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Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504

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Summary

Few effective countermeasures currently exist to deal with chemical, biological, radiological, and nuclear terror agents. In early 2003, the Bush administration proposed Project BioShield to stimulate the development of such countermeasures and to procure them for the Strategic National Stockpile (SNS). Congress considered three bills that incorporated much of the administration's proposal: S. 15 (Gregg), H.R. 2122 (Tauzin), and S. 1504 (Gregg). H.R. 2122 passed the House on July 16, 2003. S. 15 passed the Senate on May 25, 2004 in an amended form similar to H.R. 2122. This version of S. 15 passed the House on July 14, 2004. President Bush signed S. 15 into law as the Project BioShield Act of 2004 (P.L. 108-276) on July 21, 2004.

Although many of the details of Project BioShield changed during Congressional consideration, all the proposals shared similar key provisions. Each bill would have provided expedited hiring, procurement, and grant awarding procedures for bioterrorism-related products and services. Each bill would have provided a market guarantee for countermeasure producers by allowing the Secretary of Health and Human Services (HHS) to contract to procure countermeasures still in development. Thus, several years before a company plans to be able to deliver a countermeasure, the company would have been assured that if they successfully develop the countermeasure the government is obligated to purchase a set amount of it at a set price. Each bill would have authorized the HHS Secretary to allow the emergency use of countermeasures that lack Food and Drug Administration approval.

Congress changed many important aspects of the Administration's proposal. The most important change related to the funding mechanism. The Administration requested a permanent, indefinite appropriation, to be spent at the President's discretion, for the purchase of countermeasures. The enacted version of Project BioShield authorizes the appropriation of $5.593 billion for FY2004-FY2013. The Department of Homeland Security (DHS) Appropriations Act (P.L. 108-90) appropriated this amount.

The Project BioShield Act of 2004 (P.L. 108-276) also: transfers the SNS from DHS to HHS, permits procurement of countermeasures with commercial markets, permits countermeasure procurement contracts to be written up to eight years before countermeasures are expected to be deliverable, and authorizes appropriations to allow DHS to improve its ability to perform threat analysis. A provision that would have allowed HHS to develop countermeasures directly was excluded from the enacted version Project BioShield.

This report will not be updated. For more analysis and the current status of Project BioShield, see CRS Report RS21507, *Project BioShield*, by (name redacted).

Contents

List of Tables

Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504

Introduction

Several high profile incidents since 2001 have highlighted the nation's vulnerability to bioterrorism. Most prominent of these were the anthrax mailings of 2001. These caused five deaths, required thousands to take prophylactic antibiotics, and cost millions of dollars to clean up. If there had not been an effective antibiotic treatment for this strain of anthrax, the death toll would have been even higher.

Other prominent incidents include the discovery of the toxin ricin in Senator Frist's office in the Dirksen Senate Office Building office in February 2004 and in a postal facility in Greenville, South Carolina, in October 2003. The Secret Service also intercepted a letter containing ricin addressed to the White House in October 2003. Ricin, a deadly toxin, lacks any Food and Drug Administration (FDA) approved treatments or prophylaxis.[1]

Many of the other biological threats deemed most dangerous by the Centers for Disease Control and Prevention (CDC) also lack effective FDA-approved treatments and prophylactics. For example, botulinum toxin, plague, tularemia, and many viral hemorrhagic fevers (VHFs) lack licensed vaccines, while smallpox and VHFs lack any specific treatment.[2] Additionally, many of the vaccines and treatments that currently exist are suboptimal for responding to bioterrorism. For example, the Department of Health and Human Services (HHS) has called for better vaccines for anthrax and smallpox and better treatments for anthrax, plague, and botulism.[3]

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[1] For more information on ricin, see CRS Report RS21383, *Ricin: Technical Background and Potential Role in Terrorism*, by (name redacted) and (name redacted).

[2] For more information on potential chemical and biological terrorism agents and the availability of countermeasures, see CRS Report RL32391, *Small-scale Terrorist Attacks Using Chemical and Biological Agents: An Assessment Framework and Preliminary Comparisons*, by (name redacted) and (name redacted).

[3] National Institute of Allergy and Infectious Disease, *NIAID Biodefense Research Agenda for CDC Category A Agents*, Department of Health and Human Services, Washington, DC, February, 2002.

Several factors likely contribute to this paucity of bioterrorism countermeasures, including a lack of a financial incentives to develop countermeasures,[4] the perception of a relatively high threat of litigation stemming from adverse reactions to the countermeasures,[5] and the lack of success of a Department of Defense effort to develop such countermeasures.[6] In addition, because these diseases are rare, many companies apparently have balked at spending millions of dollars developing a product with such a small potential market.[7]

To encourage the development of new biomedical countermeasures, President Bush proposed Project BioShield in his 2003 State of the Union address. The 108th Congress considered three bills that incorporated the administration's proposal: S. 15 (Gregg), H.R. 2122 (Tauzin), and S. 1504 (Gregg). Most of the attention garnered by Project BioShield has focused on countermeasures against bioterrorism. However, Project BioShield also applies to countermeasures against chemical, radiological, and nuclear attacks.

This report provides a brief legislative history and a side-by-side comparison of the three bills, including versions of S. 15 as initially reported and as enacted. Such a comparison may be useful both with respect to congressional oversight of Project BioShield activities and with respect to future legislative initiatives relating to countermeasure procurement.

Legislative History

Senate Action. Senator Gregg introduced S. 15 on March 11, 2003. The Senate Committee on Health, Education, Labor, and Pensions (HELP) reported S. 15 on March 25, 2003, with an amendment in the nature of a substitute and without a written report. In the comparison tables below, this version is referred to as "S. 15 as Reported by Committee."

Senator Gregg introduced S. 1504 on July 30, 2003. It shared many of the provisions found in H.R. 2122, which the House had passed on June 16, 2003. S. 1504 was placed directly on the Senate Legislative Calendar. In the comparison tables below, this version is listed as "S. 1504 as Introduced."

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[4] Alan Pemberton, Pharmaceutical Research and Manufacturers of America, Testimony before the U.S. House of Representatives Select Committee on Homeland Security, May 15, 2003.

[5] Dr. Kim Bush, President Vaccines Division, Baxter Healthcare Corp, Testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions, Health Subcommittee, January 30, 2003.

[6] Institute of Medicine and National Research Council, *Giving Full Measure to Countermeasures: Addressing Problems in the DoD Program to Develop Medical Countermeasures Against Biological Warfare Agents*, National Academy Press, Washington DC, 2004.

[7] See CRS Report RL30913, *Pharmaceutical Research and Development: A Description and Analysis of the Process* by Richard Rowberg.

On May 19, 2004 the Senate passed S. 15 with an amendment in the nature of a substitute (99-0). The amended and passed version of S. 15 had relatively minor differences from H.R. 2122 (see below). This version of S. 15 was passed by the House and became the Project BioShield Act of 2004 (P.L. 108-276). In the comparison tables below, this version is referred to as "S. 15 as Enacted."

House Action. Representative Tauzin introduced H.R. 2122 on May 15, 2003. It was referred to the Committee on Energy and Commerce, Committee on Government Reform, Committee on Armed Services, and the Select Committee on Homeland Security. The Committee on the Judiciary chose not to seek a serial referral.[8]

Committee Hearings. The House Committee on Energy and Commerce Subcommittee on Health held a joint hearing with the House Select Committee on Homeland Security Subcommittee on Emergency Preparedness and Response entitled "Furthering Public Health Security: Project BioShield" on March 27, 2003.

The House Committee on Government Reform held a hearing to consider the "Project Bioshield Act" on April 4, 2003.

The House Select Committee on Homeland Security held a hearing on "BioShield: Countering the Bioterrorist Threat" on May 15, 2003. The House Select Committee on Homeland Security Subcommittee on Emergency Preparedness and Response and the Subcommittee on Intelligence and Counterterrorism held a joint hearing on "Does the Homeland Security Act of 2002 Give the Department the Tools It Needs To Determine Which Bio-Warfare Threats Are Most Serious?" on June 5, 2003. On June 6, 2003 the House Select Committee on Homeland Security held a hearing on "Bioshield: Lessons from Current Efforts To Develop Bio-Warfare Countermeasures."

Committee Reports and Amendments. The House Committee on Energy and Commerce reported H.R .2122 (H.Rept. 108-147, Part 1) on June 10, 2003. The House Committee on Armed Services discharged H.R. 2122 on June 11, 2003. The House Committee on Government Reform reported H.R. 2122 with amendments on June 12, 2003 (see H.Rept. 108-147, Part 2). The House Select Committee on Homeland Security reported H.R. 2122 with amendments on July 8, 2003 (see H.Rept. 108-147, Part 3). The version reported by the House Select Committee on Homeland Security is the version that passed the House. In the comparison charts below, this is the version referred to as "H.R. 2122 as Passed by the House."

Floor Action. The House of Representatives passed H.R. 2122 on July 16, 2003 (421-2). The House passed S. 15 on July 14, 2004 (414-2).

Presidential Action. S. 15 was signed into law by President Bush on July 21, 2004 (P.L. 108-276).

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[8] U.S. Congress, *Project BioShield Act of 2003: H.Rept. 108-147 Part I*, 108th Congress, first session, pp. 20-21.

Related Legislation. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90, enacted October 1, 2003) appropriated $5.593 billion for FY2004-FY2013 to procure medical countermeasures against biological terror attacks. Of this amount, up to $890 million may be obligated in FY2004 and no more than $3.418 billion may be obligated through FY2008. The enactment of this law effectively resolved the funding differences that had been pending between S. 15 and H.R. 2122 at that time. S. 15 as reported by the Senate HELP Committee called for a permanent indefinite spending appropriation, while H.R. 2122 *authorized* a specific appropriation amount. P.L. 108-90 contained funding levels identical to those authorized in H.R. 2122. Although P.L. 108-90 specified that those funds were only for medical countermeasures against biological terror attacks, the Project BioShield Act of 2004 (P.L. 108-276) changed this to allow countermeasures against chemical, biological, radiological, and nuclear terrorism.

The National Defense Authorization Act for Fiscal Year 2004 (P.L. 108-136, enacted November 24, 2003) contained some Department of Defense-related language similar to that found in S. 15 as reported by the Senate HELP Committee and H.R. 2122. It gave the Secretary of Defense some authorities similar to those given to the Secretary of Health and Human Services by the Project BioShield Act of 2004. These new authorities relate to the hiring of biomedical countermeasure consultants, the procurement of biomedical countermeasures, and the emergency use of unapproved countermeasures for the military. The Defense Secretary's authorities relate to Department of Defense programs and military personnel, whereas the HHS Secretary's authorities relate to HHS programs and to civilian populations.

The Consolidated Appropriations Act, 2004 (P.L. 108-199, enacted January 23, 2004), reduced the funds available for obligation in FY2004 from $890 million to $885 million.

Comparison of the Bills

All of the Project BioShield-related legislative proposals shared the same goal of increasing the development and purchase of biomedical countermeasures for the SNS. Each also largely reflected the Administration's proposals on a broad scale. However, Congress, through its deliberative process, changed many of the details in each bill.

Similarities. These bills shared many provisions. Each would have provided expedited hiring, procurement, and grant awarding procedures for bioterrorism-related products and services. These provisions were designed to make it easier for HHS to quickly commit substantial funds to biomedical countermeasure projects. Each bill would have provided a market guarantee for countermeasure producers by allowing the HHS Secretary to contract to procure countermeasures still in development. Thus, several years before a company plans to be able to deliver a countermeasure, the company would be assured that if they successfully develop the countermeasure the government is obligated to purchase a set amount of it at a set price. Under each bill, the manufacturing company can only receive payment upon countermeasure delivery, with some minor exceptions. Each bill would have authorized the HHS Secretary to allow the emergency use of countermeasures that lack FDA approval.

Differences.

Funding. The largest difference among the bills was the difference in funding mechanism. S. 15 as reported by the Senate HELP Committee would have granted a permanent, indefinite appropriation for purchasing countermeasures to be spent at the President's discretion. This mandatory funding, which was also part of the original Administration proposal, would not be subject to the annual appropriations process. The Administration predicted that it would spend approximately $5.6 billion for FY2004-FY2013 for BioShield-related countermeasure procurement. The Congressional Budget Office estimated that approximately $8.1 billion would be spent over that time period.[9]

H.R. 2122, S. 1504, and S. 15 as amended and enacted authorize specific funding for the program but do not appropriate funds. All three of these authorize the exact appropriation amounts found in the Department of Homeland Security Appropriation Act, 2004 (P.L. 108-90) that was passed while the Project BioShield legislation was under consideration. There were minor differences in the mechanisms of funding between H.R. 2122 and S. 1504. S. 15 as enacted adopted the H.R. 2122 mechanism.

SNS Transfer. Congress created the National Pharmaceutical Stockpile (NPS), the forerunner to the SNS, in the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105-277). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) essentially redesignated the NPS as the SNS and listed specific requirements regarding SNS management and maintenance. The Homeland Security Act of 2002 (P.L. 107-296) transferred the SNS program to the Department of Homeland Security. S. 15 as enacted transferred the SNS back to HHS. This provision was not in any of the other bills.

Countermeasure Qualifications. The bills differed in which countermeasures qualify for procurement under Project BioShield. S. 15 as reported by the Senate HELP Committee and S. 1504 would have excluded any countermeasure that has a significant market other than as a countermeasure. H.R. 2122 and S. 15 as enacted allow the purchase of countermeasures even if they have other significant markets. This change may encourage the development of countermeasures that can protect against more than one agent, such as new wide-spectrum antibiotics. Such products are more likely to have other commercial applications and markets. Thus, while very desirable for the SNS, they would have been excluded from Project BioShield funding under S. 15 as reported and S. 1504.

S. 15 as reported by the Senate HELP Committee and S. 1504 required that products be likely to have FDA approval within five years. H.R. 2122 required that countermeasures be likely to be approved sometime in the future. S. 15 as enacted requires that countermeasures be likely to be approved within eight years. The enacted language will allow the HHS Secretary to contract to purchase

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[9] U.S. Congress. *Cost Estimate: S. 15 Project BioShield Act of 2003*. Congressional Budget Office. May 7, 2003.

countermeasures that are earlier in the development process than would the other Senate versions, but not as early as H.R. 2122 would have allowed.

H.R. 2122, S. 1504, and S. 15 as reported by the Senate HELP Committee specify that countermeasures should be deliverable within five years. S. 15 as enacted specifies that countermeasures should be deliverable within eight years.

HHS Countermeasure Development Program. H.R. 2122 would have authorized the HHS Secretary to "initiate and sustain a program that results in the delivery of priority countermeasures for placement in the stockpile." This provision would have allowed the government to directly develop countermeasures. This could be done through several mechanisms including government owned-government operated (GO-GO) facilities or government owned-contractor operated (GO-CO) facilities. This provision was not included in S. 15 as enacted.

Patient Protection during Emergencies. S. 1504 and S. 15 as enacted grant the HHS Secretary authority, during a national emergency, to temporarily waive or modify some patient protection provisions of the Social Security Act and the Public Health Security and Bioterrorism Preparedness Act of 2002. These provisions concern patient privacy and which hospitals patients can be directed to or away from pursuant to a state emergency plan. H.R. 2122 and S. 15 as reported by the Senate HELP Committee lacked this provision.

DHS Terrorism Analyst Hiring. H.R. 2122 and S. 15 as enacted authorize appropriations to hire more biological and chemical terrorism analysts in the Department of Homeland Security's Directorate for Information Analysis and Infrastructure Protection (IAIP). They also authorize appropriations to acquire and deploy facilities that permit the Undersecretary of IAIP to access all classified information to which he is entitled. S. 15 as reported by the Senate HELP Committee and S. 1504 lacked similar provisions.

Other Differences. Several other notable differences, including reporting and recordkeeping requirements, are detailed the tables below. The italics in the tables highlight language differences between the bills.

Table 1. Short Title

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Short Title	**Sec. 1** "Project BioShield Act of 2003."	**Sec. 1** Same as S. 15 as Reported by Committee.	**Sec. 1** Same as S. 15 as Reported by Committee	**Sec. 1** "Project BioShield Act of *2004*."	

Note: Italics highlight language differences between the bills.

Table 2. New Health and Human Services Secretary Authorities for Countermeasure Research and Development

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Amendment to the Public Health Services Act	**Sec. 2** Amends *Part B of title IV* of the Public Health Service Act (PHSA, 42 U.S.C. *284 et seq.*) by *adding "Sec. 409J Biomedical Countermeasure Research and Development."*	**Sec. 2** Amends *Part B of title III* of the PHSA, (42 U.S.C. *243 et seq.*) by *inserting "Sec. 319F-1 Authority for Use of Certain Procedures Regarding Biomedical Countermeasure Research and Development Activities."*	**Sec. 2** Same as S. 15 as Reported by Committee.	**Sec. 2** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Defining Counter-measures	**Sec. 2 (a) "Sec. 409J (g)"** Defines a qualified countermeasure as a drug (as that term is defined by *section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)))*, biological product (*as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i)))*, or device *(as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)))* that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to —	**Sec. 2 (a) "Sec. 319F-1 (a)(2)" and Sec. 2 (e)** Defines qualified countermeasure as a priority countermeasure (as defined in section 319F(h) and as determined by the Secretary in accordance with such section and consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) *against a* chemical, biological, radiological, or nuclear agent that may cause a public health emergency affecting national security.	**Sec. 2 (a) "Sec. 409J (g)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (a)(2)" and Sec. 2 (d)** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Defining Counter-measures (continued)		**Sec. 2 (e)** Defines a countermeasure as a drug, biological product, device, *vaccine, vaccine adjuvant, antiviral, or diagnostic test* that can be used to —	**Sec. 2 (a) "Sec. 409J (g)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (d)** Same as H.R. 2122.	
	(A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or	(1) to treat, identify, *or prevent infection by a biological agent or toxin* or harm from any other agent that may cause a public health emergency; or	Same as S. 15 as Reported by Committee.	Same as H.R. 2122.	
	(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a *drug, biological product, or device that is used as described in subparagraph* (A).	(2) to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by the administering of a *countermeasure described in* (1).	Same as H.R. 2122.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Lead Institute	**Sec. 2 (a) "Sec. 409J (a)(2)"** The Director of the National Institutes of Health (NIH) shall carry out these authorities. The National Institute of Allergy and Infectious Diseases (NIAID) shall be the lead institute within NIH for performing, administering, or supporting biomedical countermeasure research and development. The NIH Director may delegate to the NIAID Director authorities as are necessary to carry out this function. The HHS Secretary may authorize the NIH Director to work through any national research institute.	No similar provision.	**Sec. 2 (a) "Sec. 409J (a)(2)"** Same as S. 15 as Reported by Committee.	No similar provision.	
Interagency Cooperation	**Sec. 2 (a) "Sec. 409J (a)(3)"** Authorizes the HHS Secretary to enter into interagency agreements for countermeasure research and development *and to use other HHS agencies.*	**Sec. 2 (a) "Sec. 319F-1 (a)(3)"** Authorizes the HHS Secretary to enter into interagency agreements for countermeasure research and development.	**Sec. 2 (a) "Sec. 409J (a)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (a)(3)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Facility Availability to the Secretary	**Sec. 2 (a) "Sec. 409J (a)(2)(D)"** HHS Secretary can make funding for countermeasure research and development facilities dependent on allowing future emergency use of facilities by the Secretary.	**Sec. 2 (a) "Sec. 319F-1 (a)(4)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (a)(2)(D)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (a)(4)"** Same as S. 15 as Reported by Committee.	
Export Controls	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (a)(5)"** Each award agreement must state that any products developed with BioShield funding must comply with export-related controls.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (a)(5)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Expedited Procure-ment Authority	**Sec. 2 (a) "Sec. 409J (b)(1)"** (A) Procurements less than $25 million for property or services related to pressing countermeasure research and development needs can follow simplified acquisition regulations.	**Sec. (a) "Sec. 319F-1 (b)(1)"** (A) Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (b)(1)"** (A) Same as S. 15 as Reported by Committee.	**Sec. (a) "Sec. 319F-1 (b)(1)"** (A) Same as S. 15 as Reported by Committee.	Maximum would otherwise be $100,000.
	No similar provision.	(B) These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, and the Anti-Kickback Act (21 U. S. C. 57(a) and (b).	(B) These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, the Anti-Kickback Act, *bonds of contractors of public buildings, limits on subcontractor sales, middlemen fees, and veterans' employment reporting requirements.*	(B)These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, the Anti-Kickback Act, *bonds of contractors of public buildings, middlemen fees solid waste disposal, and veterans' employment reporting requirements.*	
	(B) Appropriate internal controls shall be developed for the use of this authority.	(C) Same as S. 15 as Reported by Committee.	(C) Same as S. 15 as Reported by Committee.	(C) Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Expedited Procure-ment Authority (continued)	**Sec. (a) "Sec. 409J (b)(2)"** Authorizes the use of "other than competitive procedures" in awarding contracts if that which is being procured is available from a limited number of responsible sources *and no other type of property or services will meet the need.*	**Sec. 2 (a) "Sec. 319F-1 (b)(2)"** Authorizes the use of "other than competitive procedures" in awarding contracts if that which is being procured is available from a limited number of responsible sources.	**Sec. (a) "Sec. 409J (b)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (b)(2)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Expedited Procure-ment Authority (continued)	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (b)(2)(C)"** Awards must comply with government-wide regulations, including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (b)(2)(C)"** Awards must comply with government-wide regulations (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered) *as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency 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 needs of the agency.*	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Expedited Procure-ment Authority (continued)	**Sec. 2 (a) "Sec. 409J (b)(3)"** Procurements less than $15,000 for property or services related to pressing countermeasure research and development needs can follow micropurchase regulations. Appropriate internal controls shall be developed for the use of this authority. Government purchase card preferences do not apply to these purchases if they are greater than $2,500.	**Sec. 2 (a) "Sec. 319F-1 (b)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (b)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (b)(3)"** Same as S. 15 as Reported by Committee.	Micro-purchase maximum would otherwise be $2,500.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contesting Decisions Made Under These Authorities	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (b)(4)"** Notwithstanding *any other provision of law*, contracting agency decisions relating to countermeasure research and development procurement can be reviewed by filing a protest with the contracting agency or the Comptroller General. If there is a written finding that a review-related delay would harm the United States, the decision to make the award or procurement is committed to agency discretion.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (b)(4)"** Notwithstanding *28 U.S.C.18(f), 28 U.S.C. 1491 subsection (f), and 31 U.S.C. 3556*, contracting agency decisions relating to countermeasure research and development procurement can be reviewed by filing a protest with the contracting agency or the Comptroller General. If there is a written finding that a review-related delay would harm the United States, the decision to make the award or procurement is committed to agency discretion.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Expedited Peer Review	**Sec. (a) "Sec. 409J (c)"** Allows the HHS Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts, and cooperative agreements less than $1.5 million related to biomedical countermeasure R&D activity, if the Secretary deems there is a pressing need for an expedited award.	**Sec. 2 (a) "Sec. 319F-1 (c)(1)"** Same as S. 15 as Reported by Committee.	**Sec. (a) "Sec. 409J (c)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (c)(1)"** Same as S. 15 as Reported by Committee.	
	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (c)(2)"** Determination of whether to employ expedited peer review with respect to subsequent awards shall be determined without regard to the peer review procedures used for any prior peer review of that same award.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (c)(2)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Agency Facilities	**Sec. 2(a) "Sec. 409J (d)"** HHS Secretary may acquire, lease, construct, improve, renovate, remodel, repair, operate, and maintain laboratories, other research facilities and equipment, and other real or personal property as the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasure research and development.	No similar provision.	**Sec. 2(a) "Sec. 409J (d)"** Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Personal Services Contracts	**Sec. 2 (a) "Sec. 409J (e)(1)"** Authorizes the HHS Secretary to enter into personal services contracts with up to 30 experts or consultants with no limit on period of service.	**Sec. 2 (a) "Sec. 319F-1 (d)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (e)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (d)"** Same as S. 15 as Reported by Committee.	
	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (d)(1)"** Pay cannot exceed that of the U. S. President.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (d)(1)"** Same as H.R. 2122.	
	Sec. 2 (a) "Sec. 409J (e)(2)" These contractors are treated as employees of HHS for Federal Tort Claims Act purposes.	**Sec. 2 (a) "Sec. 319F-1 (d)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (e)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (d)(2)"** Same as S. 15 as Reported by Committee.	
	Sec. 2 (a) "Sec. 409J (e)(3)" Internal controls for this authority will be implemented.	**Sec. 2 (a) "Sec. 319F-1 (d)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (e)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (d)(3)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Personal Services Contracts (continued)	**Sec. 2 (a) "Sec. 409J (e)(2)(C)"** The United States has the right to sue these contractors to recover payments (and litigation costs) made to any claimant stemming from the job-related gross misconduct of these contractors. The venue for this action will be in the district court of the United States in which such contractor resides or has its principal place of business.	No similar provision.	**Sec. 2 (a) "Sec. 409J (e)(2)(C)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (d)(2)(C)"** Same as S. 15 as Reported by Committee.	
Streamlined Personnel Authority	**Sec. 2 (a) "Sec. 409J (f)"** The HHS Secretary may appoint up to 30 professional and technical employees to help NIH respond to pressing qualified countermeasure research and development needs without regard to provisions governing appointments in the competitive service or pay rates.	**Sec. 2 (a) "Sec. 319F-1 (e)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (f)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (e)(1)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Streamlined Personnel Authority (continued)	No similar provision.	No similar provision.	No similar provision.	**Sec. 2 (a) "Sec. 319F-1 (e)(2)"** (A) Recruitment and appointments must be based solely on the individual's abilities, knowledge, and skills.	
	No similar provision.	No similar provision.	**Sec. 2 (a) "Sec. 409J (f)(2)"** Provisions in U.S.C. title 5 relating to merit system principles, prohibited personnel practices and preference eligibility apply to these appointments.	(B) Same as S. 1504.	These U.S.C. provisions include protections regarding discrimin-ation on the basis of political affiliation, race, color, religion, national origin, sex, marital status, age, or handicap. This section of U.S. Code prohibits appointment of relatives.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Streamlined Personnel Authority (continued)	**Sec. 2 (a) "Sec. 409J (f)(2)"** Internal controls for this authority will be implemented.	**Sec. 2 (a) "Sec. 319F-1 (e)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 409J (f)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (e)(3)** Same as S. 15 as Reported by Committee.	
Actions Committed to Agency Discretion	**Sec. 2 (a) "Sec. 409J (h)"** All actions by the HHS Secretary under the authority of this section are committed to agency discretion.	**Sec. 2 (a) "Sec. 319F-1 (f)"** All actions by the HHS Secretary under the authority of this section are committed to agency discretion, *except those deemed reviewable under Sec. 319F-1 (b)(4).*	**Sec. 2 (a) "Sec. 409J (h)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (f)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Technical Amendment	**Sec. 2 (b).** (1) Amends the PHSA (42 U.S.C. 287a-2) to allow the Director of NIH to work through the Director of NIAID to fund public or nonprofit entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities. Increases the federal share from 50% to 75% for NIAID funded projects and from 40% to 75% of costs associated with NIAID use for multipurpose facilities. No similar provision.	**Sec. 2 (b).** (1) Same as S. 15 as Reported by Committee. (2) Authorizes such sums as may be necessary for *FY2003 and FY2004* to fund these improvements.	**Sec. 2 (b).** Same as S. 15 as Reported by Committee. No similar provision.	**Sec. 2 (b).** (1) Same as S. 15 as Reported by Committee. (2) Authorizes such sums as may be necessary for *FY2004 and FY2005* to fund these improvements.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
HHS Program to Develop Counter — measures	No similar provision.	**Sec. 2 (c)** The HHS Secretary may initiate and sustain a program that results in the delivery of priority countermeasures for placement in the Strategic National Stockpile (SNS). Authorizes the appropriation of such sums as may be necessary for each of the fiscal years 2004 through 2013.	No similar provision.	No similar provision.	
National Vaccine Program	No similar provision.	**Sec. 2 (d)** Authorizes the appropriation of such sums as may be necessary for each of the fiscal years 2004 through 2013 for the National Vaccine Program.	No similar provision.	No similar provision.	
Technical Amendment	No similar provision.	**Sec. 2 (e)** Amends the PHSA to add the Secretary of Homeland Security to the working group on the preparedness, prevention, and response to bioterrorism and other public health emergencies.	No similar provision.	**Sec. 2 (d)** Same as H.R. 2122.	

Table 3. Biomedical Countermeasures Procurement

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
	Sec. 3 Amends PHSA by adding *Sec. 319A-1.*	**Sec. 3** Amends PHSA by adding *Sec. 319F-2.*	**Sec. 3** Same as S. 15 as Reported by Committee.	**Sec. 3** Same as H.R. 2122.	
Transfer of Strategic National Stockpile Language	No similar provision.	**Sec. 3 (a)** Transfers and amends the section of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, 42 U.S.C. 300hh-12) dealing with the Strategic National Stockpile (SNS, Sec. 121) to the Public Health Services Act as section 319F-2.	No similar provision.	**Sec. 3 (a)** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Stockpile Manage-ment	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (a)(1)"** *DHS Secretary in coordination with HHS Secretary and VA Secretary* shall maintain the Strategic National Stockpile.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (a)(1)"** *HHS Secretary in coordination with DHS Secretary* shall maintain the Strategic National Stockpile.	S. 15 as Enacted transfers the SNS from DHS to HHS.
	No similar provision.	In managing the Stockpile DHS Secretary shall:	No similar provision.	Same as H.R. 2122.	
	No similar provision.	(A) consult with the Working Group on Bioterrorism defined in PHSA Sec. 319F (a);	No similar provision.	Same as H.R. 2122.	
	No similar provision.	(B) ensure adequate procedures for inventory management and accounting, and for the physical security of the stockpile;	No similar provision.	Same as H.R. 2122.	
	No similar provision.	(C) take into consideration the timing and location of special events;	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Stockpile Manage-ment (continued)	No similar provision.	(D) review and revise, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;	No similar provision.	Same as H.R. 2122.	
	No similar provision.	(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;	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Stockpile Manage-ment (continued)	No similar provision.	No similar provision.	No similar provision.	(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;	
	No similar provision.	No similar provision.	No similar provision.	(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and	
	No similar provision.	(F) ensure adequate stockpile physical security.	No similar provision.	(H)Same as H.R. 2122.	
Procure-ment Authority	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(1)(A)"** The special reserve fund defined in Sec. 319F-2 (c)(10) can be used to procure security countermeasures for the SNS.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(1)(A)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Definitions of Security Counter — measures and Qualified Counter — measures	**Sec. 3 "Sec. 319A-1 (h)(1)"** Defines a *qualified* countermeasure as a *biomedical* countermeasure for use against a CBRN agent identified as a material threat that is approved or cleared by the Food and Drug Administration (FDA) or a biological product licensed by the HHS Secretary under 42 U.S.C. 262,	**Sec. 3 (a) "Sec. 319F-2 (c)(1)(B)"** Defines a *security* countermeasure as a *priority* countermeasure against a CBRN agent identified as a material threat, *that is determined to be a necessary countermeasure under 391F-2(c)(2)(B)*, and is approved or cleared by the Food and Drug Administration (FDA) or a biological product licensed by the HHS Secretary under 42 U.S.C. 262,	**Sec. 3 (a) "Sec. 319A-1 (h)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(1)(B)"** Defines a *security* countermeasure as a *drug, biological product, or device* countermeasure against a CBRN agent identified as a material threat, *that is determined to be a necessary countermeasure under 391F-2(B)(ii)*, and is approved or cleared by the Food and Drug Administration (FDA) or a biological product licensed by the HHS Secretary under 42 U.S.C. 262,	H.R. 2122's definition of a priority counter-measure is from Sec. 319F(h) of the Public Health Service Act.
	or is a *priority* countermeasure for which the HHS Secretary determines that sufficient and satisfactory clinical experience or research data support a reasonable conclusion that the countermeasure will qualify for approval or licensing within *five years*.	or is a *priority* countermeasure for which the HHS Secretary determines that sufficient and satisfactory clinical experience or research data support a reasonable conclusion that the countermeasure will qualify for approval or licensing *in the future*,	Same as S. 15 as Reported by Committee.	or is a countermeasure for which the HHS Secretary determines that sufficient and satisfactory clinical experience or research data support a reasonable conclusion that the countermeasure will qualify for approval or licensing within *eight years*,	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Definitions of Security Counter — measures and Qualified Counter — measures (continued)	No similar provision.	or is authorized for emergency use by the HHS Secretary.	No similar provision.	Same as H.R. 2122.	
Determination of Material Threat	**Sec. 3 "Sec. 319A-1 (a)(1)"** Requires the DHS Secretary to determine, on an ongoing basis, which CBRN agents pose a material *risk of use against the U.S. population*.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(A)"** Requires the DHS Secretary to determine, on an ongoing basis, which CBRN agents pose a material *threat.*	**Sec. 3 "Sec. 319A-1 (a)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(A)"** Same as H.R. 2122.	
Determination of Public Health Impact	**Sec. 3 "Sec. 319A-1 (a)(2)(A)"** Requires the HHS Secretary, *in consultation with the DHS Secretary*, to determine the public health consequences of use of any of the agents identified by the DHS Secretary to pose a material threat, and to determine the agents for which priority countermeasures are necessary to protect the public health from a material threat.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(B)"** Requires the HHS Secretary to determine the public health consequences of use of any of the agents identified by the DHS Secretary to pose a material threat, and to determine the agents for which priority countermeasures are necessary to protect the public health from a material threat.	**Sec. 3 "Sec. 319A-1 (a)(2)(A)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(B)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Notification to Congress	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(C)"** The DHS and HHS Secretaries will notify Congress when any material threat, public health impact, or necessary countermeasure determination is made. *Such notice shall be in unclassified or, if necessary classified form.*	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(C)"** The DHS and HHS Secretaries will notify Congress when any material threat, public health impact, or necessary countermeasure determination is made.	
Assuring Access to Threat Information	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(D)"** All information to which the DHS Secretary is entitled, regardless of classification level, will be used in making material threat determinations.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(2)(D)"** Same as H.R. 2122.	
Assessment of Availability and Appro-priateness of Counter — measures	**Sec. 3 "Sec. 319A-1 (b)"** The HHS Secretary, in consultation with the DHS Secretary, shall assess the availability and appropriateness of countermeasures to address identified material threats.	**Sec. 3 (a) "Sec. 319F-2 (c)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (b)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(3)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Call for Development of Counter — measures	**Sec. 3 "Sec. 319A-1 (c)(1)"** If a countermeasure is found appropriate but not available, the DHS and HHS Secretaries may jointly submit, for presidential approval, a call for the development of such countermeasure and a commitment to recommend the procurement of the first developed appropriate countermeasure.	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(A)"** If a countermeasure is found appropriate but not available *or available but cleared only for alternative purposes*, the DHS and HHS Secretaries may jointly submit, for presidential approval, a call for the development of such countermeasure and a commitment to recommend the procurement of the first developed appropriate countermeasure, *using the fund created by Sec. 319-F(c)(10).*	**Sec. 3 "Sec. 319A-1 (c)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(A)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Counter — measure Specifica-tions	**Sec. 3 "Sec. 319A-1 (b)(2)"** The HHS and DHS Secretaries will, to the extent practicable, include in the proposal the estimated quantity and price of the future purchase, necessary measures of minimum safety and effectiveness, and any other information necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for it.	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(B)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (b)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(B)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Notifying Potential Developers	**Sec. 3 "Sec. 319A-1 (c)(3)"** If the President approves a proposal the DHS and HHS Secretaries shall make known to persons who may respond to a call for the countermeasure involved —	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(C)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (c)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(4)(C)"** Same as S. 15 as Reported by Committee.	
	the call for the countermeasure;	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	the required specifications for the countermeasure; and	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	a commitment *for a recommendation for procurement of the first such specific countermeasure that meets the conditions for procurement under subsection (d) and the specifications under Sec. 3 "Sec. 319A-1 (d)(2)"* [see below]	*the* commitment *described in Sec. 3 (a) "Sec. 319F-2 (c)(4)(A)"* [see above]	Same as S. 15 as Reported by Committee.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Secretary's Determination of Counter—measures Appropriate for Funding	**Sec. 3 "Sec. 319A-1 (d)(1)"** The HHS Secretary, in consultation with the DHS Secretary, will determine if specific countermeasures are appropriate for procurement using the *appropriations specified in Sec. 319A-1 (i).*	**Sec. 3 (a) "Sec. 319F-2 (c)(5)(A)"** The HHS Secretary, in consultation with the DHS Secretary, will determine if specific countermeasures are appropriate for procurement using the *special reserve fund defined in Sec. 319F-2 (c)(10).*	**Sec. 3 "Sec. 319A-1 (d)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(5)(A)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Secretary's Determination of Counter — measures Appropriate for Funding (continued)	**Sec. 319A-1 (d)(2).** For countermeasures to qualify for this funding the HHS Secretary *must determine*:	**Sec. 319F-2 (c)(5)(B).** In making this determination the HHS Secretary *will determine and consider*:	**Sec. 319A-1 (d)(2).** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(5)(B)"** Same as H.R. 2122.	Both H.R. 2122 and S. 15 as Enacted require the Secretary only to consider whether products have other significant markets. This allows procurement of products that have another market.
	(B)(i) quantities of the product that will be needed for the SNS,	(i) Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	(i) Same as S. 15 as Reported by Committee.	
	(B)(ii) feasibility of delivery of sufficient quantities within *five* years, and	(iii) Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	(ii) feasibility of delivery of sufficient quantities within *eight* years, and	
	(C) *that there is no* significant commercial market for the product, at the time of *this determination,* other than as a countermeasure. *This must be annually redetermined.*	(*iii) whether there is a lack of* a significant commercial market for the product at time of *procurement* other than as a countermeasure.	Same as S. 15 as Reported by Committee.	(iii) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Presidential Approval Required for Procure-ment	**Sec. 3. "Sec. 319A-1 (e)"** (1) If a countermeasure is deemed appropriate, the HHS and DHS Secretaries, in coordination with the Director of Office of Management and Budget, will submit to the President a proposal to procure the countermeasure.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)"** (A) If a countermeasure is deemed appropriate, the HHS and DHS Secretaries, in coordination with the Director of Office of Management and Budget, will submit to the President a proposal to procure the countermeasure *using the special reserve fund defined in Sec. 319F-2 (c)(10).*	**Sec. 3. "Sec. 319A-1 (e)"** Same as S.15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)"** Same as S.15 as Reported by Committee.	
	(2) Presidential approval is required to procure countermeasures under this act.	(B) Same as S. 15 as Reported by Committee.	Same as S.15 as Reported by Committee.	Same as S.15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Notice to Congress	**Sec. 3 "Sec. 319A-1 (e)(3)"** The DHS Secretary will notify *Congress* of each presidential decision to approve the procurement of countermeasures under this *act*.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(C)"** The HHS and DHS Secretaries will notify *designated congressional committees* of each presidential decision to approve the *use of the special reserve fund. This notice will include:*	**Sec. 3 "Sec. 319A-1 (e)(3)"** Same as S.15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(C)"** Same as H.R. 2122.	
	No similar provision.	an explanation of the decision to use the special reserve fund, the potential countermeasure supplier or suppliers (when available), and whether other potential suppliers were considered and reasons for any rejection of them.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Subsequent Specific Counter — measures	**Sec. 3 "Sec. 319A-1 (c)(4)"** Countermeasures developed after a procurement can also be procured under this act if they represent an improvement over the original countermeasure. Examples of qualifying improvements are better safety or effectiveness. No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(D)"** Same as S.15 as Reported by Committee. Determination of an improvement is committed to agency discretion.	**Sec. 3 "Sec. 319A-1 (c)(4)"** Same as S.15 as Reported by Committee. No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(D)"** Same as S.15 as Reported by Committee. Same as H.R. 2122.	
Rule of Con-struction	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(E)"** Recommendations and approvals under Sec. 319F-2 (c)(6) are to the determination that the special reserve fund will be used for a procurement; not to the substance of contracts nor other matters relating to awards.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(6)(E)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Interagency Agreements for Procurement	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(A)-(B)"** The DHS Secretary will reimburse the HHS Secretary for all costs of presidentially approved countermeasure procurements.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(A)-(B)"** Same as H.R. 2122.	
	Sec. 3 "Sec. 319A-1 (i)(2)(C)" Funds *appropriated under this subsection* cannot be used for administrative costs.	However, *the special reserve fund* cannot be used to reimburse administrative costs.	Same as S. 15 as Reported by Committee.	Same as H.R. 2122.	
Procurement	**Sec. 3 "Sec. 319A-1 (f)(1)"** The HHS Secretary is responsible for arranging for countermeasure procurement, including negotiating terms of (including quantity, production schedule, and price), and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required.	**Sec 3 (a) "Sec. 319F-2 (c)(7)(C)(i)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (f)(1)"** Same as S. 15 as Reported by Committee.	**Sec 3 (a) "Sec. 319F-2 (c)(7)(C)(i)"** Same as S. 15 as Reported by Committee.	
	The HHS Secretary will promulgate any regulations necessary to implement these procurement provisions.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contract Terms	**Sec. 3 "Sec. 319A-1 (f)(2)"** The procurement contracts will include the following terms:	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(ii)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (f)(2)"** Same as S. 15 as Reported by Committee.	**Sec 3 (a) "Sec. 319F-2 (c)(7)(C)(ii)"** Same as S. 15 as Reported by Committee.	
	Payment conditioned on delivery of a substantial portion of the number of contracted units.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	No similar provision.	Up to a 10% advance payment to ensure success of a project can be made at the discretion of HHS Secretary. This advance payment must be refunded if the contractor fails to perform under the terms of the contract *except in special circumstances as determined by the Secretary*.	No similar provision.	Up to a 10% advance payment to ensure success of a project can be made at the discretion of HHS Secretary. This advance payment must be refunded if the contractor fails to perform under the terms of the contract.	
	The contract period cannot be longer than five years.	The contract period cannot be longer than five years, *or up to eight years if the HHS Secretary determines at the time of initial award that a longer period is justified.*	Same as S. 15 as Reported by Committee.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contract Terms (continued)	Contracts may be renewed for additional periods of up to five years each.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	No similar provisions.	The vendor must comply with all applicable export-related controls.	No similar provisions.	Same as H.R. 2122.	
	The vendor must seek approval, clearance or licensing of product. The HHS Secretary may waive this provision.	No similar provisions.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contract Terms (continued)	The contract may specify:	The contract may specify:	The contract may specify:	The contract may specify:	
	That the vendor must store the countermeasure. In this case the special fund can be used to pay the vendor for the costs of shipping, handling, storage and related costs of the countermeasure	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	a discounted price for a product that has not been licensed or approved at the time of delivery, and	No similar provision.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	that the HHS Secretary may terminate the contract for the failure to deliver a reasonable number (as determined by the Secretary) of units of product by three years after the contract commenced.	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Availability of Simplified Acquisition Procedures	**Sec. 3 "Sec. 319A-1 (f)(3)"** Simplified acquisition procedures will apply to *all countermeasure procurements under this section.*	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(iii)(I)"** Simplified acquisition procedures will apply to countermeasure procurements *for which the HHS Secretary determines that there is pressing need.*	**Sec. 3 "Sec. 319A-1 (f)(3)"** Same as S. 15 as Reported by Committee.	**Sec 3 (a) "Sec. 319F-2 (c)(7)(C)(iii)(I)"** Same as H.R. 2122.	
	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(iii)(II)"** These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, and the Anti-Kickback Act.	**Sec. 3 "Sec. 319A-1 (f)(3)(B)"** These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, the Anti-Kickback Act, *bonds of contractors of public buildings, limits on subcontractor sales, middlemen fees, and veterans' employment reporting requirements.*	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(iii)(II)"** These purchases must comply with laws and regulations relating to contract work hours and safety standards, examination of contractor records, the Anti-Kickback Act, *bonds of contractors of public buildings, middlemen fees, the Solid Waste Disposal Act, and veterans' employment reporting requirements.*	
	No similar provision.	No similar provision.	No similar provision.	**Sec 3 (a) "Sec. 319F-2 (c)(7)(C)(iii)(III)"** The Secretary shall establish appropriate internal controls for procurements under this clause.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Authority to Limit Competition	No similar provision.	No similar provision.	No similar provision.	**Sec. 3 (a) “”Sec. 319F-2 (c)(7)(C)(iii)(IV)”** If the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired by fair and open competition, the Secretary may conduct a procurement using other than fair and open competition.	
Use of Procedures Other than Full and Open Competition	**Sec. 3 “Sec. 319A-1 (f)(4)**” Authorizes the use of *noncompetitive* procedures to procure a product available from a limited number of responsible sources.	**Sec. 3 (a) “Sec. 319F-2 (c)(7)(C)(iv)”** Authorizes the use of *other than competitive* procedures to procure a product available from a limited number of responsible sources.	**Sec. 3 “Sec. 319A-1 (f)(4)**” Same as S. 15 as Reported by Committee.	**Sec. 3 (a) “Sec. 319F-2 (c)(7)(C)(iv)”** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Use of Procedures Other than Full and Open Competition (continued)	No similar provision.	The Secretary shall implement this clause in accordance with government-wide regulations including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.	No similar provision.	The Secretary shall implement this clause in accordance with government-wide regulations including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered, *as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency 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 needs of the agency.*	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Premium Provision in Multiple Award Contracts	**Sec. 3 "Sec. 319A-1 (f)(5)"** The HHS Secretary may enter into contracts for a single countermeasure with more than one vendor. In these cases contracts may be constructed to award a greater share of the procurement to the first vendor to successfully meet the terms of the contract. Determinations of the success of meeting all of the requirements by the HHS Secretary are committed to agency discretion.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(v)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (f)(5)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(v)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	
Extension of Closing Date for Receipt of Proposals is not Reviewable	**Sec. 3 "Sec. 319A-1 (f)(6)"** A decision by the HHS Secretary to extend the closing date for receipt of proposals for a procurement is committed to agency discretion.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(vi)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (f)(6)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(vi)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Limiting Competition to Sources Responding to Information Requests	**Sec. 3 "Sec. 319A-1 (f)(7)"** The HHS Secretary may stipulate that all potential sources must provide, on request, information that would allow the HHS to use advance procurement planning or market research. Vendors who do not provide such information can be excluded from consideration.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(vii)"** Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (f)(7)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(7)(C)(vii)"** Same as S. 15 as Reported by Committee.	
Interagency Agreements	**Sec. 3 "Sec. 319A-1 (g)"** HHS and DHS Secretaries may enter into interagency agreements with other federal agencies to facilitate procuring these countermeasures. Only the DHS and HHS Secretaries may exercise the authorities provided by this section.	**Sec. 3 (a) "Sec. 319F-2 (c)(8)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 3 "Sec. 319A-1 (g)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(8)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Restrictions on Use of Funds	**Sec. 3 "Sec. 319A-1 (i)(2)"** *Amounts appropriated under this Act* cannot be used to pay for:	**Sec. 3 (a) "Sec. 319F-2 (c)(9)"** The *special reserve fund* cannot be used to pay for:	**Sec. 3 "Sec. 319A-1 (i)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 3 (a) "Sec. 319F-2 (c)(9)"** Same as H.R. 2122.	
	(A) vaccines under procurement contracts entered into before *January 1, 2003,* or	(A) vaccines under procurement contracts entered into before the *enactment of this Act* or	Same as S. 15 as Reported by Committee.	Same as H.R. 2122.	
	(B) new contracts or obligations for procuring a countermeasure after a determination that it has significant commercial market other than as a countermeasure and;	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	
	(C) *administrative* costs.	(B) Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	(B) costs *other than payments made by the Secretary to a vendor for a procurement of a security countermeasure under Sec. 319F-2 (c)(7).*	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Definitions	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(10)(A)"** Special reserve fund in this section has the same meaning as special reserve fund in Sec. 510 of the Homeland Security Act of 2002 (6 U.S.C. 311 et seq.)	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (c)(10)(A)"** Same as H.R. 2122.	
	No similar provision.	Designates specific congressional committees for reporting purposes: In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee). In the Senate: *the Committee on Health, Education, Labor, and Pensions, the Committee on Appropriations, and the Committee on Government Affairs.*	No similar provision.	Designates specific congressional committees for reporting purposes: Same as H.R. 2122. In the Senate: *the appropriate committees*.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Definitions (continued)	**Sec. 3 "Sec. 319A-1 (h)(2)"** Defines *biomedical* countermeasure as a drug, biological product, or device used:	**Sec. 2 (e).** The PHSA, as modified by this legislation, defines a countermeasure as a drug, biological product, device, *vaccine, vaccine adjuvant, antiviral, or diagnostic test* that can be used	**Sec. 3 "Sec. 319A-1 (h)(2)"** Same as S. 15 as Reported by Committee.	**Sec. 2 (a) "Sec. 319F-1 (a)(2)" and Sec. 2 (d)** Same as S. 15 as Reported by Committee.	
	(1) to treat, identify, or prevent harm from any CBRN agent that may cause a public health emergency *affecting national security*; or	(1) to treat, identify, *or prevent infection by a biological agent or toxin* or harm from any other agent that may cause a public health emergency; or	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	(2) to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by the administering of a countermeasure described in (1).	(2) Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Technical Amend-ments	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (d-f)"** These subsections make technical amendments required by the transfer of the SNS from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to the PHSA.	No similar provision.	**Sec. 3 (a) "Sec. 319F-2 (d-f)"** Same as H.R. 2122.	
Amendment to Homeland Security Act	No similar provision.	**Sec. 3 (b)** No similar provision. Adds to the Homeland Security Act of 2002 (P.L. 107-296, 6 U.S.C. 311 et seq.) "Sec. 510 Procurement of Security Countermeasures for the Strategic National Stockpile."	No similar provision.	**Sec. 3 (b)** (1) Amends Homeland Security Act (P.L. 107-296) to be consistent with the transfer of the Strategic National Stockpile to the direct control of the HHS Secretary. Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Appropriation Authorization	**Sec. 3 "Sec. 319A-1 (i)"** *Appropriates, out of any moneys in the Treasury not otherwise appropriated, for FY2003 and for each fiscal year thereafter, such sums as may be necessary for the costs incurred by the HHS Secretary in the procurement* of presidentially approved countermeasures.	**Sec. 3 (b) "Sec. 510 (a)"** *Authorizes the appropriation of up to $5.593 billion for FY2004-2013 for* presidentially approved countermeasures. Of this total, not more than $3.418 billion may be obligated for FY2004-2008 and not more than $890 million for FY2004. *This money goes into the special reserve fund as defined in Sec. 510 (b).*	**Sec. 3 "Sec. 319A-1 (i)"** *Authorizes the appropriation of up to $5.593 billion for FY2004-2013 for* presidentially approved countermeasures. Of this total, not more than $3.418 billion may be authorized for FY2004-2008 and not more than $890 million for FY2004.	**Sec. 3 (b) "Sec. 510 (a)"** Same as H.R. 2122. Same as H.R. 2122.	The 2004 DHS Appropriations Act (P.L. 108-90) appropriated $5.593 billion for FY2004-FY2013 for "Biodefense Countermeasures" with identical obligation constraints.
Definition of Special Reserve Fund	No similar provision.	**Sec. 3 (b) "Sec. 510 (b)"** Special reserve fund means the *appropriations account established as a result of* any appropriations made under Sec. 510 (a).	No similar provision.	**Sec. 3 (b) "Sec. 510 (b)"** Special reserve fund means the *"Biodefense Countermeasures" appropriations account or any other* appropriation made under Sec. 510 (a).	S. 15 as Enacted uses the identical language used in the 2004 DHS Appropriations Act.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Limits on Special Reserve Fund	No similar provision.	**Sec. 3 (b) "Sec. 510 (c)"** (1) It is the intent of the Congress that unobligated amounts in this fund will not be applied, through reprogramming or otherwise, to any other purpose.	No similar provision.	**Sec. 3 (b) "Sec. 510 (c)"** No similar provision.	
	No similar provision.	(2)Appropriations to the special reserve fund are available to be obligated through FY2013 and only for presidentially approved countermeasures.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Related Appropriation Authorizations	No similar provision.	**Sec. 3 (b) "Sec. 510 (d)(1)"** Authorizes the appropriation of *$5 million for FY2003* and such sums as may be necessary for FY2004-2006 for the hiring of Chemical, Biological, Radiological, and Nuclear (CBRN) threat assessment analysts within the DHS Directorate for Information Analysis and Infrastructure Protection (IAIP).	No similar provision.	**Sec. 3 (b) "Sec. 510 (d)(1)"** Authorizes the appropriation of such sums as may be necessary for FY2004-2006 for the hiring of CBRN threat assessment analysts within the DHS IAIP.	
	No similar provision.	**Sec. 3 (b) "Sec. 510 (d)(2)"** Authorizes the appropriation of such sums as may be necessary for *FY2003*-FY2006 for the acquisition and deployment of secure facilities to permit the DHS Secretary to receive (*by the end of 2003*) all classified information and products to which the Undersecretary for IAIP is entitled.	No similar provision.	**Sec. 3 (b) "Sec. 510 (d)(2)"** Authorizes the appropriation of such sums as may be necessary for *FY2004*-FY2006 for the acquisition and deployment of secure facilities to permit the DHS Secretary to receive (*not later than 180 days after enactment*) all classified information and products to which the Undersecretary for IAIP is entitled.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Stockpile Functions Transferred From DHS Secretary to HHS Secretary	No similar provision.	No similar provision.	No similar provision.	**Sec. 3 (c)** The functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile are transferred from the DHS Secretary to the HHS Secretary. Exceptions: Duties of the DHS Secretary described in this act and the "Biodefense Countermeasure" funds appropriated in the 2004 DHS Appropriations Act (P.L. 108-90) are not transferred.	

Table 4. Authorization for Medical Products for Use in Emergencies

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
	Sec. 4 Authorization for Medical Products for Use in Emergencies. Amends Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) by adding "Sec. 564. Authorization for Medical Products for Use in Emergencies."	**Sec. 4** Same as S. 15 as Reported by Committee.	**Sec. 4** Same as S. 15 as Reported by Committee.	**Sec. 4** Same as S. 15 as Reported by Committee.	
Authorization to Allow the Emergency Use of a Countermeasure	**Sec. 4 (a) "Sec. 564 (a)"** The HHS Secretary may authorize the temporary introduction into interstate commerce, of a drug, device, or biological product intended for use in an actual or potential emergency.	**Sec. 4 (a) "Sec. 564 (a)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (a)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (a)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Approval Status of Product	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(2)"** The HHS Secretary may make emergency use authorizations for products that are not approved, licensed, or cleared for commercial distribution (unapproved products) and for products that are approved for other uses (unapproved use of an approved product).	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(2)"** Same as H.R. 2122.	
Relation to Other Uses	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(3)"** Emergency use authorizations are in addition to any other approved uses of the product.	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(3)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Definitions	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(4)"** Biological product has the meaning given in sec. 351 of the PHSA. Emergency use means the use of a product during an actual emergency or potential emergency. Product means a drug, device or biological product. An unapproved product is a product without approval, license, or clearance for commercial distribution. An unapproved use of an approved product is the use of a product that is not approved for that use but has been approved for another use.	No similar provision.	**Sec. 4 (a) "Sec. 564 (a)(4)"** Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122.	The PHSA defines biological product as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or ... any trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings."

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Declaration	**Sec. 4 (a) "Sec. 564 (b)(1)"** The HHS Secretary may declare an emergency if: (A) The Homeland Security (DHS) Secretary determines that there is a *domestic* emergency or significant potential for one involving the heightened risk of attack with a specified biological, chemical, radiological or nuclear (CBRN) agent, or (B) The Defense Secretary determines that there is a military emergency or significant potential for one involving the heightened risk to U.S. military forces of attack with a CBRN agent, or	**Sec. 4 (a) "Sec. 564 (b)(1)"** The HHS Secretary may declare an emergency if: (A) The Homeland Security (DHS) Secretary determines that there is a *national* emergency or significant potential for one involving the heightened risk of attack with a specified biological, chemical, radiological or nuclear (CBRN) agent, or (B) The Defense Secretary determines that there is a military emergency or significant potential for one involving the heightened risk to U.S. military forces of attack with a *specified* CBRN agent, or	**Sec. 4 (a) "Sec. 564 (b)(1)"** The HHS Secretary may declare an emergency if: Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(1)"** The HHS Secretary may declare an emergency if: Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Declaration (continued)	(C) the HHS Secretary determines that there is a public health emergency under Section 319 of the PHSA affecting national security and involving a specified CBRN agent, or a specified disease or condition that may be attributable to such agent.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
Declaration Termination	**Sec. 4 (a) "Sec. 564 (b)(2)(A)"** An emergency declaration will terminate on the earlier of: (i) a determination by the HHS Secretary, in consultation with the DHS Secretary or Defense Secretary that the circumstances requiring the declaration no longer exist, or (ii) one year from the declaration date.	**Sec. 4 (a) "Sec. 564 (b)(2)(A)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(2)(A)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(2)(A)"** Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Declaration Renewal	**Sec. 4 (a) "Sec. 564 (b)(2)(B)"** The HHS Secretary may renew a declaration. Renewed declarations will be subject to termination under the above conditions and may also be renewed.	**Sec. 4 (a) "Sec. 564 (b)(2)(B)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(2)(B)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(2)(B)"** Same as S. 15 as Reported by Committee.	
Disposition of Product	No similar provision.	No similar provision.	No similar provision.	**Sec. 4 (a) "Sec. 564 (b)(2)(C)"** If an emergency use authorization of an unapproved product is terminated, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Advance Notice of Termination	No similar provision.	**Sec. 4 (a) "Sec. 564 (b)(3)"** The HHS Secretary must provide advanced notification that the declaration will be terminated to allow enough time to: (A) allow removal of unapproved products from distribution channels and (B) allow labeling changes for products used for unapproved uses.	No similar provision.	**Sec. 4 (a) "Sec. 564 (b)(3)"** Same as H.R. 2122.	
Publication	**Sec. 4 (a) "Sec. 564 (b)(3)"** The HHS Secretary must publish in the Federal Register *and notify the appropriate congressional committees of* each declaration, determination and renewal.	**Sec. 4 (a) "Sec. 564 (b)(4)"** The HHS Secretary must publish in the Federal Register each declaration, determination and renewal.	**Sec. 4 (a) "Sec. 564 (b)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (b)(4)"** The HHS Secretary must publish in the Federal Register each declaration, determination, *advanced notice of termination*, and renewal.	H.R. 2122 Sec. 5 (a)(1)(A)(iii)(II) requires an annual report to Congress detailing any such declaration. See below.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Authorization Criteria	**Sec. 4 "Sec. 564 (c)"** The HHS Secretary may authorize the emergency use of a product only if the Secretary concludes —	**Sec. 4 "Sec. 564 (c)"** The HHS Secretary may authorize 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*, the Secretary concludes —	**Sec. 4 "Sec. 564 (c)"** Same as S. 15 as Reported by Committee.	**Sec. 4 "Sec. 564 (c)"** Same as H.R. 2122.	
	(1) that an agent specified in the emergency declaration can cause a serious or life-threatening disease or condition;	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	(2) that, based on the totality of scientific evidence available to the Secretary, it is reasonable to believe that —	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	(A) the product may be effective in *detecting*, diagnosing, treating, or preventing a life-threatening disease or condition caused by that agent or by a countermeasure against that	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	(A) the product may be effective in diagnosing, treating, or preventing a life-threatening disease or condition caused by that agent or by a countermeasure against that agent; and	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Authorization Criteria (continued)	(B) the known and potential benefits of the product outweigh its known and potential risks.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	(3) that there is no adequate, approved, and available alternative to the product for *detecting*, diagnosing, preventing, or treating such disease or condition; and	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and	
	(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Authorization Scope	**Sec. 4 "Sec. 564 (d)"** An authorization of a product under this section shall state — (1) each disease or condition *and the intended use of the product* within the scope of the authorization; and No similar provision. (2) the Secretary's conclusions, 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.	**Sec. 564 (d)(1).** Same as S. 15 as Reported by Committee. (A) each disease or condition *for which the product may be used* within the scope of the authorization; (B) the Secretary's conclusions, that the known and potential benefits of the product, outweigh the known and potential risks of the product; and (C) Same as S. 15 as Reported by Committee.	**Sec. 4 "Sec. 564 (d)"** Same as S. 15 as Reported by Committee. (1)Same as S. 15 as Reported by Committee. No similar provision. (2) Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (d)"** Same as S. 15 as Reported by Committee. (1) Same as S. 15 as Reported by Committee. (2) Same as H.R. 2122 (3) the Secretary's conclusions, concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Confidential Information	No similar provision.	**Sec. 564 (d)(2).** Nothing in this section alters or amends 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4).	No similar provision.	No similar provision.	These sections of the United States Code require the confidential handling of financial information of any person, firm, partnership, corporation, association. This includes trade secrets and information on processes and operations.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Required Conditions on Unapproved Product Emergency Authorization	**Sec. 4 "Sec. 564 (e)"** The HHS Secretary will *impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that —* (1) to the extent *feasible*, ensuring those administering the countermeasure know that the Secretary has authorized *the product solely for emergency use*, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), and of any available alternatives and their risks and benefits.	**Sec. 4(a) "Sec. 564 (e)(1)(A)"** *With respect to emergency use of an unapproved product*, the HHS Secretary will *establish authorization conditions to protect public health including —* (i) to the extent *feasible*, ensuring that those administering the countermeasure know that the Secretary has authorized *the emergency use of the product*, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), and of any available alternatives and their risks and benefits.	**Sec. 4 "Sec. 564 (e)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 4(a) "Sec. 564 (e)(1)(A)"** *With respect to emergency use of an unapproved product*, the HHS Secretary will *establish authorization conditions to protect public health including —* (i) to the extent *practical*, ensuring that those administering the countermeasure know that the Secretary has authorized the emergency use of the product, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), and of any available alternatives and their risks and benefits.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Required Conditions on Unapproved Product Emergency Authorization (continued)	(2) to the extent feasible, *(including requirements concerning product labeling and the provision of information)* ensuring that those receiving the product know —	(ii) to the extent feasible, ensuring that those receiving the product know —	(2) Same as S. 15 as Reported by Committee.	(ii) to the extent *practical*, ensuring that those receiving the product know —	
	that the Secretary has authorized *the product solely for emergency use*, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), of any available alternatives and their risks and benefits, and of the option to accept or refuse administration of the product and any consequences of doing so;	that the Secretary has authorized *the emergency use of the product*, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), of any available alternatives and their risks and benefits, and of the option to accept or refuse administration of the product and any consequences of doing so;	Same as S. 15 as Reported by Committee.	that the Secretary has authorized the *emergency use of the product*, the significant known and potential benefits and risks of the product (and the extent to which these are unknown), of any available alternatives and their risks and benefits, and of the option to accept or refuse administration of the product and any consequences of doing so;	
	Sec. 4 "Sec. 564 (e)(8)" Same as H.R. 2122.	(iii) appropriate conditions for the monitoring and reporting of adverse events associated with use of the product;	**Sec. 4 "Sec. 564 (e)(8)"** Same as H.R. 2122.	(iii) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Required Conditions on Unapproved Product Emergency Authorization (continued)	**Sec. 4 "Sec. 564 (e)(6)"** *Requirements* concerning recordkeeping and reporting, including records access by the Secretary *and publication of data.*	(iv) *For manufacturers of the product, appropriate conditions* concerning record keeping and reporting including records access by the Secretary.	**Sec. 4 "Sec. 564 (e)(6)"** Same as S. 15 as Reported by Committee.	(iv) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Optional Conditions on Unapproved Product Emergency Authorization	**Sec. 4 "Sec. 564 (e)"** The HHS Secretary is *authorized to impose such conditions on an authorization as the Secretary determines are necessary* to protect public health including —	**Sec. 4 (a) "Sec. 564 (e)(1)(B)"** *With respect to emergency use of an unapproved product*, The HHS Secretary may *establish additional conditions on authorizations* to protect public health including —	**Sec. 4 "Sec. 564 (e)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (e)(1)(B)"** *With respect to the emergency use of an unapproved product*, the Secretary may, for a person *who carries out any activity 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:	S. 15 as Reported by Committee and S. 1504 do not distinguish between unapproved products and unapproved uses of approved products.
	(3) *impose limitations* on which entities may distribute the product for emergency use and on how distribution is to be performed;	(i) on which entities may distribute the product for emergency use and on how distribution is to be performed;	(3) Same as S. 15 as Reported by Committee.	(i) Same as H.R. 2122.	
	(4) *impose limitations* on who may administer the product for emergency use, and on the categories of individuals to whom, and the circumstances under which, the product may be administered;	(ii) on who may administer the product for emergency use, and on the categories of individuals to whom, and the circumstances under which, the product may be administered.;	(4) Same as H.R. 2122.	(ii) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Optional Conditions on Unapproved Product Emergency Authorization (continued)	No similar provision.	No similar provision.	No similar provision.	(iii) Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to its emergency use;	S. 15 as Reported by Committee and S. 1504 require the imposition of record-keeping require-ments. H.R. 2122 and S. 15 as enacted permit but do not require such require-ments.
	(5) condition the authorization on the performance of studies, clinical trials, or other research needed to support marketing approval of the product.	No similar provision.	(5) Same as S. 15 as Reported by Committee.	No similar provision.	
	(6) *The Secretary shall impose, to the extent feasible and appropriate, requirements* concerning recordkeeping and reporting, including records access by the Secretary *and publication of data.*	(iii) *for persons other than 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.*	(6) Same as S. 15 as Reported by Committee.	(iv) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Optional Conditions on Unapproved Product Emergency Authorization (continued)	(7) The HHS Secretary may waive, to the extent appropriate given the circumstances of the emergency, *requirements, with respect to the product, of* current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this act.	(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 these products subject to regulation under this act, *including such requirements established in section 501 of the Federal Food, Drug, and Cosmetic Act* (FFDCA).	(7) Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (e)(3)"** Same as H.R. 2122.	The FFDCA Sec. 501 defines adulterated drugs and devices.

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Unapproved Use Emergency Authorization Conditions	**Sec. 4 "Sec. 564 (e)(1-8)"** See above.	**Sec. 4 (a) "Sec. 564 (e)(2)"** For unapproved use of an approved product authorization:	**Sec. 564 (e)(1-8).** See above.	**Sec. 4 (a) "Sec. 564 (e)(2)"** Same as H.R. 2122.	S. 15 as Reported by Committee and S. 1504 do not distinguish between unapproved products and unapproved uses of approved products.
	See above.	*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 Sec. 564 (e)(1)(A)(i - iv)	See above.	For a manufacturer of the product who carries out any activity for which the authorization is issued, *the Secretary shall, to the extent practicable given the circumstances of the emergency*, establish conditions described in clauses (i) and (ii) of Sec. 564 (e)(1)(A) (1)(A), and *may* establish conditions described in clauses (iii) and (iv) of such paragraph.	
	No similar provision.	(i) If the manufacturer of the product chooses not to make an authorized change to the product label to reflect the emergency authorization, the authorization may not allow the product distributors or any other person to alter or obscure the labeling provided by the manufacturer.	No similar provision.	(i) Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Unapproved Use Emergency Authorization Conditions (continued)	No similar provision.	(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.	No similar provision.	(ii) In the circumstances described in clause (i), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, *to the extent practicable*, authorize such person to provide *appropriate* information with respect to such product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). *While the authorization under this section is effective*, such additional information shall not be considered labeling for purposes of section 502.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Unapproved Use Emergency Authorization Conditions (continued)	No similar provision.	No similar provision.	No similar provision.	**Sec. 4 (a) "Sec. 564 (e)(4)"** The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product)	
Emergency Use Authorization Duration	**Sec. 4 "Sec. 564 (f)"** Emergency authorizations will continue until the earlier of a termination of the emergency declaration or a revocation of emergency use authorization by the HHS Secretary under Sec. 564 (g). After authorization terminates, patients already receiving the product may continue to do so for as long as is deemed necessary by the patients' attending physicians.	**Sec. 4 "Sec. 564 (f)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 4 "Sec. 564 (f)"** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	**Sec. 4 "Sec. 564 (f)"** Same as S. 15 as Reported by Committee. After authorization terminates, patients already receiving the product may continue to do so for as long as is deemed necessary by the *patient's* attending *physician.*	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Emergency Use Authorization Revocation	**Sec. 4 (a) "Sec. 564 (g)"** The HHS Secretary will periodically review the circumstances and appropriateness of these emergency use authorizations.	**Sec. 4 (a) "Sec. 564 (g)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (g)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (g)"** Same as S. 15 as Reported by Committee.	
	The HHS Secretary may revoke an authorization if the authorization criteria under Sec. 564 (c) are no longer met *or other circumstances make such a revocation appropriate*.	The HHS Secretary may revoke an authorization if the authorization criteria under Sec. 564 (c) are no longer met.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	
	This decision is not reviewable.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Publication	**Sec. 4 (a) "Sec. 564 (h)"** The HHS Secretary will promptly publish in the Federal Register, *and provide to the appropriate congressional committees*, a notice of each authorization, authorization termination and authorization revocation.	**Sec. 4 (a) "Sec. 564 (h)"** 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.	**Sec. 4 (a) "Sec. 564 (h)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (h)"** The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, *and an explanation of the reasons therefor* (*which may include a summary of data or information that has been submitted to the Secretary in an application under section 505(i) or section 520(g), even if such summary may indirectly reveal the existence of such application).*	H.R. 2122 Sec. 5 (a)(1)(A)(iii) (I) requires an annual report to Congress detailing such authoriza-tions. See below.
	No similar provision.	No similar provision.	No similar provision.	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.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Record-keeping	**Sec. 4 (a) "Sec. 564 (i)(1)"** The HHS Secretary may require persons, including a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization, to establish and maintain —	No similar provision.	**Sec. 4 (a) "Sec. 564 (i)(1)"** Same as S. 15 as Reported by Committee.	No similar provision.	
	data that is obtained from such activity and that pertains to the effectiveness or safety of such product;	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	
	such records as are necessary to determine, or facilitate a determination, whether there may be any violation of this section or of a regulation promulgated under this section; and	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	
	such additional records as the Secretary may determine necessary.	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Access to Records by HHS Secretary	**Sec. 4 (a) "Sec. 564 (i)(2)"** The HHS Secretary may require a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization, to provide to the Secretary all data that is obtained from such activity and that pertains to the safety or effectiveness of such product.	No similar provision.	**Sec. 4 (a) "Sec. 564 (i)(2)"** Same as S. 15 as Reported by Committee.	No similar provision.	
	Every person required under this section to establish or maintain records, and every person in charge or custody of such records, shall, upon request by the Secretary, permit the Secretary at all reasonable times to have access to, to copy, and to verify such records.	No similar provision.	Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Actions Committed to Agency Discretion	**Sec. 4 (a) "Sec. 564 (k)"** All HHS Secretary, Defense Secretary and DHS Secretary actions under the authority of this section are committed to agency discretion.	**Sec. 4 (a) "Sec. 564 (i)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (k)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (i)"** Same as S. 15 as Reported by Committee.	
Regulations	**Sec. 4 (a) "Sec. 564 (l)"** The HHS Secretary may promulgate regulations to implement this section.	No similar provision.	**Sec. 4 (a) "Sec. 564 (l)"** Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Rules of Con-struction	**Sec. 4 (a) "Sec. 564 (m)"** Nothing in this section shall be *construed to impair or otherwise affect* the authority of —	**Sec 4 (a) "Sec. 564 (j)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (m)"** Same as S. 15 as Reported by Committee.	**Sec 4 (a) "Sec. 564 (j)"** Nothing in this section *impairs* the authority of —	
	the President as Commander in Chief of the Armed Forces of the United States;	Same as S. 15 as Reported by Committee;	Same as S. 15 as Reported by Committee;	Same as S. 15 as Reported by Committee;	
	the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.	Same as S. 15 as Reported by Committee;	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee;	
	No similar provision.	*or the HHS Secretary* under section 319F-2 of the Public Health Services Act to manage the stockpile under such section.	No similar provision.	*the United States to use or* manage *quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under* section 319F-2 of the Public Health Service Act).	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Application to Members of the Armed Forces	**Sec. 4 (a) "Sec. 564 (n)(1)"** With respect to members of the armed forces, the President may waive any requirement designed to ensure that individuals are informed of an option to accept or refuse the product 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.	**Sec. 4 (a) "Sec. 564 (k)(1)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (n)(1)(A)"** Same as S. 15 as Reported by Committee.	No similar provision.	Similar provisions were enacted by the National Defense Authoriza-tion Act for Fiscal Year 2004 (P.L.108-136) Sec. 1603 (b) (10 U.S.C. 1107a).

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Application to Members of the Armed Forces (continued)	No similar provision.	**Sec. 4 (a) "Sec. 564 (k)(2)"** If the HHS Secretary determines that it is not feasible to provide a member of the armed forces information required by Sec. 564 (e)(1)(A)(ii) [see above] prior to the use of the product, such information will be provided to the individual or next-of-kin as soon as possible and within 30 days of use. This information must be recorded in the medical record of the member.	**Sec. 4 (a) "Sec. 564 (n)(1)(B)"** Same as H.R. 2122.	No similar provision.	10 U.S.C. 1107 addresses the procedures required for using investiga-tional new drugs (IND) on the members of the armed services. Among other provisions, it requires notification that it is an IND, or a drug unapproved for its use, the reasons for the drug's use, and potential side effects.
	Sec. 4 (a) "Sec. 564 (n)(2)" 10 U.S.C. 1107 does not apply for the emergency use of products if the basis for an emergency declaration is the Defense Secretary's conclusion of a military emergency or potential for one under Sec. 564 (b)(1)(B).	**Sec. 4 (a) "Sec. 564 (k)(3)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (n)(2)"** Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Relation to Other Provisions	**Sec. 4 (a) "Sec. 564 (o)"** If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization —	**Sec. 4 (a) "Sec. 564 (l)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (o)"** Same as S. 15 as Reported by Committee.	**Sec. 4 (a) "Sec. 564 (k)"** If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization —	These sections of U.S.C. relate to testing IND in humans.
	shall not be subject to any requirements pursuant to section 505(i) or 520(g); and	Same as S. 15 as Reported by Committee;	Same as S. 15 as Reported by Committee;	shall not be considered to *constitute a clinical investigation for purposes of* section 505(i), section 520(g);	
	shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this act.	Same as S. 15 as Reported by Committee.	Same as S. 15 as Reported by Committee.	*or* any other provision of this act *or section 351 of the* Public Health Service Act.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Discretion Regarding Use of Authorization	No similar provision.	**Sec. 4 (a) "Sec. 564 (m)"** The HHS Secretary cannot require any person to carry out any activity this section makes lawful. People who choose not to carry out such activity are not required to inform the HHS Secretary of this choice, unless they are the sole source of an unapproved product that has been authorized for emergency use. In this case the manufacturer must notify the HHS Secretary of the choice not to participate in the program, within a reasonable time from the emergency-use authorization.	No similar provision.	**Sec. 4 (a) "Sec. 564 (l)"** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Enforce-ment	**Sec. 4 (a) "Sec. 564 (j)"** A person who *violates a requirement of this section or of a regulation or order promulgated pursuant to this section shall be subject to a civil money penalty of not more than $100,000 in the case of an individual, and not more than $250,000 in the case of any other person, for each violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.*	**Sec. 4 (a) "Sec. 564 (n)"** 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 in violation of the Federal Food, Drug, and Cosmetic Act.*	**Sec. 4 (a) "Sec. 564 (j)"** Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Enforce-ment (continued)	**Sec. 4 (b)** Technical amendments to Section 301 of the Food, Drug and Cosmetic Act (21 U.S.C. 331) to allow enforcement of the new Sec. 564. Makes it a crime to: (1) Promote or use a product that is the subject of an authorization under section 564 other than as stated in the authorization, or other than during the period described by section 564(g), unless such promotion or use is permitted under another provision of this act; (2) Fail to comply with an information requirement under section 564(e).	No similar provision.	**Sec. 4 (b)** Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee. Same as S. 15 as Reported by Committee.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Repeal of Termination Provision	No similar provision.	No similar provision.	No similar provision.	**Sec. 4 (b)** Subsection (d) of section 1603 of the National Defense Authorization Act for Fiscal Year 2004 (10 U.S.C. 1107a note) is repealed.	Subsection (d) specified that enactment of Project BioShield would terminate the described "Application to Members of the Armed Forces" in the National Defense Authoriza-tion Act Section 1603 (similar to S. 15 as Reported Sec. 4 (a) "Sec. 564 (n)(1)" see above). Therefore with this repeal, those provisions remain in effect.

Table 5. Required Reports

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
	No similar provision.	**Sec. 5** Reports Regarding Authorities Under this act.	No similar provision.	**Sec. 5** Reports Regarding Authorities Under this act.	
Notices and Annual Reports	No similar provision.	**Sec. 5 (a)(1)(A)** The HHS Secretary will submit annual reports regarding the exercise of the following authorities (under Sections 2, 3 and 4 of this act):	No similar provision.	**Sec. 5 (a)(1)(A)** Same as H.R. 2122.	
	No similar provision.	use of simplified acquisition authority,	No similar provision.	Same as H.R. 2122,	
	No similar provision.	use of other than full and open competition,	No similar provision.	Same as H.R. 2122,	
	No similar provision.	use of expedited peer review,	No similar provision.	Same as H.R. 2122,	
	No similar provision.	use of premium provision in multiple-award contracts,	No similar provision.	Same as H.R. 2122,	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Notices and Annual Reports (continued)	**Sec. 4 (a) "Sec. 564 (h)"** The HHS Secretary will promptly publish in the Federal Register, *and provide to the appropriate congressional committees*, a notice of each authorization, authorization termination and authorization revocation.	authorization of the emergency use of drugs,	**Sec. 4 (a) "Sec. 564 (h)"** Same as S. 15 as Reported by Committee.	Same as H.R. 2122,	The S. 15 as Reported by Committee and S. 1504 require case-by-case notification rather than annual reports with respect to these actions.
	Sec. 4 "Sec. 564 (b)(3)" The HHS Secretary must publish in the Federal Register *and notify the appropriate congressional committees* each declaration, determination and renewal.	declaration of any emergency, and	**Sec. 4 "Sec. 564 (b)(3)"** Same as S. 15 as Reported by Committee.	Same as H.R. 2122,	
	No similar provision.	conditions placed on emergency use of drugs emergency.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contents of Reports	No similar provision.	**Sec. 5 (a)(1)(B)** These reports will be submitted to the designated congressional committees and summarize —	No similar provision.	**Sec. 5 (a)(1)(B)** Same as H.R. 2122.	
	No similar provision.	the particular actions that were taken under the authorities specified in subparagraph (A), including, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;	No similar provision.	Same as H.R. 2122;	
	No similar provision.	the reasons underlying the decision to use such authorities, including any options that were considered and rejected with respect to the use of such authorities;	No similar provision.	Same as H.R. 2122;	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Contents of Reports (continued)	No similar provision.	*the identification of each* person or entity that received, or was considered and rejected for, grants, cooperative agreements, or contracts pursuant to the use of such authorities; and	No similar provision.	*the number of, nature of, and other information concerning the* persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, *except that the report need not disclose the identity of any such person or entity; and*	
	No similar provision.	whether, with respect to each procurement that is approved by the President, a contract was entered into within one year after such presidential approval.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Annual Summaries Regarding Certain Activity	No similar provision.	**Sec. 5 (a)(2)** The HHS Secretary shall annually submit a report to the designated congressional committees that summarizes the activity relating to the exercise of the following authorities granted by Sec. 2 of this act:	No similar provision.	**Sec. 5 (a)(2)** Same as H.R. 2122.	
	No similar provision.	use of increased micropurchase threshold,	No similar provision.	Same as H.R. 2122.	
	No similar provision.	use of authority for personal services contracts (including the number of persons who were paid amounts greater than $100,000 and the number of persons who were paid amounts between $50,000 and $100,000), and	No similar provision.	Same as H.R. 2122.	
	No similar provision.	use of streamlined personnel authority.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
National Academy of Sciences Review	No similar provision.	**Sec. 5 (b)(1)** Not later than four years after the date of the enactment of this act, the HHS Secretary will request the National Academy of Sciences to review the biomedical countermeasure research and development authorities established in this act to determine whether and to what extent activities undertaken pursuant to such authorities have enhanced the development of biomedical countermeasures affecting national security, and to recommend any legislative or administrative changes necessary to improve the ability of the Secretary to carry out these activities in the future. The Secretary shall ensure that the results of the study are submitted to the designated congressional committees not later than five years after enactment.	No similar provision.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
National Academy of Sciences Review Report Contents	No similar provision.	**Sec. 5 (b)(2)** This report shall include —	No similar provision.	No similar provision.	
	No similar provision.	a summary of the most recent analysis by the Department of Homeland Security and the intelligence community of the domestic threat from chemical, biological, radiological, and nuclear agents;	No similar provision.	No similar provision.	
	No similar provision.	the Academy's assessment of the current availability of countermeasures to address such threats;	No similar provision.	No similar provision.	
	No similar provision.	the Academy's assessment of the extent to which programs and activities under this act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and	No similar provision.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
National Academy of Sciences Review Report Contents (continued)	No similar provision.	the Academy's assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on the date of the enactment of this act, the development of antibiotic- resistant, mutated, or bioengineered strains of biological agents; and	No similar provision.	No similar provision.	
	No similar provision.	recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for federal policies regarding research priorities, the development of countermeasures, and investments in technology.	No similar provision.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
General Accounting Office Review	**Sec. 6** *Not later than* four years after the date of the enactment of this act, the Comptroller General of the United States shall initiate a study *that* —	**Sec. 5 (c)** four years after the date of the enactment of this act, the Comptroller General of the United States shall initiate a study —	**Sec. 6** Same as S. 15 as Reported by Committee.	**Sec. 5 (b)** Same as H.R. 2122.	
	(1) *describes the activities conducted under the authorities provided for in section 409J(b)(1) of the Public Health Service Act (as added by section 2) and section 319A-1(f)(3) and (4) of such Act (as added by section 3);*	(1)*(A) to review the HHS Secretary's use of the authorities granted under this Act with respect to simplified acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and*	Same as S. 15 as Reported by Committee.	(A)(i) Same as H.R. 2122.	The provisions cited in S. 15 as Reported by Committee and S. 1504 refer to simplified acquisition procedures and use of non-competitive procedures.
	No similar provision.	(1)(B) to recommend any legislative or administrative changes necessary to improve the use or effectiveness of such authorities in the future;	No similar provision.	(A)(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
General Accounting Office Review (continued)	(2) identifies any procurements that would have been prohibited except for the authorities provided by this act; and.	No similar provision.	Same as S. 15 as Reported by Committee;	No similar provision.	
	(3) *to assess the adequacy of* internal controls instituted by the HHS Secretary with respect to such authorities, where required by this act.	(2)(A) *to review* the internal controls instituted by the HHS Secretary with respect to such authorities, where required by this act; and	Same as S. 15 as Reported by Committee.	(B)(i) *to review and assess the adequacy of* the internal controls instituted by such Secretary with respect to such authorities, where required by this act; and	
	No similar provision.	(2)(B) to recommend any legislative or administrative changes necessary to improve the effectiveness of such controls; and	No similar provision.	(B)(ii) to make recommendations to improve the effectiveness of such controls;	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
General Accounting Office Review (continued)	No similar provision.	(3)(A) to review the Secretary's use of the authority granted under this act to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority; and	No similar provision.	(C)(i) Same as H.R. 2122;	
	No similar provision.	(3)(B) to recommend *any legislative or administrative changes necessary* to improve the utilization or effectiveness of such authority and to enhance protection of the public health.	No similar provision.	(C)(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;	
	No similar provision.	The results of the study shall be submitted to the designated congressional committees not later than five years after the enactment of this act.	No similar provision.	Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Report Regarding Security Counter-measures Procure-ment Barriers	No similar provision.	**Sec. 5 (d)(1)** Not later than 120 days after enactment of this act, the DHS and HHS Secretaries will jointly report to the designated congressional committees whether there is a lack of adequate large-scale biocontainment facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.	No similar provision.	**Sec. 5 (c)** Same as H.R. 2122.	
	No similar provision.	**Sec. 5 (d)(2)** Not later than one year after enactment of this act, the DHS and HHS Secretaries shall jointly report to the designated congressional committees any other potential barriers to the procurement of security countermeasures that have not been addressed by this act.	No similar provision.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Report Regarding Status of Program for Chemical Terrorism Prepared-ness	No similar provision.	**Sec. 5 (e)** Not later than 270 days after enactment of this act, the DHS Secretary will submit to the designated congressional committees a report describing the status of the program carried out by the Secretary to enhance the preparedness of the United States to respond to terrorist attacks involving chemical agents.	No similar provision.	No similar provision.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Designated Congress-ional Committees	No similar provision.	**Sec. 5 (f)** The term "designated congressional committees" means the following committees of Congress:	No similar provision.	**Sec. 5 (d)** Same as H.R. 2122.	S. 15 as Reported by Committee and S. 1504 use the phrase "appropriate congress-ional committees," elsewhere in the bills, without specifying which committees they are.
	No similar provision.	the House Committees on Energy and Commerce, Appropriations, Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee);	No similar provision.	Same as H.R. 2122.	
	No similar provision.	the *Senate Committees on Health, Education, Labor, and Pensions; Appropriations; and Government Affairs.*	No similar provision.	In the Senate: *the appropriate committees*	

Table 6. Outreach

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Outreach	No similar provision.	**Sec. 6** The HHS Secretary will develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Hispanics, *Native Americans, Asian-Pacific Americans,* or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this act.	No similar provision.	**Sec. 6** The HHS Secretary will develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of *Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders*, Hispanics or *Latinos*, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this act.	

Table 7. Export Control Recommendation

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Recommendation for Export Controls on Certain Biomedical Countermeasures	No similar provision.	**Sec. 7** Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this act for the research, development, or procurement of a countermeasure the HHS Secretary will, in consultation with the heads of other appropriate federal agencies, determine whether such countermeasure is subject to existing export-related controls and, if not, may make a recommendation that such countermeasure should be included on the list of controlled items subject to export-related controls.	No similar provision.	**Sec. 7** Same as H.R. 2122.	

Table 8. Interagency Coordination

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Ensuring Coordination, Cooperation and the Elimination of Unnecessary Duplication in Programs	No similar provision.	**Sec. 8 (a)** The HHS, DHS and Defense Secretaries will ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect domestic incidents involving such agents, analyze such incidents, and develop necessary countermeasures. The Secretaries will ensure that information and technology possessed by their Departments relevant to these activities are shared with the other Departments.	No similar provision.	**Sec. 8 (a)** Same as H.R. 2122.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Designation of Agency Coordin-ation Officer	No similar provision.	**Sec. 8 (b)** The HHS, DHS and Defense Secretaries will each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments.	No similar provision.	**Sec. 8 (b)** Same as H.R. 2122.	

Table 9. Smallpox- Related Amendments to the Homeland Security Act and Public Health Services Act

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Smallpox-Related Amend-ments to the Homeland Security Act and Public Health Services Act	**Sec. 5** These provisions concern smallpox countermeasures and were considered by other legislation.	No similar provision.	No similar provision.	No similar provision.	The Smallpox Emergency Personnel Protection Act of 2003 (P.L.108-20) incorporated many of the provisions in S. 15 as Reported.

Table 10. Additional HHS Secretary Authorities During National Emergencies

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Authority of the HHS Secretary During National Emergencies	No similar provision.	No similar provision.	**Sec. 5** Amends section 1135(b) of the Social Security Act that was added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188).	**Sec. 9** Same as S. 1504.	
	No similar provision.	No similar provision.	Allows the HHS Secretary in emergencies to waive or modify —	Same as S. 1504.	
	No similar provision.	No similar provision.	sanctions relating to the examination and treatment of emergency medical conditions and women in labor, if individuals are directed to or relocated to receive medical screening in an alternative location pursuant to an appropriate State emergency preparedness plan,	Same as S. 1504.	
	No similar provision.	No similar provision.	sanctions and penalties that arise from noncompliance with the following requirements:	Same as S. 1504.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Authority of the HHS Secretary During National Emer-gencies (continued)	No similar provision.	No similar provision.	to obtain a patient's agreement to speak with family members or friends; and	Same as S. 1504.	
	No similar provision.	No similar provision.	to honor a request to opt out of the facility directory;	Same as S. 1504.	
	No similar provision.	No similar provision.	requirement to distribute a notice; or	Same as S. 1504.	
	No similar provision.	No similar provision.	relating to the patient's right to request privacy restrictions; and confidential communications.	Same as S. 1504.	

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Authority of the HHS Secretary During National Emer-gencies (continued)	No similar provision.	No similar provision.	Such waivers or modifications shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.	Such waivers or modifications *shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay,* and shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.	

Table 11. Special Funding Language

Provision	S. 15 as Reported by Committee	H.R. 2122 as Passed by House	S. 1504 as Introduced	S. 15 as Enacted	Comments
Special Funding Language for Project BioShield	No similar provision.	No similar provision.	**Sec. 7** In the Senate, for purposes of points of order under a concurrent resolution on the budget and the Congressional Budget Act of 1974, provisions contained in any bill, resolution, amendment, motion, or conference report that change the availability of any amounts appropriated pursuant to this act (or an amendment made by this act) shall not be scored with respect to the level of budget authority or outlays contained in such bill, resolution, amendment, motion, or conference report.	No similar provision.	