

Union Calendar No. 416

109TH CONGRESS
2^D SESSION

H. R. 5533

[Report No. 109-686]

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2006

Mr. ROGERS of Michigan (for himself, Ms. ESHOO, Mr. HOEKSTRA, and Mr. McHUGH) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 26, 2006

Additional sponsors: Mr. BURGESS, Mr. JEFFERSON, Mr. CLYBURN, Mrs. CAPPS, Mr. GORDON, Mr. SHIMKUS, Mr. FERGUSON, and Mr. WYNN

SEPTEMBER 26, 2006

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on June 6, 2006]

A BILL

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Biodefense and Pan-*
5 *demic Vaccine and Drug Development Act of 2006”.*

6 **SEC. 2. TABLE OF CONTENTS.**

7 *The table of contents of this Act is as follows:*

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Biomedical Advanced Research and Development Authority; National Bio-
defense Science Board.

Sec. 4. Clarification of countermeasures covered by Project BioShield.

Sec. 5. Technical assistance.

Sec. 6. Procurement.

8 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-**
9 **MENT AUTHORITY; NATIONAL BIODEFENSE**
10 **SCIENCE BOARD.**

11 *Title III of the Public Health Service Act (42 U.S.C.*
12 *241 et seq.) is amended by inserting after section 319K the*
13 *following:*

14 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**
15 **VELOPMENT AUTHORITY.**

16 *“(a) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-*
17 *OPMENT AUTHORITY.—*

18 *“(1) ESTABLISHMENT.—There is established*
19 *within the Department of Health and Human Serv-*
20 *ices the Biomedical Advanced Research and Develop-*
21 *ment Authority.*

1 “(2) *IN GENERAL.*—*The Secretary shall coordi-*
2 *nate and oversee the acceleration of countermeasure*
3 *and product advanced research and development by—*

4 “(A) *facilitating collaboration among the*
5 *Department of Health and Human Services,*
6 *other Federal agencies, relevant industries, aca-*
7 *demia, and other persons, with respect to such*
8 *advanced research and development;*

9 “(B) *promoting countermeasure and prod-*
10 *uct advanced research and development;*

11 “(C) *facilitating contacts between interested*
12 *persons and the offices or employees authorized*
13 *by the Secretary to advise such persons regard-*
14 *ing requirements under the Federal Food, Drug,*
15 *and Cosmetic Act and under section 351 of this*
16 *Act; and*

17 “(D) *promoting innovation to reduce the*
18 *time and cost of countermeasure and product ad-*
19 *vanced research and development.*

20 “(3) *DIRECTOR.*—*The BARDA shall be headed*
21 *by a Director (referred to in this section as the ‘Direc-*
22 *tor’) who shall be appointed by the Secretary and to*
23 *whom the Secretary shall delegate such functions and*
24 *authorities as necessary to implement this section.*

25 “(4) *DUTIES.*—

1 “(A) *COLLABORATION.*—*To carry out the*
2 *purpose described in paragraph (2)(A), the Sec-*
3 *retary shall—*

4 “(i) *facilitate and increase the expedi-*
5 *tious and direct communication between the*
6 *Department of Health and Human Services*
7 *and relevant persons with respect to coun-*
8 *termeasure and product advanced research*
9 *and development, including by—*

10 “(I) *facilitating such communica-*
11 *tion regarding the processes for pro-*
12 *curing such advanced research and de-*
13 *velopment with respect to qualified*
14 *countermeasures and qualified pan-*
15 *demic or epidemic products of interest;*
16 *and*

17 “(II) *soliciting information about*
18 *and data from research on potential*
19 *qualified countermeasures and quali-*
20 *fied pandemic or epidemic products*
21 *and related technologies;*

22 “(ii) *at least annually—*

23 “(I) *convene meetings with rep-*
24 *resentatives from relevant industries,*
25 *academia, other Federal agencies,*

1 *international agencies as appropriate,*
2 *and other interested persons;*

3 “(II) *sponsor opportunities to*
4 *demonstrate the operation and effec-*
5 *tiveness of relevant biodefense counter-*
6 *measure technologies; and*

7 “(III) *convene such working*
8 *groups on countermeasure and product*
9 *advanced research and development as*
10 *the Secretary may determine are nec-*
11 *essary to carry out this section; and*

12 “(iii) *carry out the activities described*
13 *in section 6 of the Biodefense and Pandemic*
14 *Vaccine and Drug Development Act of 2006.*

15 “(B) *SUPPORT ADVANCED RESEARCH AND*
16 *DEVELOPMENT.—To carry out the purpose de-*
17 *scribed in paragraph (2)(B), the Secretary*
18 *shall—*

19 “(i) *conduct ongoing searches for, and*
20 *support calls for, potential qualified coun-*
21 *termeasures and qualified pandemic or epi-*
22 *demic products;*

23 “(ii) *direct and coordinate the counter-*
24 *measure and product advanced research and*

1 *development activities of the Department of*
2 *Health and Human Services;*

3 “(iii) *establish strategic initiatives to*
4 *accelerate countermeasure and product ad-*
5 *vanced research and development and inno-*
6 *vation in such areas as the Secretary may*
7 *identify as priority unmet need areas; and*

8 “(iv) *award contracts, grants, coopera-*
9 *tive agreements, and enter into other trans-*
10 *actions, for countermeasure and product ad-*
11 *vanced research and development.*

12 “(C) *FACILITATING ADVICE.—To carry out*
13 *the purpose described in paragraph (2)(C) the*
14 *Secretary shall—*

15 “(i) *connect interested persons with the*
16 *offices or employees authorized by the Sec-*
17 *retary to advise such persons regarding the*
18 *regulatory requirements under the Federal*
19 *Food, Drug, and Cosmetic Act and under*
20 *section 351 of this Act related to the ap-*
21 *proval, clearance, or licensure of qualified*
22 *countermeasures or qualified pandemic or*
23 *epidemic products; and*

24 “(ii) *ensure that, with respect to per-*
25 *sons performing countermeasure and prod-*

1 *uct advanced research and development*
2 *funded under this section, such offices or*
3 *employees provide such advice in a manner*
4 *that is ongoing and that is otherwise des-*
5 *ignated to facilitate expeditious development*
6 *of qualified countermeasures and qualified*
7 *pandemic or epidemic products that may*
8 *achieve such approval, clearance, or licen-*
9 *sure.*

10 *“(D) SUPPORTING INNOVATION.—To carry*
11 *out the purpose described in paragraph (2)(D),*
12 *the Secretary may award contracts, grants, and*
13 *cooperative agreements, or enter into other trans-*
14 *actions, such as prize payments, to promote—*

15 *“(i) innovation in technologies that*
16 *may assist countermeasure and product ad-*
17 *vanced research and development;*

18 *“(ii) research on and development of*
19 *research tools and other devices and tech-*
20 *nologies; and*

21 *“(iii) research to promote strategic ini-*
22 *tiatives, such as rapid diagnostics, broad*
23 *spectrum antimicrobials, and vaccine man-*
24 *ufacturing technologies.*

25 *“(5) TRANSACTION AUTHORITIES.—*

1 “(A) *OTHER TRANSACTIONS.*—*In carrying*
2 *out the functions under subparagraph (B) or (D)*
3 *of paragraph (4), the Secretary shall have au-*
4 *thority to enter into other transactions for coun-*
5 *termeasure and product advanced research and*
6 *development.*

7 “(B) *EXPEDITED AUTHORITIES.*—

8 “(i) *IN GENERAL.*—*In awarding con-*
9 *tracts, grants, and cooperative agreements,*
10 *and in entering into other transactions*
11 *under subparagraph (B) or (D) of para-*
12 *graph (4), the Secretary shall have the expe-*
13 *ditated procurement authorities, the authority*
14 *to expedite peer review, and the authority*
15 *for personal services contracts, supplied by*
16 *subsections (b), (c), and (d) of section*
17 *319F-1.*

18 “(ii) *APPLICATION OF PROVISIONS.*—
19 *Provisions in such section 319F-1 that*
20 *apply to such authorities and that require*
21 *institution of internal controls, limit re-*
22 *view, provide for Federal Tort Claims Act*
23 *coverage of personal services contractors,*
24 *and commit decisions to the discretion of*

1 *the Secretary shall apply to the authorities*
2 *as exercised pursuant to this paragraph.*

3 “(iii) *AUTHORITY TO LIMIT COMPETI-*
4 *TION.—For purposes of applying section*
5 *319F–1(b)(1)(D) to this paragraph, the*
6 *phrase ‘BioShield Program under the*
7 *Project BioShield Act of 2004’ shall be*
8 *deemed to mean the countermeasure and*
9 *product advanced research and development*
10 *program under this section.*

11 “(iv) *AVAILABILITY OF DATA.—The*
12 *Secretary may require that, as a condition*
13 *of being awarded a contract, grant, coopera-*
14 *tive agreement, or other transaction under*
15 *subparagraph (B) or (D) of paragraph (4),*
16 *a person make available to the Secretary on*
17 *an ongoing basis, and submit upon request*
18 *to the Secretary, relevant data related to or*
19 *resulting from countermeasure and product*
20 *advanced research and development carried*
21 *out pursuant to this section.*

22 “(C) *ADVANCE PAYMENTS; ADVERTISING.—*
23 *The authority of the Secretary to enter into con-*
24 *tracts under this section shall not be limited by*
25 *section 3324(a) of title 31, United States Code,*

1 or by section 3709 of the Revised Statutes of the
2 United States (41 U.S.C. 5).

3 “(D) *MILESTONE-BASED PAYMENTS AL-*
4 *LOWED.—In awarding contracts, grants, and co-*
5 *operative agreements, and in entering into other*
6 *transactions, under this section, the Secretary*
7 *may use milestone-based awards and payments.*

8 “(E) *FOREIGN NATIONALS ELIGIBLE.—The*
9 *Secretary may under this section award con-*
10 *tracts, grants, and cooperative agreements to,*
11 *and may enter into other transactions with,*
12 *highly qualified foreign national persons outside*
13 *the United States, alone or in collaboration with*
14 *American participants, when such transactions*
15 *may inure to the benefit of the American people*
16 *and are consistent with National security.*

17 “(F) *ESTABLISHMENT OF ADVANCED RE-*
18 *SEARCH CENTERS.—The Secretary may establish*
19 *one or more federally-funded research and devel-*
20 *opment centers, or university-affiliated research*
21 *centers in accordance with section 303(c)(3) of*
22 *the Federal Property and Administrative Serv-*
23 *ices Act of 1949 (41 U.S.C. 253(c)(3)), provided*
24 *that such centers are consistent and complemen-*
25 *tary with the duties described in paragraph (4),*

1 *and are consistent and complementary with, and*
2 *deemed necessary after considering the avail-*
3 *ability of, existing federally-supported basic re-*
4 *search programs.*

5 “(6) *VULNERABLE POPULATIONS.*—*In carrying*
6 *out the functions under this section, the Secretary*
7 *may give priority to the advanced research and devel-*
8 *opment of qualified countermeasures and qualified*
9 *pandemic or epidemic products that are likely to be*
10 *safe and effective with respect to the emergency health*
11 *security needs of children and other vulnerable popu-*
12 *lations.*

13 “(7) *PERSONNEL AUTHORITIES.*—

14 “(A) *SPECIALLY QUALIFIED SCIENTIFIC AND*
15 *PROFESSIONAL PERSONNEL.*—*In addition to any*
16 *other personnel authorities, the Secretary may—*

17 “(i) *without regard to those provisions*
18 *of title 5, United States Code, governing ap-*
19 *pointments in the competitive service, ap-*
20 *point highly qualified individuals to sci-*
21 *entific or professional positions in BARDA,*
22 *such as program managers, to carry out*
23 *this section; and*

24 “(ii) *compensate them in the same*
25 *manner in which individuals appointed*

1 *under section 9903 of such title are com-*
2 *pensated, without regard to the provisions*
3 *of chapter 51 and subchapter III of chapter*
4 *53 of such title relating to classification and*
5 *General Schedule pay rates.*

6 “(B) *SPECIAL CONSULTANTS.*—*In carrying*
7 *out this section, the Secretary may—*

8 “(i) *appoint special consultants pursu-*
9 *ant to section 207(f); and*

10 “(ii) *accept voluntary and uncompen-*
11 *sated services.*

12 “(c) *INAPPLICABILITY OF CERTAIN PROVISIONS.*—

13 “(1) *DISCLOSURE.*—

14 “(A) *IN GENERAL.*—*The Secretary shall*
15 *withhold from disclosure under section 552 of*
16 *title 5, United States Code, specific technical*
17 *data or scientific information that is created or*
18 *obtained during the countermeasure and product*
19 *advanced research and development funded by*
20 *the Secretary that reveal vulnerabilities of exist-*
21 *ing medical or public health defenses against bio-*
22 *logical, chemical, nuclear, or radiological threats.*
23 *Such information shall be deemed to be informa-*
24 *tion described in section 552(b)(3) of title 5,*
25 *United States Code.*

1 “(B) *OVERSIGHT.*—*Information subject to*
2 *nondisclosure under subparagraph (A) shall be*
3 *reviewed by the Secretary every 5 years to deter-*
4 *mine the relevance or necessity of continued non-*
5 *disclosure.*

6 “(2) *FEDERAL ADVISORY COMMITTEE ACT.*—*Sec-*
7 *tion 14 of the Federal Advisory Committee Act (5*
8 *U.S.C. App.) shall not apply to a working group of*
9 *BARDA or to the National Biodefense Science Board*
10 *under section 319M.*

11 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*For the*
12 *purpose of carrying out advanced research and development*
13 *under this section, there are authorized to be appropriated*
14 *\$160,000,000 for each of the fiscal years 2007 and 2008.*
15 *Such authorizations are in addition to other authorizations*
16 *of appropriations that are available for such purpose.*
17 *Amounts appropriated under the preceding sentence are*
18 *available until expended.*

19 “(e) *DEFINITIONS.*—*For purposes of this section:*

20 “(1) *BARDA.*—*The term ‘BARDA’ means the*
21 *Biomedical Advanced Research and Development Au-*
22 *thority.*

23 “(2) *OTHER TRANSACTIONS.*—*The term ‘other*
24 *transactions’ means transactions, other than procure-*
25 *ment contracts, grants, and cooperative agreements,*

1 *such as the Secretary of Defense may enter into under*
2 *section 2371 of title 10, United States Code.*

3 “(3) *QUALIFIED COUNTERMEASURE.*—*The term*
4 *‘qualified countermeasure’ has the meaning given*
5 *such term in section 319F–1.*

6 “(4) *QUALIFIED PANDEMIC OR EPIDEMIC PROD-*
7 *UCT.*—*The term ‘qualified pandemic or epidemic*
8 *product’ has the meaning given the term in section*
9 *319F–3.*

10 “(5) *ADVANCED RESEARCH AND DEVELOP-*
11 *MENT.*—

12 “(A) *IN GENERAL.*—*The term ‘advanced re-*
13 *search and development’ means, with respect to*
14 *a product that is or may become a qualified*
15 *countermeasure or a qualified pandemic or epi-*
16 *demic product, activities that predominantly—*

17 “(i) *are conducted after basic research*
18 *and preclinical development of the product;*
19 *and*

20 “(ii) *are related to manufacturing the*
21 *product on a commercial scale and in a*
22 *form that satisfies the regulatory require-*
23 *ments under the Federal Food, Drug, and*
24 *Cosmetic Act or under section 351 of this*
25 *Act.*

1 “(B) *ACTIVITIES INCLUDED.*—*The term*
2 *under subparagraph (A) includes—*

3 “(i) *testing of the product to determine*
4 *whether the product may be approved,*
5 *cleared, or licensed under the Federal Food,*
6 *Drug, and Cosmetic Act or under section*
7 *351 of this Act for a use that is or may be*
8 *the basis for such product becoming a quali-*
9 *fied countermeasure or qualified pandemic*
10 *or epidemic product, or to help obtain such*
11 *approval, clearance, or license;*

12 “(ii) *design and development of tests or*
13 *models, including animal models, for such*
14 *testing;*

15 “(iii) *activities to facilitate manufac-*
16 *ture of the product on a commercial scale*
17 *with consistently high quality, as well as to*
18 *improve and make available new tech-*
19 *nologies to increase manufacturing surge*
20 *capacity;*

21 “(iv) *activities to improve the shelf-life*
22 *of the product or technologies for admin-*
23 *istering the product; and*

24 “(v) *such other activities as are part of*
25 *the advanced stages of testing, refinement,*

1 *improvement, or preparation of the product*
2 *for such use and as are specified by the Sec-*
3 *retary.*

4 “(6) *RESEARCH TOOL.*—*The term ‘research tool’*
5 *means a device, technology, biological material, rea-*
6 *gent, animal model, computer system, computer soft-*
7 *ware, or analytical technique that is developed to as-*
8 *assist in the discovery, development, or manufacture of*
9 *qualified countermeasures or qualified pandemic or*
10 *epidemic products.*

11 “(7) *PROGRAM MANAGER.*—*The term ‘program*
12 *manager’ means an individual appointed to carry*
13 *out functions under this section and authorized to*
14 *provide project oversight and management of strategic*
15 *initiatives.*

16 “(8) *PERSON.*—*The term ‘person’ includes an in-*
17 *dividual, partnership, corporation, association, enti-*
18 *ty, or public or private corporation, and a Federal,*
19 *State, or local government agency or department.*

20 **“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND**
21 **WORKING GROUPS.**

22 “(a) *IN GENERAL.*—

23 “(1) *ESTABLISHMENT AND FUNCTION.*—*The Sec-*
24 *retary shall establish the National Biodefense Science*
25 *Board (referred to in this section as the ‘Board’) to*

1 *provide expert advice and guidance to the Secretary*
2 *on scientific, technical and other matters of special*
3 *interest to the Department of Health and Human*
4 *Services regarding current and future chemical, bio-*
5 *logical, nuclear, and radiological agents, whether nat-*
6 *urally occurring, accidental, or deliberate.*

7 “(2) *MEMBERSHIP.*—*The membership of the*
8 *Board shall be comprised of individuals who represent*
9 *the Nation’s preeminent scientific, public health, and*
10 *medical experts, as follows—*

11 “(A) *such Federal officials as the Secretary*
12 *may determine are necessary to support the*
13 *functions of the Board;*

14 “(B) *four individuals representing the*
15 *pharmaceutical, biotechnology, and device indus-*
16 *tries;*

17 “(C) *four individuals representing aca-*
18 *demia; and*

19 “(D) *five other members as determined ap-*
20 *propriate by the Secretary.*

21 “(3) *TERM OF APPOINTMENT.*—*A member of the*
22 *Board described in subparagraph (B), (C), or (D) of*
23 *paragraph (2) shall serve for a term of 3 years, except*
24 *that the Secretary may adjust the terms of the initial*

1 *Board appointees in order to provide for a staggered*
2 *term of appointment for all members.*

3 “(4) *CONSECUTIVE APPOINTMENTS; MAXIMUM*
4 *TERMS.—A member may be appointed to serve not*
5 *more than 3 terms on the Board and may serve not*
6 *more than 2 consecutive terms.*

7 “(5) *DUTIES.—The Board shall—*

8 “(A) *advise the Secretary on current and*
9 *future trends, challenges, and opportunities pre-*
10 *sented by advances in biological and life sciences,*
11 *biotechnology, and genetic engineering with re-*
12 *spect to threats to biodefense or public health se-*
13 *curity posed by naturally occurring infectious*
14 *diseases and chemical, biological, radiological,*
15 *and nuclear agents;*

16 “(B) *at the request of the Secretary, review*
17 *and consider any information and findings re-*
18 *ceived from the working groups established under*
19 *subsection (b); and*

20 “(C) *at the request of the Secretary, provide*
21 *recommendations and findings for expanded, in-*
22 *tensified, and coordinated biodefense research*
23 *and development activities.*

24 “(6) *MEETINGS.—*

1 “(A) *INITIAL MEETING.*—Not later than one
2 year after the date of enactment of the *Biodefense*
3 *and Pandemic Vaccine and Drug Development*
4 *Act of 2006, the Secretary shall hold the first*
5 *meeting of the Board.*

6 “(B) *SUBSEQUENT MEETINGS.*—The Board
7 shall meet at the call of the Secretary, but in no
8 case less than twice annually.

9 “(7) *VACANCIES.*—Any vacancy in the Board
10 shall not affect its powers, but shall be filled in the
11 same manner as the original appointment.

12 “(8) *CHAIRPERSON.*—The Secretary shall ap-
13 point a chairperson from among the members of the
14 Board.

15 “(9) *POWERS.*—

16 “(A) *HEARINGS.*—The Board may hold
17 such hearings, sit and act at such times and
18 places, take such testimony, and receive such evi-
19 dence as the Board considers advisable to carry
20 out this subsection.

21 “(B) *POSTAL SERVICES.*—The Board may
22 use the United States mails in the same manner
23 and under the same conditions as other depart-
24 ments and agencies of the Federal Government.

25 “(10) *PERSONNEL.*—

1 “(A) *EMPLOYEES OF THE FEDERAL GOV-*
2 *ERNMENT.—A member of the Board that is an*
3 *employee of the Federal Government may not re-*
4 *ceive additional pay, allowances, or benefits by*
5 *reason of the member’s service on the Board.*

6 “(B) *OTHER MEMBERS.—A member of the*
7 *Board that is not an employee of the Federal*
8 *Government may be compensated at a rate not*
9 *to exceed the daily equivalent of the annual rate*
10 *of basic pay prescribed for level IV of the Execu-*
11 *tive Schedule under section 5315 of title 5,*
12 *United States Code, for each day (including*
13 *travel time) during which the member is engaged*
14 *in the actual performance of duties as a member*
15 *of the Board.*

16 “(C) *TRAVEL EXPENSES.—Each member of*
17 *the Board shall receive travel expenses, including*
18 *per diem in lieu of subsistence, in accordance*
19 *with applicable provisions under subchapter I of*
20 *chapter 57 of title 5, United States Code.*

21 “(D) *DETAIL OF GOVERNMENT EMPLOY-*
22 *EES.—Any Federal Government employee may*
23 *be detailed to the Board with the approval for*
24 *the contributing agency without reimbursement,*

1 *and such detail shall be without interruption or*
2 *loss of civil service status or privilege.*

3 “(b) *DEFINITIONS.*—*Any term that is defined in sec-*
4 *tion 319L and that is used in this section shall have the*
5 *same meaning in this section as such term is given in sec-*
6 *tion 319L.*

7 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
8 *authorized to be appropriated \$1,000,000 to carry out this*
9 *section for each of the fiscal years 2007 and 2008.”.*

10 **SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED**
11 **BY PROJECT BIOSHIELD.**

12 (a) *QUALIFIED COUNTERMEASURES.*—*Section 319F-*
13 *1(a)(2) of the Public Health Service Act (42 U.S.C. 247d-*
14 *6a(a)(2)) is amended—*

15 (1) *by amending subparagraph (A) to read as*
16 *follows:*

17 “(A) *diagnose, mitigate, prevent, or treat*
18 *harm from any biological agent (including orga-*
19 *nisms that cause an infectious disease) or toxin,*
20 *or from any chemical, radiological, or nuclear*
21 *agent, that may cause a public health emergency*
22 *affecting national security; or”;*

23 (2) *in subparagraph (B), by striking “treat,*
24 *identify, or prevent harm” and inserting “diagnose,*
25 *mitigate, prevent, or treat harm”; and*

1 (3) by adding after and below subparagraph (B)
2 the following:

3 *“If through publication in the Federal Register the*
4 *Secretary makes a determination that there is credible*
5 *evidence that a biological agent has the potential to*
6 *cause an epidemic or pandemic that may constitute*
7 *a public health emergency, a countermeasure to such*
8 *agent shall, without further administrative action, be*
9 *considered a qualified countermeasure within the*
10 *meaning of this paragraph.”.*

11 (b) *SECURITY COUNTERMEASURES.—Section 319F–*
12 *2(c)(1)(B)(i)(I) of the Public Health Service Act (42 U.S.C.*
13 *247d–6b(c)(1)(B)(i)(I)) is amended by striking “to treat”*
14 *the first place such term appears and all that follows*
15 *through “from a condition” and inserting the following: “to*
16 *diagnose, mitigate, prevent, or treat harm from any biologi-*
17 *cal agent (including organisms that cause an infectious dis-*
18 *ease) or toxin or from any chemical, radiological, or nuclear*
19 *agent identified as a material threat under paragraph*
20 *(2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm*
21 *from a condition”.*

22 **SEC. 5. TECHNICAL ASSISTANCE.**

23 *Subchapter E of chapter V of the Federal Food, Drug,*
24 *and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended*
25 *by adding at the end the following:*

1 **“SEC. 565. TECHNICAL ASSISTANCE.**

2 *“The Secretary, in consultation with the Commis-*
3 *sioner of Food and Drugs, shall establish within the Food*
4 *and Drug Administration a team of experts on manufac-*
5 *turing and regulatory activities (including compliance with*
6 *current Good Manufacturing Practice) to provide both off-*
7 *site and on-site technical assistance to the manufacturers*
8 *of qualified countermeasures (as defined in section 319F-*
9 *1 of the Public Health Service Act), security counter-*
10 *measures (as defined in section 319F-2 of such Act), or vac-*
11 *cines, at the request of such a manufacturer and at the dis-*
12 *cretion of the Secretary, if the Secretary determines that*
13 *a shortage or potential shortage may occur in the United*
14 *States in the supply of such vaccines or countermeasures*
15 *and that the provision of such assistance would be beneficial*
16 *in helping alleviate or avert such shortage.”.*

17 **SEC. 6. PROCUREMENT.**

18 *Section 319F-2 of the Public Health Service Act (42*
19 *U.S.C. 247d-6b) is amended—*

20 *(1) in the section heading, by inserting “**AND***
21 ***SECURITY COUNTERMEASURE PROCURE-***
22 ***MENTS”* before the period; and**

23 *(2) in subsection (c)—*

24 *(A) in the subsection heading, by striking*
25 ***“BIOMEDICAL”;***

1 (B) in paragraph (5)(B)(i), by striking “to
2 meet the needs of the stockpile” and inserting “to
3 meet the stockpile needs”;

4 (C) in paragraph (7)(B)—

5 (i) by striking the subparagraph head-
6 ing and all that follows through “Homeland
7 Security Secretary” and inserting the fol-
8 lowing: “INTERAGENCY AGREEMENT;
9 COST.—The Homeland Security Secretary”;
10 and

11 (ii) by striking clause (ii);

12 (D) in paragraph (7)(C)(i)—

13 (i) by amending clause (I) to read as
14 follows:

15 “(I) PAYMENT CONDITIONED ON
16 DELIVERY.—The contract shall provide
17 that no payment may be made until
18 delivery of a portion, acceptable to the
19 Secretary, of the total number of units
20 contracted for, except that, notwith-
21 standing any other provision of law,
22 the contract may provide that, if the
23 Secretary determines (in the Sec-
24 retary’s discretion) that an advance
25 payment, partial payment for signifi-

1 *cant milestones, or payment to increase*
2 *manufacturing capacity is necessary to*
3 *ensure success of a project, the Sec-*
4 *retary shall pay an amount, not to ex-*
5 *ceed 10 percent of the contract amount,*
6 *in advance of delivery. The Secretary*
7 *shall, to the extent practicable, make*
8 *the determination of advance payment*
9 *at the same time as the issuance of a*
10 *solicitation. The contract shall provide*
11 *that such advance payment is required*
12 *to be repaid if there is a failure to per-*
13 *form by the vendor under the contract.*
14 *The contract may also provide for ad-*
15 *ditional advance payments of 5 percent*
16 *each for meeting the milestones speci-*
17 *fied in such contract. Provided that the*
18 *specified milestones are reached, these*
19 *advance payments of 5 percent shall*
20 *not be required to be repaid. Nothing*
21 *in this subclause shall be construed as*
22 *affecting the rights of vendors under*
23 *provisions of law or regulation (includ-*
24 *ing the Federal Acquisition Regula-*
25 *tion) relating to the termination of*

1 *contracts for the convenience of the*
2 *Government.”; and*

3 *(ii) by adding at the end the following:*

4 *“(VII) PROCUREMENT OF MUL-*
5 *TIPLE PRODUCTS AND TECH-*
6 *NOLOGIES.—The Secretary may enter*
7 *into multiple transactions for the pro-*
8 *curement of multiple technologies and*
9 *products from multiple manufacturers*
10 *of security countermeasures in order to*
11 *mitigate against the risks associated*
12 *with dependence on a single supplier*
13 *or technology.*

14 *“(VIII) SALES EXCLUSIVITY.—*
15 *The contract may provide that the ven-*
16 *dor is the exclusive supplier of the*
17 *product to the Federal Government for*
18 *a specified period of time, not to exceed*
19 *the term of the contract, on the condi-*
20 *tion that the vendor is able to satisfy*
21 *the needs of the Government. During*
22 *the agreed period of sales exclusivity,*
23 *the vendor shall not assign its rights of*
24 *sales exclusivity to another entity or*
25 *entities without approval by the Sec-*

1 *retary. Such a sales exclusivity provi-*
2 *sion in such a contract shall constitute*
3 *a valid basis for a sole source procure-*
4 *ment under section 303(c)(1) of the*
5 *Federal Property and Administrative*
6 *Services Act of 1949 (41 U.S.C.*
7 *253(c)(1)).*

8 *“(IX) SURGE CAPACITY.—The*
9 *contract may provide that the vendor*
10 *establish domestic manufacturing ca-*
11 *capacity of the product to ensure that ad-*
12 *ditional production of the product is*
13 *available in the event that the Sec-*
14 *retary determines that there is a need*
15 *to quickly purchase additional quan-*
16 *tities of the product. Such contract*
17 *may provide a fee to the vendor for es-*
18 *tablishing and maintaining such ca-*
19 *capacity in excess of the initial require-*
20 *ment for the purchase of the product.*
21 *Additionally, the cost of maintaining*
22 *the domestic manufacturing capacity*
23 *shall be an allowable and allocable di-*
24 *rect cost of the contract.*

1 “(X) *ADDITIONAL CONTRACT*
2 *TERMS.—The Secretary, in any con-*
3 *tract for procurement under this sec-*
4 *tion, may specify—*

5 “*(aa) the dosing and admin-*
6 *istration requirements for coun-*
7 *termeasures to be developed and*
8 *procured;*

9 “*(bb) the amount of funding*
10 *that will be dedicated by the Sec-*
11 *retary for development and acqui-*
12 *sition of the countermeasure; and*

13 “*(cc) the specifications the*
14 *countermeasure must meet to*
15 *qualify for procurement under a*
16 *contract under this section.”; and*

17 *(E) in paragraph (8)(A), by adding at the*
18 *end the following: “In the case of such agree-*
19 *ments by the Secretary, the Secretary may allow*
20 *other executive agencies to order qualified and*
21 *security countermeasures under procurement*
22 *contracts or other agreements established by the*
23 *Secretary, and such ordering process (including*
24 *transfers of appropriated funds between an agen-*
25 *cy and the Department of Health and Human*

1 *Services as reimbursements for such orders for*
2 *countermeasures) may be conducted under the*
3 *authority of section 1535 of title 31, United*
4 *States Code, except that all such orders shall be*
5 *processed under the terms established under this*
6 *section for the procurement of countermeasures.”.*

Union Calendar No. 416

109TH CONGRESS
2^D SESSION

H. R. 5533

[Report No. 109-686]

A BILL

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

SEPTEMBER 26, 2006

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed