

SANDERS #4

Barack Sanders

AMENDMENT NO. _____

Calendar No. _____

Purpose: To eliminate requirements to undertake duplicative clinical testing of new pharmaceutical drugs, vaccines, biological products, or medical devices, when such duplication is inconsistent with relevant ethical norms.

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, add the following:

2 **TITLE XII—ETHICAL PATHWAY**

3 **ACT**

4 **SEC. 1201. SHORT TITLE.**

5 This title may be cited as the “Ethical Pathway Act
6 of 2012”.

7 **SEC. 1202. PURPOSE.**

8 The purpose of this title is to eliminate requirements
9 to undertake duplicative clinical testing of new pharma-

1 ceutical drugs, vaccines, biological products or medical de-
2 vices, when such duplication is inconsistent with relevant
3 ethical norms, by providing for the opportunity to rely
4 upon existing trials, subject to sharing of the costs of
5 those trials, during the period when regulatory test data
6 is protected.

7 **SEC. 1203. ETHICAL PATHWAY FOR THE APPROVAL AND LI-**
8 **CENSOR OF REGULATED PRODUCTS.**

9 (a) DEFINITIONS.—For purposes of this title:

10 (1) APPLICANT.—The term “applicant” means
11 a person who submits to the Secretary an applica-
12 tion to sell a regulated product.

13 (2) COMMISSIONER.—The term “Commis-
14 sioner” means the Commissioner of Food and
15 Drugs.

16 (3) REGULATED PRODUCT.—The term “regu-
17 lated product” includes any new pharmaceutical
18 drug, vaccine, biologic product or medical device,
19 that requires regulatory approval by the Secretary.

20 (4) REGULATORY TEST DATA.—The term “reg-
21 ulatory test data” means the evidence regarding the
22 safety and efficacy of new pharmaceutical drugs or
23 biological products used in order to obtain marketing
24 approval for use in humans or vertebrate animals.

1 (5) RELEVANT APPLICATION OR LICENSE.—The
2 term “relevant application or license” means a new
3 drug application or new biological product license
4 application approved by the Secretary or relevant
5 authority in a foreign country which contains regu-
6 latory test data requested by an applicant under this
7 section.

8 (6) SECRETARY.—The term “Secretary” means
9 the Secretary of Health and Human Services.

10 (b) ETHICAL PATHWAY.—As soon as practicable
11 after the date of enactment of this Act, the Secretary, act-
12 ing through the Commissioner, shall establish a mecha-
13 nism by which an applicant may request a cost-sharing
14 arrangement described in subsection (c). An applicant
15 may request such an arrangement if, but for the arrange-
16 ment—

17 (1) the applicant would be required to conduct
18 clinical investigations involving human subjects that
19 violate Article 20 of the Declaration of Helsinki on
20 Ethical Principles for Medical Research Involving
21 Human Subjects in order to obtain regulatory ap-
22 proval of a regulated product; or

23 (2) the duplication of the clinical investigations
24 required for such application would violate other ap-

1 plicable ethical standards concerning the testing of
2 products on humans or other vertebrate animals.

3 (c) COST-SHARING ARRANGEMENT.—

4 (1) RESPONSIBILITY OF APPLICANT.—An appli-
5 cant that intends to perform clinical investigations
6 involving humans or vertebrate animals in order to
7 file an application for a regulated product shall take
8 all necessary measures to verify that those investiga-
9 tions have not been performed or initiated by an-
10 other person.

11 (2) VOLUNTARY AGREEMENT PROCEDURES.—
12 An applicant shall make reasonable efforts to obtain
13 voluntary agreements to use existing regulatory test
14 data, such as by offering to make contributions to-
15 ward the cost of undertaking such tests, which the
16 applicant does not have the right to rely upon in the
17 absence of a license or a cost-sharing agreement.

18 (3) FAILURE TO REACH VOLUNTARY AGREE-
19 MENT.—The applicant shall notify the Commissioner
20 or the appropriate designee of the Commissioner if
21 there is a failure to reach a voluntary agreement to
22 use such test data. Upon receipt of a notification of
23 a failure to reach a voluntary agreement, the Com-
24 missioner or such designee shall ask the parties to
25 agree to binding arbitration to determine the reason-

1 able and fair fee for relying upon relevant regulatory
2 test data. If one or more of the parties refuses to
3 participate in such arbitration, the Commissioner
4 shall determine a reasonable and fair fee for the reli-
5 ance by the applicant on such regulatory test data.

6 (4) REASONABLE AND FAIR FEE.—The reason-
7 able and fair fee for the reliance by the applicant on
8 the regulatory test data shall be determined after
9 considering the following factors:

10 (A) The actual out-of-pocket costs of the
11 applicable clinical investigations.

12 (B) The risks of the investigations, as re-
13 flected in the probabilities that similar inves-
14 tigations result in successful applications for
15 marketing.

16 (C) Any Federal grants, tax credits, or
17 other subsidies that reduce the net cost of the
18 investigations.

19 (D) The expected share of the global mar-
20 ket for the product involved, by the party seek-
21 ing to rely upon the investigations for mar-
22 keting approval.

23 (E) The amount of the time the holder or
24 holders of the relevant applications or licenses
25 has benefitted from exclusive rights, and the cu-

1 cumulative revenue earned on the products that
2 relied upon the regulatory test data at issue.

3 (d) PUBLIC DISCLOSURE.—

4 (1) IN GENERAL.—In order to enhance the
5 transparency of the costs of innovation, and to pro-
6 vide greater predictability as to the liability associ-
7 ated with nonvoluntary reliance upon regulatory test
8 data, the Secretary shall adopt procedures and rules
9 under which sufficient information about the costs
10 and fees will be made public by the arbitrator or the
11 Commissioner (or the appropriate designee of the
12 Commissioner), as applicable.

13 (2) CONTENT.—The information made public
14 under paragraph (1) shall include at least summary
15 data of the actual costs of the clinical investigations,
16 the factors considered under subsection (c)(4), and
17 the amount of the fee provided to the holder or hold-
18 ers of the relevant applications or licenses.

19 (3) LIMITATIONS.—The requirements for public
20 disclosure of the costs of the clinical investigations
21 shall not apply to cases where the owner of the
22 rights in the regulatory test data does not assert an
23 exclusive right to rely upon such test data. If the
24 owner of the rights in the regulatory test data as-
25 serts an exclusive right, but reaches a voluntary

1 agreement on the fee for relying upon the data
2 under subsection (c)(2), the amount of the fee paid
3 by the applicant shall be provided to the Secretary
4 or a designee, and be made public.