

## \$1 billion would go toward developing bioterror remedies

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October 6, 2006

Several cash-strapped biotechnology companies in San Diego are embracing proposed federal legislation that would provide a new funding source for the development of vaccines, therapies or medical devices that could be used in response to a bioterrorist attack.

That additional cash could help San Diego-based Aethlon Medical speed up and expand research of its device that filters toxins out of blood. Safe Life, another San Diego company, would use the funding to speed up production of face mask technology that the company says blocks 99.99 percent of toxic pathogens. Invitrogen of Carlsbad could use it to develop its biosensor technology.

With part of the proposed \$1 billion fund, the companies said they could bring their products closer to being production-ready when the government might buy them for the nation's defense stockpile.

But many biotech companies are apprehensive that the Department of Health and Human Services would control the spigot to the money because of the department's performance as a partner in the bio-defense arena over the past two years.

"There's fear that we could see the same problems as we did with Project BioShield: It won't be implemented the way it is supposed to be," said Frank Rapoport, a biotech lawyer with McKenna, Long & Aldridge, who helped write Project BioShield.



JOHN GASTALDO / Union-Tribune  
James A. Joyce, Aethlon Medical CEO, held two of his company's hemopurifiers, which help filter pathogens out of blood.

Project BioShield was Congress' response to the anthrax attacks of 2001, which killed five people. The measure, passed two years ago, gave the government \$5.6 billion for the procurement and stockpiling of treatments in case of another bioterrorist attack.

It was also supposed to create the incentive for the pharmaceutical industry to invest in the development of products that otherwise would not have a market – most people aren't going to buy an anthrax treatment until immediately after an anthrax attack.

Project BioShield was also supposed to allow companies to circumvent some regulatory requirements because the products cannot be tested on healthy humans. Biotech executives also contend the government was supposed to take risks, committing funds to buy drugs that seemed promising, not drugs that were proven safe and ready for production.

The results have been lackluster at best.

The money wasn't big enough enticement to attract interest from Big Pharma. However, much smaller and often-unproven biotechnology companies, including Aethlon, Safe Life, Isis, Invitrogen and Hollis-Eden in San Diego wanted to meet the challenge.

“But HHS didn't put out enough procurements fast enough,” Rapoport said. “During the last two years they've made only 10 or 12 procurements, mostly in the smallpox or anthrax area. They haven't spent all the money and this money wasn't supposed to last 10 years. You are supposed to spend it and then go back looking for more.”

As a result, the investor market never really materialized for the biotech companies in bio-defense.

“Look at the share price of all the companies that were getting involved in bio-defense two years ago and there's not one that hasn't been hurt by this,” said Rob Housman, a biodefense consultant to biotechnology companies including Hollis-Eden and VaxGen, based in the Bay Area.

Congress wants to solve some of these problems with legislation that would make \$1 billion of Project BioShield money available to biotech companies for research, long before they have a product ready for government procurement.

Last week, the House passed the measure commonly referred to as BARDA, which would create the Biomedical Advanced Research and Development Authority.

It now is being considered by the Senate and is tentatively scheduled to be brought to the floor for a vote in November, according to the staff of Sen. Richard Burr, R-N.C., one of its sponsors.

BARDA “recognizes that our nation must do more to ensure the development of medical countermeasures against bioterrorism and pandemic diseases,” said Jim Greenwood, who heads the Biotechnology Industry Organization in Washington D.C.

"Currently, many promising countermeasures are not making it through the advance research and development necessary to bring products to the point of eligibility for procurement by the landmark Project BioShield," Greenwood said.

The initial science behind a product is typically provided by grants from the National Institutes of Health. At the other end of the product chain is Project BioShield, which pays for the finished product upon delivery.

The gap between the two is referred to as the "Valley of Death" for biotechnology companies because it is where a good idea can stall and die for lack of funding.

BARDA theoretically would provide some Valley of Death funding.

While San Diego biotech executives said they would seek some of the funds, they wonder how long the money will last. And there are concerns about it tapping into Project BioShield, which isn't very big.

"It's not a lot of money when you look at the long list of pathogens that they are worried about protecting against," said James A. Joyce, chief executive of Aethlon Medical.

Rapoport said the important part of the bill is that it established the mechanism for funding. Congress can always look for additional funding later, he said.

Bill Folkerts, who runs the environmental diagnostic division of Invitrogen, recalled an analogy used last week in a meeting of companies and government stakeholders in biodefense: "What's the cost of one aircraft carrier versus the amount generated toward this?"

"There has to be an opportunity to provide additional funding and greater opportunity for Big Pharma and small biotechs here," Folkerts said.

Several medical device companies have already shown that Congress is willing to work with industry on biodefense. Aethlon Medical, Invitrogen and others successfully lobbied to expand the types of biodefense measures Project BioShield and BARDA would fund by including medical devices.

Aethlon's hemopurifier functions similarly to a dialysis machine, with a patient's blood flowing through a filter to remove impurities, Joyce said. Aethlon's filter removes larger pathogens when they stick to affinity agents in the filter, he said.

Unlike the dialysis filter, the hemopurifier filter is a closed cartridge, which means the procedure can be done at home or locations other than doctors offices and clinics, he said.

The filter is supposed to remove the pathogens and lessen the viral load in a patient's body to a point that the immune system wards off illness.

"This is something that could be a first line countermeasure . . . and it can be used in the hours or days when the medical community is still trying to figure out what the pathogen is," Joyce said. "It took 90 days to figure out SARS."

The company completed a small early-stage trial in India. BARDA funding would help in additional trials and also development of other applications of the technology, such as HVAC filters for use in hospitals and schools, he said.

Rapoport credited the avian flu scare with helping to breathe new life into Project BioShield and give fuel to BARDA.

"When have you ever seen Congress go back and revisit a funding bill after two years? Never," Rapoport said. "There's a sense of urgency here and a willingness to be flexible."

And that creates hope for biotech companies that want several issues addressed.

For instance, Richard Jaffe, chief executive of Safe Life, which makes face masks, wants HHS to disclose why it is focusing on certain bioterror agents and selecting some products over others.

The government has stockpiled large quantities of face masks by other companies. Jaffe said those products have not been proven to resist 99.99 percent of pathogens as Safe Life's masks has been shown to achieve.

Several biotech executives said that HHS must also fulfill its contract.

The industry insiders point to the experience of struggling Bay Area biotech VaxGen, which had never produced a marketable product, as a troubling example of why they are wary of working with HHS.

In November 2004, VaxGen received an \$877.5 million contract under Project BioShield to produce 75 million doses of its new anthrax vaccine, enough to inoculate 25 million Americans.

VaxGen later told the government it would miss its original deadline of November 2005 for delivery of the drug by a year.

In March, the government said it wouldn't pay VaxGen until the company completed a costly and time-consuming human test to ensure the vaccine was safe. The new requirement, which was not supposed to be done until after delivery of the drug and payment to VaxGen, forced the company to sell its stake in another biotechnology company for \$79 million to stay afloat and finance the new test.

With BARDA, Burr sought to address some of the complaints from both sides of the debate.

It requires HHS to develop a strategic plan, which would be made public and articulate specifically what it views as bioterror and naturally occurring threats and the type of combative agents it wants to support.

To assist, the measure would create a National Biodefense Science Board to advise the secretary on threats, challenges and opportunities presented by advances in biological and life sciences.

BARDA also contains an antitrust exemption to allow the government to have a more direct dialogue with companies.

It would also require a company receiving research funds to share scientific data with HHS, so that the government can make real-time decisions about whether the product remains promising and funding should continue.

It also allows the government to provide the research funding based on milestones being met, which is different than Project BioShield, which promised most of the funding on delivery of the product.