

*Bob Sanders**SANDERS #3*

AMENDMENT NO. _____

Calendar No. _____

Purpose: To de-link research and development incentives from drug prices for new antibiotics and to stimulate greater sharing of scientific knowledge.

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 _____

Viz:

1 Strike title VIII and insert the following:

2 **TITLE VIII—PRIZE FUND FOR**
3 **ANTIBIOTICS**

4 **SECTION 801. SHORT TITLE.**

5 This title may be cited as the “Prize Fund for Anti-
6 biotics Act”.

7 **SEC. 802. PURPOSE.**

8 It is the purpose of this title to provide sustainable
9 financing of incentives to encourage investments in re-

1 search and development of new antibiotics and to share
2 knowledge, data, materials, and technology, through the
3 establishment of a Prize Fund for Antibiotics, while en-
4 hancing access to such medicines by eliminating legal mo-
5 nopolies on the manufacture, distribution, and sale of such
6 medicines.

7 **SEC. 803. DEFINITIONS.**

8 In this title:

9 (1) ANTIBIOTIC.—The term “antibiotic” has
10 the meaning given the term “antibiotic drug” section
11 201(jj) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S. C. 321(jj)).

13 (2) BIOLOGICAL PRODUCT.—The term “biologi-
14 cal product” has the meaning given such term in
15 section 351 of the Public Health Service Act (42
16 U.S.C. 262).

17 (3) DRUG.—The term “drug” has the meaning
18 given such term in section 201 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 321).

20 (4) FUND.—The term “Fund” means the Prize
21 Fund for Antibiotics established under section 805.

22 (5) MARKET CLEARANCE.—The term “market
23 clearance” means the approval of an application
24 under section 505 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355) or the approval of a

1 biologics license application under subsection (a) of
2 section 351 of the Public Health Service Act (42
3 U.S.C. 262).

4 **SEC. 804. ELIMINATION OF EXCLUSIVE RIGHTS TO MARKET**
5 **DRUGS AND BIOLOGICAL PRODUCTS.**

6 (a) IN GENERAL.—Notwithstanding title 35, United
7 States Code, relevant provisions of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (including
9 amendments made by the Drug Price Competition and
10 Patent Term Restoration Act of 1984 (Public Law 98–
11 417; commonly referred to as the “Hatch-Waxman Act”)),
12 the Medicare Prescription Drug, Improvement, and Mod-
13 ernization Act of 2003 (Public Law 108–173), and any
14 other provision of law providing any patent right or exclu-
15 sive marketing period for any antibiotic or manufacturing
16 process for an antibiotic (such as pediatric extensions
17 under section 505A of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355a) or orphan drug marketing ex-
19 clusivity under subchapter B of chapter V of such Act (21
20 U.S.C. 360aa et seq.)), no person shall have the right to
21 exclusively manufacture, distribute, sell, or use an anti-
22 biotic or a manufacturing process for an antibiotic in
23 interstate commerce, including the exclusive right to rely
24 on health registration data or the 30-month stay-of-effec-

1 tiveness period for Orange Book patents under section
2 505(j) of such Act (21 U.S.C. 355(j)).

3 (b) REMUNERATION.—A person that is eligible for
4 prize payments from the Prize Fund for Antibiotics shall
5 receive such payments—

6 (1) in lieu of any remuneration the person
7 would have otherwise received for the exclusive mar-
8 keting, distribution, sale, or use of an antibiotic or
9 manufacturing process for an antibiotic but for the
10 application of subsection (a); and

11 (2) in addition to any other remuneration that
12 such person receives by reason of the nonexclusive
13 marketing, distribution, sale, or use of the antibiotic
14 or manufacturing process for an antibiotic.

15 (c) APPLICATION.—This section shall apply only with
16 respect to the marketing, distribution, sale, or use of an
17 antibiotic or a manufacturing process for an antibiotic
18 that occurs on or after October 1, 2013.

19 **SEC. 805. PRIZE FUND FOR ANTIBIOTICS.**

20 (a) ESTABLISHMENT.—There is hereby established in
21 the Treasury of the United States a revolving fund to be
22 known as the “Prize Fund for Antibiotics”, which shall
23 consist of amounts appropriated to the Fund and amounts
24 credited to the Fund under subsection (d).

1 (b) PRIZE FUND ADMINISTRATION.—The Secretary
2 of Health and Human Services shall designate a Prize
3 Fund Director and other officials as needed to administer
4 the Fund.

5 (c) ADVISORY BOARD.—The Secretary of Health and
6 Human Services shall appoint an advisory board for the
7 Fund.

8 (d) AMOUNTS CREDITED TO THE FUND.—The Sec-
9 retary of the Treasury shall credit to the Fund the interest
10 on, and the proceeds from sale or redemption of, obliga-
11 tions held in the Fund.

12 **SEC. 806. PRIZE PAYMENTS FOR MEDICAL INNOVATION.**

13 (a) AWARD.—For fiscal year 2014, and each subse-
14 quent fiscal year, the Prize Fund Director shall award to
15 persons described in subsection (b) prize payments for
16 medical innovation relating to an antibiotic, or a new man-
17 ufacturing process for such an antibiotic.

18 (b) ELIGIBILITY.—To be eligible to receive a prize
19 payment under subsection (a) a person shall be—

20 (1) in the case of an antibiotic that is a drug
21 or biological product, the first person to receive mar-
22 ket clearance with respect to the drug or biological
23 product;

1 (2) in the case of a manufacturing process for
2 an antibiotic, the holder of the patent with respect
3 to such process; or

4 (3) in the case of open source contributions
5 with respect to an antibiotic, the persons or commu-
6 nities that openly shared knowledge, data, materials,
7 and technology on a royalty-free and nondiscrim-
8 inatory basis.

9 (c) CRITERIA.—The Prize Fund Director shall, by
10 regulation, establish criteria for the selection of recipients,
11 and for determining the amount, of prize payments under
12 this section. Such criteria shall include consideration of
13 the following:

14 (1) The number of patients who benefit from
15 the antibiotic or manufacturing process involved.

16 (2) The incremental therapeutic benefit of the
17 antibiotic or manufacturing process involved as com-
18 pared to existing drugs, biological products, and
19 manufacturing processes available to treat the same
20 disease or condition as well as emerging diseases or
21 conditions, except that the Prize Fund Director shall
22 provide for cases where drugs, biological products, or
23 manufacturing processes are developed at roughly
24 the same time, so that the comparison is to products
25 that were not recently developed.

1 (3) Improved efficiency of manufacturing proe-
2 esses for drugs or biological processes.

3 (4) The extent to which knowledge, data, mate-
4 rials, and technology that are openly shared have
5 contributed to the successful development of new
6 products or improved processes for manufacturing
7 products.

8 (d) REQUIREMENTS.—In awarding prize payments
9 under this section, the Prize Fund Director shall comply
10 with the following:

11 (1) In cases where a new antibiotic or manufac-
12 turing process for an antibiotic offers an improve-
13 ment over an existing antibiotic or manufacturing
14 process for an antibiotic and such new antibiotic or
15 manufacturing process competes with or replaces the
16 existing antibiotic or manufacturing process, the
17 Prize Fund Director shall continue to make prize
18 payments for the existing antibiotic or manufac-
19 turing process to the degree that the new antibiotic
20 or manufacturing process was based on or benefitted
21 from the development of the existing antibiotic or
22 manufacturing process.

23 (2) The Prize Fund Director may award prize
24 payments for an antibiotic or a manufacturing proc-

1 ess for an antibiotic for not more than 10 fiscal
2 years, regardless of the term of any related patents.

3 (3) For any fiscal year, the Prize Fund Direc-
4 tor may not award a prize payment for any single
5 antibiotic or manufacturing process for an antibiotic
6 in an amount that exceeds 50 percent of the total
7 amount appropriated to the Fund for that year.

8 (4) For every antibiotic that receives market
9 clearance, the Prize Fund Director shall determine
10 whether and in what amount to award a prize pay-
11 ment for the antibiotic not later than the end of the
12 fourth full calendar-year quarter following the cal-
13 endar-year quarter in which the antibiotic receives
14 market clearance.

15 **SEC. 807. OPEN SOURCE DIVIDEND PRIZES.**

16 (a) IN GENERAL.—In order to induce greater access
17 and the open sharing of knowledge, data, materials, and
18 technology, at least 5 percent of the prize payments from
19 the Fund shall be dedicated to Open Source Dividend
20 Prizes.

21 (b) PROCEDURES.—

22 (1) IN GENERAL.—The Prize Fund Director
23 shall adopt procedures for the allocation of Open
24 Source Dividend Prizes. Such procedures shall—

1 (A) be fully transparent regarding the
2 process for evaluating the value of open sharing
3 of knowledge, data, materials, and technology;

4 (B) reward the open, nondiscriminatory,
5 and royalty-free sharing of knowledge, data,
6 materials, and technology that has contributed
7 to the development of the new antibiotic or
8 manufacturing processes that are rewarded
9 under section 806;

10 (C) in the case of rewards for contributing
11 to the development of new antibiotics or manu-
12 facturing processes rewarded under section 806,
13 provide for a time-limited period of nominations
14 for persons or communities whose contributions
15 were considered useful, including the evidence
16 to support such nominations to describe the sig-
17 nificance of the contribution; and

18 (D) provide for rules and procedures to
19 protect against conflicts of interest.

20 (2) PUBLIC AVAILABILITY OF NOMINATIONS.—

21 The nominations described in paragraph (1)(C), and
22 the evidence supporting such nominations, shall be
23 public. The public shall be allowed to provide com-
24 mentary and additional evidence on such nomina-
25 tions before awards are made.

1 **SEC. 808. COMPETITIVE INTERMEDIARIES FOR FUNDING**
2 **INTERIM TECHNOLOGIES.**

3 (a) IN GENERAL.—The Prize Fund Director may au-
4 thorize multiple nonprofit intermediaries to manage Fund
5 payments to reward projects for interim research and de-
6 velopment of new antibiotics, or for open source dividend
7 prizes. Such intermediaries shall compete for funding from
8 non-Federal entities that co-fund the Fund.

9 (b) AVAILABILITY.—Prizes awarded by competitive
10 intermediaries shall be available to persons or commu-
11 nities that provide open, nondiscriminatory, and royalty-
12 free licenses to relevant intellectual property rights.

13 (c) RULES.—The Prize Fund Director shall adopt
14 rules to ensure the transparency and accountability of any
15 entities authorized to act as competitive intermediaries
16 under subsection (a).

17 (d) ALLOCATION.—The Secretary of Health and
18 Human Services shall determine how much of the Fund
19 shall be managed by competitive intermediaries to reward
20 projects for interim research and development of new anti-
21 biotics or for open source dividend prizes.

22 **SEC. 809. SPECIAL TRANSITION RULES.**

23 (a) IN GENERAL.—An antibiotic that is on the mar-
24 ket on October 1, 2013, shall remain eligible for prize pay-
25 ments for not more than 10 fiscal years, consistent with
26 section 806(d)(3).

1 (b) DETERMINATION OF VALUE.—In determining the
2 amount of a prize payment for an antibiotic described in
3 subsection (a), the Prize Fund Director shall calculate the
4 incremental value of the antibiotic as of the date on which
5 the antibiotic was first introduced in the market.

6 (c) MAXIMUM AMOUNT.—With respect to antibiotics
7 described in subsection (a), the Prize Fund Director may
8 award—

9 (1) of the amount appropriated to the Fund for
10 fiscal year 2014, not more than 90 percent of such
11 amount; and

12 (2) of the amount appropriated to the Fund for
13 each of the succeeding 9 fiscal years, not more than
14 a percentage of such amount that is equal to 9 per-
15 cent less the percentage applicable to the preceding
16 fiscal year under this subsection.

17 **SEC. 810. ARBITRATION.**

18 In the case of an antibiotic that is on the market on
19 October 1, 2013, and subject to patents owned by a party
20 other than the person who first received market clearance
21 for the antibiotic, the Prize Fund Director shall establish
22 an arbitration procedure to determine an equitable divi-
23 sion of any prize payments under this Act among the pat-
24 ent owners and the person who first received market clear-
25 ance for the antibiotic.

1 **SEC. 811. FUNDING.**

2 (a) APPROPRIATIONS.—

3 (1) START-UP COSTS.—For fiscal year 2014,
4 there are authorized to be appropriated to the Fund,
5 such sums as may be necessary to carry out this
6 Act.

7 (2) PROGRAM IMPLEMENTATION.—For fiscal
8 year 2014 and each subsequent fiscal year, there is
9 authorized to be appropriated to the Fund, and
10 there is appropriated, out of any funds in the Treas-
11 ury not otherwise appropriated, an amount equal to
12 0.015 percent of the gross domestic product of the
13 United States for the preceding fiscal year (as such
14 amount is determined by the Secretary of Com-
15 merce).

16 (3) AVAILABILITY.—Funds appropriated to the
17 Fund for a fiscal year shall remain available for ex-
18 penditure in accordance with this Act until the end
19 of the 3-year period beginning on October 1 of such
20 fiscal year. Any such funds that are unexpended at
21 the end of such period shall revert to the Treasury.

22 (b) IMPOSITION OF ANNUAL FEE ON HEALTH IN-
23 SURANCE PROVIDERS.—

24 (1) IN GENERAL.—Each covered entity engaged
25 in the business of providing health insurance shall
26 pay to the Secretary, not later than the annual pay-

1 ment date of each calendar year beginning after
2 2013, a fee in an amount determined under para-
3 graph (3).

4 (2) ANNUAL PAYMENT DATE.—For purposes of
5 this section, the term “annual payment date”
6 means, with respect to any calendar year, a date de-
7 termined by the Secretary, which in no event, may
8 be later than September 30 of such calendar year.

9 (3) DETERMINATION OF FEE AMOUNT.—

10 (A) IN GENERAL.—The total of all fees
11 paid by all covered entities for any given year
12 shall be the amount described in subsection
13 (a)(2) multiplied by the ratio of the number of
14 persons receiving antibiotics that are insured in
15 the private sector to the number of persons re-
16 ceiving antibiotics who received insurance or re-
17 imbursements or care from the public sector.

18 (B) INDIVIDUAL CONTRIBUTIONS.—With
19 respect to each covered entity, the fee under
20 this section for any calendar year shall be equal
21 to the ratio of the covered entity’s net pre-
22 miums written with respect to health insurance
23 for any United States health risk taken into ac-
24 count under subsection (c) during the preceding
25 calendar year, to the sum of such net premiums

1 for all covered entities, multiplied by the
2 amount under subparagraph (A).

3 (c) AMOUNTS TAKEN INTO ACCOUNT.—For purposes
4 of subsection (b)(3), the net premiums written with re-
5 spect to health insurance for any United States health risk
6 that are taken into account during any calendar year with
7 respect to any covered entity shall be determined as fol-
8 lows:

9 (1) With respect to a covered entity's net pre-
10 miums written during the calendar year that are not
11 more than \$25,000,000, the percentage of net pre-
12 miums written that are taken into account is 0 per-
13 cent.

14 (2) With respect to a covered entity's net pre-
15 miums written during the calendar year that are
16 more than \$25,000,000 but less than \$50,000,000,
17 the percentage of net premiums written that are
18 taken into account is 50 percent.

19 (3) With respect to a covered entity's net pre-
20 miums written during the calendar year that are
21 \$50,000,000 or more, the percentage of net pre-
22 miums written that are taken into account is 100
23 percent.

24 (d) COVERED ENTITY.—

1 (1) IN GENERAL.—For purposes of this section,
2 the term “covered entity” means any entity which
3 provides health insurance for any United States
4 health risk.

5 (2) EXCLUSION.—Such term does not include
6 any governmental entity.