

AMENDMENT
TO RULES COMMITTEE PRINT 116–41
OFFERED BY MR. GOTTHEIMER OF NEW JERSEY

At the end of subtitle B of title VII, insert the following:

1 SEC. ____. 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

1 and Human Services determines meets the criteria speci-
2 fied in subsection (a).

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

5 (a) IN GENERAL.—Subpart D of part IV of sub-
6 chapter A of chapter 1 of the Internal Revenue Code of
7 1986 is amended by adding at the end the following new
8 section:

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

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

15 “(b) QUALIFIED CLINICAL TESTING EXPENSES.—
16 For purposes of this section—

17 “(1) QUALIFIED CLINICAL TESTING EX-
18 PENSES.—

19 “(A) IN GENERAL.—Except as otherwise
20 provided in this paragraph, the term ‘qualified
21 clinical testing expenses’ means the amounts
22 which are paid or incurred by the taxpayer dur-
23 ing the taxable year which would be described
24 in subsection (b) of section 41 if such sub-

1 section were applied with the modifications set
2 forth in subparagraph (B).

3 “(B) MODIFICATIONS.—For purposes of
4 subparagraph (A), subsection (b) of section 41
5 shall be applied—

6 “(i) by substituting ‘clinical testing’
7 for ‘qualified research’ each place it ap-
8 pears in paragraphs (2) and (3) of such
9 subsection, and

10 “(ii) by substituting ‘100 percent’ for
11 ‘65 percent’ in paragraph (3)(A) of such
12 subsection.

13 “(C) EXCLUSION FOR AMOUNTS FUNDED
14 BY GRANTS, ETC.—The term ‘qualified clinical
15 testing expenses’ shall not include any amount
16 to the extent such amount is funded by any
17 grant, contract, or otherwise by another person
18 (or any governmental entity).

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

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

25 “(B) which occurs—

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

3 “(ii) before the date on which an ap-
4 plication with respect to such drug is ap-
5 proved under section 505(b) of such Act
6 or, if the drug is a biological product, be-
7 fore the date on which a license for such
8 drug is issued under section 351 of the
9 Public Health Service Act.

10 “(c) COORDINATION WITH CREDIT FOR INCREASING
11 RESEARCH EXPENDITURES.—

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

18 “(2) EXPENSES INCLUDED IN DETERMINING
19 BASE PERIOD RESEARCH EXPENSES.—Any qualified
20 clinical testing expenses for any taxable year which
21 are qualified research expenses (within the meaning
22 of section 41(b)) shall be taken into account in de-
23 termining base period research expenses for pur-
24 poses of applying section 41 to subsequent taxable
25 years.

1 “(d) SPECIAL RULES.—

2 “(1) CERTAIN RULES MADE APPLICABLE.—

3 Rules similar to the rules of paragraphs (1) and (2)
4 of section 41(f) shall apply for purposes of this sec-
5 tion.

6 “(2) ELECTION.—This section shall apply to
7 any taxpayer for any taxable year only if such tax-
8 payer elects (at such time and in such manner as
9 the Secretary may by regulations prescribe) to have
10 this section apply for such taxable year.”.

11 (b) CREDIT MADE PART OF GENERAL BUSINESS
12 CREDIT.—Subsection (b) of section 38 of the Internal
13 Revenue Code of 1986 is amended by striking “plus” at
14 the end of paragraph (31), by striking the period at the
15 end of paragraph (32) and inserting “, plus”, and by add-
16 ing at the end the following new paragraph:

17 “(33) the credit determined under section
18 45T.”.

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

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

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

