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113TH CONGRESS
1ST SESSION

H. R. 3116

To promote the development of meaningful treatments for patients.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 17, 2013

Mr. LANCE (for himself, Mr. ROSKAM, Mr. GUTHRIE, Mr. PAULSEN, Mr. RANGEL, Mr. RUNYAN, Ms. SCHWARTZ, Mr. KING of New York, Mr. MCCAUL, Mr. WALDEN, Mr. TIBERI, Mr. LOEBSACK, Mr. BEN RAY LUJÁN of New Mexico, Mr. ELLISON, Mr. JONES, and Mr. LONG) 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 2013'' or the ''MODDERN Cures Act of 2013''.

SEC. 2. TABLE OF CONTENTS.

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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 billion 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 ''medicine'' means a biological product or a drug.

(4) 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 of 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.—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:

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

(B) TECHNICAL CHARACTERISTICS.—The technical characteristics of the new test, and

the resources required to develop, validate, and perform the new test.

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

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

(E) 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.

(F) 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.

(G) 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.—Subject to subparagraph (D), the independent advisory panel shall be comprised of 19 members, including—

(i) 7 individuals with expertise and experience with clinical diagnostic laboratory tests including expertise in the technical characteristics of the new test as well as expertise in the requirements to develop, validate, and perform 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) 2 laboratorians;

(v) 2 individuals with expertise in the area of pharmacoeconomics or health technology assessment; and

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

(C) TERMS.—Subject to subparagraph (D), 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) TEMPORARY APPOINTMENT OF EXPERTS.—Insofar as the Secretary determines with respect to a new test that there are an insufficient number of members of the panel with expertise with respect to that specific test, the Secretary may appoint individuals who have expertise pertaining to the new test involved to serve on the panel.

(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.

(3) JUSTIFICATION FOR PAYMENT DETERMINATIONS.—

(A) INITIAL JUSTIFICATION.—With respect to decisions regarding payments made under the clinical laboratory fee schedule for new clinical diagnostic laboratory tests, the Secretary shall publicly provide a justification for the payment basis and payment rate determination, including a detailed summary of the information submitted to, or obtained by, the Secretary regarding the factors specified in paragraph (1), such that interested stakeholders can readily understand the Secretary's rationale for the payment basis and rate determinations.

(B) RECONSIDERATION PERIOD.—After providing such justification for a payment basis and payment rate determination, the Secretary

shall provide for a reasonable period of reconsideration to receive any appeal of the determination and to evaluate any additional information received regarding the justification and the factors specified in paragraph (1).

(C) FINAL DETERMINATION.—After the period of reconsideration the Secretary shall make a final payment basis and payment rate determination and provide a justification for such final determination explaining what additional information was evaluated during the reconsideration and how such information was taken into account with respect to the final determination. Nothing in this paragraph shall be construed as authorizing the Secretary to reveal proprietary information which is otherwise prohibited from disclosure under law.

(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 Web site 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, 2014.

(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 a temporary national HCPCS code is granted under subsection (b) on or after January 1, 2014.

(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.—

(1) IN GENERAL.—Subject to paragraph (2), this section shall take effect on the date of enactment of this Act and shall apply with respect to new clinical diagnostic laboratory tests.

(2) APPLICATION OF JUSTIFICATIONS TO CURRENT RATE DETERMINATIONS.—Subsection (a)(3)

shall apply to payment basis and payment rate determinations made on or after January 1, 2013.

SEC. 103. PROMOTING THE DEVELOPMENT OF INNOVATIVE DIAGNOSTICS.

(a) DETERMINATION.—

(1) REQUEST.—The manufacturer or sponsor of a medicine 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 medicine; 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 medicine will or will not be used in accordance with its approved indications;

(ii) provides for or improves the determination of the most appropriate treatment option for a patient population with the medicine in accordance with its approved indications; or

(iii) provides for the detection of a qualifying pathogen (as defined in section

505E(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(f)).

(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 medicine 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 medicine.

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

(1) not more than twice with respect to the same medicine; and

(2) not more than once with respect to the same indication to be treated by the same medicine.

TITLE II—CAPTURING LOST OPPORTUNITIES FOR PATIENTS

SEC. 201. DORMANT THERAPIES.

(a) DESIGNATION AS DORMANT THERAPY.—The Secretary shall designate a medicine as a dormant therapy if—

(1) the sponsor of the medicine submits a request for such designation meeting the requirements under subsection (b), and the request has not been withdrawn under subsection (d)(1); and

(2) the Secretary determines that—

(A) the medicine is being investigated or is intended to be investigated for an indication to address one or more unmet medical needs;

(B) a suitable clinical plan for such investigations of the medicine has been developed by the sponsor;

(C) 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 medicine for an indication described in subparagraph (A); and

(D) the request for designation was made on or before the date of submission of any 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 approval or licensure of commercial marketing or use of a medicine that in the case of a drug shares an active moiety that is the same as, and in the case of a biologic contains an active moiety that is highly similar to, an active moiety in the medicine for which designation is being requested.

(b) REQUIREMENTS FOR REQUEST FOR DESIGNATION AS DORMANT THERAPY.—A request under subsection (a)(1) with respect to a medicine may only be made by the sponsor of the medicine and shall contain each of the following:

(1) A listing of all patents and applications for patents under which the sponsor has rights and that may be reasonably construed to provide protection for the medicine.

(2) A waiver of patent rights to the extent required under subsection (c) to take effect, if at all, as provided under subsection (c)(3).

(3) Such additional information as the Secretary may require by regulation in order to determine eligibility for designation under subsection (a).

(c) WAIVER OF PATENT RIGHTS EXPIRING AFTER THE PROTECTION PERIOD ENDS.—

(1) PATENT WAIVER.—

(A) IN GENERAL.—Subject to subparagraph (B), the request under this subsection shall include a waiver of the right to enforce or otherwise assert any patent described in subsection (b)(1) (or any patent issued on the basis of an application described in subsection (b)(1)), which may expire after the end of the protection period for the dormant therapy, against any applicable product described in paragraph (2). The waiver shall be made by the owner of the patent or application for patent, as the case may be.

(B) LIMITATIONS ON PATENT WAIVER.—Any patent waiver provided pursuant to this section, should it become effective—

(i) shall have no effect during the protection period for the medicine to which the waiver relates; and

(ii) shall have no effect with respect to the subject matter of a claimed invention in a patent that does not provide any protection for such medicine with respect to an applicable product described in paragraph (2).

(2) APPLICABLE PRODUCTS DESCRIBED.—An applicable product is described in this paragraph only if—

(A) it is approved or licensed pursuant to an application that—

(i) 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) references or otherwise relies upon the approval or licensure of the dormant therapy to which the waiver relates; and

(B) the approval of the product occurs after the expiration of the protection period applicable to the medicine to which the request under subsection (a)(1) relates.

(3) EFFECTIVE DATE OF WAIVER.—A waiver under subsection (b)(2) with respect to a patent shall take effect, if at all, on the date the Director publishes the notice required under subsection (e)(2)(F) relating to the patent.

(d) WITHDRAWAL OF REQUEST FOR DESIGNATION, REVOCATION BY THE SECRETARY.—

(1) IN GENERAL.—The sponsor of a medicine may withdraw a request for designation under subsection (a)(1) with respect to a medicine unless the medicine has been approved or licensed 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). The Secretary shall deny a designation request or revoke any designation granted if at any time the Secretary finds that the sponsor is not in compliance with subsections (c)(1) and (g)(1).

(2) EFFECTS OF WITHDRAWAL OF REQUEST OR REVOCATION OF DESIGNATION.—If the sponsor of a medicine withdraws a request under subsection (b)

or the Secretary denies a designation request or revokes a designation with respect to the medicine—

(A) any patent waiver submitted under this section with respect to the medicine, but not yet effective, is canceled and deemed a nullity;

(B) any patent waiver that has taken effect under this section with respect to the medicine shall remain in effect;

(C) any patent term extension granted by the Director under subsection (e)(2) with respect to the medicine shall be canceled, except that the Director shall maintain the patent term extension for one patent, to be selected by the sponsor of the medicine, for the period of extension that would have been applicable under section 156 of title 35, United States Code; and

(D) the designation, if made, otherwise shall be treated as never having been requested or made or having effect.

(3) BASIS FOR REVOCATION.—The Secretary may revoke a designation made under subsection (a), but only based upon a finding by the Secretary under paragraph (1).

(e) GUARANTEED PROTECTIONS FOR DORMANT THERAPIES.—

(1) 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 medicine that is not the dormant therapy, was approved subsequent to the approval of the dormant therapy,

and contains the same active moiety as the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are the same); or

(ii) an application filed pursuant to such section 351(k) that references or otherwise relies on the approval or licensure of a medicine that is not the dormant therapy, was approved subsequent to the approval or licensure of the dormant therapy, and contains an active moiety that is highly similar to the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are highly similar); 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 active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are the same), 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 that is highly similar to the active moiety in the dormant therapy (or if the dormant therapy contains more than one active moiety, all of the active moieties are highly similar), unless—

(i) 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 for the dormant therapy 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)); and

(ii) if such clinical testing had not commenced before the approval of the application for the dormant therapy, the clinical testing establishes clinical superiority in the form of a significant therapeutic advantage over and above that provided by

the dormant therapy in one or more of the following ways:

(I) Greater effectiveness on a clinically meaningful endpoint.

(II) Greater safety in a substantial portion of the target populations.

(III) Where neither greater safety nor greater effectiveness has been shown, a demonstration that the drug otherwise makes a major contribution to patient care.

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

(A) IN GENERAL.—Notwithstanding any provision of title 35, United States Code, a sponsor of a medicine designated as a dormant therapy under subsection (a)(1), upon the approval or licensure thereof 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), and in lieu of filing a patent term extension application under section 156(d) of such title 35, shall be entitled to patent term extensions in accordance with this paragraph.

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

(i) SUBMISSION.—The sponsor of the dormant therapy, within a period to be set by the Director of not less than 2 months beginning on the date the Secretary approves or licenses the dormant therapy, shall submit to the Director—

(I) the listing of patents and applications for patents provided to the Secretary under subsection (b)(1);

(II) any revisions to such listing as may be required for compliance with subsection (b)(1); and

(III) any documentation the Director may require from the patentee or patent applicant (as the case may be) of the waiver of patent rights required under subsection (b)(2).

(ii) FAILURE TO PROVIDE SUFFICIENT DOCUMENTATION OF WAIVER.—If the Director determines that the sponsor has not complied with the waiver requirements under subsection (c), after providing the

sponsor the opportunity to remedy any insufficiency, the Director shall so notify the Secretary that the patent waiver requirements for designation have not been satisfied.

(C) EXTENSION OF PATENTS.—

(i) IN GENERAL.—Unless the Director has notified the Secretary of a determination under subparagraph (B)(ii), for each patent identified in a submission pursuant to subparagraph (B)(i), and for each patent issuing based upon an application for patent so identified, the Director shall, within the 3-month period beginning on the date of the submission, extend the patent to expire at the end of the protection period for the dormant therapy, if the patent would otherwise expire before the end of the protection period. If the Director has so notified the Secretary under subparagraph (B)(ii), the Director shall extend one such patent, selected by the sponsor, for the period that would have been applicable had an application for extension been filed under section 156 of title 35,

United States Code, with respect to such patent.

(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) INTERIM PATENT EXTENSIONS.—Notwithstanding any provision of title 35, United States Code, with respect to any patent listed (or patent issuing on an application listed) under subsection (b)(1) that would otherwise expire before the sponsor could make a submission under subparagraph (B), the Director, upon application of the patentee, shall grant to the patentee an interim extension of such patent, subject to the limitations in section 156(d)(5)(F) of such title 35, for such period as may be necessary to permit the sponsor to submit the listing under subparagraph (B) and, if the patent is therein listed, to extend the patent as provided under subparagraph (C). The Director may require, for any patent extended under this subparagraph, that the sponsor of the dormant therapy to which the patent relates provide periodic certifications that development of the dormant therapy is continuing. The Director may terminate any interim extension for which a required certification has not been made.

(E) NOTICE OF EXTENSION.—For each patent that is extended under this paragraph,

the Director shall publish a notice of such extension and issue a certificate of extension described in section 156(e)(1) of title 35, United States Code.

(F) NOTICE OF WAIVER.—For each patent identified in a submission under subparagraph (B)(i), and each patent issuing based upon an application for patent so identified, that expires after the end of the protection period for the dormant therapy, the Director shall publish a notice that the patent is subject to the limited waiver of the right to enforce described in subsection (c)(1).

(f) CERTAIN FDA PROTECTIONS INAPPLICABLE.—If a medicine has been designated as a dormant therapy under subsection (a), the protections otherwise applicable with respect to such medicine under sections 505A, 505E, and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355f, 360cc) shall not apply. The preceding sentence shall not be construed to affect any protections applicable with respect to a drug, including a drug designated under section 526 of such Act (21 U.S.C. 360bb) for a rare disease or condition, under provisions other than such sections 505A, 505E, and 527.

(g) DEVELOPMENT CERTIFICATIONS.—

(1) IN GENERAL.—The Secretary shall require that the sponsor of a dormant therapy provide periodic certifications that development of the dormant therapy to address one or more unmet medical needs is continuing.

(2) DETERMINATION OF NONCOMPLIANCE.—If the Secretary concludes that the sponsor has not complied with paragraph (1), after providing the sponsor the opportunity to remedy any insufficiency, the Secretary shall, for purposes of subsection (d)(1), determine that the sponsor is not in compliance with the certification requirement under paragraph (1).

(h) COLLABORATION.—Nothing in this section shall be construed as preventing a sponsor from collaborating with other entities in developing a dormant therapy or applying for a dormant therapy designation.

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

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

(A) addressing a need for medicines 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 medicine 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.

(2) The term ''Director'' means the Under Secretary of Commerce for Intellectual Property and

Director of the United States Patent and Trademark Office.

(3) The term ''dormant therapy'' means a medicine designated as a dormant therapy under subsection (a).

(4) The term ''protection period'' for a dormant therapy means the period that—

(A) begins on the date on which the Secretary first 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 dormant therapy for any indication; and

(B) ends on the date that is 15 years after the date of such approval.

(5) The term ''sponsor'' for a dormant therapy is the person who takes responsibility for the designation and development of the dormant therapy. The sponsor may be a single entity or an entity collaborating with one or more other entities.

SEC. 202. STUDY REGARDING NEW INDICATIONS FOR EXISTING THERAPIES.

Not later than one year after the date of the enactment of this Act, the Secretary shall enter into an ar-

rangement with the Institute of Medicine (or, if the Institute declines, another appropriate entity)—

(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 such date of the enactment, to submit a report to the Secretary and the Congress containing the results of such study.

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