TAM12227 S.L.C.

5-17-12
2:58 pm

Bef Sanders

AMENDMENT NO._____ Calendar No._____

Purpose: To require transparency in applications to the Food and Drug Administration.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. 3187

To : **AMENDMENT Nº 2110** Act to
iption
By Sanders : pro-
To: other
S. 3187
Re 5 and
Page(s)

GPO: 2010 63-070 (mac)

AMENDMENT intended to be proposed by Mr Sanders

Viz:

At the end of title XI, add the following:

SEC. 11___. TRANSPARENCY IN NEW DRUG APPLICATIONS.

(a) GENERAL REQUIREMENTS.—Subchapter A of chapter V (21 U.S.C. 351 et seq.), as amended by section 802, is further amended by adding at the end the following:

"SEC. 524B. TRANSPARENCY IN DRUG APPLICATIONS TO THE FDA.

"(a) INITIAL DISCLOSURE OF FINANCIAL INFORMATION.—

"(1) IN GENERAL.—A drug application submitted under subsection (b) or (j) of section 505, an application for a biologics license under subsection (a) or (k) of section 351 of the Public Health Service Act, an investigational new drug application under section 505(i), an application for an extension of market exclusivity following the completion of pediatric studies under section 505A(c), an application for a priority review voucher under section 524, a request for a designation as an orphan drug under section 526, and any other application to the Food and Drug Administration with respect to approval of a drug or an extension of the market exclusivity of a drug shall include a disclosure to the Secretary of such financial information associated with the research and development of the drug as required by the Secretary, as described in paragraph (2). The Secretary shall make such information public.

"(2) REQUIRED INFORMATION.—The financial information provided to the Secretary and made public under paragraph (1) shall include—

"(A) the total amount expended for preclinical research and for each phase of clinical trials of the drug;

"(B) a description of any grant or other economic incentive for research and development of such drug the sponsor receives from private, public, or any other funding source or research institution, including the National Institutes of Health, and the amount obtained from each source; and

"(C) such other information, as the Secretary may require.

"(3) RESEARCH AND DEVELOPMENT DEFINED.—For purposes of this section, 'research and development' of a drug shall include identification of chemical compounds, proof of concepts, testing of concepts, and all phases of clinical trials, including failed tests or trials. Research and development of a particular drug does not include the costs of failed drugs other than the drug that is the subject of the application described in paragraph (1).

"(b) SUBSEQUENT FINANCIAL DISCLOSURES.—A sponsor of a drug approved under subsection (b) or (j) of section 505, or a biological product approved under subsection (a) or (k) of section 351 of the Public Health Service Act, on an annual basis during the period during which the sponsor claims market exclusivity with respect to the drug and for 7 years thereafter, shall report to the Sec-

retary the quarterly domestic and global unit sales and sales revenue of the drug.

"(c) PUBLIC DISCLOSURE OF CLINICAL TRIALS.—

"(1) IN GENERAL.—The Secretary shall require the sponsor of a drug to register each clinical trial of such drug on the Internet web site of the National Institutes of Health, clinicaltrials.gov (or such successor Internet website developed by the Secretary).

"(2) TDP.—In the case of a sponsor that claims test data protection, the sponsor shall register the required information of the related drug with a clinicaltrials.gov identifier supplied by the Secretary.

"(d) DISCLOSURE OF NUMBERS OF INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.—A manufacturer or sponsor who submits a request under paragraph (1) shall also submit to the Secretary the following information with respect to clinical trials of the drug, which the Secretary shall make public:

"(1) The numbers of individuals participating in each phase of clinical trials, using de-identified data.

"(2) A description of each participant's dosage of the drug, using de-identified data.

"(3) A description of each participant's results, using de-identified data.".

(b) DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA.—Section 505(l)(1) (21 U.S.C. 355(l)(1)) is amended, in the matter preceding subparagraph (A), by striking ", unless extraordinary circumstances are shown".