

Bob Sanders

S.L.C.

Amendment #4

AMENDMENT NO. _____ Calendar No. _____

Purpose: To condition drug exclusivity upon certain factors.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

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. SANDERS

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . CONDITIONS ON AWARD OF DRUG EXCLUSIVITY.**

3 Subchapter E of chapter V of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
5 amended by adding at the end the following:

6 **“SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLU-
7 SIVITY.**

8 **“(a) TERMINATION OF EXCLUSIVITY.—**Notwith-
9 standing any other provision of this Act, any period of
10 exclusivity described in subsection (b) granted to a person
11 or assigned to a person on or after the date of enactment

1 of this section with respect to a drug shall be terminated
2 if the person to which such exclusivity was granted or any
3 person to which such exclusivity is assigned commits a vio-
4 lation described in subsection (c)(1) with respect to such
5 drug.

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

9 “(1) Clause (ii), (iii), or (iv) of section
10 505(c)(3)(E).

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

12 “(3) Clause (ii), (iii), or (iv) of section
13 505(j)(5)(F).

14 “(4) Section 505A.

15 “(5) Section 505E.

16 “(6) Section 527.

17 “(7) Section 351(k)(7) of the Public Health
18 Service Act.

19 “(8) Any other provision of this Act that pro-
20 vides for market exclusivity (or extension of market
21 exclusivity) with respect to a drug.

22 “(c) VIOLATIONS.—

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

1 “(A) a criminal conviction of a person de-
2 scribed in subsection (a);

3 “(B) a civil judgment against a person de-
4 scribed in subsection (a); or

5 “(C) a settlement agreement in which a
6 person described in subsection (a) admits to
7 fault.

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

10 “(A) The provisions of this Act that pro-
11 hibit—

12 “(i) the adulteration or misbranding
13 of a drug;

14 “(ii) the making of false statements to
15 the Secretary or committing fraud; or

16 “(iii) the illegal marketing of a drug.

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

20 “(C) Section 287 of title 18, United States
21 Code.

22 “(D) The Medicare and Medicaid Patient
23 Protection and Program Act of 1987 (com-
24 monly known as the ‘Antikickback Statute’).

1 “(E) Section 1927 of the Social Security
2 Act.

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

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

10 “(1) a final judgment is entered relating to a
11 violation described in subparagraph (A) or (B) of
12 subsection (c)(1); or

13 “(2)(A) a settlement agreement described in
14 subsection (c)(1)(C) is approved by a court order
15 that is or becomes final and nonappealable; or

16 “(B) if there is no court order approving a set-
17 tlement agreement described in subsection (c)(1)(C),
18 a court order dismissing the applicable case, issued
19 after the settlement agreement, is or becomes final
20 and nonappealable.

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

1 “(1) a final judgment is entered relating to a
2 violation described in subparagraph (A) or (B) of
3 subsection (c)(1); or

4 “(2)(A) a settlement agreement described in
5 subsection (c)(1)(C) is approved by a court order
6 that is or becomes final and nonappealable; or

7 “(B) if there is no court order approving a set-
8 tlement agreement described in subsection (c)(1)(C),
9 a court order dismissing the applicable case, issued
10 after the settlement agreement, is or becomes final
11 and nonappealable.”.