§ 247d–6b. Strategic National Stockpile and security countermeasure procurements

(a) Strategic National Stockpile

(1) In general

The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and determination consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The Secretary shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.

(2) Procedures

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

(A) consult with the working group under section 247d–6(a) of this title;

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

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

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(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;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(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

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

(b) Smallpox vaccine development

(1) In general

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

(2) Rule of construction

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

(c) Additional authority regarding procurement of certain countermeasures; availability of special reserve fund

(1) In general

(A) Use of fund

A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) Security countermeasure

For purposes of this subsection, the term “security countermeasure” means 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 262(i) of this title), 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—

(i) is approved or cleared under section 360bbb–3.


(iii) is a contraindication that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(iv) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(v) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) or licensed under section 262 of this title or

(b) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or


(vi) is a countermeasure that is approved or cleared under section 355 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a).

(2) Rule of construction

Nothing in this section shall be construed to—

(A) affect any countermeasure that has been approved or licensed under such section 355 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a).

(B) override the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or any other law.

(C) require the Secretary to take any action that will result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent.

(D) prevent the Secretary from entering into cooperative agreements with such other persons.

(E) determine that a countermeasure is or is not a necessary countermeasure.

(F) prevent the Secretary from entering into cooperative agreements with such other persons.

(G) prevent the Secretary from entering into cooperative agreements with such other persons.

(H) prevent the Secretary from entering into cooperative agreements with such other persons.

(I) prevent the Secretary from entering into cooperative agreements with such other persons.

(J) prevent the Secretary from entering into cooperative agreements with such other persons.

(K) prevent the Secretary from entering into cooperative agreements with such other persons.

(L) prevent the Secretary from entering into cooperative agreements with such other persons.

(M) prevent the Secretary from entering into cooperative agreements with such other persons.

(N) prevent the Secretary from entering into cooperative agreements with such other persons.

(O) prevent the Secretary from entering into cooperative agreements with such other persons.

(P) prevent the Secretary from entering into cooperative agreements with such other persons.

(Q) prevent the Secretary from entering into cooperative agreements with such other persons.

(R) prevent the Secretary from entering into cooperative agreements with such other persons.
(2) Determination of material threats
(A) Material threat
The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—
(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and
(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) Public health impact; necessary countermeasures
The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis—
(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and
(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(C) Notice to Congress
The Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—
(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);
(ii) necessary measures of minimum safety and effectiveness;
(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and
(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(D) Assurance of access to threat information
In making the determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 122 of title 6, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) Assessment of availability and appropriateness of countermeasures
(A) In general
The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) Information
The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—
(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or
(ii) would otherwise be exempt from disclosure under section 552 of title 5.

(4) Call for development of countermeasures; commitment for recommendation for procurement
(A) Proposal to the President
If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—
(i) issue a call for the development of such countermeasure; and
(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure.

(B) Countermeasure specifications
The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—
(i) the call for the countermeasure;
(ii) specifications for the countermeasure under subparagraph (B); and
(iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund
(A) In general
The Secretary, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) of this section pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a “procurement under this subsection”).

(B) Requirements
In making a determination under subparagraph (A) with respect to a security counter-
measure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.
(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.
(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendation for President’s approval

(A) Recommendation for procurement

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

(B) Presidential approval

The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) Notice to appropriate congressional committees

The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) Rule of construction

Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) Procurement

(A) In general

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

(B) Interagency agreement; cost

The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement.

(C) Procurement

(i) In general

The Secretary shall be responsible for—
(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and
(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) Contract terms

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

(I) Payment conditioned on delivery

The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary’s discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide
that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) Discounted payment

The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) Contract duration

The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) Storage by vendor

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

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) Sales exclusivity

The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 3304(a)(1) of title 41.

(VIII) Warm based surge capacity

The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) Contract terms

The Secretary, in any contract for procurement under this section—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) Availability of simplified acquisition procedures

(I) In general

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 134 of title 41, for purposes of application to such procurement, pursuant to section 3101(b)(1)(A) of title 41, of—
(aa) section 3305(a)(1) of title 41 and its implementing regulations; and
(bb) section 3101(b)(1)(B) of title 41 and its implementing regulations.

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

(aa) Chapter 37 of title 40 (relating to contract work hours and safety standards);
(bb) Section 8703(a) of title 41.
(cc) Section 4706 of title 41 (relating to the examination of contractor records).
(dd) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).
(ee) Section 3901 of title 41 (relating to contingent fees to middlemen).
(ff) Section 6862 of this title.
(gg) Section 1354 of title 31 (relating to the examination of contractor records).

(III) Internal controls to be established
The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) Authority to limit competition
In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) Procedures other than full and open competition

(I) In general
In using the authority provided in section 3304(a)(1) of title 41 to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase “available from only one responsible source” in such section 3304(a)(1) shall be deemed to mean “available from only one responsible source or only from a limited number of responsible sources.”

(II) Relation to other authorities
The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) Applicable government-wide regulations
The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 3304(a)(1) (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.

(v) Premium provision in multiple award contracts

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

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and
(bb) promises to pay one or more specified premiums based on the priority of such vendors’ production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) Determination of Government’s requirement not reviewable
If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary’s determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) Extension of closing date for receipt of proposals not reviewable
A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) Limiting competition to sources responding to request for information
In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 3306(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.
(viii) Flexibility

In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) Limitation

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

(d) Disclosures

No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) of this section are stored.

(e) Definition

For purposes of subsection (a) of this section, the term “stockpile” includes—

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

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

(f) Authorization of appropriations

(1) Strategic National Stockpile

For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated $533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) Smallpox vaccine development

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

(g) Special reserve fund

(1) Authorization of appropriations

In addition to amounts appropriated to the special reserve fund prior to March 13, 2013, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

(2) Use of special reserve fund for advanced research and development

The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 247d–7e of this title (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 247d–7e of this title are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) Restrictions on use of funds

Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 247d–7e of this title) or for procurement of a security countermeasure under subsection (c)(7).

(4) Report

Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300b–10(d) of this title).

(h) Definitions

In this section:

(1) The term “advanced research and development” has the meaning given such term in section 247d–7e(a) of this title.

(2) The term “special reserve fund” means the “Biodefense Countermeasures” appropriations account, any appropriation made available pursuant to section 321(a) of title 6, and any appropriation made available pursuant to subsection (g)(1).

Stat. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which
substituted for "section 303A(a)(1)(B) of the Federal
Property and Administrative Services Act of 1949 (41
§ 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted
Title 41, Public Contracts.
Section was formerly classified to section 300hh-12 of

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"consistent with section 300hh-10 of this title" after
amounts as are determined and "and shall submit
to the appropriate congressional committees of
jurisdiction to the extent that disclosure of such
information does not compromise national security"
after "based on such review".
"and that the potential depletion of countermeasures
currently in the stockpile is identified and appro-
priately addressed, including through necessary replen-
ishment" before semicolon at end.
Subsec. (c). Pub. L. 113–5, § 401(b)(1)(A), substituted
"special reserve fund as defined in subsection (b)" for
"special reserve fund under paragraph (10)" wherever
appearing.
"the appropriate committees of Congress" for "the
designated congressional committees (as defined in par-
agraph (10))".
Subsec. (c)(5)(B)(ii). Pub. L. 113–5, § 401(a)(3), substi-
tuted "10 years" for "eight years".
"appropriate congressional committees" for "des-
dnated congressional committees" in heading and in
text.
Prior to amendment, text read as follows: "The Sec-
retary, in any contract for procurement under this sec-
tion, may specify—
"(aa) the dosing and administration requirements for
countermeasures to be developed and procured;

(bb) the amount of funding that will be dedicated
by the Secretary for development and acquisition of
the countermeasure; and

(cc) the specifications the countermeasure must
meet to qualify for procurement under a contract
under this section."
out pars. (9) and (10) which described restrictions on the
use of funds and defined "special reserve fund" and
"designated congressional committees".
Subsec. (f)(1). Pub. L. 113–5, § 403(2), substituted
"$351,800,000 for each of fiscal years 2014 through 2018.
Such authorization is in addition to amounts in the
special reserve fund referred to in subsection (h)." for
"$60,000,000 for fiscal year 2002, and such sums as may
be necessary for each of fiscal years 2003 through 2006.
Such authorization is in addition to amounts in the
special reserve fund referred to in subsection (c)(10)(A)
of this section.
Subsec. (g). (h). Pub. L. 113–5, § 401(b)(2), added sub-
secs. (g) and (h).
countermeasure procurements" after "Stockpile" in
section catchline.

References in Text
The Federal Food, Drug, and Cosmetic Act, referred
in subsection (b)(3) of this section, was added Pub. L.
52 Stat. 1040, as amended. Chapter V of the Act is
classified generally to subchapter V (§ 351 et seq.) of
chapter 9 of Title 21, Food and Drugs.

Public Contracts
Title 41, Public Contracts.
non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.”


Subsec. (c)(1)(B)(i)(D). Pub. L. 109–417, § 406(2)(B), which directed amendment of section 319P–2(c)(1)(B) by substituting “diagnose, mitigate, prevent, or treat” for “treat, identify, or prevent” wherever appearing, was executed by making the substitution in two places in subsec. (c)(1)(B)(i) of this section, which is section 319P–2 of the Public Health Service Act, to reflect the probable intent of Congress.


Subsec. (c)(5)(B)(i). Pub. L. 109–417, § 406(2)(D), substituted “to meet the stockpile needs” for “to meet the need”.

Subsec. (c)(7)(B). Pub. L. 109–417, § 406(2)(E), substituted “cost” for “costs” in subpar. heading, struck out cl. (i) designation and heading before “The Homeland Security”, and struck out heading and text of cl. (ii). Text read as follows: “The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.”

Subsec. (c)(7)(C)(i)(I). Pub. L. 109–417, § 406(2)(F)(I), amended heading and text of subcl. (I) generally. Prior to amendment, text read as follows: “The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary’s discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery.

The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subsection may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.”


Subsec. (c)(8)(A). Pub. L. 109–417, § 406(2)(G), inserted at end “Such agreements may allow other executive agencies to order qualified and security countermeasures of the Department of Health and Human Services as reimbursement for such orders for countermeasures.”

2004—Pub. L. 108–276, § 83(a)(2), amended section generally. Prior to amendment, text related in subsec. (a) to Strategic National Stockpile, in subsec. (b) to smallpox vaccine development, in subsec. (c) to disclosures, in subsec. (d) to definition of “stockpile”, and in subsec. (e) to authorization of appropriations.

2002—Subsec. (a)(1). Pub. L. 107–206, § 1705(a)(1), substituted “The Secretary of Homeland Security” for “The Secretary of Health and Human Services” and inserted “the Secretary of Health and Human Services” after “as are determined by the Secretary”.

ulations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

"(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

"(D) GUIDELINES.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

"(E) REPORTS.—

"(1) President.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

"(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

"(B) the measures taken by the President to implement this section.

"(2) NATIONAL ACADEMY OF SCIENCES.—

"(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale.

"(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act [June 12, 2002], the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

"(F) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.

"[Memorandum of President of the United States, July 3, 2007, 72 F.R. 27627, provided:

"[Memorandum for the Secretary of Health and Human Services[,] the Secretary of Energy[,] the Secretary of Homeland Security[,] the Chairman of the Nuclear Regulatory Commission[,] and the Director of the Office of Science and Technology Policy

"By the authority vested in me by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, and section 204(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976, as amended (42 U.S.C. 6613(b)), the functions of the President under section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (42 U.S.C. 247d–6b note) are assigned as follows:

(1) the function of making a determination under subsection 127(f) of Public Law 107–188 is assigned to the Director of the Office of Science and Technology Policy; and

(2) the functions of the President under section 127 of Public Law 107–188 other than that assigned under subsection 127(f) are assigned to the Chairman of the Nuclear Regulatory Commission.

[In the performance of such functions the Chairman and the Director should consult each other and the Secretaries of Health and Human Services, Energy, and Homeland Security, as appropriate.]

[The Director is authorized and directed to publish this memorandum in the Federal Register.]

DESIGNATION AND AUTHORIZATION TO PERFORM FUNCTIONS UNDER SECTION 319F–3 OF THE PUBLIC HEALTH SERVICE ACT

Memorandum of President of the United States, Oct. 21, 2004, 69 F.R. 70349, provided:

"Memorandum for the Director of the Office of Management and Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby direct you to perform the functions vested in the President under section 319F–2(c)(6) of the Public Health Service Act, 42 U.S.C. 247d–6b(c)(6).

Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the Federal Register.

GEORGE W. BUSH.


§ 247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) of this section has been issued with respect to such countermeasure.

(b) Scope of claims for loss

(A) Loss

For purposes of this section, the term ‘loss’ means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal rela-