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112TH CONGRESS
1ST SESSION

H. R. 3497

To promote the development of meaningful treatments for patients.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2011

Mr. LANCE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and the Judiciary, 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 promote the development of meaningful treatments for patients.

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 ''Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2011'' or the ''MODDERN Cures Act of 2011''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

The Congress makes the following findings:

(1) More than 133 million Americans, or 45 percent of the population, have at least one chronic condition. A quarter of Americans have multiple chronic conditions.

(2) Chronic diseases have become the leading cause of death and disability in the United States. Seven out of every 10 deaths are attributable to chronic disease. Chronic diseases also compromise the quality of life of millions of Americans.

(3) Despite $80,000,000,000 spent annually on research and development, many diseases and conditions lack effective treatments.

(4) Many commonly used drugs are effective in only 50 to 75 percent of the patient population, which can lead to devastating long-term side effects, resulting in the potential risks outweighing the benefits for some patients.

(5) Advanced and innovative diagnostic tests have the potential to dramatically increase the efficacy and safety of drugs by better predicting how patients will respond to a given therapy.

(6) Despite their promise, many drugs and diagnostics may go undeveloped due to uncertain regulatory and reimbursement processes, among other reasons.

(7) In addition, there is reason to believe that potential treatments with tremendous value to patients are never developed or are discontinued during research and development due to insufficiencies in the intellectual property system.

(8) It is in the public interest to address the hurdles that may be precluding new treatments from reaching patients and to remove the disincentives for the development of therapies for these unmet needs.

SEC. 4. DEFINITIONS.

In this Act:

(1) 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).

(2) 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).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE I—ADVANCING DIAGNOSTICS FOR PATIENTS

SEC. 101. DEVELOPING A COMMON LEXICON TO FACILITATE PROGRESS ON DIAGNOSTICS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary shall establish within the Department of Health and Human Services the Advanced Diagnostics Education Council (in this section referred to as the ''Council'').

(b) DUTIES.—

(1) IN GENERAL.—The Council shall promote an improved understanding of key concepts related to innovative diagnostics by recommending standard terms and definitions for use by patients, physicians, health care providers, payers, and policymakers.

(2) GUIDE.—The Secretary shall publish and disseminate a guide regarding such recommended terms and definitions for patients, physicians, health care providers, payers, and policymakers.

(3) REPORT.—Not later than 12 months after the establishment of the Council, the Secretary shall prepare and submit a report to the Congress and to the public on the Council's deliberations, activities,

and determinations with respect to meeting its duties described in paragraphs (1) and (2).

(c) CHAIRPERSON.—The Secretary, or the Secretary's designee, shall serve as chairperson of the Council.

(d) MEMBERS.—In addition to the Secretary, the Council shall consist of the following:

(1) The head of each the following agencies (or a designee thereof):

(A) The National Institutes of Health.

(B) The Centers for Disease Control and Prevention.

(C) The Food and Drug Administration.

(D) The Agency for Healthcare Research and Quality.

(E) The Centers for Medicare & Medicaid Services.

(F) The Department of Defense.

(G) The Department of Veterans Affairs.

(H) The Health Resources and Services Administration.

(I) The Substance Abuse and Mental Health Services Administration.

(J) The Indian Health Service.

(2) Seven members appointed by the Secretary from among individuals who collectively—

(A) represent a broad range of perspectives; and

(B) have expertise in—

(i) basic and translational research, including with respect to molecular biology and genetics;

(ii) bioinformatics;

(iii) the discovery, development, and commercialization of in vitro diagnostics; and

(iv) law and ethics.

(3) Four members appointed by the Secretary who are each a chief medical or scientific officer of a patient advocacy organization.

(e) PUBLIC INPUT.—In carrying out its duties, the Council shall solicit input from relevant stakeholders and the public.

(f) TERMINATION.—The Council shall terminate after publishing the guide required by subsection (b)(2) and submitting the report required by subsection (b)(3), or later at the discretion of the Secretary.

SEC. 102. CREATING INCENTIVES FOR INNOVATIVE DIAGNOSTICS.

(a) IMPROVEMENTS TO PROCESS FOR DETERMINING FEE SCHEDULE AMOUNTS FOR NEW TESTS.—

(1) CLARIFYING FACTORS FOR RATE-SETTING.—

(A) IN GENERAL.—In determining the payment amount under gapfilling procedures (as described in section 414.508(b) of title 42, Code of Federal Regulations, or any successor regulation to such section) for new clinical diagnostic laboratory tests under section 1833(h)(8) of the Social Security Act (42 U.S.C. 1395l(h)(8)), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall take into account, as applicable and available, the following factors with respect to such a new test:

(i) IMPACT ON PATIENT CARE.—The impact of the new test on patient care, patient management, or patient treatment.

(ii) TECHNICAL CHARACTERISTICS.—The technical characteristics of the new test, and the resources required to develop, validate, and perform the new test.

(iii) CLAIMS DATA.—Data from claims for which payment is made under part B of title XVIII of the Social Security Act.

(iv) LABORATORY CHARGES.—Amounts charged by laboratories to self-pay patients for the new test.

(v) PRIVATE INSURANCE RATES.—Amounts paid to laboratories for such new test under private health insurance coverage offered in the group market and the individual market.

(vi) ADVISORY PANEL RECOMMENDATIONS.—The findings and recommendations of the independent advisory panel convened under paragraph (2) with respect to that new test and any comments received during the open meeting of the advisory panel.

(vii) ADDITIONAL FACTORS.—Such other factors as the Secretary may specify.

(2) INPUT FROM PATIENTS, CLINICIANS, AND TECHNICAL EXPERTS.—

(A) REQUIREMENT FOR INDEPENDENT ADVISORY PANEL.—The Secretary shall convene an independent advisory panel from which the

Secretary shall request information and recommendations regarding any new test (as referred to under subparagraph (A) of section 1833(h)(8) of the Social Security Act (42 U.S.C. 1395l(h)(8))) for which payment is made under such section, including technical, clinical, and quality information.

(B) COMPOSITION OF INDEPENDENT ADVISORY PANEL.—The independent advisory panel shall be comprised of 19 members, including—

(i) 4 individuals with expertise and experience with advanced clinical diagnostic laboratory tests, including expertise in the technical characteristics of the new test;

(ii) 3 representatives of patients, including a patient representative for rare disorders;

(iii) 3 clinicians who use results of the new test in patient care;

(iv) 3 individuals with expertise in the requirements to develop, validate, and perform the new test;

(v) 2 laboratorians;

(vi) 2 experts in the area of pharmacoeconomics or health technology assessment; and

(vii) 2 individuals with expertise on the impact of new tests on quality of patient care, including genetic counselors.

(C) TERMS.—A member of the panel shall be appointed to serve a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments.

(D) EXPERT CONSULTANTS.—The Secretary may include to serve temporarily on the panel individuals who have expertise pertaining to the new test involved.

(E) OPEN MEETINGS.—The Secretary shall receive or review the findings and recommendations of the independent advisory panel with respect to the new tests described in subparagraph (A) involved during a meeting open to the public and provide opportunity for public comment.

(F) CLARIFICATION OF AUTHORITY OF SECRETARY TO CONSULT CARRIERS.—Nothing in this section shall be construed as affecting

the authority of the Secretary to consult with appropriate Medicare administrative contractors.

(b) PROCESS FOR ASSIGNMENT OF TEMPORARY CODES FOR DIAGNOSTIC TESTS.—The Secretary shall establish a process for application for the assignment of a temporary national HCPCS code to uniquely identify a diagnostic test until a permanent national HCPCS code is available for assignment to that test. Assignments of a temporary national HCPCS code shall occur on a quarterly basis. The Secretary shall provide public notice through the Centers for Medicare & Medicaid Services website of applications made for such temporary national HCPCS codes. Upon assignment of a temporary code under this process, the Secretary shall treat such test as a new test for purposes of section 1833(h)(8) of the Social Security Act.

(c) DEVELOPMENT OF FURTHER IMPROVEMENTS IN RATE-SETTING PROCESSES.—The Secretary shall analyze the process used for the gapfilling procedure used in determining payment amounts for new clinical diagnostic laboratory tests under section 1833(h)(8) of the Social Security Act. Taking into account the changes made by this section, the Secretary shall identify further changes to improve the accuracy and appropriateness of resulting rates

and the openness, transparency, and predictability of the process. The Secretary shall examine what and how many entities should perform gapfilling, under contract or otherwise, and how to ensure that the process is informed by appropriate expertise and proceeds in a transparent and accountable manner. The Secretary shall implement improvements in the process, insofar as these are possible under the law through regulations, after public notice and opportunity for comment. For changes the Secretary determines would require a change in law, the Secretary shall transmit recommendations to the Speaker of the House and the President of the Senate not later than July 1, 2013.

(d) DEFINITIONS.—For purposes of this section:

(1) NEW CLINICAL DIAGNOSTIC LABORATORY TESTS.—The term ''new clinical diagnostic laboratory test'' means a clinical diagnostic laboratory test—

(A) that is assigned a new or substantially revised code on or after January 1, 2013; or

(B) for which an application for a temporary national HCPCS code is made under subsection (b) on or after January 1, 2013.

(2) SELF-PAY PATIENT.—The term ''self-pay patient'' means, with respect to a health care item

or service, an individual who pays out of pocket for such item or service and who does not have health insurance coverage for such item or service.

(e) EFFECTIVE DATE.—This section shall take effect on the date of enactment of this Act, and shall apply with respect to new clinical diagnostic laboratory tests.

SEC. 103. PROMOTING THE DEVELOPMENT OF INNOVATIVE DIAGNOSTICS.

(a) DETERMINATION.—

(1) REQUEST.—The manufacturer or sponsor of a drug or biological product may request the Secretary to determine that—

(A) a diagnostic test has been developed by, or with the participation of, the manufacturer or sponsor of the drug or biological product; and

(B) use of the diagnostic test, as demonstrated through valid scientific information such as peer-reviewed literature—

(i) provides for or improves the identification of a patient population for which the drug or biological product will or will not be used in accordance with its approved indications; or

(ii) provides for or improves the determination of the most appropriate treatment option for a patient population with the drug or biological product in accordance with its approved indications.

(2) RESPONSE BY SECRETARY.—Not later than 30 days after the submission of a request under paragraph (1), the Secretary, shall—

(A) make the requested determination and publish a notice of such determination and any extension under this section resulting from such determination; or

(B) provide an explanation to the manufacturer or sponsor submitting the request of why the determination is not warranted.

(b) APPLICABLE EXTENSION PERIOD.—For purposes of subsections (c) and (d), the applicable extension period is—

(1) with respect to a diagnostic test developed (as described in subsection (a)(1)(A)) contemporaneously with the development of the drug or biological product involved, 12 months; and

(2) with respect to a diagnostic test developed otherwise, 6 months.

(c) EXTENSION FOR DRUGS.—If, at the request of the manufacturer or sponsor of a drug, the Secretary makes the determination described in subsection (a)(1) with respect to such drug and a diagnostic test, then—

(1) the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the three-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of such section 505, or the seven-year period described in section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc), as applicable, shall be extended by the applicable extension period;

(2) if the drug is the subject of—

(A) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of such section 505; or

(B) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of such section 505,

then the period during which an application may not be approved under subsection (c)(3) or (j)(5)(B) of

such section 505 shall be extended by the applicable extension period after the date the patent expires (including any patent extensions); and

(3) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of such section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(5)(B) of such section 505 shall be extended by the applicable extension period after the date the patent expires (including any patent extension).

(d) EXTENSION FOR BIOLOGICAL PRODUCTS.—If, at the request of the manufacturer or sponsor of a biological product, the Secretary makes the determination described in subsection (a)(1) with respect to such biological product and a diagnostic test, then the 12-year period described in subsection (k)(7)(A) of section 351 of the Public Health Service Act (42 U.S.C. 262), the 4-year period described in subsection (k)(7)(B) of such section 351, and the 7-year period described in section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc), as applicable, shall be extended by the applicable extension period.

(e) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (c) or (d) of a period shall be in addition to any extension of the period under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) with respect to the drug or biological product.

(f) LIMITATIONS.—Extensions under this section may apply—

(1) not more than twice with respect to the same drug or biological product; and

(2) not more than once with respect to the same indication to be treated by the same drug or biological product.

TITLE II—CAPTURING LOST OPPORTUNITIES FOR PATIENTS

SEC. 201. DESIGNATION OF DORMANT THERAPIES.

(a) DESIGNATION.—The Secretary shall designate a drug or biological product as a dormant therapy if—

(1) the sponsor of the drug or biological product submits a request in accordance with subsection (b); and

(2) the Secretary determines that—

(A) the indication for which the drug or biological product is being investigated or is in-

tended to be investigated is to address one or more unmet medical needs; and

(B) the sponsor intends to file an application pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for approval or licensing of the drug or biological product for such indication.

(b) REQUEST FOR DESIGNATION.—

(1) SUBMISSION.—The sponsor of a drug or biological product may submit a request to the Secretary to designate the drug or biological product as a dormant therapy.

(2) CONTENTS.—Any request under paragraph (1) with respect to a drug or biological product shall contain each of the following:

(A) A listing of all patents and applications for patents—

(i) under which the sponsor has rights; and

(ii) which may be reasonably construed to provide protection for the drug or biological product.

(B) A waiver of enforcement rights in accordance with paragraph (3).

(C) A certification by the sponsor that the new drug or new biological product has prospectively insufficient patent protection.

(3) WAIVER.—

(A) REQUIREMENT.—A request under paragraph (1) shall contain a waiver of the right to enforce any patent or patent application, which issues as a patent described in paragraph (2)(A) with respect to any product described in subparagraph (B).

(B) PRODUCTS DESCRIBED.—A product is described in this subparagraph if—

(i) it is approved or licensed pursuant to an application that is filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(ii) the filing occurs after the expiration of the protection period (as defined in section 202(a)(1) of this Act) applicable to

the drug or biological product to which the request under paragraph (1) relates.

(C) EFFECTIVE ONLY UPON DESIGNATION.—A waiver under this paragraph shall be effective only upon the designation under this section of the drug or biological product to which it relates as a dormant therapy.

(D) INABILITY TO WAIVE RIGHT TO ENFORCE ONE OR MORE PATENTS.—If a sponsor of a drug or biological product is unable to grant an effective waiver of the right to enforce one or more patents or applications for patent as described in subparagraph (A)—

(i) the sponsor may not make a request under this subsection with respect to the drug or biological product; and

(ii) if the sponsor has made such a request, the sponsor shall promptly withdraw the request.

(4) TIMING.—

(A) REQUEST.—Any request for designation of a drug or biological product as a dormant therapy under subsection (a) shall be made before the submission of an application under section 505 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) for the first approval or licensure of commercial marketing or use of a drug or biological product that shares at least one active moiety with an active moiety in the drug or biological product for which designation is being requested.

(B) WITHDRAWAL OF REQUEST.—The sponsor of a drug or biological product may withdraw a request under paragraph (1) with respect to the drug or biological product, but only prior to approval or licensing of the drug or biological product.

(5) EFFECTS OF WITHDRAWAL OF REQUEST.—If the sponsor of a drug or biological product withdraws a request under paragraph (1) with respect to the drug or biological product—

(A) any designation of the drug or biological product as a dormant therapy under subsection (a) is cancelled; and

(B) any waiver submitted under this subsection with respect to the drug or biological product is cancelled.

(c) CRITERIA FOR DESIGNATION.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall establish a comprehensive methodology and criteria for the designation of a drug or biological product as a dormant therapy in accordance with subsection (a). No designation shall be made under subsection (a) during such 18-month period unless the Secretary has established such methodology and criteria.

(2) PUBLIC INPUT.—The Secretary shall consult with relevant stakeholders and provide an opportunity for public notice and comment in—

(A) establishing the methodology and criteria under paragraph (1); and

(B) establishing criteria for determining whether the indication for which the drug or biological product is being investigated or is intended to be investigated is to address one or more unmet medical needs (as described in subsection (a)(2)(A)).

(d) DEFINITIONS.—In this section:

(1) The term ''prospectively insufficient patent protection'' means, with respect to a drug or biological product for which a request for designation is submitted under subsection (b) (in this paragraph

referred to as the ''dormant therapy''), that the protection afforded under patents and patent applications, when issued as a patent, relating to the dormant therapy, in the aggregate—

(A) are not reasonably anticipated by the sponsor of the dormant therapy to provide an adequate scope of protection to prevent the approval of products that would rely upon or reference the dormant therapy, in an application filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), or

(B) are not reasonably anticipated by the sponsor of the dormant therapy to provide patent protection under such patents and applications, when issued as a patent,

for a period of 14 years from the date of first approval or licensing of the dormant therapy for marketing pursuant to an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) The term ''address one or more unmet medical needs'' refers to—

(A) addressing a need for drugs or biological products for the treatment of one or more life-threatening or other serious diseases or conditions for which no therapy exists; or

(B) if one or more therapies are available for the treatment of such a disease or condition, demonstrating through clinical investigations—

(i) one or more improved effects on serious outcomes of the disease or condition that are affected by alternative therapies, such as superiority of the drug or biological product used alone or in combination with other therapies in an active controlled trial assessing an endpoint reflecting serious morbidity;

(ii) one or more effects on serious outcomes of the disease or condition not known to be affected by alternative therapies, such as progressive disability in multiple sclerosis when alternative therapies have shown an effect on exacerbations but have not shown an effect on progressive disability;

(iii) an ability—

(I) to provide one or more benefits in patients who are unable to tolerate or are unresponsive to alternative therapies, such as an antipsychotic agent that is effective in people failing standard therapy; or

(II) to be used effectively in combination with other critical agents that cannot be combined with alternative therapies;

(iv) an ability to provide one or more benefits similar to those of alternative therapies while—

(I) avoiding serious toxicity that is present in alternative therapies; or

(II) avoiding less serious toxicity that is common in alternative therapies and causes discontinuation of treatment of a life-threatening or serious disease; or

(v) an ability to provide one or more benefits similar to those of alternative therapies but with improvement in some factor, such as compliance or convenience,

that is shown to lead to improved effects on serious outcomes.

(e) PUBLIC NOTICE OF DESIGNATION.—The Secretary request for and notice of the designation of a dormant therapy under paragraph (4) shall be made available to the public.

SEC. 202. PROMOTING THE DEVELOPMENT OF DORMANT THERAPIES.

(a) PROTECTIONS FOR DORMANT THERAPY.—

(1) PROTECTION PERIOD.—The term ''protection period'' means, with respect to a drug or biological product designated as a dormant therapy under section 201(a) (in this section referred to as the ''dormant therapy''), the 15-year period beginning on the date on which the Secretary approves an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the drug or biological product.

(2) APPLICATIONS FILED DURING THE PROTECTION PERIOD.—During the protection period for a dormant therapy, notwithstanding any other provision of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.)—

(A) absent a right of reference from the holder of such approved application for the dormant therapy, the Secretary shall not approve an application filed pursuant to section 505(b)(2) or section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) referencing or otherwise relying on the approval or licensure of the dormant therapy;

(B) the Secretary shall not approve—

(i) an application filed pursuant to such section 505(b)(2) or 505(j) that references or otherwise relies on the approval or licensure of a drug or biological product that is not the dormant therapy but contains the same active moiety as the dormant therapy; or

(ii) an application filed pursuant to such section 351(k) that references or otherwise relies on the approval or licensure of a drug or biological product that is not the dormant therapy but contains an active

moiety highly similar to that of the dormant therapy; and

(C) the Secretary shall not approve an application filed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a drug that contains the same active moiety as the dormant therapy, or an application filed pursuant to section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a biological product that contains an active moiety highly similar to that of the dormant therapy, unless the information provided to support approval of such application is comparable in scope and extent (including with respect to design and extent of preclinical and clinical testing) to the information provided to support approval of the application (described in paragraph (1)) for the dormant therapy.

(3) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Secretary, in consultation with relevant Federal agencies, shall promulgate such regulations as are required to implement the incentives described in paragraph (2).

(4) PATENT TERM ALIGNMENT WITH DATA PACKAGE PROTECTION PERIOD.—

(A) IN GENERAL.—Notwithstanding any provision of title 35, United States Code, a sponsor of a drug or biologic product designated as a dormant therapy under section 201(a), upon the approval or licensure thereof under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and in lieu of filing a patent term extension application under section 156(d) of such title 35 (other than applications for interim extensions filed under paragraph (5) of such section 156(d)), shall be entitled to patent term extension in accordance with this paragraph.

(B) SUBMISSION OF LISTING OF PATENTS AND APPLICATIONS FOR PATENTS.—

(i) SUBMISSION.—The sponsor of the dormant therapy, within a period to be set by the Director of the United States Patent and Trademark Office (in this paragraph referred to as the ''Director''), shall submit to the Director—

(I) the listing of patents and applications for patents required by sec-

tion 201(b)(2)(A) with respect to the dormant therapy; and

(II) a listing of any additional patents and applications for patents that, at the time of the submission, meet the description in section 201(b)(2)(A).

(ii) PERIOD.—The period set by the Director under clause (i) shall not be less than 6 months from the date on which the Secretary approves or licenses the dormant therapy.

(C) EXTENSION OF PATENTS.—

(i) IN GENERAL.—For each patent identified pursuant to subparagraph (B)(i), and for each patent issuing based upon an application for patent so identified, the Director shall extend the patent to expire at the end of the protection period under paragraph (1) for the dormant therapy, if the patent would otherwise expire prior to the end of the protection period.

(ii) APPLICATION OF CERTAIN PROVISIONS.—During the period of an extension under clause (i)—

(I) the rights under the patent shall be limited in the manner provided under section 156(b) of title 35, United States Code; and

(II) the terms ''product'' and ''approved product'' in such section 156(b) shall be deemed to include forms of the active moiety of the dormant therapy and highly similar active moieties that might be approved by the Secretary based upon an application filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2), (j)) or under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that references or otherwise relies upon the dormant therapy.

(D) NOTICE OF EXTENSION.—For each patent that is extended under this paragraph, the Director shall publish a notice of such extension.

(E) NOTICE OF WAIVER.—For each patent identified pursuant to subparagraph (B)(i), and

each patent issuing based upon an application for patent so identified, that expires subsequent to the end of the protection period for the dormant therapy under paragraph (1), the Director shall publish a notice that the patent is subject to the waiver of the right to enforce as described section 201(b)(3).

(b) ORPHAN PRODUCTS.—If a drug or biological product has been designated as a dormant therapy under section 201(a) of this Act, the protections otherwise applicable with respect to such drug or biological product under section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) shall not apply.

(c) STUDY REGARDING DORMANT THERAPIES.—Not later than one year after the enactment of this Act, the Secretary shall enter into an agreement with the Director of the Institute of Medicine—

(1) to conduct a study on intellectual property laws and their impact on therapy and diagnostic development in order to formulate recommendations on how to facilitate the clinical evaluation and development of therapies currently available on the market for new potential indications; and

(2) not later than 18 months after the date of the enactment of this Act, to submit a report to the

Secretary and the Congress containing the results of such study.

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