

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5533

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

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## 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

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## 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 Biodefense Science Board.

- Sec. 4. Clarification of countermeasures covered by Project BioShield.  
 Sec. 5. Technical assistance.  
 Sec. 6. Procurement.  
 Sec. 7. Rule of construction.

1 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-**  
 2 **MENT AUTHORITY; NATIONAL BIODEFENSE**  
 3 **SCIENCE BOARD.**

4 Title III of the Public Health Service Act (42 U.S.C.  
 5 241 et seq.) is amended by inserting after section 319K  
 6 the following:

7 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**  
 8 **VELOPMENT AUTHORITY.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) BARDA.—The term ‘BARDA’ means the  
 11 Biomedical Advanced Research and Development  
 12 Authority.

13 “(2) FUND.—The term ‘Fund’ means the Bio-  
 14 defense Medical Countermeasure Development Fund  
 15 established under subsection (d).

16 “(3) OTHER TRANSACTIONS.—The term ‘other  
 17 transactions’ means transactions, other than pro-  
 18 curement contracts, grants, and cooperative agree-  
 19 ments, such as the Secretary of Defense may enter  
 20 into under section 2371 of title 10, United States  
 21 Code.

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

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

8           “(6) ADVANCED RESEARCH AND DEVELOP-  
9           MENT.—

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

15                   “(i) are conducted after basic research  
16                   and preclinical development of the product;  
17                   and

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

24           “(B) ACTIVITIES INCLUDED.—The term  
25           under subparagraph (A) includes—

1           “(i) testing of the product to deter-  
2           mine whether the product may be ap-  
3           proved, cleared, or licensed under the Fed-  
4           eral Food, Drug, and Cosmetic Act or  
5           under section 351 of this Act for a use  
6           that is or may be the basis for such prod-  
7           uct becoming a qualified countermeasure  
8           or qualified pandemic or epidemic product,  
9           or to help obtain such approval, clearance,  
10          or license;

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

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

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

23          “(v) such other activities as are part  
24          of the advanced stages of testing, refine-  
25          ment, improvement, or preparation of the

1 product for such use and as are specified  
2 by the Secretary.

3 “(7) RESEARCH TOOL.—The term ‘research  
4 tool’ means a device, technology, biological material  
5 (including a cell line or an antibody), reagent, ani-  
6 mal model, computer system, computer software, or  
7 analytical technique that is developed to assist in the  
8 discovery, development, or manufacture of qualified  
9 countermeasures or qualified pandemic or epidemic  
10 products.

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

16 “(9) PERSON.—The term ‘person’ includes an  
17 individual, partnership, corporation, association, en-  
18 tity, or public or private corporation, and a Federal,  
19 State, or local government agency or department.

20 “(b) STRATEGIC PLAN FOR COUNTERMEASURE RE-  
21 SEARCH, DEVELOPMENT, AND PROCUREMENT.—

22 “(1) IN GENERAL.—Not later than 6 months  
23 after the date of enactment of the Biodefense and  
24 Pandemic Vaccine and Drug Development Act of  
25 2006, the Secretary shall develop, make public, and

1 present to the appropriate Congressional committees  
2 a strategic plan to integrate biodefense and emerg-  
3 ing infectious disease requirements with the ad-  
4 vanced research and development, strategic initia-  
5 tives for innovation, and the procurement of quali-  
6 fied countermeasures and qualified pandemic or epi-  
7 demic products. The Secretary shall periodically re-  
8 view and, as appropriate, revise the plan.

9 “(2) CONTENT.—The strategic plan under  
10 paragraph (1) shall—

11 “(A) guide research and development, con-  
12 ducted or supported by the Department of  
13 Health and Human Services, of qualified coun-  
14 termeasures and qualified pandemic or epidemic  
15 products against possible biological, chemical,  
16 radiological, and nuclear agents and to emerg-  
17 ing infectious diseases;

18 “(B) guide innovation in technologies that  
19 may assist advanced research and development  
20 of qualified countermeasures and qualified pan-  
21 demic or epidemic products (such research and  
22 development referred to in this section as ‘coun-  
23 termeasure and product advanced research and  
24 development’);

1           “(C) guide procurement of such qualified  
2 countermeasures and qualified pandemic or epi-  
3 demic products by such Department;

4           “(D) include immediate, short-term, and  
5 long-term goals;

6           “(E) include immediate, short-term, and  
7 long-term procurement priorities; and

8           “(F) identify processes used to designate a  
9 range of funds available for various types of  
10 countermeasure procurements.

11       “(c) BIOMEDICAL ADVANCED RESEARCH AND DE-  
12 VELOPMENT AUTHORITY.—

13           “(1) ESTABLISHMENT.—There is established  
14 within the Department of Health and Human Serv-  
15 ices the Biomedical Advanced Research and Develop-  
16 ment Authority.

17           “(2) IN GENERAL.—Based upon the strategic  
18 plan described in subsection (b), the Secretary shall  
19 coordinate and oversee the acceleration of counter-  
20 measure and product advanced research and devel-  
21 opment by—

22           “(A) facilitating collaboration among the  
23 Department of Health and Human Services,  
24 other Federal agencies, relevant industries, aca-

1 demia, and other persons, with respect to such  
2 advanced research and development;

3 “(B) promoting countermeasure and prod-  
4 uct advanced research and development;

5 “(C) facilitating contacts between inter-  
6 ested persons and the offices or employees au-  
7 thorized by the Secretary to advise such persons  
8 regarding requirements under the Federal  
9 Food, Drug, and Cosmetic Act and under sec-  
10 tion 351 of this Act; and

11 “(D) promoting innovation to reduce the  
12 time and cost of countermeasure and product  
13 advanced research and development.

14 “(3) DIRECTOR.—The BARDA shall be headed  
15 by a Director (referred to in this section as the ‘Di-  
16 rector’) who shall be appointed by the Secretary and  
17 to whom the Secretary shall delegate such functions  
18 and authorities as necessary to implement this sec-  
19 tion.

20 “(4) DUTIES.—

21 “(A) COLLABORATION.—To carry out the  
22 purpose described in paragraph (2)(A), the Sec-  
23 retary shall—

24 “(i) facilitate and increase the expedi-  
25 tious and direct communication between



1 the Department of Health and Human  
2 Services and relevant persons with respect  
3 to countermeasure and product advanced  
4 research and development, including by—

5 “(I) facilitating such communica-  
6 tion regarding the processes for pro-  
7 curing such advanced research and  
8 development with respect to qualified  
9 countermeasures and qualified pan-  
10 demic or epidemic products of inter-  
11 est; and

12 “(II) soliciting information about  
13 and data from research on potential  
14 qualified countermeasures and quali-  
15 fied pandemic or epidemic products  
16 and related technologies;

17 “(ii) at least annually—

18 “(I) convene meetings with rep-  
19 resentatives from relevant industries,  
20 academia, other Federal agencies,  
21 international agencies as appropriate,  
22 and other interested persons;

23 “(II) sponsor opportunities to  
24 demonstrate the operation and effec-

1           tiveness of relevant biodefense coun-  
2           termeasure technologies; and

3           “(III) convene such working  
4           groups on countermeasure and prod-  
5           uct advanced research and develop-  
6           ment as the Secretary may determine  
7           are necessary to carry out this sec-  
8           tion; and

9           “(iii) carry out the activities described  
10          in section 7 of the Biodefense and Pan-  
11          demic Vaccine and Drug Development Act  
12          of 2006.

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

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

21                 “(ii) direct and coordinate the coun-  
22                 termeasure and product advanced research  
23                 and development activities of the Depart-  
24                 ment of Health and Human Services;

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

7           “(iv) award contracts, grants, cooper-  
8           ative agreements, and enter into other  
9           transactions, for countermeasure and prod-  
10          uct advanced research and development.

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

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

23               “(ii) ensure that, with respect to per-  
24               sons performing countermeasure and prod-  
25               uct advanced research and development

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

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

15 “(i) innovation in technologies that  
16 may assist countermeasure and product  
17 advanced 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  
22 initiatives, 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  
3 (D) of paragraph (4), the Secretary shall have  
4 authority to enter into other transactions for  
5 countermeasure and product advanced research  
6 and 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 ex-  
13 pedited procurement authorities, the au-  
14 thority to expedite peer review, and the au-  
15 thority for personal services contracts, sup-  
16 plied by subsections (b), (c), and (d) of  
17 section 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 develop-  
10 ment program under this section.

11 “(iv) AVAILABILITY OF DATA.—The  
12 Secretary shall require that, as a condition  
13 of being awarded a contract, grant, cooper-  
14 ative agreement, or other transaction  
15 under subparagraph (B) or (D) of para-  
16 graph (4), a person make available to the  
17 Secretary on an ongoing basis, and submit  
18 upon request to the Secretary, all data re-  
19 lated to or resulting from countermeasure  
20 and product advanced research and devel-  
21 opment carried out pursuant to this sec-  
22 tion.

23 “(C) ADVANCE PAYMENTS; ADVER-  
24 TISING.—The authority of the Secretary to  
25 enter into contracts under this section shall not

1 be limited by section 3324(a) of title 31, United  
2 States Code, or by section 3709 of the Revised  
3 Statutes of the United States (41 U.S.C. 5).

4 “(D) MILESTONE-BASED PAYMENTS AL-  
5 LOWED.—In awarding contracts, grants, and  
6 cooperative agreements, and in entering into  
7 other transactions, under this section, the Sec-  
8 retary may use milestone-based awards and  
9 payments.

10 “(E) FOREIGN NATIONALS ELIGIBLE.—  
11 The Secretary may under this section award  
12 contracts, grants, and cooperative agreements  
13 to, and may enter into other transactions with,  
14 highly qualified foreign national persons outside  
15 the United States, alone or in collaboration with  
16 American participants, when such transactions  
17 may inure to the benefit of the American peo-  
18 ple.

19 “(F) ESTABLISHMENT OF RESEARCH CEN-  
20 TERS.—The Secretary may establish one or  
21 more federally-funded research and development  
22 centers, or university-affiliated research centers  
23 in accordance with section 303(e)(3) of the  
24 Federal Property and Administrative Services  
25 Act of 1949 (41 U.S.C. 253(e)(3)), provided

1           that such centers are consistent and com-  
2           plementary with the duties described in para-  
3           graph (4), and are consistent and complemen-  
4           tary with, and deemed necessary after consid-  
5           ering the availability of, existing federally-sup-  
6           ported basic research programs.

7           “(6) VULNERABLE POPULATIONS.—In carrying  
8           out the functions under this section, the Secretary  
9           may give priority to the advanced research and de-  
10          velopment of qualified countermeasures and qualified  
11          pandemic or epidemic products that are likely to be  
12          safe and effective with respect to children, pregnant  
13          women, and other vulnerable populations.

14          “(7) PERSONNEL AUTHORITIES.—

15                 “(A) SPECIALLY QUALIFIED SCIENTIFIC  
16                 AND PROFESSIONAL PERSONNEL.—In addition  
17                 to any other personnel authorities, the Sec-  
18                 retary may—

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



1           “(ii) compensate them in the same  
2           manner in which individuals appointed  
3           under section 9903 of such title are com-  
4           pensated, without regard to the provisions  
5           of chapter 51 and subchapter III of chap-  
6           ter 53 of such title relating to classification  
7           and General Schedule pay rates.

8           “(B) SPECIAL CONSULTANTS.—In carrying  
9           out this section, the Secretary may—

10                   “(i) appoint special consultants pursu-  
11                   ant to section 207(f); and

12                   “(ii) accept voluntary and uncompen-  
13                   sated services.

14           “(d) FUND.—

15                   “(1) ESTABLISHMENT.—There is established  
16                   the Biodefense Medical Countermeasure Develop-  
17                   ment Fund, which shall be available to carry out this  
18                   section in addition to such amounts as are otherwise  
19                   available for this purpose.

20                   “(2) FUNDING.—To carry out the purposes of  
21                   this section, there are authorized to be appropriated  
22                   to the Fund—

23                   “(A) \$1,070,000,000 for fiscal years 2006  
24                   through 2008, the amounts to remain available  
25                   until expended; and

1           “(B) such sums as may be necessary for  
2           subsequent fiscal years, the amounts to remain  
3           available until expended.

4           “(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

5           “(1) DISCLOSURE.—

6           “(A) IN GENERAL.—The Secretary shall  
7           withhold from disclosure under section 552 of  
8           title 5, United States Code, specific technical  
9           data or scientific information that is created or  
10          obtained during the countermeasure and prod-  
11          uct advanced research and development funded  
12          by the Secretary that reveal vulnerabilities of  
13          existing medical or public health defenses  
14          against biological, chemical, nuclear, or radio-  
15          logical threats. Such information shall be  
16          deemed to be information described in section  
17          552(b)(3) of title 5, United States Code.

18          “(B) OVERSIGHT.—Information subject to  
19          nondisclosure under subparagraph (A) shall be  
20          reviewed by the Secretary every 5 years to de-  
21          termine the relevance or necessity of continued  
22          nondisclosure.

23          “(2) FEDERAL ADVISORY COMMITTEE ACT.—

24          Section 14 of the Federal Advisory Committee Act  
25          (5 U.S.C. App.) shall not apply to a working group

1 of BARDA or to the National Biodefense Science  
2 Board under section 319M.

3 **“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND**  
4 **WORKING GROUPS.**

5 “(a) IN GENERAL.—

6 “(1) ESTABLISHMENT AND FUNCTION.—The  
7 Secretary shall establish the National Biodefense  
8 Science Board (referred to in this section as the  
9 ‘Board’) to provide expert advice and guidance to  
10 the Secretary on scientific, technical and other mat-  
11 ters of special interest to the Department of Health  
12 and Human Services regarding current and future  
13 chemical, biological, nuclear, and radiological agents,  
14 whether naturally occurring, accidental, or delib-  
15 erate.

16 “(2) MEMBERSHIP.—The membership of the  
17 Board shall be comprised of individuals who rep-  
18 resent the Nation’s preeminent scientific, public  
19 health, and medical experts, as follows—

20 “(A) such Federal officials as the Sec-  
21 retary may determine are necessary to support  
22 the functions of the Board;

23 “(B) four individuals representing the  
24 pharmaceutical, biotechnology, and device in-  
25 dustries;

1           “(C) four individuals representing aca-  
2 demia; and

3           “(D) five other members as determined ap-  
4 propriate by the Secretary.

5           “(3) TERM OF APPOINTMENT.—A member of  
6 the Board described in subparagraph (B), (C), or  
7 (D) of paragraph (2) shall serve for a term of 3  
8 years, except that the Secretary may adjust the  
9 terms of the initial Board appointees in order to  
10 provide for a staggered term of appointment for all  
11 members.

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

16           “(5) DUTIES.—The Board shall—

17           “(A) advise the Secretary on current and  
18 future trends, challenges, and opportunities pre-  
19 sented by advances in biological and life  
20 sciences, biotechnology, and genetic engineering  
21 with respect to threats posed by naturally oc-  
22 ccurring infectious diseases and chemical, bio-  
23 logical, radiological, and nuclear agents;

24           “(B) at the request of the Secretary, re-  
25 view and consider any information and findings

1 received from the working groups established  
2 under subsection (b); and

3 “(C) at the request of the Secretary, pro-  
4 vide recommendations and findings for ex-  
5 panded, intensified, and coordinated biodefense  
6 research and development activities.

7 “(6) MEETINGS.—

8 “(A) INITIAL MEETING.—Not later than  
9 one year after the date of enactment of the Bio-  
10 defense and Pandemic Vaccine and Drug Devel-  
11 opment Act of 2006, the Secretary shall hold  
12 the first meeting of the Board.

13 “(B) SUBSEQUENT MEETINGS.—The  
14 Board shall meet at the call of the Secretary,  
15 but in no case less than twice annually.

16 “(7) VACANCIES.—Any vacancy in the Board  
17 shall not affect its powers, but shall be filled in the  
18 same manner as the original appointment.

19 “(8) CHAIRPERSON.—The Secretary shall ap-  
20 point a chairperson from among the members of the  
21 Board.

22 “(9) POWERS.—

23 “(A) HEARINGS.—The Board may hold  
24 such hearings, sit and act at such times and  
25 places, take such testimony, and receive such

1 evidence as the Board considers advisable to  
2 carry out this subsection.

3 “(B) POSTAL SERVICES.—The Board may  
4 use the United States mails in the same man-  
5 ner and under the same conditions as other de-  
6 partments and agencies of the Federal Govern-  
7 ment.

8 “(10) PERSONNEL.—

9 “(A) EMPLOYEES OF THE FEDERAL GOV-  
10 ERNMENT.—A member of the Board that is an  
11 employee of the Federal Government may not  
12 receive additional pay, allowances, or benefits  
13 by reason of the member’s service on the  
14 Board.

15 “(B) OTHER MEMBERS.—A member of the  
16 Board that is not an employee of the Federal  
17 Government may be compensated at a rate not  
18 to exceed the daily equivalent of the annual rate  
19 of basic pay prescribed for level IV of the Exec-  
20 utive Schedule under section 5315 of title 5,  
21 United States Code, for each day (including  
22 travel time) during which the member is en-  
23 gaged in the actual performance of duties as a  
24 member of the Board.

1           “(C) TRAVEL EXPENSES.—Each member  
2 of the Board shall receive travel expenses, in-  
3 cluding per diem in lieu of subsistence, in ac-  
4 cordance with applicable provisions under sub-  
5 chapter I of chapter 57 of title 5, United States  
6 Code.

7           “(D) DETAIL OF GOVERNMENT EMPLOY-  
8 EES.—Any Federal Government employee may  
9 be detailed to the Board with the approval for  
10 the contributing agency without reimbursement,  
11 and such detail shall be without interruption or  
12 loss of civil service status or privilege.

13       “(b) OTHER WORKING GROUPS.—The Secretary may  
14 establish a working group of experts, or may use an exist-  
15 ing working group or advisory committee, to—

16           “(1) identify innovative research with the po-  
17 tential to be developed as a qualified countermeasure  
18 or a qualified pandemic or epidemic product;

19           “(2) identify accepted animal models for par-  
20 ticular diseases and conditions associated with any  
21 biological, chemical, radiological, or nuclear agent,  
22 any toxin, or any potential pandemic infectious dis-  
23 ease, and identify strategies to accelerate animal  
24 model and research tool development and validation;  
25 and





1 (as that term is defined by section 201(g)(1) of  
2 the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 321(g)(1))), biological product (as that  
4 term is defined by section 351(i) of this Act (42  
5 U.S.C. 262(i))), or device (as that term is de-  
6 fined by section 201(h) of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 321(h))),  
8 that the Secretary determines to be a priority  
9 (consistent with sections 302(2) and 304(a) of  
10 the Homeland Security Act of 2002) to—

11 “(i) diagnose, mitigate, prevent, or  
12 treat harm from any biological agent (in-  
13 cluding organisms that cause an infectious  
14 disease) or toxin, chemical, radiological, or  
15 nuclear agent that may cause a public  
16 health emergency affecting national secu-  
17 rity; or

18 “(ii) diagnose, mitigate, prevent, or  
19 treat harm from a condition that may re-  
20 sult in adverse health consequences or  
21 death and may be caused by administering  
22 a drug, biological product, or device that is  
23 used as described in this subparagraph.

24 “(B) INFECTIOUS DISEASE.—The term ‘in-  
25 fectious disease’ means a disease potentially

1           caused by a pathogenic organism (including a  
2           bacteria, virus, fungus, or parasite) that is ac-  
3           quired by a person and that reproduces in that  
4           person.”.

5           (b) SECURITY COUNTERMEASURE.—Section 319F-  
6 2(c)(1)(B)(i)(I) is amended by striking “to treat” the first  
7 place such term appears and all that follows through  
8 “from a condition” and inserting the following: “to diag-  
9 nose, mitigate, prevent, or treat harm from any biological  
10 agent (including organisms that cause an infectious dis-  
11 ease) or toxin, chemical, radiological, or nuclear agent  
12 identified as a material threat under paragraph (2)(A)(ii),  
13 or to diagnose, mitigate, prevent, or treat harm from a  
14 condition”.

15 **SEC. 5. TECHNICAL ASSISTANCE.**

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

19 **“SEC. 565. TECHNICAL ASSISTANCE.**

20           “The Secretary, in consultation with the Commis-  
21 sioner of Food and Drugs, shall establish within the Food  
22 and Drug Administration a team of experts on manufac-  
23 turing and regulatory activities (including compliance with  
24 current Good Manufacturing Practice) to provide both off-  
25 site and on-site technical assistance to the manufacturers

1 of qualified countermeasures (as defined in section 319F–  
 2 1 of the Public Health Service Act), security counter-  
 3 measures (as defined in section 319F–2 of such Act), or  
 4 vaccines, at the request of such a manufacturer and at  
 5 the discretion of the Secretary, if the Secretary determines  
 6 that a shortage or potential shortage may occur in the  
 7 United States in the supply of such vaccines or counter-  
 8 measures and that the provision of such assistance would  
 9 be beneficial in helping alleviate or avert such shortage.”.

10 **SEC. 6. PROCUREMENT.**

11 (a) SECURITY COUNTERMEASURES.—Section 319F–  
 12 2 of the Public Health Service Act (42 U.S.C. 247d–6b)  
 13 is amended—

14 (1) in the section heading, by inserting “**AND**  
 15 **SECURITY COUNTERMEASURE PROCUREMENTS**” before the period; and

17 (2) in subsection (c)—

18 (A) in the subsection heading, by striking  
 19 “BIOMEDICAL”;

20 (B) in paragraph (5)(B)(i), by striking “to  
 21 meet the needs of the stockpile” and inserting  
 22 “to meet the stockpile needs”;

23 (C) in paragraph (7)(B)—

24 (i) by striking the subparagraph head-  
 25 ing and all that follows through “Home-

1 land Security Secretary” and inserting the  
2 following: “INTERAGENCY AGREEMENT;  
3 COST.—The Homeland Security Sec-  
4 retary”; and

5 (ii) by striking clause (ii);

6 (D) in paragraph (7)(C)(ii)—

7 (i) by amending clause (I) to read as  
8 follows:

9 “(I) PAYMENT CONDITIONED ON  
10 DELIVERY.—The contract shall pro-  
11 vide that no payment may be made  
12 until delivery of a portion, acceptable  
13 to the Secretary, of the total number  
14 of units contracted for, except that,  
15 notwithstanding any other provision of  
16 law, the contract may provide that, if  
17 the Secretary determines (in the Sec-  
18 retary’s discretion) that an advance  
19 payment, partial payment for signifi-  
20 cant milestones, or payment to in-  
21 crease manufacturing capacity is nec-  
22 essary to ensure success of a project,  
23 the Secretary shall pay an amount,  
24 not to exceed 10 percent of the con-  
25 tract amount, in advance of delivery.

1           The Secretary shall, to the extent  
2           practicable, make the determination of  
3           advance payment at the same time as  
4           the issuance of a solicitation. The con-  
5           tract shall provide that such advance  
6           payment is required to be repaid if  
7           there is a failure to perform by the  
8           vendor under the contract. The con-  
9           tract may also provide for additional  
10          advance payments of 5 percent each  
11          for meeting the milestones specified in  
12          such contract. Provided that the spec-  
13          ified milestones are reached, these ad-  
14          vanced payments of 5 percent shall  
15          not be required to be repaid. Nothing  
16          in this subclause shall be construed as  
17          affecting the rights of vendors under  
18          provisions of law or regulation (in-  
19          cluding the Federal Acquisition Regu-  
20          lation) relating to the termination of  
21          contracts for the convenience of the  
22          Government.”; and  
23          (ii) by adding at the end the fol-  
24          lowing:

1                   “(VII) PROCUREMENT OF MUL-  
2                   TIPLE PRODUCTS AND TECH-  
3                   NOLOGIES.—Notwithstanding any  
4                   other provision of law or regulation,  
5                   the Secretary shall, where possible,  
6                   enter into multiple transactions for  
7                   the procurement of multiple tech-  
8                   nologies and products from multiple  
9                   manufacturers of security counter-  
10                  measures in order to mitigate against  
11                  the risks associated with dependence  
12                  on a single supplier or technology.

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

1 exclusivity provision in such a con-  
2 tract shall constitute a valid basis for  
3 a sole source procurement under sec-  
4 tion 303(c)(1) of the Federal Property  
5 and Administrative Services Act of  
6 1949 (41 U.S.C. 253(c)(1)).

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

24 “(X) ADDITIONAL CONTRACT  
25 TERMS.—The Secretary, in any con-

1                   tract for procurement under this sec-  
2                   tion, may specify—

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

7                                 “(bb) the amount of funding  
8                                 that will be dedicated by the Sec-  
9                                 retary for development and ac-  
10                                quisition of the countermeasure;  
11                                and

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

16                   (E) in paragraph (8)(A), by adding at the  
17                   end the following: “Such agreements may allow  
18                   other executive agencies to order qualified and  
19                   security countermeasures under procurement  
20                   contracts or other agreements established by  
21                   the Secretary. Such ordering process (including  
22                   transfers of appropriated funds between an  
23                   agency and the Department of Health and  
24                   Human Services as reimbursements for such or-  
25                   ders for countermeasures) may be conducted



1 under the authority of section 1535 of title 31,  
2 United States Code, except that all such orders  
3 shall be processed under the terms established  
4 under this section for the procurement of coun-  
5 termeasures.”.

6 (b) QUALIFIED COUNTERMEASURES.—Section  
7 319F–1(b) of the Public Health Service Act (42 U.S.C.  
8 247d–6a(b)) is amended by adding at the end the fol-  
9 lowing:

10 “(5) PROCUREMENT OF MULTIPLE PRODUCTS  
11 AND TECHNOLOGIES.—Notwithstanding any other  
12 provision of law or regulation, the Secretary shall,  
13 where possible, enter into multiple transactions for  
14 the procurement of multiple technologies and prod-  
15 ucts from multiple manufacturers of qualified coun-  
16 termeasures in order to mitigate against the risks  
17 associated with dependence on a single supplier or  
18 technology.”.

19 **SEC. 7. RULE OF CONSTRUCTION.**

20 Nothing in this Act, or any amendment made by this  
21 Act, shall be construed to affect any law that applies to  
22 the National Vaccine Injury Compensation Program under  
23 title XXI of the Public Health Service Act (42 U.S.C.  
24 300aa–1 et seq.), including such laws regarding—

1           (1) whether claims may be filed or compensa-  
2           tion may be paid for a vaccine-related injury or  
3           death under such Program;

4           (2) claims pending under such Program; and

5           (3) any petitions, cases, or other proceedings  
6           before the United States Court of Federal Claims  
7           pursuant to such title.

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