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116TH CONGRESS
1ST SESSION

H. R. 5402

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study on high-risk, high-reward drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2019

Mr. GOTTHEIMER (for himself and Mr. UPTON) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, 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 direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study on high-risk, high-reward 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 ''Protecting America's Life Saving Medicines Act of 2019''.

SEC. 2. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall conduct a study to determine which of the drugs that are being tested (as of such date of enactment) under subsection (i) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) are unlikely to be approved under subsection (c) of such section, but would, if approved, address an unmet medical need for the treatment of a serious or life-threatening disease or condition or a rare disease or condition.

(b) SUBMISSION TO TREASURY.—Not later than 180 days after the completion of the study under subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall transmit to the Secretary of the Treasury (or the Secretary's delegate) a list of the drugs that the Secretary of Health and Human Services determines meets the criteria specified in subsection (a).

SEC. 3. CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN HIGH-RISK, HIGH-REWARD DRUGS.

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

"SEC. 45T. CLINICAL TESTING EXPENSES FOR CERTAIN HIGH-RISK, HIGH-REWARD DRUGS.

''(a) IN GENERAL.—For purposes of section 38, the credit determined under this section for the taxable year is an amount equal to 25 percent of the qualified clinical testing expenses for the taxable year.

''(b) QUALIFIED CLINICAL TESTING EXPENSES.—For purposes of this section—

''(1) QUALIFIED CLINICAL TESTING EXPENSES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified clinical testing expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

''(B) MODIFICATIONS.—For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

''(i) by substituting 'clinical testing' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

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

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

"(2) CLINICAL TESTING.—The term 'clinical testing' means any human clinical testing—

"(A) which is carried out with respect to a drug on a list submitted to the Secretary under subsection (b) of the Protecting America's Life Saving Medicines Act of 2019,

"(B) which occurs—

"(i) after the date such list is so submitted, and

"(ii) before the date on which an application with respect to such drug is approved under section 505(b) of such Act or, if the drug is a biological product, before the date on which a license for such drug is issued under section 351 of the Public Health Service Act.

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

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

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

''(d) SPECIAL RULES.—

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

''(2) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as

the Secretary may by regulations prescribe) to have this section apply for such taxable year.''.

(b) CREDIT MADE PART OF GENERAL BUSINESS CREDIT.—Subsection (b) of section 38 of the Internal Revenue Code of 1986 is amended by striking ''plus'' at the end of paragraph (31), by striking the period at the end of paragraph (32) and inserting '', plus'', and by adding at the end the following new paragraph:

''(33) the credit determined under section 45T.''.

(c) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 45T. Clinical testing expenses for certain high-risk, high-reward drugs.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

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