

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

A BILL

To promote the development of meaningful treatments for patients.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Modernizing Our Drug
5 & Diagnostics Evaluation and Regulatory Network Cures
6 Act of 2011” or the “MODDERN Cures Act of 2011”.

7 **SEC. 2. TABLE OF CONTENTS.**

8 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Findings.

Sec. 4. Definitions.

TITLE I—ADVANCING DIAGNOSTICS FOR PATIENTS

Sec. 101. Developing a common lexicon to facilitate progress on diagnostics.

Sec. 102. Creating incentives for innovative diagnostics.

Sec. 103. Promoting the development of innovative diagnostics.

TITLE II—CAPTURING LOST OPPORTUNITIES FOR PATIENTS

Sec. 201. Designation of dormant therapies.

Sec. 202. Promoting the development of dormant therapies.

1 **SEC. 3. FINDINGS.**

2 The Congress makes the following findings:

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

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

12 (3) Despite \$80,000,000,000 spent annually on
13 research and development, many diseases and condi-
14 tions lack effective treatments.

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

1 (5) Advanced and innovative diagnostic tests
2 have the potential to dramatically increase the effi-
3 cacy and safety of drugs by better predicting how
4 patients will respond to a given therapy.

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

9 (7) In addition, there is reason to believe that
10 potential treatments with tremendous value to pa-
11 tients are never developed or are discontinued during
12 research and development due to insufficiencies in
13 the intellectual property system.

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

18 **SEC. 4. DEFINITIONS.**

19 In this Act:

20 (1) The term “biological product” has the
21 meaning given to that term in section 351 of the
22 Public Health Service Act (42 U.S.C. 262).

23 (2) The term “drug” has the meaning given to
24 that term in section 201 of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 321).

1 (3) The term “Secretary” means the Secretary
2 of Health and Human Services.

3 **TITLE I—ADVANCING**
4 **DIAGNOSTICS FOR PATIENTS**

5 **SEC. 101. DEVELOPING A COMMON LEXICON TO FACILI-**
6 **TATE PROGRESS ON DIAGNOSTICS.**

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

12 (b) **DUTIES.**—

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

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

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

1 and determinations with respect to meeting its du-
2 ties described in paragraphs (1) and (2).

3 (c) CHAIRPERSON.—The Secretary, or the Sec-
4 retary’s designee, shall serve as chairperson of the Coun-
5 cil.

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

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

10 (A) The National Institutes of Health.

11 (B) The Centers for Disease Control and
12 Prevention.

13 (C) The Food and Drug Administration.

14 (D) The Agency for Healthcare Research
15 and Quality.

16 (E) The Centers for Medicare & Medicaid
17 Services.

18 (F) The Department of Defense.

19 (G) The Department of Veterans Affairs.

20 (H) The Health Resources and Services
21 Administration.

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

24 (J) The Indian Health Service.

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

3 (A) represent a broad range of perspec-
4 tives; and

5 (B) have expertise in—

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

9 (ii) bioinformatics;

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

13 (iv) law and ethics.

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

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

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

1 **SEC. 102. CREATING INCENTIVES FOR INNOVATIVE**
2 **DIAGNOSTICS.**

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

5 (1) CLARIFYING FACTORS FOR RATE-SET-
6 TING.—

7 (A) IN GENERAL.—In determining the pay-
8 ment amount under gapfilling procedures (as
9 described in section 414.508(b) of title 42,
10 Code of Federal Regulations, or any successor
11 regulation to such section) for new clinical diag-
12 nostic laboratory tests under section 1833(h)(8)
13 of the Social Security Act (42 U.S.C.
14 1395l(h)(8)), the Secretary of Health and
15 Human Services (in this section referred to as
16 the “Secretary”) shall take into account, as ap-
17 plicable and available, the following factors with
18 respect to such a new test:

19 (i) IMPACT ON PATIENT CARE.—The
20 impact of the new test on patient care, pa-
21 tient management, or patient treatment.

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

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

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

7 (v) PRIVATE INSURANCE RATES.—
8 Amounts paid to laboratories for such new
9 test under private health insurance cov-
10 erage offered in the group market and the
11 individual market.

12 (vi) ADVISORY PANEL RECOMMENDA-
13 TIONS.—The findings and recommenda-
14 tions of the independent advisory panel
15 convened under paragraph (2) with respect
16 to that new test and any comments re-
17 ceived during the open meeting of the advi-
18 sory panel.

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

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

23 (A) REQUIREMENT FOR INDEPENDENT AD-
24 VISORY PANEL.—The Secretary shall convene
25 an independent advisory panel from which the

1 Secretary shall request information and rec-
2 ommendations regarding any new test (as re-
3 ferred to under subparagraph (A) of section
4 1833(h)(8) of the Social Security Act (42
5 U.S.C. 1395l(h)(8))) for which payment is
6 made under such section, including technical,
7 clinical, and quality information.

8 (B) COMPOSITION OF INDEPENDENT ADVI-
9 SORY PANEL.—The independent advisory panel
10 shall be comprised of 19 members, including—

11 (i) 4 individuals with expertise and ex-
12 perience with advanced clinical diagnostic
13 laboratory tests, including expertise in the
14 technical characteristics of the new test;

15 (ii) 3 representatives of patients, in-
16 cluding a patient representative for rare
17 disorders;

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

20 (iv) 3 individuals with expertise in the
21 requirements to develop, validate, and per-
22 form the new test;

23 (v) 2 laboratorians;

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

4 (vii) 2 individuals with expertise on
5 the impact of new tests on quality of pa-
6 tient care, including genetic counselors.

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

12 (D) EXPERT CONSULTANTS.—The Sec-
13 retary may include to serve temporarily on the
14 panel individuals who have expertise pertaining
15 to the new test involved.

16 (E) OPEN MEETINGS.—The Secretary shall
17 receive or review the findings and recommenda-
18 tions of the independent advisory panel with re-
19 spect to the new tests described in subpara-
20 graph (A) involved during a meeting open to
21 the public and provide opportunity for public
22 comment.

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

1 the authority of the Secretary to consult with
2 appropriate Medicare administrative contrac-
3 tors.

4 (b) PROCESS FOR ASSIGNMENT OF TEMPORARY
5 CODES FOR DIAGNOSTIC TESTS.—The Secretary shall es-
6 tablish a process for application for the assignment of a
7 temporary national HCPCS code to uniquely identify a di-
8 agnostic test until a permanent national HCPCS code is
9 available for assignment to that test. Assignments of a
10 temporary national HCPCS code shall occur on a quar-
11 terly basis. The Secretary shall provide public notice
12 through the Centers for Medicare & Medicaid Services
13 website of applications made for such temporary national
14 HCPCS codes. Upon assignment of a temporary code
15 under this process, the Secretary shall treat such test as
16 a new test for purposes of section 1833(h)(8) of the Social
17 Security Act.

18 (c) DEVELOPMENT OF FURTHER IMPROVEMENTS IN
19 RATE-SETTING PROCESSES.—The Secretary shall analyze
20 the process used for the gapfilling procedure used in deter-
21 mining payment amounts for new clinical diagnostic lab-
22 oratory tests under section 1833(h)(8) of the Social Secu-
23 rity Act. Taking into account the changes made by this
24 section, the Secretary shall identify further changes to im-
25 prove the accuracy and appropriateness of resulting rates

1 and the openness, transparency, and predictability of the
2 process. The Secretary shall examine what and how many
3 entities should perform gapfilling, under contract or other-
4 wise, and how to ensure that the process is informed by
5 appropriate expertise and proceeds in a transparent and
6 accountable manner. The Secretary shall implement im-
7 provements in the process, insofar as these are possible
8 under the law through regulations, after public notice and
9 opportunity for comment. For changes the Secretary de-
10 termines would require a change in law, the Secretary
11 shall transmit recommendations to the Speaker of the
12 House and the President of the Senate not later than July
13 1, 2013.

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

15 (1) NEW CLINICAL DIAGNOSTIC LABORATORY
16 TESTS.—The term “new clinical diagnostic labora-
17 tory test” means a clinical diagnostic laboratory
18 test—

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

21 (B) for which an application for a tem-
22 porary national HCPCS code is made under
23 subsection (b) on or after January 1, 2013.

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

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

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

7 **SEC. 103. PROMOTING THE DEVELOPMENT OF INNOVATIVE**
8 **DIAGNOSTICS.**

9 (a) DETERMINATION.—

10 (1) REQUEST.—The manufacturer or sponsor
11 of a drug or biological product may request the Sec-
12 retary to determine that—

13 (A) a diagnostic test has been developed
14 by, or with the participation of, the manufac-
15 turer or sponsor of the drug or biological prod-
16 uct; and

17 (B) use of the diagnostic test, as dem-
18 onstrated through valid scientific information
19 such as peer-reviewed literature—

20 (i) provides for or improves the identi-
21 fication of a patient population for which
22 the drug or biological product will or will
23 not be used in accordance with its ap-
24 proved indications; or

1 (ii) provides for or improves the deter-
2 mination of the most appropriate treat-
3 ment option for a patient population with
4 the drug or biological product in accord-
5 ance with its approved indications.

6 (2) RESPONSE BY SECRETARY.—Not later than
7 30 days after the submission of a request under
8 paragraph (1), the Secretary, shall—

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

13 (B) provide an explanation to the manufac-
14 turer or sponsor submitting the request of why
15 the determination is not warranted.

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

19 (1) with respect to a diagnostic test developed
20 (as described in subsection (a)(1)(A)) contempora-
21 neously with the development of the drug or biologi-
22 cal product involved, 12 months; and

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

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

5 (1) the four- and five-year periods described in
6 subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section
7 505 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 355), the three-year periods described in
9 clauses (iii) and (iv) of subsection (c)(3)(E) and
10 clauses (iii) and (iv) of subsection (j)(5)(F) of such
11 section 505, or the seven-year period described in
12 section 527 of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 360cc), as applicable, shall be
14 extended by the applicable extension period;

15 (2) if the drug is the subject of—

16 (A) a listed patent for which a certification
17 has been submitted under subsection
18 (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of such section
19 505; or

20 (B) a listed patent for which a certification
21 has been submitted under subsection
22 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of such sec-
23 tion 505,

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

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

4 (3) if the drug is the subject of a listed patent
5 for which a certification has been submitted under
6 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of such
7 section 505, and in the patent infringement litiga-
8 tion resulting from the certification the court deter-
9 mines that the patent is valid and would be in-
10 fringed, the period during which an application may
11 not be approved under subsection (c)(3) or (j)(5)(B)
12 of such section 505 shall be extended by the applica-
13 ble extension period after the date the patent expires
14 (including any patent extension).

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

1 (e) RELATION TO PEDIATRIC EXCLUSIVITY.—Any
2 extension under subsection (c) or (d) of a period shall be
3 in addition to any extension of the period under section
4 505A of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 355a) with respect to the drug or biological prod-
6 uct.

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

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

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

14 **TITLE II—CAPTURING LOST** 15 **OPPORTUNITIES FOR PATIENTS**

16 **SEC. 201. DESIGNATION OF DORMANT THERAPIES.**

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

19 (1) the sponsor of the drug or biological prod-
20 uct submits a request in accordance with subsection

21 (b); and

22 (2) the Secretary determines that—

23 (A) the indication for which the drug or bi-
24 ological product is being investigated or is in-

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

3 (B) the sponsor intends to file an applica-
4 tion pursuant to section 505(b) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(b)) or section 351(a) of the Public Health
7 Service Act (42 U.S.C. 262(a)) for approval or
8 licensing of the drug or biological product for
9 such indication.

10 (b) REQUEST FOR DESIGNATION.—

11 (1) SUBMISSION.—The sponsor of a drug or bi-
12 ological product may submit a request to the Sec-
13 retary to designate the drug or biological product as
14 a dormant therapy.

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

18 (A) A listing of all patents and applica-
19 tions for patents—

20 (i) under which the sponsor has
21 rights; and

22 (ii) which may be reasonably con-
23 strued to provide protection for the drug or
24 biological product.

1 (B) A waiver of enforcement rights in ac-
2 cordance with paragraph (3).

3 (C) A certification by the sponsor that the
4 new drug or new biological product has prospec-
5 tively insufficient patent protection.

6 (3) WAIVER.—

7 (A) REQUIREMENT.—A request under
8 paragraph (1) shall contain a waiver of the
9 right to enforce any patent or patent applica-
10 tion, which issues as a patent described in para-
11 graph (2)(A) with respect to any product de-
12 scribed in subparagraph (B).

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

15 (i) it is approved or licensed pursuant
16 to an application that is filed under section
17 505(b)(2) or 505(j) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C.
19 355(b)(2), (j)) or section 351(k) of the
20 Public Health Service Act (42 U.S.C.
21 262(k)); and

22 (ii) the filing occurs after the expira-
23 tion of the protection period (as defined in
24 section 202(a)(1) of this Act) applicable to

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

3 (C) EFFECTIVE ONLY UPON DESIGNA-
4 TION.—A waiver under this paragraph shall be
5 effective only upon the designation under this
6 section of the drug or biological product to
7 which it relates as a dormant therapy.

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

14 (i) the sponsor may not make a re-
15 quest under this subsection with respect to
16 the drug or biological product; and

17 (ii) if the sponsor has made such a re-
18 quest, the sponsor shall promptly withdraw
19 the request.

20 (4) TIMING.—

21 (A) REQUEST.—Any request for designa-
22 tion of a drug or biological product as a dor-
23 mant therapy under subsection (a) shall be
24 made before the submission of an application
25 under section 505 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 355) or section
2 351 of the Public Health Service Act (42
3 U.S.C. 262) for the first approval or licensure
4 of commercial marketing or use of a drug or bi-
5 ological product that shares at least one active
6 moiety with an active moiety in the drug or bio-
7 logical product for which designation is being
8 requested.

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

15 (5) EFFECTS OF WITHDRAWAL OF REQUEST.—
16 If the sponsor of a drug or biological product with-
17 draws a request under paragraph (1) with respect to
18 the drug or biological product—

19 (A) any designation of the drug or biologi-
20 cal product as a dormant therapy under sub-
21 section (a) is cancelled; and

22 (B) any waiver submitted under this sub-
23 section with respect to the drug or biological
24 product is cancelled.

25 (c) CRITERIA FOR DESIGNATION.—

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

10 (2) PUBLIC INPUT.—The Secretary shall con-
11 sult with relevant stakeholders and provide an op-
12 portunity for public notice and comment in—

13 (A) establishing the methodology and cri-
14 teria under paragraph (1); and

15 (B) establishing criteria for determining
16 whether the indication for which the drug or bi-
17 ological product is being investigated or is in-
18 tended to be investigated is to address one or
19 more unmet medical needs (as described in sub-
20 section (a)(2)(A)).

21 (d) DEFINITIONS.—In this section:

22 (1) The term “prospectively insufficient patent
23 protection” means, with respect to a drug or biologi-
24 cal product for which a request for designation is
25 submitted under subsection (b) (in this paragraph

1 referred to as the “dormant therapy”), that the pro-
2 tection afforded under patents and patent applica-
3 tions, when issued as a patent, relating to the dor-
4 mant therapy, in the aggregate—

5 (A) are not reasonably anticipated by the
6 sponsor of the dormant therapy to provide an
7 adequate scope of protection to prevent the ap-
8 proval of products that would rely upon or ref-
9 erence the dormant therapy, in an application
10 filed under section 505(b)(2) or 505(j) of the
11 Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355(b)(2), (j)) or section 351(k) of the
13 Public Health Service Act (42 U.S.C. 262(k)),
14 or

15 (B) are not reasonably anticipated by the
16 sponsor of the dormant therapy to provide pat-
17 ent protection under such patents and applica-
18 tions, when issued as a patent,

19 for a period of 14 years from the date of first ap-
20 proval or licensing of the dormant therapy for mar-
21 keting pursuant to an application under section
22 505(b) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 355(b)) or section 351(a) of the Public
24 Health Service Act (42 U.S.C. 262(a)).

1 (2) The term “address one or more unmet med-
2 ical needs” refers to—

3 (A) addressing a need for drugs or biologi-
4 cal products for the treatment of one or more
5 life-threatening or other serious diseases or con-
6 ditions for which no therapy exists; or

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

10 (i) one or more improved effects on
11 serious outcomes of the disease or condi-
12 tion that are affected by alternative thera-
13 pies, such as superiority of the drug or bio-
14 logical product used alone or in combina-
15 tion with other therapies in an active con-
16 trolled trial assessing an endpoint reflect-
17 ing serious morbidity;

18 (ii) one or more effects on serious out-
19 comes of the disease or condition not
20 known to be affected by alternative thera-
21 pies, such as progressive disability in mul-
22 tiple sclerosis when alternative therapies
23 have shown an effect on exacerbations but
24 have not shown an effect on progressive
25 disability;

1 (iii) an ability—

2 (I) to provide one or more bene-
3 fits in patients who are unable to tol-
4 erate or are unresponsive to alter-
5 native therapies, such as an
6 antipsychotic agent that is effective in
7 people failing standard therapy; or

8 (II) to be used effectively in com-
9 bination with other critical agents
10 that cannot be combined with alter-
11 native therapies;

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

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

17 (II) avoiding less serious toxicity
18 that is common in alternative thera-
19 pies and causes discontinuation of
20 treatment of a life-threatening or seri-
21 ous disease; or

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

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

3 (e) PUBLIC NOTICE OF DESIGNATION.—The Sec-
4 retary request for and notice of the designation of a dor-
5 mant therapy under paragraph (4) shall be made available
6 to the public.

7 **SEC. 202. PROMOTING THE DEVELOPMENT OF DORMANT**
8 **THERAPIES.**

9 (a) PROTECTIONS FOR DORMANT THERAPY.—

10 (1) PROTECTION PERIOD.—The term “protec-
11 tion period” means, with respect to a drug or bio-
12 logical product designated as a dormant therapy
13 under section 201(a) (in this section referred to as
14 the “dormant therapy”), the 15-year period begin-
15 ning on the date on which the Secretary approves an
16 application under section 505(b) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 355(b))
18 or section 351(a) of the Public Health Service Act
19 (42 U.S.C. 262(a)) for the drug or biological prod-
20 uct.

21 (2) APPLICATIONS FILED DURING THE PROTEC-
22 TION PERIOD.—During the protection period for a
23 dormant therapy, notwithstanding any other provi-
24 sion of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 301 et seq.) or the Public Health Service
2 Act (42 U.S.C. 201 et seq.)—

3 (A) absent a right of reference from the
4 holder of such approved application for the dor-
5 mant therapy, the Secretary shall not approve
6 an application filed pursuant to section
7 505(b)(2) or section 505(j) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(b)(2), (j)) or section 351(k) of the Public
10 Health Service Act (42 U.S.C. 262(k)) ref-
11 erencing or otherwise relying on the approval or
12 licensure of the dormant therapy;

13 (B) the Secretary shall not approve—

14 (i) an application filed pursuant to
15 such section 505(b)(2) or 505(j) that ref-
16 erences or otherwise relies on the approval
17 or licensure of a drug or biological product
18 that is not the dormant therapy but con-
19 tains the same active moiety as the dor-
20 mant therapy; or

21 (ii) an application filed pursuant to
22 such section 351(k) that references or oth-
23 erwise relies on the approval or licensure of
24 a drug or biological product that is not the
25 dormant therapy but contains an active

1 moiety highly similar to that of the dor-
2 mant therapy; and

3 (C) the Secretary shall not approve an ap-
4 plication filed pursuant to section 505(b)(1) of
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 355(b)(1)) for a drug that contains the
7 same active moiety as the dormant therapy, or
8 an application filed pursuant to section 351(a)
9 of the Public Health Service Act (42 U.S.C.
10 262(a)) for a biological product that contains
11 an active moiety highly similar to that of the
12 dormant therapy, unless the information pro-
13 vided to support approval of such application is
14 comparable in scope and extent (including with
15 respect to design and extent of preclinical and
16 clinical testing) to the information provided to
17 support approval of the application (described
18 in paragraph (1)) for the dormant therapy.

19 (3) REGULATIONS.—Not later than 18 months
20 after the date of the enactment of this Act, the Sec-
21 retary, in consultation with relevant Federal agen-
22 cies, shall promulgate such regulations as are re-
23 quired to implement the incentives described in
24 paragraph (2).

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

3 (A) IN GENERAL.—Notwithstanding any
4 provision of title 35, United States Code, a
5 sponsor of a drug or biologic product des-
6 ignated as a dormant therapy under section
7 201(a), upon the approval or licensure thereof
8 under the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 301 et seq.), and in lieu of fil-
10 ing a patent term extension application under
11 section 156(d) of such title 35 (other than ap-
12 plications for interim extensions filed under
13 paragraph (5) of such section 156(d)), shall be
14 entitled to patent term extension in accordance
15 with this paragraph.

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

18 (i) SUBMISSION.—The sponsor of the
19 dormant therapy, within a period to be set
20 by the Director of the United States Pat-
21 ent and Trademark Office (in this para-
22 graph referred to as the “Director”), shall
23 submit to the Director—

24 (I) the listing of patents and ap-
25 plications for patents required by sec-

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

3 (II) a listing of any additional
4 patents and applications for patents
5 that, at the time of the submission,
6 meet the description in section
7 201(b)(2)(A).

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

13 (C) EXTENSION OF PATENTS.—

14 (i) IN GENERAL.—For each patent
15 identified pursuant to subparagraph (B)(i),
16 and for each patent issuing based upon an
17 application for patent so identified, the Di-
18 rector shall extend the patent to expire at
19 the end of the protection period under
20 paragraph (1) for the dormant therapy, if
21 the patent would otherwise expire prior to
22 the end of the protection period.

23 (ii) APPLICATION OF CERTAIN PROVI-
24 SIONS.—During the period of an extension
25 under clause (i)—

1 (I) the rights under the patent
2 shall be limited in the manner pro-
3 vided under section 156(b) of title 35,
4 United States Code; and

5 (II) the terms “product” and
6 “approved product” in such section
7 156(b) shall be deemed to include
8 forms of the active moiety of the dor-
9 mant therapy and highly similar ac-
10 tive moieties that might be approved
11 by the Secretary based upon an appli-
12 cation filed under section 505(b)(2) or
13 505(j) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C.
15 355(b)(2), (j)) or under section
16 351(k) of the Public Health Service
17 Act (42 U.S.C. 262(k)) that ref-
18 erences or otherwise relies upon the
19 dormant therapy.

20 (D) NOTICE OF EXTENSION.—For each
21 patent that is extended under this paragraph,
22 the Director shall publish a notice of such ex-
23 tension.

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

1 each patent issuing based upon an application
2 for patent so identified, that expires subsequent
3 to the end of the protection period for the dor-
4 mant therapy under paragraph (1), the Direc-
5 tor shall publish a notice that the patent is sub-
6 ject to the waiver of the right to enforce as de-
7 scribed section 201(b)(3).

8 (b) ORPHAN PRODUCTS.—If a drug or biological
9 product has been designated as a dormant therapy under
10 section 201(a) of this Act, the protections otherwise appli-
11 cable with respect to such drug or biological product under
12 section 527 of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 360cc) shall not apply.

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

18 (1) to conduct a study on intellectual property
19 laws and their impact on therapy and diagnostic de-
20 velopment in order to formulate recommendations on
21 how to facilitate the clinical evaluation and develop-
22 ment of therapies currently available on the market
23 for new potential indications; and

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

- 1 Secretary and the Congress containing the results of
- 2 such study.

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