

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 3506

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

AUGUST 2, 2012

Mr. SANDERS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

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.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

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

6       **SEC. 2. PURPOSE.**

7       The purpose of this Act is to eliminate requirements  
8 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. 3. ETHICAL PATHWAY FOR THE APPROVAL AND LI-**  
8 **CENSOR OF REGULATED PRODUCTS.**

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

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.

○