



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

May 7, 2003

S. 15

Project BioShield Act of 2003

*As reported by the Senate Committee on Health, Education, Labor, and Pensions on
March 25, 2003*

SUMMARY

S. 15 would amend the Public Health Service Act (PHSA) to create permanent, indefinite funding authority for the procurement of certain biomedical countermeasures (drugs, devices, and biological products to treat, identify, and prevent the public health consequences of terrorism). Funding to buy these biomedical 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. CBO estimates that enacting this provision of S. 15 would increase direct spending by \$270 million in 2004 and \$8.1 billion over the 2004-2013 period. CBO estimates that the administrative costs for this program would amount to \$7 million in 2004 and \$0.1 billion over the 2004-2013 period, subject to the appropriation of the necessary funds.

The bill also would clarify a provision of the PHSA related to federal assumption of liability under the Federal Tort Claims Act for injuries related to the administration of the smallpox vaccine. CBO estimates that enacting that provision of S. 15 would have no budgetary effect.

In addition, S. 15 would relax certain requirements for federal agencies related to the development and approval of countermeasures. The bill would provide the National Institutes of Health (NIH) with increased authority and flexibility to award contracts and grants for research and development of biomedical 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 grant authority for the Food and Drug Administration (FDA) to approve the use of certain biomedical countermeasures during emergencies designated by the

Secretary of HHS. CBO estimates this provision would have no budgetary effect. S. 15 would allow the Secretary to seek civil monetary penalties against individuals who violate requirements of the emergency use authorization. CBO estimates that implementing that provision of the bill would have no significant effect on direct spending or receipts.

S. 15 would impose two mandates as defined in the Unfunded Mandates Reform Act (UMRA). It would preempt state laws that would otherwise limit the federal government’s ability to recover damages from biomedical contractors; this would be an intergovernmental mandate. The bill also would allow HHS to require medical practitioners to keep certain records when they authorize the use of certain biomedical products during emergencies; this would be both an intergovernmental and private-sector mandate. CBO has no basis for estimating the cost of the latter mandate because it would depend on the scope of the requirements that might be imposed by the Secretary and the frequency of emergencies requiring the use of biomedical products. Therefore, CBO cannot determine whether the annual thresholds established in UMRA would be exceeded (\$59 million for intergovernmental mandates and \$117 million for private-sector mandates in 2003, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 15 is shown in the following table. The costs of this legislation fall within budget function 550 (health). CBO assumes that S. 15 would be enacted October 1, 2003.

	By Fiscal Year, in Millions of Dollars									
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CHANGES IN DIRECT SPENDING										
Estimated Budget Authority	890	1,160	1,110	850	850	900	900	900	900	900
Estimated Outlays	270	640	870	900	900	900	900	900	900	900
CHANGES IN DISCRETIONARY SPENDING										
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 Biomedical 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. About \$400 million was appropriated in 2003 for stockpiling activities.

S. 15 would provide permanent, indefinite funding authority to DHS to augment the SNS with products for which there is no significant commercial market. That effort, called Project BioShield, would allow the federal government to enter into contracts to procure new or emerging biomedical countermeasures, which are defined in the bill as drugs, devices, or biological products used to treat, identify, or prevent harm from an agent used in a biological, chemical, radiological, or nuclear attack. The federal government could also acquire products used to treat the adverse effects of drugs or biologic products used as biomedical countermeasures. Project BioShield would seek to encourage the development of countermeasures that would not have significant commercial applications but would be necessary to protect the public's health in an emergency.

Because S. 15 would provide open-ended financing authority, spending under the bill 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. Current or future Administrations would have the discretion to enter into multiple contracts for the manufacture of biomedical countermeasures or to cease contracting altogether for a period of years.

To estimate the costs of S. 15, 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 biomedical 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.

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. 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 under the permanent, indefinite authority that S. 15 would provide.

Authorities and Requirements Under S. 15. Under Project BioShield, the federal government could enter into contracts to procure new or emerging biomedical countermeasures. Decisions regarding what types of biomedical countermeasures to procure would be made by the President after reviewing recommendations of the Secretaries of DHS and HHS regarding the biomedical countermeasures necessary to protect the public's health. Subject to Presidential approval, the Secretaries of DHS and HHS would seek potential vendors to produce the countermeasures and, subject to certain requirements, the Secretary of HHS would enter into contracts to buy the countermeasures from those manufacturers. First among those requirements (or conditions of procurement) is that the Secretary of HHS must determine that the product is a qualified countermeasure to a chemical, biological, radiological, or nuclear agent that the Secretary of DHS identifies as a material threat. The bill defines a qualified countermeasure as a drug, device, or biological product that has been licensed or approved by the FDA, or is otherwise determined by the Secretary of HHS to have the potential to be licensed or approved by the FDA within five years.

An additional condition of procurement is that the Secretary must determine the quantity of the product necessary for the stockpile and that the production and delivery of sufficient quantities of the product is feasible within five years. Furthermore, the Secretary would be required to determine that there is not a significant commercial market for the product other than as a biomedical countermeasure. Each year, the Secretary would have to redetermine whether a significant commercial market has developed.

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. Payment would be conditioned on both the delivery of a substantial portion of units contracted for and the vendor seeking approval, clearance, or licensing of the product from the Secretary. There would be some flexibility to contract for products not licensed or approved at the time of delivery, and the Secretary could pay vendors for storage, shipping,

and handling. The Secretary would be allowed to terminate the contract after three years for failure to deliver a reasonable number of units. The Secretary would be permitted to use noncompetitive procedures if the product is available only from a limited number of sources. The procurement authority would not be limited to one countermeasure per threat. Additional countermeasures for the same threat also could be procured, if they provide improved safety or effectiveness or otherwise enhance public health preparedness.

Funding would not be available for the purchase of vaccines under contracts entered into prior to January 1, 2003, or for the costs under new contracts after a determination has been made by the Secretary of HHS that there is a significant commercial market for the countermeasure. 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. More than half of those costs would be for the improved smallpox and anthrax vaccines. A brief description follows of the biomedical 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 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 Cost of Project BioShield. S. 15 would grant permanent, indefinite spending authority to the federal government to procure biomedical countermeasures. Although the bill would place some constraints on procurement, it would give the executive branch unlimited spending authority for qualifying products. Any plan to acquire biomedical countermeasures is likely to change 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 unforeseen countermeasure options. Acquisition of countermeasures would also be affected by how flexibly this and future Administrations interpret certain provisions of the bill, such as which products have the potential to be licensed in five years or whether or not the product has a significant commercial market.

CBO's Estimate of the Administration's Plan. CBO anticipates that the Administration's plans for the MVA smallpox vaccine, the rPA anthrax vaccine, and the botulism antitoxins would likely take shape as described. However, CBO expects that acquisition of those products would take slightly longer—and outlays would occur more slowly—than the Administration estimates.

CBO estimates that spending for vaccines and monoclonal antibodies for botulism, and for vaccines for plague and Ebola would likely be lower than the Administration estimates. 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.

For the products the Administration has announced it would procure under Project BioShield, CBO estimates that federal spending would total about \$4.8 billion over the 2004-2013 period, \$0.8 billion less than the administration projects. (Budget authority over this period would total about \$5.2 billion.)

Estimated Spending for Products Not Listed in the Administration's Plan. CBO anticipates other countermeasures could and would be funded in the future through Project BioShield. These might include additional countermeasures—not included in the Administration's initial plan for Project BioShield—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. Although any new antiviral or antibiotic could have a significant commercial market, and thus not be part of Project BioShield, it is also possible that those products could have only a limited market, and thus be eligible for purchase under Project BioShield.

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 S. 15, Project BioShield would be able to fund the procurement of devices to detect and diagnose pathogens and other agents. Costs for such devices are also not included in the Administration's estimate.

To estimate the cost of additional countermeasures that would likely be acquired and stockpiled under Project BioShield, 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 qualified countermeasures. After

accounting for such factors, CBO estimates that enactment of Project BioShield would result in outlays of about \$3.3 billion over the 2004-2013 period for products that are not included in the Administration's announced plan.

In total, CBO estimates that implementing the biomedical countermeasure provisions of S. 15 would cost \$270 million in 2004 and \$8.1 billion over the 2004-2013 period. Total new budget authority for government contracts under Project BioShield would be about \$9.4 billion over the same period. Biomedical countermeasures that would be purchased under the Administration's plan account for \$4.8 billion of the estimated spending—acquisition costs would comprise about 70 percent of that amount, while inventory management and replacement costs would make up the balance.

CBO estimates that an additional \$2.4 billion in spending would be for countermeasures for biological agents. The balance of \$900 million would be for diagnostics and devices, as well as for countermeasures for chemical, nuclear, and radiological agents. CBO estimates that acquisition costs would comprise 80 percent to 85 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 would increase by \$7 million in 2004 and \$0.1 billion over the 2004-2013 period.

Amendments to Provisions of the Homeland Security Act

S. 15 also would clarify provisions of the Public Health Service Act that establish liability protection for certain health care entities that administer the smallpox vaccine to certain individuals during a period specified by the Secretary of HHS. Those provisions were enacted initially under section 304 of the Homeland Security Act and revised in the Smallpox Emergency Personnel Protection Act of 2003 (Public Law 108-20). Under current law, certain individuals receiving the smallpox vaccine or vaccine immune globulin during a specified period are prohibited from bringing a claim for injury or death against certain health care entities. Instead, those individuals may bring claims against the United States

under the Federal Tort Claims Act (FTCA). Any compensable claims will be paid out of the Treasury's Judgment Fund.

S. 15 would specify that individuals who receive the smallpox vaccine because the Secretary makes it broadly available to the public would be prohibited from bringing claims for injuries or death against protected health care entities and would be permitted to bring claims against the United States under the FTCA. The Secretary currently has the authority to permit those individuals to bring claims under the FTCA, and CBO assumes the Secretary will exercise that authority. Therefore, CBO estimates that enactment of this provision would have no budgetary effect.

Research and Development Into Biomedical Countermeasures

S. 15 would provide the Secretary of HHS, through NIH, with the authority to expedite procurement and peer review for research related to biomedical countermeasures, and to secure the services of experts or consultants with relevant expertise. The National Institute of Allergy and Infectious Diseases at NIH would be designated the lead institute for research into biological countermeasures. 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 regulatory process allows for expedited approval of biomedical 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 biomedical countermeasures, the FDA has implemented a rule that allows approval of certain drugs based on tests in animals.

S. 15 would allow the Secretary of HHS to authorize the FDA to approve the use of certain biomedical countermeasures 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.

Based on information from Administration officials, CBO expects that implementing this provision in S. 15 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 biomedical 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 S. 15 would have no budgetary effect.

S. 15 would allow the Secretary of HHS to seek civil penalties against violators of requirements imposed under FDA's emergency use authority. Those penalties are limited to \$100,000 in the case of an individual and \$250,000 in the case of any other person, with a limit of \$1 million for all violations in a single proceeding. Civil penalties are recorded in the budget as governmental receipts (revenues). CBO expects that revenues from civil penalties under S. 15 would not be significant.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 15 would allow the United States, notwithstanding any provision of state law, to recover damages, interest, and litigation costs from biomedical contractors who fail to fulfill their obligations or who engage in grossly negligent, reckless, or illegal conduct. By preempting state law, the provision would constitute an intergovernmental mandate as defined in UMRA. However, it would impose no duty on states that would result in additional spending.

Under the bill, the Secretary of HHS could require persons who manufacture, distribute, prescribe, or administer medical products authorized for use in emergencies to maintain records on their safety and effectiveness during such emergencies. In some instances, the record-keeping requirement would still be required after the state of emergency has been lifted. This requirement would be an intergovernmental mandate (on public hospitals and public health clinics), as well as a mandate on the private sector. Because the scope and nature of the requirement would depend on future actions of the Secretary (both in declaring an emergency and in establishing record-keeping requirements), CBO has no basis for predicting how often such authority would be invoked, the number of cases that could be affected, or the scope of the record-keeping requirements. While some of the potential record-keeping requirements might be fulfilled by medical practitioners anyway in the normal course of providing care, the Secretary could establish more extensive requirements. Thus, CBO cannot estimate whether the cost to affected entities would be significant or whether the annual thresholds established in UMRA would be exceeded (in 2003,

\$59 million for intergovernmental mandates and \$117 million for private-sector mandates, adjusted annually for inflation).

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