

118TH CONGRESS
2^D SESSION

H. R. 8267

To amend titles XVIII and XIX of the Social Security Act to provide that priority research drugs shall not be treated as line extensions of existing drugs for purposes of calculating manufacturer rebates under the Medicare and Medicaid programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2024

Mr. DAVIS of North Carolina (for himself and Mr. PFLUGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 amend titles XVIII and XIX of the Social Security Act to provide that priority research drugs shall not be treated as line extensions of existing drugs for purposes of calculating manufacturer rebates under the Medicare and Medicaid programs, 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 “Old Drugs, New Cures
5 Act”.

1 **SEC. 2. PRIORITY RESEARCH DRUGS.**

2 (a) IN GENERAL.—Section 1927(c)(2)(C) of the So-
3 cial Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is amend-
4 ed by inserting the following new clause before the flush
5 matter at the end:

6 “(iv) PRIORITY RESEARCH DRUG.—

7 “(I) REQUEST FOR DESIGNA-
8 TION.—Not later than 90 days fol-
9 lowing the date of enactment of this
10 clause, the Secretary shall establish
11 and make effective a process for the
12 manufacturer of a covered outpatient
13 drug to request that the Secretary
14 designate the drug as a priority re-
15 search drug.

16 “(II) DESIGNATION.—Not later
17 than 60 calendar days after the re-
18 ceipt of a request under subclause (I),
19 the Secretary shall designate a cov-
20 ered outpatient drug as a priority re-
21 search drug so long as it meets the
22 following criteria:

23 “(aa) As of the date of sub-
24 mission of such request, at least
25 10 years have elapsed since the
26 date the drug was approved

1 under section 505(c) of the Fed-
2 eral Food, Drug, and Cosmetic
3 Act or section 351(a) of the Pub-
4 lic Health Service Act.

5 “(bb) The manufacturer of
6 the drug is investigating such
7 drug under section 505(i) of the
8 Federal Food, Drug, and Cos-
9 metic Act or section 351(a)(3) of
10 the Public Health Service Act for
11 a new indication that would ad-
12 dress a significant unmet medical
13 need because there is no alter-
14 native drug approved under sec-
15 tion 505 of the Federal Food,
16 Drug, and Cosmetic Act or li-
17 censed under section 351 of the
18 Public Health Service Act for
19 such indication on the date that
20 the request under subclause (I)
21 was submitted to the Secretary.

22 “(cc) The new indication de-
23 scribed in item (bb) is for a dis-
24 ease or condition that has a high
25 prevalence among beneficiaries of

1 Federal health care programs.
2 For purposes of this clause, a
3 disease or condition has a high
4 prevalence among beneficiaries of
5 Federal health care programs if
6 at least 33 percent of claims in
7 the population targeted by the
8 new indication during the prior
9 calendar year were paid for
10 under—

11 “(AA) a State plan
12 under this title or a State
13 child health plan under title
14 XXI;

15 “(BB) part D of title
16 XVIII with respect to an in-
17 dividual who is eligible for
18 subsidies under section
19 1860D–14;

20 “(CC) the drug dis-
21 count program under section
22 340B of the Public Health
23 Service Act (42 U.S.C.
24 256b; or

1 “(DD) a health care
2 program administered by the
3 Department of Veterans Af-
4 fairs.”.

5 (b) EXCLUSION OF PRIORITY RESEARCH DRUGS
6 FROM MEDICAID DEFINITION OF LINE EXTENSION.—
7 The flush matter at the end of section 1927(c)(2)(C) of
8 the Social Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is
9 amended by inserting “a priority research drug (as des-
10 ignated under clause (iv)) or” after “does not include”.

11 (c) EXCLUSION OF PRIORITY RESEARCH DRUGS
12 FROM MEDICAID BEST PRICE SPECIAL RULE FOR SE-
13 LECTED DRUGS.—Section 1927(c)(1)(C)(ii)(V) of the So-
14 cial Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(V)) is
15 amended by inserting “unless such drug is also designated
16 as a priority research drug under paragraph (2)(C)(iv)
17 during such period” before the period.

18 (d) EXCLUSION OF PRIORITY RESEARCH DRUGS
19 FROM MEDICARE DEFINITION OF LINE EXTENSION.—
20 Section 1860D–14B(b)(5)(B)(ii) of the Social Security
21 Act (42 U.S.C. 1395w–114b(b)(5)(B)(ii)) is amended by
22 inserting “a priority research drug (as designated under
23 section 1927(c)(2)(C)(iv)) or” after “does not include”.

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