CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 6, 2003

H.R. 2122
Project BioShield Act of 2003

As ordered reported by the House Committee on Government Reform on May 22, 2003

SUMMARY

H.R. 2122 would amend the Public Health Service Act (PHSA) to authorize appropriations of up to $5.6 billion for fiscal years 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 years 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. 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 through 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 approved 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 priorities. 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 advance 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 antigen (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 fevers (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 infection 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 periods 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 ESTIMATES

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.

On June 6, 2003, CBO transmitted a cost estimate for H.R. 2122 as ordered reported by the House Committee on Energy and Commerce on May 15, 2003. That version of H.R. 2122 is nearly identical to the version of H.R. 2122 approved by the Committee on Government Reform. CBO's estimates of the costs of the two versions of H.R. 2122 are identical.

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.

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