II

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ethical Pathway Act of 2010''.

SEC. 2. ETHICAL PATHWAY FOR THE APPROVAL AND LICENSOR OF PHARMACEUTICAL AND BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—

(1) IN GENERAL.—In this section:

(A) APPLICANT.—The term ''applicant'' means a person who submits to the Secretary an application described in subsection (a)(2).

(B) COMMISSIONER.—The term ''Commissioner'' means the Commissioner of Food and Drugs.

(C) REGULATORY TEST DATA.—The term ''regulatory test data'' means the evidence regarding the safety and efficacy of new pharmaceutical drugs or biological products used in order to obtain marketing approval for use in humans or vertebrate animals.

(D) RELEVANT APPLICATION OR LICENSE.—The term ''relevant application or license'' means a new drug application or new biological product license application approved by the Secretary or relevant authority in a foreign country which contains regulatory test data requested by an applicant under this section.

(E) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

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

(B) an application for license of a biosimilar biological product submitted under section 351(k) of the Public Health Service Act; or

(C) an application for a license to sell a drug in the United States that has been approved for marketing in a foreign country, as permitted by the Secretary.

(b) ETHICAL PATHWAY.—As soon as practicable after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall establish a mechanism by which an applicant may request a cost-sharing arrangement described in subsection (c). Such an applicant may request such an arrangement if, but for the arrangement—

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

violate Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects in order to obtain approval or licensure from the Secretary of the application described in subsection (a)(2) submitted by the applicant; or

(2) the duplication of the clinical investigations required for such application would violate other applicable ethical standards concerning the testing of products on humans or other vertebrate animals.

(c) COST-SHARING ARRANGEMENT.—

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

(2) VOLUNTARY AGREEMENT PROCEDURES.—

(A) IN GENERAL.—An applicant and the holder or holders of relevant applications or licenses shall make every effort to ensure that any regulatory test data and results of clinical investigations involving humans and vertebrate animals conducted with respect to such relevant

applications or licenses is shared with the applicant, including the regulatory test data necessary for the applicant to obtain marketing approval from the Secretary with respect to an application described under subsection (a)(2).

(B) REASONABLE FEE.—

(i) IN GENERAL.—An applicant and the holder or holders of the relevant applications or licenses shall make every effort to agree upon a fee that is reasonable and fair that permits the applicant to rely upon information from the regulatory test data referred to in subparagraph (A).

(ii) LIMITED TO CERTAIN DATA.—Clause (i) shall apply only to the regulatory test data that such applicant is required to submit with the application described in subsection (a)(2), and upon which such applicant does not have the right to rely in the absence of a license or a cost-sharing agreement.

(3) FAILURE TO REACH VOLUNTARY AGREEMENT.—

(A) NOTIFICATION TO COMMISSIONER.—The applicant shall notify the Commissioner or the appropriate designee of the Commissioner—

(i) if the applicant or the holder or holders of the relevant applications or licenses refuses to participate in the efforts to agree upon a fee described in paragraph (2)(B); or

(ii) if the applicant and the holder or holders of the relevant applications or licenses fail to reach agreement on a reasonable and fair fee for reliance by the applicant on the regulatory test data described in paragraph (2).

(B) EFFECT OF NOTIFICATION.—Upon receipt of a notification under subparagraph (A), the Commissioner or such designee—

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

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

termined appropriate by the Commissioner, shall determine a reasonable and fair fee for the reliance by the applicant on such regulatory test data.

(4) RELIANCE ON REGULATORY TEST DATA IN APPLICATION.—If the applicant or the holder or holders of the relevant applications or licenses refuses to participate in the efforts to agree upon a fee described in paragraph (2)(B), or if an applicant and the holder or holders of the relevant applications or licenses fail to reach agreement on a reasonable and fair fee for reliance by the applicant on the regulatory test data under paragraph (2)—

(A) the applicant shall—

(i) pay to the holder or holders of such relevant applications or licenses a fee in the amount of the reasonable and fair share of the costs of the regulatory test data determined through binding arbitration or by the Commissioner or appropriate designee under paragraph (3), as applicable; and

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

Commissioner that the Commissioner shall incorporate into the application the regulatory test data contained in such relevant applications or licenses that is the subject of the reasonable and fair fee; and

(B) subject to the payment of the fee described in subparagraph (A)(i), the Commissioner shall incorporate into the application such regulatory test data.

(d) PROCEDURES.—The reasonable and fair fee for the reliance by the application on the regulatory test data under subsection (c)(3) shall be determined after considering the following factors:

(1) The actual out-of-pocket costs of the applicable clinical investigations.

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

(3) Any Federal grants, tax credits, or other subsidies that reduce the net cost of the investigations.

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

(5) The amount of the time the holder or holders of the relevant applications or licenses has benefitted from exclusive rights, and the cumulative revenue earned on the products that relied upon the regulatory test data at issue.

(e) PUBLIC DISCLOSURE.—

(1) IN GENERAL.—In order to enhance the transparency of the costs of innovation, and to provide greater predictability as to the liability associated with nonvoluntary reliance upon regulatory test data, the Secretary shall adopt procedures and rules under which sufficient information about the costs and fees will be made public by the arbitrator or the Commissioner (or the appropriate designee of the Commissioner), as applicable.

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

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

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

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