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

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Summary

During his 2003 State of the Union Address, President Bush proposed that Congress enact legislation to establish Project BioShield to stimulate the development of countermeasures to protect against chemical and biological terrorism. Three bills have been introduced that incorporate many of the President's suggestions. S. 15 (Gregg) was reported by the Senate Health, Education, Labor and Pensions Committee on March 25, 2003 with a substitute amendment. H.R. 2122 (Tauzin) passed the House, amended, on July 16, 2003. S. 1504 (Gregg) was introduced directly for floor consideration on July 30, 2003.

Each bill would

- provide the Secretary of Health and Human Services (HHS) expedited procurement procedures for bioterrorism-related products and services;
- allow the use of an expedited review process for bioterrorism-related research and development proposals;
- attempt to encourage companies to develop countermeasures by allowing the HHS Secretary to contract to purchase countermeasures up to five years before the product is expected to be delivered; and
- allow the HHS Secretary to permit the emergency use of countermeasures that lack Food and Drug Administration approval.

The bills differ in how Project BioShield countermeasure procurement would be funded. S. 15 grants a permanent, indefinite appropriation, to be spent at the President's discretion, for the purchase of countermeasures, as was proposed by the Administration. This mandatory funding would not be subject to the annual appropriations process. In contrast, H.R. 2122 and S. 1504 each authorize specific appropriations of $5.593 billion for FY2004-FY2013. The Congressional Budget Office estimated that S. 15 would cost approximately $8.1 billion to implement for that period, while the Administration predicted that the cost would be $5.6 billion.

The House and Senate versions differ in which countermeasures would qualify for procurement under Project BioShield. In both Senate versions, any countermeasure that had a significant market other than as a countermeasure or that was not likely to be approved for use within 5 years would not be eligible for procurement under the project. In contrast, under H.R. 2122, countermeasures with other significant markets would be eligible for procurement under Project BioShield. H.R. 2122 requires that countermeasures be likely to be approved eventually but does not specify a time limit.

This report will be updated in response to legislative developments. For more analysis of Project BioShield, see CRS Report RS21507, *Project BioShield*, by Frank Gottron.

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Introduction

The anthrax attacks in the fall of 2001 underscored the nation's vulnerability to biological terrorism. Five people were killed by those attacks and thousands required prophylactic antibiotic treatment. If there had not been effective medical countermeasures for this strain of anthrax, the death toll would probably have been higher. Effective countermeasures do not exist for many of the biological threats deemed the most dangerous by the Centers for Disease Control and Prevention (CDC). For example, botulinum toxin, plague, tularemia, and many viral hemorrhagic viral fevers (VHFs) lack licensed vaccines, while smallpox and VHFs lack any specific treatments. The Department of Health and Human Services (HHS) recognizes a need for better vaccines for anthrax and smallpox and better treatments for anthrax, plague and botulism.[1]

Many attribute the paucity of bioterrorism countermeasures to the lack of a significant commercial market for them.[2] Because these diseases occur infrequently, there has been little economic incentive for investment of the millions of dollars required to bring a new treatment to market.[3]

To encourage the development of new bioterrorism countermeasures, President Bush proposed Project Bioshield in his 2003 State of the Union address. In response to this call for legislation, three bills entitled "Project BioShield Act of 2003," have been introduced. S. 15 (Gregg) was introduced on March 11, 2003, and reported by the Senate committee on Health, Education Labor and Pensions on March 25, with an amendment in the nature of a substitute. H.R. 2122 (Tauzin) was introduced May 15, 2003, reported by the House Committees on Energy and Commerce (June 10), Government Reform (June 12, amended), and Homeland Security (July 8, amended), and passed the House (421-2) with a substitute amendment on July 17, 2003. S. 1504 (Gregg) was introduced July 30, 2003 and placed directly on the Senate Legislative Calendar.

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[1] 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.

[2] Ceci Connolly, "U.S. Hopes Incentives Will Push Vaccine Development," *Washington Post*, January 30, 2003, p. A08.

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

Similarities

These bills share many provisions. Each would provide expedited procurement procedures for bioterrorism-related products and services and an expedited peer-review process for research and development (R&D) proposals, making it easier for HHS to quickly commit substantial funds to countermeasure projects. Each bill would provide a market guarantee by allowing the HHS Secretary to contract to procure a countermeasure up to five years before it is expected to be delivered. Each bill would allow the HHS Secretary to allow the emergency use of countermeasures that lack Food and Drug Administration approval.

Differences

The three bills differ in how funds would be appropriated for countermeasure procurement. S. 15 grants a permanent, indefinite appropriation to be spent at the President's discretion for the purchase of countermeasures. This mandatory funding, which was 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. The Congressional Budget Office estimated that approximately $8.1 billion would be spent over that time period. H.R. 2122 and S. 1504 provide specific funding authorization for the program but do not appropriate funds. H.R. 2122 authorizes the appropriation of $5.593 billion for FY2004-FY2013. Money appropriated pursuant to H.R. 2122 would go into a special fund that would be available for obligation only through FY2013. S. 1504 authorizes the appropriation of amounts identical to those in H.R. 2122. As in the House bill, funds appropriated pursuant to S. 1504 could be obligated through 2013, although no special reserve fund is explicitly created by S. 1504.

The House and Senate versions differ in which countermeasures would qualify for procurement under Project BioShield. Under both Senate bills, any countermeasure that has a significant market other than as a countermeasure or that is not likely to be approved for use within 5 years would not be eligible for procurement under Project BioShield. In contrast, under H.R. 2122, countermeasures with other significant markets are eligible. H.R. 2122 further requires that countermeasures be likely to be approved eventually but does not set a specific time limit.

H.R. 2122 authorizes appropriations to hire more biological and chemical terrorism analysts in the Department of Homeland Security's Directorate for Information Analysis and Infrastructure Protection (IAIP) and to acquire and deploy facilities that permit the Undersecretary of IAIP to access all classified information to which he is entitled. The Senate versions have no similar provisions.

S. 1504 grants the HHS Secretary authority 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 during a national emergency, while H.R. 2122 and S. 15 lack this provision. These include provisions designed to protect patient privacy and to allow patients to be directed to or away from certain hospitals pursuant to a state emergency plan.

Several other notable differences, including in 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	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Short Title	**Sec. 1.** "Project BioShield Act of 2003."	**Sec. 1.** Same as H.R. 2122.	**Sec. 1.** Same as H.R. 2122.	

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

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Amendment of the Public Health Services Act	**Sec. 2.** Amends *Part B of title III* of the Public Health Service Act (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.** Amends *Part B of title IV* of the PHSA (*42 U.S.C. 284 et seq.*) by *adding "Sec. 409J Biomedical Countermeasure Research and Development."*	**Sec. 2.** Same as S. 15.	
Defining Counter-measures	**Sec. 319F-1 (a)(2) and Sec. 2 (e).** Defines a qualified *countermeasure as a countermeasure as defined by the PHSA that can act against a chemical, biological, radiological, or nuclear (CBRN) agent whose use would affect national security.*	**Sec. 3 and Sec. 319A-1 (h)(1).** Defines qualified countermeasure as a *biomedical countermeasure for use against a CBRN agent that poses a material threat to the United States, that is approved, licensed or cleared for use or for which the HHS Secretary determines that there is enough data to support a reasonable conclusion that the product will qualify for approval or licensing within 5 years.*	**Sec. 409J (g).** Same as S. 15.	The Senate version excludes countermeasures that are not approved, licensed, cleared or are unlikely to be within 5 years.

Note: Italics highlight language differences between the bills.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Defining Counter-measures (continued)	**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 (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 (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).	**Sec. 409J (g).** Defines *biomedical* countermeasure as a drug, biological product, or device used (1) to treat, identify, or prevent harm from any CBRN agent that may cause a public health emergency *affecting national security*; or (2) Same as H.R. 2122.	**Sec. 409J (g).** Same as S. 15. Same as S. 15. Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Lead Institute	No similar provision.	**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.	**Sec. 409J (a)(2).** Same as S. 15.	
Interagency Cooperation	**Sec. 319F-1 (a)(3).** Authorizes the HHS Secretary to enter into interagency agreements for countermeasure research and development.	**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. 409J (a)(3).** Same as S. 15.	
Facility Availability to the Secretary	**Sec. 319F-1 (a)(4).** HHS Secretary can make BioShield funding for countermeasure research and development facilities dependent on allowing future emergency use of facilities by the Secretary.	**Sec. 409J (a)(2)(D).** Same as H.R. 2122.	**Sec. 409J (a)(2)(D).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Export Controls	**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.	No similar provision.	
Expedited Procurement Authority	**Sec. 319F-1 (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. 409J (b)(1).** (A) Same as H.R. 2122.	**Sec. 409J (b)(1).** (A) Same as H.R. 2122.	Current maximum is $100,000.
	(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).	No similar provision.	(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.*	
	(C) Appropriate internal controls shall be developed for the use of this authority.	(B) Same as H.R. 2122.	(C) Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Expedited Procurement Authority (continued)	**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. 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. 409J (b)(2).** Same as S. 15.	
	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.	No similar provision.	
	Sec. 319F-1 (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. 409J (b)(3).** Same as H.R. 2122.	**Sec. 409J (b)(3).** Same as H.R. 2122.	Current micropurchase threshold is $2,500.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Contesting Decisions Made Under These Authorities	**Sec. 319F-1 (b)(4).** 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.	No similar provision.	
Expedited Peer Review	**Sec. 319F-1 (c)(1).** 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. 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.	**Sec. 409J (c).** Same as H.R. 2122. No similar provision.	**Sec. 409J (c).** Same as H.R. 2122. No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Agency Facilities	No similar provision.	**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.	**Sec. 409J (d).** Same as S. 15.	
Personal Services Contracts	**Sec. 319F-1 (d).** 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. 409J (e)(1).** Same as H.R. 2122.	**Sec. 409J (e)(1).** Same as H.R. 2122.	
	Sec. 319F-1 (d)(1). Pay cannot exceed that of the U. S. President.	No similar provision.	No similar provision.	
	Sec. 319F-1 (d)(2). These contractors are treated as employees of HHS for Federal Tort Claims Act purposes.	**Sec. 409J (e)(2).** Same as H.R. 2122	**Sec. 409J (e)(2).** Same as H.R. 2122	
	Sec. 319F-1 (d)(3). Internal controls for this authority will be implemented.	**Sec. 409J (e)(3).** Same as in H.R. 2122.	**Sec. 409J (e)(3).** Same as in H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Personal Services Contracts (continued)	No similar provision.	**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.	**Sec. 409J (e)(2)(C).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Streamlined Personnel Authority	**Sec. 319F-1 (e).** 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. 409J (f).** Same as H.R. 2122.	**Sec. 409J (f)(1).** Same as H.R. 2122.	
	No similar provision.	No similar provision.	**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.	These U.S.C. provisions include protections regarding discrimination on the basis of political affiliation, race, color, religion, national origin, sex, marital status, age, or handicap.
	Sec. 319F-1 (e)(2). Internal controls for this authority will be implemented.	**Sec. 409J (f)(2).** Same as H.R. 2122.	**Sec. 409J (f)(3).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Actions Committed to Agency Discretion	**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. 409J (h).** All actions by the HHS Secretary under the authority of this section are committed to agency discretion.	**Sec. 409J (h).** Same as S. 15.	
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. (2) Authorizes such sums as may be necessary for FY2003 and FY2004 to fund these improvements.	**Sec. 2 (b).** Same as H.R. 2122. No similar provision.	**Sec. 2 (b).** Same as H.R. 2122. No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
HHS Program to Develop Counter–measures	**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	**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	**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.	No similar provision.	

Table 3. Biomedical Countermeasures Procurement

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
	Sec. 3. Amends PHSA by adding *Sec. 319F-2.*	**Sec. 3.** Amends PHSA by adding *Sec. 319A-1.*	**Sec. 3.** Same as S. 15.	
Transfer of Strategic National Stockpile Language	**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.	No similar provision.	
Procurement Authority	**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.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Definitions of Security Counter–measures and Qualified Counter–measures	**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, 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*, or is authorized for emergency use by the HHS Secretary.	**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, 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 5 years*. No similar provision.	**Sec. 319A-1 (h)(1).** Same as S. 15. Same as S. 15. No similar provision.	The House bill's definition of priority countermeasure is from Sec. 319F(h) of the PHSA.
Determination of Material Threat	**Sec. 319F-2 (c)(2)(A).** Requires the DHS Secretary to determine, on an ongoing basis, which CBRN agents pose a material *threat.*	**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. 319A-1 (a)(1).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Determination of Public Health Impact	**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. 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. 319A-1 (a)(2)(A).** Same as S. 15.	
Notification to Congress	**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.	No similar provision.	No similar provision.	
Assuring Access to Threat Information	**Sec. 319F-2 (c)(2)(D).** All information to which the DHS Secretary is entitled, regardless of classification level, will be used in making a material threat determinations.	No similar provision.	No similar provision.	
Assessment of Availability and Appro-priateness of Counter–measures	**Sec. 319F-2 (c)(3).** The HHS Secretary, in consultation with the DHS Secretary, shall assess the availability and appropriateness of countermeasures to address identified material threats.	**Sec. 319A-1 (b).** Same as H.R. 2122.	**Sec. 319A-1 (b).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Call for Development of Counter–measures	**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. 319A-1 (c)(1).** If a countermeasure is found appropriate but not available, the DHS and HHS Secretaries may 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. 319A-1 (c)(1).** Same as S. 15.	
Counter–measure Specifications	**Sec. 319F-2 (c)(4)(B).** 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. 319A-1 (b)(2).** Same as H.R. 2122.	**Sec. 319A-1 (b)(2).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Notifying Potential Developers	**Sec. 319F-2 (c)(4)(C).** 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– the call for the countermeasure; the required specifications for the countermeasure; and the commitment described in subparagraph (A)(ii).	**Sec. 319A-1 (c)(3).** Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122. 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 paragraph (2).	**Sec. 319A-1 (c)(3).** Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122. Same as S. 15.	
Secretary's Determination of Counter–measures Appropriate for Funding	**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. 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. 319A-1 (d)(1).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Secretary's Determination of Counter–measures Appropriate for Funding (continued)	**Sec. 319F-2 (c)(5)(B).** In making this determination the HHS Secretary *will determine and consider*:	**Sec. 319A-1 (d)(2).** For countermeasures to qualify for this funding the HHS Secretary *must determine*:	**Sec. 319A-1 (d)(2).** Same as S. 15.	The Senate versions exclude countermeasures that have another market. The House version requires the Secretary only to consider if products have other significant markets. Therefore, products that have another market could be procured under the House version but not the Senate versions.
	(i) quantities of the product that will be needed for the SNS,	(B)(i) Same as H.R. 2122.	Same as H.R. 2122.	
	(iii) feasibility of delivery of sufficient quantities within 5 years, and	(B)(ii) Same as H.R. 2122.	Same as H.R. 2122.	
	(iii)whether there is a lack of a significant commercial market for the product at time of procurement other than as a countermeasure.	(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.	Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Presidential Approval Required for Procurement	**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).* (B) Presidential approval is required to procure countermeasures under this Act.	**Sec. 319A-1 (e).** 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. 319A-1 (e)(2).** Same as H.R. 2122.	**Sec. 319A-1 (e).** Same as S. 15. **Sec. 319A-1 (e)(2).** Same as H.R. 2122.	
Notice to Congress	**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:* 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.	**Sec. 319A-1 (e)(3).** The DHS Secretary will notify *Congress* of each presidential decision to approve the procurement of countermeasures under this *Act*. No similar provision.	**Sec. 319A-1 (e)(3).** Same as S. 15. No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Subsequent Specific Counter–measures	**Sec. 319F-2 (c)(6)(D).** 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. Determination of an improvement is committed to agency discretion.	**Sec. 319A-1 (c)(4).** Same as H.R. 2122. No similar provision.	**Sec. 319A-1 (c)(4).** Same as H.R. 2122. No similar provision.	
Rule of Construction	**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.	No similar provision.	
Interagency Agreements for Procurement	**Sec. 319F-2 (c)(7)(A)-(B)**. The DHS Secretary will reimburse the HHS Secretary for the costs, including administrative costs, of presidentially approved countermeasure procurements. The special reserve fund cannot be used to reimburse administrative costs.	No similar provision. **Sec. 319A-1 (i)(2)(C).** Funds appropriated under this subsection cannot be used for administrative costs.	No similar provision. **Sec. 319A-1 (i)(2)(C).** Same as S.15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Procurement	**Sec. 319F-2 (c)(7)(C)(i).** 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. The HHS Secretary will promulgate any regulations necessary to implement these procurement provisions.	**Sec. 319A-1 (f)(1).** Same as H.R. 2122. Same as H.R. 2122.	**Sec. 319A-1 (f)(1).** Same as H.R. 2122. Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Contract Terms	**Sec. 319F-2 (c)(7)(C)(ii).** The procurement contracts will include the following terms: Payment conditioned on delivery of a substantial portion of the number of contracted units. However, 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 a substantial delivery is not made. This language cannot be construed as affecting rights of vendors under provisions of law or regulation relating to termination of contracts for the convenience of the federal government.	**Sec. 319A-1 (f)(2).** Same as H.R. 2122. Same as H.R. 2122. No similar provision.	**Sec. 319A-1 (f)(2).** Same as H.R. 2122. Same as H.R. 2122. No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Contract Terms (continued)	The contract period cannot be longer than 5 years, *or up to 8 years if the HHS Secretary determines at the time of initial award that a longer period is justified.*	The contract period cannot be longer than 5 years.	Same as S. 15.	
	Contracts may be renewed for additional periods of up to 5 years each.	Same as H.R. 2122.	Same as H.R. 2122.	
	The vendor must comply with all applicable export-related controls.	No similar provisions.	No similar provisions.	
	No similar provisions.	The vendor must seek approval, clearance or licensing of product. The HHS Secretary may waive this provision.	Same as S. 15.	
	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 H.R. 2122,	Same as H.R. 2122,	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Contract Terms (continued)	No similar provision.	a discounted price for a product that has not been licensed or approved at the time of delivery, and	Same as S. 15,	
	No similar provision.	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 3 years after the contract commenced.	Same as S. 15.	
Availability of Simplified Acquisition Procedures	**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. 319A-1 (f)(3).** Simplified acquisition procedures will apply to *all countermeasure procurements under this section.*	**Sec. 319A-1 (f)(3).** Same as S. 15.	
	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.	No similar provision.	**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.*	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Use of Procedures Other than Full and Open Competition	**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. Awards must comply with government-wide regulations, including requirements that offers be solicited from as many potential sources as practicable, that required notices be published, and that submitted offers be considered.	**Sec. 319A-1 (f)(4).** Authorizes the use of *noncompetitive procedures* to procure a product available from a limited number of responsible sources. No similar provision.	**Sec. 319A-1 (f)(4).** Same as S. 15. No similar provision.	
Premium Provision in Multiple Award Contracts	**Sec. 319F-2 (c)(7)(C)(v).** 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. 319A-1 (f)(5).** Same as H.R. 2122. Same as H.R. 2122.	**Sec. 319A-1 (f)(5).** Same as H.R. 2122. Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Extension of Closing Date for Receipt of Proposals is not Reviewable	**Sec. 319F-2 (c)(7)(C)(vi).** A decision by the HHS Secretary to extend the closing date for receipt of proposals for a procurement is committed to agency discretion.	**Sec. 319A-1 (f)(6).** Same as H.R. 2122.	**Sec. 319A-1 (f)(6).** Same as H.R. 2122.	
Limiting Competition to Sources Responding to Information Requests	**Sec. 319F-2 (c)(7)(C)(vii).** 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. 319A-1 (f)(7).** Same as H.R. 2122.	**Sec. 319A-1 (f)(7).** Same as H.R. 2122.	
Interagency Agreements	**Sec. 319F-2 (c)(8).** 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. 319A-1 (g).** Same as H.R. 2122. Same as H.R. 2122.	**Sec. 319A-1 (g).** Same as H.R. 2122. Same as H.R. 2122.	

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

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Definitions (continued)	**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 (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 (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).	**Sec. 319A-1 (h)(2).** Defines *biomedical* countermeasure as a drug, biological product, or device used (1) to treat, identify, or prevent harm from any CBRN agent that may cause a public health emergency *affecting national security*; or (2) Same as H.R. 2122.	**Sec. 319A-1 (h)(2).** Same as S. 15. Same as S. 15. Same as H.R. 2122.	H.R. 2122 defines countermeasures only in Sec. 2. The Senate versions define countermeasures in Sec. 2 and repeat the definition here.
Technical Amendments	**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.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Amendment to Homeland Security Act	**Sec. 3 (b).** 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.	No similar provision.	
Appropriation Authorization	**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. 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. 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.	H.R. 2122 sets up a special reserve fund that sunsets in FY2013. S. 15 has a permanent, indefinite, appropriation. S. 1507 authorizes identical levels of funding as H.R. 2122, but does not set up a special reserve fund.
Definition of Special Reserve Fund	**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.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Limits on Special Reserve Fund	**Sec. 510 (c).** Appropriations to the special reserve fund are available to be obligated through FY2013 and only for presidentially approved countermeasures. 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. No similar provision.	No similar provision. No similar provision.	
Related Appropriation Authorizations	**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 CBRN threat assessment analysts within the DHS Directorate for Information Analysis and Infrastructure Protection (IAIP). **Sec. 510 (d)(2).** Authorizes the appropriation of such sums as may be necessary for FY2003-2006 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. No similar provision.	No similar provision. No similar provision.	

Table 4. Authorization for Medical Products for Use in Emergencies

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	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 H.R. 2122.	**Sec. 4.** Same as H.R. 2122.	
Authorization to Allow the Emergency Use of a Counter-measure	**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. 564 (a).** Same as H.R. 2122.	**Sec. 564 (a).** Same as H.R. 2122.	
Approval Status of Product	**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.	No similar provision.	
Relation to Other Uses	**Sec. 564 (a)(3).** Emergency use authorizations are in addition to any other approved uses of the product.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Definitions	**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.	No similar provision.	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	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Emergency Declaration	**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 CBRN agent, or (C) the HHS Secretary determines that there is a public health emergency under sec. 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.	**Sec. 564 (b)(1).** Same as H.R. 2122. (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 Same as H.R. 2122. Same as H.R. 2122.	**Sec. 564 (b)(1).** Same as H.R. 2122. Same as S. 15. Same as H.R. 2122. Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Declaration Termination	**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. 564 (b)(2)(A).** Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122.	**Sec. 564 (b)(2)(A).** Same as H.R. 2122. Same as H.R. 2122. Same as H.R. 2122.	
Declaration Renewal	**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. 564 (b)(2)(B).** Same as H.R. 2122.	**Sec. 564 (b)(2)(B).** Same as H.R. 2122.	
Advance Notice of Termination	**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. No similar provision. No similar provision.	No similar provision. No similar provision. No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Publication	**Sec. 564 (b)(4).** The HHS Secretary must publish in the Federal Register each declaration, determination and renewal.	**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. 564 (b)(3).** Same as S. 15.	H.R. 2122 Sec. 5 (a)(1)(A)(iii)(II) requires an annual report to Congress detailing any such declaration. See below.

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

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Emergency Authorization Criteria (continued)	(B) the known and potential benefits of the product outweigh its known and potential risks.	Same as H.R. 2122.	Same as H.R. 2122.	
	(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 H.R. 2122.	Same as H.R. 2122.	
	(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.	Same as H.R. 2122.	Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Emergency Authorization Scope	**Sec. 564 (d)(1).** An authorization of a product under this section shall state–	**Sec. 564 (d).** Same as H.R. 2122.	**Sec. 564 (d).** Same as H.R. 2122.	
	(A) each disease or condition *for which the product may be used* within the scope of the authorization;	(1) each disease or condition *and the intended use of the product* within the scope of the authorization; and	(1) Same as S. 15.	
	(B) the Secretary's conclusions, that the known and potential benefits of the product, outweigh the known and potential risks of the product; and	No similar provision.	No similar provision.	
	(C) 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.	(2) Same as H.R. 2122.	(2) Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Confidential Information	**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 U.S.C. require the confidential handling of financial information of any person, firm, partnership, corporation, association. This includes trade secrets, processes and operations.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Required Conditions on Unapproved Product Emergency Authorization	**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 –* **Sec. 564 (e)(1)(A)(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. 564 (e).** The HHS Secretary will *impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that–* **Sec. 564 (e)(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. 564 (e).** Same as S. 15. Same as S. 15.	The Senate versions do not distinguish between unapproved products and unapproved uses of approved products.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Required Conditions on Unapproved Product Emergency Authorization (continued)	**Sec. 564 (e)(1)(A)(ii).** to the extent feasible, ensuring that those receiving the product know–	**Sec. 564 (e)(2).** to the extent feasible, *(including requirements concerning product labeling and the provision of information)* ensuring that those receiving the product know –	**Sec. 564 (e)(2).** Same as S. 15.	
	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.	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.	Same as S. 15.	
	Sec. 564 (e)(1)(A)(iii). appropriate conditions for the monitoring and reporting of adverse events associated with use of the product.	**Sec. 564 (e)(8).** Same as H.R. 2122.	**Sec. 564 (e)(8).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Required Conditions on Unapproved Product Emergency Authorization (continued)	**Sec. 564 (e)(1)(A)(iv).** *For manufacturers of the product, appropriate conditions* concerning record keeping and reporting including records access by the Secretary.	**Sec. 564 (e)(6).** *Requirements* concerning recordkeeping and reporting, including records access by the Secretary *and publication of data.*	**Sec. 564 (e)(6).** Same as S. 15.	The Senate versions do not have separate sections specifically for manufacturers regarding recordkeeping and reporting.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Optional Conditions on Unapproved Product Emergency Authorization	**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. 564 (e)(3-5).** The HHS Secretary is *authorized to impose such conditions on an authorization as the Secretary determines are necessary* to protect public health including –	**Sec. 564 (e)(3-8).** Same as S. 15.	The Senate versions do not distinguish between unapproved products and unapproved uses of approved products.
	Sec. 564 (e)(1)(B)(i). on which entities may distribute the product for emergency use and on how distribution is to be performed.	**Sec. 564 (e)(3).** *impose limitations* on which entities may distribute the product for emergency use and on how distribution is to be performed.	**Sec. 564 (e)(3).** Same as H.R. 2122.	
	Sec. 564 (e)(1)(B)(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.	**Sec. 564 (e)(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.	**Sec. 564 (e)(4).** Same as H.R. 2122.	
	No similar provision.	**Sec. 564 (e)(5).** condition the authorization on the performance of studies, clinical trials, or other research needed to support marketing approval of the product.	**Sec. 564 (e)(5).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Optional Conditions on Unapproved Product Emergency Authorization (continued)	**Sec. 564 (e)(1)(B)(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.*	**Sec. 564 (e)(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.*	**Sec. 564 (e)(6).** Same as S. 15.	The Senate versions require the imposition of recordkeeping requirements. H.R. 2122 permits but does not demand such requirements. The Senate versions do not have separate sections for manufacturers and non-manufacturers regarding recordkeeping.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Optional Conditions on Unapproved Product Emergency Authorization (continued)	**Sec. 564 (e)(1)(B)(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).	**Sec. 564 (e)(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.	**Sec. 564 (e)(7).** Same as S. 15.	The FFDCA Sec. 501 defines adulterated drugs and devices.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Unapproved Use Emergency Authorization Conditions	**Sec. 564 (e)(2).** For unapproved use of an approved product authorization: The Secretary may, for manufacturers of the product establish any of the conditions described in Sec. 564 (e)(1)(A)(i - iv) [see Unapproved Product Emergency Authorization Conditions above] 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. However, emergency authorizations may allow such persons to supply additional information with the product. Such additional information shall not be considered labeling.	**Sec. 564 (e)(1-8).** See above. See above. No similar provision.	**Sec. 564 (e)(1-8).** Same as S. 15. Same as S. 15. No similar provision.	The Senate versions do not distinguish between unapproved products and unapproved uses of approved products.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Emergency Use Authorization Duration	**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 patient's attending physician.	**Sec. 564 (f).** Same as H.R. 2122. Same as H.R. 2122.	**Sec. 564 (f).** Same as H.R. 2122. Same as H.R. 2122.	
Emergency Use Authorization Revocation	**Sec. 564 (g).** The HHS Secretary will periodically review the circumstances and appropriateness of these emergency use authorizations. The HHS Secretary may revoke an authorization if the authorization criteria under Sec. 564 (c) are no longer met. This decision is not reviewable.	**Sec. 564 (g).** Same as H.R. 2122. 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*. Same as H.R. 2122.	**Sec. 564 (g).** Same as H.R. 2122. Same as S. 15. Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Publication	**Sec. 564 (h).** The HHS Secretary will promptly publish in the Federal Register a notice of each authorization, authorization termination and authorization revocation. *This publication must include the reasons for the action.*	**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. 564 (h).** Same as S. 15.	H.R. 2122 Sec. 5 (a)(1)(A)(iii)(I) requires an annual report to Congress detailing such authorizations. See below.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Recordkeeping	No similar provision.	**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–	**Sec. 564 (i)(1).** Same as S. 15.	
	No similar provision.	data that is obtained from such activity and that pertains to the effectiveness or safety of such product;	Same as S. 15.	
	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	Same as S. 15.	
	No similar provision.	such additional records as the Secretary may determine necessary.	Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Access to Records by HHS Secretary	No similar provision. No similar provision.	**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. 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.	**Sec. 564 (i)(2).** Same as S. 15. Same as S. 15.	
Actions Committed to Agency Discretion	**Sec. 564 (i).** All HHS Secretary, Defense Secretary and DHS Secretary actions under the authority of this section are committed to agency discretion.	**Sec. 564 (k).** Same as H.R. 2122.	**Sec. 564 (k).** Same as H.R. 2122.	
Regulations	No similar provision.	**Sec. 564 (l).** The HHS Secretary may promulgate regulations to implement this section.	**Sec. 564 (l).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Rules of Construction	**Sec. 564 (j).** Nothing in this section shall be construed to impair or otherwise affect–	**Sec. 564 (m).** Same as H.R. 2122.	**Sec. 564 (m).** Same as H.R. 2122.	
	the authority of the President as Commander in Chief of the Armed Forces of the United States;	Same as H.R. 2122.	Same as H.R. 2122.	
	the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of federal law; or	Same as H.R. 2122.	Same as H.R. 2122.	
	the authority of the HHS Secretary under section 319F-2 of the Public Health Services Act to manage the stockpile under such section.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Application to Members of the Armed Forces	**Sec. 564 (k)(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. 564 (n)(1).** Same as H.R. 2122.	**Sec. 564 (n)(1)(A).** Same as H.R. 2122.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Application to Members of the Armed Forces (continued)	**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. 564 (k)(3).** 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).	No similar provision. **Sec. 564 (n)(2).** Same as H.R. 2122.	**Sec. 564 (n)(1)(B).** Same as H.R. 2122. **Sec. 564 (n)(2).** Same as H.R. 2122.	10 U.S.C. 1107 addresses the procedures required for using investigational 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.
Relation to Other Provisions	**Sec. 564 (l).** Products within the scope of an emergency authorization are not subject to section 505(i) or 520(g) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb et seq.) nor any requirements otherwise applicable to clinical investigations pursuant to other provisions of that Act.	**Sec. 564 (o).** Same as H.R. 2122.	**Sec. 564 (o).** Same as H.R. 2122.	These sections of U.S.C. relate to testing IND in humans.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Discretion Regarding Use of Authorization	**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.	No similar provision.	
Enforcement	**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. 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. 564 (j).** Same as S. 15.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Enforcement (continued)	No similar provision.	**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).	**Sec. 4(b).** Same as S. 15. Same as S. 15. Same as S. 15.	

Table 5. Required Reports

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
	Sec. 5 Reports Regarding Authorities Under this Act.	No similar provision.	No similar provision.	
Annual Reports	**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.	No similar provision.	
	use of simplified acquisition authority,	No similar provision.	No similar provision.	
	use of other than full and open competition,	No similar provision.	No similar provision.	
	use of expedited peer review,	No similar provision.	No similar provision.	
	use of premium provision in multiple-award contracts,	No similar provision.	No similar provision.	
	authorization of the emergency use of drugs,	**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. 564 (h).** Same as S. 15.	The Senate versions require case-by-case notification rather than annual reports with respect to these actions.

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Annual Reports (continued)	declaration of any emergency, and	**Sec. 564 (b)(3).** The HHS Secretary must publish in the Federal Register *and notify the appropriate congressional committees* each declaration, determination and renewal.	**Sec. 564 (b)(3).** Same as S. 15.	
	conditions placed on emergency use of drugs emergency.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Contents of Reports	**Sec. 5 (a)(1)(B).** These reports will be submitted to the designated congressional committees and summarize–	No similar provision.	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.	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.	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.	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.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Annual Summaries Regarding Certain Activity	**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.	No similar provision.	
	use of increased micropurchase threshold,	No similar provision.	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.	No similar provision.	
	use of streamlined personnel authority.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
National Academy of Sciences Review	**Sec. 5 (b)(1).** Not later than 4 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 5 years after enactment.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
National Academy of Sciences Review Report Contents	**Sec. 5 (b)(2).** This report shall include–	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.	
	the Academy's assessment of the current availability of countermeasures to address such threats;	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	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
National Academy of Sciences Review Report Contents (continued)	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.	
	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	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
General Accounting Office Review	**Sec. 5 (c).** 4 years after the date of the enactment of this Act, the Comptroller General of the United States shall initiate a study–	**Sec. 6 .** *Not later than* 4 years after the date of the enactment of this Act, the Comptroller General of the United States shall initiate a study *that*–	**Sec. 6 .** Same as S. 15.	
	(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	(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);	Same as S. 15.	The provisions cited in the Senate bills refer to simplified acquisition procedures and use of non-competitive procedures.
	(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.	No similar provision.	

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

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
General Accounting Office Review (continued)	(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.	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.	No similar provision.	
	The results of the study shall be submitted to the designated congressional committees not later than 5 years after the enactment of this Act.	No similar provision.	No similar provision.	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Report Regarding Security Counter-measures Procurement Barriers	**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. **Sec. 5 (d)(2).** Not later than 1 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.	No similar provision. No similar provision.	
Report Regarding Status of Program for Chemical Terrorism Preparedness	**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	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Designated Congressional Committees	**Sec. 5 (f).** The term `designated congressional committees' means the following committees of Congress:	No similar provision.	No similar provision.	The Senate versions use the phrase "appropriate congressional committees," elsewhere in the bills, without specifying which committees they are.
	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.	No similar provision.	
	the Senate Committees on Health, Education, Labor, and Pensions; Appropriations; and Government Affairs.	No similar provision.	No similar provision.	

Table 6. Outreach

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Outreach	**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.	No similar provision.	

Table 7. Export Control Recommendation

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Recommendation for Export Controls on Certain Biomedical Countermeasures	**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.	No similar provision.	

Table 8. Interagency Coordination

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Ensuring Coordination, Cooperation and the Elimination of Unnecessary Duplication in Programs	**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.	No similar provision.	
Designation of Agency Coordination Officer	**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.	No similar provision.	

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

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Smallpox-Related Amendments to the Homeland Security Act and Public Health Services Act	No similar provision.	**Sec. 5.** These provisions concern smallpox countermeasures and were considered by other legislation. The Smallpox Emergency Personnel Protection Act of 2003 (P.L.108-020) has incorporated many of these provisions.	No similar provision.	

Table 10. Additional HHS Secretary Authorities During National Emergencies

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	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).	
	No similar provision.	No similar provision.	Allows the HHS Secretary in emergencies to waive or modify –	
	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,	
	No similar provision.	No similar provision.	sanctions and penalties that arise from noncompliance with the following requirements,	

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Authority of the HHS Secretary During National Emergencies (continued)	No similar provision.	No similar provision.	to obtain a patient's agreement to speak with family members or friends; and	
	No similar provision.	No similar provision.	to honor a request to opt out of the facility directory;	
	No similar provision.	No similar provision.	requirement to distribute a notice; or	
	No similar provision.	No similar provision.	relating to the patient's right to request privacy restrictions; and confidential communications.	
	No similar provision.	No similar provision.	These waivers shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. The 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 Senate Funding Language

Provision	H.R. 2122 as Passed by House	S. 15 as Reported by Committee	S. 1504 as Introduced	Comments
Special Senate 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.	