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New law retools effort on bioterror

Research authority to manage program

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WASHINGTON – The House and Senate have passed legislation that will revamp the Bush administration's \$5.6 billion effort to counter bioterrorism threats, reorganizing management of the program and providing struggling companies with periodic cash infusions to help fund their research and testing.

"It's a relief," Sen. Richard Burr, R-N.C., one of the measure's principal backers, said Monday. "We're a little further ahead of the fear of bioterrorism and pandemic because we've got a solid plan in place."

The House passed the legislation early Saturday and it passed the Senate on Dec. 5. President Bush intends to sign the legislation, but a date has not been set, White House officials said.

More than a year in the making, the legislation was considered by many to be an effort to salvage the 2-year-old Project BioShield, which has been marked by delays and operational problems. Sen. Harry Reid, D-Nev., the incoming majority leader, listed it among his priorities.

"I think it's already made a difference," Burr said of the legislation, which also was pushed by Sen. Edward Kennedy, D-Mass. "We have more people, more companies, more academic institutions, that have looked at this legislation and planned how they can plug into it. It has brought more people to the table interested" in the program.

The legislation creates the Biomedical Advanced Research and Development Authority, within the Health and Human Services Department, to manage the effort. It also allocates \$1 billion over three years for research not funded by a Project BioShield contract or the National Institutes of Health and attempts to pump more government money into the private sector sooner.

Under current law, participating companies are not paid until they deliver the drugs. The legislation would speed up the development cycle by allowing HHS to pay companies up to 5 percent of their contract's value when they reach certain milestones.

That additional cash could help San Diego-based Aethlon Medical speed up and expand research of its device that filters toxins out of blood. SafeLife, 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.

The legislation "complements important work that HHS has already begun to improve the BioShield program," said Christina Pearson, a Health and Human Services spokeswoman. "Passage (of) this bipartisan legislation supports much needed late-stage research-and-development funding. . . . It also supports our efforts to improve coordination of preparedness and response programs across the department."

The program's most significant investment, a nearly \$1 billion effort by VaxGen to develop an anthrax vaccine, has been in limbo since the Food and Drug Administration held up human testing last month because of concerns about the drug's reliability. After threatening to end its contract, HHS gave the firm until Dec. 18 to

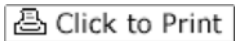
resolve the concerns and begin human testing.

"It is regrettable that we have been unable to engage HHS in a productive discussion regarding how to ensure that this program moves forward," said Lance Igon, VaxGen's vice president for corporate affairs. "We need to engage in a true partnership or we risk losing all the work on this vaccine and undermining our nation's biodefense programs."

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