

B. Sanders

SANDERS #1

AMENDMENT NO. _____

Calendar No. _____

Purpose: To revoke the exclusivity of certain entities that are responsible for violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other certain laws.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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. SANDERS

Viz:

- 1 At the end of title XI, insert the following:
- 2 **SEC. 11__.** **CONDITIONS ON AWARD OF DRUG EXCLU-**
- 3 **SIVITY.**
- 4 Subchapter E of chapter V of the Federal Food,
- 5 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
- 6 amended by inserting after section 569A, as added by this
- 7 Act, the following:

1 **“SEC. 569B. CONDITIONS ON AWARD OF DRUG EXCLU-**
2 **SIVITY.**

3 “(a) **TERMINATION OF EXCLUSIVITY.**—Notwith-
4 standing any other provision of this Act, any period of
5 exclusivity described in subsection (b) granted to a person
6 or assigned to a person on or after the date of enactment
7 of this section with respect to a drug shall be terminated
8 if the person to which such exclusivity was granted or any
9 person to which such exclusivity is assigned—

10 “(1) commits a violation described in subsection
11 (c)(1) with respect to such drug; or

12 “(2) fails to report such a violation as required
13 by subsection (e).

14 “(b) **EXCLUSIVITIES AFFECTED.**—The periods of ex-
15 clusivity described in this subsection are those periods of
16 exclusivity granted under any of the following sections:

17 “(1) Clause (ii), (iii), or (iv) of section
18 505(c)(3)(E).

19 “(2) Clause (iv) of section 505(j)(5)(B).

20 “(3) Clause (ii), (iii), or (iv) of section
21 505(j)(5)(F).

22 “(4) Section 505A.

23 “(5) Section 527.

24 “(6) Section 351(k)(7) of the Public Health
25 Service Act.

26 “(c) **VIOLATIONS.**—

1 “(1) IN GENERAL.—A violation described in
2 this subsection is a violation of a law described in
3 paragraph (2) that results in—

4 “(A) a criminal conviction of a person de-
5 scribed in subsection (a);

6 “(B) a finding of civil liability of a person
7 described in subsection (a); or

8 “(C) a settlement agreement in which a
9 person described in subsection (a) admits to
10 fault.

11 “(2) LAWS DESCRIBED.—The laws described in
12 this paragraph are the following:

13 “(A) This Act.

14 “(B) The provisions of subchapter III of
15 chapter 37 of title 31, United States Code
16 (commonly known as the ‘False Claims Act’).

17 “(C) The Medicare and Medicaid Patient
18 Protection and Program Act of 1987 (com-
19 monly known as the ‘Antikickback Statute’).

20 “(D) The Foreign Corrupt Practices Act of
21 1977.

22 “(E) Section 1927 of the Social Security
23 Act.

1 “(F) A State law against fraud comparable
2 to a law described in subparagraphs (A)
3 through (E).

4 “(d) DATE OF EXCLUSIVITY TERMINATION.—The
5 date on which the exclusivity shall be terminated as de-
6 scribed in subsection (a) is the date on which, as applica-
7 ble—

8 “(1) a final judgement is entered relating to a
9 violation described in subparagraph (A) or (B) of
10 subsection (c)(1); or

11 “(2) a settlement agreement described in sub-
12 section (c)(1)(C) is approved by a court order that
13 is or becomes final and nonappealable.

14 “(e) REPORTING OF INFORMATION.—A person de-
15 scribed in subsection (a) that commits a violation de-
16 scribed in subsection (c)(1) shall report such violation to
17 the Secretary no later than 30 days after the date that—

18 “(1) a final judgement is entered relating to a
19 violation described in subparagraph (A) or (B) of
20 subsection (c)(1); or

21 “(2) a settlement agreement described in sub-
22 section (c)(1)(C) is approved by a court order that
23 is or becomes final and nonappealable.”.