

112TH CONGRESS
2D SESSION

S. _____

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.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

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 REGU-**
7 **LATORY SCIENCE AND INNO-**
8 **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 including 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 advo-
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.”.