

Rand Paul #1

AMENDMENT NO. _____ Calendar No. _____

Purpose: To amend title XVIII of the Social Security Act to provide incentives to encourage the use of generics and biosimilars under part D of the Medicare program.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. PAUL

Viz:

1 At the appropriate place, insert the following:
2 **SEC. ____ . INCENTIVIZING THE USE OF GENERICS AND**
3 **BIOSIMILARS UNDER MEDICARE PART D.**

4 Section 1860D–4(b)(3) of the Social Security Act (42
5 U.S.C. 1395w–104(b)(3)) is amended by adding at the
6 end the following new subparagraphs:

7 “(I) GENERIC DRUGS ON FORMULARY.—

8 “(i) IN GENERAL.—For plan year
9 2024, and subsequent plan years, the for-
10 mulary shall include a generic drug that

1 references a brand drug if the negotiated
2 price (as described in section 1860D–2(d))
3 under the plan for the generic drug is less
4 than the negotiated price for the brand
5 drug.

6 “(ii) BRAND DRUG DEFINED.—In this
7 subparagraph, the term ‘brand drug’
8 means a covered part D drug that is mar-
9 keted under a new drug application ap-
10 proved under section 505(c) of the Federal
11 Food, Drug, and Cosmetic Act or under a
12 biological product license application ap-
13 proved under section 351(a) of the Public
14 Health Service Act.

15 “(iii) GENERIC DRUG DEFINED.—In
16 this subparagraph, the term ‘generic drug’
17 means any covered part D drug that is not
18 a brand drug, including a biosimilar bio-
19 logical product (as defined in section
20 1847A(c)(6)(H)).

21 “(J) LABELING OF FORMULARY TIERS.—

22 “(i) SEPARATE TIERS FOR BRAND
23 AND GENERIC DRUGS.—For plan year
24 2024, and subsequent plan years:

1 “(I) IN GENERAL.—The for-
2 mulary may use drug tiers with dif-
3 ferential in cost-sharing or copay-
4 ments between tiers. Formulary tiers
5 may not include both brand drugs and
6 generic drugs, but shall have separate
7 designated drug tiers for brand drugs
8 and generic drugs.

9 “(II) TIERS.—The formulary
10 may include a separate tier for—

11 “(aa) preferred brand drugs
12 and preferred generic drugs, but
13 the cost-sharing or copayment as-
14 sociated with the preferred ge-
15 neric drug tier shall be lower
16 than the cost-sharing or copay-
17 ment associated with the pre-
18 ferred brand drug tier;

19 “(bb) nonpreferred brand
20 drugs and nonpreferred generic
21 drugs, but the cost-sharing or co-
22 payment associated with the non-
23 preferred generic drug tier shall
24 be lower than the cost-sharing or
25 copayment associated with the

1 nonpreferred brand drug tier;
2 and

3 “(cc) brand specialty drugs
4 and generic specialty drugs, but
5 the cost-sharing or copayment as-
6 sociated with the generic spe-
7 cialty drug tier shall be lower
8 than the cost-sharing or copay-
9 ment associated with the brand
10 specialty drug tier.

11 “(ii) DEFINITIONS.—In this subpara-
12 graph:

13 “(I) BRAND SPECIALTY DRUG.—
14 The term ‘brand specialty drug’
15 means brand drug (as defined in sub-
16 paragraph (I)(2)) that is a specialty
17 drug.

18 “(II) GENERIC SPECIALTY
19 DRUG.—The term ‘generic specialty
20 drug’ means generic drug (as defined
21 in subparagraph (I)(3)) that is a spe-
22 cialty drug.

23 “(III) SPECIALTY DRUG.—The
24 term ‘specialty drug’ means a covered
25 part D drug that exceeds a cost

1 threshold established by the Sec-
2 retary.”.