

111TH CONGRESS
2D SESSION

S. 3921

To ensure that rules for the approval of pharmaceutical and biological products do not require violations of medical ethics in the testing of products in humans and vertebrate animals.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2010

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

A BILL

To ensure that rules for the approval of pharmaceutical and biological products do not require violations of medical ethics in the testing of products in humans and vertebrate animals.

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 2010”.

1 **SEC. 2. ETHICAL PATHWAY FOR THE APPROVAL AND LI-**
2 **CENSOR OF PHARMACEUTICAL AND BIOLOGI-**
3 **CAL PRODUCTS.**

4 (a) DEFINITIONS.—

5 (1) IN GENERAL.—In this section:

6 (A) APPLICANT.—The term “applicant”
7 means a person who submits to the Secretary
8 an application described in subsection (a)(2).

9 (B) COMMISSIONER.—The term “Commis-
10 sioner” means the Commissioner of Food and
11 Drugs.

12 (C) REGULATORY TEST DATA.—The term
13 “regulatory test data” means the evidence re-
14 garding the safety and efficacy of new pharma-
15 ceutical drugs or biological products used in
16 order to obtain marketing approval for use in
17 humans or vertebrate animals.

18 (D) RELEVANT APPLICATION OR LI-
19 CENSE.—The term “relevant application or li-
20 cense” means a new drug application or new bi-
21 ological product license application approved by
22 the Secretary or relevant authority in a foreign
23 country which contains regulatory test data re-
24 quested by an applicant under this section.

1 (E) SECRETARY.—The term “Secretary”
2 means the Secretary of Health and Human
3 Services.

4 (2) TYPES OF APPLICATIONS.—An application
5 described in this paragraph is—

6 (A) an abbreviated new drug application
7 submitted under section 505(j) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(j));

10 (B) an application for license of a bio-
11 similar biological product submitted under sec-
12 tion 351(k) of the Public Health Service Act; or

13 (C) an application for a license to sell a
14 drug in the United States that has been ap-
15 proved for marketing in a foreign country, as
16 permitted by the Secretary.

17 (b) ETHICAL PATHWAY.—As soon as practicable
18 after the date of enactment of this Act, the Secretary, act-
19 ing through the Commissioner, shall establish a mecha-
20 nism by which an applicant may request a cost-sharing
21 arrangement described in subsection (c). Such an appli-
22 cant may request such an arrangement if, but for the ar-
23 rangement—

24 (1) such applicant would be required to conduct
25 clinical investigations involving human subjects that

1 violate Article 20 of the Declaration of Helsinki on
 2 Ethical Principles for Medical Research Involving
 3 Human Subjects in order to obtain approval or li-
 4 censure from the Secretary of the application de-
 5 scribed in subsection (a)(2) submitted by the appli-
 6 cant; or

7 (2) the duplication of the clinical investigations
 8 required for such application would violate other ap-
 9 plicable ethical standards concerning the testing of
 10 products on humans or other vertebrate animals.

11 (c) COST-SHARING ARRANGEMENT.—

12 (1) RESPONSIBILITY OF APPLICANT.—An appli-
 13 cant that intends to perform clinical investigations
 14 involving humans or vertebrate animals in order to
 15 file an application described in subsection (a)(2)
 16 shall take all necessary measures to verify that those
 17 investigations have not been performed or initiated
 18 by another person.

19 (2) VOLUNTARY AGREEMENT PROCEDURES.—

20 (A) IN GENERAL.—An applicant and the
 21 holder or holders of relevant applications or li-
 22 censes shall make every effort to ensure that
 23 any regulatory test data and results of clinical
 24 investigations involving humans and vertebrate
 25 animals conducted with respect to such relevant

1 applications or licenses is shared with the appli-
2 cant, including the regulatory test data nec-
3 essary for the applicant to obtain marketing ap-
4 proval from the Secretary with respect to an
5 application described under subsection (a)(2).

6 (B) REASONABLE FEE.—

7 (i) IN GENERAL.—An applicant and
8 the holder or holders of the relevant appli-
9 cations or licenses shall make every effort
10 to agree upon a fee that is reasonable and
11 fair that permits the applicant to rely upon
12 information from the regulatory test data
13 referred to in subparagraph (A).

14 (ii) LIMITED TO CERTAIN DATA.—

15 Clause (i) shall apply only to the regu-
16 latory test data that such applicant is re-
17 quired to submit with the application de-
18 scribed in subsection (a)(2), and upon
19 which such applicant does not have the
20 right to rely in the absence of a license or
21 a cost-sharing agreement.

22 (3) FAILURE TO REACH VOLUNTARY AGREE-
23 MENT.—

1 (A) NOTIFICATION TO COMMISSIONER.—

2 The applicant shall notify the Commissioner or
3 the appropriate designee of the Commissioner—

4 (i) if the applicant or the holder or
5 holders of the relevant applications or li-
6 censes refuses to participate in the efforts
7 to agree upon a fee described in paragraph
8 (2)(B); or

9 (ii) if the applicant and the holder or
10 holders of the relevant applications or li-
11 censes fail to reach agreement on a reason-
12 able and fair fee for reliance by the appli-
13 cant on the regulatory test data described
14 in paragraph (2).

15 (B) EFFECT OF NOTIFICATION.—Upon re-
16 ceipt of a notification under subparagraph (A),
17 the Commissioner or such designee—

18 (i) shall refer the matter to binding
19 arbitration to determine a reasonable and
20 fair fee for the reliance by the applicant on
21 the regulatory test data, and encourage the
22 parties to participate in such arbitration;
23 or

24 (ii) if 1 or more of the parties refuses
25 to participate in such arbitration, or if de-

1 terminated appropriate by the Commissioner,
2 shall determine a reasonable and fair fee
3 for the reliance by the applicant on such
4 regulatory test data.

5 (4) RELIANCE ON REGULATORY TEST DATA IN
6 APPLICATION.—If the applicant or the holder or
7 holders of the relevant applications or licenses re-
8 fuses to participate in the efforts to agree upon a fee
9 described in paragraph (2)(B), or if an applicant
10 and the holder or holders of the relevant applications
11 or licenses fail to reach agreement on a reasonable
12 and fair fee for reliance by the applicant on the reg-
13 ulatory test data under paragraph (2)—

14 (A) the applicant shall—

15 (i) pay to the holder or holders of
16 such relevant applications or licenses a fee
17 in the amount of the reasonable and fair
18 share of the costs of the regulatory test
19 data determined through binding arbitra-
20 tion or by the Commissioner or appropriate
21 designee under paragraph (3), as applica-
22 ble; and

23 (ii) in the application described in
24 subsection (a)(2) that is submitted by the
25 applicant, include a notification to the

1 Commissioner that the Commissioner shall
2 incorporate into the application the regu-
3 latory test data contained in such relevant
4 applications or licenses that is the subject
5 of the reasonable and fair fee; and

6 (B) subject to the payment of the fee de-
7 scribed in subparagraph (A)(i), the Commis-
8 sioner shall incorporate into the application
9 such regulatory test data.

10 (d) PROCEDURES.—The reasonable and fair fee for
11 the reliance by the application on the regulatory test data
12 under subsection (c)(3) shall be determined after consid-
13 ering the following factors:

14 (1) The actual out-of-pocket costs of the appli-
15 cable clinical investigations.

16 (2) The risks of the investigations, as reflected
17 in the probabilities that similar investigations result
18 in successful applications for marketing.

19 (3) Any Federal grants, tax credits, or other
20 subsidies that reduce the net cost of the investiga-
21 tions.

22 (4) The expected share of the global market for
23 the product involved, by the party seeking to rely
24 upon the investigations for marketing approval.

1 (5) The amount of the time the holder or hold-
2 ers of the relevant applications or licenses has bene-
3 fitted from exclusive rights, and the cumulative rev-
4 enue earned on the products that relied upon the
5 regulatory test data at issue.

6 (e) PUBLIC DISCLOSURE.—

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

16 (2) CONTENT.—The information made public
17 under paragraph (1) shall include at least summary
18 data of the actual costs of the clinical investigations,
19 the factors considered under subsection (d), and the
20 amount of the fee provided to the holder or holders
21 of the relevant applications or licenses.

22 (3) LIMITATIONS.—The requirements for public
23 disclosure of the costs of the clinical investigations
24 shall not apply to cases where the owner of the
25 rights in the regulatory test data does not assert an

1 exclusive right to rely upon such test data. If the
2 owner of the rights in the regulatory test data as-
3 serts an exclusive right, but reaches a voluntary
4 agreement on the fee for relying upon the data
5 under subsection (c)(2), the amount of the fee paid
6 by the applicant shall be provided to the Secretary
7 or a designee, and be made public.

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