

[Committee Print]110TH CONGRESS
1ST SESSION**H. R.** _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of the Reagan-Udall Institute for Applied Biomedical Research, 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 Institute for Applied Biomedical Research, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. THE REAGAN-UDALL INSTITUTE FOR APPLIED**
4 **BIOMEDICAL RESEARCH.**

5 (a) IN GENERAL.—Chapter VII of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as

1 amended by Public Law 109–462, is amended by adding
2 at the end the following:

3 **“Subchapter I—Reagan-Udall Institute for**
4 **Applied Biomedical Research**

5 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE INSTI-**
6 **TUTE.**

7 “(a) IN GENERAL.—The Secretary shall establish a
8 nonprofit corporation to be known as the Reagan-Udall
9 Institute for Applied Biomedical Research (referred to in
10 this subchapter as the ‘Institute’). The Institute shall be
11 headed by an Executive Director, appointed by the mem-
12 bers of the Board of Directors under subsection (e). The
13 Institute shall not be an agency or instrumentality of the
14 United States Government.

15 “(b) PURPOSE OF INSTITUTE.—The purpose of the
16 Institute is to advance the Critical Path Initiative of the
17 Food and Drug Administration to modernize medical
18 product development, accelerate innovation, and enhance
19 product safety.

20 “(c) DUTIES OF THE INSTITUTE.—The Institute
21 shall—

22 “(1) taking into consideration the 2004 report
23 published by the Food and Drug Administration en-
24 titled ‘Innovation or Stagnation? Challenge and Op-
25 portunity on the Critical Path to New Medical Prod-

1 ucts’, identify unmet needs in the sciences of devel-
2 oping, manufacturing, and evaluating the safety and
3 effectiveness of diagnostics, devices, biologics, and
4 drugs, including—

5 “(A) the identification and validation of
6 biomarkers for use in diagnostic, device, bio-
7 logic, and drug development;

8 “(B) the development and validation of
9 animal models for human disease and medical
10 product safety;

11 “(C) pharmacogenomics and inter-indi-
12 vidual variability in drug, biologic, and device
13 response;

14 “(D) the development of data analysis
15 technology and methodology for use in device,
16 biologic, drug, and diagnostic development;

17 “(E) advancing improvements to the de-
18 sign and conduct of clinical trials;

19 “(F) toxicological quality assessment tech-
20 nologies;

21 “(G) diagnostic, device, biologic, and drug
22 manufacturing, design, and materials science;

23 “(H) failure mode assessment for medical
24 product development;

1 “(I) improving adverse event reporting and
2 analysis;

3 “(J) bridging engineering data and clinical
4 performance for devices; and

5 “(K) computer modeling;

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

8 “(3) in consultation with the Secretary, assess
9 existing and proposed Federal intramural and extra-
10 mural research and development programs relating
11 to the goals and priorities established under para-
12 graph (2) and facilitate and encourage interagency
13 coordination of such programs;

14 “(4) award grants to, or enter into contracts or
15 cooperative agreements with, scientists and entities
16 to advance the goals and priorities established under
17 paragraph (2);

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

22 “(6) release and publish information and data
23 and, to the extent practicable, license, distribute,
24 and release material, reagents, and techniques to
25 maximize, promote, and coordinate the availability of

1 such material, reagents, and techniques for use by
2 the Food and Drug Administration, nonprofit orga-
3 nizations, and academic and industrial researchers
4 to further the goals and priorities established under
5 paragraph (2);

6 “(7) ensure that—

7 “(A) action is taken as necessary to obtain
8 patents for inventions developed by the Insti-
9 tute or with funds from the Institute;

10 “(B) action is taken as necessary to enable
11 the licensing of inventions developed by the In-
12 stitute or with funds from the Institute; and

13 “(C) executed licenses, memoranda of un-
14 derstanding, material transfer agreements, con-
15 tracts, and other such instruments promote, to
16 the maximum extent practicable, the broadest
17 conversion to commercial and noncommercial
18 applications of licensed and patented inventions
19 of the Institute to further the goals and prior-
20 ities established under paragraph (2);

21 “(8) provide objective clinical and scientific in-
22 formation to the Food and Drug Administration
23 and, upon request, to other Federal agencies to as-
24 sist in agency determinations of how to ensure that
25 regulatory policy accommodates scientific advances;

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

3 “(10) carry out such other activities consistent
4 with the purposes of the Institute as the Board de-
5 termines appropriate.

6 “(d) BOARD OF DIRECTORS.—

7 “(1) ESTABLISHMENT.—

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

14 “(B) EX OFFICIO MEMBERS.—The ex offi-
15 cio members of the Board shall be—

16 “(i) the immediate past Chair of the
17 Board of Directors of the Institute;

18 “(ii) the Commissioner of Food and
19 Drugs;

20 “(iii) the Director of the National In-
21 stitutes of Health;

22 “(iv) the Director of the Centers for
23 Disease Control and Prevention; and

24 “(v) the Director of the Agency for
25 Healthcare Research and Quality.

1 “(C) APPOINTED MEMBERS.—

2 “(i) IN GENERAL.—The ex officio
3 members of the Board under subparagraph
4 (B) shall, by majority vote, appoint to the
5 Board 12 individuals. Of such appointed
6 members—

7 “(I) 3 shall be representatives of
8 the general pharmaceutical, device,
9 and biotechnology industries;

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

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

16 “(IV) 3 shall be representatives
17 of patient advocacy and consumer or-
18 ganizations; and

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

21 “(ii) REQUIREMENT.—The ex officio
22 members shall ensure the Board member-
23 ship includes individuals with expertise in
24 areas including clinical pharmacology, bio-
25 medical informatics, product safety, proc-

1 ess improvement and pharmaceutical
2 sciences, and medical device and bio-
3 medical engineering.

4 “(D) INITIAL MEETING.—

5 “(i) IN GENERAL.—Not later than 30
6 days after the date of the enactment of
7 this section, the Secretary shall convene a
8 meeting of the ex officio members of the
9 Board to—

10 “(I) incorporate the Institute;
11 and

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

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

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

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

1 “(A) establish bylaws for the Institute
2 that—

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

5 “(ii) establish policies for the selection
6 of the officers, employees, agents, and con-
7 tractors of the Institute;

8 “(iii) establish policies, including eth-
9 ical standards, for the acceptance, sollicita-
10 tion, and disposition of donations and
11 grants to the Institution and for the dis-
12 position of the assets of the Institute;

13 “(iv) establish policies whereby any
14 individual who is an officer, employee, or
15 member of the Board of the Institute may
16 not personally or substantially participate
17 in the consideration or determination by
18 the Institute of any matter that would di-
19 rectly or predictably affect any financial
20 interest of the individual or a relative (as
21 such term is defined in section 109(16) of
22 the Ethics in Government Act of 1978) of
23 the individual, of any business organization
24 or other entity, or of which the individual
25 is an officer or employee or is negotiating

1 for employment, or in which the individual
2 has any other financial interest;

3 “(v) establish licensing, distribution,
4 and publication policies that support the
5 widest and least restrictive use by the pub-
6 lic of information and inventions developed
7 by the Institute or with Institute funds to
8 carry out the duties described in para-
9 graphs (6) and (7) of subsection (c);

10 “(vi) specify principles for the review
11 of proposals and awarding of grants and
12 contracts that include peer review and that
13 are substantially consistent with those of
14 the Foundation for the National Institutes
15 of Health;

16 “(vii) specify a process for annual
17 Board review of the operations of the Insti-
18 tute; and

19 “(viii) establish specific duties of the
20 Executive Director;

21 “(B) prioritize and provide overall direc-
22 tion to the activities of the Institute;

23 “(C) evaluate the performance of the Exec-
24 utive Director; and

1 “(D) carry out any other necessary activi-
2 ties regarding the functioning of the Institute.

3 “(3) ADDITIONAL BOARD FUNCTIONS.—The
4 Board may coordinate and collaborate with other en-
5 tities to conduct research, education, and outreach,
6 and to modernize the sciences of developing, manu-
7 facturing, and evaluating the safety and effective-
8 ness of diagnostics, devices, biologics, and drugs.

9 “(4) TERMS AND VACANCIES.—

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

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

18 “(i) shall not affect the power of the
19 remaining members to execute the duties
20 of the Board; and

21 “(ii) shall be filled by appointment by
22 the individuals described in clauses (i)
23 through (v) of paragraph (1)(B) by major-
24 ity vote.

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

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

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

18 “(e) INCORPORATION.—The ex officio members of the
19 Board shall serve as incorporators and shall take whatever
20 actions necessary to incorporate the Institute.

21 “(f) NONPROFIT STATUS.—The Institute shall be
22 considered to be a corporation under section 501(c) of the
23 Internal Revenue Code of 1986, and shall be subject to
24 the provisions of such section.

25 “(g) EXECUTIVE DIRECTOR.—

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

7 “(2) COMPENSATION.—The compensation of
8 the Executive Director shall be fixed by the Board
9 but shall not be greater than the compensation of
10 the Commissioner of Food and Drugs.

11 “(h) ADMINISTRATIVE POWERS.—In carrying out
12 this subchapter, the Board, acting through the Executive
13 Director, may—

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

16 “(2) hire, promote, compensate, and discharge
17 1 or more officers, employees, and agents, as may be
18 necessary, and define their duties;

19 “(3) prescribe the manner in which—

20 “(A) real or personal property of the Insti-
21 tute is acquired, held, and transferred;

22 “(B) general operations of the Institute
23 are to be conducted; and

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

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

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

8 “(6) hold, administer, invest, and spend any
9 gift, devise, or bequest of real or personal property
10 made to the Institute under subsection (i);

11 “(7) enter into such other contracts, leases, co-
12 operative agreements, and other transactions as the
13 Board considers appropriate to conduct the activities
14 of the Institute;

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

18 “(9) take such action as may be necessary to
19 obtain patents and licenses for devices and proce-
20 dures developed by the Institute and its employees;

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

1 “(11) appoint other groups of advisors as may
2 be determined necessary to carry out the functions
3 of the Institute; and

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

8 “(i) ACCEPTANCE OF FUNDS FROM OTHER
9 SOURCES.—The Executive Director may solicit and accept
10 on behalf of the Institute, any funds, gifts, grants, devises,
11 or bequests of real or personal property made to the Insti-
12 tute, including from private entities, for the purposes of
13 carrying out the duties of the Institute.

14 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
15 Government employees may serve on committees advisory
16 to the Institute and otherwise cooperate with and assist
17 the Institute in carrying out its functions, so long as such
18 employees do not direct or control Institute activities.

19 “(k) DETAIL OF GOVERNMENT EMPLOYEES.—Fed-
20 eral Government employees may be detailed from Federal
21 agencies with or without reimbursement to those agencies
22 to the Institute at any time, and such detail shall be with-
23 out interruption or loss of civil service status or privilege.
24 Each such employee shall abide by the statutory, regu-
25 latory, ethical, and procedural standards applicable to the

1 employees of the agency from which such employee is de-
2 tailed and those of the Institute.

3 “(1) ANNUAL REPORTS.—

4 “(1) REPORTS TO INSTITUTE.—Any recipient of
5 a grant, contract, or cooperative agreement from the
6 Institute under this section shall submit to the Insti-
7 tute a report on an annual basis for the duration of
8 such grant, contract, or cooperative agreement, that
9 describes the activities carried out under such grant,
10 contract, or cooperative agreement.

11 “(2) REPORT TO FDA.—Beginning with fiscal
12 year 2009, the Executive Director shall submit to
13 the Commissioner an annual report that—

14 “(A) details the progress of the Institute in
15 furthering the goals and priorities established
16 under subsection (c)(2); and

17 “(B) provides recommendations for incor-
18 porating such progress into regulatory and
19 product review activities of the Food and Drug
20 Administration.

21 “(3) REPORT TO CONGRESS.—Beginning with
22 fiscal year 2009, the Executive Director shall submit
23 to the Committee on Health, Education, Labor, and
24 Pensions and the Committee on Appropriations of
25 the Senate and the Committee on Energy and Com-

1 merce and the Committee on Appropriations of the
2 House of Representatives an annual report that—

3 “(A) describes the activities of the Insti-
4 tute and of the recipients of a grant, contract,
5 or cooperative agreement under this section, in-
6 cluding the practical impact of the Institute on
7 medical product development;

8 “(B) provides a specific accounting of the
9 source of all funds used by the Institute to
10 carry out such activities; and

11 “(C) describes how such funds were used
12 by the Institute.

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

17 “(n) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as may be
19 necessary for each of fiscal years 2008 through 2013 to
20 carry out subsections (a), (b), and (d) through (m).”.

21 (b) OTHER INSTITUTE PROVISIONS.—Chapter VII of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
23 et seq.) (as amended by subsection (a)) is amended by
24 adding at the end the following:

1 **“SEC. 771. LOCATION OF INSTITUTE.**

2 “(a) IN GENERAL.—The Institute shall, if prac-
3 ticable, be located not more than 20 miles from the Dis-
4 trict of Columbia.

5 “(b) USE OF SPACE.—The Secretary shall consult
6 with the Administrator of General Services to ensure the
7 most cost-efficient arrangement for the leasing or pur-
8 chase of real property for adequate facilities which, if
9 practicable, shall be located at the Food and Drug Admin-
10 istration, to meet the needs of the Institute in carrying
11 out this subchapter.

12 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
13 **TRATION.**

14 “(a) IN GENERAL.—The Commissioner shall receive
15 and assess the report submitted to the Commissioner by
16 the Executive Director of the Institute under section
17 770(1)(2).

18 “(b) REPORT TO CONGRESS.—The Commissioner
19 shall submit to the Committee on Health, Education,
20 Labor, and Pensions and the Committee on Appropria-
21 tions of the Senate and the Committee on Energy and
22 Commerce and the Committee on Appropriations of the
23 House of Representatives an annual report that describes
24 the implementation of any recommendations included in
25 the report described under subsection (a).”.