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112TH CONGRESS
2D SESSION

H. R. 6502

To amend title V of the Federal Food, Drug, and Cosmetic Act to provide for extensions of marketing exclusivity periods for drugs in certain combinations of such drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2012

Mr. BILBRAY (for himself, Mrs. MALONEY, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title V of the Federal Food, Drug, and Cosmetic Act to provide for extensions of marketing exclusivity periods for drugs in certain combinations of such drugs, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Life-Threatening Diseases Compassion through Combination Therapy Act of 2012''.

SEC. 2. PROMOTING THE DEVELOPMENT OF COMBINATIONS OF INVESTIGATIONAL NEW DRUGS FOR SERIOUS DISEASES.

(a) IN GENERAL.—Subchapter A of chapter 5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting, after section 505, the following new section:

"SEC. 505E. MARKETING EXCLUSIVITY AND PRIORITY REVIEW FOR SIGNIFICANT DRUG COMBINATIONS.

''(a) SIGNIFICANT DRUG COMBINATION DESIGNATION.—

''(1) IN GENERAL.—The Secretary may designate a combination of drugs as a significant drug combination if such combination of drugs—

''(A) includes 2 or more drugs (which may include one or more biologics subject to licensure under section 351 of the Public Health Service Act) that—

''(i) when used in combination, offer the potential to significantly advance treatment for a serious or life-threatening disease; and

''(ii) in combination, meet the criteria for codevelopment of drug combinations, as specified in the Food and Drug Adminis-

tration's guidance document entitled 'Guidance for Industry: Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination' or a successor document; and

''(B) includes at least 2 drugs that, as of the date on which such designation is made, are not approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act.

''(2) PURPOSE.—The purpose of the designation under paragraph (1) is to encourage the codevelopment of such drug combinations.

''(3) TASK FORCE RECOMMENDATIONS.—In making designations under paragraph (1), the Secretary shall take into account the recommendations submitted by the codevelopment task force under section 3(c)(1) of the Life-Threatening Diseases Compassion through Combination Therapy Act of 2012.

''(4) REQUESTS.—

''(A) IN GENERAL.—The manufacturer or sponsor of a drug may request that the Secretary determine whether a combination of 2 or more drugs is a significant drug combination.

"(B) RESPONSE TO REQUEST.—Not later than 30 days after the submission of the request under subparagraph (A), the Secretary shall review the request and—

"(i) if the combination of drugs subject to the request has previously been designated under paragraph (1) and the combination of drugs continues to meet the requirements for such a designation, the Secretary shall provide notice to the person who submitted the request that such combination of drugs is a significant drug combination;

"(ii) if the combination of drugs subject to the request has not previously been designated under paragraph (1), but the combination of drugs meets the requirements for such a designation, the Secretary shall designate such drug as a significant drug combination under paragraph (1) and provide notice to the person who submitted the request that such combination of drugs is a significant drug combination; or

"(iii) if the combination of drugs subject to the request does not meet the requirements for designation as a significant drug combination under paragraph (1), the Secretary shall provide notice to the person who submitted the request that such combination of drugs is not a significant drug combination.

"(C) DEADLINE.—A request for designation under subparagraph (A) shall be made concurrently with, or after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act, but not later than the first date on which phase I trials for any of the drugs involved in the drug combination are completed.

"(b) LIST OF SIGNIFICANT DRUG COMBINATIONS.—

"(1) INITIAL LIST.—Not later than 180 days after the date of enactment of the Life-Threatening Diseases Compassion through Combination Therapy Act of 2012, the Secretary shall develop, and shall publish on the public Web site of the Food and Drug Administration, an initial list of combinations of 2

or more drugs that the Secretary has designated as significant drug combinations under subsection (a).

''(2) UPDATE.—The Secretary shall revise and update the list under paragraph (1) on an annual basis—

''(A) to include additional drug combinations that the Secretary has designated as significant drug combinations under subsection (a); and

''(B) to exclude drug combinations which were previously designated as significant drug combinations under subsection (a), but which no longer meet the requirements of subsection (a)(1)(B) (relating to the minimum number of unapproved drugs in a significant drug combination).

''(c) EXTENSION OF MARKET EXCLUSIVITY.—

''(1) IN GENERAL.—If, prior to approval of a drug pursuant to an application submitted under section 505(b), the Secretary designated a significant drug combination under subsection (a) that includes such drug, then the four- and five-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, 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 section 505, or the seven-year period described in section 527, as applicable, shall be extended by 6 months for such drug.

''(2) LIMITATIONS.—Paragraph (1) does not apply to the approval of—

''(A) a supplement to an application under section 505(b) for a drug in a designated significant drug combination, if an extension described in paragraph (1) is in effect or has expired for the original application (or a prior supplement to such application); or

''(B) a subsequent application filed by the same sponsor or manufacturer of a drug in a designated significant drug combination described in subparagraph (A) (or a licensor, predecessor in interest, or other related entity) for—

''(i) a change (not including a modification to the structure of the drug) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(ii) a modification to the structure of the drug that does not result in a change in safety or effectiveness.

"(d) PRIORITY REVIEW.—If a drug is a drug in a significant drug combination designated under subsection (a), the Secretary shall review and take action on any application submitted for such drug under section 505(b) or section 351(k) not later than 6 months after receipt by the Secretary of such application.

"(e) SIGNIFICANTLY ADVANCE TREATMENT DEFINITION.—For purposes of this section, the phrase 'significantly advance treatment' means, with respect to a drug combination—

"(1) the drug combination provides for the treatment of one or more life-threatening or other serious diseases or conditions for which no therapy exists; or

"(2) if one or more therapies are available for the treatment of such a disease or condition, the drug combination is demonstrated, through clinical investigations to cause one or more improved effects on serious outcomes of the disease or condition that are affected by alternative therapies, such as—

"(A) superiority of the drug combination; or

''(B) the drug combination minimizes the development of drug resistance,

in an active controlled trial assessing an endpoint reflecting serious morbidity.''.

(b) FAST TRACK PRODUCT.—Paragraph (1) of section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)) is amended by inserting after ''if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition'' the following: ''or if such drug is a drug in a significant drug combination designated under section 505E(a)''.

SEC. 3. CODEVELOPMENT TASK FORCE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall establish an interagency task force for the purpose of encouraging the codevelopment of drugs in significant drug combinations.

(b) MEMBERSHIP.—The membership of the task force under subsection (a) shall include experts on—

(1) basic and translational research; and

(2) preclinical and clinical drug development related to serious and life-threatening diseases, including cancer.

(c) DUTIES.—The task force under subsection (a) shall have the following duties:

(1) RECOMMENDED SIGNIFICANT DRUG COMBINATION LIST.—

(A) INITIAL RECOMMENDATIONS.—The task force shall develop a list of types of drug combinations that the task force recommends that the Secretary designate as significant drug combinations under section 505E of the Federal Food, Drug, and Cosmetic Act.

(B) PUBLIC COMMENT.—The task force shall make the list developed under subparagraph (A) publicly available, and shall provide an opportunity for members of the public to comment on the content of such list.

(C) REVISED RECOMMENDATIONS.—Not later than 60 days after making the list publicly available under subparagraph (B), the task force shall revise the list under subparagraph (A) in response to the comments received under subparagraph (B) and shall submit such revised list to the Secretary and the Congress.

(D) UPDATES.—On an annual basis, the task force shall submit to the Secretary and the Congress updates to the list under subpara-

graph (C), after making such updates publicly available and providing an opportunity for public comment.

(2) POLICY REPORT.—

(A) IN GENERAL.—Not later than one year after the date of enactment of this Act, and annually thereafter, the task force shall submit to the Secretary and the Congress a report that—

(i) identifies—

(I) issues that present challenges to the codevelopment of drugs in significant drug combinations; and

(II) opportunities to further support the codevelopment of drugs in significant drug combinations; and

(ii) contains recommendations to the Secretary and the Congress on policy changes that could provide additional support for the codevelopment of drugs in significant drug combinations.

(B) PUBLIC COMMENT.—Before submitting the report under subparagraph (A), the task force shall make a draft of the report publicly available, and shall provide an opportunity

for members of the public to comment on such report.

(d) APPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act shall not apply to the duration of the task force under subsection (a).

(e) SIGNIFICANT DRUG COMBINATION DEFINED.—For purposes of this section, the term ''significant drug combination'' means a combination of 2 or more drugs (which may include one or more biologics subject to licensure under section 351 of the Public Health Service Act) that—

(1) when used in combination, offer the potential to significantly advance treatment for a serious or life-threatening disease;

(2) in combination, meet the criteria for codevelopment of drug combinations, as specified in the Food and Drug Administration's guidance document entitled ''Guidance for Industry: Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination'' or a successor document; and

(3) includes at least 2 drugs that are not approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 4. STUDY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study on the impact of the extensions of exclusivity under section 505E(c) of the Federal Food, Drug, and Cosmetic Act, as added by section 2, on the development of significant drug combinations, as defined in section 3(e).

(b) INTERIM FINDINGS.—The Secretary shall—

(1) make the interim findings from the study under subsection (a) available to the task force under section 4 and the public; and

(2) shall provide an opportunity for the task force and members of the public to make comments on such findings.

(c) FINAL FINDINGS.—Not later than 5 years after the date of the enactment of this Act, after providing the opportunity for comment described in subsection (b), the Secretary shall submit the findings of the study under subsection (a) to the Congress.

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