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109TH CONGRESS
1ST SESSION

# H. R. 3154

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 an infectious disease, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 2005

Mrs. CUBIN (for herself, Mr. BAIRD, Mr. MATHESON, Mr. BAKER, Mr. LAHOOD, Mr. BONNER, Mr. DAVIS of Alabama, Mr. GINGREY, and Mr. WELDON of Florida) 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

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# 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 an infectious disease, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Infectious Diseases Research and Development Act of 2005''.

**SEC. 2. FINDINGS.**

The Congress finds as follows:

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

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

(3) Resistant pathogens lead to higher health care costs because they often require more expensive drugs and extended hospital stays. The total cost to United States society is nearly $5,000,000,000 annually.

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

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

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

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

(7) Drug research and development is expensive, risky, and time-consuming. An aggressive research and development program initiated today would likely require 10 or more years and an investment of $800,000,000 to $1,700,000,000 to bring a new drug to market.

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

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

(10) The Centers for Disease Control and Prevention estimates that, without adequate preparation, 100,000 to 250,000 deaths could occur in the United States from a mild pandemic of influenza.

(11) The limited influenza vaccine market and few dedicated manufacturers pose a substantial challenge to the Nation's preparedness efforts. Currently, there are two manufacturers of influenza vaccine for the United States market. In 2004, the Food and Drug Administration suspended a manufacturer's license due to bacterial contamination. This action led to a shortage of injectable influenza vaccine in the United States.

(12) New rapid diagnostics would greatly reduce the cost and time needed to conduct clinical trials for new anti-infectives. For many infectious diseases, there currently are no rapid diagnostic tests available to assist in identifying eligible patients for clinical trials. Cutting costs and time will serve as incentives for greater investment in this area. In addition, new rapid diagnostics will permit physicians to diagnose specific bacterial infections in their patients. This will enable physicians to prescribe the most appropriate therapies, including

antibiotics, which will slow the evolution of new antimicrobial resistance.

**SEC. 3. DEFINITIONS.**

In this Act:

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

(2) The term ''antiviral'' means a drug or biological product intended for human use that impedes the reproduction of a virus.

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

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

(5) The term ''diagnostic test'' means a device or product used to detect the presence, concentration, or characteristics of an infectious human disease.

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

(7) The term ''qualified infectious disease product'' means any antibiotic drug, antiviral, diagnostic

test, or vaccine that is developed for the purpose of treating, detecting, preventing, or identifying—

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

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

(8) The term ''qualifying pathogen'' means—

(A) community-acquired methicillin-resistant staphylococcus areus (CA–MRSA);

(B) life-threatening gram negative bacteria, such as Escherichia coli (E. coli), Acinetobacter, Klebsiella species, and Pseudomonas aeruginosa;

(C) influenza; or

(D) any other infectious pathogen identified for purposes of this Act by the Secretary of Health and Human Services, in concurrence with infectious disease clinicians and appro-

priate professional associations, as a significant threat to public health because of drug resistance or other factors (or likely to become such a threat).

(9) The term ''vaccine'' means a vaccine intended for human use.

**SEC. 4. LIABILITY PROTECTION.**

(a) APPLICABILITY.—This section applies when—

(1) an individual is injured or dies as the result of a use or misuse of a qualified infectious disease product (other than a vaccine);

(2) a person is entitled, by reason of such injury or death, to recover damages from a manufacturer of the product; and

(3) such manufacturer was, as of the date of such injury or death, in substantial compliance with all applicable Federal requirements with respect to the product.

(b) FEDERAL ACTION REQUIRED.—The district courts of the United States shall have jurisdiction over a civil action covered by subsection (a). Such a civil action may not be brought in any Federal, State, or local court other than a district court of the United States.

(c) LIMITATION ON PUNITIVE DAMAGES.—In a civil action covered by subsection (a), the person may recover

punitive damages from the manufacturer to the extent otherwise available by law, except that—

(1) it must be proven, in addition to any other matter that must be proven, that the manufacturer—

(A) acted with malicious intent to injure the individual; or

(B) deliberately failed to avoid unnecessary injury that the manufacturer knew the individual was substantially certain to suffer; and

(2) the person may not recover punitive damages from the manufacturer if the person does not recover compensatory damages from the manufacturer.

(d) LIMITATION ON NON-ECONOMIC DAMAGES.—In a civil action covered by subsection (a), the person may recover non-economic damages from the manufacturer to the extent otherwise available by law, except that the amount of such damages may not exceed $250,000.

**SEC. 5. PATENT PROTECTION.**

(a) PURPOSE.—The purpose of this section is to provide an incentive for research and development relating to qualified infectious disease products.

(b) RESTORATION OF PATENT TERMS.—

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

**"SEC. 156a. RESTORATION OF PATENT TERMS RELATING TO QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

"(a) DEFINITIONS.—In this section—

"(1) the term 'diagnostic test' has the meaning given to that term in section 3 of the Infectious Diseases Research and Development Act of 2005;

"(2) the term 'qualified infectious disease product' has the meaning given to that term in section 3 of the Infectious Diseases Research and Development Act of 2005;

"(3) the term 'regulatory review period' means the period of time that—

"(A) starts on the date that is the later of—

"(i) the date that an eligible patent sought to be extended under this section is issued;

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

"(iii) the date on which an investigational device exemption is approved pursuant to section 520(g) of the Federal Food, Drug and Cosmetic Act; and

"(B) ends on the date that is—

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

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

"(iii) in the case of a medical device, the date on which an application for premarket approval submitted for such device under the Federal Food, Drug, and Cosmetic Act is approved; and

"(4) the term 'eligible patent' means a patent that—

"(A) claims a qualified infectious disease product, or claims an active ingredient of such product, or a process of making or using the product or an active ingredient of such product; and

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

"(b) PATENT TERM EXTENSION.—The term of an eligible patent shall be extended from the expiration date of the patent that would otherwise apply, which shall include any patent term adjustment granted under section 154(b), by a period equal to the number of days in the regulatory review period if each of the following is met:

"(1) An application in conformance with the requirements of subsection (c) is submitted to the Director by either the owner of record of the patent or its agent by the later of 60 days after the end of the regulatory review period or 45 days after issuance of the patent.

"(2) The patent that is the basis of the application has not been previously extended under this section, or under section 156.

"(3) The term of the patent that is the basis of the application has not expired before the date that the application is submitted under subsection (c).

"(4) The regulatory review period for the qualified infectious disease product has not been relied upon to support an application to extend the term

of another patent under this section or under section 156.

''(c) ADMINISTRATIVE PROVISIONS.—

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

''(2) CONTENT.—The application shall contain—

''(A) a description of the qualified infectious disease product and the Federal statute under which regulatory review occurred;

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

''(C) such other information as the Director may require including to establish that the applicant meets the requirements of this section.

''(3) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A patent that has been the basis of an application made under this section may not be the subject of an application made under section 156 or 158.''.

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

"156a. Restoration of patent terms relating to qualified infectious disease products.".

(c) EXTENSION OF PATENT TERMS.—

(1) CERTIFICATION OF SUCCESSFUL DEVELOPMENT.—

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

(i) has successfully developed a qualified infectious disease prevention product, as that term is defined in section 158 of title 35, United States Code; and

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

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

(i) approve the application if the Secretary determines that the entity has suc-

cessfully developed the qualified infectious disease prevention product;

(ii) deny the application if the Secretary determines that the entity has not successfully developed the product; and

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

(C) SUCCESSFUL DEVELOPMENT.—In carrying out subparagraph (B), the Secretary shall determine that an entity has successfully developed a product if—

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

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

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

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

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

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

**"§ 158. Extension of patent terms relating to qualified infectious disease prevention products.**

''(a) DEFINITIONS.—In this section:

''(1) The term 'qualified infectious disease prevention product' means a qualified infectious disease prevention product, as that term is defined in section 3 of the Infectious Diseases Research and Development Act of 2005.

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

''(3) The term 'diagnostic test' has the meaning given to that term in section 3 of the Infectious Diseases Research and Development Act of 2005.

''(4) The term 'eligible entity' means a natural or legal person that has successfully developed a qualified infectious disease prevention product.

''(5) The term 'eligible patent' means a patent that at the time the eligible entity entered into the contract to develop the qualified infectious disease prevention product involved, was owned by or licensed to that eligible entity, and claims a designated product, an active ingredient of a designated product, a method of making or using a designated product or a method of making or using an active ingredient of a designated product.

''(b) PATENT TERM EXTENSION.—The term of an eligible patent shall be extended for a period of 2 years, in addition to the term which would otherwise apply except for this section, if—

''(1) an application under subsection (c) is submitted to the Director by either the owner of record of the patent or its agent on or before the date specified in subsection (c)(3);

''(2) the patent has not been previously extended under this section, or under section 156 or 156a;

''(3) the patent has not expired before the date that the application is submitted;

''(4) the term of no other patent has been extended based on the certification being relied upon by the eligible entity to request extension of the patent; and

''(5) no other patent that claims the designated product, an active ingredient of the designated product, a method of making or using a designated product or a method of making or using an active ingredient of a designated product has been extended under this section or under section 156a.

''(c) ADMINISTRATIVE PROVISIONS.—

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

''(2) CONTENT.—An application filed under this section shall contain—

''(A) a description of the approved qualified infectious disease prevention product and the Federal statute under which regulatory review occurred;

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

"(C) the identity of the eligible entity and the applicant (if different from the eligible entity);

"(D) the identity of the designated product to which the eligible patent relates;

"(E) information concerning the certification specified in section 5(c)(1) of the Infectious Diseases Research and Development Act of 2005 being relied upon as the basis of the extension being requested;

"(F) information indicating that the entity owned or licensed the eligible patent at the time it entered into the contract to develop the qualified infectious disease prevention product; and

"(G) such other information as the Director may require including to establish that the applicant meets the requirements of this section.

"(3) SUBMISSION OF APPLICATION.—An application under this section shall be submitted to the Director within 60 days after the date of the certification specified in section 5(c)(1) of the Infectious Diseases Research and Development Act of 2005 that is being relied upon to request extension of the patent that is the subject of the application.

"(d) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the patent that is the basis of the application. A patent that has been the basis of an application made under this section may not be the subject of an application made under sections 156 or 156a.".

(3) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"158. Extension of patent terms relating to countermeasure products.".

**SEC. 6. ACCELERATED APPROVAL OF QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

(a) DESIGNATION AS FAST-TRACK PRODUCT.—

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

(A) a request for designation by the sponsor or applicant; or

(B) an application for the investigation of the qualified infectious disease product under

section 505 or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a sponsor or applicant from declining a designation under paragraph (1).

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

**"SEC. 447C. CLINICAL TRIALS ON QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

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

''(b) DEFINITION.—In this section, the term 'qualified infectious disease product' has the meaning given to that term in section 3 of the Infectious Diseases Research and Development Act of 2005.''.

**SEC. 7. TAX CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

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

**"SEC. 45J. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

''(a) GENERAL RULE.—For purposes of section 38, the infectious disease research credit determined under this section for the taxable year is an amount equal to 35 percent of the qualified infectious disease research expenses for the taxable year.

''(b) QUALIFIED INFECTIOUS DISEASE RESEARCH EXPENSES.—For purposes of this section—

''(1) QUALIFIED INFECTIOUS DISEASE RESEARCH EXPENSES.—Except as otherwise provided in this subsection, the term 'qualified infectious disease research expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year with respect to any research and development of qualified infectious disease products which would be described in subsection (b) of section 41 if

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

''(2) MODIFICATIONS; INCREASED INCENTIVE FOR CONTRACT RESEARCH PAYMENTS.—For purposes of paragraph (1), subsection (b) of section 41 shall be applied—

''(A) by substituting 'qualified infectious disease research' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

''(B) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

''(3) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified infectious disease research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

''(4) QUALIFIED INFECTIOUS DISEASE RESEARCH.—The term 'qualified infectious disease research' means qualified research (as defined in section 41(d)) which relates to the development of a qualified infectious disease product, except that qualified infectious disease research shall include ex-

penses related to re-formulating existing qualified infectious disease products.

''(5) QUALIFIED INFECTIOUS DISEASE PRODUCTS.—The term 'qualified infectious disease products' has the meaning given such term in section 3 of the Infectious Diseases Research and Development Act of 2005.

''(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

''(1) IN GENERAL.—Except as provided in paragraph (2), any qualified infectious disease research expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified infectious disease research expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) SPECIAL RULES.—

''(1) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(2) COORDINATION WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any qualified infectious disease research expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 45C for such taxable year.

''(3) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.''.

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

''(20) the infectious disease research credit determined under section 45J.''.

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

''(e) CREDIT FOR QUALIFIED INFECTIOUS DISEASE RESEARCH EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified infectious disease research expenses (as defined in section 45J(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45J(a).

''(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.''.

(d) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of the Internal Revenue Code of 1986 (defining qualified business credits) is amended by striking ''and'' at the end of paragraph (11), by striking the period at the end of paragraph (12) and inserting '', and'', and by adding at the end the following new paragraph:

''(13) the infectious disease research credit determined under section 45J(a) (other than such

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

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

''Sec. 45J. Credit for medical research related to developing qualified infectious disease products.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2004.

**SEC. 8. INCENTIVES FOR THE CONSTRUCTION OF QUALIFIED INFECTIOUS DISEASE PRODUCTS MANUFACTURING FACILITIES.**

(a) QUALIFIED INFECTIOUS DISEASE PRODUCTS MANUFACTURING FACILITIES INVESTMENT TAX CREDIT.—

(1) ALLOWANCE OF CREDIT.—Section 46 of the Internal Revenue Code of 1986 (relating to amount of investment credit) is amended by striking ''and'' at the end of paragraph (1), by striking the period at the end of paragraph (2) and inserting '', and'', and by adding at the end the following new paragraph:

''(3) the qualified infectious disease products manufacturing facilities investment credit.''.

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

**"SEC. 48A. QUALIFIED INFECTIOUS DISEASE PRODUCTS MANUFACTURING FACILITIES CREDIT.**

''(a) IN GENERAL.—For purposes of section 46, the qualified infectious disease products manufacturing facilities investment credit for any taxable year is an amount equal to 20 percent of the qualified investment for such taxable year.

''(b) QUALIFIED INVESTMENT.—

''(1) IN GENERAL.—For purposes of subsection (a), the qualified investment for any taxable year is the basis of each qualified infectious disease products manufacturing facilities property placed in service by the taxpayer during such taxable year.

''(2) QUALIFIED INFECTIOUS DISEASE PRODUCTS MANUFACTURING FACILITIES PROPERTY.—For purposes of this section, the term 'qualified infectious disease products manufacturing facilities property' means real and tangible personal property—

''(A)(i) the original use of which commences with the taxpayer, or

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

"(B) which is depreciable under section 167,

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

"(D) which is in compliance with any standards and regulations which are promulgated by the Food and Drug Administration, the Occupational Safety and Health Administration, or the Environmental Protection Agency and which are applicable to such property.

"(3) QUALIFIED INFECTIOUS DISEASE PRODUCTS.—For purposes of this subsection, the term 'qualified infectious disease products' has the meaning given such term in section 3 of the Infectious Diseases Research and Development Act of 2005.

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

''(d) TERMINATION.—This subsection shall not apply to any property placed in service after December 31, 2009.''.

(b) TECHNICAL AMENDMENTS.—

(1) Clause (iii) of section 49(a)(1)(C) of such Code is amended to read as follows:

''(iii) the basis of any qualified infectious disease products manufacturing facilities property.''.

(2) Subparagraph (E) of section 50(a)(2) of such Code is amended by inserting ''or 48A(c)'' before the period.

(3) The table of sections for subpart E of part IV of subchapter A of chapter 1 of such Code is amended by inserting after the item relating to section 48 the following:

''Sec. 48A. Qualified infectious disease products manufacturing facilities credit.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to property placed in service after December 31, 2004, under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the day before the date of enactment of the Revenue Reconciliation Act of 1990).

**SEC. 9. COMBATING ANTIMICROBIAL RESISTANCE.**

Subsection (g) of section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended to read as follows:

''(g) AUTHORIZATION OF APPROPRIATIONS.—

''(1) AUTHORIZATION.—There are authorized to be appropriated to carry out this section $40,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2006.

''(2) ALLOCATION.—

''(A) IN GENERAL.—Of the amount appropriated to carry out this section for a fiscal year, the Secretary shall make available not less than $25,000,000 for activities of the Centers for Disease Control and Prevention under subsections (b), (c), (d), and (e).

''(B) RATABLE REDUCTION.—If amounts appropriated to carry out this section for a fiscal year are less than $25,000,000, the Secretary shall ratably reduce the amount to be made available under subparagraph (A).''.

**SEC. 10. COMMISSION ON INFECTIOUS DISEASES PRODUCT DEVELOPMENT.**

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

**"SEC. 319E–1. COMMISSION ON INFECTIOUS DISEASES PRODUCT DEVELOPMENT.**

''(a) ESTABLISHMENT.—There is established a permanent commission to be known as the 'Commission on Infectious Diseases Product Development'.

''(b) DUTIES.—

''(1) IDENTIFICATION OF PATHOGENS.—The Commission shall—

''(A) not later than the end of calendar year 2006, identify the infectious pathogens that are (or are likely to become) a significant threat to public health because of drug resistance or other factors;

''(B) taking into consideration the risks and benefits to public health, make recommendations to the Secretary on how best to address such pathogens, including through the development of qualified infectious disease products to prevent, detect, and treat such pathogens; and

''(C) periodically review and update the list of pathogens identified under subparagraph (A).

''(2) RECOMMENDATIONS.—Not later than 90 days after the date of the enactment of this section, the Commission shall submit a report to the Secretary containing recommendations on the actions the Secretary should take to ensure that a sufficient quantity of vaccines and anti-virals are available to treat the American population in the event of a pandemic influenza outbreak.

''(c) ANTIMICROBIAL RESISTANCE TASK FORCE.—In carrying out this section, the Commission shall consult with the Antimicrobial Resistance Task Force established under section 319–E.

''(d) MEMBERSHIP.—

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

''(A) not more than 19 voting members appointed by the President under paragraph (2); and

''(B) the nonvoting ex officio members listed in paragraph (3).

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

''(A) 12 of the voting members shall be appointed from among the leading representatives (including individuals in industry) of the infectious disease medical, research, pharmaceutical, and biological communities.

''(B) 7 of the voting members—

''(i) shall be appointed from among the general public; and

''(ii) shall include leaders in the fields of public policy, law, health policy, economics, and management.

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

''(A) The Secretary of Homeland Security (or the Secretary's designee).

''(B) The Secretary of Health and Human Services (or the Secretary's designee).

''(C) The Director of the National Institutes of Health (or the Director's designee).

''(D) The Commissioner of Food and Drugs (or the Commissioner's designee).

"(E) The Director of the Centers for Disease Control and Prevention (or the Director's designee).

"(F) The Assistant Secretary of Defense for Health Affairs (or the Assistant Secretary's designee).

"(G) The Under Secretary for Health of the Department of Veterans Affairs (or the Under Secretary's designee).

"(H) The Secretary of Agriculture (or the Secretary's designee).

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

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

"(5) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled

in the manner in which the original appointment was made.

"(6) BASIC PAY.—

"(A) RATES OF PAY.—Members of the Commission who are officers or employees of the United States shall not receive any compensation for service on the Commission. The other members of the Commission shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the Commission, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–15 of the General Schedule.

"(B) TRAVEL EXPENSES.—Each member of the Commission shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

"(7) CHAIRPERSON.—The Chairperson of the Commission shall be a representative of the infectious disease medical or research community selected by the President from among the members appointed under subsection (d)(2). The term of office of the Chairperson shall be 2 years.

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

''(e) DIRECTOR AND STAFF OF COMMISSION; EXPERTS AND CONSULTANTS.—

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

''(2) STAFF.—The Director of the Commission may appoint such additional personnel as the Director considers appropriate.

''(3) APPLICABILITY OF CERTAIN CIVIL SERVICES LAWS.—The Director and staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification of positions and General Schedule pay rates, except that the rate of pay for the Director and staff of the Commission may not exceed the daily equivalent of the annual rate in effect for grade GS–15 of the General Schedule.

''(4) EXPERTS AND CONSULTANTS.—The Commission may procure temporary and intermittent

services under section 3109(b) of title 5, United States Code.

''(5) STAFF OF FEDERAL AGENCIES.—Upon the request of the Commission, the head of any Federal agency may detail, without reimbursement, any of the personnel of such agency to the Commission to assist in carrying out the duties of the Commission. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

''(f) POWERS OF COMMISSION.—

''(1) HEARINGS AND SESSIONS.—The Commission may, for the purpose of carrying out this Act, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Commission considers appropriate.

''(2) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Commission may, if authorized by the Commission, take any action which the Commission is authorized to take by this section.

''(3) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

''(4) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this section.

''(g) ANNUAL REPORTS.—Not later than the end of calendar year 2006 and annually thereafter, the Commission shall prepare and submit to the President, the appropriate committees of the Congress, and the Secretary of Health and Human Services a report that contains a detailed statement of the recommendations, findings, and conclusions of the Commission. Each such report shall include an updated list of the infectious pathogens identified by the Commission pursuant to subsection (b)(1)(A).

''(h) DEFINITIONS.—In this section:

''(1) The term 'Commission' means the Commission on Infectious Diseases Product Development established under this section.

''(2) The term 'qualified infectious disease product' has the meaning given to that term in section 3 of the Infectious Diseases Research and Development Act of 2005.

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

priated $3,000,000 for fiscal year 2006 and such sums as may be necessary for each subsequent fiscal year.''.

**SEC. 11. CLINICAL TRIAL GUIDELINES FOR ANTIBIOTIC DRUGS.**

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

**''SEC. 511. CLINICAL TRIAL GUIDELINES FOR ANTIBIOTIC DRUGS.**

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Infectious Diseases Research and Development Act of 2005, the Secretary, acting through the Commissioner of Food and Drugs, shall issue guidelines for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat resistant pathogens, bacterial meningitis, acute bacterial sinusitis, acute bacterial otitis media, and acute exacerbation of chronic bronchitis. Such guidelines shall indicate the appropriate animal models of infection, in vitro techniques, and valid microbiologic surrogate markers.

''(b) REVIEW.—Not later than 5 years after the date of enactment of the Infectious Diseases Research and Development Act of 2005, the Secretary, acting through the Commissioner of Food and Drugs, shall review and update the guidelines described under subsection (a) to reflect de-

velopments in scientific and medical information and technology.''.

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