



Sanders #3

AMENDMENT NO. _____ Calendar No. _____

Purpose: To prohibit approval of excessively priced drugs.

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 _____

Viz:

1 At the appropriate place in title V insert the fol-
2 lowing:

3 **SEC. 5____. PROHIBITING APPROVAL OF EXCESSIVELY**
4 **PRICED DRUGS.**

5 Section 505 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355), as amended by section 501(a)(2),
7 is further amended by adding at the end the following:

8 “(aa) PROHIBITING APPROVAL OF EXCESSIVELY
9 PRICED DRUGS.—

10 “(1) IN GENERAL.—The Secretary shall deny
11 approval of a drug under subsection (d) if the Sec-

1 retary finds, in accordance with such subsection,
2 that the drug has an excessive price.

3 “(2) EXCESSIVE PRICE.—For purposes of para-
4 graph (1), the Secretary shall determine that a drug
5 has an excessive price if the price of the drug is
6 higher than reasonable taking into account the fol-
7 lowing factors:

8 “(A) The size of the affected patient popu-
9 lation.

10 “(B) The value of the drug to patients, in-
11 cluding the impact of the price on access to the
12 drug and the relationship of the price of the
13 drug to its therapeutic health benefits.

14 “(C) The risk adjusted value of Federal
15 Government subsidies and investments related
16 to the drug.

17 “(D) The costs associated with develop-
18 ment of the drug.

19 “(E) Whether the drug provided a signifi-
20 cant improvement in health outcomes, com-
21 pared to other therapies available at the time of
22 its approval.

23 “(F) The cumulative global revenues gen-
24 erated by the drug.

1 “(G) Whether the domestic average manu-
2 facturer price of the drug increased during any
3 annual quarter by a percentage that is more
4 than the percentage increase in the consumer
5 price index for all urban consumers for the re-
6 spective annual quarter.

7 “(H) Whether the domestic average manu-
8 facturing price exceeds the median price
9 charged for the drug in Canada, the United
10 Kingdom, Germany, France, and Japan.

11 “(I) Other factors the Secretary deter-
12 mines appropriate.

13 “(3) CLARIFICATION.—For purposes of this
14 Act, the grounds for denying approval of an applica-
15 tion under this subsection shall be deemed a grounds
16 for denying approval specified in subsection (d).”.