political pressure due to the terrorism scare is playing more of a role than quality control in expediting FDA approval. But BioPort officials say FDA approval for their renovated facility is long overdue.

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"We have heard the process will be speeded up, and it has taken an incredibly long time," said Jay Coupe, a longtime aide to Adm. William Crowe, who with Fuad El-Hibri serves as one of BioPort's owners, and who served as chairman of the Joints Chiefs of Staff during the Reagan

administration. (Fuad's father, Ibrahim El-Hibri, also well-connected to the defense establishment, is a third partner in the venture.) "While BioPort certainly supports the FDA, and doesn't want any special consideration and wants a safe and effective vaccine, the approval process has gone on for a very long time for most vaccine manufacturers. This is one of the reasons people are getting out of the vaccine business."

"We have been manufacturing vaccine," BioPort spokeswoman Kim Brennan Root said. "As we submit final documentation for approval from the FDA, we have been manufacturing vaccine and contributing it to the stockpile so when approval comes we can be in a position to release the vaccine."

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But critics of BioPort say that repeated FDA inspections have shown the company has failed to prove it can produce the same dose of vaccine twice.

"The most fundamental problem has to do with the quality of the process of vaccine manufacture," a congressional aide, who asked not to be named, told Salon. "They cannot show they can produce the same vaccine of the same potency and consistency twice in a row. The quality of the process is not validated. That means they don't have the data to show that, within this process, within this heat range, this process produces this vaccine. They are trying to retrofit a modern inspection and validation process on an old system."

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"BioPort has tried to say it didn't know how much it would cost to bring the company to 2001 FDA standards," another congressional staffer told Salon. "But that is kind of a hard pill to swallow. They consistently showed deviations from good manufacturing practices. Some of the FDA complaints are substantive. There were contaminants in the lot. There were some deficiencies in packaging. There were problems with paperwork and record keeping. There was an inability to show consistency from one lot to the next."

"They have come a long way," he added, "at significant taxpayer support."

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Even if BioPort gets FDA approval to resume vaccine sales, anthrax vaccine will be available only to the military, not to the general public. That is, unless BioPort can step up production, and get the Defense Department to agree to sales to federal health agencies. If the current anthrax scare in New York and Florida grows, some members of the public are certain to pressure their political leaders for access to the vaccine.

"I will tell you right now, I wish I had access to the vaccine myself, I can tell you," says Dr. Zsolt Harsyani, a former business partner of Fuad and Ibrahim El-Hibri who is president of the Washington office of Porton International.

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BioPort's Kim Brennan Root would not disclose how much vaccine the company had stockpiled while awaiting FDA approval for their renovated facility since renovation was completed in 1999. But a congressional aide who has researched the matter estimates that approximately 5 million doses are stockpiled. Vaccination requires six doses over 18 months, and a yearly booster shot.

In testimony to congressional committees, BioPort CEO Fuad El-Hibri has indicated BioPort's viability depends on being able to sell anthrax vaccine to a much larger market than to just the Defense Department, which he said is getting "rock-bottom prices."

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"It has become clear to us that the prices paid by the Department of Defense for anthrax vaccine are significantly below BioPort's costs for producing anthrax vaccine," El-Hibri told the House Government Reform Committee in June 1999, a year after he purchased the Defense Department's former anthrax vaccine supplier. "Traditionally vaccine manufacturers have been able to offer lower prices to the government by recovering a substantial portion of their costs through commercial sales. Because of the current unavailability of product, the commercial sales market has not materialized as anticipated. Without a second market, the government cannot expect the rock-bottom pricing it enjoys with some of the other vaccines it purchases."

"As a commercial entity," el-Hibri added, "BioPort cannot continue to subsidize the DoD."

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Critics of BioPort are outraged at El-Hibri's contention that BioPort has subsidized the Defense Department. Chief among them is U.S. Rep. Walter Jones, R-N.C., who sits on the House Armed Services Committee. Jones estimates that the Pentagon has paid BioPort almost \$150 million since BioPort purchased the state-owned Michigan Biologics Products Institute (MBPI) in 1998, giving it the exclusive U.S. license to make anthrax vaccine -- with no new shipped vaccine to show for the money.

"My whole concern has been that this company cannot meet FDA requirements to produce the product," Jones told Salon Thursday. "So how long does the government continue to put taxpayers' money into a company that cannot produce the product?"

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"Since former Secretary of Defense Bill Cohen raised the concern about the possibility of anthrax being used on the military or civilians," Jones added, "the Clinton administration made the decision to go with BioPort."

As his comment suggests, partisan politics may at least initially have played a part in Jones' troubles with BioPort, and its co-founder, Adm. Crowe. Alone among top military brass, particularly those who served Republican administrations, Adm. Crowe endorsed the election of "draft-dodger" Bill Clinton, who was widely despised by the Republican-leaning military establishment. Clinton rewarded Crowe for his endorsement, Jones suggests, with a plumb ambassadorship to England from 1994 to 1997.

And England in the years during and after the Gulf War is key to understanding the close links between the half dozen people who have come to dominate the sale of vaccines against deadly bioweapons in the U.S. and the U.K. Only two countries, the U.S. and Britain, make anthrax vaccine, and El-Hibri has been involved in both, first at Porton International in Britain during the Gulf War, and now with BioPort in the U.S., as the world faces a new terrorism scare. Sources say El-Hibri remained involved with Porton International up until the firm partnered with defense contractor DynCorps in 1997 to get a new Defense Department contract to make a second generation of vaccines against bioweapons. The new company is named DynPort Vaccine Company, and its license to make second generation vaccines to protect against small pox, anthrax and other bioweapons was publicly announced Thursday, although the contract appears to date from 1997.

It was in Britain that Ambassador Crowe resumed his acquaintance with an old family friend, Ibrahim El-Hibri, a wealthy Venezuelan citizen of Sunni Lebanese descent, and his son Fuad. Ibrahim El Hibri had made a fortune in the telecom business with Phillips Company, working in the Gulf states.

Crowe and Ibrahim el-Hibri were first introduced decades ago by a U.S. Naval Academy classmate of the admiral who, like Ibrahim El-Hibri, lived in Venezuela. They had stayed in close contact during the 1970s when Adm. Crowe was posted to head the U.S. Central Command in Qatar, in the Middle East, where Ibrahim El-Hibri was active in his businesses. And in England during his ambassadorship, they met again.

The mania for privatization in Margaret Thatcher's England made it a great place for entrepreneurs like El-Hibri. In the 1980s, an El-Hibri acquaintance named Zsolt Harsyani, an American Ph.D. in genetics who had spearheaded an early report on biotechnology for the U.S. Office of Technology Assessment, became involved in what would become in its time the largest private biotechnology firm in the world, Porton International. Porton got the rights to sell vaccines and other products developed by the U.K.-government run laboratory, the Centre for Applied Microbiology and Research (CAMR), on commercial markets. CAMR had done the early research into products like botulinum toxin, or botox, a bacterium that can be injected to stop spasms (as well as prevent wrinkles, its most popular use in the U.S., at least until now) and anthrax vaccine.

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The marketing relationship between Porton and CAMR ended in the 1990s, Dr. Harsyani said, and CAMR now markets its own products.

"At the time of Mrs. Thatcher, there was a philosophy in the U.K. supporting taking public works to the private sector," Harsyani told Salon. The spirit of public-private partnership that existed in Thatcher's England in the 1980s then moved to the States, Harsyani explained. "A lot of U.S. government and military research was not commercialized because there was no mechanism for it. One of the things that has changed in the United States in the last 20 years is that intellectual property that came out could in fact be owned by the institution where the researchers worked. The U.S. has now taken steps towards that kind of privatization."

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In 1989-1990, with Persian Gulf tensions heating up and the U.S. and Britain preparing to lead a war against Saddam Hussein's invasion of Kuwait, El-Hibri became a principal silent investor in Porton, while his Yale and Stanford-educated son Fuad was installed as director of a Porton subsidiary, Porton Products. Their Middle East connections were put to use, as Porton sold tens of millions of dollars worth of anthrax vaccine to Saudi Arabia and other countries -- deals all approved by the British Ministry of Defense.

(A U.S. government investigator says Porton sold vaccine to Saudi Arabia at the insanely high price of \$300-\$500 per dose -- some 30 to 50 times what the U.S. Defense Department agreed to pay BioPort per dose.)

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The Gulf War was a boon to businesses like Porton, as well as its officers, the el Hibris and Dr. Harsyani. Increasingly, they started to look for similar business opportunities in the U.S., particularly in areas that revolved around biodefense. They gravitated to opportunities where the government-run defense industry meets the private sector.

After the Gulf War, with concerns mounting in the U.S. about reports of Iraq's production of anthrax, Adm. Crowe was posted as ambassador to England. There, he resumed his friendship with the El-Hibris. About the same time, the El-Hibri family was hearing that the U.S.'s lone anthrax vaccine manufacturer, the state-owned Michigan Biologics Products Institute (MBPI), was financially troubled and looking for a buyer.

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In 1970, the Michigan lab had received the only U.S. license to make anthrax vaccine, but its facility was antiquated. By the late 1980s, according to Judith Miller's "Germs," Michigan's Biologic Products Institute was making small batches of the vaccine -- 15,000 to 17,000 doses -- every four years, and selling them mostly commercially, to people in the animal hides business who came into contact with anthrax. But in 1988, the U.S. Army went to the lab and signed a contract to buy 300,000 doses in five years. The order was ambitious. By the time Gulf War troops assembled in early 1991, there was only enough vaccine to protect 150,000 of the half million troops assembled there, and none for civilians or allies, though the Saudis were able to buy some from the U.K.'s Porton International.

After the war, as worry increased over Iraq's biowarfare capacity, some in the Pentagon proposed that the military build its own vaccine factory, but officials thought it best left to the private sector. By 1996, however, concerns were mounting that the Michigan facility, already inadequate to the challenge of producing enough vaccine for the entire military, was having new problems. After several years of troubling inspections, the FDA threatened to close the lab in 1997, citing problems with sterility and equipment maintenance as well as scientific procedure. The only other facility producing a vaccine, Britain's CAMR, which at one time had a marketing relationship with Porton, now terminated, was using a different anthrax strain, and wasn't licensed for U.S. use anyway.

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The el-Hibris and Crowe came up with the idea for BioPort, which they thought could do in the U.S. what Porton had done in Britain: bring private-sector methods (and profits) to a public research lab. As Fuad el-Hibri testified to Congress in 1999, "When BioPort was originally conceived, we believed that Admiral Crowe's background would be important in ensuring that we did everything correctly in establishing a company that would best serve DoD's needs."

El-Hibri and Crowe also partnered with two former managers of the state-owned facility, Robert Myers, who serves as BioPort's COO, and Rob van Ravenswaay -- a deal former Michigan state Sen. Linng Brewer, a Lansing Democrat, has long charged was ethically suspect, because Myers and Ravenswaay as employees of MBPI "knew the identities of at least two bidders (El-Hibri and Crowe) and the substance of their bids, information not made available to the general public. It appears they used information not available to others to enhance their financial position relative to the other bidders, a clear violation." The BioPort partners have long denied the charges.

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In June 1998, BioPort's \$24 million bid for MBPI -- \$17 million upfront and the rest in loans to be paid over five years -- beat out competitors, including a \$16.6 million bid endorsed by the Defense Department by Gruppo Marcucci, that involved no debt. Some expressed concern about selling the sensitive national security facility to a foreign company. (Brewer says the Marcucci bid lost out because it had failed to partner with managers of the Institute, but he has been unable to bring his ethical violations against Myers and Ravenswaay to court.)

A former Porton employee who asked not to be named says the company was looking to make a fortune on the Pentagon contract. "When El-Hibri bought the Michigan plant, he thought they would make a killing. The lab was already knocking out this product. The vaccine was already FDA approved. It's an essential business but no one wanted to talk about bioweapons back then, even though they knew Iraq and other countries had anthrax."

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But it didn't turn out to be so easy.

Despite El-Hibri's experience marketing anthrax vaccine at Porton, Crowe's strong ties with the defense establishment, and growing interest from the Pentagon in protecting troops from anthrax, BioPort's problems quickly mounted after it acquired the MBPI facility.

Troubles seemed unlikely, because in May 1998, shortly before BioPort's bid for MBPI was finalized, Defense Secretary William Cohen announced plans to require all 2.4 million U.S.

soldiers and reservists to be inoculated against anthrax, which looked like a windfall for the new venture.

In testimony to Congress, Adm. Crowe has adamantly denied that he had any insider knowledge that led to his purchase of the anthrax vaccine facility. "It has on occasion been rumored that the decision to inoculate all service personnel was made to benefit BioPort Corporation and indirectly me, presumably because of my past associations with the military and the administration," Crowe told the House Committee on Government Reform in October 1999. "If this charge were not so ridiculous, it would be offensive. It outrageously exaggerates my influence. Let me be completely clear. I never, repeat never, solicited any official of this administration to install or promote a mandatory inoculation program."

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Despite the Pentagon's decision to require anthrax vaccination for all troops, which clearly could have been lucrative for the new firm, BioPort was struggling. Only three months after their acquisition of MBPI, El-Hibri and Crowe were prevented from shipping any new vaccine, by a scathing FDA inspection that found over 40 items wrong with the plant, the vaccine, its consistency, the firm's accounting, and other problems. Indeed, by September 1999, BioPort was already appealing to the DoD for relief from a contract requesting BioPort's delivery of some 8 million doses of anthrax vaccine. It simply could not deliver, and certainly not at that price.

A Defense Department audit from July 12, 2000, shows that shortly after BioPort bought MBPI, the DoD awarded it a \$29.4 million contract to supply 8.7 million doses of anthrax vaccine at the price of \$4.36 a dose. But a year later, unable to ship product, BioPort requested and the DoD granted \$24.1 million in relief to BioPort, reduced the number of doses demanded from 7.9 million to 4.6 million, and agreed to raise the price per dose from \$4.36 to \$10.36.

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Even after a full-scale yearlong renovation of its manufacturing facilities, and significant efforts to meet FDA requirements to get its new facility reapproved, BioPort continues to wait for FDA approval to ship doses of the vaccine it has been manufacturing all this time. Problems have been found not simply with BioPort's process, but with the doses of the anthrax vaccine already produced. FDA tests found a lack of consistency in dosage and other problems with the finished product.

The delay has prevented the Pentagon from vaccinating all but the troops it is currently sending abroad, and has forced some soldiers to actually suspend vaccination mid-process.

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"Now we're in a situation with the terrorist attack that we still have this company that has still not met FDA approval," Rep. Walter Jones says, "and we're spending almost \$3 million per month on this company that is still months away from having FDA approval."

So why did the DoD stick with BioPort all these years of their failing to get final FDA approval -- until now, when the U.S. faces a real anthrax crisis?

"I blame everybody," says a congressional staffer well versed in the BioPort controversy. "The buyer -- the Pentagon -- kept BioPort alive. The DoD should have pulled the plug on this outfit a long time ago."

To be fair to the Pentagon and BioPort, however, it's not as if major pharmaceutical companies have been clamoring for the contract. A reliable anthrax vaccine has proven hard to make, and questions about its safety have likely scared off other manufacturers (although the Defense Department agreed to protect BioPort against lawsuits by military personnel.)

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Even now, just as BioPort seems set to perhaps overcome its long regulatory and financial difficulties, many in the industry and government are coming to consensus that the anthrax vaccine BioPort produces is outdated.

Increasingly, the government is also supporting research into a second generation of vaccines that can protect against multiple bacteria -- perhaps all in one shot. The government has also turned to the well-connected defense contractor, DynCorps, known for its involvement in the drug war in Colombia, and sending retired U.S. cops to Bosnia and Kosovo to serve as U.N. police, to subcontract vaccine research. (DynCorps was implicated in the accidental killing of an American Baptist missionary and her infant daughter by the Peruvian military earlier this year.) In 1997, DynCorps partnered with the El-Hibris' old company Porton International, to form DynPort Vaccine Company (DVC), just in time to beat out four other bids for a \$322 million, 10-year contract.

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Under the award, "DVC acts as a prime system contractor for the management of the existing stockpile of biological defense vaccines (except anthrax vaccine) and the advanced development, testing, production, FDA licensure, and storage of up to 18 new biological defense vaccines, including new vaccines against anthrax, small pox, plague, botulism and tularemia," according to Pentagon spokesman Jim Turner.

Why did the Pentagon turn to the unknown DynPort over more established companies? Some in the industry say not a whole lot of pharmaceutical companies want to get into bioweapons vaccine research, because the capital costs to build a dedicated lab safe from airborne toxins are so high, and the market -- at least until now -- has been so small, primarily just the Pentagon.

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"No one else wants these contracts," insists Ron Rader, who leads an industry research firm called BioPharm.com. "Spore-forming microorganisms, because of FDA regulations, require totally separate facilities. Botulinum toxin, anthrax -- the facilities have to be dedicated. No one wants to have a dedicated, one-product facility. The trend now is to have multiple suites, and/or large manufacturing facilities. That way, you can switch from product to product every few months. No one wants to deal with spore-forming organisms.

"Also back then, anthrax vaccine was just not an attractive product. It's associated with biological warfare -- and that's not a positive thing. It's not the kind of thing you want to put in your brochure. Mainstream pharmaceutical companies had no interest. And you're also talking about being absolutely dependent on one customer. Very few companies are willing to take that risk. Any day, the Defense Department could just walk away." But P.W. Singer, a scholar at the Brookings Institution who has studied private military companies such as DynCorps and Military Professional Resources Inc., says the Pentagon seems to be treating

bioweapons vaccines as just another weapons system they want to outsource to a trusted private-sector insider.

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"The Pentagon is in search of two things: efficiency, and expediency," Singer said. "They either think they can get a better product in terms of quality or price or rapidity, or for expedient reasons. DynCorps provides a disconnection, when they would rather not have the government involved in some activity."

"My concern," he added, "is that the company in Michigan [BioPort] is actually a government lab that was privatized. It strikes me that for something so important for societal security, that you don't want to leave it in private hands. There are just some things that are too important."

And indeed, for BioPort CEO Fuad El-Hibri, BioPort is not an exclusive priority. El-Hibri, who became a U.S. citizen around the time of the BioPort purchase of MBPI, does not work out of the Michigan company, but out of the Rockville, Md., offices of his company East West Resources Management. His secretary there, Sheila Glick, says BioPort is one of 15 different companies El-Hibri runs, including some mobile phone operators in El Salvador, Venezuela and Jamaica. El-Hibri did not respond to numerous requests by Salon for an interview, and his secretary later referred questions to back to BioPort.

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Dr. Zsolt Harsyani, president of Porton International, which has now been bought by the French pharmaceutical company Ipsen, and who is now involved in the DynPort vaccine contract with the Defense Department, said there is nothing sinister about the way the El-Hibris have approached the business of anthrax vaccine -- as a business opportunity.

"Mr. Ibrahim El-Hibri is a wonderful gentleman," Harsyani said Friday. "He started a charity for orphans." A scan of the Internet shows Mr. El-Hibri on the board of a Beirut-based Sunni charity, Dar Al Aytam Al Islamyah, that provides relief to orphans and widows, and espouses "commitment to the humanitarian principles of Islam such as justice, tolerance, and abhorrence of confessionism or sectarianism."

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Harsyani said he had not spoken with Ibrahim El-Hibri in over a year, but that the two parted on good terms. The El-Hibris divested from Porton International about three years ago, about the time when DynPort got the Pentagon contract to begin work on a second generation of bioweapon vaccines.

The former Porton employee, who asked not to be named, says the El-Hibris should be viewed as defense contractors, and their relationship with the Pentagon is not unique. "You have to realize: BioPort and now DynPort, these are arms dealers. They are part absolutely of the military industrial complex. This is their business. They are selling to a captive audience: the Defense Department. That's all-American. All these defense contracts -- they are boondoggles -- and that's the American way, to make as much money as possible. There's not that much unique about BioPort."

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