

114TH CONGRESS
2D SESSION

S. 2742

To amend title IV of the Public Health Service Act regarding the national research institutes, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 4, 2016

Mr. ALEXANDER (for himself, Mrs. MURRAY, Mr. KIRK, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend title IV of the Public Health Service Act regarding the national research institutes, 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. SHORT TITLE.**

4 This Act may be cited as the “Promoting Biomedical
5 Research and Public Health for Patients Act”.

6 **SEC. 2. TRIENNIAL REPORTS OF DIRECTOR OF NIH.**

7 Section 403 of the Public Health Service Act (42
8 U.S.C. 283) is amended—

9 (1) in the heading, by striking “**BIENNIAL**”
10 and inserting “**TRIENNIAL**”; and

1 (2) in subsection (a)—

2 (A) in the matter preceding paragraph (1),
3 by striking “biennial” and inserting “triennial”;

4 (B) by amending paragraph (3) to read as
5 follows:

6 “(3) A description of intra-NIH activities, in-
7 cluding identification of the percentage of funds
8 made available by each national research institute
9 and national center with respect to each applicable
10 fiscal year for conducting or supporting research
11 that involves collaboration between the institute or
12 center and 1 or more other national research insti-
13 tutes or national centers and recommendations for
14 promoting coordination of information among the
15 centers of excellence.”;

16 (C) in paragraph (4)—

17 (i) in subparagraph (B), by striking
18 “demographic variables and other vari-
19 ables” and inserting “demographic vari-
20 ables, including biological and social vari-
21 ables and relevant age categories, and de-
22 terminants of health”; and

23 (ii) in subparagraph (C)(v)—

24 (I) by striking “demographic
25 variables and such” and inserting

1 “demographic variables, including rel-
2 evant age categories, information sub-
3 mitted by each national research insti-
4 tute and national center to the Direc-
5 tor of NIH under section 492B(f),
6 and such”; and

7 (II) by striking “(regarding in-
8 clusion of women and minorities in
9 clinical research)” and inserting “and
10 other applicable requirements regard-
11 ing inclusion of demographic groups”;
12 and

13 (D) in paragraph (6)—

14 (i) in the matter preceding subpara-
15 graph (A), by striking “the following:” and
16 inserting “the following—”;

17 (ii) in subparagraph (A)—

18 (I) by striking “An evaluation”
19 and inserting “an evaluation”; and

20 (II) by striking the period and
21 inserting “; and”;

22 (iii) by striking subparagraphs (B)
23 and (D);

24 (iv) by redesignating subparagraph
25 (C) as subparagraph (B); and

1 (v) in subparagraph (B), as redesignated by clause (iv), by striking “Recommendations” and inserting “recommendations”.

5 **SEC. 3. ADMINISTRATIVE BURDEN ON INVESTIGATORS.**

6 (a) DISCLOSURE OF FINANCIAL CONFLICTS OF INTEREST.—

8 (1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall—

12 (A) lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest; and

17 (B) make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants.

22 (2) CONSIDERATIONS.—In updating policies under paragraph (1)(B), the Secretary shall consider—

1 (A) modifying the timelines for the report-
2 ing of financial conflicts of interest to just in
3 time information by institutions receiving grant
4 or cooperative agreement funding from the Na-
5 tional Institutes of Health;

6 (B) ensuring that financial interest dislo-
7 sure reporting requirements are appropriate for,
8 and relevant to, awards that will directly fund
9 research, which may include modification of the
10 definition of the term “investigator”; and

11 (C) updating any applicable training mod-
12 ules of the National Institutes of Health related
13 to Federal financial interest disclosure.

14 (b) MONITORING OF SUBRECIPIENTS OF FUNDING
15 FROM THE NATIONAL INSTITUTES OF HEALTH.—The Di-
16 rector of the National Institutes of Health shall implement
17 measures to reduce the administrative burdens related to
18 monitoring of subrecipients of grants by primary awardees
19 of funding from the National Institutes of Health, which
20 may incorporate findings and recommendations from ex-
21 isting and ongoing activities. Such measures may include,
22 as appropriate—

23 (1) an exemption from subrecipient monitoring
24 requirements, upon request from the primary award-
25 ees, provided that—

1 (A) the subrecipient is subject to Federal
2 audit requirements pursuant to the Uniform
3 Guidance of the Office of Management and
4 Budget;

5 (B) the primary awardee conducts a for-
6 mal or informal evaluation of each subrecipi-
7 ent's risk of noncompliance with Federal stat-
8 utes and regulations, and the conditions of the
9 subaward; and

10 (C) such exemption does not absolve the
11 primary awardee of liability for misconduct by
12 subrecipients; and

13 (2) the implementation of alternative grant
14 structures that obviate the need for subrecipient
15 monitoring, which may include collaborative grant
16 models allowing for multiple primary awardees.

17 (c) REPORTING OF FINANCIAL EXPENDITURES.—

18 The Secretary, in consultation with the Director of the
19 National Institutes of Health, shall evaluate financial ex-
20 penditure reporting procedures and requirements for re-
21 cipients of funding from the National Institutes of Health
22 and take action, as appropriate, to avoid duplication be-
23 tween department and agency procedures and require-
24 ments and minimize burden to funding recipients.

1 (d) ANIMAL CARE AND USE IN RESEARCH.—Not
2 later than 2 years after the date of enactment of this Act,
3 the Director of the National Institutes of Health, in col-
4 laboration with the Secretary of Agriculture and the Com-
5 missioner of Food and Drugs, shall complete a review of
6 applicable regulations and policies for the care and use
7 of laboratory animals and make revisions, as appropriate,
8 to reduce administrative burden on investigators while
9 maintaining the integrity and credibility of research find-
10 ings and protection of research animals. In carrying out
11 this effort, the Director shall seek the input of experts,
12 as appropriate. The Director shall—

13 (1) identify ways to ensure such regulations
14 and policies are not inconsistent, overlapping, or un-
15 necessarily duplicative, including with respect to in-
16 spection and review requirements by Federal agen-
17 cies and accrediting associations;

18 (2) take steps to eliminate or reduce identified
19 inconsistencies, overlap, or duplication among such
20 regulations and policies; and

21 (3) take other actions, as appropriate, to im-
22 prove the coordination of regulations and policies
23 with respect to research with laboratory animals.

24 (e) DOCUMENTATION OF PERSONNEL EXPENSES.—
25 The Secretary shall clarify the applicability of the require-

1 ments under the Office of Management and Budget Uni-
2 form Guidance for management and certification systems
3 adopted by entities receiving Federal research grants
4 through the Department of Health and Human Services
5 regarding documentation of personnel expenses, including
6 clarification of the extent to which any flexibility to such
7 requirements specified in such Uniform Guidance applies
8 to entities receiving grants through the Department of
9 Health and Human Services.

10 (f) RESEARCH POLICY BOARD.—

11 (1) ESTABLISHMENT.—Not later than 1 year
12 after the date of enactment of this Act, the Director
13 of the Office of Management and Budget shall es-
14 tablish an advisory committee, to be known as the
15 “Research Policy Board” (referred to in this sub-
16 section as the “Board”), to provide the Director and
17 other members of the Federal Government with in-
18 formation on the effects of regulations related to
19 Federal research requirements.

20 (2) MEMBERSHIP.—

21 (A) IN GENERAL.—The Board shall in-
22 clude not more than 10 Federal members, in-
23 cluding each of the following Federal members
24 or their designees:

1 (i) The Administrator of the Office of
2 Information and Regulatory Affairs of the
3 Office of Management and Budget.

4 (ii) The Director of the Office of
5 Science and Technology Policy.

6 (iii) The Secretary of Health and
7 Human Services.

8 (iv) The Director of the National
9 Science Foundation.

10 (v) The secretaries and directors of
11 other departments and agencies that sup-
12 port or regulate scientific research, as de-
13 termined by the Director of the Office of
14 Management and Budget.

15 (B) NON-FEDERAL MEMBERS.—The Board
16 shall be comprised of not less than 9 and not
17 more than 12 representatives of academic re-
18 search institutions, other private, nonprofit re-
19 search institutions, or other nonprofit organiza-
20 tions with relevant expertise. Such members
21 shall be appointed by a formal process, to be es-
22 tablished by the Director of the Office of Man-
23 agement and Budget, in consultation with the
24 Federal membership, and that incorporates—

1 (i) nomination by members of the
2 nonprofit scientific research community,
3 including academic research institutions;
4 and

5 (ii) procedures to fill membership po-
6 sitions vacated before the end of a mem-
7 ber's term.

8 (3) PURPOSE AND RESPONSIBILITIES.—The
9 Board shall make recommendations regarding the
10 modification and harmonization of regulations and
11 policies having similar purposes across research
12 funding agencies to ensure that the administrative
13 burden of such research policy and regulation is
14 minimized to the greatest extent possible and con-
15 sistent with maintaining responsible oversight of fed-
16 erally funded research. Activities of the Board may
17 include—

18 (A) providing thorough and informed anal-
19 ysis of regulations and policies;

20 (B) identifying negative or adverse con-
21 sequences of existing policies and making ac-
22 tionable recommendations regarding possible
23 improvement of such policies;

24 (C) making recommendations with respect
25 to efforts within the Federal Government to im-

1 prove coordination of regulation and policy re-
2 lated to research;

3 (D) creating a forum for the discussion of
4 research policy or regulatory gaps, challenges,
5 clarification, or harmonization of such policies
6 or regulation, and best practices; and

7 (E) conducting ongoing assessment and
8 evaluation of regulatory burden, including de-
9 velopment of metrics, periodic measurement,
10 and identification of process improvements and
11 policy changes.

12 (4) EXPERT SUBCOMMITTEES.—The Board
13 may form temporary expert subcommittees, as ap-
14 propriate, to develop timely analysis on pressing
15 issues and assist the Board in anticipating future
16 regulatory challenges, including those emerging from
17 new scientific advances.

18 (5) REPORTING REQUIREMENTS.—Not later
19 than 2 years after the date of enactment of this Act,
20 and once thereafter, the Board shall submit a report
21 to the Director of the Office of Management and
22 Budget, the Administrator of the Office of Informa-
23 tion and Regulatory Affairs of the Office of Manage-
24 ment and Budget, the Director of the Office of
25 Science and Technology Policy, the heads of relevant

1 Federal departments and agencies, the Committee
2 on Health, Education, Labor, and Pensions of the
3 Senate, and the Committee on Energy and Com-
4 merce of the House of Representatives containing
5 formal recommendations on the conceptualization,
6 development, harmonization, and reconsideration of
7 scientific research policy, including the regulatory
8 benefits and burdens.

9 (6) SUNSET.—The Board shall terminate on
10 September 30, 2020.

11 (7) GAO REPORT.—Not later than 4 years
12 after the date of enactment of this Act, the Comp-
13 troller General of the United States shall conduct an
14 independent evaluation of the activities carried out
15 by the Board pursuant to this subsection and submit
16 to the appropriate committees of Congress a report
17 regarding the results of the independent evaluation.
18 Such report shall review and assess the Board’s ac-
19 tivities with respect to the responsibilities described
20 in paragraph (3).

21 **SEC. 4. REIMBURSEMENT FOR RESEARCH SUBSTANCES**
22 **AND LIVING ORGANISMS.**

23 Section 301 of the Public Health Service Act (42
24 U.S.C. 241) is amended—

1 (1) in the flush matter at the end of subsection

2 (a)—

3 (A) by redesignating such matter as sub-
4 section (f)(1); and

5 (B) by moving such matter so as to appear
6 at the end of such section; and

7 (2) in subsection (f) (as so redesignated), by
8 adding at the end the following:

9 “(2) Where research substances and living organisms
10 are made available under paragraph (1) through contrac-
11 tors, the Secretary may direct such contractors to collect
12 payments on behalf of the Secretary for the costs incurred
13 to make available such substances and organisms and to
14 forward amounts so collected to the Secretary, in the time
15 and manner specified by the Secretary.

16 “(3) Amounts collected under paragraph (2) shall be
17 credited to the appropriations accounts that incurred the
18 costs to make available the research substances and living
19 organisms involved, and shall remain available until ex-
20 pended for carrying out activities under such accounts.”.

21 **SEC. 5. STREAMLINING NIH REPORTING REQUIREMENTS.**

22 (a) TRANS-NIH RESEARCH REPORTING.—Section
23 402A(c)(2) of the Public Health Service Act (42 U.S.C.
24 282a(c)(2)) is amended—

1 (1) by amending subparagraph (B) to read as
2 follows:

3 “(B) REPORTING.—Not later than 2 years
4 after the date of enactment of Promoting Bio-
5 medical Research and Public Health for Pa-
6 tients Act, the head of each national research
7 institute or national center shall submit to the
8 Director of NIH a report, to be included in the
9 triennial report under section 403, on the
10 amount made available by the institute or cen-
11 ter for conducting or supporting research that
12 involves collaboration between the institute or
13 center and 1 or more other national research
14 institutes or national centers.”; and

15 (2) in subparagraphs (D) and (E) by striking
16 “(B)(i)” each place it appears and inserting “(B)”.

17 (b) FRAUD AND ABUSE REPORTING.—Section 403B
18 of the Public Health Service Act (42 U.S.C. 283a–1) is
19 amended—

20 (1) by striking subsection (b);

21 (2) by redesignating subsection (c) as sub-
22 section (b); and

23 (3) in subsection (b) (as so redesignated), by
24 striking “subsections (a) and (b)” and inserting
25 “subsection (a)”.

1 (c) DOCTORAL DEGREES REPORTING.—Section
2 403C(a)(2) of the Public Health Service Act (42 U.S.C.
3 283a–2(a)(2)) is amended by striking “(not including any
4 leaves of absence)”.

5 (d) VACCINE REPORTING.—Section 404B of the Pub-
6 lic Health Service Act (42 U.S.C. 283d) is amended—

7 (1) by striking subsection (b); and

8 (2) by striking “(a) DEVELOPMENT OF NEW
9 VACCINES.—The Secretary” and inserting “The
10 Secretary”.

11 (e) NATIONAL CENTER FOR ADVANCING
12 TRANSLATIONAL SCIENCES.—Section 479(c) of the Public
13 Health Service Act (42 U.S.C. 287(c)) is amended—

14 (1) in the subsection heading, by striking “AN-
15 NUAL” and inserting “BIENNIAL”; and

16 (2) in the matter preceding paragraph (1), by
17 striking “an annual report” and inserting “a report
18 on a biennial basis”.

19 (f) REVIEW OF CENTERS OF EXCELLENCE.—

20 (1) REPEAL.—Section 404H of the Public
21 Health Service Act (42 U.S.C. 283j) is repealed.

22 (2) CONFORMING AMENDMENT.—Section
23 399EE(e) of the Public Health Service Act (42
24 U.S.C. 280i–4(c)) is amended by striking “399CC,
25 404H,” and inserting “399CC”.

1 (g) RAPID HIV TEST REPORT.—Section 502(a) of
2 the Ryan White CARE Act Amendments of 2000 (42
3 U.S.C. 300cc note) is amended—

4 (1) by striking paragraph (2); and

5 (2) by redesignating paragraph (3) as para-
6 graph (2).

7 (h) BIENNIAL REPORT.—

8 (1) REPEAL.—Section 464Y of the Public
9 Health Service Act (42 U.S.C. 285q-3) is repealed.

10 (2) CONFORMING AMENDMENT.—Section
11 464X(g) of the Public Health Service Act (42
12 U.S.C. 285q-2(g)) is amended by striking “biennial
13 report made under section 464Y,” and inserting
14 “triennial report made under section 403”.

15 **SEC. 6. NATIONAL VACCINE INJURY COMPENSATION PRO-**
16 **GRAM.**

17 (a) ADDITIONAL VACCINES.—Section 2114(e) of the
18 Public Health Service Act (42 U.S.C. 300aa-14(e)) is
19 amended by adding at the end the following:

20 “(3) VACCINES RECOMMENDED FOR USE IN
21 PREGNANT WOMEN.—The Secretary shall revise the
22 Vaccine Injury Table included in subsection (a),
23 through the process described in subsection (c), to
24 include vaccines recommended by the Centers for
25 Disease Control and Prevention for routine adminis-

1 tration in pregnant women and the information de-
2 scribed in subparagraphs (B) and (C) of paragraph
3 (2) with respect to such vaccines.”.

4 (b) PETITION CONTENT.—Section 2111 of the Public
5 Health Service Act (42 U.S.C. 300aa–11) is amended by
6 adding at the end the following:

7 “(f) MATERNAL IMMUNIZATION.—

8 “(1) IN GENERAL.—Notwithstanding any other
9 provision of law, for purposes of this subtitle, both
10 a woman who received a covered vaccine while preg-
11 nant and any child who was in utero at the time
12 such woman received the vaccine shall be considered
13 persons to whom the covered vaccine was adminis-
14 tered and persons who received the covered vaccine.

15 “(2) DEFINITION.—As used in this subsection,
16 the term ‘child’ shall have the meaning given that
17 term by subsections (a) and (b) of section 8 of title
18 1, United States Code, except that, for purposes of
19 this subsection, such section 8 shall be applied as if
20 the term ‘include’ in subsection (a) of such section
21 were replaced with the term ‘mean’.”.

22 (c) PETITIONERS.—Section 2111(b)(2) of the Public
23 Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amend-
24 ed by adding “A covered vaccine administered to a preg-
25 nant woman shall constitute more than one administra-

1 tion, one to the mother and one to each child (as such
 2 term is defined in subsection (f)(2)) who was in utero at
 3 the time such woman was administered the vaccine.” at
 4 the end.

5 **SEC. 7. VACCINE MEETINGS; REPORT ON VACCINE INNOVA-**
 6 **TION.**

7 (a) VACCINE MEETINGS.—The Director of the Cen-
 8 ters for Disease Control and Prevention shall ensure that
 9 appropriate staff within the relevant centers and divisions
 10 of the Office of Infectious Diseases, and others, as appro-
 11 priate, coordinate with respect to the public health needs,
 12 epidemiology, and program planning and implementation
 13 considerations related to immunization, including with re-
 14 gard to meetings with stakeholders related to such topics.

15 (b) REPORT ON VACCINE INNOVATION.—

16 (1) IN GENERAL.—Not later than 1 year after
 17 the date of enactment of this Act, the Secretary of
 18 Health and Human Services (referred to in this sec-
 19 tion as the “Secretary”), in collaboration with ap-
 20 propriate agencies or offices within the Department
 21 of Health and Human Services, including the Na-
 22 tional Institute of Allergy and Infectious Diseases
 23 and the Biomedical Advanced Research and Devel-
 24 opment Authority, shall issue to the Committee on
 25 Health, Education, Labor, and Pensions of the Sen-

1 ate and the Committee on Energy and Commerce of
2 the House of Representatives, and post publicly on
3 the Internet website of the Department of Health
4 and Human Services, a report on ways to promote
5 innovation in the development of vaccines that mini-
6 mize the burden of infectious disease.

7 (2) CONTENTS.—The report described in para-
8 graph (1) shall review the current status of vaccine
9 development and, as appropriate—

10 (A) consider the optimal process to deter-
11 mine which vaccines would be beneficial and
12 how information on such vaccines is dissemi-
13 nated to key stakeholders;

14 (B) examine and identify whether obstacles
15 exist that inhibit the development of beneficial
16 vaccines; and

17 (C) make recommendations about how best
18 to remove any obstacles identified under sub-
19 paragraph (B) in order to promote and
20 incentivize vaccine innovation and development.

21 (3) CONSULTATION.—In preparing the report
22 under subsection (a), the Secretary may consult
23 with—

24 (A) representatives of relevant Federal
25 agencies and departments, including the De-

1 partment of Defense and the Department of
2 Veterans Affairs;

3 (B) academic researchers;

4 (C) developers and manufacturers of vac-
5 cines;

6 (D) medical and public health practi-
7 tioners;

8 (E) representatives of patient, policy, and
9 advocacy organizations; and

10 (F) representatives of other entities, as the
11 Secretary determines appropriate.

12 **SEC. 8. TECHNICAL UPDATES TO CLINICAL TRIALS DATA-**
13 **BASE.**

14 Section 402(j)(2)(D) of the Public Health Service Act
15 (42 U.S.C. 282(j)(2)(D)) is amended—

16 (1) in clause (ii)(I), by inserting before the
17 semicolon “, unless the responsible party affirma-
18 tively requests that the Director of NIH publicly
19 post such clinical trial information for an applicable
20 device clinical trial prior to such date of clearance or
21 approval”; and

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

23 “(iii) OPTION TO MAKE CERTAIN
24 CLINICAL TRIAL INFORMATION AVAILABLE
25 EARLIER.—The Director of NIH shall in-

1 form responsible parties of the option to
2 request that clinical trial information for
3 an applicable device clinical trial be pub-
4 licly posted prior to the date of clearance
5 or approval, in accordance with clause
6 (ii)(I).

7 “(iv) COMBINATION PRODUCTS.—An
8 applicable clinical trial for a product that
9 is a combination of drug, device, or biologi-
10 cal product shall be considered—

11 “(I) an applicable drug clinical
12 trial, if the Secretary determines
13 under section 503(g) of the Federal
14 Food, Drug, and Cosmetic Act that
15 the primary mode of action of such
16 product is that of a drug or biological
17 product; or

18 “(II) an applicable device clinical
19 trial, if the Secretary determines
20 under such section that the primary
21 mode of action of such product is that
22 of a device.”.

23 **SEC. 9. COMPLIANCE ACTIVITIES REPORTS.**

24 (a) DEFINITIONS.—In this section:

1 (1) APPLICABLE CLINICAL TRIAL.—The term
2 “applicable clinical trial” has the meaning given the
3 term in section 402(j) of the Public Health Service
4 Act (42 U.S.C. 282(j)).

5 (2) DIRECTOR OF NIH.—The term “Director of
6 NIH” means the Director of the National Institutes
7 of Health.

8 (3) SECRETARY.—The term “Secretary” means
9 the Secretary of Health and Human Services.

10 (b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLI-
11 ANCE.—Not later than 2 years after the date of enactment
12 of this Act, the Secretary, acting through the Director of
13 NIH and in collaboration with the Commissioner of Food
14 and Drugs, shall submit to the Committee on Health,
15 Education, Labor, and Pensions of the Senate and the
16 Committee on Energy and Commerce of the House of
17 Representatives, a report that describes education and
18 outreach, guidance, enforcement, and other activities un-
19 dertaken to encourage compliance with section 402(j) of
20 the Public Health Service Act (42 U.S.C. 282(j)).

21 (c) REPORTS ON CLINICAL TRIALS.—

22 (1) IN GENERAL.—Not later than 2 years after
23 the final compliance date under the final rule imple-
24 menting section 402(j) of the Public Health Service
25 Act, and every 2 years thereafter for the next 4

1 years, the Secretary, acting through the Director of
2 NIH and in collaboration with the Commissioner of
3 Food and Drugs, shall submit to the Committee on
4 Health, Education, Labor, and Pensions of the Sen-
5 ate and the Committee on Energy and Commerce of
6 the House of Representatives, a report describing—

7 (A) the total number of applicable clinical
8 trials with complete data bank registration in-
9 formation registered during the period for
10 which the report is being prepared (broken
11 down by each year of such reporting period);

12 (B) the total number of applicable clinical
13 trials registered during the period for which the
14 report is being prepared for which results have
15 been submitted to the data bank (broken down
16 by each year of such reporting period);

17 (C) the activities undertaken by the Sec-
18 retary during the period for which the report is
19 being prepared to educate responsible persons
20 about data bank registration and results sub-
21 mission requirements, including through
22 issuance of guidance documents, informational
23 meetings, and training sessions; and

24 (D) the activities described in the report
25 submitted under subsection (b).

1 (2) ACTIONS TO ENFORCE COMPLIANCE.—After
 2 the Secretary has undertaken the educational activi-
 3 ties described in paragraph (1)(C), the Secretary
 4 shall include in subsequent reports submitted under
 5 paragraph (1) the number of actions taken by the
 6 Secretary during the period for which the report is
 7 being prepared to enforce compliance with data bank
 8 registration and results submission requirements.

9 **SEC. 10. APPOINTMENT OF DIRECTORS OF NATIONAL RE-**
 10 **SEARCH INSTITUTES AND NATIONAL CEN-**
 11 **TERS.**

12 Subsection (a) of section 405 of the Public Health
 13 Service Act (42 U.S.C. 284) is amended as follows:

14 “(a) APPOINTMENT.—

15 “(1) IN GENERAL.—The Director of the Na-
 16 tional Cancer Institute shall be appointed by the
 17 President and the Directors of the other national re-
 18 search institutes and centers shall be appointed by
 19 the Secretary, acting through the Director of NIH.
 20 Each Director of a national research institute or na-
 21 tional center shall report directly to the Director of
 22 NIH.

23 “(2) APPOINTMENT.—

24 “(A) TERM.—A Director of a national re-
 25 search institute or national center who is ap-

1 pointed by the Secretary, acting through the
2 Director of NIH, shall be appointed for 5 years.

3 “(B) REAPPOINTMENT.—At the end of the
4 term of a Director of a national research insti-
5 tute or national center, the Director may be re-
6 appointed. There shall be no limit on the num-
7 ber of terms that a Director may serve.

8 “(C) VACANCIES.—If the office of a Direc-
9 tor of a national research institute or national
10 center becomes vacant before the end of such
11 Director’s term, the Director appointed to fill
12 the vacancy shall be appointed for a 5-year
13 term starting on the date of such appointment.

14 “(D) CURRENT DIRECTORS.—Each Direc-
15 tor of a national research institute or national
16 center who is serving on the date of enactment
17 of the Promoting Biomedical Research and
18 Public Health for Patients Act shall be deemed
19 to be appointed for a 5-year term under this
20 subsection beginning on such date of enact-
21 ment.

22 “(E) RULE OF CONSTRUCTION.—Nothing
23 in this subsection shall be construed to limit the
24 ability of the Director of NIH or a Director of
25 a national research institute or center to termi-

1 nate the appointment of such Director of a na-
 2 tional research institute or center prior to the
 3 expiration of such Director’s 5-year term.

4 “(3) NONAPPLICATION OF CERTAIN PROVI-
 5 SION.—The restrictions contained in section 202 of
 6 the Departments of Labor, Health and Human
 7 Services, and Education, and Related Agencies Ap-
 8 propriations Act, 1993 (Public Law 102–394; 42
 9 U.S.C. 238f note) related to consultants and indi-
 10 vidual scientists appointed for limited periods of
 11 time shall not apply to Directors appointed under
 12 this subsection.”.

13 **SEC. 11. NATIONAL CENTER FOR ADVANCING**
 14 **TRANSLATIONAL SCIENCES.**

15 Section 479(b) of the Public Health Service Act (42
 16 U.S.C. 287(b)) is amended—

17 (1) in paragraph (1), by striking “phase IIA”
 18 and inserting “phase IIB”; and

19 (2) in paragraph (2)—

20 (A) in the matter preceding subparagraph
 21 (A), by striking “phase IIB” and inserting
 22 “phase III”;

23 (B) in subparagraph (A), by striking
 24 “phase IIB” and inserting “phase III”;

- 1 (C) in subparagraph (B), by striking
- 2 “phase IIA” and inserting “phase IIB”; and
- 3 (D) in subparagraph (C), by striking
- 4 “phase IIB” and inserting “phase III”.

○