

.....  
(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend title XI of the Social Security Act to establish a research and development-intensive small biotech manufacturer exception from the Medicare drug price negotiation program.

\_\_\_\_\_  
**IN THE HOUSE OF REPRESENTATIVES**

Mr. PFLUGER introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend title XI of the Social Security Act to establish a research and development-intensive small biotech manufacturer exception from the Medicare drug price negotiation program.

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 “Small Biotech Innova-  
5       tion Act”.

1 **SEC. 2. RESEARCH AND DEVELOPMENT-INTENSIVE SMALL**  
2 **BIOTECH MANUFACTURER EXCEPTION FROM**  
3 **MEDICARE DRUG PRICE NEGOTIATION PRO-**  
4 **GRAM.**

5 Section 1192(d)(2) of the Social Security Act (42  
6 U.S.C. 1320f–1(d)(2)) is amended by adding at the end  
7 the following new subparagraph:

8 “(D) RESEARCH AND DEVELOPMENT-IN-  
9 TENSIVE SMALL BIOTECH MANUFACTURER EX-  
10 CEPTION FOR 2029 AND SUBSEQUENT YEARS.—

11 “(i) IN GENERAL.—With respect to  
12 initial price applicability years (beginning  
13 with initial price applicability year 2029),  
14 subject to the succeeding provisions of this  
15 subparagraph, the term ‘negotiation eligi-  
16 ble drug’ shall not include a qualifying sin-  
17 gle source drug (as defined in subsection  
18 (e)) of a research and development-inten-  
19 sive small biotech manufacturer (as de-  
20 fined in clause (ii)).

21 “(ii) DEFINITIONS.—In this subpara-  
22 graph:

23 “(I) APPLICABLE PERCENT.—

24 The term ‘applicable percent’  
25 means—

1 “(aa) in the case of a small  
2 biotech manufacturer that has 1  
3 qualifying single source drug, 30  
4 percent;

5 “(bb) in the case of a small  
6 biotech manufacturer that has 2  
7 qualifying single source drugs, 40  
8 percent;

9 “(cc) in the case of a small  
10 biotech manufacturer that has 3  
11 qualifying single source drugs, 50  
12 percent;

13 “(dd) in the case of a small  
14 biotech manufacturer that has 4  
15 qualifying single source drugs, 60  
16 percent; and

17 “(ee) in the case of a small  
18 biotech manufacturer that has 5  
19 qualifying single source drugs, 70  
20 percent.

21 “(II) SMALL BIOTECH MANUFAC-  
22 Turer DEFINED.—The term ‘small  
23 biotech manufacturer’ means a manu-  
24 facturer that—

1 “(aa) has 5 or less quali-  
2 fying single source drugs; and

3 “(bb) is not owned by, con-  
4 trolled by, or subject to the juris-  
5 diction or direction of a govern-  
6 ment of a foreign country, or or-  
7 ganized under the laws of a for-  
8 eign country that is a covered na-  
9 tion (as defined in section  
10 4872(f) of title 10, United States  
11 Code).

12 “(III) RESEARCH AND DEVELOP-  
13 MENT-INTENSIVE SMALL BIOTECH  
14 MANUFACTURER DEFINED.—The term  
15 ‘research and development-intensive  
16 small biotech manufacturer’ means a  
17 small biotech manufacturer that in-  
18 vests at least the applicable percent of  
19 their net revenue from the average of  
20 the previous three years in research  
21 and development (determined based  
22 on generally accepted accounting prin-  
23 ciples).

24 “(iii) TREATMENT IN CASE OF ACQUI-  
25 SITION.—A drug shall not be considered to

1 be a qualifying single source drug of a re-  
2 search and development-intensive small  
3 biotech manufacturer if the manufacturer  
4 of such drug is acquired after 2029 by an-  
5 other manufacturer that does not meet the  
6 definition of a research and development-  
7 intensive small biotech manufacturer, ef-  
8 fective at the beginning of the plan year  
9 immediately following such acquisition.

10 “(iv) ANNUAL APPLICATION.—In  
11 order for a qualifying single source drug of  
12 a research and development-intensive small  
13 biotech manufacturer to be eligible for the  
14 exception under this subparagraph with re-  
15 spect to an initial price applicability year  
16 (beginning with initial price applicability  
17 year 2029), the manufacturer shall submit  
18 an application to the Secretary (at a time  
19 specified by the Secretary) containing—

20 “(I) information on the net prod-  
21 uct revenue and research and develop-  
22 ment expenditures of the manufac-  
23 turer during the relevant time period;

24 “(II) a certification that the in-  
25 formation submitted by the manufac-

1 turer under subclause (I) is accurate  
2 and complete to the best of the manu-  
3 facturer's knowledge; and

4 “(III) such other information as  
5 the Secretary may specify.

6 “(v) DISPUTE RESOLUTION.—The  
7 Secretary shall develop a process under  
8 which a manufacturer may appeal a deter-  
9 mination by the Secretary that the manu-  
10 facturer is not a research and develop-  
11 ment-intensive small biotech manufacturer.  
12 Such process shall conclude, with respect  
13 to a manufacturer, not later than the se-  
14 lected drug publication date with respect to  
15 the initial price applicability year for which  
16 the manufacturer submitted an application  
17 under clause (iv).”.