110TH CONGRESS
1ST SESSION

S. 1024

To improve the underlying science of drug safety decisionmaking and strengthen the ability of the Food and Drug Administration to assess, manage, and communicate drug safety information to patients and providers.

IN THE SENATE OF THE UNITED STATES

MARCH 29, 2007

Mr. GREGG (for himself, Mr. BURR, and Mr. COBURN) 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 improve the underlying science of drug safety decisionmaking and strengthen the ability of the Food and Drug Administration to assess, manage, and communicate drug safety information to patients and providers.

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 ''Safer Drug Assessment Technology Advancement Act'' or the ''Safer DATA Act''.

SEC. 2. POSTMARKET RISK IDENTIFICATION AND ANALYSIS; DISSEMINATION OF POSTMARKET DRUG SAFETY INFORMATION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

"SEC. 505C. POSTMARKET RISK IDENTIFICATION AND ANALYSIS; DISSEMINATION OF POSTMARKET DRUG SAFETY INFORMATION.

''(a) POSTMARKET RISK IDENTIFICATION AND ANALYSIS.—

''(1) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—The Secretary shall, not later than 2 years after the date of enactment of the Safer DATA Act, act in collaboration with academic institutions and private entities to—

''(A) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

''(B) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources.

''(2) DATA COLLECTION ACTIVITIES.—

''(A) IN GENERAL.—The Secretary shall, not later than 1 year after the establishment of the minimum standards and the identification and analysis system under paragraph (1), establish and maintain an active surveillance infrastructure—

''(i) to collect and report data for pharmaceutical postmarket risk identification and analysis, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

''(ii) that includes, in addition to the current collection and monitoring (in a standardized form) of data on all pharmaceutical serious adverse events (as defined in section 760) required to be submitted to the Secretary, and those events voluntarily submitted from patients, providers, and drug, when appropriate, procedures to—

''(I) provide for adverse event surveillance by collecting and monitoring Federal health-related electronic data (such as data from the Medicare program and the health sys-

tems of the Department of Veterans Affairs);

''(II) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data);

''(III) provide for adverse event surveillance by monitoring standardized electronic health records, as available;

''(IV) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

''(V) enable the program to identify certain trends and patterns with respect to data reported to the program;

''(VI) enable the program to provide regular reports to the Secretary concerning adverse event trends, ad-

verse event patterns, incidence and prevalence of adverse events, laboratory data, and other information determined appropriate, which may include data on comparative national adverse event trends; and

"(VII) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

"(B) TIMELINESS OF REPORTING.—The procedures developed under subparagraph (A) shall ensure that such data are collected, monitored, and reported in a timely, routine, and automatic manner, taking into consideration the need for data completeness, coding, cleansing, and transmission.

"(C) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active surveillance infrastructure by the date described under subparagraph (A), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

"(D) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public

and private entities to fulfill the requirements of this paragraph.

''(3) RISK IDENTIFICATION AND ANALYSIS.—

''(A) PURPOSE.—To carry out this subsection, the Secretary shall establish collaborations with other Government, academic, and private entities to provide for the risk identification and analysis of the data collected under paragraph (2) and data that is publicly available or is provided by the Secretary, in order to—

''(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

''(ii) provide the Secretary with routine access to expertise to study advanced drug safety data; and

''(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

''(B) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

''(i) IN GENERAL.—Not later than 180 days after the date of establishment of the active surveillance infrastructure under

paragraph (2), the Secretary shall establish and implement procedures under which the Secretary may routinely collaborate with a qualified entity to—

"(I) clean, classify, or aggregate data collected under paragraph (2) and data that is publicly available or is provided by the Secretary;

"(II) perform advanced research on identified drug safety risks;

"(III) identify safety questions that require further clinical study;

"(IV) convene an expert advisory committee to oversee the establishment of standards for the ethical and scientific uses for, and communication of, postmarketing data collected under paragraph (2), including advising on the development of effective research methods for the study of drug safety questions; and

"(V) carry out other activities as the Secretary deems necessary to carry out the purpose of this paragraph.

''(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

''(C) QUALIFIED ENTITIES.—

''(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

''(ii) QUALIFICATIONS.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity—

''(I) has the research capability and expertise to conduct and complete the activities under this subsection;

''(II) has in place an information technology infrastructure to support adverse event surveillance data and operational standards to provide security for such data;

''(III) has experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data;

''(IV) has an understanding of drug development and risk/benefit balancing in a clinical setting; and

''(V) has a significant business presence in the United States.

''(D) CONTRACT REQUIREMENTS.—Each contract with a qualified entity shall contain the following requirements:

''(i) ENSURING PRIVACY.—The qualified entity shall provide assurances that the entity will not use the data provided by the Secretary in a manner that violates—

''(I) the Federal regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (concerning the privacy of individually-identifiable beneficiary health information); or

''(II) sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-

identifiable beneficiary health information.

''(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

''(I) the qualified entity shall maintain the data related to the activities carried out under this subsection separate from the other components of the organization and establish appropriate security measures to maintain the confidentiality and privacy of such data; and

''(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

''(iii) TERMINATION OR NONRENEWAL.—If a contract under this subsection is terminated or not renewed, the following requirements shall apply:

''(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confiden-

tiality and privacy requirements under this subsection with respect to all data disclosed to the entity.

"(II) DISPOSITION OF DATA.—The entity shall return to the Secretary all data disclosed to the entity or, if returning the data is not practicable, destroy the data.

"(E) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (C).

"(F) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.

"(4) COORDINATION.—In carrying out this subsection, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and provide for the coordination of the

activities of private entities, professional associations, or other entities that may have sources of surveillance data.

''(b) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Safer DATA Act, the Secretary shall improve the transparency of pharmaceutical data and allow patients and health care providers better access to pharmaceutical data by developing and maintaining an Internet site that—

''(A) provides comprehensive drug safety information for prescription drugs that are approved by the Secretary under this Act and on the market; and

''(B) improves communication of drug safety information to patients and providers.

''(2) INTERNET SITE.—Not later than 1 year after the date of enactment of the Safer DATA Act, the Secretary shall carry out paragraph (1) by—

''(A) developing and maintaining an accessible, consolidated Internet site with easily searchable drug safety information, including the information found on United States Govern-

ment Internet sites, such as the United States National Library of Medicine's Daily Med and Medline Plus sites, in addition to other such sites maintained by the Secretary;

"(B) ensuring that the information provided on the Internet site is comprehensive and includes, when available and appropriate—

"(i) patient labeling, including medication guides and patient packaging inserts;

"(ii) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this Act, such as product recalls, warning letters, and import alerts;

"(iii) publicly available information about implemented RiskMAPs;

"(iv) guidance documents and regulations related to drug safety; and

"(v) other material determined appropriate by the Secretary;

"(C) including links to non-Food and Drug Administration Internet resources that provide

access to relevant drug safety information, such as medical journals and studies;

''(D) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (a)(2) to provide information of known and serious side-effects for drugs approved by the Secretary under this Act;

''(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet site;

''(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

''(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet site.

''(3) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet site by the date described under paragraph (2), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(4) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and pri-

vate entities to fulfill the requirements of this subsection.

''(5) REVIEW.—The Advisory Committee on Communication of the Food and Drug Administration shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet site described in paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for such Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

''(c) AUTHORIZATION OF APPROPRIATIONS.—

''(1) ACTIVITIES COVERED BY PRESCRIPTION DRUG USER FEES.—To carry out activities under this section for which funds are made available under section 736, there are authorized to be appropriated, in addition to such funds, such sums as may be necessary for fiscal year 2008 and each subsequent fiscal year.

''(2) OTHER ACTIVITIES.—To carry out the activities under this section not described in paragraph

(1), there are authorized to be appropriated $20,000,000 for fiscal year 2008 and such sums as may be necessary for each subsequent fiscal year.''.

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