

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

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.

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 “Protecting America’s
5 Life Saving Medicines Act of 2019”.

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

2 (a) IN GENERAL.—Not later than 180 days after the
3 date of the enactment of this Act, the Secretary of Health
4 and Human Services, acting through the Commissioner of
5 Food and Drugs, shall conduct a study to determine which
6 of the drugs that are being tested (as of such date of en-
7 actment) under subsection (i) of section 505 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) are
9 unlikely to be approved under subsection (c) of such sec-
10 tion, but would, if approved, address an unmet medical
11 need for the treatment of a serious or life-threatening dis-
12 ease or condition or a rare disease or condition.

13 (b) SUBMISSION TO TREASURY.—Not later than 180
14 days after the completion of the study under subsection
15 (a), the Secretary of Health and Human Services, acting
16 through the Commissioner of Food and Drugs, shall trans-
17 mit to the Secretary of the Treasury (or the Secretary's
18 delegate) a list of the drugs that the Secretary of Health
19 and Human Services determines meets the criteria speci-
20 fied in subsection (a).

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

23 (a) IN GENERAL.—Subpart D of part IV of sub-
24 chapter A of chapter 1 of the Internal Revenue Code of
25 1986 is amended by adding at the end the following new
26 section:

1 **“SEC. 45T. CLINICAL TESTING EXPENSES FOR CERTAIN**
2 **HIGH-RISK, HIGH-REWARD DRUGS.**

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

7 “(b) QUALIFIED CLINICAL TESTING EXPENSES.—
8 For purposes of this section—

9 “(1) QUALIFIED CLINICAL TESTING EX-
10 PENSES.—

11 “(A) IN GENERAL.—Except as otherwise
12 provided in this paragraph, the term ‘qualified
13 clinical testing expenses’ means the amounts
14 which are paid or incurred by the taxpayer dur-
15 ing the taxable year which would be described
16 in subsection (b) of section 41 if such sub-
17 section were applied with the modifications set
18 forth in subparagraph (B).

19 “(B) MODIFICATIONS.—For purposes of
20 subparagraph (A), subsection (b) of section 41
21 shall be applied—

22 “(i) by substituting ‘clinical testing’
23 for ‘qualified research’ each place it ap-
24 pears in paragraphs (2) and (3) of such
25 subsection, and

1 “(ii) by substituting ‘100 percent’ for
2 ‘65 percent’ in paragraph (3)(A) of such
3 subsection.

4 “(C) EXCLUSION FOR AMOUNTS FUNDED
5 BY GRANTS, ETC.—The term ‘qualified clinical
6 testing expenses’ shall not include any amount
7 to the extent such amount is funded by any
8 grant, contract, or otherwise by another person
9 (or any governmental entity).

10 “(2) CLINICAL TESTING.—The term ‘clinical
11 testing’ means any human clinical testing—

12 “(A) which is carried out with respect to a
13 drug on a list submitted to the Secretary under
14 subsection (b) of the Protecting America’s Life
15 Saving Medicines Act of 2019,

16 “(B) which occurs—

17 “(i) after the date such list is so sub-
18 mitted, and

19 “(ii) before the date on which an ap-
20 plication with respect to such drug is ap-
21 proved under section 505(b) of such Act
22 or, if the drug is a biological product, be-
23 fore the date on which a license for such
24 drug is issued under section 351 of the
25 Public Health Service Act.

1 “(c) COORDINATION WITH CREDIT FOR INCREASING
2 RESEARCH EXPENDITURES.—

3 “(1) IN GENERAL.—Except as provided in para-
4 graph (2), any qualified clinical testing expenses for
5 a taxable year to which an election under this sec-
6 tion applies shall not be taken into account for pur-
7 poses of determining the credit allowable under sec-
8 tion 41 for such taxable year.

9 “(2) EXPENSES INCLUDED IN DETERMINING
10 BASE PERIOD RESEARCH EXPENSES.—Any qualified
11 clinical testing expenses for any taxable year which
12 are qualified research expenses (within the meaning
13 of section 41(b)) shall be taken into account in de-
14 termining base period research expenses for pur-
15 poses of applying section 41 to subsequent taxable
16 years.

17 “(d) SPECIAL RULES.—

18 “(1) CERTAIN RULES MADE APPLICABLE.—
19 Rules similar to the rules of paragraphs (1) and (2)
20 of section 41(f) shall apply for purposes of this sec-
21 tion.

22 “(2) ELECTION.—This section shall apply to
23 any taxpayer for any taxable year only if such tax-
24 payer elects (at such time and in such manner as

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

3 (b) CREDIT MADE PART OF GENERAL BUSINESS
 4 CREDIT.—Subsection (b) of section 38 of the Internal
 5 Revenue Code of 1986 is amended by striking “plus” at
 6 the end of paragraph (31), by striking the period at the
 7 end of paragraph (32) and inserting “, plus”, and by add-
 8 ing at the end the following new paragraph:

9 “(33) the credit determined under section
 10 45T.”.

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

“Sec. 45T. Clinical testing expenses for certain high-risk, high-reward drugs.”.

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

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