

109TH CONGRESS
1ST SESSION

H. R. 4429

To amend the Federal Food, Drug, and Cosmetic Act with respect to drug safety, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2005

Mr. TIERNEY (for himself and Mr. RAMSTAD) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to drug safety, and for other purposes.

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 “Food and Drug Ad-
5 ministration Safety Act of 2005”.

6 **SEC. 2. CENTER FOR POSTMARKET DRUG EVALUATION**

7 **AND RESEARCH.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
10 ed by inserting after section 506C the following:

1 **“SEC. 507. DRUG SAFETY.**

2 “(a) ESTABLISHMENT OF THE CENTER FOR
3 POSTMARKET DRUG EVALUATION AND RESEARCH.—

4 There is established within the Food and Drug Adminis-
5 tration a Center for Postmarket Drug Evaluation and Re-
6 search (referred to in the section as the ‘Center’). The
7 Director of the Center shall report directly to the Commis-
8 sioner of Food and Drugs.

9 “(b) DUTIES OF THE CENTER FOR POSTMARKET
10 DRUG EVALUATION AND RESEARCH.—

11 “(1) RESPONSIBILITIES OF DIRECTOR.—The
12 Director of the Center shall—

13 “(A) conduct postmarket risk assessment
14 of drugs approved under section 505 of this Act
15 and of biological products licensed under section
16 351 of the Public Health Service Act;

17 “(B) conduct and improve postmarket sur-
18 veillance of approved drugs and licensed biologi-
19 cal products using postmarket surveillance pro-
20 grams and activities (including MedWatch),
21 risk-benefit analyses, adverse event reports, the
22 scientific literature, any clinical or observational
23 studies (including studies required under sub-
24 section (d) or (e)), and any other resources that
25 the Director of the Center determines appro-
26 priate;

1 “(C) determine whether a study is required
2 under subsection (d) or (e) and consult with the
3 sponsors of drugs and biological products to en-
4 sure that such studies are completed by the
5 date, and according to the terms, specified by
6 the Director of the Center;

7 “(D) contract, or require the sponsor of an
8 application or the holder of an approved appli-
9 cation or license to contract, with the holders of
10 domestic and international surveillance data-
11 bases to conduct epidemiologic and other obser-
12 vational studies;

13 “(E) determine, based on postmarket sur-
14 veillance programs and activities (including
15 MedWatch), risk-benefit analyses, adverse event
16 reports, the scientific literature, and any clinical
17 or observational studies (including studies re-
18 quired under subsection (d) or (e)), and any
19 other resources that the Director of the Center
20 determines appropriate, whether a drug or bio-
21 logical product may present an unreasonable
22 risk to the health of patients or the general
23 public, and take corrective action if such an un-
24 reasonable risk may exist;

1 “(F) make information about the safety
2 and effectiveness of approved drugs and li-
3 censed biological products available to the pub-
4 lic and healthcare providers in a timely manner;
5 and

6 “(G) conduct other activities as the Direc-
7 tor of the Center determines appropriate to en-
8 sure the safety and effectiveness of all drugs
9 approved under section 505 and all biological
10 products licensed under section 351 of the Pub-
11 lic Health Service Act.

12 “(2) DETERMINATION OF UNREASONABLE
13 RISK.—In determining whether a drug or biological
14 product may present an unreasonable risk to the
15 health of patients or the general public, the Director
16 of the Center shall consider the risk in relation to
17 the known benefits of such drug or biological prod-
18 uct.

19 “(c) SECRETARIAL AUTHORITY.—

20 “(1) IN GENERAL.—Approval of a drug under
21 section 505 of this Act or issuance of a license for
22 a biological product under section 351 of the Public
23 Health Service Act may be subject to the require-
24 ment that the sponsor conduct 1 or more postmarket
25 studies as described in subsection (d) or (e) of this

1 section, or other postmarket studies as required by
2 the Secretary, to validate the safety and effective-
3 ness of the drug or biological product.

4 “(2) DEFINITION.—For purposes of this sec-
5 tion, the term ‘postmarket’ means—

6 “(A) with respect to a drug, after approval
7 of an application under section 505; and

8 “(B) with respect to a biological product,
9 after licensure under section 351 of the Public
10 Health Service Act.

11 “(d) PREAPPROVAL REVIEW.—

12 “(1) REVIEW OF APPLICATION.—

13 “(A) IN GENERAL.—

14 “(i) REVIEW.—At any time before a
15 drug is approved under section 505 of this
16 Act or a biological product is licensed
17 under section 351 of the Public Health
18 Service Act, the Director of the Center
19 shall review the application (or supplement
20 to the application), and any analyses asso-
21 ciated with the application, of such drug or
22 biological product.

23 “(ii) EFFECT OF APPROVAL OR LI-
24 CENSURE.—The approval of a drug under
25 section 505 or the licensure of a biological

1 product under such section 351 shall not
2 affect the continuation and completion of a
3 review under clause (i).

4 “(B) LIMITATION.—In no case shall the
5 review under subparagraph (A) delay a decision
6 with respect to an application for a drug under
7 section 505 of this Act or for a biological prod-
8 uct under section 351 of the Public Health
9 Service Act.

10 “(2) RESULT OF REVIEW.—The Director of the
11 Center may, based on the review under paragraph
12 (1)—

13 “(A) require that the sponsor of the appli-
14 cation agree to conduct 1 or more postmarket
15 studies to determine the safety or effectiveness
16 of a drug or biological product, including such
17 safety or effectiveness as compared to other
18 drugs or biological products, to be completed by
19 a date, and according to the terms, specified by
20 the Director of the Center; or

21 “(B) contract, or require the sponsor of
22 the application to contract, with a holder of a
23 domestic or an international patient database to
24 conduct 1 or more epidemiologic or other obser-
25 vational studies.

1 “(e) POSTMARKETING STUDIES OF DRUG SAFETY.—

2 “(1) IN GENERAL.—At any time after a drug is
3 approved under section 505 of this Act or a biological
4 product is licensed under section 351 of the Public
5 Health Service Act, the Director of the Center,
6 may—

7 “(A) require that the holder of an approved
8 application or license conduct 1 or more
9 studies to determine the safety or effectiveness
10 of such drug or biological product, including
11 such safety and effectiveness as compared to
12 other drugs or biological products, to be completed
13 by a date, and according to the terms,
14 specified by such Director; or

15 “(B) contract, or require the holder of the
16 approved application or license to contract, with
17 a holder of a domestic or an international patient
18 database to conduct 1 or more epidemiologic
19 or other observational studies.

20 “(2) REVIEW OF OUTSTANDING STUDIES.—Not
21 later than 90 days after the date of enactment of
22 the Food and Drug Administration Safety Act of
23 2005, the Director of the Center shall—

24 “(A) review and publish a list in the Federal
25 Register of any postmarketing studies out-

1 standing on the date of enactment of the Food
2 and Drug Administration Safety Act of 2005;
3 and

4 “(B) as the Director determines appro-
5 priate, require the sponsor of a study described
6 in subparagraph (A) to conduct such study
7 under this subsection.

8 “(f) PUBLICATION OF PROGRESS REPORTS AND
9 COMPLETED STUDIES.—

10 “(1) IN GENERAL.—The Director of the Center
11 shall require that the sponsor of a study under sub-
12 section (d) or (e) submit to the Secretary—

13 “(A) not less frequently than every 90
14 days, an up-to-date report describing the
15 progress of such study; and

16 “(B) upon the completion date of such
17 study, the results of such study.

18 “(2) COMPLETION DATE.—For purposes of this
19 section, the completion date of such study shall be
20 determined by the Director of the Center.

21 “(g) DETERMINATIONS BY DIRECTOR.—

22 “(1) RESULTS OF STUDY.—The Director of the
23 Center shall determine, upon receipt of the results of
24 a study required under subsection (d) or (e)—

1 “(A) whether the drug or biological prod-
2 uct studied may present an unreasonable risk to
3 the health of patients or the general public; and

4 “(B) what, if any, corrective action under
5 subsection (k) shall be taken to protect patients
6 and the public health.

7 “(2) RESULTS OF EVIDENCE.—The Director of
8 the Center may, at any time, based on the empirical
9 evidence from postmarket surveillance programs and
10 activities (including MedWatch), risk-benefit anal-
11 yses, adverse event reports, the scientific literature,
12 any clinical or observational studies (including stud-
13 ies required under subsection (d) or (e)), or any
14 other resources that the Director of the Center de-
15 termines appropriate—

16 “(A) make a determination that a drug or
17 biological product may present an unreasonable
18 risk to the health of patients or the general
19 public; and

20 “(B) order a corrective action under sub-
21 section (k) be taken to protect patients and the
22 public health.

23 “(3) REQUIRED CONSULTATION AND CONSIDER-
24 ATIONS.—Before making a determination under
25 paragraph (2), ordering a study under subsection

1 (d) or (e), or taking a corrective action under sub-
2 section (k), the Director of the Center shall—

3 “(A) consult with the Director of the Cen-
4 ter for Drug Evaluation and Research or the
5 Director of the Center for Biologics Evaluation
6 and Research, as appropriate; and

7 “(B) consider—

8 “(i) the benefit-to-risk profile of the
9 drug or biological product;

10 “(ii) the effect that a corrective ac-
11 tion, or failure to take corrective action,
12 will have on the patient population that re-
13 lies on the drug or biological product; and

14 “(iii) the extent to which the drug or
15 biological product presents a meaningful
16 therapeutic benefit as compared to other
17 available treatments.

18 “(h) PUBLIC INFORMATION.—Periodically, but not
19 less often than every 90 days, the Secretary shall make
20 available to the public, by publication in the Federal Reg-
21 ister and posting on an Internet website, the following in-
22 formation:

23 “(1) Studies required under subsection (d) or
24 (e) including—

25 “(A) the type of study;

1 “(B) the nature of the study;

2 “(C) the primary and secondary outcomes
3 of the study;

4 “(D) the date the study was required
5 under subsection (d) or (e) or was agreed to by
6 the sponsor;

7 “(E) the deadline for completion of the
8 study; and

9 “(F) if the study has not been completed
10 by the deadline under subparagraph (E), a
11 statement that explains why.

12 “(2) The periodic progress reports and results
13 of completed studies described under subsection (f).

14 “(3) Any determinations made by the Director
15 of the Center under subsection (g), including—

16 “(A) reasons for the determination, includ-
17 ing factual basis for such determination;

18 “(B) reference to supporting empirical
19 data; and

20 “(C) an explanation that describes why
21 contrary data is insufficient.

22 “(i) DRUG ADVISORY COMMITTEE.—The Drug Safe-
23 ty and Risk Management Drugs Advisory Committee with-
24 in the Center of the Food and Drug Administration
25 shall—

1 “(1) meet not less frequently than every 180
2 days; and

3 “(2) make recommendations to the Director of
4 the Center with respect to—

5 “(A) which drugs and biological products
6 should be the subject of a study under sub-
7 section (d) or (e);

8 “(B) the design and duration for studies
9 under subsection (d) or (e);

10 “(C) which drugs and biological products
11 may present an unreasonable risk to the health
12 of patients or the general public; and

13 “(D) appropriate corrective actions under
14 subsection (k).

15 “(j) PENALTIES.—

16 “(1) IN GENERAL.—If the Secretary deter-
17 mines, after notice and opportunity for an informal
18 hearing, that a sponsor of a drug or biological prod-
19 uct or other entity has failed to complete a study re-
20 quired under subsection (d) or (e) by the date or to
21 the terms specified by the Secretary under such sub-
22 section, the Secretary may order such sponsor or
23 other entity to—

24 “(A) complete the study in a specified
25 time;

1 “(B) revise the study to comply with the
2 terms specified by the Secretary under sub-
3 section (d) or (e); or

4 “(C) pay a civil penalty.

5 “(2) AMOUNT OF PENALTIES.—

6 “(A) IN GENERAL.—The civil penalty or-
7 dered under paragraph (1) shall be \$250,000
8 for the first 30-day period after the date speci-
9 fied by the Secretary that the study is not com-
10 pleted, and shall double in amount for every 30-
11 day period thereafter that the study is not com-
12 pleted.

13 “(B) LIMITATION.—In no case shall a pen-
14 alty under subparagraph (A) exceed \$2,000,000
15 for any 30-day period.

16 “(3) NOTIFICATION OF PENALTY.—The Sec-
17 retary shall publish in the Federal Register any civil
18 penalty ordered under this subsection.

19 “(k) RESULT OF DETERMINATION.—

20 “(1) IN GENERAL.—If the Director of the Cen-
21 ter makes a determination that a drug or biological
22 product may present an unreasonable risk to the
23 health of patients or the general public under sub-
24 section (g), such Director shall order a corrective ac-
25 tion, as described under paragraph (2).

1 “(2) CORRECTIVE ACTIONS.—The corrective ac-
2 tion described under subsection (g)—

3 “(A) may include—

4 “(i) requiring a change to the drug or
5 biological product label by a date specified
6 by the Director of the Center;

7 “(ii) modifying the approved indica-
8 tion of the drug or biological product to re-
9 strict use to certain patients;

10 “(iii) placing restriction on the dis-
11 tribution of the drug or biological product
12 to ensure safe use;

13 “(iv) requiring the sponsor of the
14 drug or biological product or license to es-
15 tablish a patient registry;

16 “(v) requiring patients to sign a con-
17 sent form prior to receiving a prescription
18 of the drug or biological product;

19 “(vi) requiring the sponsor to monitor
20 sales and usage of the drug or biological
21 product to detect unsafe use;

22 “(vii) requiring patient or physician
23 education; and

1 “(viii) requiring the establishment of
2 a risk management plan by the sponsor;
3 and

4 “(B) shall include the requirements with
5 respect to promotional material under sub-
6 section (l)(1).

7 “(3) PENALTIES.—

8 “(A) IN GENERAL.—If the Secretary deter-
9 mines, after notice and opportunity for an in-
10 formal hearing, that a sponsor of a drug or bio-
11 logical product has failed to take the corrective
12 action ordered by the Director of the Center
13 under this subsection or has failed to comply
14 with subsection (l)(2), the Secretary may order
15 such sponsor to pay a civil penalty.

16 “(B) AMOUNT OF PENALTIES.—

17 “(i) IN GENERAL.—The civil penalty
18 order under subparagraph (A) shall be
19 \$250,000 for the first 30-day period that
20 the sponsor does not comply with the order
21 under paragraph (1), and shall double in
22 amount for every 30-day period thereafter
23 that the order is not complied with.

1 “(ii) LIMITATION.—In no case shall a
2 penalty under clause (i) exceed \$2,000,000
3 for any 30-day period.

4 “(C) NOTIFICATION OF PENALTY.—The
5 Secretary shall publish in the Federal Register
6 any civil penalty ordered under this paragraph.

7 “(l) PROMOTION MATERIAL.—

8 “(1) SAFETY ISSUE.—If the Director of the
9 Center makes a determination that a drug or bio-
10 logical product may present an unreasonable risk to
11 the health of patients or the general public under
12 subsection (g), such Director, in consultation with
13 the Division of Drug Marketing, Advertising, and
14 Communications of the Food and Drug Administra-
15 tion, shall—

16 “(A) notwithstanding section 502(n), re-
17 quire that the sponsor of such drug or biological
18 product submit to the Director of the Cen-
19 ter copies of all promotional material with re-
20 spect to the drug or biological product not less
21 than 30 days prior to the dissemination of such
22 material; and

23 “(B) require that all promotional material
24 with respect to the drug or biological product
25 include certain disclosures, which shall be dis-

1 played prominently and in a manner easily un-
2 derstood by the general public, including—

3 “(i) a statement that describes the
4 unreasonable risk to the health of patients
5 or the general public as determined by the
6 Director of the Center;

7 “(ii) a statement that encourages pa-
8 tients to discuss potential risks and bene-
9 fits with their healthcare provider;

10 “(iii) a description of the corrective
11 actions required under subsection (k);

12 “(iv) where appropriate, a statement
13 explaining that there may be products
14 available to treat the same disease or con-
15 dition that present a more favorable ben-
16 efit-to-risk profile, and that patients should
17 talk to their healthcare provider about the
18 risks and benefits of alternative treat-
19 ments;

20 “(v) a description of any requirements
21 of outstanding clinical and observational
22 studies, including the purpose of each
23 study; and

24 “(vi) contact information to report a
25 suspected adverse reaction.

1 “(2) NEW PRODUCTS; OUTSTANDING STUD-
2 IES.—For the first 2-year period after a drug is ap-
3 proved under section 505 of this Act or a biological
4 product is licensed under section 351 of the Public
5 Health Service Act, and with respect to drugs and
6 biological products for which there are outstanding
7 study requirements under subsection (d) or (e), the
8 Director of the Center, in consultation with the Divi-
9 sion of Drug Marketing, Advertising, and Commu-
10 nications of the Food and Drug Administration,
11 shall—

12 “(A) notwithstanding section 502(n), re-
13 quire that the sponsor of such drug or biologi-
14 cal product submit to the Director of the Cen-
15 ter copies of all promotional material with re-
16 spect to the drug or biological product not less
17 than 30 days prior to the dissemination of such
18 material; and

19 “(B) require that all promotional material
20 with respect to the drug or biological product
21 include certain disclosures, which shall be dis-
22 played prominently and in a manner easily un-
23 derstood by the general public, including—

24 “(i) a statement explaining that the
25 drug or biological product is newly ap-

1 proved or licensed or the subject of out-
2 standing clinical or observational studies,
3 as the case may be, and, as a result, not
4 all side effects or drug interactions may be
5 known;

6 “(ii) the number of people in which
7 the drug or biological product has been
8 studied and the duration of time during
9 which the drug or biological product has
10 been studied;

11 “(iii) a statement that encourages pa-
12 tients to discuss the potential risks and
13 benefits of treatment with their healthcare
14 provider;

15 “(iv) a description of any require-
16 ments of outstanding clinical and observa-
17 tional studies, including the purpose of
18 each study; and

19 “(v) contact information to report a
20 suspected adverse reaction.

21 “(3) EFFECT OF VOLUNTARY SUBMISSION.—

22 Paragraphs (1)(A) and (2)(A) shall not apply to the
23 sponsor of a drug or biological product if such spon-
24 sor has voluntarily submitted to the Division of
25 Drug Marketing, Advertising, and Communications

1 of the Food and Drug Administration all pro-
2 motional material with respect the drug or biological
3 product prior to the dissemination of such material.

4 “(m) WITHDRAWAL OR SUSPENSION OF APPROVAL
5 OR LICENSURE.—

6 “(1) IN GENERAL.—The Director of the Center,
7 may withdraw or suspend approval of a drug or li-
8 cense of a biological product using expedited proce-
9 dures (as prescribed by the Secretary in regulations
10 promulgated not later than 1 year after the date of
11 enactment of the Food and Drug Administration
12 Safety Act of 2005, which shall include an oppor-
13 tunity for an informal hearing) after consultation
14 with the Director of Center for Drug Evaluation and
15 Research or the Director of the Center for Biologics
16 Evaluation and Research, as appropriate, and any
17 other person as determined appropriate by the Di-
18 rector of the Center, if—

19 “(A) the Director of the Center makes a
20 determination that the drug or biological prod-
21 uct may present an unreasonable risk to the
22 health of patients or the general public, and
23 that risk cannot be satisfactorily alleviated by a
24 corrective action under subsection (k); or

1 “(B) the sponsor fails to comply with an
2 order or requirement under this section.

3 “(2) PUBLIC INFORMATION.—The Secretary
4 shall make available to the public, by publication in
5 the Federal Register and posting on an Internet
6 website, the details of the consultation described in
7 paragraph (1), including—

8 “(A) the reason for the determination to
9 withdraw, suspend, or failure to withdraw or
10 suspend, approval for the drug or licensure for
11 the biological product;

12 “(B) the factual basis for such determina-
13 tion;

14 “(C) reference to supporting empirical
15 data;

16 “(D) an explanation that describes why
17 contrary data is insufficient; and

18 “(E) the position taken by each individual
19 consulted.

20 “(n) EFFECT OF SECTION.—The authorities con-
21 ferred by this section shall be separate from and in addi-
22 tion to the authorities conferred by section 505B.

23 “(o) ADMINISTRATION OF SECTION.—The provisions
24 of this section shall be carried out by the Secretary, acting
25 through the Director of the Center.”.

1 (b) MISBRANDING.—Section 502 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
3 ed by inserting after subsection (j) the following:

4 “(k) If it is a drug or biological product for which
5 the sponsor of an application or holder of an approved ap-
6 plication or license has not complied with an order or re-
7 quirement under section 507.”.

8 (c) REPORT ON DEVICES.—Not later than 6 months
9 after the date of enactment of this Act, the Secretary of
10 Health and Human Services, in consultation with the
11 Commissioner of Food and Drugs, the Director of the
12 Center for Postmarket Drug Evaluation and Research,
13 and the Director of the Center for Devices and Radio-
14 logical Health, shall submit to Congress a report that—

15 (1) identifies deficiencies in the current process
16 of postmarket surveillance of devices approved under
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 321 et seq.);

19 (2) includes recommendations on ways to im-
20 prove deficiencies of postmarket surveillance of de-
21 vices; and

22 (3) identifies the changes in authority needed to
23 make those improvements, recognizing the legitimate
24 differences between devices and other medical prod-

1 ucts regulated by the Food and Drug Administra-
2 tion.

3 (d) TRANSFER OF FUNCTIONS.—The functions and
4 duties of the Office of Drug Safety, including the Drug
5 Safety and Risk Management Drugs Advisory Committee,
6 of the Food and Drug Administration on the day before
7 the date of enactment of this Act shall be transferred to
8 the Center for Postmarket Drug Evaluation and Research
9 established under section 507 of the Federal Food, Drug,
10 and Cosmetic Act (as added by this section). The Center
11 for Postmarket Drug Evaluation and Research shall be
12 a separate entity within the Food and Drug Administra-
13 tion and shall not be an administrative office of the Center
14 for Drug Evaluation and Research or the Center for Bio-
15 logics Evaluation and Research.

16 (e) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this Act
18 (and the amendments made by this Act)—

- 19 (1) \$50,000,000 for fiscal year 2006;
20 (2) \$75,000,000 for fiscal year 2007;
21 (3) \$100,000,000 for fiscal year 2008;
22 (4) \$125,000,000 for fiscal year 2009; and
23 (5) \$150,000,000 for fiscal year 2010.

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