

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

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.

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 “Safer Drug Assess-
5 ment Technology Advancement Act” or the “Safer DATA
6 Act”.

1 **SEC. 2. POSTMARKET RISK IDENTIFICATION AND ANAL-**
2 **YSIS; DISSEMINATION OF POSTMARKET**
3 **DRUG SAFETY INFORMATION.**

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

7 **“SEC. 505C. POSTMARKET RISK IDENTIFICATION AND**
8 **ANALYSIS; DISSEMINATION OF POSTMARKET**
9 **DRUG SAFETY INFORMATION.**

10 “(a) POSTMARKET RISK IDENTIFICATION AND ANAL-
11 YSIS.—

12 “(1) DEVELOPMENT OF THE POSTMARKET RISK
13 IDENTIFICATION AND ANALYSIS SYSTEM.—The Sec-
14 retary shall, not later than 2 years after the date of
15 enactment of the Safer DATA Act, act in collabora-
16 tion with academic institutions and private entities
17 to—

18 “(A) establish minimum standards for col-
19 lection and transmission of postmarketing data
20 elements from electronic health data systems;
21 and

22 “(B) establish, through partnerships, a
23 validated and integrated postmarket risk identi-
24 fication and analysis system to integrate and
25 analyze safety data from multiple sources.

26 “(2) DATA COLLECTION ACTIVITIES.—

1 “(A) IN GENERAL.—The Secretary shall,
2 not later than 1 year after the establishment of
3 the minimum standards and the identification
4 and analysis system under paragraph (1), es-
5 tablish and maintain an active surveillance in-
6 frastructure—

7 “(i) to collect and report data for
8 pharmaceutical postmarket risk identifica-
9 tion and analysis, in compliance with the
10 regulations promulgated under section
11 264(c) of the Health Insurance Portability
12 and Accountability Act of 1996; and

13 “(ii) that includes, in addition to the
14 current collection and monitoring (in a
15 standardized form) of data on all pharma-
16 ceutical serious adverse events (as defined
17 in section 760) required to be submitted to
18 the Secretary, and those events voluntarily
19 submitted from patients, providers, and
20 drug, when appropriate, procedures to—

21 “(I) provide for adverse event
22 surveillance by collecting and moni-
23 toring Federal health-related elec-
24 tronic data (such as data from the
25 Medicare program and the health sys-

1 tems of the Department of Veterans
2 Affairs);

3 “(II) provide for adverse event
4 surveillance by collecting and moni-
5 toring private sector health-related
6 electronic data (such as pharma-
7 ceutical purchase data and health in-
8 surance claims data);

9 “(III) provide for adverse event
10 surveillance by monitoring standard-
11 ized electronic health records, as
12 available;

13 “(IV) provide for adverse event
14 surveillance by collecting and moni-
15 toring other information as the Sec-
16 retary deems necessary to create a ro-
17 bust system to identify adverse events
18 and potential drug safety signals;

19 “(V) enable the program to iden-
20 tify certain trends and patterns with
21 respect to data reported to the pro-
22 gram;

23 “(VI) enable the program to pro-
24 vide regular reports to the Secretary
25 concerning adverse event trends, ad-

1 verse event patterns, incidence and
2 prevalence of adverse events, labora-
3 tory data, and other information de-
4 termined appropriate, which may in-
5 clude data on comparative national
6 adverse event trends; and

7 “(VII) enable the program to ex-
8 port data in a form appropriate for
9 further aggregation, statistical anal-
10 ysis, and reporting.

11 “(B) TIMELINESS OF REPORTING.—The
12 procedures developed under subparagraph (A)
13 shall ensure that such data are collected, mon-
14 itored, and reported in a timely, routine, and
15 automatic manner, taking into consideration the
16 need for data completeness, coding, cleansing,
17 and transmission.

18 “(C) PRIVATE SECTOR RESOURCES.—To
19 ensure the establishment of the active surveil-
20 lance infrastructure by the date described under
21 subparagraph (A), the Secretary may, on a
22 temporary or permanent basis, implement sys-
23 tems or products developed by private entities.

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

1 and private entities to fulfill the requirements
2 of this paragraph.

3 “(3) RISK IDENTIFICATION AND ANALYSIS.—

4 “(A) PURPOSE.—To carry out this sub-
5 section, the Secretary shall establish collabora-
6 tions with other Government, academic, and
7 private entities to provide for the risk identi-
8 fication and analysis of the data collected under
9 paragraph (2) and data that is publicly avail-
10 able or is provided by the Secretary, in order
11 to—

12 “(i) improve the quality and efficiency
13 of postmarket drug safety risk-benefit
14 analysis;

15 “(ii) provide the Secretary with rou-
16 tine access to expertise to study advanced
17 drug safety data; and

18 “(iii) enhance the ability of the Sec-
19 retary to make timely assessments based
20 on drug safety data.

21 “(B) PROCEDURES FOR THE DEVELOP-
22 MENT OF DRUG SAFETY COLLABORATIONS.—

23 “(i) IN GENERAL.—Not later than
24 180 days after the date of establishment of
25 the active surveillance infrastructure under

1 paragraph (2), the Secretary shall estab-
2 lish and implement procedures under which
3 the Secretary may routinely collaborate
4 with a qualified entity to—

5 “(I) clean, classify, or aggregate
6 data collected under paragraph (2)
7 and data that is publicly available or
8 is provided by the Secretary;

9 “(II) perform advanced research
10 on identified drug safety risks;

11 “(III) identify safety questions
12 that require further clinical study;

13 “(IV) convene an expert advisory
14 committee to oversee the establish-
15 ment of standards for the ethical and
16 scientific uses for, and communication
17 of, postmarketing data collected under
18 paragraph (2), including advising on
19 the development of effective research
20 methods for the study of drug safety
21 questions; and

22 “(V) carry out other activities as
23 the Secretary deems necessary to
24 carry out the purpose of this para-
25 graph.

1 “(ii) REQUEST FOR SPECIFIC METH-
2 ODOLOGY.—The procedures described in
3 clause (i) shall permit the Secretary to re-
4 quest that a specific methodology be used
5 by the qualified entity. The qualified entity
6 shall work with the Secretary to finalize
7 the methodology to be used.

8 “(C) QUALIFIED ENTITIES.—

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

14 “(ii) QUALIFICATIONS.—The Sec-
15 retary shall enter into a contract with an
16 entity under clause (i) only if the Secretary
17 determines that the entity—

18 “(I) has the research capability
19 and expertise to conduct and complete
20 the activities under this subsection;

21 “(II) has in place an information
22 technology infrastructure to support
23 adverse event surveillance data and
24 operational standards to provide secu-
25 rity for such data;

1 “(III) has experience with, and
2 expertise on, the development of drug
3 safety and effectiveness research using
4 electronic population data;

5 “(IV) has an understanding of
6 drug development and risk/benefit bal-
7 ancing in a clinical setting; and

8 “(V) has a significant business
9 presence in the United States.

10 “(D) CONTRACT REQUIREMENTS.—Each
11 contract with a qualified entity shall contain the
12 following requirements:

13 “(i) ENSURING PRIVACY.—The quali-
14 fied entity shall provide assurances that
15 the entity will not use the data provided by
16 the Secretary in a manner that violates—

17 “(I) the Federal regulations pro-
18 mulgated under section 264(c) of the
19 Health Insurance Portability and Ac-
20 countability Act of 1996 (concerning
21 the privacy of individually-identifiable
22 beneficiary health information); or

23 “(II) sections 552 or 552a of
24 title 5, United States Code, with re-
25 gard to the privacy of individually-

1 identifiable beneficiary health infor-
2 mation.

3 “(ii) COMPONENT OF ANOTHER ORGA-
4 NIZATION.—If a qualified entity is a com-
5 ponent of another organization—

6 “(I) the qualified entity shall
7 maintain the data related to the ac-
8 tivities carried out under this sub-
9 section separate from the other com-
10 ponents of the organization and estab-
11 lish appropriate security measures to
12 maintain the confidentiality and pri-
13 vacy of such data; and

14 “(II) the entity shall not make
15 an unauthorized disclosure of such
16 data to the other components of the
17 organization in breach of such con-
18 fidentiality and privacy requirement.

19 “(iii) TERMINATION OR NON-
20 RENEWAL.—If a contract under this sub-
21 section is terminated or not renewed, the
22 following requirements shall apply:

23 “(I) CONFIDENTIALITY AND PRI-
24 VACY PROTECTIONS.—The entity shall
25 continue to comply with the confiden-

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

4 “(II) DISPOSITION OF DATA.—
5 The entity shall return to the Sec-
6 retary all data disclosed to the entity
7 or, if returning the data is not prac-
8 ticable, destroy the data.

9 “(E) COMPETITIVE PROCEDURES.—The
10 Secretary shall use competitive procedures (as
11 defined in section 4(5) of the Federal Procure-
12 ment Policy Act) to enter into contracts under
13 subparagraph (C).

14 “(F) REVIEW OF CONTRACT IN THE
15 EVENT OF A MERGER OR ACQUISITION.—The
16 Secretary shall review the contract with a quali-
17 fied entity under this subsection in the event of
18 a merger or acquisition of the entity in order to
19 ensure that the requirements under this sub-
20 section will continue to be met.

21 “(4) COORDINATION.—In carrying out this sub-
22 section, the Secretary shall provide for appropriate
23 communications to the public, scientific, public
24 health, and medical communities, and other key
25 stakeholders, and provide for the coordination of the

1 activities of private entities, professional associa-
2 tions, or other entities that may have sources of sur-
3 veillance data.

4 “(b) POSTMARKET DRUG SAFETY INFORMATION FOR
5 PATIENTS AND PROVIDERS.—

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

13 “(A) provides comprehensive drug safety
14 information for prescription drugs that are ap-
15 proved by the Secretary under this Act and on
16 the market; and

17 “(B) improves communication of drug
18 safety information to patients and providers.

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

22 “(A) developing and maintaining an acces-
23 sible, consolidated Internet site with easily
24 searchable drug safety information, including
25 the information found on United States Govern-

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

5 “(B) ensuring that the information pro-
6 vided on the Internet site is comprehensive and
7 includes, when available and appropriate—

8 “(i) patient labeling, including medi-
9 cation guides and patient packaging in-
10 serts;

11 “(ii) the most recent safety informa-
12 tion and alerts issued by the Food and
13 Drug Administration for drugs approved
14 by the Secretary under this Act, such as
15 product recalls, warning letters, and im-
16 port alerts;

17 “(iii) publicly available information
18 about implemented RiskMAPs;

19 “(iv) guidance documents and regula-
20 tions related to drug safety; and

21 “(v) other material determined appro-
22 priate by the Secretary;

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

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

3 “(D) providing access to summaries of the
4 assessed and aggregated data collected from the
5 active surveillance infrastructure under sub-
6 section (a)(2) to provide information of known
7 and serious side-effects for drugs approved by
8 the Secretary under this Act;

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

12 “(F) providing educational materials for
13 patients and providers about the appropriate
14 means of disposing of expired, damaged, or un-
15 usable medications; and

16 “(G) supporting initiatives that the Sec-
17 retary determines to be useful to fulfill the pur-
18 poses of the Internet site.

19 “(3) PRIVATE SECTOR RESOURCES.—To ensure
20 development of the Internet site by the date de-
21 scribed under paragraph (2), the Secretary may, on
22 a temporary or permanent basis, implement systems
23 or products developed by private entities.

24 “(4) AUTHORITY FOR CONTRACTS.—The Sec-
25 retary may enter into contracts with public and pri-

1 vate entities to fulfill the requirements of this sub-
2 section.

3 “(5) REVIEW.—The Advisory Committee on
4 Communication of the Food and Drug Administra-
5 tion shall, on a regular basis, perform a comprehen-
6 sive review and evaluation of the types of risk com-
7 munication information provided on the Internet site
8 described in paragraph (1) and, through other
9 means, shall identify, clarify, and define the pur-
10 poses and types of information available to facilitate
11 the efficient flow of information to patients and pro-
12 viders, and shall recommend ways for such Adminis-
13 tration to work with outside entities to help facilitate
14 the dispensing of risk communication information to
15 patients and providers.

16 “(c) AUTHORIZATION OF APPROPRIATIONS.—

17 “(1) ACTIVITIES COVERED BY PRESCRIPTION
18 DRUG USER FEES.—To carry out activities under
19 this section for which funds are made available
20 under section 736, there are authorized to be appro-
21 priated, in addition to such funds, such sums as may
22 be necessary for fiscal year 2008 and each subse-
23 quent fiscal year.

24 “(2) OTHER ACTIVITIES.—To carry out the ac-
25 tivities under this section not described in paragraph

1 (1), there are authorized to be appropriated
2 \$20,000,000 for fiscal year 2008 and such sums as
3 may be necessary for each subsequent fiscal year.”.

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