

[COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE
ON HEALTH ON JUNE 19, 2007]

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of the Reagan-Udall Foundation for the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M. _____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of the Reagan-Udall Foundation for the Food and Drug Administration, 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,*

1 **SECTION 1. THE REAGAN-UDALL FOUNDATION FOR THE**
2 **FOOD AND DRUG ADMINISTRATION.**

3 (a) IN GENERAL.—Chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
5 ed by adding at the end the following:

6 **“Subchapter I—Reagan-Udall Foundation for**
7 **the Food and Drug Administration**

8 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUN-**
9 **DATION.**

10 “(a) IN GENERAL.—A nonprofit corporation to be
11 known as the Reagan-Udall Foundation for the Food and
12 Drug Administration (referred to in this subchapter as the
13 ‘Foundation’) shall be established in accordance with this
14 section. The Foundation shall be headed by an Executive
15 Director, appointed by the members of the Board of Direc-
16 tors under subsection (e). The Foundation shall not be
17 an agency or instrumentality of the United States Govern-
18 ment.

19 “(b) PURPOSE OF FOUNDATION.—The purpose of
20 the Foundation is to advance the mission of the Food and
21 Drug Administration to modernize medical, veterinary,
22 food, food ingredient, and cosmetic product development,
23 accelerate innovation, and enhance product safety.

24 “(c) DUTIES OF THE FOUNDATION.—The Founda-
25 tion shall—

1 “(1) taking into consideration the Critical Path
2 reports and priorities published by the Food and
3 Drug Administration, identify unmet needs in the
4 development, manufacture, and evaluation of the
5 safety and effectiveness, including postapproval, of
6 devices, including diagnostics, biologics, and drugs,
7 and the safety of food, food ingredients, and cos-
8 metics;

9 “(2) establish goals and priorities in order to
10 meet the unmet needs identified in paragraph (1);

11 “(3) in consultation with the Secretary, identify
12 existing and proposed Federal intramural and extra-
13 mural research and development programs relating
14 to the goals and priorities established under para-
15 graph (2), coordinate Foundation activities with
16 such programs, and minimize Foundation duplica-
17 tion of existing efforts;

18 “(4) award grants to, or enter into contracts,
19 memoranda of understanding, or cooperative agree-
20 ments with, scientists and entities, which may in-
21 clude the Food and Drug Administration, university
22 consortia, public-private partnerships, institutions of
23 higher education, entities described in section
24 501(c)(3) of the Internal Revenue Code (and exempt
25 from tax under section 501(a) of such Code), and

1 industry, to efficiently and effectively advance the
2 goals and priorities established under paragraph (2);

3 “(5) recruit meeting participants and hold or
4 sponsor (in whole or in part) meetings as appro-
5 priate to further the goals and priorities established
6 under paragraph (2);

7 “(6) release and publish information and data
8 and, to the extent practicable, license, distribute,
9 and release material, reagents, and techniques to
10 maximize, promote, and coordinate the availability of
11 such material, reagents, and techniques for use by
12 the Food and Drug Administration, nonprofit orga-
13 nizations, and academic and industrial researchers
14 to further the goals and priorities established under
15 paragraph (2);

16 “(7) ensure that—

17 “(A) action is taken as necessary to obtain
18 patents for inventions developed by the Founda-
19 tion or with funds from the Foundation;

20 “(B) action is taken as necessary to enable
21 the licensing of inventions developed by the
22 Foundation or with funds from the Foundation;
23 and

24 “(C) executed licenses, memoranda of un-
25 derstanding, material transfer agreements, con-

1 tracts, and other such instruments, promote, to
2 the maximum extent practicable, the broadest
3 conversion to commercial and noncommercial
4 applications of licensed and patented inventions
5 of the Foundation to further the goals and pri-
6 orities established under paragraph (2);

7 “(8) provide objective clinical and scientific in-
8 formation to the Food and Drug Administration
9 and, upon request, to other Federal agencies to as-
10 sist in agency determinations of how to ensure that
11 regulatory policy accommodates scientific advances
12 and meets the agency’s public health mission;

13 “(9) conduct annual assessments of the unmet
14 needs identified in paragraph (1); and

15 “(10) carry out such other activities consistent
16 with the purposes of the Foundation as the Board
17 determines appropriate.

18 “(d) BOARD OF DIRECTORS.—

19 “(1) ESTABLISHMENT.—

20 “(A) IN GENERAL.—The Foundation shall
21 have a Board of Directors (referred to in this
22 subchapter as the ‘Board’), which shall be com-
23 posed of ex officio and appointed members in
24 accordance with this subsection. All appointed
25 members of the Board shall be voting members.

1 “(B) EX OFFICIO MEMBERS.—The ex offi-
2 cio members of the Board shall be the following
3 individuals or their designees:

4 “(i) The Commissioner.

5 “(ii) The Director of the National In-
6 stitutes of Health.

7 “(iii) The Director of the Centers for
8 Disease Control and Prevention.

9 “(iv) The Director of the Agency for
10 Healthcare Research and Quality.

11 “(C) APPOINTED MEMBERS.—

12 “(i) IN GENERAL.—The ex officio
13 members of the Board under subparagraph
14 (B) shall, by majority vote, appoint to the
15 Board 12 individuals, from a list of can-
16 didates to be provided by the National
17 Academy of Sciences. Of such appointed
18 members—

19 “(I) 4 shall be representatives of
20 the general pharmaceutical, device,
21 food, cosmetic, and biotechnology in-
22 dustries;

23 “(II) 3 shall be representatives of
24 academic research organizations;

1 “(III) 2 shall be representatives
2 of Government agencies, including the
3 Food and Drug Administration and
4 the National Institutes of Health;

5 “(IV) 2 shall be representatives
6 of patient or consumer advocacy orga-
7 nizations; and

8 “(V) 1 shall be a representative
9 of health care providers.

10 “(ii) REQUIREMENT.—The ex officio
11 members shall ensure the Board member-
12 ship includes individuals with expertise in
13 areas including the sciences of developing,
14 manufacturing, and evaluating the safety
15 and effectiveness of devices, including
16 diagnostics, biologics, and drugs, and the
17 safety of food, food ingredients, and cos-
18 metics.

19 “(D) INITIAL MEETING.—

20 “(i) IN GENERAL.—Not later than 30
21 days after the date of the enactment of the
22 Enhancing Drug Safety and Innovation
23 Act of 2007, the Secretary shall convene a
24 meeting of the ex officio members of the
25 Board to—

1 “(I) incorporate the Foundation;
2 and

3 “(II) appoint the members of the
4 Board in accordance with subpara-
5 graph (C).

6 “(ii) SERVICE OF EX OFFICIO MEM-
7 BERS.—Upon the appointment of the
8 members of the Board under clause (i)(II),
9 the terms of service of the ex officio mem-
10 bers of the Board as members of the
11 Board shall terminate.

12 “(iii) CHAIR.—The ex officio members
13 of the Board under subparagraph (B) shall
14 designate an appointed member of the
15 Board to serve as the Chair of the Board.

16 “(2) DUTIES OF BOARD.—The Board shall—

17 “(A) establish bylaws for the Foundation
18 that—

19 “(i) are published in the Federal Reg-
20 ister and available for public comment;

21 “(ii) establish policies for the selection
22 of the officers, employees, agents, and con-
23 tractors of the Foundation;

24 “(iii) establish policies, including eth-
25 ical standards, for the acceptance, sollicita-

1 tion, and disposition of donations and
2 grants to the Foundation and for the dis-
3 position of the assets of the Foundation,
4 including appropriate limits on the ability
5 of donors to designate, by stipulation or re-
6 striction, the use or recipient of donated
7 funds;

8 “(iv) establish policies that would sub-
9 ject all employees, fellows, and trainees of
10 the Foundation to the conflict of interest
11 standards under section 208 of title 18,
12 United States Code;

13 “(v) establish licensing, distribution,
14 and publication policies that support the
15 widest and least restrictive use by the pub-
16 lic of information and inventions developed
17 by the Foundation or with Foundation
18 funds to carry out the duties described in
19 paragraphs (6) and (7) of subsection (c),
20 and may include charging cost-based fees
21 for published material produced by the
22 Foundation;

23 “(vi) specify principles for the review
24 of proposals and awarding of grants and
25 contracts that include peer review and that

1 are consistent with those of the Founda-
2 tion for the National Institutes of Health,
3 to the extent determined practicable and
4 appropriate by the Board;

5 “(vii) specify a cap on administrative
6 expenses for recipients of a grant, con-
7 tract, or cooperative agreement from the
8 Foundation;

9 “(viii) establish policies for the execu-
10 tion of memoranda of understanding and
11 cooperative agreements between the Foun-
12 dation and other entities, including the
13 Food and Drug Administration;

14 “(ix) establish policies for funding
15 training fellowships, whether at the Foun-
16 dation, academic or scientific institutions,
17 or the Food and Drug Administration, for
18 scientists, doctors, and other professionals
19 who are not employees of regulated indus-
20 try, to foster greater understanding of and
21 expertise in new scientific tools,
22 diagnostics, manufacturing techniques, and
23 potential barriers to translating basic re-
24 search into clinical and regulatory practice;

1 “(x) specify a process for annual
2 Board review of the operations of the
3 Foundation; and

4 “(xi) establish specific duties of the
5 Executive Director;

6 “(B) prioritize and provide overall direc-
7 tion to the activities of the Foundation;

8 “(C) evaluate the performance of the Exec-
9 utive Director; and

10 “(D) carry out any other necessary activi-
11 ties regarding the functioning of the Founda-
12 tion.

13 “(3) TERMS AND VACANCIES.—

14 “(A) TERM.—The term of office of each
15 member of the Board appointed under para-
16 graph (1)(C) shall be 4 years, except that the
17 terms of offices for the initial appointed mem-
18 bers of the Board shall expire on a staggered
19 basis as determined by the ex officio members.

20 “(B) VACANCY.—Any vacancy in the mem-
21 bership of the Board—

22 “(i) shall not affect the power of the
23 remaining members to execute the duties
24 of the Board; and

1 “(ii) shall be filled by appointment by
2 the appointed members described in para-
3 graph (1)(C) by majority vote.

4 “(C) PARTIAL TERM.—If a member of the
5 Board does not serve the full term applicable
6 under subparagraph (A), the individual ap-
7 pointed under subparagraph (B) to fill the re-
8 sulting vacancy shall be appointed for the re-
9 mainder of the term of the predecessor of the
10 individual.

11 “(D) SERVING PAST TERM.—A member of
12 the Board may continue to serve after the expi-
13 ration of the term of the member until a suc-
14 cessor is appointed.

15 “(4) COMPENSATION.—Members of the Board
16 may not receive compensation for service on the
17 Board. Such members may be reimbursed for travel,
18 subsistence, and other necessary expenses incurred
19 in carrying out the duties of the Board, as set forth
20 in the bylaws issued by the Board.

21 “(e) INCORPORATION.—The ex officio members of the
22 Board shall serve as incorporators and shall take whatever
23 actions necessary to incorporate the Foundation.

24 “(f) NONPROFIT STATUS.—The Foundation shall be
25 considered to be a corporation under section 501(c) of the

1 Internal Revenue Code of 1986, and shall be subject to
2 the provisions of such section.

3 “(g) EXECUTIVE DIRECTOR.—

4 “(1) IN GENERAL.—The Board shall appoint an
5 Executive Director who shall serve at the pleasure of
6 the Board. The Executive Director shall be respon-
7 sible for the day-to-day operations of the Foundation
8 and shall have such specific duties and responsibil-
9 ities as the Board shall prescribe.

10 “(2) COMPENSATION.—The compensation of
11 the Executive Director shall be fixed by the Board
12 but shall not be greater than the compensation of
13 the Commissioner.

14 “(h) ADMINISTRATIVE POWERS.—In carrying out
15 this subchapter, the Board, acting through the Executive
16 Director, may—

17 “(1) adopt, alter, and use a corporate seal,
18 which shall be judicially noticed;

19 “(2) hire, promote, compensate, and discharge
20 1 or more officers, employees, and agents, as may be
21 necessary, and define their duties;

22 “(3) prescribe the manner in which—

23 “(A) real or personal property of the
24 Foundation is acquired, held, and transferred;

1 “(B) general operations of the Foundation
2 are to be conducted; and

3 “(C) the privileges granted to the Board
4 by law are exercised and enjoyed;

5 “(4) with the consent of the applicable executive
6 department or independent agency, use the informa-
7 tion, services, and facilities of such department or
8 agencies in carrying out this section;

9 “(5) enter into contracts with public and pri-
10 vate organizations for the writing, editing, printing,
11 and publishing of books and other material;

12 “(6) hold, administer, invest, and spend any
13 gift, devise, or bequest of real or personal property
14 made to the Foundation under subsection (i);

15 “(7) enter into such other contracts, leases, co-
16 operative agreements, and other transactions as the
17 Board considers appropriate to conduct the activities
18 of the Foundation;

19 “(8) modify or consent to the modification of
20 any contract or agreement to which it is a party or
21 in which it has an interest under this subchapter;

22 “(9) take such action as may be necessary to
23 obtain patents and licenses for devices and proce-
24 dures developed by the Foundation and its employ-
25 ees;

1 “(10) sue and be sued in its corporate name,
2 and complain and defend in courts of competent ju-
3 risdiction;

4 “(11) appoint other groups of advisors as may
5 be determined necessary to carry out the functions
6 of the Foundation; and

7 “(12) exercise other powers as set forth in this
8 section, and such other incidental powers as are nec-
9 essary to carry out its powers, duties, and functions
10 in accordance with this subchapter.

11 “(i) ACCEPTANCE OF FUNDS FROM OTHER
12 SOURCES.—The Executive Director may solicit and accept
13 on behalf of the Foundation, any funds, gifts, grants, de-
14 vises, or bequests of real or personal property made to the
15 Foundation, including from private entities, for the pur-
16 poses of carrying out the duties of the Foundation.

17 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
18 Government employees may serve on committees advisory
19 to the Foundation and otherwise cooperate with and assist
20 the Foundation in carrying out its functions, so long as
21 such employees do not direct or control Foundation activi-
22 ties.

23 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
24 LOWSHIPS.—

1 “(1) DETAIL FROM FEDERAL AGENCIES.—Fed-
2 eral Government employees may be detailed from
3 Federal agencies with or without reimbursement to
4 those agencies to the Foundation at any time, and
5 such detail shall be without interruption or loss of
6 civil service status or privilege. Each such employee
7 shall abide by the statutory, regulatory, ethical, and
8 procedural standards applicable to the employees of
9 the agency from which such employee is detailed and
10 those of the Foundation.

11 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
12 FEDERAL EMPLOYEES.—

13 “(A) FOUNDATION.—The Executive Direc-
14 tor of the Foundation may accept the services
15 of employees detailed from Federal agencies
16 with or without reimbursement to those agen-
17 cies.

18 “(B) FOOD AND DRUG ADMINISTRATION.—
19 The Commissioner may accept the uncompen-
20 sated services of Foundation fellows or trainees.
21 Such services shall be considered to be under-
22 taking an activity under contract with the Sec-
23 retary as described in section 708.

24 “(1) ANNUAL REPORTS.—

1 “(1) REPORTS TO FOUNDATION.—Any recipient
2 of a grant, contract, fellowship, memorandum of un-
3 derstanding, or cooperative agreement from the
4 Foundation under this section shall submit to the
5 Foundation a report on an annual basis for the du-
6 ration of such grant, contract, fellowship, memo-
7 randum of understanding, or cooperative agreement,
8 that describes the activities carried out under such
9 grant, contract, fellowship, memorandum of under-
10 standing, or cooperative agreement.

11 “(2) REPORT TO CONGRESS AND THE FDA.—
12 Beginning with fiscal year 2009, the Executive Di-
13 rector shall submit to Congress and the Commis-
14 sioner an annual report that—

15 “(A) describes the activities of the Foun-
16 dation and the progress of the Foundation in
17 furthering the goals and priorities established
18 under subsection (c)(2), including the practical
19 impact of the Foundation on regulated product
20 development;

21 “(B) provides a specific accounting of the
22 source and use of all funds used by the Foun-
23 dation to carry out such activities; and

24 “(C) provides information on how the re-
25 sults of Foundation activities could be incor-

1 annual report summarizing the incorporation of the infor-
2 mation provided by the Foundation in the report described
3 under section 770(l)(2) and by other recipients of grants,
4 contracts, memoranda of understanding, or cooperative
5 agreements into regulatory and product review activities
6 of the Food and Drug Administration.

7 “(c) EXTRAMURAL GRANTS.—The provisions of this
8 subchapter shall have no effect on any grant, contract,
9 memorandum of understanding, or cooperative agreement
10 between the Food and Drug Administration and any other
11 entity entered into before, on, or after the date of enact-
12 ment of the Enhancing Drug Safety and Innovation Act
13 of 2007.”.

14 (c) CONFORMING AMENDMENT.—Section 742(b) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379l(b)) is amended by adding at the end the following:
17 “Any such fellowships and training programs under this
18 section or under section 770(d)(2)(A)(ix) may include pro-
19 vision by such scientists and physicians of services on a
20 voluntary and uncompensated basis, as the Secretary de-
21 termines appropriate. Such scientists and physicians shall
22 be subject to all legal and ethical requirements otherwise
23 applicable to officers or employees of the Department of
24 Health and Human Services.”.

1 **SEC. 2. OFFICE OF THE CHIEF SCIENTIST.**

2 Chapter IX of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 391 et seq.) is amended by adding at the
4 end the following:

5 **“SEC. 910. OFFICE OF THE CHIEF SCIENTIST.**

6 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
7 retary shall establish within the Office of the Commis-
8 sioner an office to be known as the Office of the Chief
9 Scientist. The Secretary shall appoint a Chief Scientist to
10 lead such Office.

11 “(b) DUTIES OF THE OFFICE.—The Office of the
12 Chief Scientist shall—

13 “(1) oversee, coordinate, and ensure quality and
14 regulatory focus of the intramural research pro-
15 grams of the Food and Drug Administration;

16 “(2) track and, to the extent necessary, coordi-
17 nate intramural research awards made by each cen-
18 ter of the Administration or science-based office
19 within the Office of the Commissioner, and ensure
20 that there is no duplication of research efforts sup-
21 ported by the Reagan-Udall Foundation for the
22 Food and Drug Administration;

23 “(3) develop and advocate for a budget to sup-
24 port intramural research;

25 “(4) develop a peer review process by which in-
26 tramural research can be evaluated; and

1 “(5) identify and solicit intramural research
2 proposals from across the Food and Drug Adminis-
3 tration through an advisory board composed of em-
4 ployees of the Administration that shall include—

5 “(A) representatives of each of the centers
6 and the science-based offices within the Office
7 of the Commissioner; and

8 “(B) experts on trial design, epidemiology,
9 demographics, pharmacovigilance, basic science,
10 and public health.”.