Testimony of

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Aventis Pasteur
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TESTIFYING ON BEHALF OF
A VENTIS PASTEUR
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REGARDING PROJECT BIOSmELD II, S. 666
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Mr. Chaimlan and Members of the Committee, it is an honor for me to testify before you today regarding Project BioShield and its likely impact in bringing private sector talent and investment into our nation's bio-defense effort.
I represent one company -A ventis Pasteur, the largest company in the world d~voted entirely to vaccine research, development and manufacturing. The company produces approximately 1.4 billion doses of vaccines annually, protecting 500 million people against 20 bacterial and viral diseases.
The company manufactures influenza vaccine and several other vaccines at its United States headquarters in Swiftwater, Pennsylvania. Aventis Pasteur has had enormous successes, including the first application of conjugate vaccine technology and the licensing of the first infant acellular pertussis vaccine. Aventis Pasteur routinely supplies vaccines and biologicals for use by civilian and military populations. This includes vaccines protecting against tetanus and diphtheria, yellow fever, Japanese encephalitis, meningitis, typhoid fever, and influenza. We are working on government contracts directed to combat SARS and Avian influenza.
Aventis Pasteur has partnered with the Federal government in times of peace and times of conflict. Immediately following the attacks on the World Trade Center on September 11,2001, the company provided New York and New Jersey public health and city officials with 50,000 doses of Tetanus Diphtheria Toxoids Adsorbed vaccine for the relief efforts. A ventis Pasteur donated approximately 85 million doses of smallpox vaccine to the Federal government's emergency preparedness stockpiles. The company has always supplied the United States

military with needed vaccines, including those being used today by our troops fighting in Iraq. Aventis Pasteur has been a leading participant in the Global Polio Eradication Initiative, a partnership created to deliver polio vaccine to every child under five, worldwide. Aventis Pasteur has donated a total of 120 million vaccine doses since 1997 under this initiative. The company has responded to Federal requests for proposals for bio-defense measures and, therefore, has current experience on this subject of BioShield II.

Aventis Pasteur supports many of the objectives of Project BioShield I. This included authorizing the Federal government to contract for needed biodefense products over a number of years and providing the multiyear appropriations to pay for these contracts. Development and production of complex medical and

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biological products requires advance certainty that support will be available over a number of years under the most favorable circumstances. This is why allowing multiyear contracting remains so important.

Now that Bioshield I is law, our company will watch for actions giving reassurance that the Bill is implemented by the agencies as Congress intended. While we recognize that the legislation includes significant positive steps toward developing the nation's biodefense capabilities, we are hopeful that Congress will consider the need for adding liability protection in Bioshield II that was not included in the first law. Several important continuing contracting reforms will also help.

HHS must ensure that ke rovisions 0 Pro "ect Bioshield are im lemented to their fullest

During the Congressional debate on Project Bioshield, Aventis Pasteur supported the need to provide for the possibility of the Federal government entering into a variety of types of agreements (including contracts, grants, cooperative agreements and "other transactions") that permit the HHS Secretary to contract for research and development and manufacturing/production all under one agreement. Reports supporting the House version of Project Bioshield issued by all three Committees of jurisdiction make clear this was the unquestionable and worthy intent of Congress. However, we encourage that this authority be made explicit.

A company like A ventis Pasteur, which not only does research and development, but also reliably manufactures millions of doses of vaccines, will be much more likely to be interested in biodefense contracts if there is the certainty that satisfactory completion of research and development will lead to a manufacturing agreement. In the meantime, HHS can make clear that it intends to use this flexibility in the Bioshield I regulations. Similarly, Project Bioshield I provides HHS with streamlined procurement authorities to ensure that the contract process is expedited with as little additional burden to commercial contractors as possible. Competent, experienced vaccine manufacturers tend to operate at near capacity. Taking on a new biodefense project imposes opportunity costs. Being subjected to extensive paperwork in the contracting process lowers enthusiasm to participate. We also hope that Congress will encourage HHS and DHS to make sure their contract staffs are made fully aware of their new contract procurement authorities.

These innovative R&D and manufacturing contracts are different from the

traditional "research only" or procurement of routinely manufactured products.


We hope contract staff will feel energized, encouraged and empowered during the "Request for Proposal" process to make maximum use of the authorities that you have provided to them.

The Need for Project Bioshield II

Project Bioshield was a significant step in the right direction. We commend Congress and the Administration for their leadership. This includes particularly the staff at HHS and DHS who are charged with implementing this new program. However, several unresolved issues still must be addressed in BioShield II to enable our company to be able to effectively and efficiently participate.

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Project Bioshield is silent with respect to addressing liability. In our view, the issue of potential liability protection for biodefense contractors must be addressed to stimulate private sector interest in entering into agreements for such countermeasures. For example, the absence of liability protection was a major obstacle in our participation in the recent procurement by NIH for development of the next-generation of Anthrax vaccine. Absence of clear guidelines and provision of liability protection continues to be a major hurdle for our company. We try to obtain commercial insurance for these contracts, but the practical reality today is that it is unlikely to be available for such projects of this nature, or available at only such a premium that it would be unreasonable for our company to participate.

The Homeland Security Act of 2002 radically altered the way the United States will go about promoting the development of technologies designed to counter a terrorist attack. This was accomplished by means of the SAFETY Act (which stands for the "Support Anti-Terrorism by Fostering Effective Technology"). Under the SAFETY Act, a wide array of legal protections is now available to qualified sellers, vendors, subcontractors and buyers of anti-terror technology products and services, including biodefense countermeasures. Such protections take the form of drastically reduced liability in the event an anti-terror technology fails and damages or casualties result.


Products and services that are developed in response to, or recovery from an act of terrorism might also be considered to be deployed in defense against, in response to, or recovery from an act of terrorism, and thus be eligible to receive the protection of the SAFETY Act. In the context of phannaceutical products, this would encompass giving SAFETY Act coverage to vaccines or drugs that were designed to counter a future use of a biological agent that was previously used in a terror attack. Indeed, we have been advised by counsel that there is a very strong argument to be made that pharmaceutical products manufactured in part as a response to the 2001 anthrax attacks are eligible for SAFETY Act protection. Providing SAFETY Act coverage to pharmaceutical products currently being

manufactured is in line with the purposes and the legislative language of the SAFETY Act, as it was explicitly written to provide protection for technology and services deployed in "response" to an act of terrorism.

In response to the 2001 anthrax attacks, a number of pharmaceutical products are being prepared and deployed in order to reduce the vulnerability of the United States to another anthrax attack. Since those products are in "response" to an act of terrorism, there should be no doubt that they are eligible for SAFETY Act protections, and extending coverage to them is in line with the intent of the SAFETY Act. For example, DHS has explicitly stated that the success of the SAFETY Act depends "upon encouraging Sellers to develop new and innovative technologies to respond to the ever-changing threats to the American people," 68 Fed. Reg. 59,692 (2003). It would be in line with that directive then to extend protection to pharmaceutical products that are developed and deployed specifically to respond to the threat demonstrated by a previous attack.

Recognizing that the protection of the SAFETY Act already extend to pharmaceutical products is an important step in fostering homeland security. Moreover, pharmaceutical products that are developed and manufactured after an act of terrorism has occurred should also be eligible for protection under the SAFETY Act. The perfect example would be the vaccines and drugs developed, manufactured and deployed in the wake of the 2001 anthrax attacks. Such products should be eligible for SAFETY Act protection as they are being deployed in response to an event that represents a triggering act of terrorism. That position is logical in light of the liability risks faced by pharmaceutical companies as well as the risks faced by the United States as a whole if it is unprepared for a new biological attack.

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It is also worth noting that both the Secretary of Health and Human Services and the Secretary of Homeland Security currently have the authority to provide for Federal indemnity to private entities engaging in research, development and production of biomedical countermeasures under Public Law 85-804. However, use of such authority is extremely rare. In addition, in March 2003, President Bush revised Executive Order 10,789, governing use of the authority to provide for indemnity under Public Law 85-804 in the context of anti-terrorism technologies, such as those to be developed under Project Bioshield. While HHS has been proactive in recognizing the need to consider use of the SAFETY Act, it must ensure that Federal indemnity remains available, where appropriate, as was the intention of both the law and the Executive Order.

While HHS is currently using its authority under Public Law 85-804 in very limited circumstances, it is our best understanding that the agency is not providing such indernnification/liability protection until a contact is awarded; and will not guarantee that this protection will be forthcoming as part of the award process. The advice we have been given is that this is not the intention of the law nor is it the practice of other agencies that have the authority to provide such liability protection to contractors. Congress should ensure, through Project Bioshield II, that HHS applies this provision in a way that was intended by both the law and

regulations implementing Public Law 85-804.
Moreover, absence of advance certainty about the availability of liability protection places a potential contractor in the untenable position of having to perform "bare" and assume an unusually high legal risk or refuse to perform and be found in breach of the just signed agreement. Once a contract is awarded, a contractor has no meaningful negotiating strength, and is reliant on the contracting agency to follow through aggressively to get approval to extend liability protection. In essence, we are reallocating scarce labor, capital and resources and investing in high-risk products without sufficient assurance that liability protection will be available. We hope you will work with us on this issue.
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As I mentioned previously, report language for Bioshield I encourages use of "other transactions." Aventis Pasteur recommends that Project Bioshield be amended to expressly permit the Secretary of HHS to enter into "other

transactions" in order to provide the maximum degree of flexibility suggested by the proposed legislation. "Other transaction" authority will permit agreements between HHS and industry that more closely resemble a fully negotiated commercial transaction. Similar authority has been provided to both the Department of Defense and NASA, and has resulted in numerous success stories including, most recently, the "Predator" unmanned aerial vehicle program in use in Afghanistan and Iraq today.
While HHS received "other transaction" authority, generally, for anti-terrorism activities under Title XVI of the Defense Authorization Act of 2004, no steps appear to have been taken to implement use of this authority inside or outside the context of Project Bioshield. Moreover, under this legislation, HHS is required to receive permission from the Director of the Office of Management and Budget before entering into such an agreement. Providing HHS with explicit authority to enter into "other transactions" without additional approval would allow HHS to maximize private sector participation. Mr. Chairman, thank you for the opportunity to testify on this tremendously important issue. A ventis Pasteur has been and remains committed to contributing to our nation's common defense. I will be pleased to respond to any questions from members of the Committee.