

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO THE COMMITTEE PRINT
OFFERED BY _____**

[Reagan-Udall Foundation]

Strike all after the enacting clause and insert the following:

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

1 an agency or instrumentality of the United States Govern-
2 ment.

3 “(b) PURPOSE OF FOUNDATION.—The purpose of
4 the Foundation is to advance the mission of the Food and
5 Drug Administration to modernize medical, veterinary,
6 food, food ingredient, and cosmetic product development,
7 accelerate innovation, and enhance product safety.

8 “(c) DUTIES OF THE FOUNDATION.—The Founda-
9 tion shall—

10 “(1) taking into consideration the Critical Path
11 reports and priorities published by the Food and
12 Drug Administration, identify unmet needs in the
13 development, manufacture, and evaluation of the
14 safety and effectiveness, including postapproval, of
15 devices, including diagnostics, biologics, and drugs,
16 and the safety of food, food ingredients, and cos-
17 metics;

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

20 “(3) in consultation with the Secretary, identify
21 existing and proposed Federal intramural and extra-
22 mural research and development programs relating
23 to the goals and priorities established under para-
24 graph (2), coordinate Foundation activities with

1 such programs, and minimize Foundation duplica-
2 tion of existing efforts;

3 “(4) award grants to, or enter into contracts,
4 memoranda of understanding, or cooperative agree-
5 ments with, scientists and entities, which may in-
6 clude the Food and Drug Administration, university
7 consortia, public-private partnerships, institutions of
8 higher education, entities described in section
9 501(c)(3) of the Internal Revenue Code (and exempt
10 from tax under section 501(a) of such Code), and
11 industry, to efficiently and effectively advance the
12 goals and priorities established under paragraph (2);

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

17 “(6) release and publish information and data
18 and, to the extent practicable, license, distribute,
19 and release material, reagents, and techniques to
20 maximize, promote, and coordinate the availability of
21 such material, reagents, and techniques for use by
22 the Food and Drug Administration, nonprofit orga-
23 nizations, and academic and industrial researchers
24 to further the goals and priorities established under
25 paragraph (2);

1 “(7) ensure that—

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

5 “(B) action is taken as necessary to enable
6 the licensing of inventions developed by the
7 Foundation or with funds from the Foundation;
8 and

9 “(C) executed licenses, memoranda of un-
10 derstanding, material transfer agreements, con-
11 tracts, and other such instruments, promote, to
12 the maximum extent practicable, the broadest
13 conversion to commercial and noncommercial
14 applications of licensed and patented inventions
15 of the Foundation to further the goals and pri-
16 orities established under paragraph (2);

17 “(8) provide objective clinical and scientific in-
18 formation to the Food and Drug Administration
19 and, upon request, to other Federal agencies to as-
20 sist in agency determinations of how to ensure that
21 regulatory policy accommodates scientific advances
22 and meets the agency’s public health mission;

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

1 “(10) carry out such other activities consistent
2 with the purposes of the Foundation as the Board
3 determines appropriate.

4 “(d) BOARD OF DIRECTORS.—

5 “(1) ESTABLISHMENT.—

6 “(A) IN GENERAL.—The Foundation shall
7 have a Board of Directors (referred to in this
8 subchapter as the ‘Board’), which shall be com-
9 posed of ex officio and appointed members in
10 accordance with this subsection. All appointed
11 members of the Board shall be voting members.

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

15 “(i) The Commissioner.

16 “(ii) The Director of the National In-
17 stitutes of Health.

18 “(iii) The Director of the Centers for
19 Disease Control and Prevention.

20 “(iv) The Director of the Agency for
21 Healthcare Research and Quality.

22 “(C) APPOINTED MEMBERS.—

23 “(i) IN GENERAL.—The ex officio
24 members of the Board under subparagraph
25 (B) shall, by majority vote, appoint to the

1 Board 12 individuals, from a list of can-
2 didates to be provided by the National
3 Academy of Sciences. Of such appointed
4 members—

5 “(I) 4 shall be representatives of
6 the general pharmaceutical, device,
7 food, cosmetic, and biotechnology in-
8 dustries;

9 “(II) 3 shall be representatives of
10 academic research organizations;

11 “(III) 2 shall be representatives
12 of Government agencies, including the
13 Food and Drug Administration and
14 the National Institutes of Health;

15 “(IV) 2 shall be representatives
16 of patient or consumer advocacy orga-
17 nizations; and

18 “(V) 1 shall be a representative
19 of health care providers.

20 “(ii) REQUIREMENT.—The ex officio
21 members shall ensure the Board member-
22 ship includes individuals with expertise in
23 areas including the sciences of developing,
24 manufacturing, and evaluating the safety
25 and effectiveness of devices, including

1 diagnostics, biologics, and drugs, and the
2 safety of food, food ingredients, and cos-
3 metics.

4 “(D) INITIAL MEETING.—

5 “(i) IN GENERAL.—Not later than 30
6 days after the date of the enactment of the
7 Enhancing Drug Safety and Innovation
8 Act of 2007, the Secretary shall convene a
9 meeting of the ex officio members of the
10 Board to—

11 “(I) incorporate the Foundation;
12 and

13 “(II) appoint the members of the
14 Board in accordance with subpara-
15 graph (C).

16 “(ii) SERVICE OF EX OFFICIO MEM-
17 BERS.—Upon the appointment of the
18 members of the Board under clause (i)(II),
19 the terms of service of the ex officio mem-
20 bers of the Board as members of the
21 Board shall terminate.

22 “(iii) CHAIR.—The ex officio members
23 of the Board under subparagraph (B) shall
24 designate an appointed member of the
25 Board to serve as the Chair of the Board.

- 1 “(2) DUTIES OF BOARD.—The Board shall—
- 2 “(A) establish bylaws for the Foundation
- 3 that—
- 4 “(i) are published in the Federal Reg-
- 5 ister and available for public comment;
- 6 “(ii) establish policies for the selection
- 7 of the officers, employees, agents, and con-
- 8 tractors of the Foundation;
- 9 “(iii) establish policies, including eth-
- 10 ical standards, for the acceptance, sollicita-
- 11 tion, and disposition of donations and
- 12 grants to the Foundation and for the dis-
- 13 position of the assets of the Foundation,
- 14 including appropriate limits on the ability
- 15 of donors to designate, by stipulation or re-
- 16 striction, the use or recipient of donated
- 17 funds;
- 18 “(iv) establish policies that would sub-
- 19 ject all employees, fellows, and trainees of
- 20 the Foundation to the conflict of interest
- 21 standards under section 208 of title 18,
- 22 United States Code;
- 23 “(v) establish licensing, distribution,
- 24 and publication policies that support the
- 25 widest and least restrictive use by the pub-

1 lic of information and inventions developed
2 by the Foundation or with Foundation
3 funds to carry out the duties described in
4 paragraphs (6) and (7) of subsection (c),
5 and may include charging cost-based fees
6 for published material produced by the
7 Foundation;

8 “(vi) specify principles for the review
9 of proposals and awarding of grants and
10 contracts that include peer review and that
11 are consistent with those of the Founda-
12 tion for the National Institutes of Health,
13 to the extent determined practicable and
14 appropriate by the Board;

15 “(vii) specify a cap on administrative
16 expenses for recipients of a grant, con-
17 tract, or cooperative agreement from the
18 Foundation;

19 “(viii) establish policies for the execu-
20 tion of memoranda of understanding and
21 cooperative agreements between the Foun-
22 dation and other entities, including the
23 Food and Drug Administration;

24 “(ix) establish policies for funding
25 training fellowships, whether at the Foun-

1 dation, academic or scientific institutions,
2 or the Food and Drug Administration, for
3 scientists, doctors, and other professionals
4 who are not employees of regulated indus-
5 try, to foster greater understanding of and
6 expertise in new scientific tools,
7 diagnostics, manufacturing techniques, and
8 potential barriers to translating basic re-
9 search into clinical and regulatory practice;

10 “(x) specify a process for annual
11 Board review of the operations of the
12 Foundation; and

13 “(xi) establish specific duties of the
14 Executive Director;

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

17 “(C) evaluate the performance of the Exec-
18 utive Director; and

19 “(D) carry out any other necessary activi-
20 ties regarding the functioning of the Founda-
21 tion.

22 “(3) TERMS AND VACANCIES.—

23 “(A) TERM.—The term of office of each
24 member of the Board appointed under para-
25 graph (1)(C) shall be 4 years, except that the

1 terms of offices for the initial appointed mem-
2 bers of the Board shall expire on a staggered
3 basis as determined by the ex officio members.

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

6 “(i) shall not affect the power of the
7 remaining members to execute the duties
8 of the Board; and

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

12 “(C) PARTIAL TERM.—If a member of the
13 Board does not serve the full term applicable
14 under subparagraph (A), the individual ap-
15 pointed under subparagraph (B) to fill the re-
16 sulting vacancy shall be appointed for the re-
17 mainder of the term of the predecessor of the
18 individual.

19 “(D) SERVING PAST TERM.—A member of
20 the Board may continue to serve after the expi-
21 ration of the term of the member until a suc-
22 cessor is appointed.

23 “(4) COMPENSATION.—Members of the Board
24 may not receive compensation for service on the
25 Board. Such members may be reimbursed for travel,

1 subsistence, and other necessary expenses incurred
2 in carrying out the duties of the Board, as set forth
3 in the bylaws issued by the Board.

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

7 “(f) NONPROFIT STATUS.—The Foundation shall be
8 considered to be a corporation under section 501(c) of the
9 Internal Revenue Code of 1986, and shall be subject to
10 the provisions of such section.

11 “(g) EXECUTIVE DIRECTOR.—

12 “(1) IN GENERAL.—The Board shall appoint an
13 Executive Director who shall serve at the pleasure of
14 the Board. The Executive Director shall be respon-
15 sible for the day-to-day operations of the Foundation
16 and shall have such specific duties and responsibil-
17 ities as the Board shall prescribe.

18 “(2) COMPENSATION.—The compensation of
19 the Executive Director shall be fixed by the Board
20 but shall not be greater than the compensation of
21 the Commissioner.

22 “(h) ADMINISTRATIVE POWERS.—In carrying out
23 this subchapter, the Board, acting through the Executive
24 Director, may—

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

3 “(2) hire, promote, compensate, and discharge
4 1 or more officers, employees, and agents, as may be
5 necessary, and define their duties;

6 “(3) prescribe the manner in which—

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

9 “(B) general operations of the Foundation
10 are to be conducted; and

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

13 “(4) with the consent of the applicable executive
14 department or independent agency, use the informa-
15 tion, services, and facilities of such department or
16 agencies in carrying out this section;

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

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

23 “(7) enter into such other contracts, leases, co-
24 operative agreements, and other transactions as the

1 Board considers appropriate to conduct the activities
2 of the Foundation;

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

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

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

13 “(11) appoint other groups of advisors as may
14 be determined necessary to carry out the functions
15 of the Foundation; and

16 “(12) exercise other powers as set forth in this
17 section, and such other incidental powers as are nec-
18 essary to carry out its powers, duties, and functions
19 in accordance with this subchapter.

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

1 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
2 Government employees may serve on committees advisory
3 to the Foundation and otherwise cooperate with and assist
4 the Foundation in carrying out its functions, so long as
5 such employees do not direct or control Foundation activi-
6 ties.

7 “(k) DETAIL OF GOVERNMENT EMPLOYEES; FEL-
8 LOWSHIPS.—

9 “(1) DETAIL FROM FEDERAL AGENCIES.—Fed-
10 eral Government employees may be detailed from
11 Federal agencies with or without reimbursement to
12 those agencies to the Foundation at any time, and
13 such detail shall be without interruption or loss of
14 civil service status or privilege. Each such employee
15 shall abide by the statutory, regulatory, ethical, and
16 procedural standards applicable to the employees of
17 the agency from which such employee is detailed and
18 those of the Foundation.

19 “(2) VOLUNTARY SERVICE; ACCEPTANCE OF
20 FEDERAL EMPLOYEES.—

21 “(A) FOUNDATION.—The Executive Direc-
22 tor of the Foundation may accept the services
23 of employees detailed from Federal agencies
24 with or without reimbursement to those agen-
25 cies.

1 “(B) FOOD AND DRUG ADMINISTRATION.—

2 The Commissioner may accept the uncompen-
3 sated services of Foundation fellows or trainees.
4 Such services shall be considered to be under-
5 taking an activity under contract with the Sec-
6 retary as described in section 708.

7 “(1) ANNUAL REPORTS.—

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

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

22 “(A) describes the activities of the Foun-
23 dation and the progress of the Foundation in
24 furthering the goals and priorities established
25 under subsection (c)(2), including the practical

1 impact of the Foundation on regulated product
2 development;

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

6 “(C) provides information on how the re-
7 sults of Foundation activities could be incor-
8 porated into the regulatory and product review
9 activities of the Food and Drug Administration.

10 “(m) SEPARATION OF FUNDS.—The Executive Di-
11 rector shall ensure that the funds received from the Treas-
12 ury are held in separate accounts from funds received
13 from entities under subsection (i).

14 “(n) FUNDING.—From amounts appropriated to the
15 Food and Drug Administration for each fiscal year, the
16 Commissioner shall transfer not less than \$500,000 and
17 not more than \$1,250,000, to the Foundation to carry out
18 subsections (a), (b), and (d) through (m).”.

19 (b) OTHER FOUNDATION PROVISIONS.—Chapter VII
20 (21 U.S.C. 371 et seq.) (as amended by subsection (a))
21 is amended by adding at the end the following:

22 **“SEC. 771. LOCATION OF FOUNDATION.**

23 “The Foundation shall, if practicable, be located not
24 more than 20 miles from the District of Columbia.

1 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
2 **TRATION.**

3 “(a) IN GENERAL.—The Commissioner shall receive
4 and assess the report submitted to the Commissioner by
5 the Executive Director of the Foundation under section
6 770(l)(2).

7 “(b) REPORT TO CONGRESS.—Beginning with fiscal
8 year 2009, the Commissioner shall submit to Congress an
9 annual report summarizing the incorporation of the infor-
10 mation provided by the Foundation in the report described
11 under section 770(l)(2) and by other recipients of grants,
12 contracts, memoranda of understanding, or cooperative
13 agreements into regulatory and product review activities
14 of the Food and Drug Administration.

15 “(c) EXTRAMURAL GRANTS.—The provisions of this
16 subchapter shall have no effect on any grant, contract,
17 memorandum of understanding, or cooperative agreement
18 between the Food and Drug Administration and any other
19 entity entered into before, on, or after the date of enact-
20 ment of the Enhancing Drug Safety and Innovation Act
21 of 2007.”.

22 (c) CONFORMING AMENDMENT.—Section 742(b) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379l(b)) is amended by adding at the end the following:
25 “Any such fellowships and training programs under this
26 section or under section 770(d)(2)(A)(ix) may include pro-

1 vision by such scientists and physicians of services on a
2 voluntary and uncompensated basis, as the Secretary de-
3 termines appropriate. Such scientists and physicians shall
4 be subject to all legal and ethical requirements otherwise
5 applicable to officers or employees of the Department of
6 Health and Human Services.”.

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

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

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

12 “(a) ESTABLISHMENT; APPOINTMENT.—The Sec-
13 retary shall establish within the Office of the Commis-
14 sioner an office to be known as the Office of the Chief
15 Scientist. The Secretary shall appoint a Chief Scientist to
16 lead such Office.

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

19 “(1) oversee, coordinate, and ensure quality and
20 regulatory focus of the intramural research pro-
21 grams of the Food and Drug Administration;

22 “(2) track and, to the extent necessary, coordi-
23 nate intramural research awards made by each cen-
24 ter of the Administration or science-based office
25 within the Office of the Commissioner, and ensure

1 that there is no duplication of research efforts sup-
2 ported by the Reagan-Udall Foundation for the
3 Food and Drug Administration;

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

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

8 “(5) identify and solicit intramural research
9 proposals from across the Food and Drug Adminis-
10 tration through an advisory board composed of em-
11 ployees of the Administration that shall include—

12 “(A) representatives of each of the centers
13 and the science-based offices within the Office
14 of the Commissioner; and

15 “(B) experts on trial design, epidemiology,
16 demographics, pharmacovigilance, basic science,
17 and public health.”.