

110TH CONGRESS  
1ST SESSION

# H. R. 788

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

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2007

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

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## 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 2007”.

6 **SEC. 2. CENTER FOR POSTMARKET EVALUATION AND RE-**  
7 **SEARCH FOR DRUGS AND BIOLOGICS.**

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 EVALUATION AND RESEARCH FOR DRUGS  
4 AND BIOLOGICS.—There is established within the Food  
5 and Drug Administration a Center for Postmarket Eval-  
6 uation and Research for Drugs and Biologics (referred to  
7 in the section as the ‘Center’). The Director of the Center  
8 shall report directly to the Commissioner of Food and  
9 Drugs.

10       “(b) DUTIES OF THE CENTER FOR POSTMARKET  
11 EVALUATION AND RESEARCH FOR DRUGS AND BIO-  
12 LOGICS.—

13               “(1) RESPONSIBILITIES OF DIRECTOR.—The  
14 Director of the Center in consultation with the Di-  
15 rector of the Center for Drug Evaluation and Re-  
16 search or the Director of the Center for Biologics  
17 Evaluation and Research, as appropriate, shall—

18                       “(A) conduct postmarket risk assessment  
19 of drugs approved under section 505 of this Act  
20 and of biological products licensed under section  
21 351 of the Public Health Service Act;

22                       “(B) conduct and improve postmarket sur-  
23 veillance of approved drugs and licensed biologi-  
24 cal products using postmarket surveillance pro-  
25 grams and activities (including Midwatch), risk-  
26 benefit analyses, adverse event reports, the sci-

1           entific literature, any clinical or observational  
2           studies (including studies required under sub-  
3           section (d) or (e)), and any other resources that  
4           the Director of the Center determines appro-  
5           priate;

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

12          “(D) contract, or require the sponsor of an  
13          application or the holder of an approved appli-  
14          cation or license to contract, with the holders of  
15          domestic and international patient databases to  
16          conduct epidemiologic and other observational  
17          studies;

18          “(E) determine, based on postmarket sur-  
19          veillance programs and activities (including  
20          Midwatch), risk-benefit analyses, adverse event  
21          reports, the scientific literature, and any clinical  
22          or observational studies (including studies re-  
23          quired under subsection (d) or (e)), and any  
24          other resources that the Director of the Center  
25          determines appropriate, whether a drug or bio-

1           logical product may present an unreasonable  
2           risk to the health of patients or the general  
3           public, and take corrective action if such an un-  
4           reasonable risk may exist;

5           “(F) make information about the safety  
6           and effectiveness of approved drugs and li-  
7           censed biological products available to the pub-  
8           lic and healthcare providers in a timely manner;  
9           and

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

16          “(2) DETERMINATION OF UNREASONABLE  
17          RISK.—In determining whether a drug or biological  
18          product may present an unreasonable risk to the  
19          health of patients or the general public, the Director  
20          of the Center in consultation with the Director of  
21          the Center for Drug Evaluation and Research or the  
22          Director of the Center for Biologic Evaluation and  
23          Research, as appropriate, shall consider the risk in  
24          relation to the known benefits of such drug or bio-  
25          logical product.

1 “(c) SECRETARIAL AUTHORITY.—

2 “(1) IN GENERAL.—Approval of a drug under  
3 section 505 of this Act or issuance of a license for  
4 a biological product under section 351 of the Public  
5 Health Service Act may be subject to the require-  
6 ment that the sponsor conduct 1 or more postmarket  
7 studies as described in subsection (d) or (e) of this  
8 section, or other postmarket studies as required by  
9 the Secretary, to validate the safety and effective-  
10 ness of the drug or biological product.

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

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

15 “(B) with respect to a biological product,  
16 after licensure under section 351 of the Public  
17 Health Service Act.

18 “(d) PREAPPROVAL REVIEW.—

19 “(1) REVIEW OF APPLICATION.—

20 “(A) IN GENERAL.—

21 “(I) REVIEW.—At any time before a  
22 drug is approved under section 505 of this  
23 Act or a biological product is licensed  
24 under section 351 of the Public Health  
25 Service Act, the Director of the Center

1 shall review the application (or supplement  
2 to the application), and any analyses asso-  
3 ciated with the application, of such drug or  
4 biological product.

5 “(ii) EFFECT OF APPROVAL OR LI-  
6 CENSOR.—The approval of a drug under  
7 section 505 or the licenser of a biological  
8 product under such section 351 shall not  
9 affect the continuation and completion of a  
10 review under clause (I).

11 “(B) LIMITATION.—In no case shall the  
12 review under subparagraph (A) delay a decision  
13 with respect to an application for a drug under  
14 section 505 of this Act or for a biological prod-  
15 uct under section 351 of the Public Health  
16 Service Act.

17 “(2) RESULT OF REVIEW.—The Director of the  
18 Center may, based on the review under paragraph  
19 (1)—

20 “(A) require that the sponsor of the appli-  
21 cation agree to conduct 1 or more postmarket  
22 studies to determine the safety or effectiveness  
23 of a drug or biological product, including such  
24 safety or effectiveness as compared to other  
25 drugs or biological products, to be completed by

1 a date, and according to the terms, specified by  
2 the Director of the Center; or

3 “(B) contract, or require the sponsor of  
4 the application to contract, with a holder of a  
5 domestic or an international patient database to  
6 conduct 1 or more epidemiologic or other obser-  
7 vational studies.

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

9 “(1) IN GENERAL.—At any time after a drug is  
10 approved under section 505 of this Act or a biologi-  
11 cal product is licensed under section 351 of the Pub-  
12 lic Health Service Act, the Director of the Center,  
13 may—

14 “(A) require that the holder of an ap-  
15 proved application or license conduct 1 or more  
16 studies to determine the safety or effectiveness  
17 of such drug or biological product, including  
18 such safety and effectiveness as compared to  
19 other drugs or biological products, to be com-  
20 pleted by a date, and according to the terms,  
21 specified by such Director; or

22 “(B) contract, or require the holder of the  
23 approved application or license to contract, with  
24 a holder of a domestic or an international pa-

1           tient database to conduct 1 or more epidemio-  
2           logic or other observational studies.

3           “(2) REVIEW OF OUTSTANDING STUDIES.—Not  
4           later than 90 days after the date of enactment of  
5           the Food and Drug Administration Safety Act of  
6           2007, the Director of the Center shall—

7                   “(A) review and publish a list in the Fed-  
8                   eral Register of any postmarketing studies out-  
9                   standing on the date of enactment of the Food  
10                  and Drug Administration Safety Act of 2007;  
11                  and

12                   “(B) as the Director determines appro-  
13                  priate, require the sponsor of a study described  
14                  in subparagraph (A) to conduct such study  
15                  under this subsection.

16           “(f) PUBLICATION OF PROGRESS REPORTS AND  
17           COMPLETED STUDIES.—

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

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

24                   “(B) upon the completion date of such  
25                  study, the results of such study.

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

4           “(g) DETERMINATIONS BY DIRECTOR.—

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

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

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

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

23                   “(A) make a determination that a drug or  
24 biological product may present an unreasonable

1 risk to the health of patients or the general  
2 public; and

3 “(B) order a corrective action under sub-  
4 section (k) be taken to protect patients and the  
5 public health.

6 “(3) REQUIRED CONSULTATION AND CONSIDER-  
7 ATIONS.—Before making a determination under  
8 paragraph (2), ordering a study under subsection  
9 (d) or (e), or taking a corrective action under sub-  
10 section (k), the Director of the Center shall—

11 “(A) consult with the Director of the Cen-  
12 ter for Drug Evaluation and Research or the  
13 Director of the Center for Biologics Evaluation  
14 and Research, as appropriate; and

15 “(B) consider—

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

18 “(ii) the effect that a corrective ac-  
19 tion, or failure to take corrective action,  
20 will have on the patient population that re-  
21 lies on the drug or biological product; and

22 “(iii) the extent to which the drug or  
23 biological product presents a meaningful  
24 therapeutic benefit as compared to other  
25 available treatments.

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

6               “(1) Studies required under subsection (d) or  
7 (e) including—

8                       “(A) the type of study;

9                       “(B) the nature of the study;

10                      “(C) the primary and secondary outcomes  
11 of the study;

12                      “(D) the date the study was required  
13 under subsection (d) or (e) or was agreed to by  
14 the sponsor;

15                      “(E) the deadline for completion of the  
16 study; and

17                      “(F) if the study has not been completed  
18 by the deadline under subparagraph (E), a  
19 statement that explains why.

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

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

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

1           “(B) reference to supporting empirical  
2           data; and

3           “(C) an explanation that describes why  
4           contrary data is insufficient.

5           “(i) DRUG ADVISORY COMMITTEE.—The Drug Safe-  
6           ty and Risk Management Drugs Advisory Committee with-  
7           in the Center of the Food and Drug Administration  
8           shall—

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

11          “(2) make recommendations to the Director of  
12          the Center with respect to—

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

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

18                 “(C) which drugs and biological products  
19                 may present an unreasonable risk to the health  
20                 of patients or the general public; and

21                 “(D) appropriate corrective actions under  
22                 subsection (k).

23          “(j) PENALTIES.—

24                 “(1) IN GENERAL.—If the Secretary deter-  
25                 mines, after notice and opportunity for an informal

1 hearing, that a sponsor of a drug or biological prod-  
2 uct or other entity has failed to complete a study re-  
3 quired under subsection (d) or (e) by the date or to  
4 the terms specified by the Secretary under such sub-  
5 section, the Secretary may order such sponsor or  
6 other entity to—

7 “(A) complete the study in a specified  
8 time;

9 “(B) revise the study to comply with the  
10 terms specified by the Secretary under sub-  
11 section (d) or (e); or

12 “(C) pay a civil penalty.

13 “(2) AMOUNT OF PENALTIES.—

14 “(A) IN GENERAL.—The civil penalty or-  
15 dered under paragraph (1) shall be \$250,000  
16 for the first 30-day period after the date speci-  
17 fied by the Secretary that the study is not com-  
18 pleted, and shall double in amount for every 30-  
19 day period thereafter that the study is not com-  
20 pleted.

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

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

4           “(k) RESULT OF DETERMINATION.—

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

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

13                 “(A) may include—

14                         “(i) requiring a change to the drug or  
15                         biological product label by a date specified  
16                         by the Director of the Center;

17                         “(ii) modifying the approved indica-  
18                         tion of the drug or biological product to re-  
19                         strict use to certain patients;

20                         “(iii) placing restriction on the dis-  
21                         tribution of the drug or biological product  
22                         to ensure safe use;

23                         “(iv) requiring the sponsor of the  
24                         drug or biological product or license to es-  
25                         tablish a patient registry;

1           “(v) requiring patients to sign a con-  
2           sent form prior to receiving a prescription  
3           of the drug or biological product;

4           “(vi) requiring the sponsor to monitor  
5           sales and usage of the drug or biological  
6           product to detect unsafe use;

7           “(vii) requiring patient or physician  
8           education; and

9           “(viii) requiring the establishment of  
10          a risk management plan by the sponsor;  
11          and

12          “(B) shall include the requirements with  
13          respect to promotional material under sub-  
14          section (l)(1).

15          “(3) PENALTIES.—

16                 “(A) IN GENERAL.—If the Secretary deter-  
17                 mines, after notice and opportunity for an in-  
18                 formal hearing, that a sponsor of a drug or bio-  
19                 logical product has failed to take the corrective  
20                 action ordered by the Director of the Center  
21                 under this subsection or has failed to comply  
22                 with subsection (l)(2), the Secretary may order  
23                 such sponsor to pay a civil penalty.

24                 “(B) AMOUNT OF PENALTIES.—

1           “(i) IN GENERAL.—The civil penalty  
2           ordered under subparagraph (A) shall be  
3           \$250,000 for the first 30-day period that  
4           the sponsor does not comply with the order  
5           under paragraph (1), and shall double in  
6           amount for every 30-day period thereafter  
7           that the order is not complied with.

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

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

14          “(l) PROMOTION MATERIAL.—

15          “(1) SAFETY ISSUE.—If the Director of the  
16          Center makes a determination that a drug or bio-  
17          logical product may present an unreasonable risk to  
18          the health of patients or the general public under  
19          subsection (g), such Director, in consultation with  
20          the Division of Drug Marketing, Advertising, and  
21          Communications of the Food and Drug Administra-  
22          tion, shall—

23                 “(A) notwithstanding section 502(n), re-  
24                 quire that the sponsor of such drug or biologi-  
25                 cal product submit to the Director of the Cen-

1 ter copies of all promotional material with re-  
2 spect to the drug or biological product not less  
3 than 30 days prior to the dissemination of such  
4 material; and

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

10 “(i) a statement that describes the  
11 unreasonable risk to the health of patients  
12 or the general public as determined by the  
13 Director of the Center;

14 “(ii) a statement that encourages pa-  
15 tients to discuss potential risks and bene-  
16 fits with their healthcare provider;

17 “(iii) a description of the corrective  
18 actions required under subsection (k);

19 “(iv) where appropriate, a statement  
20 explaining that there may be products  
21 available to treat the same disease or con-  
22 dition that present a more favorable ben-  
23 efit-to-risk profile, and that patients should  
24 talk to their healthcare provider about the

1 risks and benefits of alternative treat-  
2 ments;

3 “(v) a description of any requirements  
4 of outstanding clinical and observational  
5 studies, including the purpose of each  
6 study; and

7 “(vi) contact information to report a  
8 suspected adverse reaction.

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

20 “(A) notwithstanding section 502(n), re-  
21 quire that the sponsor of such drug or biologi-  
22 cal product submit to the Director of the Cen-  
23 ter copies of all promotional material with re-  
24 spect to the drug or biological product not less

1 than 30 days prior to the dissemination of such  
2 material; and

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

8 “(i) a statement explaining that the  
9 drug or biological product is newly ap-  
10 proved or licensed or the subject of out-  
11 standing clinical or observational studies,  
12 as the case may be, and, as a result, not  
13 all side effects or drug interactions may be  
14 known;

15 “(ii) the number of people in which  
16 the drug or biological product has been  
17 studied and the duration of time during  
18 which the drug or biological product has  
19 been studied;

20 “(iii) a statement that encourages pa-  
21 tients to discuss the potential risks and  
22 benefits of treatment with their healthcare  
23 provider;

24 “(iv) a description of any require-  
25 ments of outstanding clinical and observa-

1                    tional studies, including the purpose of  
2                    each study; and

3                    “(v) contact information to report a  
4                    suspected adverse reaction.

5                    “(3) EFFECT OF VOLUNTARY SUBMISSION.—  
6                    Paragraphs (1)(A) and (2)(A) shall not apply to the  
7                    sponsor of a drug or biological product if such spon-  
8                    sor has voluntarily submitted to the Division of  
9                    Drug Marketing, Advertising, and Communications  
10                   of the Food and Drug Administration all pro-  
11                   motional material with respect to the drug or bio-  
12                   logical product prior to the dissemination of such  
13                   material.

14                   “(m) WITHDRAWAL OR SUSPENSION OF APPROVAL  
15 OR LICENSURE.—

16                   “(1) IN GENERAL.—The Director of the Center,  
17                   may withdraw or suspend approval of a drug or li-  
18                   censure of a biological product using expedited pro-  
19                   cedures (as prescribed by the Secretary in regula-  
20                   tions promulgated not later than 1 year after the  
21                   date of enactment of the Food and Drug Adminis-  
22                   tration Safety Act of 2007, which shall include an  
23                   opportunity for an informal hearing) after consulta-  
24                   tion with the Director of the Center for Drug Eval-  
25                   uation and Research or the Director of the Center

1 for Biologics Evaluation and Research, as appro-  
2 priate, and any other person as determined appro-  
3 priate by the Director of the Center, if—

4 “(A) the Director of the Center makes a  
5 determination that the drug or biological prod-  
6 uct may present an unreasonable risk to the  
7 health of patients or the general public, and  
8 that risk cannot be satisfactorily alleviated by a  
9 corrective action under subsection (k); or

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

12 “(2) PUBLIC INFORMATION.—The Secretary  
13 shall make available to the public, by publication in  
14 the Federal Register and posting on an Internet  
15 website, the details of the consultation described in  
16 paragraph (1), including—

17 “(A) the reason for the determination to  
18 withdraw, suspend, or failure to withdraw or  
19 suspend, approval for the drug or licensure for  
20 the biological product;

21 “(B) the factual basis for such determina-  
22 tion;

23 “(C) reference to supporting empirical  
24 data;

1           “(D) an explanation that describes why  
2           contrary data is insufficient; and

3           “(E) the position taken by each individual  
4           consulted.

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

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

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

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

18          (c) REPORT ON DEVICES.—Not later than 6 months  
19          after the date of enactment of this Act, the Secretary of  
20          Health and Human Services, in consultation with the  
21          Commissioner of Food and Drugs, the Director of the  
22          Center for Postmarket Evaluation and Research for Drugs  
23          and Biologics, and the Director of the Center for Devices  
24          and Radiological Health, shall submit to Congress a report  
25          that—

1           (1) identifies gaps in the current process of  
2           postmarket surveillance of devices approved under  
3           the Federal Food, Drug, and Cosmetic Act (21  
4           U.S.C. 321 et seq.);

5           (2) includes recommendations on ways to im-  
6           prove gaps in postmarket surveillance of devices; and

7           (3) identifies the changes in authority needed to  
8           make those improvements, recognizing the legitimate  
9           differences between devices and other medical prod-  
10          ucts regulated by the Food and Drug Administra-  
11          tion.

12          (d) TRANSFER OF FUNCTIONS.—The functions and  
13          duties of the Office of Surveillance and Epidemiology, in-  
14          cluding the Drug Safety and Risk Management Drugs Ad-  
15          visory Committee, of the Food and Drug Administration  
16          on the day before the date of enactment of this Act shall  
17          be transferred to the Center for Postmarket Evaluation  
18          and Research for Drugs and Biologics established under  
19          section 507 of the Federal Food, Drug, and Cosmetic Act  
20          (as added by this section). The Center for Postmarket  
21          Evaluation and Research for Drugs and Biologics shall be  
22          a separate entity within the Food and Drug Administra-  
23          tion and shall not be an administrative office of the Center  
24          for Drug Evaluation and Research or the Center for Bio-  
25          logics Evaluation and Research.

1       (e) AUTHORIZATION OF APPROPRIATIONS.—There  
2 are authorized to be appropriated to carry out this Act  
3 (and the amendments made by this Act)—

- 4           (1) \$50,000,000 for fiscal year 2008;  
5           (2) \$75,000,000 for fiscal year 2009;  
6           (3) \$100,000,000 for fiscal year 2010;  
7           (4) \$125,000,000 for fiscal year 2011; and  
8           (5) \$150,000,000 for fiscal year 2012.

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