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Part 1

PROJECT BIOSHIELD ACT OF 2003

JUNE 10, 2003.—Ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2122]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2122) to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of the Project BioShield Act of 2003 is to provide the Secretary of Health and Human Services with greater authority and flexibility to facilitate the research and development of bio-

medical countermeasures; to authorize the appropriation of funding for the procurement of security countermeasures through the creation of a special reserve fund; and to authorize the emergency use of unapproved drugs, devices, and biologics and the emergency unapproved use of approved drugs, devices, and biologics.

BACKGROUND AND NEED FOR LEGISLATION

During times of nation, military, or public health emergency, the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents. Unfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents. Currently, companies have little incentive to research, develop, or produce vaccines or other drugs simply for a possible one-time purchase by the Federal government for the Strategic National Stockpile. Most current private sector research and development dollars go for drugs or devices that will have continuous commercial application. In addition, some of the current generation of drugs or devices may have special uses as countermeasures to biological agents like Ebola, but there is little incentive to perform the research or development or production activities that might tailor the drug or drug approvals for such a purpose.

Even if a product has been developed to treat such diseases or conditions, if the product has not yet been approved by the Food and Drug Administration (FDA), access to the therapy is greatly limited. Nothing in the Food and Drug Act allows the Secretary to suspend the approval requirements to ensure access to unapproved drugs and devices on a large-scale basis in times of emergency.

Under present law, if a product is not approved by the FDA, then it is unlawful to provide that product to an individual, unless the product has been authorized for distribution under an investigational new drug (IND) application (for a drug and biologic) or an investigational device exemption (IDE). When a drug or device is available under such procedures, a number of conditions apply that make the use of an IND or IDE infeasible in times of national emergency, where drugs and devices may need to be deployed at rapid rates. Even if a drug, biologic, or device is highly promising in treating a disease or condition associated with biological chemical radiological or nuclear agents, and even if it is the only therapy available, current FDA law does not allow for rapid deployment of the product.

The Project Bioshield Act is designed to help resolve these problems and make our nation more secure. Like the Public Health Security and Bioterrorism Preparedness and Response Act, the project Bioshield Act is designed to help the administration and the nation in public health emergency preparedness, but relies on the ingenuity and hard work of Americans in the private and public sector to achieve these goals.

HEARINGS

The Subcommittee on Health held a joint hearing with the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security on "Furthering Public Health Security: Project Bioshield" on March 27, 2003. The Subcommittee re-

ceived testimony from: The Honorable Tommy Thompson, Secretary, U.S. Department of Health and Human Services; Mr. Leighton Read M.D., General Partner, Alloy Ventures, on behalf of Biotechnology Industry Organization; Mr. Michael Friedman M.D., Chief Medical Officer for Biomedical Preparedness, PhRMA; Mr. James Baker Jr., Ruth Dow Doan Professor, Center for Biological Nanotechnology; and, Mr. Gary Noble M.D., Vice President of Medical and Public Affairs, Johnson & Johnson, on behalf of AdvaMed.

COMMITTEE CONSIDERATION

On Thursday, May 15, 2003, the Full Committee met in open markup session and ordered a Committee Print reported to the House, as amended, by voice vote. A request by Mr. Tauzin to allow a report to be filed on a bill to be introduced by Mr. Tauzin, and that the actions of the Committee be deemed as actions on that bill, was agreed to by unanimous consent.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering the Committee Print reported. A motion by Mr. Tauzin to order the Committee Print reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has held oversight hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of the Project BioShield Act of 2003 is to provide the Secretary of Health and Human Services with greater authority and flexibility to facilitate the research and development of biomedical countermeasures.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2212, the Project Bioshield Act of 2003, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by

the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2003.

Hon. W. J. "BILLY" TAUZIN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2122, the Project BioShield Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Jeanne De Sa and Sam Papenfuss.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 2122—Project BioShield Act of 2003

Summary: H.R. 2122 would amend the Public Health Service Act (PHSA) to authorize appropriations of up to $5.6 billion for fiscal year 2004 through 2013 for procurement of certain security countermeasures (drugs, devices, and biological products to treat, identify, and prevent the public health consequences of terrorism). Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal year 2004 through 2008. Funding to buy these security countermeasures would be provided to the Department of Homeland Security (DHS), but the Department of Health and Human Services (HHS) would be responsible for procuring and stockpiling the countermeasures.

Assuming appropriation of authorized amount and including administrative costs, CBO estimates that implementing H.R. 2122 would increase discretionary spending by $0.3 billion in 2004, $3.1 billion for fiscal years 2004 through 2008, and $5.6 billion over the 2004–2013 period. In addition, H.R. 2122 would relax certain requirements for federal agencies related to the development and approval of countermeasures. The bill would provide HHS with increased authority and flexibility to award contracts and grants for research and development of qualified countermeasures, hire technical experts, and procure items necessary for research. Those provisions might result in higher discretionary spending, but CBO does not have sufficient information to estimate their budgetary effect.

The bill also would authorize the Food and Drug Administration (FDA) to approve the use of certain security countermeasures during emergencies designated by the Secretary of HHS. CBO estimates this provision would have no budgetary effect.

H.R. 2122 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated Cost to the Federal Government: The estimated budgetary impact of H.R. 2122 is shown in the following table. The costs

of this legislation fall within budget function 550 (health). CBO assumes that H.R. 2112 would be enacted by October 1, 2003.

	By fiscal year, in millions of dollars—									
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CHANGES IN DISCRETIONARY SPENDING										
Project BioShield:										
Estimated Authorization Level	890	2,528	0	0	0	2,175	0	0	0	0
Estimated Outlays	270	680	870	770	510	440	560	650	490	250
Administrative Costs:										
Estimated Authorization Level	9	9	9	9	10	10	10	10	11	11
Estimated Outlays	7	8	9	9	10	10	10	10	11	11

Basis of estimate

CBO assumes that this bill will be enacted during fiscal year 2003 and will take effect in October 2003.

Procurement of security countermeasures: Project BioShield

Under current law, HHS administers the Strategic National Stockpile (SNS), which contains drugs, diagnostic devices, vaccines, and other biological products to combat the public health consequences of a terrorist attack or other public health emergencies. DHS currently provides the financing for those efforts, which include the procurement of a new smallpox vaccine and stockpiling of that vaccine and older versions of the vaccine. Authorization for those programs was established in the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (Public Law 107–88). That act authorized appropriations of $640 million in 2002 and such sums as may be necessary for fiscal years 2003 through 2006 for the SNS and $509 million in 2002 and such sums as may be necessary for fiscal years 2003 and 2006 for the development of the smallpox vaccine. About $400 million was appropriated in 2003 for those activities.

H.R. 2122 would modify the existing authorizations for the SNS and for the development of the smallpox vaccine by codifying the provision in the PHSA instead of in Public Law 107–88. CBO estimates that this modification would have no budgetary effect.

H.R. 2122 also would authorize DHS to augment the SNS with certain additional products. That effort, called Project BioShield, would allow the federal government to enter into contracts to procure security countermeasures, which are defined in the bill as drugs, devices, biological products, vaccines, vaccine adjuvants, antivirals, or diagnostic tests used to treat, identify, or prevent harm from an agent that the Secretary determines may cause a public health emergency affecting national security. Such drugs, devices, or biological products would have to be licensed or approved by the FDA, or otherwise determined by the Secretary of HHS to have the potential to be licensed or approval by the FDA. The federal government also could acquire products used to treat the adverse effects of drugs or biologic products used as security countermeasures.

The rate at which the funding authorized by the bill would be appropriated and spent would depend upon many factors, including the nature of advances in biotechnology, the degree of industry interest and capacity, the threat environment, and government prior-

ities. Assuming appropriation of the authorized amounts, current and future Administrations would have the discretion to enter into multiple contracts for the manufacture of security countermeasures or to cease contracting altogether for a period of years.

To estimate spending under H.R. 2122, CBO consulted with Administration officials about activities they are planning or would consider if Project BioShield were enacted. Officials described plans to acquire and maintain stockpiles of seven security countermeasures to combat five biological agents. The Administration estimates that the cost of procuring, storing, and replacing those countermeasures would be about $5.6 billion over the 2004–2013 period if there were no constraints on funding.

Those currently planned acquisitions do not include any countermeasures for chemical, radiological, or nuclear agents, and they address only a subset of the threats for which research and development activities on countermeasures is being conducted or funded by HHS, the Department of Defense (DoD), and the private sector. Based on information provided by government officials and in consultation with outside experts, CBO has concluded that it is likely that drugs, devices, or biological products addressing some of those other threats will be developed in the coming decade and that some of those countermeasures would be stockpiled under Project Bioshield if funds were appropriated for that purpose. CBO's estimate does not assume that any specific product would be developed and procured at any specific time. It does, however, account for a range of possibilities that would be available to the government if the authorized funds are appropriated.

Authorities and Requirements Under H.R. 2122. H.R. 2122 would authorize appropriations of up to $5.6 billion for fiscal years 2004 through 2013 for the federal government to enter into contracts to procure security countermeasures. Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal years 2004 through 2008.

Decisions regarding what types of security countermeasures to procure would be made by the President after reviewing recommendations of the Secretaries of DHS and HHS. Subject to Presidential approval and a determination that inclusion of certain countermeasures in the stockpile is appropriate, the Secretaries of DHS and HHS would seek potential vendors to produce the countermeasures and enter into contracts to buy the countermeasures from those vendors. In making that determination, the Secretary would determine and consider several factors, including the quantity of the product necessary for the stockpile, the feasibility of obtaining sufficient quantities of the product within five years, and whether there is a significant commercial market for the product other than as a security countermeasure. Those factors would not be requirements for procurement, but considerations in determining the appropriateness for inclusion of the countermeasure in the stockpile.

The Secretary of HHS would be responsible for arranging the procurement, including negotiating the quantity, price, and production schedule in five-year contracts or cooperative agreements, though eight-year contracts would be permitted for first awards. Payment would be conditioned on the delivery of a substantial portion of promised units. However, the Secretary could provide an ad-

vance payment of not to exceed 10 percent of the contract if the Secretary determines such payment is necessary to the project's success. The Secretary could pay vendors for storage, shipping, and handling and would be permitted to use noncompetitive procedures if the product is available only from a limited number of sources. Additional countermeasures for the same threat also could be procured, if they were to provide improved safety or effectiveness or otherwise enhance public health preparedness.

The authorized funds could not be used for the purchase of vaccines under contracts entered into prior to enactment, or for administrative costs. Based on information from Administration officials, CBO expects that funding would not be available specifically for research and development, although the price for the completed products would probably cover some development costs.

The Administration's Plans to Implement Project BioShield. Based on existing science and a current assessment of potential threats to public health, the Administration has identified several agents for which countermeasures are needed to protect the public health and could be included in Project BioShield. Those agents are smallpox, anthrax, botulinum toxin, plague, and Ebola. The Administration estimates that spending for countermeasures under Project BioShield, including purchase, storage, and replacement costs, would total about $5.6 billion over the 2004–2013 period, assuming the successful development of those countermeasures and no constraints on funding. More than half of those costs would be for the improved smallpox and anthrax vaccines. A brief description follows of the security countermeasures the Administration plans to acquire and stockpile.

Smallpox. Under Project BioShield, the Administration plans to procure a next-generation version of the smallpox vaccine called modified vaccinia Ankara (MVA). This new vaccine is an attenuated version of the existing vaccine and may be used to safely vaccinate about 30 million individuals with compromised immune systems, eczema, or certain other high-risk conditions. Under the authority provided for Project BioShield, HHS plans to purchase 60 million doses of the new vaccine at about $15 per dose over a three-year period for a cost of about $900 million. The Administration expects to be able to enter into contracts and begin acquiring the vaccine in 2004. Additional costs for inventory management and replacement of expired stocks over the 2007–2013 period would likely add another $1 billion, according to Administration estimates, but could be lower if long-term refrigerated storage proves to be effective.

Anthrax. The Administration also expects to purchase about 60 million doses of a next-generation anthrax vaccine, called a recombinant protective antigent (rPA) vaccine, under Project BioShield. The rPA vaccine would require fewer doses per person than the current vaccine, and potentially could be effective for people who have already been exposed to anthrax, giving the government the ability to vaccinate about 20 million people. The Administration anticipates beginning the procurement process in the next few years and spending about $700 million on the vaccine over a three-year period. Because the rPA anthrax vaccine has an expected shelf life of five to six years, additional costs would be incurred for inventory management and replacement. The Administration estimates that

costs for the rPA vaccine could total $1.4 billion over the 2004–2013 period.

Botulinum Toxin. Under current law, HHS has stockpiled some antitoxins to treat botulism, a paralytic and often fatal illness caused by a nerve toxin produced by the botulinum bacteria. However, those antitoxins are no longer manufactured, and the manufacturing process, which requires horse serum, is complicated and time intensive. After identifying a manufacturer, the Administration plans to spend about $800 million acquiring newly produced antitoxin at a cost of about $2,000 per dose as part of Project BioShield. Acquisition would be spread over a three-year period, beginning in the next few years. This antitoxin would require specialized storage and refrigeration.

In addition, the Administration has indicated that it would like to purchase both a vaccine that would protect against botulism and monoclonal antibodies to neutralize the effects of the toxin. (Monoclonal antibodies are engineered proteins that can neutralize and destroy certain pathogens and toxins.) The Administration anticipates buying vaccine and monoclonal antibodies by 2007 or 2008, at a cost of about $140 million for 750,000 doses of the vaccine and $750 million for monoclonal antibodies. The Administration estimates that spending for botulinum countermeasures, including the cost of storage and inventory management, would total $1.8 billion over the 2004–2013 period.

Plague. Plague is an infectious disease caused by a bacterium. Plague has several forms—pneumonic, bubonic, and septicemic—and can be treated by existing antibiotics. A vaccine for the plague is currently in the research and development phase, with the expectation that a product potentially could reach the advanced development phase next year. Beginning in 2005, the Administration expects to procure about 2 million doses (enough to treat people in areas surrounding any outbreak) at an estimated cost of about $40 per dose—for a total cost of about $80 million. With additional costs related to the acquisition of the vaccine, the Administration estimates spending on plague countermeasures would total about $220 million over the 2004–2013 period.

Ebola. There is no current treatment for Ebola, one of several viral hemorrhagic fevers, but the National Institutes of Health (NIH) is conducting research on a vaccine that the Administration would be interested in purchasing when it reaches an advanced development stage. Under current plans, the Administration intends to purchase enough vaccine for 3 million individuals to prevent the spread of an outbreak. Because this vaccine is still in the research and development phase, when the vaccine would become available and the potential cost per dose are unclear. The Administration assumes the vaccine will become available in 2005, and estimates the price to be about $30 per dose, for a total acquisition cost of $90 million. Combined with other costs related to the Ebola vaccine, including storage and replacement, the Administration anticipates spending would total about $260 million over the 2004–2013 period for this aspect of Project BioShield.

CBO's Estimate of the Potential Cost of Project BioShield. CBO has estimated both the cost of implementing the Administration's plan and the potential cost of acquiring other products not encompassed by that plan.

CBO's Estimate of the Administration's Plan. Without any funding constraints, CBO expects that the Administration's plans for MVA smallpox vaccine, the anthrax rPA vaccine, and the botulism antitoxins would likely take shape as described, albeit more slowly than the Administration estimates. CBO estimates that spending for vaccines and monoclonal antibodies for botulism and vaccines for plague and Ebola would likely be lower than the Administration estimates, even without funding constraints. CBO's lower estimate reflects the possibility that development of those vaccines and monoclonal antibodies might not succeed as quickly as the Administration's estimate assumes. It also reflects the possibility that Project BioShield would spend less on some of the botulism countermeasures if all three countermeasures (vaccine, antitoxins, and monoclonal antibodies) became available.

CBO estimates that about $5.2 billion would be required to procure products identified by the Administration over the 2004–2013 period.

Estimated Spending for Products Not Listed in the Administration's Plan. Under the bill, other countermeasures not in the Administration's plan could be purchased with appropriations provided through Project BioShield. Consequently, the specific security countermeasures that would be acquired under H.R. 2122 are likely to evolve over time as the result of many factors, including scientific advances, the interest and cooperation of biotech and other manufacturing companies, the emergence of new threats, and changes in this and future Administrations' assessments of which potential countermeasures should be a priority. Barriers to technological advance such as restricted laboratory space or shortage of primates for testing could slow development of countermeasures for certain agents. At the same time, rapid advances in products currently in the early-stage research and development could present the government with unforseen countermeasure options. Acquisition of countermeasures would also be affected by whether this and future Administrations decide to procure products that require more than five years to be licensed or have a significant commercial market.

Acquisitions under the bill might include additional countermeasures for agents addressed by the Administration's plan. For instance, potential emerging treatments include the use of monoclonal antibodies. This technology has had initial application in the treatment of cancer, and possibly could be applied to anthrax, the plague, or viral hemorrhagic fevers in the coming years. Other potential countermeasures include new antiviral drugs to treat smallpox and viral hemorrhagic fever (both biodefense research priorities for NIH) and a narrow-spectrum antibiotic for anthrax.

In addition, CBO's research indicates there are numerous other biological agents for which countermeasures ultimately could be purchased under Project BioShield. HHS has established three classes of biological agents that pose significant risks to national security and the public health. Category A agents pose the greatest risk due to their ease of transmission, mortality rates, and overall risk to the public. All of the agents included in the Administration's plan are considered Category A agents, but that initial plan does not address such Category A agents as tularemia, a bacterial infec-

tion affecting the respiratory system, and viral hemorrhagic fevers other than Ebola. Vaccines for both of those agents are biodefense research priorities of NIH. Further, the government might seek countermeasures for some Category B and C agents, including toxins such as ricin, certain bacteria such as brucellosis, and several forms of viral encephalitis.

Also, under the authority provided by the bill, the government could procure countermeasures against chemical agents (nerve, blister, blood, and pulmonary agents) and radiological and nuclear agents. The Administration currently does not plan to use the bill's authority to purchase agents that could mitigate threats from these sources, but it could do so if the perceived threat from these agents changed or if certain treatments became scientifically feasible. Countermeasures that could be acquired under Project BioShield include existing treatments for many nerve gases (including VX, Sarin, and Soman gas), Prussian Blue (a treatment for certain types of radiation poisoning), and hydroxycobalamin (a treatment for cyanide poisoning that is in an advanced stage of development).

Finally, under H.R. 2122, Project BioShield would be able to purchase devices to detect and diagnose pathogens and other agents. Costs for such devices are also not included in the Administration's estimate.

To estimate potential spending for additional countermeasures not mentioned in the Administration's plan, CBO identified several category A, B, and C biological agents and chemical and radiological agents for which countermeasures exist or are under development. The set of selected agents and countermeasures is not intended as a prediction of which countermeasures would be acquired by Project BioShield. Rather, it is intended to be representative of the countermeasures that would be eligible for acquisition if current research and development activities succeed in producing qualified countermeasures during the coming decade.

For each of the representative biological agents, CBO determined whether the countermeasure is likely to be a vaccine, an antitoxin or antiviral, or a monoclonal antibody, the dosage and method of delivery (intravenously or in pill form), and the amount necessary to treat the population that could potentially be affected. the estimate assumes that vaccines would cost $30 to $40 per dose, on average, with Project BioShield acquiring 500,000 to 2 million doses of qualified vaccines, depending on whether the agent is infectious. CBO estimates that monoclonal antibodies would cost $5,000 per treatment, and that Project BioShield would acquire enough to treat several hundred thousand people if qualified products became available. The estimate assumes that, if other types of qualified antivirals or antitoxins became available, Project BioShield would acquire enough to treat 500,000 people, at costs ranging from $2,000 to $5,000 per person for certain intravenously-administered forms. Other countermeasures could be less expensive on a per-person basis. For example, certain antivirals or narrow-spectrum antibiotics in pill form could cost about $100 per treatment, CBO estimates. Additionally, CBO estimates that per-person costs would average $50 for Prussian Blue, $100 for intravenous treatments for hydrogen cyanide, and $300 per treatment for countermeasures for certain radiological and nuclear agents. If Project BioShield acquired those types of countermeasures, CBO assumes that the

quantity procured would be sufficient to respond to simultaneous events in several large cities.

Under optimistic assumptions about when countermeasures for the representative agents would become available, the cost of acquiring, storing, and replacing all qualified countermeasures for those agents could total $10 billion to $20 billion during the 2004–2013 period. However, CBO assumes that research and development efforts for some countermeasures will proceed slowly or be unsuccessful, and that the Administration would not acquire all products that could be designated as security countermeasures.

Assuming appropriation of the authorized amount, CBO estimates that discretionary spending to acquire and store BioShield products would total $0.3 billion in 2004 and $5.5 billion over the 2004–2013 period. Acquisition costs would comprise 70 percent to 80 percent of that amount, while inventory management and replacement costs would make up the balance.

CBO also estimates that implementing Project BioShield would add to the administrative costs of HHS and DHS, both for the contracting process and managing the stockpile. Funding for those costs would come from appropriated funds. Based on current spending for program support services for bioterrorism-related activities (including the SNS) at the Centers for Disease Control and Prevention, CBO estimates that administrative costs would be about $10 million a year. Subject to the appropriation of necessary amounts, CBO estimates that discretionary spending for such costs would increase by $7 million in 2004 and $0.1 billion over the 2004–2013 period.

Research and development into qualified countermeasures

H.R. 2122 would authorize the Secretary of HHS to expedite procurement and peer review for research related to qualified countermeasures. The bill also would allow the Secretary to secure the services of experts or consultants with relevant expertise. Implementation of these measures could increase the resources required by the agency, accelerate spending, or both. CBO does not have sufficient information to estimate the additional resources that might be required by the agency or the rate at which spending might accelerate under the bill. Such spending would come from appropriated funds.

Authorization for medical products for use in emergencies

The FDA's regulatory process allows for expedited approval of security countermeasures under current law. Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the FDA may allow certain drugs, devices, and biologics defined as priority countermeasures to move more quickly through the agency's regulatory process. To further expedite the development of security countermeasures, the FDA has implemented a rule that allows approval of certain drugs based on tests in animals.

H.R. 2122 would allow the Secretary of HHS to authorize the FDA to approve the use of certain drugs or devices for use during designated as emergencies by the Secretary of HHS, DHS, or Defense. The authorization would remain in effect for no more than one year, unless the Secretary determines otherwise based on the

nature of the emergency. When the Secretary authorizes the emergency use of a product that is an unapproved use of an approved product, the bill would provide some flexibility to manufacturers in carrying out activities under the emergency use authorization.

Based on information from Administration officials, CBO expects that implementing this provision in H.R. 2122 would not increase costs to the FDA. Over the past year, the FDA has hired about 100 people to review drug applications and provide assistance to companies engaged in research and development into security countermeasures. Thus, the agency already has the infrastructure to handle the additional authority related to the proposed emergency-use authorization and would not require additional resources. Therefore, CBO estimates that this provision of H.R. 2122 would have no budgetary effect.

Previous CBO estimate: S. 15, the Project BioShield Act of 2003, as reported by the Senate Committee on Health, Education, Labor and Pensions on March 25, 2003, would amend the Public Health Service Act (PHSA) to create permanent, indefinite funding authority for the procurement of certain biomedical countermeasures. In its cost estimate dated May 7, 2003, CBO estimated that enacting S. 15 would increase direct spending by $270 million in 2004 and $8.1 billion over the 2004–2013 period.

Although both H.R. 2122 and S. 15 would authorize programs to procure countermeasures to protect the public health against terrorism, H.R. 2122 would not have an effect on direct spending; instead, the bill would authorize appropriations of up to $5.6 billion over the 2004–2013 period. Estimated spending under H.R. 2122 is less than under S. 15 because the House bill would authorize a set amount of appropriations, whereas the Senate bill would provide unlimited direct spending authority.

In several areas, H.R. 2122 would allow the Secretary more flexibility in terms of what products could be procured and how contracts would be structured. H.R. 2122 would allow the procurement of countermeasures even if they have a significant commercial application, while S. 15 would restrict the procurement authority to those without such application. While S. 15 would require the Secretary to determine that a countermeasure is likely to be approved by the FDA within five years as a condition of procurement, H.R. 2122 would require only that the Secretary consider whether a five-year limit is feasible. H.R. 2122 would provide additional flexibility in contracting by permitting the Secretary to extend first-time contracts to eight years (versus five in S. 15) and would allow the Secretary discretion to provide a 10 percent advance to companies developing new products. Those provisions would accelerate spending relative to S. 15.

Intergovernmental and private-sector impact: H.R. 2122 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Jeanne De Sa and Sam Papenfuss: impact on state, local, and tribal governments: Leo Lex; impact on the private sector: Samuel Kina.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the Act as the "Project BioShield Act of 2003."

Section 2. Biomedical countermeasure research and development authorities

Section 2(a) of the Project BioShield Act of 2003 amends the Public Health Service Act to add a new section 319F–1. The section grants the Secretary of Health and Human Services (HHS) additional flexibility and authority in conducting research and development with respect to biomedical countermeasures against biological, chemical, nuclear and radiological agents that may affect national security.

The Act defines the scope of the new authorities set forth in this section as applying to countermeasures against agents that "may cause a public health emergency affecting national security." In making a determination about whether a potential public health emergency could affect national security, the Secretary of HHS may consider all information deemed pertinent and appropriate, and nothing in this Act requires that such Secretary of HHS consult with other executive branch officials prior to making such a determination. The Committee expects that the Secretary of HHS will consider the threat of use of such agents by terrorists against the U.S. population to be a significant factor in making scope determinations under these provisions. However, the Committee also recognizes and encourages the Secretary of HHS to consider the emerging threats to public health and national security that may be caused by the spread of antibiotic resistant organisms or dangerous viruses that may spread rapidly and lack effective counter-

measures today. These threats may affect national security whether by terrorists or through natural conditions. The Secretary of HHS should consider such factors in determining whether to use these new authorities to promote research, development, and production of specific security countermeasures.

Indeed, antimicrobial-resistant infectious microbes are viable biological agents that could be used by both domestic and foreign terrorists to wreak havoc and injury upon U.S. citizens. In addition, the emergency of drug resistance in one organism may have the effect of limiting that drug's ability to treat other biological agents, as genetic material may be transferred naturally or purposefully from one infectious agent to another. Advancing the discovery of new antimicrobial drugs to treat resistant organisms, through Bioshield and other research and development initiatives, through Bioshield and other research and development initiatives, may well pay dividends for both national security and public health.

New subsection 319F–1(b) provides general authority. Proposed subparagraph 319F–1(a)(4) makes the facilities of entities that enter into a grant or cooperative agreement with the Secretary of HHS under this section available as needed to such Secretary of HHS to respond to public health emergencies affecting national security.

New subsection 319F–1(b) provides expedited authority for governmental procurements used to perform, administer, or support pressing research and development activities under this section, by (1) increasing the simplified acquisition threshold from $100,000 to $25 million; (2) authorizing the use of procedures providing for less than full and open competition when there are only a limited number of responsible sources and no other type of services will satisfy the Secretary of HHS needs; and (3) increasing the micropurchase threshold for such procurements to $15,000.

New subsection 319F–1(c) authorizes the Secretary of HHS to use expedited peer-review procedures in lieu of otherwise applicable peer-review procedures in the case of grants and contracts for biomedical countermeasure research and development activity, if such grants and contracts do not exceed $1,500,000 and are necessary to respond to pressing research needs.

New subsection 319F–1(d) provides additional flexibility to the Secretary of HHS with respect to the hiring of experts and consultants when necessary to respond to pressing qualified countermeasure research and development needs. Under paragraph 319F–1(d)(2), such experts and consultants are deemed to be employees of HHS for purposes of the Federal Torts Claims Act, which provides the exclusive remedy against such personnel for claims relating to the performance of covered duties.

New subsection 319F–1(e) provides streamlined personnel authority for the HHS Secretary to appoint up to 30 people to positions in the National Institutes of Health without regard to ordinary classification criteria, when necessary to respond to pressing qualified countermeasure research and development needs.

New subsection 391F–1(f) provides that actions by the Secretary of HHS under the section are committed to agency discretion.

Section 2(b) of the Project BioShield Act of 2003 amends section 481A of the Public Health Service act to add the Director of the National Institute of Allergy and Infectious Diseases to that sec-

tion, and thus provide to that Director certain authorities concerning modernization and construction of research facilities. Section 2(b) further authorizes such sums as may be necessary for such purposes.

Section 3. Biomedical countermeasures procurement

Section 3(a) of the Project BioShield Act of 2003 adds a new section 319F–2 to the Public Health Service Act. Several provisions of new section 319F–2 simply transfer existing provisions of law from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended by the Homeland Security Act of 2002. Proposed Subsection 319F–2(a) contains language from existing law establishing the Strategic National Stockpile. New section 319F–2(b) contains language from existing law concerning authorizing procurement of smallpox vaccine for the National Strategic Stockpile.

New section 319F–2(c) requires the Secretary of the Department of Homeland Security (DHS) to assess threats that may be posed by chemical, biological, radiological, and nuclear agents, and requires the HHS Secretary to assess the public health consequences of such agents and the availability and appropriateness of countermeasures for the threats identified. After these steps, the Secretaries jointly may determine and recommend to the President that funding for procurement of such a countermeasure for the nation's stockpile is appropriate from the special reserve funds established by this Act.

Under section 319F–2(c)(4), the Secretaries of HHS and DHS may recommend to the President a proposal to issue a call for the development of a security countermeasure. Such a call, at a minimum, includes a commitment from the Secretaries to make a recommendation for funding of such a countermeasure from the special reserve funds, if government specifications for the product are achieved. The Secretaries also may secure a Presidential approval for funding prior to, or without, conducting a call.

New section 319F–2(c)(4)(B) provides that the Secretaries should include in any call for proposals for countermeasure production information that may be necessary to encourage or facilitate research and development into such countermeasures. The Committee recognizes that an important factor companies will consider in determining whether to invest scarce research and development dollars into security countermeasures is whether and to what extent they may face liability relating to the development or production of such countermeasures. The Committee thus encourages the Secretaries to indicate in any call for proposals the potential availability of indemnification or liability protections under other laws.

Under section 319F–2(c)(7), if the President approves a recommendation for funding from the special reserve funds, DHS would then enter into an agreement with HHS under which HHS may procure the countermeasure for the stockpile using the DHS special reserve fund. Contracts under this paragraph are subject to certain conditions. The Secretary of HHS may use simplified acquisition procedures or procedures providing for less than full and open competition under certain circumstances. Certain determinations of the Secretary are committed to agency discretion.

The Committee recognizes that existing procurement authorities may allow for a single agreement that provides for research and development as well as production of a countermeasure or vaccine. Nothing in this Act shall limit the use of these existing authorities where a single agreement (including a contract, grant, cooperative agreement or other acquisition instrument) for research, development, and production of a countermeasure or vaccine is deemed appropriate by the contracting officer, including when a separate funding source is authorized and used for the research and development and it is different than the funding source authorized and used for production. The Committee recognizes that such agreements providing express linkage between research, development, and production may be necessary in order to encourage entities to enter the government market for countermeasures and vaccines in accordance with the authorities provided by Project Bioshield. Similarly, existing procurement authorities may allow the Secretaries to limit competition for a production contract under section 3 of this Act to those entities that successfully competed for research and development contracts under section 2 of this Act or other provisions of law. However, the Committee emphasizes that the monies obligated from the special reserve fund created under section 3 of this Act may not be use to pay for research or development activities, but only for procurement of countermeasures paid upon substantial delivery of product—consistent with the express limitation contained in the Homeland Security Act of 2002 excluding from the DHS Secretary's responsibilities the conduct or support of human health-related countermeasure research and development.

Section 319F–2(d) contains prohibitions on disclosure of information transferred from existing law. Section 319F–3(e) contains definitions transferred from existing law.

Section 319F–2(f) contains authorization of appropriations for the Strategic National Stockpile and smallpox vaccine development transferred from existing law with one addition. The new paragraph makes clear that such existing authorizations are in addition to amounts authorized under the special reserve fund. Nothing in the Act would restrict or alter the Secretaries' existing authority to purchase items for the stockpile using existing discretionary appropriations for such purpose.

Section 3(b) of the Project BioShield Act of 2003 adds a new section 510 to the Homeland Security Act of 2002. This new section authorizes appropriations for the special reserve fund referenced in the new section 319F–2(c) of the Public Health Service Act. The bill authorizes $890 million in FY 04 for such procurements, and aggregate amounts of $3.4 billion and $5.6 billion over the next five and ten fiscal years respectively. All amounts appropriated under this authorization would be available for obligation through the end of FY 2013.

The act defines the scope of the new authorities set forth in this section as applying to countermeasures against agents that the Secretary of HHS believes "may cause a public health emergency affecting national security," and about which the HHS and DHS Secretaries make certain additional findings. In making a determination about whether a potential public health emergency could affect national security, the Secretary of HHS may consider all in-

formation deemed pertinent and appropriate, and nothing in this Act requires that such Secretary of HHS consult with other executive branch officials prior to making such a determination. The Committee expects that both Secretaries will consider the threat of use of such agents by terrorists against the U.S. population to be a significant factor in making their respective scope determinations under these provisions. However, the Committee also recognizes and encourages the Secretaries to consider the emerging threats to public health and national security that may be caused by the spread of antibiotic resistant organisms or dangerous viruses that may spread rapidly and lack effective countermeasures today. These threats may affect national security whether by terrorists or through natural conditions. The Secretaries should consider such factors in determining whether to use these new authorities to promote research, development, and production of specific security countermeasures.

Section 4. Authorization for medical products for use in emergencies

Section 4 adds a new section 564 to the Federal Food, Drug, and Cosmetic Act. New section 564(a) allows the Secretary of Health and Human Services to authorize for introduction into interstate commerce unapproved drugs, devices, and biological products or unapproved uses of approved drugs, approved/cleared devices, and biological products intended for use in an actual or potential emergency during the effective period of a declaration.

New section 564(b) allows the Secretary of HHS to declare an emergency justifying an emergency use authorization based upon a determination by the Secretary of Homeland Security that there is a national emergency or the significant potential of one, or by a determination of the Secretary of Defense that there is a military emergency, or a significant potential of one. Such emergencies must involve a heightened risk of attack with biological, chemical, radiological, or nuclear agents. Similarly, an emergency use authorization can be based upon a determination of the Secretary of HHS that there is a public health emergency affecting national security and involving biological, chemical, radiological, or nuclear agents. In making a determination about whether a public health emergency under section 319 of the Public Health Service Act affects national security, the Secretary may consider all information he deems pertinent and appropriate, and nothing in this Act requires that the Secretary consult with other executive branch officials prior to making such a determination.

Under this section, any declaration of emergency will last for one year, unless the Secretary of HHS terminates it at an earlier time. The Secretary of HHS may renew a declaration. The Secretary of HHS must publish all declarations, determinations, and renewals in the Federal Register, and the Secretary must provide reasonable advanced notice that declarations are to be terminated under this section. The Committee intends that, after a declaration is terminated, final disposition of labeling or intrastate disposition of a product may occur. Further, the Committee believes that the Commissioner of the Food and Drug Administration may exercise enforcement discretion not to object to interstate shipment of an unapproved product for return to a manufacturer. A determination of what is a "reasonable" period for advanced notice of termination

should consider all factors, so in some cases notice immediately preceding termination may be reasonable, while in other circumstances it may not.

Section 564(c) details the criteria for issuance of an emergency use authorization. Under this new section, the Secretary of HHS, acting through the Commissioner, may issue an authorization upon concluding (1) that a biological, chemical, radiological, or nuclear agent or agents can cause a serious or life-threatening disease or condition; (2) that the drug, device or biological product may be effective in detecting, diagnosing, treating, or preventing such disease or condition (or a serious disease or condition caused by taking a product already approved, licensed or cleared by FDA for treating or preventing such disease or condition), and the benefits of the product outweigh risks; (3) that there is no adequate, approved, and available alternative to the product; and (4) other criteria the Secretary may by regulation specify. The Commissioner should consult with the Directors of the National Institutes of Health and the Centers for Disease Control and Prevention prior to issuing an authorization, but such consultation is limited by considerations of feasibility and appropriateness given the circumstances of the emergency.

Section 564(d) concerns the scope of an emergency use authorization. Under this section, the authorization shall state the disease or condition that the product may be used to detect, diagnose, prevent, or treat, as well as the Commissioner's conclusions about known benefits and risks of the product and conclusions concerning safety and potential effectiveness. The Committee intends that before issuing an authorization under this section, the Commissioner will, where feasible given the nature and the extent of the emergency, notify the holder of any relevant application under this chapter or under section 351 of the Public Health Service Act. The purpose of such notification is to allow for discussion of the conditions of this authorization as required by subsection (e), as well as discussion of whether such product should be delivered pursuant to section 319F–2(c) of the Public Health Service Act.

Section 564(e) pertains to products that have never been approved, licensed, or cleared by FDA. Under this subsection, conditions shall, to the extent feasible given the circumstances of the emergency, be applied to persons who choose to carry out an activity for which the authorization is issued. Such mandatory conditions include information to providers about the emergency use of the product as well as significant known potential risks and benefits, as well as appropriate conditions designed to ensure that to the maximum extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed of the emergency use of the product, risks and benefits of the product, and of the option to accept or refuse the product. Further, the Commissioner is given the authority to impose other conditions on those who carry out activities for which the authorization is issued. Such conditions imposed by the Commissioner should be designed to provide maximum flexibility to ensure that those who wish to take the product can indeed take the product, if made available by the manufacturer.

Section 564(e) also applies to unapproved uses of approved products and the Commissioner may, for manufacturers who choose to

carry out one or more activities pursuant to an emergency use authorization, apply certain conditions. This subsection makes clear that manufacturers do not have to avail themselves of the emergency use authorization for unapproved uses of approved products, and it makes clear that no individual may alter or obscure the labeling of already approved products. It does authorize, however, persons other than the manufacturer to provide information about the product concerning the emergency use of the product.

Under section 564(e), the Commissioner may establish conditions regarding product labeling and information conveyance concerning unapproved products. Further, the Committee intends that the Commissioner may establish conditions regarding product labeling and information conveyance on manufacturers that carry out one or more activities pursuant to an emergency use authorization with respect to the emergency use of that product that is an unapproved use of an approved product.

Subsection (f) makes clear that an emergency use authorization is effective until the declaration is terminated or revoked, but allows patients to continue using such products in certain instances. Nothing in this subsection is intended to require manufacturers or others to provide such products to patients.

Subsection (g) makes clear that the Commissioner shall periodically review the appropriations of an authorization, and it provides the Commissioner needed flexibility to revoke an authorization if the criteria justifying the authorization are no longer met.

Subsection (h) ensures that the Commissioner shall promptly publish in the Federal Register notices of all authorizations, terminations, and revocations, Subsection (i) makes clear that all determinations under this new section are committed to agency discretion. Subsection (j) is a rule of construction nothing that this new section does not impair or otherwise affect certain existing authorities.

New section 564(k) pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are informed of the option to accept or refuse administration of an emergency use product, upon certain findings (which are identical to the findings found in section 1107 of Title 10). Further, the subsection requires that if certain information is not provided to members of the Armed Forces prior to an emergency use product being administered to them, then information concerning the administration of the product shall be placed in the medical record of the member.

Subsection (l) makes clear that if a product is authorized for emergency use under this new section, the investigational sections of the Act shall not apply to the products.

Subsection (m) ensures that no authority in new section 564 can require a manufacturer of a drug, device, or biological product to perform any activity that becomes lawful pursuant to the new section. That is, the Commissioner in no way is goven the authority to, among other things, require a manufacturer to introduce into interstate commerce or deliver for introduction into interstate commerce any unapproved product or an approved product for an unapproved use under this section. Further, even if the Commissioner authorizes the emergency use of an already-approved, licensed or cleared product, a manufacturer can refuse to avail themselves of

such emergency use authorization and continue introducing into interstate commerce its approved or cleared product under the Federal Food, Drug and Cosmetic Act, or licensed product pursuant to the Public Health Service Act. The only obligation in subsection (m) is that if the Commissioner authorizes the emergency use of a sole-source unapproved product, then the manufacturer of such product must inform the Commissioner of its intention not to carry out any activity under the authorization within a reasonable period of time. Nothing in this section shall be construed as authorizing the Commissioner to establish conditions on the distribution, administration, or labeling of any other product in any other circumstance.

Subsection (n) ensures that the present enforcement regime of the Federal Food, Drug, and Cosmetic Act will apply to individuals who carry out an activity or activities pursuant to an authorization, but fail to comply with applicable conditions. If any person carries out an activity pursuant to section 564, but violates a condition imposed by the Commissioner, then that person will be subject to Chapter III of the Act, where the "prohibited acts" are found. If a person is found to be in violation of a prohibited act found in section 301, then the Committee intends for that person to be subject to the enforcement provisions found in sections 302, 303, and 304. A violation of any condition applied to an emergency use product in no way alters or affects the emergency use status of the underlying product.

The Committee intends that new section 564, as made clear in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act, the Secretary, through the Commissioner of Food and Drugs, shall be responsible for executing the Federal Food Drug, and Cosmetic Act as amended by the Project BioShield Act.

Section 5. Reports

Section 5(a) requires the Secretary of HHS to submit annual reports to Congress concerning the exercise of many of the new authorities under the Act. Section 5(b) requires a report from the National Academy of Sciences concerning whether and to what extent the research authorities granted under the Act have enhanced the development of biomedical countermeasures affecting national security. Section 5(c) requires the General Accounting Office to issue a report concerning the Secretary of HHS utilization of these new authorities.

COMMITTEE CORRESPONDENCE

COMMITTEE ON THE JUDICIARY,
Washington, DC, June 10, 2003.

Hon. BILLY TAUZIN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC

DEAR CHAIRMAN TAUZIN: In recognition of the desire to expedite floor consideration of H.R. 2122, the "Project BioShield Act of 2003," the Committee on the Judiciary hereby waives consideration of the bill. Section 2 of the bill creates a new section 319F–1 of the Public Health Service Act. New subsection 319F–1(d) gives the Secretary of Health and Human Services new authority to enter into personal services contracts with scientists and consultants for lim-

ited periods of time for the purposes of expedited research on countermeasures against biological weapons. New subsection 319F–1(d) further provides that scientists and consultants who receive contracts under this provision shall have the protections of the Federal Tort Claims Act as if they were regular federal employees. These FTCA provisions fall within the Committee on the Judiciary's Rule X jurisdiction. However, given the need to expedite this legislation, I will not seek a sequential referral based on their inclusion.

The Committee on the Judiciary takes this action with the understanding that the Committee's jurisdiction over these provisions is in no way diminished or altered. I would appreciate your including this letter in the Congressional Record during consideration of H.R. 2122 on the House floor.

Sincerely,

F. JAMES SENSENBRENNER, Jr.,
Chairman.

COMMITTEE ON ENERGY AND COMMERCE
Washington, DC, June 10, 2003.

Hon. F. JAMES SENSENBRENNER, Jr.,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR CHAIRMAN SENSENBRENNER: Thank you for your letter regarding H.R. 2122, the "Project BioShield Act of 2003." As you noted, new subsection 319F–1(d) of the Public Health Service Act as added by the bill contains provisions that fall within the Rule X jurisdiction of the Committee on the Judiciary.

I appreciate your willingness not to seek a referral on H.R. 2122. I agree that your decision to forego action on the bill will not prejudice the Committee on the Judiciary with respect to its jurisdictional prerogatives on this or similar legislation.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 2122 of the House floor.

Sincerely,

W.J. "BILLY" TAUZIN,
Chairman.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

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SEC. 319F–1. AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.

(a) IN GENERAL.—

(1) AUTHORITY.—In conducting and supporting research and development activities regarding biomedical countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section if the activities concern qualified countermeasures.

(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term "qualified countermeasure" means a priority countermeasure (as defined in section 319F(h)) that affects national security.

(3) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any grant or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, and supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(b) EXPEDITED PROCUREMENT AUTHORITY.—

(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR BIOMEDICAL COUNTERMEASURE PROCUREMENTS.—

(A) IN GENERAL.—For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(ii) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

(i) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(ii) Subsections (a) and (b) of Section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(iii) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the —— examination of contractor records).

(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph.

(2) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures when—

(A) the procurement is as described by paragraph (1); and

(B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of responsible sources, and no other type of property or services will satisfy the Secretary's needs.

(3) INCREASED MICROPURCHASE THRESHOLD.—

(A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

(B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than $2,500.

(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures

that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—

(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

(B) the amount of which is not greater than $1,500,000.

(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.

(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

(1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.

(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the person, officer, employee, or governing board member.

(3) INTERNAL CONTROLS TO BE INSTITUTED.—

(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be

final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

(4) NUMBER OF PERSONAL SERVICES CONTRACTS LIMITED.—The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

(e) STREAMLINED PERSONNEL AUTHORITY.—

(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to such provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

(2) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for appointments under this subsection.

(f) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions by the Secretary under the authority of this section are committed to agency discretion.

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), in coordination with the Secretary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a);

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

(F) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN BIOMEDICAL COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a priority countermeasure (as defined in section 319F(h))—

(i) that affects national security;

(ii) that is determined under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(iii)(I) that is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act, for use as a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii); or

(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5).

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences of use against the United States population of agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents for which priority countermeasures are necessary to protect the public health from a material threat.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(4) CALL FOR SECURITY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a security countermeasure would be appropriate, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such security countermeasure; and

(ii) make a commitment that, upon the first development of such security countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such security countermeasure.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the security countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) a commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consulta-

tion with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the needs of the stockpile.

(ii) The feasibility of production and delivery within five years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (2), (3), and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The special reserve fund under paragraph (10) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall notify the Congress of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the identification of the potential supplier or suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological,

chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) PROCUREMENT.—

(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) INTERAGENCY AGREEMENTS.—

(i) FOR PROCUREMENT.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for the Secretary's costs of such procurement, other than as provided in clause (ii).

(ii) FOR ADMINISTRATIVE COSTS.—The agreement entered into between the Homeland Security Secretary and the Secretary for managing the stockpile under subsection (a) shall provide for reimbursement of the Secretary's administrative costs relating to procurements under this subsection.

(C) PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this subparagraph; and

(II) promulgating regulations to implement clauses (v), (vi), and (vii), and any other provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to

exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform under the contract, except in special circumstances as determined by the Secretary on a contract by contract basis.

(II) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(III) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—The amount of any procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of Section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the —— examination of contractor records).

(iv) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures for a procurement under this subsection if the product is available from only one responsible source or only from a limited number of responsible sources, and no other type of product will satisfy the Secretary's needs.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative under-

takings with other agencies of the United States Government.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2003; or

(B) administrative costs.

(10) SPECIAL RESERVE FUND.—For purposes of this subsection, the term "special reserve fund" has the meaning given such term in section 510 of the Homeland Security Act of 2002.

(d) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Homeland Security Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund under subsection (c)(10).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART E—OTHER AGENCIES OF NIH

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SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or con-

struct new research facilities, subject to the provisions of this section.

* * * * * * *

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) * * *

* * * * * * *

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated under ⟦subsection (i)⟧ *subsection (i)(1)* for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over $50,000,000, the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) * * *

* * * * * * *

(d) REQUIREMENT OF APPLICATION.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, except that such amount shall not exceed—

(A) 50 percent *(or, in the case of the Institute, 75 percent)* of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent *(or, in the case of the Institute, 75 percent)* of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amend-

ment of the application or on the revision of the estimated cost of construction of the facility.

* * * * * * *

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director *of the Center or the Director of the National Institute of Allergy and Infectious Diseases* for applicants meeting the conditions described in subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) *in the case of an award by the Director of the Center,* the applicant or other owner of the facility shall cease to be a public or non profit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director *of the Center or the Director of the National Institute of Allergy and Infectious Diseases* determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

* * * * * * *

(i) AUTHORIZATION OF [APPROPRIATIONS.—For the purpose of carrying out this section,] *APPROPRIATIONS.—*

(1) CENTER.—For the purpose of carrying out this section with respect to the Center, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for fiscal year 2003.

SECTION 510 OF THE HOMELAND SECURITY ACT OF 2002

SEC. 510. PROCUREMENT OF SECURITY COUNTERMEASURES FOR STRATEGIC NATIONAL STOCKPILE.

(a) AUTHORIZATION OF APPROPRIATIONS.—For procurement of security countermeasures under section 319F–2(c) of the Public Health Service Act (referred to in this section as the "security countermeasures program"), there is authorized to be appropriated up to $5,593,000,000 for the fiscal years 2004 through 2013. Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term "special reserve fund" means the appropriations account established as a result of any appropriations made under subsection (a).

(c) AVAILABILITY.—

(1) DURATION OF AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013, provided that any portion of such amount that remains unobligated for such purposes on the expiration of such term shall be returned to the United States Treasury and shall not be available for subsequent obligation for any purpose.

(2) INITIAL AVAILABILITY FOR PARTICULAR PROCUREMENTS.—Amounts appropriated under subsection (a) become available for a procurement under the security countermeasures program only upon the approval by the President of such availability for the procurement in accordance with paragraph (6)(B) of such program.

SECTION 121 OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

[SEC. 121. STRATEGIC NATIONAL STOCKPILE.

[(a) STRATEGIC NATIONAL STOCKPILE.—

[(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

[(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

[(A) consult with the working group under section 319F(a) of the Public Health Service Act;

[(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

[(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

[(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

[(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

[(F) ensure the adequate physical security of the stockpile.

[(b) SMALLPOX VACCINE DEVELOPMENT.—

[(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States.

[(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

[(c) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

[(d) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

[(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

[(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary supplies described in subsection (a).

[(e) AUTHORIZATION OF APPROPRIATIONS.—

[(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

[(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.]

SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—

(1) EMERGENCY USES.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug or device intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an "unapproved product"); or

(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

(4) DEFINITIONS.—For purposes of this section:

(A) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(B) The term "product" means a drug or device.

(C) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

(D) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) DECLARATION OF EMERGENCY.—

(1) IN GENERAL.—The Secretary may declare an emergency justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a national emergency, or a significant potential for a national emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; or

(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

(2) TERMINATION OF DECLARATION.—

(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

(3) ADVANCE NOTICE OF TERMINATION.—In terminating a declaration under this section, the Secretary shall provide advance notice that the declaration will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of shipments of the product, including the return of such shipments to the manufacturer (in the case of a manufacturer that chooses to have the shipments returned); and

(B) in the case of unapproved uses of approved products, a sufficient period for the disposition of any labeling that was provided with respect to the emergency use involved.

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, and renewal under this subsection.

(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, the Secretary concludes—

(1) that an agent specified in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in detecting, diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for detecting, diagnosing, preventing, or treating such disease or condition; and

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) SCOPE OF AUTHORIZATION.—

(1) IN GENERAL.—An authorization of a product under this section shall state—

(A) each disease or condition that the product may be used to detect, diagnose, prevent, or treat within the scope of the authorization;

(B) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

(C) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the

product in detecting, diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.

(2) CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, shall, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, may, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this

section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) For persons other than manufacturers of the product, appropriate conditions concerning record-keeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(iv) With respect to the emergency use of the product, waive or limit, to the extent appropriate given the circumstances of the emergency, conditions regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established in section 501.

(2) UNAPPROVED USE.—With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) The Secretary may, for manufacturers of the product who choose to carry out one or more activities for which the authorization is issued, establish any of the conditions described in clauses (i) through (iv) of paragraph (1)(A).

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer.

(ii) In the circumstances described in clause (i), an authorization under this section regarding the emergency use may, for persons who do not manufacture the product and who choose to act under this clause, authorize such persons to provide information on the product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). Such additional information shall not be considered labeling for purposes of section 502.

(f) DURATION OF AUTHORIZATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—An authorization shall continue to be effective for continued use with respect to patients to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patients' attending physicians.

(g) REVOCATION OF AUTHORIZATION.—

(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section.

(2) REVOCATION.—The Secretary may revoke an authorization under this section if, in the Secretary's unreviewable discretion, the criteria under subsection (c) for issuance of such authorization are no longer met.

(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons therefor, under this section.

(i) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to impair or otherwise affect—

(1) the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution;

(2) the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law; or

(3) the authority of the Secretary under section 319F–2 to manage the stockpile under such section.

(k) APPLICATION TO MEMBERS OF ARMED FORCES.—

(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived by the President if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

(2) PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

(3) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(l) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization —

(1) shall not be subject to any requirements pursuant to section 505(i) or 520(g); and

(2) shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this Act.

(m) DISCRETION REGARDING USE OF AUTHORIZATION.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall notify the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out an activity or activities under the authorization. This section does not have any legal effect on a person who does not carry out any activity for which an authorization under this section is issued, or who carries out such an activity pursuant to other provisions of this Act or section 351 of the Public Health Service Act.

(n) ENFORCEMENT.—A person who carries out an activity pursuant to an authorization under this section, but who fails to comply with applicable conditions under subsection (e), is with respect to that act of noncompliance subject to the provisions of law specified in subsection (a) and to the enforcement of such provisions under section 301.

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medical countermeasures; to authorize the appropriation of funding for the procurement of security countermeasures through the creation of a special reserve fund; and to authorize the emergency use of unapproved drugs, devices, and biologics and the emergency unapproved use of approved drugs, devices, and biologics.

BACKGROUND AND NEED FOR LEGISLATION

During times of nation, military, or public health emergency, the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents. Unfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents. Currently, companies have little incentive to research, develop, or produce vaccines or other drugs simply for a possible one-time purchase by the Federal government for the Strategic National Stockpile. Most current private sector research and development dollars go for drugs or devices that will have continuous commercial application. In addition, some of the current generation of drugs or devices may have special uses as countermeasures to biological agents like Ebola, but there is little incentive to perform the research or development or production activities that might tailor the drug or drug approvals for such a purpose.

Even if a product has been developed to treat such diseases or conditions, if the product has not yet been approved by the Food and Drug Administration (FDA), access to the therapy is greatly limited. Nothing in the Food and Drug Act allows the Secretary to suspend the approval requirements to ensure access to unapproved drugs and devices on a large-scale basis in times of emergency.

Under present law, if a product is not approved by the FDA, then it is unlawful to provide that product to an individual, unless the product has been authorized for distribution under an investigational new drug (IND) application (for a drug and biologic) or an investigational device exemption (IDE). When a drug or device is available under such procedures, a number of conditions apply that make the use of an IND or IDE infeasible in times of national emergency, where drugs and devices may need to be deployed at rapid rates. Even if a drug, biologic, or device is highly promising in treating a disease or condition associated with biological chemical radiological or nuclear agents, and even if it is the only therapy available, current FDA law does not allow for rapid deployment of the product.

The Project Bioshield Act is designed to help resolve these problems and make our nation more secure. Like the Public Health Security and Bioterrorism Preparedness and Response Act, the project Bioshield Act is designed to help the administration and the nation in public health emergency preparedness, but relies on the ingenuity and hard work of Americans in the private and public sector to achieve these goals.

HEARINGS

The Subcommittee on Health held a joint hearing with the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security on "Furthering Public Health Security: Project Bioshield" on March 27, 2003. The Subcommittee re-

ceived testimony from: The Honorable Tommy Thompson, Secretary, U.S. Department of Health and Human Services; Mr. Leighton Read M.D., General Partner, Alloy Ventures, on behalf of Biotechnology Industry Organization; Mr. Michael Friedman M.D., Chief Medical Officer for Biomedical Preparedness, PhRMA; Mr. James Baker Jr., Ruth Dow Doan Professor, Center for Biological Nanotechnology; and, Mr. Gary Noble M.D., Vice President of Medical and Public Affairs, Johnson & Johnson, on behalf of AdvaMed.

COMMITTEE CONSIDERATION

On Thursday, May 15, 2003, the Full Committee met in open markup session and ordered a Committee Print reported to the House, as amended, by voice vote. A request by Mr. Tauzin to allow a report to be filed on a bill to be introduced by Mr. Tauzin, and that the actions of the Committee be deemed as actions on that bill, was agreed to by unanimous consent.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering the Committee Print reported. A motion by Mr. Tauzin to order the Committee Print reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has held oversight hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of the Project BioShield Act of 2003 is to provide the Secretary of Health and Human Services with greater authority and flexibility to facilitate the research and development of biomedical countermeasures.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2212, the Project Bioshield Act of 2003, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by

the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2003.

Hon. W. J. "BILLY" TAUZIN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2122, the Project BioShield Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Jeanne De Sa and Sam Papenfuss.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 2122—Project BioShield Act of 2003

Summary: H.R. 2122 would amend the Public Health Service Act (PHSA) to authorize appropriations of up to $5.6 billion for fiscal year 2004 through 2013 for procurement of certain security countermeasures (drugs, devices, and biological products to treat, identify, and prevent the public health consequences of terrorism). Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal year 2004 through 2008. Funding to buy these security countermeasures would be provide to the Department of Homeland Security (DHS), but the Department of Health and Human Services (HHS) would be responsible for procuring and stockpiling the countermeasures.

Assuming appropriation of authorized amount and including administrative costs, CBO estimates that implementing H.R. 2122 would increase discretionary spending by $0.3 billion in 2004, $3.1 billion for fiscal years 2004 through 2008, and $5.6 billion over the 2004–2013 period. In addition, H.R. 2122 would relax certain requirements for federal agencies related to the development and approval of countermeasures. The bill would provide HHS with increased authority and flexibility to award contracts and grants for research and development of qualified countermeasures, hire technical experts, and procure items necessary for research. Those provisions might result in higher discretionary spending, but CBO does not have sufficient information to estimate their budgetary effect.

The bill also authorize the Food and Drug Administration (FDA) to approve the use of certain security countermeasures during emergencies designated by the Secretary of HHS. CBO estimates this provision would have no budgetary effect.

H.R. 2122 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated Cost to the Federal Government: The estimated budgetary impact of H.R. 2112 is shown in the following table. The costs

of this legislation fall within budget function 550 (health). CBO assumes that H.R. 2122 would be enacted by October 1, 2003.

	By fiscal year, in millions of dollars—									
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CHANGES IN DISCRETIONARY SPENDING										
Project BioShield:										
Estimated Authorization Level	890	2,528	0	0	0	2,175	0	0	0	0
Estimated Outlays	270	680	870	770	510	440	560	650	490	250
Administrative Costs:										
Estimated Authorization Level	9	9	9	9	10	10	10	10	11	11
Estimated Outlays	7	8	9	9	10	10	10	10	11	11

Basis of estimate

CBO assumes that this bill will be enacted during fiscal year 2003 and will take effect in October 2003.

Procurement of security countermeasures: Project BioShield

Under current law, HHS administers the Strategic National Stockpile (SNS), which contains drugs, diagnostic devices, vaccines, and other biological products to combat the public health consequences of a terrorist attack or other public health emergencies. DHS currently provides the financing for those efforts, which include the procurement of a new smallpox vaccine and stockpiling of that vaccine and older versions of the vaccine. Authorization for those programs was established in the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (Public Law 107–88). That act authorized appropriations of $640 million in 2002 and such sums as may be necessary for fiscal years 2003 through 2006 for the SNS and $509 million in 2002 and such sums as may be necessary for fiscal years 2003 and 2006 for the development of the smallpox vaccine. About $400 million was appropriated in 2003 for those activities.

H.R. 2122 would modify the existing authorizations for the SNS and for the development of the smallpox vaccine by codifying the provision in the PHSA instead of in Public Law 107–88. CBO estimates that this modification would have no budgetary effect.

H.R. 2122 also would authorize DHS to augment the SNS with certain additional products. That effort, called Project BioShield, would allow the federal government to enter into contracts to procure security countermeasures, which are defined in the bill as drugs, devices, biological products, vaccines, vaccine adjuvants, antivirals, or diagnostic tests used to treat, identify, or prevent harm from an agent that the Secretary determines may cause a public health emergency affecting national security. Such drugs, devices, or biological products would have to be licensed or approved by the FDA, or otherwise determined by the Secretary of HHS to have the potential to be licensed or approval by the FDA. The federal government also could acquire products used to treat the adverse effects of drugs or biologic products used as security countermeasures.

The rate at which the funding authorized by the bill would be appropriated and spent would depend upon many factors, including the nature of advances in biotechnology, the degree of industry interest and capacity, the threat environment, and government prior-

ities. Assuming appropriation of the authorized amounts, current and future Administrations would have the discretion to enter into multiple contracts for the manufacture of security countermeasures or to cease contracting altogether for a period of years.

To estimate spending under H.R. 2122, CBO consulted with Administration officials about activities they are planning or would consider if Project BioShield were enacted. Officials described plans to acquire and maintain stockpiles of seven security countermeasures to combat five biological agents. The Administration estimates that the cost of procuring, storing, and replacing those countermeasures would be about $5.6 billion over the 2004–2013 period if there were no constraints on funding.

Those currently planned acquisitions do not include any countermeasures for chemical, radiological, or nuclear agents, and they address only a subset of the threats for which research and development activities on countermeasures is being conducted or funded by HHS, the Department of Defense (DoD), and the private sector. Based on information provided by government officials and in consultation with outside experts, CBO has concluded that it is likely that drugs, devices, or biological products addressing some of those other threats will be developed in the coming decade and that some of those countermeasures would be stockpiled under Project Bioshield if funds were appropriated for that purpose. CBO's estimate does not assume that any specific product would be developed and procured at any specific time. It does, however, account for a range of possibilities that would be available to the government if the authorized funds are appropriated.

Authorities and Requirements Under H.R. 2122. H.R. 2122 would authorize appropriations of up to $5.6 billion for fiscal years 2004 through 2013 for the federal government to enter into contracts to procure security countermeasures. Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal years 2004 through 2008.

Decisions regarding what types of security countermeasures to procure would be made by the President after reviewing recommendations of the Secretaries of DHS and HHS. Subject to Presidential approval and a determination that inclusion of certain countermeasures in the stockpile is appropriate, the Secretaries of DHS and HHS would seek potential vendors to produce the countermeasures and enter into contracts to buy the countermeasures from those vendors. In making that determination, the Secretary would determine and consider several factors, including the quantity of the product necessary for the stockpile, the feasibility of obtaining sufficient quantities of the product within five years, and whether there is a significant commercial market for the product other than as a security countermeasure. Those factors would not be requirements for procurement, but considerations in determining the appropriateness for inclusion of the countermeasure in the stockpile.

The Secretary of HHS would be responsible for arranging the procurement, including negotiating the quantity, price, and production schedule in five-year contracts or cooperative agreements, though eight-year contracts would be permitted for first awards. Payment would be conditioned on the delivery of a substantial portion of promised units. However, the Secretary could provide an ad-

vance payment of not to exceed 10 percent of the contract if the Secretary determines such payment is necessary to the project's success. The Secretary could pay vendors for storage, shipping, and handling and would be permitted to use noncompetitive procedures if the product is available only from a limited number of sources. Additional countermeasures for the same threat also could be procured, if they were to provide improved safety or effectiveness or otherwise enhance public health preparedness.

The authorized funds could not be used for the purchase of vaccines under contracts entered into prior to enactment, or for administrative costs. Based on information from Administration officials, CBO expects that funding would not be available specifically for research and development, although the price for the completed products would probably cover some development costs.

The Administration's Plans to Implement Project BioShield. Based on existing science and a current assessment of potential threats to public health, the Administration has identified several agents for which countermeasures are needed to protect the public health and could be included in Project BioShield. Those agents are smallpox, anthrax, botulinum toxin, plague, and Ebola. The Administration estimates that spending for countermeasures under Project BioShield, including purchase, storage, and replacement costs, would total about $5.6 billion over the 2004–2013 period, assuming the successful development of those countermeasures and no constraints on funding. More than half of those costs would be for the improved smallpox and anthrax vaccines. A brief description follows of the security countermeasures the Administration plans to acquire and stockpile.

Smallpox. Under Project BioShield, the Administration plans to procure a next-generation version of the smallpox vaccine called modified vaccinia Ankara (MVA). This new vaccine is an attenuated version of the existing vaccine and may be used to safely vaccinate about 30 million individuals with compromised immune systems, eczema, or certain other high-risk conditions. Under the authority provided for Project BioSheild, HHS plans to purchase 60 million doses of the new vaccine at about $15 per dose over a three-year period for a cost of about $900 million. The Administration expects to be able to enter into contracts and begin acquiring the vaccine in 2004. Additional costs for inventory management and replacement of expired stocks over the 2007–2013 period would likely add another $1 billion, according to Administration estimates, but could be lower if long-term refrigerated storage proves to be effective.

Anthrax. The Administration also expects to purchase about 60 million doses of a next-generation anthrax vaccine, called a recombinant protective antigent (rPA) vaccine, under Project BioSheild. The rPA vaccine would require fewer doses per person than the current vaccine, and potentially could be effective for people who have already been exposed to anthrax, giving the government the ability to vaccinate about 20 million people. The Administration anticipates beginning the procurement process in the next few years and spending about $700 million on the vaccine over a three-year period. Because the rPA anthrax vaccine has an expected shelf life of five to six years, additional costs would be incurred for inventory management and replacement. The Administration estimates that

costs for the rPA vaccine could total $1.4 billion over the 2004–2013 period.

Botulinum Toxin. Under current law, HHS has stockpiled some antitoxins to treat botulism, a paralytic and often fatal illness caused by a nerve toxin produced by the botulinum bacteria. However, those antitoxins are no longer manufactured, and the manufacturing process, which requires horse serum, is complicated and time intensive. After identifying a manufacturer, the Administration plans to spend about $800 million acquiring newly produced antitoxin at a cost of about $2,000 per dose as part of Project BioSheild. Acquisition would be spread over a three-year period, beginning in the next few years. This antitoxin would require specialized storage and refrigeration.

In addition, the Administration has indicated that it would like to purchase both a vaccine that would protect against botulism and monoclonal antibodies to neutralize the effects of the toxin (Monoclonal antibodies are engineered proteins that can neutralize and destroy certain pathogens and toxins.) The Administration anticipates buying vaccine and monoclonal antibodies by 2007 or 2008, at a cost of about $140 million for 750,000 doses of the vaccine and $750 million for monoclonal antibodies. The Administration estimates that spending for botulinum countermeasures, including the cost of storage and inventory management, would total $1.8 billion over the 2004–2013 period.

Plague. Plague is an infectious disease caused by a bacterium. Plague has several forms—pneumonic, bubonic, and septicemic—and can be treated by existing antibiotics. A vaccine for the plague is currently in the research and development phase, with the expectation that a product potentially could reach the advanced development phase next year. Beginning in 2005, the Administration expects to procure about 2 million doses (enough to treat people in areas surrounding any outbreak) at an estimated cost of about $40 per dose—for a total cost of about $80 million. With additional costs related to the acquisition of the vaccine, the Administration estimates spending on plague countermeasures would total about $220 million over the 2004–2013 period.

Ebola. There is no current treatment for Ebola, one of several viral hemorrhagic fevers, but the National Institutes of Health (NIH) is conducting research on a vaccine that the Administration would be interested in purchasing when it reaches an advanced development stage. Under current plans, the Administration intends to purchase enough vaccine for 3 million individuals to prevent the spread of an outbreak. Because this vaccine is still in the research and development phase, when the vaccine would become available and the potential cost per dose are unclear. The Administration assumes the vaccine will become available in 2005, and estimates the price to be about $30 per dose, for a total acquisition cost of $90 million. Combined with other costs related to the Ebola vaccine, including storage and replacement, the Administration anticipates spending would total about $260 million over the 2004–2013 period for this aspect of Project BioShield.

CBO's Estimate of the Potential Cost of Project BioShield. CBO has estimated both the cost of implementing the Administration's plan and the potential cost of acquiring other products not encompassed by that plan.

CBO's Estimate of the Administration's Plan. Without any funding constraints, CBO expects that the Administration's plans for MVA smallpox vaccine, the anthrax rPA vaccine, and the botulism antitoxins would likely take shape as described, albeit more slowly than the Administration estimates. CBO estimates that spending for vaccines and monoclonal antibodies for botulism and vaccines for plague and Ebola would likely be lower than the Administration estimates, even without funding constraints. CBO's lower estimate reflects the possibility that development of those vaccines and monoclonal antibodies might not succeed as quickly as the Administration's estimate assumes. It also reflects the possibility that Project BioShield would spend less on some of the botulism countermeasures if all three countermeasures (vaccine, antitoxins, and monoclonal antibodies) became available.

CBO estimates that about $5.2 billion would be required to procure products identified by the Administration over the 2004–2013 period.

Estimated Spending for Products Not Listed in the Administration's Plan. Under the bill, other countermeasures not in the Administration's plan could be purchased with appropriations provided through Project BioShield. Consequently, the specific security countermeasures that would be acquired under H.R. 2122 are likely to evolve over time as the result of many factors, including scientific advances, the interest and cooperation of biotech and other manufacturing companies, the emergence of new threats, and changes in this and future Administrations' assessments of which potential countermeasures should be a priority. Barriers to technological advance such as restricted laboratory space or shortage of primates for testing could slow development of countermeasures for certain agents. At the same time, rapid advances in products currently in the early-stage research and development could present the government with unforseen countermeasure options. Acquisition of countermeasures would also be affected by whether this and future Administrations decide to procure products that require more than five years to be licensed or have a significant commercial market.

Acquisitions under the bill might include additional countermeasures for agents addressed by the Administration's plan. For instance, potential emerging treatments include the use of monoclonal antibodies. This technology has had initial application in the treatment of cancer, and possibly could be applied to anthrax, the plague, or viral hemorrhagic fevers in the coming years. Other potential countermeasures include new antiviral drugs to treat smallpox and viral hemorrhagic fever (both biodefense research priorities for NIH) and a narrow-spectrum antibiotic for anthrax.

In addition, CBO's research indicates there are numerous other biological agents for which countermeasures ultimately could be purchased under Project BioShield. HHS has established three classes of biological agents that pose significant risks to national security and the public health. Category A agents pose the greatest risk due to their ease of transmission, mortality rates, and overall risk to the public. All of the agents included in the Administration's plan are considered Category A agents, but that initial plan does not address such Category A agents as tularemia, a bacterial infec-

tion affecting the respiratory system, and viral hemorrhagic fevers other than Ebola. Vaccines for both of those agents are biodefense research priorities of NIH. Further, the government might seek countermeasures for some Category B and C agents, including toxins such as ricin, certain bacteria such as brucellosis, and several forms of viral encephalitis.

Also, under the authority provided by the bill, the government could procure countermeasures against chemical agents (nerve, blister, blood, and pulmonary agents) and radiological and nuclear agents. The Administration currently does not plan to use the bill's authority to purchase agents that could mitigate threats from these sources, but it could do so if the perceived threat from these agents changed or if certain treatments became scientifically feasible. Countermeasures that could be acquired under Project BioShield include existing treatments for many nerve gases (including VX, Sarin, and Soman gas), Prussian Blue (a treatment for certain types of radiation poisoning), and hydroxycobalamin (a treatment for cyanide poisoning that is in an advanced stage of development).

Finally, under H.R. 2122, Project BioShield would be able to purchase devices to detect and diagnose pathogens and other agents. Costs for such devices are also not included in the Administration's estimate.

To estimate potential spending for additional countermeasures not mentioned in the Administration's plan, CBO identified several category A, B, and C biological agents and chemical and radiological agents for which countermeasures exist or are under development. The set of selected agents and countermeasures is not intended as a prediction of which countermeasures would be acquired by Project BioShield. Rather, it is intended to be representative of the countermeasures that would be eligible for acquisition if current research and development activities succeed in producing qualified countermeasures during the coming decade.

For each of the representative biological agents, CBO determined whether the countermeasure is likely to be a vaccine, an antitoxin or antiviral, or a monoclonal antibody, the dosage and method of delivery (intravenously or in pill form), and the amount necessary to treat the population that could potentially be affected. the estimate assumes that vaccines would cost $30 to $40 per dose, on average, with Project BioShield acquiring 500,000 to 2 million doses of qualified vaccines, depending on whether the agent is infectious. CBO estimates that monoclonal antibodies would cost $5,000 per treatment, and that Project BioShield would acquire enough to treat several hundred thousand people if qualified products became available. The estimate assumes that, if other types of qualified antivirals or antitoxins became available, Project BioShield would acquire enough to treat 500,000 people, at costs ranging from $2,000 to $5,000 per person for certain intravenously-administered forms. Other countermeasures could be less expensive on a per-person basis. For example, certain antivirals or narrow-spectrum antibiotics in pill form could cost about $100 per treatment, CBO estimates. Additionally, CBO estimates that per-person costs would average $50 for Prussian Blue, $100 for intravenous treatments for hydrogen cyanide, and $300 per treatment for countermeasures for certain radiological and nuclear agents. If Project BioShield acquired those types of countermeasures, CBO assumes that the

quantity procured would be sufficient to respond to simultaneous events in several large cities.

Under optimistic assumptions about when countermeasures for the representative agents would become available, the cost of acquiring, storing, and replacing all qualified countermeasures for those agents could total $10 billion to $20 billion during the 2004–2013 period. However, CBO assumes that research and development efforts for some countermeasures will proceed slowly or be unsuccessful, and that the Administration would not acquire all products that could be designated as security countermeasures.

Assuming appropriation of the authorized amount, CBO estimates that discretionary spending to acquire and store BioShield products would total $0.3 billion in 2004 and $5.5 billion over the 2004–2013 period. Acquisition costs would comprise 70 percent to 80 percent of that amount, while inventory management and replacement costs would make up the balance.

CBO also estimates that implementing Project BioShield would add to the administrative costs of HHS and DHS, both for the contracting process and managing the stockpile. Funding for those costs would come from appropriated funds. Based on current spending for program support services for bioterrorism-related activities (including the SNS) at the Centers for Disease Control and Prevention, CBO estimates that administrative costs would be about $10 million a year. Subject to the appropriation of necessary amounts, CBO estimates that discretionary spending for such costs would increase by $7 million in 2004 and $0.1 billion over the 2004–2013 period.

Research and development into qualified countermeasures

H.R. 2122 would authorize the Secretary of HHS to expedite procurement and peer review for research related to qualified countermeasures. The bill also would allow the Secretary to secure the servcies of experts or consultants with relevant expertise. Implementation of these measures could increase the resources required by the agency, accelerate spending, or both. CBO does not have sufficient information to estimate the additional resources that might be required by the agency or the rate at which spending might accelerate under the bill. Such spending would come from appropriated funds.

Authorization for medical products for use in emergencies

The FDA's regulatory process allows for expedited approval of security countermeasures under current law. Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the FDA may allow certain drugs, devices, and biologics defined as priority countermeasures to move more quickly through the agency's regulatory process. To further expedite the development of security countermeasures, the FDA has implemented a rule that allows approval of certain drugs based on tests in animals.

H.R. 2122 would allow the Secretary of HHS to authorize the FDA to approve the use of certain drugs or devices for use during designated as emergencies by the Secretary of HHS, DHS, or Defense. The authorization would remain in effect for no more than one year, unless the Secretary determines otherwise based on the

nature of the emergency. When the Secretary authorizes the emergency use of a product that is an unapproved use of an approved product, the bill would provide some flexibility to manufacturers in carrying out activities under the emergency use authorization.

Based on information from Administration officials, CBO expects that implementing this provision in H.R. 2122 would not increase costs to the FDA. Over the past year, the FDA has hired about 100 people to review drug applications and provide assistance to companies engaged in research and development into security countermeasures. Thus, the agency already has the infrastructure to handle the additional authority related to the proposed emergency-use authorization and would not require additional resources. Therefore, CBO estimates that this provision of H.R. 2122 would have no budgetary effect.

Previous CBO estimate: S. 15, the Project BioShield Act of 2003, as reported by the Senate Committee on Health, Education, Labor and Pensions on March 25, 2003, would amend the Public Health Service Act (PHSA) to create permanent, indefinite funding authority for the procurement of certain biomedical countermeasures. In its cost estimate dated May 7, 2003, CBO estimated that enacting S. 15 would increase direct spending by $270 million in 2004 and $8.1 billion over the 2004–2013 period.

Although both H.R. 2122 and S. 15 would authorize programs to procure countermeasures to protect the public health against terrorism, H.R. 2122 would not have an effect on direct spending; instead, the bill would authorize appropriations of up to $5.6 billion over the 2004–2013 period. Estimated spending under H.R. 2122 is less than under S. 15 because the House bill would authorize a set amount of appropriations, whereas the Senate bill would provide unlimited direct spending authority.

In several areas, H.R. 2122 would allow the Secretary more flexibility in terms of what products could be procured and how contracts would be structured. H.R. 2122 would allow the procurement of countermeasures even if they have a significant commercial application, while S. 15 would restrict the procurement authority to those without such application. While S. 15 would require the Secretary to determine that a countermeasure is likely to be approved by the FDA within five years as a condition of procurement, H.R. 2122 would require only that the Secretary consider whether a five-year limit is feasible. H.R. 2122 would provide additional flexibility in contracting by permitting the Secretary to extend first-time contracts to eight years (versus five in S. 15) and would allow the Secretary discretion to provide a 10 percent advance to companies developing new products. Those provisions would accelerate spending relative to S. 15.

Intergovernmental and private-sector impact: H.R. 2122 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Jeanne De Sa and Sam Papenfuss: impact on state, local, and tribal governments: Leo Lex; impact on the private sector: Samuel Kina.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the Act as the "Project BioShield Act of 2003."

Section 2. Biomedical countermeasure research and development authorities

Section 2(a) of the Project BioShield Act of 2003 amends the Public Health Service Act to add a new section 319F–1. The section grants the Secretary of Health and Human Services (HHS) additional flexibility and authority in conducting research and development with respect to biomedical countermeasures against biological, chemical, nuclear and radiological agents that may affect national security.

The Act defines the scope of the new authorities set forth in this section as applying to countermeasures against agents that "may cause a public health emergency affecting national security." In making a determination about whether a potential public health emergency could affect national security, the Secretary of HHS may consider all information deemed pertinent and appropriate, and nothing in this Act requires that such Secretary of HHS consult with other executive branch officials prior to making such a determination. The Committee expects that the Secretary of HHS will consider the threat of use of such agents by terrorists against the U.S. population to be a significant factor in making scope determinations under these provisions. However, the Committee also recognizes and encourages the Secretary of HHS to consider the emerging threats to public health and national security that may be caused by the spread of antibiotic resistant organisms or dangerous viruses that may spread rapidly and lack effective counter-

measures today.These threats may affect national security whether by terrorists or through natural conditions. The Secretary of HHS should consider such factors in determining whether to use these new authorities to promote research, development, and production of specific security countermeasures.

Indeed, antimicrobial-resistant infectious microbes are viable biological agents that could be used by both domestic and foreign terrorists to wreak havoc and injury upon U.S. citizens. In addition, the emergency of drug resistance in one organism may have the effect of limiting that drug's ability to treat other biological agents, as genetic material may be transferred naturally or purposefully from one infectious agent to another. Advancing the discovery of new antimicrobial drugs to treat resistant organisms, through Bioshield and other research and development initiatives, through Bioshield and other research and development initiatives, may well pay dividends for both national security and public health.

New subsection 319F–1(b) provides general authority. Proposed subparagraph 319F–1(a)(4) makes the facilities of entities that enter into a grant or cooperative agreement with the Secretary of HHS under this section available as needed to such Secretary of HHS to respond to public health emergencies affecting national security.

New subsection 319F–1(b) provides expedited authority for governmental procurements used to perform, administer, or support pressing research and development activities under this section, by (1) increasing the simplified acquisition threshold from $100,000 to $25 million; (2) authorizing the use of procedures providing for less than full and open competition when there are only a limited number of responsible sources and no other type of services will satisfy the Secretary of HHS needs; and (3) increasing the micropurchase threshold for such procurements to $15,000.

New subsection 319F–1(c) authorizes the Secretary of HHS to use expedited peer-review procedures in lieu of otherwise applicable peer-review procedures in the case of grants and contracts for biomedical countermeasure research and development activity, if such grants and contracts do not exceed $1,500,000 and are necessary to respond to pressing research needs.

New subsection 319F–1(d) provides additional flexibility to the Secretary of HHS with respect to the hiring of experts and consultants when necessary to respond to pressing qualified countermeasure research and development needs. Under paragraph 319F–1(d)(2), such experts and consultants are deemed to be employees of HHS for purposes of the Federal Torts Claims Act, which provides the exclusive remedy against such personnel for claims relating to the performance of covered duties.

New subsection 319F–1(e) provides streamlined personnel authority for the HHS Secretary to appoint up to 30 people to positions in the National Institutes of Health without regard to ordinary classification criteria, when necessary to respond to pressing qualified countermeasure research and development needs.

New subsection 391F–1(f) provides that actions by the Secretary of HHS under the section are committed to agency discretion.

Section 2(b) of the Project BioShield Act of 2003 amends section 481A of the Public Health Service act to add the Director of the National Institute of Allergy and infectious Diseases to that sec-

tion, and thus provide to that Director certain authorities concerning modernization and construction of research facilities. Section 2(b) further authorizes such sums as may be necessary for such purposes.

Section 3. Biomedical countermeasures procurement

Section 3(a) of the Project BioShield Act of 2003 adds a new section 319F–2 to the Public Health Service Act. Several provisions of new section 319F–2 simply transfer existing provisions of law from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended by the Homeland Security Act of 2002. Proposed Subsection 319F–2(a) contains language from existing law establishing the Strategic National Stockpile. New section 319F–2(b) contains language from existing law concerning authorizing procurement of smallpox vaccine for the National Strategic Stockpile.

New section 319F–2(c) requires the Secretary of the Department of Homeland Security (DHS) to assess threats that may be posed by chemical, biological, radiological, and nuclear agents, and requires the HHS Secretary to assess the public health consequences such agents and the availability and appropriateness of countermeasures for the threats identified. After these steps, the Secretaries jointly may determine and recommend to the President that funding for procurement of such a countermeasure for the nation's stockpile is appropriate from the special reserve funds established by this Act.

Under section 319F–2(c)(4), the Secretaries of HHS and DHS may recommend to the President a proposal to issue a call for the development of a security countermeasure. Such a call, at a minimum, includes a commitment from the Secretaries to make a recommendation for funding of such a countermeasure from the special reserve funds, if government specifications for the product are achieved. The Secretaries also may secure a Presidential approval for funding prior to, or without, conducting a call.

New section 319F–2(c)(4)(B) provides that the Secretaries should include in any call for proposals for countermeasure production information that may be necessary to encourage or facilitate research and development into such countermeasures. The Committee recognizes that an important factor companies will consider in determining whether to invest scarce research and development dollars into security countermeasures is whether and to what extent they may face liability relating to the development or production of such countermeasures. The Committee thus encourages the Secretaries to indicate in any call for proposals the potential availability of indemnification or liability protections under other laws.

Under section 319F–2(c)(7), if the President approves a recommendation for funding from the special reserve funds, DHS would then enter into an agreement with HHS under which HHS may procure the countermeasure for the stockpile using the DHS special reserve fund. Contracts under this paragraph are subject to certain conditions. The Secretary of HHS may use simplified acquisition procedures or procedures providing for less than full and open competition under certain circumstances. Certain determinations of the Secretary are committed to agency discretion.

The Committee recognizes that existing procurement authorities may allow for a single agreement that provides for research and development as well as production of a countermeasure or vaccine. Nothing in this Act shall limit the use of these existing authorities where a single agreement (including a contract, grant, cooperative agreement or other acquisition instrument) for research, development, and production of a countermeasure or vaccine is deemed appropriate by the contracting officer, including when a separate funding source is authorized and used for the research and development and it is different than the funding source authorized and used for production. The Committee recognizes that such agreements providing express linkage between research, development, and production may be necessary in order to encourage entities to enter the government market for countermeasures and vaccines in accordance with the authorities provided by Project Bioshield. Similarly, existing procurement authorities may allow the Secretaries to limit competition for a production contract under section 3 of this Act to those entities that successfully competed for research and development contracts under section 2 of this Act or other provisions of law. However, the Committee emphasizes that the monies obligated from the special reserve fund created under section 3 of this Act may not be use to pay for research or development activities, but only for procurement of countermeasures paid upon substantial delivery of product—consistent with the express limitation contained in the Homeland Security Act of 2002 excluding from the DHS Secretary's responsibilities the conduct or support of human health-related countermeasure research and development.

Section 319F–2(d) contains prohibitions on disclosure of information transferred from existing law. Section 319F–3(e) contains definitions transferred from existing law.

Section 319F–2(f) contains authorization of appropriations for the Strategic National Stockpile and smallpox vaccine development transferred from existing law with one addition. The new paragraph makes clear that such existing authorizations are in addition to amounts authorized under the special reserve fund. Nothing in the Act would restrict or alter the Secretaries' existing authority to purchase items for the stockpile using existing discretionary appropriations for such purpose.

Section 3(b) of the Project BioShield Act of 2003 adds a new section 510 to the Homeland Security Act of 2002. This new section authorizes appropriations for the special reserve fund referenced in the new section 319F–2(c) of the Public Health Service Act. The bill authorizes $890 million in FY 04 for such procurements, and aggregate amounts of $3.4 billion and $5.6 billion over the next five and ten fiscal years respectively. All amounts appropriated under this authorization would be available for obligation through the end of FY 2013.

The act defines the scope of the new authorities set forth in this section as applying to countermeasures against agents that the Secretary of HHS believes "may cause a public health emergency affecting national security," and about which the HHS and DHS Secretaries make certain additional findings. In making a determination about whether a potential public health emergency could affect national security, the Secretary of HHS may consider all in-

formation deemed pertinent and appropriate, and nothing in this Act requires that such Secretary of HHS consult with other executive branch officials prior to making such a determination. The Committee expects that both Secretaries will consider the threat of use of such agents by terrorists against the U.S. population to be a significant factor in making their respective scope determinations under these provisions. However, the Committee also recognizes and encourages the Secretaries to consider the emerging threats to public health and national security that may be caused by the spread of antibiotic resistant organisms or dangerous viruses that may spread rapidly and lack effective countermeasures today. These threats may affect national security whether by terrorists or through natural conditions. The Secretaries should consider such factors in determining whether to use these new authorities to promote research, development, and production of specific security countermeasures.

Section 4. Authorization for medical products for use in emergencies

Section 4 adds a new section 564 to the Federal Food, Drug, and Cosmetic Act. New section 564(a) allows the Secretary of Health and Human Services to authorize for introduction into interstate commerce unapproved drugs, devices, and biological products or unapproved uses of approved drugs, approved/cleared devices, and biological products intended for use in an actual or potential emergency during the effective period of a declaration.

New section 564(b) allows the Secretary of HHS to declare an emergency justifying an emergency use authorization based upon a determination by the Secretary of Homeland Security that there is a national emergency or the significant potential of one, or by a determination of the Secretary of Defense that there is a military emergency, or a significant potential of one. Such emergencies must involve a heightened risk of attack with biological, chemical, radiological, or nuclear agents. Similarly, an emergency use authorization can be based upon a determination of the Secretary of HHS that there is a public health emergency affecting national security and involving biological, chemical, radiological, or nuclear agents. In making a determination about whether a public health emergency under section 319 of the Public Health Service Act affects national security, the Secretary may consider all information he deems pertinent and appropriate, and nothing in this Act requires that the Secretary consult with other executive branch officials prior to making such a determination.

Under this section, any declaration of emergency will last for one year, unless the Secretary of HHS terminates it at an earlier time. The Secretary of HHS may renew a declaration. The Secretary of HHS must publish all declarations, determinations, and renewals in the Federal Register, and the Secretary must provide reasonable advanced notice that declarations are to be terminated under this section. The Committee intends that, after a declaration is terminated, final disposition of labeling or intrastate disposition of a product may occur. Further, the Committee believes that the Commissioner of the Food and Drug Administration may exercise enforcement discretion not to object to interstate shipment of an unapproved product for return to a manufacturer. A determination of what is a "reasonable" period for advanced notice of termination

should consider all factors, so in some cases notice immediately preceding termination may be reasonable, while in other circumstances it may not.

Section 564(c) details the criteria for issuance of an emergency use authorization. Under this new section, the Secretary of HHS, acting through the Commissioner, may issue an authorization upon concluding (1) that a biological, chemical, radiological, or nuclear agent or agents can cause a serious or life-threatening disease or condition; (2) that the drug, device or biological product may be effective in detecting, diagnosing, treating, or preventing such disease or condition (or a serious disease or condition caused by taking a product already approved, licensed or cleared by FDA for treating or preventing such disease or condition), and the benefits of the product outweigh risks; (3) that there is no adequate, approved, and available alternative to the product; and (4) other criteria the Secretary may by regulation specify. The Commissioner should consult with the Directors of the National Institutes of Health and the Centers for Disease Control and Prevention prior to issuing an authorization, but such consultation is limited by considerations of feasibility and appropriateness given the circumstances of the emergency.

Section 564(d) concerns the scope of an emergency use authorization. Under this section, the authorization shall state the disease or condition that the product may be used to detect, diagnose, prevent, or treat, as well as the Commissioner's conclusions about known benefits and risks of the product and conclusions concerning safety and potential effectiveness. The Committee intends that before issuing an authorization under this section, the Commissioner will, where feasible given the nature and the extent of the emergency, notify the holder of any relevant application under this chapter or under section 351 of the Public Health Service Act. The purpose of such notification is to allow for discussion of the conditions of this authorization as required by subsection (e), as well as discussion of whether such product should be delivered pursuant to section 319F–2(c) of the Public Health Service Act.

Section 564(e) pertains to products that have never been approved, licensed, or cleared by FDA. Under this subsection, conditions shall, to the extent feasible given the circumstances of the emergency, be applied to persons who choose to carry out an activity for which the authorization is issued. Such mandatory conditions include information to providers about the emergency use of the product as well as significant known potential risks and benefits, as well as appropriate conditions designed to ensure that to the maximum extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed of the emergency use of the product, risks and benefits of the product, and of the option to accept or refuse the product. Further, the Commissioner is given the authority to impose other conditions on those who carry out activities for which the authorization is issued. Such conditions imposed by the Commissioner should be designed to provide maximum flexibility to ensure that those who wish to take the product can indeed take the product, if made available by the manufacturer.

Section 564(e) also applies to unapproved uses of approved products and the Commissioner may, for manufacturers who choose to

carry out one or more activities pursuant to an emergency use authorization, apply certain conditions. This subsection makes clear that manufacturers do not have to avail themselves of the emergency use authorization for unapproved uses of approved products, and it makes clear that no individual may alter or obscure the labeling of already approved products. It does authorize, however, persons other than the manufacturer to provide information about the product concerning the emergency use of the product.

Under section 564(e), the Commissioner may establish conditions regarding product labeling and information conveyance concerning unapproved products. Further, the Committee intends that the Commissioner may establish conditions regarding product labeling and information conveyance on manufacturers that carry out one or more activities pursuant to an emergency use authorization with respect to the emergency use of that product that is an unapproved use of an approved product.

Subsection (f) makes clear that an emergency use authorization is effective until the declaration is terminated or revoked, but allows patients to continue using such products in certain instances. Nothing in this subsection is intended to require manufacturers or others to provide such products to patients.

Subsection (g) makes clear that the Commissioner shall periodically review the appropriations of an authorization, and it provides the Commissioner needed flexibility to revoke an authorization if the criteria justifying the authorization are no longer met.

Subsection (h) ensures that the Commissioner shall promptly publish in the Federal Register notices of all authorizations, terminations, and revocations, Subsection (i) makes clear that all determinations under this new section are committed to agency discretion. Subsection (j) is a rule of construction nothing that this new section does not impair or otherwise affect certain existing authorities.

New section 564(k) pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are informed of the option to accept or refuse administration of an emergency use product, upon certain findings (which are identical to the findings found in section 1107 of Title 10). Further, the subsection requires that if certain information is not provided to members of the Armed Forces prior to an emergency use product being administered to them, then information concerning the administration of the product shall be placed in the medical record of the member.

Subsection (l) makes clear that if a product is authorized for emergency use under this new section, the investigational sections of the Act shall not apply to the products.

Subsection (m) ensures that no authority in new section 564 can require a manufacturer of a drug, device, or biological product to perform any activity that becomes lawful pursuant to the new section. That is, the Commissioner in no way is goven the authority to, among other things, require a manufacturer to introduce into interstate commerce or deliver for introduction into interstate commerce any unapproved product or an approved product for an unapproved use under this section. Further, even if the Commissioner authorizes the emergency use of an already-approved, licensed or cleared product, a manufacturer can refuse to avail themselves of

such emergency use authorization and continue introducing into interstate commerce its approved or cleared product under the Federal Food, Drug and Cosmetic Act, or licensed product pursuant to the Public Health Service Act. The only obligation in subsection (m) is that if the Commissioner authorizes the emergency use of a sole-source unapproved product, then the manufacturer of such product must inform the Commissioner of its intention not to carry out any activity under the authorization within a reasonable period of time. Nothing in this section shall be construed as authorizing the Commissioner to establish conditions on the distribution, administration, or labeling of any other product in any other circumstance.

Subsection (n) ensures that the present enforcement regime of the Federal Food, Drug, and Cosmetic Act will apply to individuals who carry out an activity or activities pursuant to an authorization, but fail to comply with applicable conditions. If any person carries out an activity pursuant to section 564, but violates a condition imposed by the Commissioner, then that person will be subject to Chapter III of the Act, where the "prohibited acts" are found. If a person is found to be in violation of a prohibited act found in section 301, then the Committee intends for that person to be subject to the enforcement provisions found in sections 302, 303, and 304. A violation of any condition applied to an emergency use product in no way alters or affects the emergency use status of the underlying product.

The Committee intends that new section 564, as made clear in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act, the Secretary, through the Commissioner of Food and Drugs, shall be responsible for executing the Federal Food Drug, and Cosmetic Act as amended by the Project BioShield Act.

Section 5. Reports

Section 5(a) requires the Secretary of HHS to submit annual reports to Congress concerning the exercise of many of the new authorities under the Act. Section 5(b) requires a report from the National Academy of Sciences concerning whether and to what extent the research authorities granted under the Act have enhanced the development of biomedical countermeasures affecting national security. Section 5(c) requires the General Accounting Office to issue a report concerning the Secretary of HHS utilization of these new authorities.

COMMITTEE CORRESPONDENCE

COMMITTE ON THE JUDICIARY
Washington, DC, June 10, 2003.

Hon. BILLY TAUZIN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC

DEAR CHAIRMAN TAUZIN: In recognition of the desire to expedite floor consideration of H.R. 2122, the "Project BioShield Act of 2003," the Committee on the Judiciary hereby waives consideration of the bill. Section 2 of the bill creates a new section 319F–1 of the Public Health Service Act. New subsection 319F–1(d) gives the Secretary of Health and Human Services new authority to enter into personal services contracts with scientists and consultants for lim-

ited periods of time for the purposes of expedited research on countermeasures against biological weapons. New subsection 319F–1(d) further provides that scientists and consultants who receive contracts under this provision shall have the protections of the Federal Tort Claims Act as if they were regular federal employees. These FTCA provisions fall within the Committee on the Judiciary's Rule X jurisdiction. However, given the need to expedite this legislation, I will not seek a sequential referral based on their inclusion.

The Committee on the Judiciary takes this action with the understanding that the Committee's jurisdiction over these provisions is in no way diminished or altered. I would appreciate your including this letter in the Congressional Record during consideration of H.R. 211 of the House floor.

Sincerely,

F. JAMES SENSENBRENNER, Jr.,
Chairman.

COMMITTEE ON ENERGY AND COMMERCE
Washington, DC, June 10, 2003.

Hon. F. JAMES SENSENBRENNER, Jr.,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR CHAIRMAN SENSENBRENNER: Thank you for your letter regarding H.R. 2122, the "Project BioShield Act of 2003." As you noted, new subsection 319F–1(d) of the Public Health Service Act as added by the bill contains provisions that fall within the Rule X jurisdiction of the Committee on the Judiciary.

I appreciate your willingness not to seek a referral on H.R. 2122. I agree that your decision to forego action on the bill will not prejudice the Committee on the Judiciary with respect to its jurisdictional prerogatives on this or similar legislation.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 2122 of the House floor.

Sincerely,

W.J. "BILLY" TAUZIN,
Chairman.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

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SEC. 319F–1. AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.

(a) IN GENERAL.—

(1) AUTHORITY.—In conducting and supporting research and development activities regarding biomedical countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section if the activities concern qualified countermeasures.

(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term "qualified countermeasure" means a priority countermeasure (as defined in section 319F(h)) that affects national security.

(3) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any grant or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, and supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(b) EXPEDITED PROCUREMENT AUTHORITY.—

(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR BIOMEDICAL COUNTERMEASURE PROCUREMENTS.—

(A) IN GENERAL.—For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(ii) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

(i) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(ii) Subsections (a) and (b) of Section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(iii) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the —— examination of contractor records).

(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph.

(2) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures when—

(A) the procurement is as described by paragraph (1); and

(B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of responsible sources, and no other type of property or services will satisfy the Secretary's needs.

(3) INCREASED MICROPURCHASE THRESHOLD.—

(A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

(B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than $2,500.

(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures

that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—

(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

(B) the amount of which is not greater than $1,500,000.

(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.

(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

(1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.

(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the person, officer, employee, or governing board member.

(3) INTERNAL CONTROLS TO BE INSTITUTED.—

(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be

final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

(4) NUMBER OF PERSONAL SERVICES CONTRACTS LIMITED.—The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

(e) STREAMLINED PERSONNEL AUTHORITY.—

(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to such provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

(2) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for appointments under this subsection.

(f) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions by the Secretary under the authority of this section are committed to agency discretion.

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), in coordination with the Secretary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a);

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

(F) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN BIOMEDICAL COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a priority countermeasure (as defined in section 319F(h))—

(i) that affects national security;

(ii) that is determined under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(iii)(I) that is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act, for use as a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii); or

(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5).

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences of use against the United States population of agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents for which priority countermeasures are necessary to protect the public health from a material threat.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(4) CALL FOR SECURITY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a security countermeasure would be appropriate, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such security countermeasure; and

(ii) make a commitment that, upon the first development of such security countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such security countermeasure.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the security countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) a commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consulta-

tion with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the needs of the stockpile.

(ii) The feasibility of production and delivery within five years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (2), (3), and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The special reserve fund under paragraph (10) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall notify the Congress of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the identification of the potential supplier or suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological,

chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) PROCUREMENT.—

(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) INTERAGENCY AGREEMENTS.—

(i) FOR PROCUREMENT.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for the Secretary's costs of such procurement, other than as provided in clause (ii).

(ii) FOR ADMINISTRATIVE COSTS.—The agreement entered into between the Homeland Security Secretary and the Secretary for managing the stockpile under subsection (a) shall provide for reimbursement of the Secretary's administrative costs relating to procurements under this subsection.

(C) PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this subparagraph; and

(II) promulgating regulations to implement clauses (v), (vi), and (vii), and any other provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to

exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform under the contract, except in special circumstances as determined by the Secretary on a contract by contract basis.

(II) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(III) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—The amount of any procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of Section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the —— examination of contractor records).

(iv) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures for a procurement under this subsection if the product is available from only one responsible source or only from a limited number of responsible sources, and no other type of product will satisfy the Secretary's needs.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative under-

takings with other agencies of the United States Government.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2003; or

(B) administrative costs.

(10) SPECIAL RESERVE FUND.—For purposes of this subsection, the term "special reserve fund" has the meaning given such term in section 510 of the Homeland Security Act of 2002.

(d) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Homeland Security Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund under subsection (c)(10).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART E—OTHER AGENCIES OF NIH

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SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or con-

struct new research facilities, subject to the provisions of this section.

* * * * * * *

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) * * *

* * * * * * *

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated under ⟦subsection (i)⟧ *subsection (i)(1)* for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over $50,000,000, the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) * * *

* * * * * * *

(d) REQUIREMENT OF APPLICATION.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, except that such amount shall not exceed—

(A) 50 percent *(or, in the case of the Institute, 75 percent)* of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent *(or, in the case of the Institute, 75 percent)* of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amend-

ment of the application or on the revision of the estimated cost of construction of the facility.

* * * * * * *

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director *of the Center or the Director of the National Institute of Allergy and Infectious Diseases* for applicants meeting the conditions described in subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) *in the case of an award by the Director of the Center,* the applicant or other owner of the facility shall cease to be a public or non profit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director *of the Center or the Director of the National Institute of Allergy and Infectious Diseases* determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

* * * * * * *

(i) AUTHORIZATION OF [APPROPRIATIONS.—For the purpose of carrying out this section,] *APPROPRIATIONS.—*

(1) CENTER.—For the purpose of carrying out this section with respect to the Center, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for fiscal year 2003.

SECTION 510 OF THE HOMELAND SECURITY ACT OF 2002

SEC. 510. PROCUREMENT OF SECURITY COUNTERMEASURES FOR STRATEGIC NATIONAL STOCKPILE.

(a) AUTHORIZATION OF APPROPRIATIONS.—For procurement of security countermeasures under section 319F–2(c) of the Public Health Service Act (referred to in this section as the "security countermeasures program"), there is authorized to be appropriated up to $5,593,000,000 for the fiscal years 2004 through 2013. Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term "special reserve fund" means the appropriations account established as a result of any appropriations made under subsection (a).

(c) AVAILABILITY.—

(1) DURATION OF AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013, provided that any portion of such amount that remains unobligated for such purposes on the expiration of such term shall be returned to the United States Treasury and shall not be available for subsequent obligation for any purpose.

(2) INITIAL AVAILABILITY FOR PARTICULAR PROCUREMENTS.—Amounts appropriated under subsection (a) become available for a procurement under the security countermeasures program only upon the approval by the President of such availability for the procurement in accordance with paragraph (6)(B) of such program.

SECTION 121 OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

[SEC. 121. STRATEGIC NATIONAL STOCKPILE.

[(a) STRATEGIC NATIONAL STOCKPILE.—

[(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

[(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

[(A) consult with the working group under section 319F(a) of the Public Health Service Act;

[(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

[(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

[(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

[(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

[(F) ensure the adequate physical security of the stockpile.

[(b) SMALLPOX VACCINE DEVELOPMENT.—

[(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States.

[(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

[(c) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

[(d) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

[(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

[(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary supplies described in subsection (a).

[(e) AUTHORIZATION OF APPROPRIATIONS.—

[(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

[(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.]

SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—

(1) EMERGENCY USES.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug or device intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an "unapproved product"); or

(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

(4) DEFINITIONS.—For purposes of this section:

(A) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(B) The term "product" means a drug or device.

(C) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

(D) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) DECLARATION OF EMERGENCY.—

(1) IN GENERAL.—The Secretary may declare an emergency justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a national emergency, or a significant potential for a national emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; or

(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

(2) TERMINATION OF DECLARATION.—

(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

(3) ADVANCE NOTICE OF TERMINATION.—In terminating a declaration under this section, the Secretary shall provide advance notice that the declaration will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of shipments of the product, including the return of such shipments to the manufacturer (in the case of a manufacturer that chooses to have the shipments returned); and

(B) in the case of unapproved uses of approved products, a sufficient period for the disposition of any labeling that was provided with respect to the emergency use involved.

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, and renewal under this subsection.

(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, the Secretary concludes—

(1) that an agent specified in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in detecting, diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for detecting, diagnosing, preventing, or treating such disease or condition; and

(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) SCOPE OF AUTHORIZATION.—

(1) IN GENERAL.—An authorization of a product under this section shall state—

(A) each disease or condition that the product may be used to detect, diagnose, prevent, or treat within the scope of the authorization;

(B) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

(C) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the

product in detecting, diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.

(2) CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, shall, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, may, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this

section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) For persons other than manufacturers of the product, appropriate conditions concerning record-keeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(iv) With respect to the emergency use of the product, waive or limit, to the extent appropriate given the circumstances of the emergency, conditions regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established in section 501.

(2) UNAPPROVED USE.—With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) The Secretary may, for manufacturers of the product who choose to carry out one or more activities for which the authorization is issued, establish any of the conditions described in clauses (i) through (iv) of paragraph (1)(A).

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer.

(ii) In the circumstances described in clause (i), an authorization under this section regarding the emergency use may, for persons who do not manufacture the product and who choose to act under this clause, authorize such persons to provide information on the product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). Such additional information shall not be considered labeling for purposes of section 502.

(f) DURATION OF AUTHORIZATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—An authorization shall continue to be effective for continued use with respect to patients to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patients' attending physicians.

(g) REVOCATION OF AUTHORIZATION.—

(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section.

(2) REVOCATION.—The Secretary may revoke an authorization under this section if, in the Secretary's unreviewable discretion, the criteria under subsection (c) for issuance of such authorization are no longer met.

(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons therefor, under this section.

(i) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to impair or otherwise affect—

(1) the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution;

(2) the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law; or

(3) the authority of the Secretary under section 319F–2 to manage the stockpile under such section.

(k) APPLICATION TO MEMBERS OF ARMED FORCES.—

(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived by the President if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

(2) PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

(3) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(l) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization —

(1) shall not be subject to any requirements pursuant to section 505(i) or 520(g); and

(2) shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this Act.

(m) DISCRETION REGARDING USE OF AUTHORIZATION.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall notify the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out an activity or activities under the authorization. This section does not have any legal effect on a person who does not carry out any activity for which an authorization under this section is issued, or who carries out such an activity pursuant to other provisions of this Act or section 351 of the Public Health Service Act.

(n) ENFORCEMENT.—A person who carries out an activity pursuant to an authorization under this section, but who fails to comply with applicable conditions under subsection (e), is with respect to that act of noncompliance subject to the provisions of law specified in subsection (a) and to the enforcement of such provisions under section 301.

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