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. 37627, 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 as President 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–2 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–6c. Reports regarding authorities under this Act

### (a) Secretary of Health and Human Services

#### (1) Annual reports on particular exercises of authority

##### (A) Relevant authorities

The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

(i) With respect to section 247d–6a of this title:

(I) Subsection (b)(1) (relating to increased simplified acquisition threshold).

(II) Subsection (b)(2) (relating to procedures other than full and open competition).

(III) Subsection (c) (relating to expedited peer review procedures).

(ii) With respect to section 247d–6b of this title:

(I) Subsection (c)(7)(C)(iii) (relating to simplified acquisition procedures).

(II) Subsection (c)(7)(C)(iv) (relating to procedures other than full and open competition).

(III) Subsection (c)(7)(C)(v) (relating to premium provision in multiple-award contracts).

(iii) With respect to section 360bbb–3 of title 21:

(I) Subsection (a)(1) (relating to emergency uses of certain drugs and devices).

(II) Subsection (b)(1) (relating to a declaration of an emergency).

(III) Subsection (e) (relating to conditions on authorization).

##### (B) Contents of reports

The Secretary shall annually submit to the designated congressional committees a report that summarizes—

(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and

(iv) whether, with respect to each procurement that is approved by the President under section 247d–6b(c)(6) of this title, a contract was entered into within one year after such approval by the President.

#### (2) Annual summaries regarding certain activity

The Secretary shall annually submit to the designated congressional committees a report that summarizes the activity undertaken pursuant to the following authorities under section 247d–6a of this title:

(A) Subsection (b)(3) (relating to increased micropurchase threshold).

(B) Subsection (d) (relating to authority for personal services contracts).

(C) Subsection (e) (relating to streamlined personnel authority).

With respect to subparagraph (B), the report shall include a provision specifying, for the one-year period for which the report is submit-

ted, 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.

**(3) Report on additional barriers to procurement of security countermeasures**

Not later than one year after July 21, 2004, the Secretary, in consultation with the Secretary of Homeland Security, shall report to the designated congressional committees any potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

**(b) Government Accountability Office review**

**(1) In general**

Four years after July 21, 2004, the Comptroller General of the United States shall initiate a study—

(A)(i) to review the Secretary of Health and Human Services' utilization 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

(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;

(B)(i) to review and assess the adequacy of the internal controls instituted by such Secretary with respect to such authorities, where required by this Act; and

(ii) to make recommendations to improve the effectiveness of such controls;

(C)(i) to review such Secretary's utilization 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

(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;

(D) to identify any purchases or procurements that would not have been made or would have been significantly delayed except for the authorities described in subparagraph (A)(i); and

(E)(i) to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities established in this Act have enhanced the development of biomedical countermeasures affecting national security; and

(ii) to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

**(2) Additional provisions regarding determination on development of biomedical countermeasures affecting national security**

In the report under paragraph (1), the determination under subparagraph (E) of such paragraph shall include—

(A) the Comptroller General's assessment of the current availability of countermeasures to address threats identified by the Secretary of Homeland Security;

(B) the Comptroller General'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

(C)(i) the Comptroller General's assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on July 21, 2004, the development of antibiotic resistant, mutated, or bioengineered strains of biological agents; and

(ii) 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.

**(3) Report**

A report providing the results of the study under paragraph (1) shall be submitted to the designated congressional committees not later than five years after July 21, 2004.

**(c) Report regarding biocontainment facilities**

Not later than 120 days after July 21, 2004, the Secretary of Homeland Security and the Secretary of Health and Human Services shall 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.

**(d) Designated congressional committees**

For purposes of this section, the term ''designated congressional committees'' means the following committees of the Congress:

(1) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(2) In the Senate: the appropriate committees.

(Pub. L. 108–276, § 5, July 21, 2004, 118 Stat. 860.)

REFERENCES IN TEXT

This Act, referred to in subsecs. (a)(3) and (b)(1), (2)(B), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835, known as the Project BioShield Act of 2004. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Project BioShield Act of 2004, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Committee on Government Reform of House of Representatives changed to Committee on Oversight and Government Reform of House of Representatives by House Resolution No. 6, One Hundred Tenth Congress, Jan. 5, 2007.

## § 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.

#### (2) 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 relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

#### (3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) of this section with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

#### (4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

#### (5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b) of this section, the declaration under such subsection provides that subsection (a) of this section applies only to covered countermeasures obtained through a particular means of distribution.

#### (6) Rebuttable presumption

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b) of this section, of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

### (b) Declaration by Secretary

#### (1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) of this section is in effect with respect to the activities so recommended.

#### (2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—