112TH CONGRESS
2D 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

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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.

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 2012''.

SEC. 2. PURPOSE.

The purpose of this Act is to eliminate requirements to undertake duplicative clinical testing of new pharma-

ceutical drugs, vaccines, biological products or medical devices, when such duplication is inconsistent with relevant ethical norms, by providing for the opportunity to rely upon existing trials, subject to sharing of the costs of those trials, during the period when regulatory test data is protected.

SEC. 3. ETHICAL PATHWAY FOR THE APPROVAL AND LICENSOR OF REGULATED PRODUCTS.

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

(1) APPLICANT.—The term ''applicant'' means a person who submits to the Secretary an application to sell a regulated product.

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

(3) REGULATED PRODUCT.—The term ''regulated product'' includes any new pharmaceutical drug, vaccine, biologic product or medical device, that requires regulatory approval by the Secretary.

(4) 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.

(5) 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.

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

(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). An applicant may request such an arrangement if, but for the arrangement—

(1) the 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 regulatory approval of a regulated product; or

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

plicable 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 for a regulated product shall take all necessary measures to verify that those investigations have not been performed or initiated by another person.

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

(3) FAILURE TO REACH VOLUNTARY AGREEMENT.—The applicant shall notify the Commissioner or the appropriate designee of the Commissioner if there is a failure to reach a voluntary agreement to use such test data. Upon receipt of a notification of a failure to reach a voluntary agreement, the Commissioner or such designee shall ask the parties to agree to binding arbitration to determine the reason-

able and fair fee for relying upon relevant regulatory test data. If one or more of the parties refuses to participate in such arbitration, the Commissioner shall determine a reasonable and fair fee for the reliance by the applicant on such regulatory test data.

(4) REASONABLE AND FAIR FEE.—The reasonable and fair fee for the reliance by the applicant on the regulatory test data shall be determined after considering the following factors:

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

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

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

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

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

mulative revenue earned on the products that relied upon the regulatory test data at issue.

(d) 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 (c)(4), 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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