

Bio Terror Bible

EXPOSING THE COMING BIO-TERROR PANDEMIC

BIOTERRORBIBLE.COM: The following news and events are in respect to the field of bio-terror and pandemic related contracts which occurred within the calendar year of 2003. The American government, more than any other nation, has been systematically preparing its population for an upcoming bio-terror related pandemic by funding draconian bio-terror contracts in the wake of the 9/11 attacks.

Title: Bush Initiative May Help Struggling Biotech Firms

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Source: [Desert News](#)

Abstract: A blueprint for battling terrorism is taking shape in the nation's capital.

But this time, instead of focusing on the nation's airports and borders, this war will be fought in the laboratories of cutting-edge biotech companies across the country.

The weapons in this conflict aren't bombs or guns, but rather microscopic agents — anthrax, smallpox and the plague — that can ravage a community within hours.

Nearly two years after anthrax-laden letters killed five people and wreaked havoc on the nation's postal system, the United States still is ill-prepared to handle biological or chemical attacks. But the White House and Congress are working to quickly make a change. President Bush has proposed a \$6 billion plan to develop biomedical countermeasures over 10 years, and Congress is expected to pass a modified version of the proposal within the next few months.

The initiative could provide a sorely needed infusion of cash to an industry that's struggling to climb out of a three-year slump. While the first six months of this year have seen biotech stocks climb nearly 50 percent, the industry's market capitalization is still 35 percent below its lofty highs from 2000, according to Burrill & Company, a San Francisco-based biotech venture capital firm.

"This is a moonshot for the industry," said Steve Burrill, chief executive of Burrill & Co. "The impact of bioterrorism is enormously positive for this industry."

But biotech companies aren't lining up to get a piece of the government pie.

Instead they're eyeing it warily, skeptical that the so-called "Project BioShield" will set out the kinds of incentives and protections they need to develop vaccines and drugs that will protect against the most deadly of diseases.

"The government doesn't have a good model there that would say why we should be putting our very valuable resources in this area," said Robert Chess, chairman of San Carlos, Calif.-based Nektar Therapeutics, which is working on an inhaled insulin product. "They need to do a lot more work to make it lucrative."

Biotech is an inherently risky business, where only a handful of the many drugs being researched ever make it to market. But after tens of millions of dollars spent in research and decades worth of grueling lab

work and clinical tests, at the end of the road is the prospect of making a fortune off the next big breakthrough.

For vaccines and drugs to combat smallpox, anthrax, botulism and the plague, the same doesn't necessarily hold true. The U.S. government will be the only customer — at least for now. So companies seeking to dip their toe in the bioterrorism field are looking for some guarantees that the government will pony up the cash when the product is ready.

The government already has handed out a number of contracts to companies to develop a new anthrax vaccine and treatment for infected humans. But companies that have agreed to do the research and development are doing so with a big risk — they have no guarantee the government will purchase the finished product.

And another pressing question for the industry is: Who will bear the liability cost of developing these new bioterrorism countermeasures? Many of the products can't be tested on humans because of the deadly consequences if they don't work.

If there are side effects, a company could face multimillion-dollar lawsuits, driving it into bankruptcy.

"Even the threat of a lawsuit can put us out of business," said Una Ryan, CEO of Avant Immunotherapeutics in Needham, Mass.

Avant has a contract with the National Institutes of Health to develop an oral vaccine against anthrax and the plague. Project BioShield in its current form doesn't have a provision guaranteeing liability protection.

The industry also is concerned about changes made to the project in Congress.

A House committee stripped out language that would have guaranteed Project BioShield continuous funding, without going through the annual appropriations process that many other government programs face. That means that even though a multiyear project to develop a drug or vaccine is under way, it could get caught up in the annual political struggle in Congress over where to spend the government's money.

Meanwhile, many biotech companies are carefully watching Brisbane, Calif.-based VaxGen and others who have dabbled in government bioterrorism contracts to see how their experiences play out.

VaxGen won a \$16.1 million contract with the National Institute of Allergy and Infectious Diseases to develop a new anthrax vaccine and create a plan to manufacture a stockpile of 25 million doses.

Like many government contracts, VaxGen's deal follows a "cost-plus" formula, which means all its costs are covered, plus it earns a modest profit of less than 10 percent.

That model guarantees that the company isn't losing money on the deal, but it's not yielding the kind of 25 percent return that venture capitalists usually look to reap when funding biotech projects.

The contract only goes as far as phase I clinical trials. VaxGen has to bid again to win the phase II contract, and then again to actually produce the 25 million-dose stockpile.

But VaxGen CEO Lance Gordon is optimistic that the contract will yield long-term benefits and profits for the company.

"Neither VaxGen nor any other biotech company would have incentives to go into servicing one of these (contracts) for the benefit of research support," he said.

Rather, he's hoping for a trickle-down effect. He expects to first win with the government stockpiling contract. Even though that profit also will be modest, from there it could lead to more lucrative agreements with state and city governments, foreign entities and other private groups.

"I wish there were great guarantees in business. But unfortunately, such guarantees don't generally exist," Gordon said. But VaxGen would never have tread this dangerous territory if it didn't believe it had a high probability of success, he said.

For Anacor Pharmaceuticals, an early-stage biotech company in Palo Alto, Calif., working with the government was a natural fit. It won a \$22.6 million contract with the Defense Department to develop an antibiotic for anthrax.

There's nothing in the contract to say the government will purchase the product in the end, but that works for them.

"We get paid to do the research. All the work we're doing is work we'd be doing anyway to develop commercial antibiotics," Anacor CEO David Perry said ([Desert News, 2003](#)).