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1ST SESSION

H. R. 1496

To provide incentives for pharmaceutical companies, biotechnology companies, and medical device companies to invest in research and development with respect to antibiotic drugs, antivirals, diagnostic tests, and vaccines that may be used to identify, treat, or prevent serious and life-threatening infectious diseases.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2007

Mr. BAIRD (for himself, Mrs. CUBIN, and Mr. MATHESON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide incentives for pharmaceutical companies, biotechnology companies, and medical device companies to invest in research and development with respect to antibiotic drugs, antivirals, diagnostic tests, and vaccines that may be used to identify, treat, or prevent serious and life-threatening infectious diseases.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Beating Infections
3 through Research and Development Act of 2007”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Infections caused by resistant bacteria can
7 strike anyone, including the young and the old, the
8 healthy and the chronically ill. Antibiotic resistance
9 is a particularly serious problem for patients whose
10 immune systems are compromised, such as people
11 with HIV/AIDS and patients in critical care units.

12 (2) About 2 million people acquire bacterial in-
13 fections in United States hospitals each year, and
14 90,000 die as a result. About 70 percent of those in-
15 fections are resistant to at least one drug. The
16 trends toward increasing numbers of infection and
17 increasing drug resistance show no sign of abating.

18 (3) Resistant pathogens lead to higher health
19 care costs because they often require more expensive
20 drugs and extended hospital stays. The total cost to
21 United States society is nearly \$5,000,000,000 an-
22 nually.

23 (4) The Institute of Medicine, the Infectious
24 Diseases Society of America, and Federal officials
25 have identified antibiotic resistance and the dearth

1 of antibiotic research and development as increasing
2 threats to United States public health.

3 (5) Without innovative public policy and addi-
4 tional financial support, fewer and fewer antibiotics
5 will be available to treat the increasing number of
6 drug-resistant and dangerous microbes that threaten
7 Americans and the global community.

8 (6) The pipeline of new antibiotics is drying up.
9 Major pharmaceutical companies are losing interest
10 in the antibiotics market because these drugs simply
11 are not as profitable as drugs that treat chronic
12 (long-term) conditions and lifestyle issues.

13 (7) Drug research and development is expen-
14 sive, risky, and time-consuming. An aggressive re-
15 search and development program initiated today
16 would likely require 10 or more years and an invest-
17 ment of \$800,000,000 to \$1,700,000,000 to bring a
18 new drug to market.

19 (8) Resistant bacterial infections are not only a
20 public health problem; they have national and global
21 security implications as well.

22 (9) The Institute of Medicine in its 2004 report
23 entitled “The Threat of Pandemic Influenza” stated
24 that the United States is not adequately prepared to
25 deal with the next pandemic of influenza.

1 (10) The Centers for Disease Control and Pre-
2 vention estimates that, without adequate prepara-
3 tion, 100,000 to 250,000 deaths could occur in the
4 United States from a mild pandemic of influenza.

5 (11) The limited influenza vaccine market and
6 few dedicated manufacturers pose a substantial chal-
7 lenge to the Nation's preparedness efforts. Cur-
8 rently, there are two manufacturers of influenza vac-
9 cine for the United States market. In 2004, the
10 Food and Drug Administration suspended a manu-
11 facturer's license due to bacterial contamination.
12 This action led to a shortage of injectable influenza
13 vaccine in the United States.

14 (12) New rapid diagnostics would greatly re-
15 duce the cost and time needed to conduct clinical
16 trials for new anti-infectives. For many infectious
17 diseases, there currently are no rapid diagnostic
18 tests available to assist in identifying eligible pa-
19 tients for clinical trials. Cutting costs and time will
20 serve as incentives for greater investment in this
21 area. In addition, new rapid diagnostics will permit
22 physicians to diagnose specific bacterial infections in
23 their patients. This will enable physicians to pre-
24 scribe the most appropriate therapies, including

1 antibiotics, which will slow the evolution of new anti-
2 microbial resistance.

3 (13) Extensively drug-resistant tuberculosis
4 (XDR-TB) is highly drug-resistant not only to first
5 line anti-tuberculosis drugs, but also to second line
6 oral and even injectable drugs. In 2004, there were
7 about 424,000 new cases of multi-drug resistant tu-
8 berculosis. Four percent of all multi-drug resistant
9 tuberculosis cases in the United States fit the defini-
10 tion of XDR-TB. The Advisory Council for the
11 Elimination of Tuberculosis (ACET) has warned
12 that XDR-TB poses “an imminent airborne biologi-
13 cal threat” to the United States and requires imme-
14 diate action.

15 **SEC. 3. DEFINITIONS.**

16 In this Act:

17 (1) The term “antibiotic drug” has the meaning
18 given to that term in section 201 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 321).

20 (2) The term “antiviral” means a drug or bio-
21 logical product intended for human use that impedes
22 the reproduction of a virus.

23 (3) The term “biological product” has the
24 meaning given to that term in section 351 of the
25 Public Health Service Act (42 U.S.C. 262).

1 (4) The term “device” has the meaning given to
2 that term in section 201 of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 321).

4 (5) The term “diagnostic test” means a device
5 or product used to detect the presence, concentra-
6 tion, or characteristics of an infectious human dis-
7 ease.

8 (6) The term “drug” has the meaning given to
9 that term in section 201 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 321).

11 (7) The term “qualified infectious disease prod-
12 uct” means any antibiotic drug, antiviral, diagnostic
13 test, or vaccine that is developed for the purpose of
14 treating, detecting, preventing, or identifying—

15 (A) a qualifying pathogen (for the period
16 beginning on the date of the enactment of this
17 Act and ending on commencement of the period
18 described in subparagraph (B)); or

19 (B) an infectious pathogen identified by
20 the Commission under section 319E–1(b) of the
21 Public Health Service Act, as added by section
22 10 of this Act (for the period beginning on the
23 date on which the Commission on Infectious
24 Diseases Product Development first identifies
25 infectious pathogens under such section).

1 (8) The term “qualifying pathogen” means—

2 (A) community-acquired methicillin-resist-
3 ant staphylococcus aureus (CA-MRSA);

4 (B) life-threatening gram negative bac-
5 teria, such as Escherichia coli (E. coli),
6 Acinetobacter, Klebsiella species, and
7 Pseudomonas aeruginosa;

8 (C) influenza;

9 (D) extensively drug resistant tuberculosis
10 (XDR-TB); or

11 (E) any other infectious pathogen identi-
12 fied for purposes of this Act by the Secretary
13 of Health and Human Services, in concurrence
14 with infectious disease clinicians and appro-
15 priate professional associations, as a significant
16 threat to public health because of drug resist-
17 ance or other factors (or likely to become such
18 a threat).

19 (9) The term “vaccine” means a vaccine in-
20 tended for human use.

21 **SEC. 4. PATENT PROTECTION.**

22 (a) PURPOSE.—The purpose of this section is to pro-
23 vide an incentive for research and development relating
24 to qualified infectious disease products.

25 (b) RESTORATION OF PATENT TERMS.—

1 (1) IN GENERAL.—Chapter 14 of title 35,
2 United States Code, is amended by inserting after
3 section 156 the following:

4 **“SEC. 156a. RESTORATION OF PATENT TERMS RELATING TO**
5 **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

6 “(a) DEFINITIONS.—In this section—

7 “(1) the term ‘diagnostic test’ has the meaning
8 given to that term in section 3 of the Beating Infec-
9 tions through Research and Development Act of
10 2007;

11 “(2) the term ‘qualified infectious disease prod-
12 uct’ has the meaning given to that term in section
13 3 of the Beating Infections through Research and
14 Development Act of 2007;

15 “(3) the term ‘regulatory review period’ means
16 the period of time that—

17 “(A) starts on the date that is the later
18 of—

19 “(i) the date that an eligible patent
20 sought to be extended under this section is
21 issued;

22 “(ii) the date that an exemption under
23 section 505(i) of the Federal Food, Drug,
24 and Cosmetic Act became effective for the
25 product; or

1 “(iii) the date on which an investiga-
2 tional device exemption is approved pursu-
3 ant to section 520(g) of the Federal Food,
4 Drug and Cosmetic Act; and

5 “(B) ends on the date that is—

6 “(i) in the case of a drug, the date on
7 which an application submitted for such
8 drug under section 505(b) of the Federal
9 Food, Drug, and Cosmetic Act is approved;

10 “(ii) in the case of a biologic, the date
11 on which an application submitted under
12 section 351 of the Public Health Service
13 Act is approved; or

14 “(iii) in the case of a medical device,
15 the date on which an application for pre-
16 market approval submitted for such device
17 under the Federal Food, Drug, and Cos-
18 metic Act is approved; and

19 “(4) the term ‘eligible patent’ means a patent
20 that—

21 “(A) claims a qualified infectious disease
22 product, or claims an active ingredient of such
23 product, or a process of making or using the
24 product or an active ingredient of such product;
25 and

1 “(B) is owned by or licensed to an entity
2 that sponsored the application described in
3 paragraph (3)(B) for the product.

4 “(b) PATENT TERM EXTENSION.—The term of an el-
5 igible patent shall be extended from the expiration date
6 of the patent that would otherwise apply, which shall in-
7 clude any patent term adjustment granted under section
8 154(b), by a period equal to the number of days in the
9 regulatory review period if each of the following is met:

10 “(1) An application in conformance with the re-
11 quirements of subsection (c) is submitted to the Di-
12 rector by either the owner of record of the patent or
13 its agent by the later of 60 days after the end of the
14 regulatory review period or 45 days after issuance of
15 the patent.

16 “(2) The patent that is the basis of the applica-
17 tion has not been previously extended under this sec-
18 tion, or under section 156.

19 “(3) The term of the patent that is the basis
20 of the application has not expired before the date
21 that the application is submitted under subsection
22 (c).

23 “(4) The regulatory review period for the quali-
24 fied infectious disease product has not been relied
25 upon to support an application to extend the term

1 of another patent under this section or under section
2 156.

3 “(c) ADMINISTRATIVE PROVISIONS.—

4 “(1) IN GENERAL.—To obtain an extension of
5 the term of a patent under this section, the owner
6 of record of the patent or its agent shall submit an
7 application to the Director.

8 “(2) CONTENT.—The application shall con-
9 tain—

10 “(A) a description of the qualified infec-
11 tious disease product and the Federal statute
12 under which regulatory review occurred;

13 “(B) the identity of the patent for which
14 an extension is sought under this section; and

15 “(C) such other information as the Direc-
16 tor may require including to establish that the
17 applicant meets the requirements of this sec-
18 tion.

19 “(3) IRREVOCABLE ELECTION.—The submis-
20 sion of an application under this section is an irrev-
21 ocable election of the application of this section to
22 the patent that is the basis of the application. A pat-
23 ent that has been the basis of an application made
24 under this section may not be the subject of an ap-
25 plication made under section 156 or 158.”.

1 (2) TECHNICAL AND CONFORMING AMEND-
2 MENT.—The table of sections for chapter 14 of title
3 35, United States Code, is amended by inserting
4 after the item relating to section 156 the following:

“156a. Restoration of patent terms relating to qualified infectious disease prod-
ucts.”.

5 (c) EXTENSION OF PATENT TERMS.—

6 (1) CERTIFICATION OF SUCCESSFUL DEVELOP-
7 MENT.—

8 (A) APPLICATION.—An entity may submit
9 to the Secretary of Health and Human Services
10 (in this section referred to as the “Secretary”)
11 an application for certification that the entity—

12 (i) has successfully developed a quali-
13 fied infectious disease product, as that
14 term is defined in section 158 of title 35,
15 United States Code; and

16 (ii) the entity may receive a patent
17 term extension under the provisions of
18 such section.

19 (B) CERTIFICATION.—With respect to an
20 application submitted by an entity under this
21 paragraph, the Secretary shall—

22 (i) approve the application if the Sec-
23 retary determines that the entity has suc-

1 cessfully developed the qualified infectious
2 disease product;

3 (ii) deny the application if the Sec-
4 retary determines that the entity has not
5 successfully developed the product; and

6 (iii) notify the entity of the approval
7 or denial, and the reasons therefore.

8 (C) SUCCESSFUL DEVELOPMENT.—In car-
9 rying out subparagraph (B), the Secretary shall
10 determine that an entity has successfully devel-
11 oped a product if—

12 (i) the product is a qualified infectious
13 disease product; and

14 (ii) the product has been approved
15 under section 505 or 515 of the Federal
16 Food, Drug, and Cosmetic Act or section
17 351 of the Public Health Service Act.

18 (D) EFFECT OF CERTIFICATION.—If the
19 Secretary approves an application submitted by
20 an entity under this paragraph, the entity may
21 use the patent extension provisions of section
22 158 of title 35, United States Code.

23 (E) APPLICATION.—This paragraph and
24 the amendment made by paragraph (2) apply
25 only with respect to a product that is approved

1 under section 505 or 515 of the Federal Food,
2 Drug, and Cosmetic Act or section 351 of the
3 Public Health Service Act after the date of the
4 enactment of this Act.

5 (2) IN GENERAL.—Chapter 14 of title 35,
6 United States Code, is amended by adding at the
7 end the following:

8 **“§ 158. Extension of patent terms relating to qualified**
9 **infectious disease products**

10 “(a) DEFINITIONS.—In this section:

11 “(1) The term ‘qualified infectious disease
12 product’ means a qualified infectious disease prod-
13 uct, as that term is defined in section 3 of the Beat-
14 ing Infections through Research and Development
15 Act of 2007.

16 “(2) The term ‘designated product’ means a
17 drug, antibiotic drug, or device, as those terms are
18 defined in section 201 of the Federal Food, Drug
19 and Cosmetic Act (21 U.S.C. 321), or a biological
20 product, as that term is defined in section 351 of
21 the Public Health Service Act.

22 “(3) The term ‘diagnostic test’ has the meaning
23 given to that term in section 3 of the Beating Infec-
24 tions through Research and Development Act of
25 2007.

1 “(4) The term ‘eligible entity’ means a natural
2 or legal person that has successfully developed a
3 qualified infectious disease product.

4 “(5) The term ‘eligible patent’ means a patent
5 that at the time the eligible entity entered into the
6 contract to develop the qualified infectious disease
7 product involved, was owned by or licensed to that
8 eligible entity, and claims a designated product, an
9 active ingredient of a designated product, a method
10 of making or using a designated product or a meth-
11 od of making or using an active ingredient of a des-
12 igned product.

13 “(b) PATENT TERM EXTENSION.—The term of an el-
14 ible patent shall be extended for a period of 2 years,
15 in addition to the term which would otherwise apply except
16 for this section, if—

17 “(1) an application under subsection (c) is sub-
18 mitted to the Director by either the owner of record
19 of the patent or its agent on or before the date spec-
20 ified in subsection (c)(3);

21 “(2) the patent has not been previously ex-
22 tended under this section, or under section 156 or
23 156a;

24 “(3) the patent has not expired before the date
25 that the application is submitted;

1 “(4) the term of no other patent has been ex-
2 tended based on the certification being relied upon
3 by the eligible entity to request extension of the pat-
4 ent; and

5 “(5) no other patent that claims the designated
6 product, an active ingredient of the designated prod-
7 uct, a method of making or using a designated prod-
8 uct or a method of making or using an active ingre-
9 dient of a designated product has been extended
10 under this section or under section 156a.

11 “(c) ADMINISTRATIVE PROVISIONS.—

12 “(1) IN GENERAL.—To obtain an extension of
13 the term of a patent under this section, the owner
14 of record of the patent or the agent of the owner
15 shall submit an application to the Director.

16 “(2) CONTENT.—An application filed under this
17 section shall contain—

18 “(A) a description of the approved quali-
19 fied infectious disease product and the Federal
20 statute under which regulatory review occurred;

21 “(B) the identity of the eligible patent for
22 which an extension is sought under this section;

23 “(C) the identity of the eligible entity and
24 the applicant (if different from the eligible enti-
25 ty);

1 “(D) the identity of the designated product
2 to which the eligible patent relates;

3 “(E) information concerning the certifi-
4 cation specified in section 4(c)(1) of the Beat-
5 ing Infections through Research and Develop-
6 ment Act of 2007 being relied upon as the basis
7 of the extension being requested;

8 “(F) information indicating that the entity
9 owned or licensed the eligible patent at the time
10 it entered into the contract to develop the quali-
11 fied infectious disease product; and

12 “(G) such other information as the Direc-
13 tor may require including to establish that the
14 applicant meets the requirements of this sec-
15 tion.

16 “(3) SUBMISSION OF APPLICATION.—An appli-
17 cation under this section shall be submitted to the
18 Director within 60 days after the date of the certifi-
19 cation specified in section 4(c)(1) of the Beating In-
20 fections through Research and Development Act of
21 2007 that is being relied upon to request extension
22 of the patent that is the subject of the application.

23 “(d) IRREVOCABLE ELECTION.—The submission of
24 an application under this section is an irrevocable election
25 of the application of this section to the patent that is the

1 basis of the application. A patent that has been the basis
2 of an application made under this section may not be the
3 subject of an application made under sections 156 or
4 156a.”.

5 (3) TECHNICAL AND CONFORMING AMEND-
6 MENT.—The table of sections for chapter 14 of title
7 35, United States Code, is amended by adding at
8 the end the following:

“158. Extension of patent terms relating to countermeasure products.”.

9 **SEC. 5. ACCELERATED APPROVAL OF QUALIFIED INFEC-**
10 **TIOUS DISEASE PRODUCTS.**

11 (a) DESIGNATION AS FAST-TRACK PRODUCT.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services shall designate qualified infectious
14 disease products as fast-track products, pursuant to
15 section 506 or section 515(d)(5), as applicable, of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 356, 360e(5)). Such designation may be
18 made prior to the submission of—

19 (A) a request for designation by the spon-
20 sor or applicant; or

21 (B) an application for the investigation of
22 the qualified infectious disease product under
23 section 505 or 520(g) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355) or

1 section 351 of the Public Health Service Act
2 (42 U.S.C. 262).

3 (2) RULE OF CONSTRUCTION.—Nothing in this
4 section shall be construed to prohibit a sponsor or
5 applicant from declining a designation under para-
6 graph (1).

7 (b) GRANTS FOR CLINICAL TESTS.—Subpart 6 of
8 part C of title IV of the Public Health Service Act (42
9 U.S.C. 285f et seq.) is amended by adding at the end the
10 following:

11 **“SEC. 447C. CLINICAL TRIALS ON QUALIFIED INFECTIOUS**
12 **DISEASE PRODUCTS.**

13 “(a) GRANTS.—In carrying out section 446, the Di-
14 rector of the Institute shall expand and intensify efforts
15 to assist small manufacturers to conduct end-stage clinical
16 trials on qualified infectious disease products, including by
17 awarding grants for such clinical trials.

18 “(b) DEFINITION.—In this section, the term ‘quali-
19 fied infectious disease product’ has the meaning given to
20 that term in section 3 of the Beating Infections through
21 Research and Development Act of 2007.”.

1 **SEC. 6. TAX CREDIT FOR MEDICAL RESEARCH RELATED TO**
2 **DEVELOPING QUALIFIED INFECTIOUS DIS-**
3 **EASE PRODUCTS.**

4 (a) IN GENERAL.—Subpart D of part IV of sub-
5 chapter A of chapter 1 of the Internal Revenue Code of
6 1986 (relating to business-related credits) is amended by
7 adding at the end the following new section:

8 **“SEC. 450. CREDIT FOR MEDICAL RESEARCH RELATED TO**
9 **DEVELOPING QUALIFIED INFECTIOUS DIS-**
10 **EASE PRODUCTS.**

11 “(a) GENERAL RULE.—For purposes of section 38,
12 the infectious disease research credit determined under
13 this section for the taxable year is an amount equal to
14 50 percent of the qualified infectious disease research ex-
15 penses for the taxable year.

16 “(b) QUALIFIED INFECTIOUS DISEASE RESEARCH
17 EXPENSES.—For purposes of this section—

18 “(1) QUALIFIED INFECTIOUS DISEASE RE-
19 SEARCH EXPENSES.—Except as otherwise provided
20 in this subsection, the term ‘qualified infectious dis-
21 ease research expenses’ means the amounts which
22 are paid or incurred by the taxpayer during the tax-
23 able year with respect to any research and develop-
24 ment of qualified infectious disease products which
25 would be described in subsection (b) of section 41 if

1 such subsection were applied with the modifications
2 set forth in paragraph (2).

3 “(2) MODIFICATIONS; INCREASED INCENTIVE
4 FOR CONTRACT RESEARCH PAYMENTS.—For pur-
5 poses of paragraph (1), subsection (b) of section 41
6 shall be applied—

7 “(A) by substituting ‘qualified infectious
8 disease research’ for ‘qualified research’ each
9 place it appears in paragraphs (2) and (3) of
10 such subsection, and

11 “(B) by substituting ‘100 percent’ for ‘65
12 percent’ in paragraph (3)(A) of such sub-
13 section.

14 “(3) EXCLUSION FOR AMOUNTS FUNDED BY
15 GRANTS, ETC.—The term ‘qualified infectious dis-
16 ease research expenses’ shall not include any amount
17 to the extent such amount is funded by any grant,
18 contract, or otherwise by another person (or any
19 governmental entity).

20 “(4) QUALIFIED INFECTIOUS DISEASE RE-
21 SEARCH.—The term ‘qualified infectious disease re-
22 search’ means qualified research (as defined in sec-
23 tion 41(d)) which relates to the development of a
24 qualified infectious disease product, except that
25 qualified infectious disease research shall include ex-

1 penses related to re-formulating existing qualified in-
2 fectious disease products.

3 “(5) QUALIFIED INFECTIOUS DISEASE PROD-
4 UCTS.—The term ‘qualified infectious disease prod-
5 ucts’ has the meaning given such term in section 3
6 of the Beating Infections through Research and De-
7 velopment Act of 2007.

8 “(c) COORDINATION WITH CREDIT FOR INCREASING
9 RESEARCH EXPENDITURES.—

10 “(1) IN GENERAL.—Except as provided in para-
11 graph (2), any qualified infectious disease research
12 expenses for a taxable year to which an election
13 under this section applies shall not be taken into ac-
14 count for purposes of determining the credit allow-
15 able under section 41 for such taxable year.

16 “(2) EXPENSES INCLUDED IN DETERMINING
17 BASE PERIOD RESEARCH EXPENSES.—Any qualified
18 infectious disease research expenses for any taxable
19 year which are qualified research expenses (within
20 the meaning of section 41(b)) shall be taken into ac-
21 count in determining base period research expenses
22 for purposes of applying section 41 to subsequent
23 taxable years.

24 “(d) SPECIAL RULES.—

1 “(1) CERTAIN RULES MADE APPLICABLE.—
2 Rules similar to the rules of paragraphs (1) and (2)
3 of section 41(f) shall apply for purposes of this sec-
4 tion.

5 “(2) COORDINATION WITH CREDIT FOR CLIN-
6 ICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR
7 RARE DISEASES.—Any qualified infectious disease
8 research expenses for a taxable year to which an
9 election under this section applies shall not be taken
10 into account for purposes of determining the credit
11 allowable under section 45C for such taxable year.

12 “(3) ELECTION.—This section shall apply to
13 any taxpayer for any taxable year only if such tax-
14 payer elects (at such time and in such manner as
15 the Secretary may by regulations prescribe) to have
16 this section apply for such taxable year.”.

17 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—
18 Section 38(b) of the Internal Revenue Code of 1986 is
19 amended by striking “plus” at the end of paragraph (30),
20 by striking the period at the end of paragraph (31) and
21 inserting “, plus”, and by adding at the end the following
22 new paragraph:

23 “(32) the infectious disease research credit de-
24 termined under section 45O.”.

1 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
2 the Internal Revenue Code of 1986 (relating to certain
3 expenses for which credits are allowable) is amended by
4 adding at the end the following new subsection:

5 “(e) CREDIT FOR QUALIFIED INFECTIOUS DISEASE
6 RESEARCH EXPENSES.—

7 “(1) IN GENERAL.—No deduction shall be al-
8 lowed for that portion of the qualified infectious dis-
9 ease research expenses (as defined in section
10 45O(b)) otherwise allowable as a deduction for the
11 taxable year which is equal to the amount of the
12 credit determined for such taxable year under sec-
13 tion 45O(a).

14 “(2) CERTAIN RULES TO APPLY.—Rules similar
15 to the rules of paragraphs (2), (3), and (4) of sub-
16 section (c) shall apply for purposes of this sub-
17 section.”.

18 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
19 IT.—Section 196(c) of the Internal Revenue Code of 1986
20 (defining qualified business credits) is amended by strik-
21 ing “and” at the end of paragraph (12), by striking the
22 period at the end of paragraph (13) and inserting “, and”,
23 and by adding at the end the following new paragraph:

24 “(14) the infectious disease research credit de-
25 termined under section 45O(a) (other than such

1 credit determined under the rules of section
2 280C(e)(2)).”.

3 (e) TECHNICAL AMENDMENT.—The table of sections
4 for subpart D of part IV of subchapter A of chapter 1
5 of the Internal Revenue Code of 1986 is amended by add-
6 ing at the end the following new item:

“Sec. 450. Credit for medical research related to developing qualified infectious
disease products.”.

7 (f) EFFECTIVE DATE.—The amendments made by
8 this section shall apply to taxable years beginning after
9 December 31, 2006.

10 **SEC. 7. INCENTIVES FOR THE CONSTRUCTION OF QUALI-**
11 **FIED INFECTIOUS DISEASE PRODUCTS MANU-**
12 **FACTURING FACILITIES.**

13 (a) QUALIFIED INFECTIOUS DISEASE PRODUCTS
14 MANUFACTURING FACILITIES INVESTMENT TAX CRED-
15 IT.—

16 (1) ALLOWANCE OF CREDIT.—Section 46 of the
17 Internal Revenue Code of 1986 (relating to amount
18 of investment credit) is amended by striking “and”
19 at the end of paragraph (3), by striking the period
20 at the end of paragraph (4) and inserting “, and”,
21 and by adding at the end the following new para-
22 graph:

23 “(5) the qualified infectious disease products
24 manufacturing facilities investment credit.”.

1 (2) AMOUNT OF CREDIT.—Subpart E of part
2 IV of subchapter A of chapter 1 of such Code (relat-
3 ing to rules for computing investment credit) is
4 amended by inserting after section 48B the following
5 new section:

6 **“SEC. 48C. QUALIFIED INFECTIOUS DISEASE PRODUCTS**
7 **MANUFACTURING FACILITIES CREDIT.**

8 “(a) IN GENERAL.—For purposes of section 46, the
9 qualified infectious disease products manufacturing facili-
10 ties investment credit for any taxable year is an amount
11 equal to 20 percent of the qualified investment for such
12 taxable year.

13 “(b) QUALIFIED INVESTMENT.—

14 “(1) IN GENERAL.—For purposes of subsection
15 (a), the qualified investment for any taxable year is
16 the basis of each qualified infectious disease prod-
17 ucts manufacturing facilities property placed in serv-
18 ice by the taxpayer during such taxable year.

19 “(2) QUALIFIED INFECTIOUS DISEASE PROD-
20 UCTS MANUFACTURING FACILITIES PROPERTY.—For
21 purposes of this section, the term ‘qualified infec-
22 tious disease products manufacturing facilities prop-
23 erty’ means real and tangible personal property—

24 “(A)(i) the original use of which com-
25 mences with the taxpayer, or

1 “(ii) which is acquired through purchase
2 (as defined by section 179(d)(2)),

3 “(B) which is depreciable under section
4 167,

5 “(C) which is used for the manufacture,
6 distribution, or research and development of
7 qualified infectious disease products, and

8 “(D) which is in compliance with any
9 standards and regulations which are promul-
10 gated by the Food and Drug Administration,
11 the Occupational Safety and Health Adminis-
12 tration, or the Environmental Protection Agen-
13 cy and which are applicable to such property.

14 “(3) QUALIFIED INFECTIOUS DISEASE PROD-
15 UCTS.—For purposes of this subsection, the term
16 ‘qualified infectious disease products’ has the mean-
17 ing given such term in section 3 of the Beating In-
18 fections through Research and Development Act of
19 2007.

20 “(c) CERTAIN PROGRESS EXPENDITURE RULES
21 MADE APPLICABLE.—Rules similar to rules of subsections
22 (c)(4) and (d) of section 46 (as in effect on the day before
23 the date of the enactment of the Revenue Reconciliation
24 Act of 1990) shall apply for purposes of this subsection.

1 “(d) TERMINATION.—This subsection shall not apply
2 to any property placed in service after December 31,
3 2011.”.

4 (b) TECHNICAL AMENDMENTS.—

5 (1) Subparagraph (C) of section 49(a)(1) of
6 such Code is amended by striking “and” at the end
7 of clause (iii), by striking the period at the end of
8 clause (iv) and inserting “, and”, and by adding at
9 the end the following new clause:

10 “(v) the basis of any qualified infec-
11 tious disease products manufacturing fa-
12 cilities property under section 48C.”.

13 (2) Subparagraph (E) of section 50(a)(2) of
14 such Code is amended by inserting “or 48C(e)” be-
15 fore the period.

16 (3) The table of sections for subpart E of part
17 IV of subchapter A of chapter 1 of such Code is
18 amended by inserting after the item relating to sec-
19 tion 48B the following:

“Sec. 48C. Qualified infectious disease products manufacturing facilities cred-
it.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to property placed in service after
22 December 31, 2006, under rules similar to the rules of
23 section 48(m) of the Internal Revenue Code of 1986 (as

1 in effect on the day before the date of enactment of the
2 Revenue Reconciliation Act of 1990).

3 **SEC. 8. DEVELOPMENT AND DISSEMINATION OF MODEL**
4 **STATE LAWS AND INCENTIVES.**

5 The Secretary of Health and Human Services, acting
6 jointly with the Secretary of Commerce, shall—

7 (1) not less than 24 months after the enact-
8 ment of this Act, conduct a survey of current State
9 laws and incentives that support research and devel-
10 opment of qualified infectious disease products;

11 (2) based on the results of the survey and an
12 analysis of the effectiveness of such laws and incen-
13 tives, develop recommendations for model State laws
14 and incentives to support research and development
15 of qualified infectious disease products; and

16 (3) disseminate the model State laws and incen-
17 tives to State legislatures and State economic devel-
18 opment offices.

19 **SEC. 9. COMMISSION ON INFECTIOUS DISEASES PRODUCT**
20 **DEVELOPMENT.**

21 Part B of title III of the Public Health Service Act
22 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
23 tion 319E the following:

1 **“SEC. 319E-1. COMMISSION ON INFECTIOUS DISEASES**
2 **PRODUCT DEVELOPMENT.**

3 “(a) ESTABLISHMENT.—There is established a per-
4 manent commission to be known as the ‘Commission on
5 Infectious Diseases Product Development’.

6 “(b) DUTIES.—The Commission shall—

7 “(1) not later than the end of calendar year
8 2008, identify the infectious pathogens that are (or
9 are likely to become) a significant threat to public
10 health because of drug resistance or other factors;

11 “(2) taking into consideration the risks and
12 benefits to public health, make recommendations to
13 the Secretary on how best to address such patho-
14 gens, including through the development of qualified
15 infectious disease products to prevent, detect, and
16 treat such pathogens; and

17 “(3) periodically review and update the list of
18 pathogens identified under paragraph (1).

19 “(c) CONSULTATION.—In carrying out this section,
20 the Commission shall consult with—

21 “(1) the Antimicrobial Resistance Task Force
22 established under section 319–E; and

23 “(2) the National Biodefense Science Board es-
24 tablished under section 319M.

25 “(d) MEMBERSHIP.—

1 “(1) IN GENERAL.—The Commission shall be
2 composed of—

3 “(A) not more than 19 voting members ap-
4 pointed by the President under paragraph (2);
5 and

6 “(B) the nonvoting ex officio members list-
7 ed in paragraph (3).

8 “(2) VOTING MEMBERS.—The President shall
9 appoint not more than 19 voting members of the
10 Commission as follows:

11 “(A) 12 of the voting members shall be ap-
12 pointed from among the leading representatives
13 (including individuals in industry) of the infec-
14 tious disease medical, research, pharmaceutical,
15 and biological communities.

16 “(B) 7 of the voting members—

17 “(i) shall be appointed from among
18 the general public; and

19 “(ii) shall include leaders in the fields
20 of public policy, law, health policy, econom-
21 ics, and management.

22 “(3) NONVOTING EX OFFICIO MEMBERS.—The
23 Commission shall include the following nonvoting ex
24 officio members:

1 “(A) The Secretary of Homeland Security
2 (or the Secretary’s designee).

3 “(B) The Secretary of Health and Human
4 Services (or the Secretary’s designee).

5 “(C) The Director of the National Insti-
6 tutes of Health (or the Director’s designee).

7 “(D) The Commissioner of Food and
8 Drugs (or the Commissioner’s designee).

9 “(E) The Director of the Centers for Dis-
10 ease Control and Prevention (or the Director’s
11 designee).

12 “(F) The Assistant Secretary of Defense
13 for Health Affairs (or the Assistant Secretary’s
14 designee).

15 “(G) The Under Secretary for Health of
16 the Department of Veterans Affairs (or the
17 Under Secretary’s designee).

18 “(H) The Secretary of Agriculture (or the
19 Secretary’s designee).

20 “(I) Such additional ex officio members as
21 the Secretary determines necessary for the
22 Commission to carry out its functions.

23 “(4) TERMS.—Each member appointed under
24 paragraph (2) shall be appointed for a term of 6
25 years.

1 “(5) VACANCIES.—Any member appointed to
2 fill a vacancy occurring before the expiration of the
3 term for which the member’s predecessor was ap-
4 pointed shall be appointed only for the remainder of
5 that term. A member may serve after the expiration
6 of that member’s term until a successor has taken
7 office. A vacancy in the Commission shall be filled
8 in the manner in which the original appointment was
9 made.

10 “(6) BASIC PAY.—

11 “(A) RATES OF PAY.—Members of the
12 Commission who are officers or employees of
13 the United States shall not receive any com-
14 pensation for service on the Commission. The
15 other members of the Commission shall receive,
16 for each day (including travel time) they are en-
17 gaged in the performance of the functions of
18 the Commission, compensation at rates not to
19 exceed the daily equivalent of the annual rate in
20 effect for grade GS–15 of the General Schedule.

21 “(B) TRAVEL EXPENSES.—Each member
22 of the Commission shall receive travel expenses,
23 including per diem in lieu of subsistence, in ac-
24 cordance with applicable provisions under sub-

1 chapter I of chapter 57 of title 5, United States
2 Code.

3 “(7) CHAIRPERSON.—The Chairperson of the
4 Commission shall be a representative of the infec-
5 tious disease medical or research community selected
6 by the President from among the members ap-
7 pointed under paragraph (2). The term of office of
8 the Chairperson shall be 2 years.

9 “(8) MEETINGS.—The Commission shall meet
10 at the call of the Chairperson of the Commission or
11 the Secretary, but not less than 4 times each year.

12 “(e) DIRECTOR AND STAFF OF COMMISSION; EX-
13 PERTS AND CONSULTANTS.—

14 “(1) DIRECTOR.—The Commission shall have a
15 Director who shall be appointed by the Commission.

16 “(2) STAFF.—The Director of the Commission
17 may appoint such additional personnel as the Direc-
18 tor considers appropriate.

19 “(3) APPLICABILITY OF CERTAIN CIVIL SERV-
20 ICES LAWS.—The Director and staff of the Commis-
21 sion shall be appointed without regard to the provi-
22 sions of title 5, United States Code, governing ap-
23 pointments in the competitive service, and shall be
24 paid without regard to the provisions of chapter 51
25 and subchapter III of chapter 53 of that title relat-

1 ing to classification of positions and General Sched-
2 ule pay rates, except that the rate of pay for the Di-
3 rector and staff of the Commission may not exceed
4 the daily equivalent of the annual rate in effect for
5 grade GS-15 of the General Schedule.

6 “(4) EXPERTS AND CONSULTANTS.—The Com-
7 mission may procure temporary and intermittent
8 services under section 3109(b) of title 5, United
9 States Code.

10 “(5) STAFF OF FEDERAL AGENCIES.—Upon the
11 request of the Commission, the head of any Federal
12 agency may detail, without reimbursement, any of
13 the personnel of such agency to the Commission to
14 assist in carrying out the duties of the Commission.
15 Any such detail shall not interrupt or otherwise af-
16 fect the civil service status or privileges of the Fed-
17 eral employee.

18 “(f) POWERS OF COMMISSION.—

19 “(1) HEARINGS AND SESSIONS.—The Commis-
20 sion may, for the purpose of carrying out this Act,
21 hold hearings, sit and act at times and places, take
22 testimony, and receive evidence as the Commission
23 considers appropriate.

24 “(2) POWERS OF MEMBERS AND AGENTS.—Any
25 member or agent of the Commission may, if author-

1 ized by the Commission, take any action which the
2 Commission is authorized to take by this section.

3 “(3) **MAILS.**—The Commission may use the
4 United States mails in the same manner and under
5 the same conditions as other departments and agen-
6 cies of the United States.

7 “(4) **ADMINISTRATIVE SUPPORT SERVICES.**—
8 Upon the request of the Commission, the Adminis-
9 trator of General Services shall provide to the Com-
10 mission, on a reimbursable basis, the administrative
11 support services necessary for the Commission to
12 carry out its responsibilities under this section.

13 “(g) **ANNUAL REPORTS.**—

14 “(1) **IN GENERAL.**—Not later than the end of
15 calendar year 2007 and annually thereafter, the
16 Commission shall prepare and submit to the Presi-
17 dent, the appropriate committees of the Congress,
18 and the Secretary of Health and Human Services a
19 report that contains a detailed statement of the rec-
20 ommendations, findings, and conclusions of the
21 Commission, including—

22 “(A) an updated list of the infectious
23 pathogens identified by the Commission pursu-
24 ant to subsection (b)(1)(A); and

1 “(B) an updated assessment of challenges
2 faced by small biotechnology companies in se-
3 curing financing for infectious disease research
4 and development.

5 “(2) FIRST REPORT.—In addition to the con-
6 tents required by paragraph (1), the first report
7 under this subsection shall include an examination
8 of—

9 “(A) the impact of medical liability insur-
10 ance payment obligations on the financing of
11 infectious disease research and development;
12 and

13 “(B) the potential benefits of medical li-
14 ability relief to infectious disease research and
15 development.

16 “(h) DEFINITIONS.—In this section:

17 “(1) The term ‘Commission’ means the Com-
18 mission on Infectious Diseases Product Development
19 established under this section.

20 “(2) The term ‘qualified infectious disease
21 product’ has the meaning given to that term in sec-
22 tion 3 of the Beating Infections through Research
23 and Development Act of 2007.

24 “(i) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this section, there are authorized to be appro-

1 priated \$3,000,000 for fiscal year 2008 and such sums
2 as may be necessary for each subsequent fiscal year.”.

3 **SEC. 10. CLINICAL TRIAL GUIDELINES FOR ANTIBIOTIC**
4 **DRUGS.**

5 Chapter V of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 351 et seq.) is amended by inserting after
7 section 510 the following:

8 **“SEC. 511. CLINICAL TRIAL GUIDELINES FOR ANTIBIOTIC**
9 **DRUGS.**

10 “(a) IN GENERAL.—Not later than 1 year after the
11 date of enactment of the Beating Infections through Re-
12 search and Development Act of 2007, the Secretary, act-
13 ing through the Commissioner of Food and Drugs, shall
14 issue guidelines for the conduct of clinical trials with re-
15 spect to antibiotic drugs, including antimicrobials to treat
16 resistant pathogens, bacterial meningitis, acute bacterial
17 sinusitis, acute bacterial otitis media, and acute exacer-
18 bation of chronic bronchitis. Such guidelines shall indicate
19 the appropriate animal models of infection, in vitro tech-
20 niques, and valid microbiologic surrogate markers.

21 “(b) REVIEW.—Not later than 5 years after the date
22 of enactment of the Beating Infections through Research
23 and Development Act of 2007, the Secretary, acting
24 through the Commissioner of Food and Drugs, shall re-
25 view and update the guidelines described under subsection

1 (a) to reflect developments in scientific and medical infor-
2 mation and technology.”.

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