

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2113

To empower the Food and Drug Administration to ensure a clear and effective pathway that will encourage innovative products to benefit patients and improve public health.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2012

Mrs. HAGAN 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 empower the Food and Drug Administration to ensure a clear and effective pathway that will encourage innovative products to benefit patients and improve public health.

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; TABLE OF CONTENTS; REF-**  
4       **ERENCES IN ACT.**

5       (a) SHORT TITLE.—This Act may be cited as the  
6       “Transforming the Regulatory Environment to Accelerate  
7       Access to Treatments” or “TREAT Act”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
 2 this Act is as follows:

Sec. 1. Short title; table of contents; references in Act.

TITLE I—ELEVATING FDA AND EMPOWERING OPERATIONAL  
 EXCELLENCE

Sec. 101. Mission statement.

Sec. 102. Management Review Board.

TITLE II—ADVANCING REGULATORY SCIENCE AND INNOVATION

Sec. 201. Chief innovation officer.

Sec. 202. Enhancing access to external scientific and medical expertise.

TITLE III—ENABLING MODERNIZED PATIENT-CENTRIC CLINICAL  
 DEVELOPMENT

Sec. 301. Enhancement of accelerated patient access to new medical treat-  
 ments.

Sec. 302. Electronic health records.

Sec. 303. Disclosure to drug sponsors of reasons for non-approval of a new  
 drug application.

3 (c) REFERENCES IN ACT.—Except as otherwise spec-  
 4 ified, amendments made by this Act to a section or other  
 5 provision of law are amendments to such section or other  
 6 provision of the Federal Food, Drug, and Cosmetic Act  
 7 (21 U.S.C. 301 et seq.).

8 **TITLE I—ELEVATING FDA AND**  
 9 **EMPOWERING OPERATIONAL**  
 10 **EXCELLENCE**

11 **SEC. 101. MISSION STATEMENT.**

12 Section 1003(b) (21 U.S.C. 393(b)) is amended—

13 (1) by redesignating paragraphs (3) and (4) as  
 14 paragraphs (4) and (5), respectively;

15 (2) by inserting after paragraph (2), the fol-  
 16 lowing:

1           “(3) advance medical innovation, and strive to  
2           make novel products available to those who need  
3           them, by incorporating modern scientific tools,  
4           standards, methodologies, and approaches to ensure  
5           the timely and effective review, and the expeditious  
6           clearance, licensure, or approval, as appropriate, of  
7           innovative drugs, devices, and other regulated prod-  
8           ucts;” and

9           (3) in paragraph (5), as so redesignated, by  
10          striking “(1) through (3)” and inserting “(1)  
11          through (4)”.

12 **SEC. 102. MANAGEMENT REVIEW BOARD.**

13          Chapter VII (21 U.S.C. 371 et seq.) is amended by  
14          inserting after section 713 the following:

15 **“SEC. 714. MANAGEMENT REVIEW BOARD.**

16          “(a) IN GENERAL.—Not later than 60 days after the  
17          date of enactment of the TREAT Act, the Secretary shall  
18          establish an advisory council within the Food and Drug  
19          Administration to be known as the Management Review  
20          Board (referred to in this section as the ‘Board’).

21          “(b) DUTIES.—

22                 “(1) IN GENERAL.—The Board shall provide  
23                 advice to the Secretary regarding the management  
24                 and organization of the Food and Drug Administra-  
25                 tion.

1           “(2) REPORTS.—The Board shall—

2                   “(A) periodically review the organization  
3                   and responsibilities of individual offices, cen-  
4                   ters, and divisions within the Food and Drug  
5                   Administration (referred to in this section as  
6                   the ‘Administration’) in order to determine the  
7                   optimal allocation of responsibilities and to im-  
8                   prove the efficiency and effectiveness of each of-  
9                   fice, center, and division in achieving individual  
10                  and overall missions of the Administration;

11                  “(B) issue proposed and final reports on  
12                  whether and to what extent changes should be  
13                  made to the management and organization of  
14                  the Administration to further the Administra-  
15                  tion’s mission as set forth in section 1003(b);  
16                  and

17                  “(C) for any proposal for organizational  
18                  changes to which the Board gives significant  
19                  consideration as a recommendation, consider—

20                          “(i) the budgetary and operational  
21                          consequences of the proposed change; and

22                          “(ii) an estimation of the level of re-  
23                          sources that would be needed to implement  
24                          the proposed change.

1           “(3) CONSULTATION.—In carrying out para-  
2 graph (2), the Board shall consult with—

3           “(A) the heads of centers and divisions  
4 within the Administration who are not members  
5 of the Board;

6           “(B) other scientific leaders who are offi-  
7 cers or employees of the Administration and are  
8 not members of the Board; and

9           “(C) organizations representing regulated  
10 industries, venture capital, patients, and disease  
11 research, and that are not otherwise rep-  
12 resented on the Board.

13           “(4) TOPICS FOR REVIEW.—

14           “(A) REQUEST OF SECRETARY.—The Sec-  
15 retary may, at any time, submit requests about  
16 management or organizational issues to the  
17 Board for assessment.

18           “(B) PUBLIC INPUT.—The Board shall  
19 seek input from the public on management and  
20 organizational issues that should be assessed by  
21 the Board, at such times as determined appro-  
22 priate by the Board.

23           “(5) POWERS.—The Board may secure directly  
24 from the Administration such information as is nec-

1       essary or appropriate for the Board to review issues  
2       under consideration.

3               “(6) CONFLICT OF INTEREST EXEMPTION.—  
4       Notwithstanding any other provision of law, the  
5       Board shall not be subject to section 712.

6               “(c) COMPOSITION OF BOARD.—

7               “(1) IN GENERAL.—The Board shall consist  
8       of—

9                       “(A) the Secretary, who shall be a perma-  
10                      nent nonvoting member on an ex officio basis;  
11                      and

12                     “(B) 21 additional members, all of whom  
13                      shall be voting members, in accordance with  
14                      paragraph (2).

15               “(2) VOTING MEMBERS.—The membership of  
16       the Board shall consist of the following:

17                     “(A) OFFICERS AND EMPLOYEES OF THE  
18                      FOOD AND DRUG ADMINISTRATION.—The Sec-  
19                      retary shall designate not less than 9 individ-  
20                      uals who are directors of centers within the Ad-  
21                      ministration, directors of divisions within such  
22                      Administration, or other similarly senior offi-  
23                      cials within such Administration.

24                     “(B) OTHER MEMBERS.—The Secretary  
25                      shall designate other individuals from among

1 individuals who are not officers or employees of  
2 the United States. Such members shall in-  
3 clude—

4 “(i) individuals representing the inter-  
5 ests of public or private academic medical  
6 centers, physicians, and patient advocacy  
7 and disease research organizations;

8 “(ii) individuals representing the in-  
9 terests of industries regulated by the Ad-  
10 ministration, which shall include at least 1  
11 representative from each of the pharma-  
12 ceutical, biotechnology, medical device, and  
13 food industries; and

14 “(iii) individuals with broad expertise  
15 regarding how the Administration func-  
16 tions and with experience in successfully  
17 managing or consulting for large scientific  
18 research or other organizations (other than  
19 public or private entities described under  
20 clause (i)).

21 “(3) TERM; VACANCIES.—

22 “(A) TERMS.—The members appointed  
23 under paragraph (2)(B) shall be appointed for  
24 a term of 3 years, which may be renewed once.

1                   “(B) VACANCIES.—A vacancy on the  
2                   Board—

3                   “(i) shall not affect the powers of the  
4                   Board; and

5                   “(ii) shall be filled in the same man-  
6                   ner as the original appointment was made.

7                   “(d) CHAIR.—The Chair of the Board shall be se-  
8                   lected by the Secretary from among the members of the  
9                   Board appointed under subsection (c)(1). The term of of-  
10                  fice of the Chair shall be 3 years.

11                  “(e) MEETINGS.—

12                  “(1) IN GENERAL.—The Board shall meet at  
13                  the call of the Chair or upon the request of the Sec-  
14                  retary, but not fewer than 6 times with respect to  
15                  issuing any particular report under subsection  
16                  (b)(2). The location of the meetings of the Board is  
17                  subject to the approval of the Secretary.

18                  “(2) PARTICULAR MEETINGS TO RECEIVE PUB-  
19                  LIC INPUT.—Of the meetings held under paragraph  
20                  (1) with respect to proposals for management or or-  
21                  ganizational changes being considered under sub-  
22                  section (b)(2)—

23                  “(A) 1 or more shall be directed towards  
24                  receiving input from the pharmaceutical, med-  
25                  ical device, and biotechnology industries, clinical

1 researchers, and the physician and medical re-  
2 search communities to address regulatory and  
3 scientific needs and opportunities related to  
4 such proposals;

5 “(B) 1 or more shall be directed towards  
6 receiving input from patient advocacy, disease  
7 research organizations, and consumer groups to  
8 address patient and consumer needs and oppor-  
9 tunities related to such proposals; and

10 “(C) 1 or more shall be directed towards  
11 receiving input from food, cosmetic, and dietary  
12 supplement industries to address regulatory and  
13 scientific needs and opportunities related to  
14 such proposals.

15 “(3) AVAILABILITY OF INFORMATION.—For  
16 each meeting held under this subsection, the Sec-  
17 retary shall post on the Internet Web site of the Ad-  
18 ministration a summary of the proceedings.

19 “(f) COMPENSATION.—Without regard to the provi-  
20 sions of title 5, United States Code, governing appoint-  
21 ments in the competitive service, and without regard to  
22 provisions of chapter 51 and subchapter III of chapter 53  
23 of such title relating to classification and General Schedule  
24 pay rates, the Secretary may—

25 “(1) establish the Board; and

1           “(2) appoint and fix the compensation of the  
2 members of the Board, except that officers and em-  
3 ployees of the United States shall not receive addi-  
4 tional compensation for service as members of such  
5 groups.

6           “(g) REPORTS.—

7           “(1) PUBLIC COMMENT.—

8           “(A) PROPOSED REPORTS.—Each pro-  
9 posed report issued under subsection (b)(2)  
10 shall be posted on the Internet Web site of the  
11 Administration and made available for public  
12 comment for not less than 60 days prior to  
13 being made final and being submitted under  
14 paragraph (2).

15           “(B) FINAL REPORTS.—Not later than 90  
16 days after receiving comments from the public  
17 on a proposed report under subparagraph (A),  
18 the Board shall post a final report on such  
19 Internet Web site incorporating an overview of  
20 comments accepted or rejected.

21           “(2) CONGRESSIONAL AND SECRETARY RE-  
22 VIEW.—Each final report issued under subsection  
23 (b)(2) shall be submitted to the—

1           “(A) the Committee on Health, Education,  
2           Labor, and Pensions and the Committee on Ap-  
3           propriations of the Senate;

4           “(B) the Committee on Energy and Com-  
5           merce and the Committee on Appropriations of  
6           the House of Representatives; and

7           “(C) the Secretary.

8           “(3) TIMING AND FREQUENCY OF REPORTS.—  
9           Not later than January 31, 2015, the Board shall  
10          issue the first report under subsection (b)(2) and  
11          shall issue subsequent reports not less than once  
12          every 5 years thereafter.

13          “(h) PROCESS FOR REVIEW OF RECOMMENDED OR-  
14          GANIZATIONAL OR MANAGEMENT CHANGES.—With re-  
15          spect to recommendations for organizational or manage-  
16          ment changes made in a report issued under subsection  
17          (b)(2), the Secretary shall, except as provided in sub-  
18          section (i)(2), implement the recommendations in accord-  
19          ance with the following process:

20                 “(1) Not later than 100 days after the report  
21                 is submitted to the Secretary under subsection  
22                 (g)(2), the Secretary shall initiate the applicable  
23                 processes under subsection (i).

24                 “(2) The recommendations shall be fully imple-  
25                 mented not later than the expiration of the 3-year

1 period beginning on the date on which such process  
2 is initiated.

3 “(i) ACTION BY THE SECRETARY.—

4 “(1) IN GENERAL.—Not less than 60 days prior  
5 to implementing any major organizational or man-  
6 agement change recommended under subsection  
7 (b)(2), the Secretary shall provide notice to the con-  
8 gressional committees specified in subsection (g)(2)  
9 of the Secretary’s agreement with the recommenda-  
10 tion and the timeline for implementation.

11 “(2) OBJECTION.—Subsection (h) shall not  
12 apply to a recommendation for an organizational or  
13 management change made in a report issued under  
14 subsection (b)(2) if, not later than 90 days after the  
15 report is submitted to the Secretary under sub-  
16 section (g)(2), the Secretary submits to the commit-  
17 tees specified in such subsection a notice indicating  
18 that the Secretary objects to the recommended  
19 change, and setting forth the reasons for such objec-  
20 tion. For purposes of this paragraph, an objection  
21 by the Secretary may be made to the entirety of the  
22 recommended organizational changes contained in a  
23 report issued under subsection (b)(2), or to 1 or  
24 more aspects of any proposed change or changes.

1           “(3) IMPLEMENTATION.—Any aspect of a pro-  
2           posed change not objected to by the Secretary in a  
3           notice under paragraph (2) shall be implemented in  
4           accordance with subsection (h), except as the Sec-  
5           retary may be directed otherwise by law.”.

6   **TITLE II—ADVANCING REGULATORY SCIENCE AND INNO-**  
7           **VATION**

9   **SEC. 201. CHIEF INNOVATION OFFICER.**

10          Chapter X is amended—

11               (1) by redesignating the second section 1011  
12               (21 U.S.C. 399e) (as added by section 209(a) of  
13               Public Law 111–353) as section 1011A; and

14               (2) by adding at the end the following:

15   **“SEC. 1013. OFFICE OF THE CHIEF INNOVATION OFFICER.**

16               “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-  
17               retary shall establish within the Office of the Commis-  
18               sioner an office to be known as the Office of the Chief  
19               Innovation Officer. The Secretary shall appoint a Chief  
20               Innovation Officer to lead such Office.

21               “(b) DUTIES.—The Chief Innovation Officer shall—

22                       “(1) identify promising new scientific and regu-  
23                       latory approaches to ensure the rapid development,  
24                       testing, and review of new drugs and devices, which  
25                       may include the validation and qualification of bio-

1 markers, the adoption of novel models or methodolo-  
2 gies to enhance clinical trial design, clinical data  
3 evaluation, or predictive toxicology, and the coordi-  
4 nation and optimization of efficient review processes  
5 for drugs, and devices;

6 “(2) ensure that such approaches are integrated  
7 into operations at all applicable levels of the Food  
8 and Drug Administration, and harmonized with the  
9 approaches of other applicable agencies;

10 “(3)(A) consider the recommendations of inter-  
11 nal and external bodies involved in advancing inno-  
12 vation in regulatory science activities, such as those  
13 described in paragraph (1); and

14 “(B) make such recommendations available on  
15 the Internet Web site of the Food and Drug Admin-  
16 istration;

17 “(4) develop pilot programs to implement and  
18 incorporate the recommendations considered under  
19 paragraph (3) into the regulatory review and ap-  
20 proval processes of such Administration; and

21 “(5) in consultation with the heads of the cen-  
22 ters and offices within such Administration, imple-  
23 ment other pilot programs as the Chief Innovation  
24 Officer determines appropriate, and ensure partici-

1       pation by cross-disciplinary teams in such implemen-  
2       tation, as applicable.

3       “(c) REPORTS AND IMPLEMENTATION PLANS.—

4             “(1) REPORTS.—The Chief Innovation Officer  
5       shall publish a report summarizing the consideration  
6       of applicable recommendations evaluated under sub-  
7       section (b)(3) at least once every 2 years. Such re-  
8       ports shall—

9             “(A) provide an explanation as to whether,  
10       how, and why such recommendations will be im-  
11       plemented by the Food and Drug Administra-  
12       tion;

13            “(B) provide a description of pilot pro-  
14       grams being implemented and the progress of  
15       such Administration with respect to the integra-  
16       tion of new scientific and regulatory approaches  
17       into its operations in order to accelerate the  
18       rapid development, review, approval, and pa-  
19       tient access to new drugs and devices;

20            “(C) be made available for public comment  
21       for not less than 60 days prior to being made  
22       final;

23            “(D) following public comment, be final-  
24       ized by the Chief Innovation Officer to include

1 an overview of public comments accepted or re-  
 2 jected; and

3 “(E) once finalized, be made available on  
 4 the Internet Web site of such Administration  
 5 and submitted to—

6 “(i) the Committee on Health, Edu-  
 7 cation, Labor and Pensions of the Senate;  
 8 and

9 “(ii) the Committee on Energy and  
 10 Commerce of the House of Representa-  
 11 tives.

12 “(2) PUBLIC COMMENT REGARDING IMPLEMEN-  
 13 TATION OF PILOT PROGRAMS.—The Chief Innova-  
 14 tion Officer shall make each plan to implement a  
 15 pilot program under subsection (b)(4) available for  
 16 public comment for not less than 60 days before the  
 17 implementation of the pilot program.

18 “(d) MAINTENANCE OF AUTHORITY OF CENTERS.—  
 19 Nothing in this section limits the authority or ability of  
 20 the individual Centers of the Food and Drug Administra-  
 21 tion to carry out any of the actions described in this sec-  
 22 tion.”.

23 **SEC. 202. ENHANCING ACCESS TO EXTERNAL SCIENTIFIC**  
 24 **AND MEDICAL EXPERTISE.**

25 (a) ADVISORY COMMITTEES.—

1           (1) CONFLICTS OF INTEREST.—Section  
2       712(c)(2) (21 U.S.C. 379d–1(c)(2)) is amended—

3           (A) in subparagraph (A), by striking “fi-  
4       nancial interest that could be affected by the  
5       advice given to the Secretary with respect to  
6       such matter” and inserting “financial interest  
7       in the outcome of such matter that is direct and  
8       predictable”;

9           (B) by striking subparagraph (B) and in-  
10       serting the following:

11           “(B) WAIVER.—

12           “(i) IN GENERAL.—If the Secretary  
13       makes a determination described in clause  
14       (ii), the Secretary may grant a waiver of  
15       the prohibition in subparagraph (A) to per-  
16       mit a member described in such subpara-  
17       graph to—

18           “(I) participate as a non-voting  
19       member with respect to a particular  
20       matter considered in a committee  
21       meeting; or

22           “(II) participate as a voting  
23       member with respect to a particular  
24       matter considered in a committee  
25       meeting.

1           “(ii) DETERMINATION.—A determina-  
2           tion described under this clause may be  
3           based on 1 or both of the following deter-  
4           minations:

5                   “(I) The need for the services of  
6                   the individual on the committee out-  
7                   weighs the potential for a conflict of  
8                   interest created by the financial inter-  
9                   est involved.

10                   “(II) The financial interest is not  
11                   so substantial as to be deemed likely  
12                   to affect the integrity of the services  
13                   provided by that individual.”; and

14                   (C) by striking subparagraph (C).

15           (2) PATIENT GROUP REPRESENTATIVES.—Sec-  
16           tion 505(n)(3) (21 U.S.C. 355(n)(3)) is amended—

17                   (A) in subparagraph (C), by striking “;  
18                   and” and inserting a semicolon;

19                   (B) in subparagraph (D), by striking the  
20                   period at the end and inserting “; and”; and

21                   (C) by adding at the end the following:

22                   “(E) 2 or more members who are medical  
23                   or scientific experts selected from a pool of  
24                   nominations provided by patient advocacy or  
25                   disease research organizations whose interests

1 are in the specific disease or diseases proposed  
2 to be treated by the drug under consideration.”.

3 (3) REVISED REGULATIONS.—

4 (A) IN GENERAL.—The Secretary of  
5 Health and Human Services shall revise and  
6 update the regulations of the Food and Drug  
7 Administration relating to the application of the  
8 Federal Advisory Committee Act (5 U.S.C.  
9 App.) to reflect updated understanding of the  
10 scope of such Act, as embodied in regulations of  
11 the General Services Administration (as in ef-  
12 fect on the date of enactment of this Act) and  
13 case law.

14 (B) CONTENT.—The revised and updated  
15 regulations under subparagraph (A) shall ex-  
16 plicitly encourage officials of the Food and  
17 Drug Administration to utilize, to the maximum  
18 extent possible, the flexibility and exceptions  
19 provided by the Federal Advisory Committee  
20 Act to interact with stakeholder groups outside  
21 the confines of the advisory committees of such  
22 Act, including patient advocacy organizations,  
23 disease specialty societies, and others.

1 (b) CHIEF MEDICAL POLICY OFFICERS.—Chapter X  
2 (21 U.S.C. 391 et seq.), as amended by section 201, is  
3 further amended by adding at the end the following:

4 **“SEC. 1014. CHIEF MEDICAL POLICY OFFICERS.**

5 “(a) ESTABLISHMENT.—The Secretary shall estab-  
6 lish an Office of the Chief Medical Policy Officer within  
7 each of the following Offices of the Food and Drug Admin-  
8 istration:

9 “(1) The Office of the Director of the Center  
10 for Drug Evaluation and Research.

11 “(2) The Office of the Director of the Center  
12 for Biologics Evaluation and Research.

13 “(3) The Office of the Director of the Center  
14 for Devices and Radiological Health.

15 “(b) SELECTION.—Each Chief Medical Policy Officer  
16 shall be selected from the Senior Executive Service by the  
17 Secretary.

18 “(c) DUTIES.—Each Chief Medical Policy Officer  
19 shall—

20 “(1) in coordination with the Chief Innovation  
21 Officer, center Directors, and other Chief Medical  
22 Policy Officers, develop proactive and consistent ap-  
23 proaches for the centers within the Food and Drug  
24 Administration and the divisions within such Admin-  
25 istration that review applications for drug or device

1 approval to address emerging medical and scientific  
2 policy issues bearing on new product review pro-  
3 cesses, including by—

4 “(A) advising on and regularly reviewing  
5 the implementation of such approaches by such  
6 centers and divisions; and

7 “(B) implementing peer learning programs  
8 to ensure the effective and consistent review  
9 and approval of new drugs and devices, includ-  
10 ing the incorporation of new scientific and regu-  
11 latory approaches recommended by the Chief  
12 Innovation Officer under section 1013(b);

13 “(2) in coordination with the center Directors,  
14 sponsors, and relevant patient advocacy and disease  
15 research organizations, promote earlier and im-  
16 proved utilization of advisory committees throughout  
17 the drug and device development and review pro-  
18 cesses, including at the investigational testing phase,  
19 and recommend as appropriate the utilization of au-  
20 thorities by the Secretary under section 1007 in  
21 cases where the ability to obtain sufficient external  
22 experts for such advisory committees is limited;

23 “(3) in coordination with the Office of Special  
24 Medical Programs and appropriate Center medical  
25 and scientific officers, improve reviewer access to ex-

1 ternal experts outside of the advisory committee  
2 process, including utilization of authorities in section  
3 1004;

4 “(4) periodically solicit input from industry,  
5 academia, and patient advocacy and disease research  
6 organizations on emerging scientific and medical pol-  
7 icy issues bearing on new product review processes,  
8 including clinical trial methodologies; and

9 “(5) coordinate with the Chief Innovation Offi-  
10 cer in the implementation of pilot programs under  
11 section 1013(b).

12 “(d) EXTERNAL EXPERTS.—When serving as officers  
13 or employees of the United States, the experts described  
14 under subsection (c)(3) shall be considered special govern-  
15 ment employees as defined in section 202(a) of title 18,  
16 United States Code.”.

17 **TITLE III—ENABLING MODERN-**  
18 **IZED PATIENT-CENTRIC CLIN-**  
19 **ICAL DEVELOPMENT**

20 **SEC. 301. ENHANCEMENT OF ACCELERATED PATIENT AC-**  
21 **CESS TO NEW MEDICAL TREATMENTS.**

22 (a) FINDINGS; SENSE OF CONGRESS.—

23 (1) FINDINGS.—Congress makes the following  
24 findings:

1 (A) The Food and Drug Administration  
2 (referred to in this section as the “FDA”)  
3 serves a critical role in helping to assure that  
4 new medicines are safe and effective. Regu-  
5 latory innovation is 1 element of the Nation’s  
6 strategy to address serious and life-threatening  
7 diseases or conditions by promoting investment  
8 in and development of innovative treatments for  
9 unmet medical needs.

10 (B) During the 2 decades following the es-  
11 tablishment of the accelerated approval mecha-  
12 nism, advances in medical sciences, including  
13 genomics, molecular biology, and bioinformatics,  
14 have provided an unprecedented understanding  
15 of the underlying biological mechanism and  
16 pathogenesis of disease. A new generation of  
17 modern, targeted medicines is under develop-  
18 ment to treat serious and life-threatening dis-  
19 eases, some applying drug development strate-  
20 gies based on biomarkers or pharmacogenomics,  
21 predictive toxicology, clinical trial enrichment  
22 techniques, and novel clinical trial designs, such  
23 as adaptive clinical trials.

24 (C) As a result of these remarkable sci-  
25 entific and medical advances, the FDA should

1 be encouraged to implement more broadly effective  
2 processes for the expedited development  
3 and review of innovative new medicines intended  
4 to address unmet medical needs for serious  
5 or life-threatening diseases or conditions,  
6 including those for rare diseases or conditions,  
7 using a broad range of surrogate or clinical  
8 endpoints and modern scientific tools earlier in  
9 the drug development cycle when appropriate.  
10 This may result in fewer, smaller, or shorter  
11 clinical trials for the intended patient population  
12 or targeted subpopulation without compromising  
13 or altering the high standards of the  
14 FDA for the approval of drugs.

15 (D) Patients benefit from expedited access  
16 to safe and effective innovative therapies to  
17 treat unmet medical needs for serious or life-  
18 threatening diseases or conditions.

19 (E) For these reasons, the statutory authority  
20 in effect on the day before the date of  
21 enactment of this Act governing expedited approval  
22 of drugs for serious or life-threatening  
23 diseases or conditions should be amended in  
24 order to enhance the authority of the FDA to  
25 consider appropriate scientific data, methods,

1 and tools, and to expedite development and ac-  
2 cess to novel treatments for patients with a  
3 broad range of serious or life-threatening dis-  
4 eases or conditions.

5 (2) SENSE OF CONGRESS.—It is the sense of  
6 Congress that the Food and Drug Administration  
7 should apply the accelerated approval and fast track  
8 provisions set forth in section 506 of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 356), as  
10 amended by this section, to the greatest extent pos-  
11 sible to help expedite the development and avail-  
12 ability to patients of treatments for serious or life-  
13 threatening diseases or conditions while maintaining  
14 appropriate safety and effectiveness standards for  
15 such treatments.

16 (b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS  
17 OR LIFE-THREATENING DISEASES OR CONDITIONS.—Sec-  
18 tion 506 of the Federal Food, Drug, and Cosmetic Act  
19 (21 U.S.C. 356) is amended to read as follows:

20 **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**  
21 **OR LIFE-THREATENING DISEASES OR CONDI-**  
22 **TIONS.**

23 “(a) DESIGNATION OF DRUG AS FAST TRACK PROD-  
24 UCT.—

1           “(1) IN GENERAL.—The Secretary shall, at the  
2 request of the sponsor of a new drug, facilitate the  
3 development and expedite the review of such drug if  
4 it is intended, whether alone or in combination with  
5 one or more other drugs, for the treatment of a seri-  
6 ous or life-threatening disease or condition, and it  
7 demonstrates the potential to address unmet medical  
8 needs for such a disease or condition. (In this sec-  
9 tion, such a drug is referred to as a ‘fast track prod-  
10 uct’.)

11           “(2) REQUEST FOR DESIGNATION.—The spon-  
12 sor of a new drug may request the Secretary to des-  
13 ignate the drug as a fast track product. A request  
14 for the designation may be made concurrently with,  
15 or at any time after, submission of an application  
16 for the investigation of the drug under section 505(i)  
17 or section 351(a)(3) of the Public Health Service  
18 Act.

19           “(3) DESIGNATION.—Within 60 calendar days  
20 after the receipt of a request under paragraph (2),  
21 the Secretary shall determine whether the drug that  
22 is the subject of the request meets the criteria de-  
23 scribed in paragraph (1). If the Secretary finds that  
24 the drug meets the criteria, the Secretary shall des-  
25 ignate the drug as a fast track product and shall

1 take such actions as are appropriate to expedite the  
2 development and review of the application for ap-  
3 proval of such product.

4 “(b) ACCELERATED APPROVAL OF A DRUG FOR A  
5 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-  
6 TION, INCLUDING A FAST TRACK PRODUCT.—

7 “(1) IN GENERAL.—

8 “(A) ACCELERATED APPROVAL.—The Sec-  
9 retary may approve an application for approval  
10 of a product for a serious or life-threatening  
11 disease or condition, including a fast track  
12 product, under section 505(c) or section 351(a)  
13 of the Public Health Service Act upon a deter-  
14 mination that the product has an effect on a  
15 surrogate endpoint that is reasonably likely to  
16 predict clinical benefit, or on a clinical end-  
17 point, including an endpoint that can be meas-  
18 ured earlier than irreversible morbidity or mor-  
19 tality, that is reasonably likely to predict an ef-  
20 fect on irreversible morbidity or mortality or  
21 other clinical benefit, taking into account the  
22 severity or rarity of the condition and the avail-  
23 ability of alternative treatments. The approval  
24 described in the preceding sentence is referred  
25 to in this section as ‘accelerated approval’.

1           “(B) EVIDENCE.—The evidence to support  
2           that an endpoint is reasonably likely to predict  
3           clinical benefit under subparagraph (A) may in-  
4           clude epidemiological, pathophysiological, thera-  
5           peutic or other evidence developed using bio-  
6           markers, for example, or other scientific meth-  
7           ods or tools.

8           “(2) LIMITATION.—Approval of a product  
9           under this subsection may be subject to 1 or both  
10          of the following requirements:

11           “(A) That the sponsor conduct appropriate  
12           post-approval studies to verify and describe the  
13           predicted effect on irreversible morbidity or  
14           mortality or other clinical benefit.

15           “(B) That the sponsor submit copies of all  
16           promotional materials related to the product  
17           during the preapproval review period and, fol-  
18           lowing approval and for such period thereafter  
19           as the Secretary determines to be appropriate,  
20           at least 30 days prior to dissemination of the  
21           materials.

22           “(3) EXPEDITED WITHDRAWAL OF AP-  
23           PROVAL.—The Secretary may withdraw approval of  
24           a product approved under accelerated approval using  
25           expedited procedures (as prescribed by the Secretary

1 in regulations which shall include an opportunity for  
2 an informal hearing) if—

3 “(A) the sponsor fails to conduct any re-  
4 quired post-approval study of the drug with due  
5 diligence;

6 “(B) a study required to verify and de-  
7 scribe the predicted effect on irreversible mor-  
8 bidity or mortality or other clinical benefit of  
9 the product fails to verify and describe such ef-  
10 fect or benefit;

11 “(C) other evidence demonstrates that the  
12 product is not safe or effective under the condi-  
13 tions of use; or

14 “(D) the sponsor disseminates false or  
15 misleading promotional materials with respect  
16 to the product.

17 “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR  
18 APPROVAL OF A FAST TRACK PRODUCT.—

19 “(1) IN GENERAL.—If the Secretary deter-  
20 mines, after preliminary evaluation of clinical data  
21 submitted by the sponsor, that a fast track product  
22 may be effective, the Secretary shall evaluate for fil-  
23 ing, and may commence review of portions of, an ap-  
24 plication for the approval of the product before the  
25 sponsor submits a complete application. The Sec-

1       retary shall commence such review only if the appli-  
2       cant—

3               “(A) provides a schedule for submission of  
4               information necessary to make the application  
5               complete; and

6               “(B) pays any fee that may be required  
7               under section 736.

8               “(2) EXCEPTION.—Any time period for review  
9               of human drug applications that has been agreed to  
10              by the Secretary and that has been set forth in goals  
11              identified in letters of the Secretary (relating to the  
12              use of fees collected under section 736 to expedite  
13              the drug development process and the review of  
14              human drug applications) shall not apply to an ap-  
15              plication submitted under paragraph (1) until the  
16              date on which the application is complete.

17              “(d) AWARENESS EFFORTS.—The Secretary shall—

18                      “(1) develop and disseminate to physicians, pa-  
19                      tient organizations, pharmaceutical and bio-  
20                      technology companies, and other appropriate persons  
21                      a description of the provisions of this section appli-  
22                      cable to accelerated approval and fast track prod-  
23                      ucts; and

24                      “(2) establish a program to encourage the de-  
25                      velopment of surrogate and clinical endpoints, in-

1 cluding biomarkers, and other scientific methods and  
2 tools that can assist the Secretary in determining  
3 whether the evidence submitted in an application is  
4 reasonably likely to predict clinical benefit for seri-  
5 ous or life-threatening conditions for which signifi-  
6 cant unmet medical needs exist.”.

7 (c) GUIDANCE; AMENDED REGULATIONS.—

8 (1) DRAFT GUIDANCE.—Not later than 1 year  
9 after the date of enactment of this Act, the Sec-  
10 retary of Health and Human Services (referred to in  
11 this section as the “Secretary”) shall issue draft  
12 guidance to implement the amendments made by  
13 this section. In developing such guidance, the Sec-  
14 retary shall specifically consider issues arising under  
15 the accelerated approval and fast track processes  
16 under section 506 of the Federal Food, Drug, and  
17 Cosmetic Act, as amended by subsection (b), for  
18 drugs designated for a rare disease or condition  
19 under section 526 of such Act (21 U.S.C. 360bb).

20 (2) FINAL GUIDANCE.—Not later than 1 year  
21 after the issuance of draft guidance under para-  
22 graph (1), and after an opportunity for public com-  
23 ment, the Secretary shall issue final guidance.

24 (3) CONFORMING CHANGES.—The Secretary  
25 shall issue, as necessary, conforming amendments to

1 the applicable regulations under title 21, Code of  
2 Federal Regulations, governing accelerated approval.

3 (4) NO EFFECT OF INACTION ON REQUESTS.—

4 If the Secretary fails to issue final guidance or  
5 amended regulations as required by this subsection,  
6 such failure shall not preclude the review of, or ac-  
7 tion on, a request for designation or an application  
8 for approval submitted pursuant to section 506 of  
9 the Federal Food, Drug, and Cosmetic Act, as  
10 amended by subsection (b).

11 (d) INDEPENDENT REVIEW.—The Secretary may, in  
12 conjunction with other planned reviews, contract with an  
13 independent entity with expertise in assessing the quality  
14 and efficiency of biopharmaceutical development and regu-  
15 latory review programs to evaluate the Food and Drug Ad-  
16 ministration's application of the processes described in  
17 section 506 of the Federal Food, Drug, and Cosmetic Act,  
18 as amended by subsection (b), and the impact of such  
19 processes on the development and timely availability of in-  
20 novative treatments for patients suffering from serious or  
21 life-threatening conditions. Any such evaluation shall in-  
22 clude consultation with regulated industries, patient advoca-  
23 cacy and disease research foundations, and relevant aca-  
24 demic medical centers.

1 (e) CONSTRUCTION.—The amendments made by this  
2 section to section 506(b) of the Federal Food, Drug, and  
3 Cosmetic Act are intended to encourage the Secretary to  
4 utilize innovative approaches to the assessment of prod-  
5 ucts under accelerated approval while maintaining appro-  
6 priate safety and effectiveness standards for such prod-  
7 ucts.

8 **SEC. 302. ELECTRONIC HEALTH RECORDS.**

9 Subchapter A of chapter VII (21 U.S.C. 371 et seq.),  
10 as amended by section 103, is further amended by adding  
11 at the end the following:

12 **“SEC. 715. CLINICAL INFORMATICS COORDINATOR.**

13 “(a) IN GENERAL.—The Secretary shall appoint,  
14 within the Office of the Commissioner, a Clinical  
15 Informatics Coordinator.

16 “(b) DUTIES.—The Clinical Informatics Coordinator  
17 shall—

18 “(1) develop a process to validate the use of  
19 health information technology in clinical research  
20 and encourage the use of new health information  
21 technologies in clinical research protocols; and

22 “(2) establish pilot programs to explore and  
23 evaluate the methods of incorporating emerging  
24 health information technology to make the clinical  
25 research process more efficient.

1       “(c) GUIDANCE.—Not later than 1 year after the con-  
 2 clusion of the pilot programs described in subsection  
 3 (b)(2), the Secretary shall issue guidance for the conduct  
 4 of clinical trials incorporating health information tech-  
 5 nology. The guidance shall explain how the Food and  
 6 Drug Administration will evaluate such information when  
 7 reviewing new drug and device applications.”.

8       **SEC. 303. DISCLOSURE TO DRUG SPONSORS OF REASONS**  
 9                               **FOR NON-APPROVAL OF A NEW DRUG APPLI-**  
 10                              **CATION.**

11       Section 505 (21 U.S.C. 355) is amended by adding  
 12 at the end the following:

13       “(w) NOTICE OF REASONS FOR DENIAL OF A NEW  
 14 DRUG APPLICATION.—If the Secretary denies approval of  
 15 a new drug application under this section or of an applica-  
 16 tion with respect to a biological product under section 351  
 17 of the Public Health Service Act, the Secretary shall pro-  
 18 vide to the sponsor of such drug or biological product—

19               “(1) a written explanation of the reasons for  
 20 denying such application, including an explanation of  
 21 the specific reasons the Secretary determines that—

22                       “(A) the data submitted in the application  
 23 are inadequate to support approval of the drug  
 24 or biological product; and

1           “(B) labeling, risk evaluation and mitiga-  
2           tion strategies under section 505–1, or post-  
3           approval studies or trials are inadequate to sup-  
4           port a determination that the benefits of ap-  
5           proval outweigh the risks; and

6           “(2) to the extent practicable, an explanation of  
7           what data will be required and what endpoints will  
8           need to be met in order to obtain approval.”.

○