

## Calendar No. 429

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.

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 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

APRIL 18, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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**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”.

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

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

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

6 (2) in subsection (a)—

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

9 (B) by amending paragraph (3) to read as  
10 follows:

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

21 (C) in paragraph (4)—

22 (i) in subparagraph (B), by striking  
23 “demographic variables and other vari-  
24 ables” and inserting “demographic vari-  
25 ables, including biological and social vari-

1 ables and relevant age categories, and de-  
 2 terminants of health”; and

3 (ii) in subparagraph (C)(v)—

4 (I) by striking “demographic  
 5 variables and such” and inserting  
 6 “demographic variables, including rel-  
 7 evant age categories, information sub-  
 8 mitted by each national research insti-  
 9 tute and national center to the Direc-  
 10 tor of NIH under section 492B(f),  
 11 and such”; and

12 (II) by striking “(regarding in-  
 13 clusion of women and minorities in  
 14 clinical research)” and inserting “and  
 15 other applicable requirements regard-  
 16 ing inclusion of demographic groups”;  
 17 and

18 (D) in paragraph (6)—

19 (i) in the matter preceding subpara-  
 20 graph (A), by striking “the following:” and  
 21 inserting “the following—”;

22 (ii) in subparagraph (A)—

23 (I) by striking “An evaluation”  
 24 and inserting “an evaluation”; and

- 1                   (II) by striking the period and  
 2                   inserting “; and”;
- 3                   (iii) by striking subparagraphs (B)  
 4                   and (D);
- 5                   (iv) by redesignating subparagraph  
 6                   (C) as subparagraph (B); and
- 7                   (v) in subparagraph (B), as redesi-  
 8                   gnated by clause (iv), by striking “Ree-  
 9                   ommendations” and inserting “rec-  
 10                  ommendations”.

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

12       (a) **DISCLOSURE OF FINANCIAL CONFLICTS OF IN-**  
 13 **TEREST.—**

14               (1) **IN GENERAL.**—Not later than 2 years after  
 15       the date of enactment of this Act, the Secretary of  
 16       Health and Human Services (referred to in this sec-  
 17       tion as the “Secretary”) shall—

18               (A) lead a review by research funding  
 19       agencies of all regulations and policies related  
 20       to the disclosure of financial conflicts of inter-  
 21       est, including the minimum threshold for re-  
 22       porting financial conflicts of interest; and

23               (B) make revisions, as appropriate, to har-  
 24       monize existing policies and reduce administra-  
 25       tive burden on researchers while maintaining

1 the integrity and credibility of research findings  
2 and protections of human participants.

3 ~~(2)~~ CONSIDERATIONS.—In updating policies  
4 under paragraph ~~(1)(B)~~, the Secretary shall con-  
5 sider—

6 (A) modifying the timelines for the report-  
7 ing of financial conflicts of interest to just in  
8 time information by institutions receiving grant  
9 or cooperative agreement funding from the Na-  
10 tional Institutes of Health;

11 (B) ensuring that financial interest disclo-  
12 sure reporting requirements are appropriate for,  
13 and relevant to, awards that will directly fund  
14 research, which may include modification of the  
15 definition of the term “investigator”; and

16 (C) updating any applicable training mod-  
17 ules of the National Institutes of Health related  
18 to Federal financial interest disclosure.

19 ~~(b) MONITORING OF SUBRECIPIENTS OF FUNDING~~  
20 ~~FROM THE NATIONAL INSTITUTES OF HEALTH.~~—The Di-  
21 rector of the National Institutes of Health shall implement  
22 measures to reduce the administrative burdens related to  
23 monitoring of subrecipients of grants by primary awardees  
24 of funding from the National Institutes of Health, which  
25 may incorporate findings and recommendations from ex-

1 isting and ongoing activities. Such measures may include,  
2 as appropriate—

3           (1) an exemption from subrecipient monitoring  
4 requirements, upon request from the primary award-  
5 ees, provided that—

6           (A) the subrecipient is subject to Federal  
7 audit requirements pursuant to the Uniform  
8 Guidance of the Office of Management and  
9 Budget;

10           (B) the primary awardee conducts a for-  
11 mal or informal evaluation of each subrecipi-  
12 ent's risk of noncompliance with Federal stat-  
13 utes and regulations, and the conditions of the  
14 subaward; and

15           (C) such exemption does not absolve the  
16 primary awardee of liability for misconduct by  
17 subrecipients; and

18           (2) the implementation of alternative grant  
19 structures that obviate the need for subrecipient  
20 monitoring, which may include collaborative grant  
21 models allowing for multiple primary awardees.

22           (c) REPORTING OF FINANCIAL EXPENDITURES.—

23 The Secretary, in consultation with the Director of the  
24 National Institutes of Health, shall evaluate financial ex-  
25 penditure reporting procedures and requirements for re-

1 recipients of funding from the National Institutes of Health  
2 and take action, as appropriate, to avoid duplication be-  
3 tween department and agency procedures and require-  
4 ments and minimize burden to funding recipients.

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

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

22 (2) take steps to eliminate or reduce identified  
23 inconsistencies, overlap, or duplication among such  
24 regulations and policies; and

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

4           (e) DOCUMENTATION OF PERSONNEL EXPENSES.—

5           The Secretary shall clarify the applicability of the require-  
6           ments under the Office of Management and Budget Uni-  
7           form Guidance for management and certification systems  
8           adopted by entities receiving Federal research grants  
9           through the Department of Health and Human Services  
10          regarding documentation of personnel expenses, including  
11          clarification of the extent to which any flexibility to such  
12          requirements specified in such Uniform Guidance applies  
13          to entities receiving grants through the Department of  
14          Health and Human Services.

15          (f) RESEARCH POLICY BOARD.—

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

25               (2) MEMBERSHIP.—



1           (A) ~~IN GENERAL.~~—The Board shall in-  
2           clude not more than 10 Federal members, in-  
3           cluding each of the following Federal members  
4           or their designees:

5                   (i) The Administrator of the Office of  
6                   Information and Regulatory Affairs of the  
7                   Office of Management and Budget.

8                   (ii) The Director of the Office of  
9                   Science and Technology Policy.

10                  (iii) The Secretary of Health and  
11                  Human Services.

12                  (iv) The Director of the National  
13                  Science Foundation.

14                  (v) The secretaries and directors of  
15                  other departments and agencies that sup-  
16                  port or regulate scientific research, as de-  
17                  termined by the Director of the Office of  
18                  Management and Budget.

19           (B) ~~NON-FEDERAL MEMBERS.~~—The Board  
20           shall be comprised of not less than 9 and not  
21           more than 12 representatives of academic re-  
22           search institutions; other private, nonprofit re-  
23           search institutions; or other nonprofit organiza-  
24           tions with relevant expertise. Such members  
25           shall be appointed by a formal process, to be es-

1           tablISHED by the Director of the Office of Man-  
2           agement and Budget, in consultation with the  
3           Federal membership, and that incorporates—

4                   (i) nomination by members of the  
5                   nonprofit scientific research community,  
6                   including academic research institutions;  
7                   and

8                   (ii) procedures to fill membership po-  
9                   sitions vacated before the end of a mem-  
10                  ber's term.

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

21                   (A) providing thorough and informed anal-  
22                   ysis of regulations and policies;

23                   (B) identifying negative or adverse con-  
24                   sequences of existing policies and making ac-

1 tionable recommendations regarding possible  
2 improvement of such policies;

3 (C) making recommendations with respect  
4 to efforts within the Federal Government to im-  
5 prove coordination of regulation and policy re-  
6 lated to research;

7 (D) creating a forum for the discussion of  
8 research policy or regulatory gaps, challenges,  
9 clarification, or harmonization of such policies  
10 or regulation, and best practices; and

11 (E) conducting ongoing assessment and  
12 evaluation of regulatory burden, including de-  
13 velopment of metrics, periodic measurement,  
14 and identification of process improvements and  
15 policy changes.

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

22 (5) REPORTING REQUIREMENTS.—Not later  
23 than 2 years after the date of enactment of this Act,  
24 and once thereafter, the Board shall submit a report  
25 to the Director of the Office of Management and

1 Budget, the Administrator of the Office of Informa-  
2 tion and Regulatory Affairs of the Office of Manage-  
3 ment and Budget, the Director of the Office of  
4 Science and Technology Policy, the heads of relevant  
5 Federal departments and agencies, the Committee  
6 on Health, Education, Labor, and Pensions of the  
7 Senate, and the Committee on Energy and Com-  
8 merce of the House of Representatives containing  
9 formal recommendations on the conceptualization,  
10 development, harmonization, and reconsideration of  
11 scientific research policy, including the regulatory  
12 benefits and burdens.

13 (6) SUNSET.—The Board shall terminate on  
14 September 30, 2020.

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

1 **SEC. 4. REIMBURSEMENT FOR RESEARCH SUBSTANCES**  
2 **AND LIVING ORGANISMS.**

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

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

6 (a)—

7 (A) by redesignating such matter as sub-  
8 section (f)(1); and

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

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

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

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

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

2 (a) ~~TRANS-NIH RESEARCH REPORTING.~~—Section  
3 402A(c)(2) of the Public Health Service Act (42 U.S.C.  
4 282a(c)(2)) is amended—

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

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

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

21 (b) ~~FRAUD AND ABUSE REPORTING.~~—Section 403B  
22 of the Public Health Service Act (42 U.S.C. 283a-1) is  
23 amended—

24 (1) by striking subsection (b);

25 (2) by redesignating subsection (e) as sub-  
26 section (b); and

1           (3) in subsection (b) (as so redesignated), by  
2           striking “subsections (a) and (b)” and inserting  
3           “subsection (a)”.

4           (e) DOCTORAL DEGREES REPORTING.—Section  
5           403C(a)(2) of the Public Health Service Act (42 U.S.C.  
6           283a–2(a)(2)) is amended by striking “(not including any  
7           leaves of absence)”.

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

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

11           (2) by striking “(a) DEVELOPMENT OF NEW  
12           VACCINES.—The Secretary” and inserting “The  
13           Secretary”.

14           (e) NATIONAL CENTER FOR ADVANCING  
15           TRANSLATIONAL SCIENCES.—Section 479(e) of the Public  
16           Health Service Act (42 U.S.C. 287(e)) is amended—

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

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

22           (f) REVIEW OF CENTERS OF EXCELLENCE.—

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

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

5           (g) RAPID HIV TEST REPORT.—Section 502(a) of  
 6 the Ryan White CARE Act Amendments of 2000 (42  
 7 U.S.C. 300ee note) is amended—

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

9           (2) by redesignating paragraph (3) as para-  
 10 graph (2).

11          (h) BIENNIAL REPORT.—

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

14          (2) CONFORMING AMENDMENT.—Section  
 15 464X(g) of the Public Health Service Act (42  
 16 U.S.C. 285q-2(g)) is amended by striking “biennial  
 17 report made under section 464Y,” and inserting  
 18 “triennial report made under section 403”.

19 **SEC. 6. NATIONAL VACCINE INJURY COMPENSATION PRO-**  
 20 **GRAM.**

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

24                 “(3) VACCINES RECOMMENDED FOR USE IN  
 25 PREGNANT WOMEN.—The Secretary shall revise the



1 Vaccine Injury Table included in subsection (a),  
 2 through the process described in subsection (e), to  
 3 include vaccines recommended by the Centers for  
 4 Disease Control and Prevention for routine adminis-  
 5 tration in pregnant women and the information de-  
 6 scribed in subparagraphs (B) and (C) of paragraph  
 7 (2) with respect to such vaccines.”.

8 (b) PETITION CONTENT.—Section 2111 of the Public  
 9 Health Service Act (42 U.S.C. 300aa-11) is amended by  
 10 adding at the end the following:

11 “(f) MATERNAL IMMUNIZATION.—

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

19 “(2) DEFINITION.—As used in this subsection,  
 20 the term ‘child’ shall have the meaning given that  
 21 term by subsections (a) and (b) of section 8 of title  
 22 1, United States Code, except that, for purposes of  
 23 this subsection, such section 8 shall be applied as if  
 24 the term ‘include’ in subsection (a) of such section  
 25 were replaced with the term ‘mean’.”.



1 tional Institute of Allergy and Infectious Diseases  
2 and the Biomedical Advanced Research and Devel-  
3 opment Authority, shall issue 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, and post publicly on  
7 the Internet website of the Department of Health  
8 and Human Services, a report on ways to promote  
9 innovation in the development of vaccines that mini-  
10 mize the burden of infectious disease.

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

14 (A) consider the optimal process to deter-  
15 mine which vaccines would be beneficial and  
16 how information on such vaccines is dissemi-  
17 nated to key stakeholders;

18 (B) examine and identify whether obstacles  
19 exist that inhibit the development of beneficial  
20 vaccines; and

21 (C) make recommendations about how best  
22 to remove any obstacles identified under sub-  
23 paragraph (B) in order to promote and  
24 incentivize vaccine innovation and development.

1           (3) CONSULTATION.—In preparing the report  
2 under subsection (a), the Secretary may consult  
3 with—

4           (A) representatives of relevant Federal  
5 agencies and departments, including the De-  
6 partment of Defense and the Department of  
7 Veterans Affairs;

8           (B) academic researchers;

9           (C) developers and manufacturers of vac-  
10 cines;

11           (D) medical and public health practi-  
12 tioners;

13           (E) representatives of patient, policy, and  
14 advocacy organizations; and

15           (F) representatives of other entities, as the  
16 Secretary determines appropriate.

17 **SEC. 8. TECHNICAL UPDATES TO CLINICAL TRIALS DATA-**  
18 **BASE.**

19           Section 402(j)(2)(D) of the Public Health Service Act  
20 (42 U.S.C. 282(j)(2)(D)) is amended—

21           (1) in clause (ii)(I), by inserting before the  
22 semicolon “, unless the responsible party affirma-  
23 tively requests that the Director of NIH publicly  
24 post such clinical trial information for an applicable

1 device clinical trial prior to such date of clearance or  
2 approval”; and

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

4 “(iii) OPTION TO MAKE CERTAIN  
5 CLINICAL TRIAL INFORMATION AVAILABLE  
6 EARLIER.—The Director of NIH shall in-  
7 form responsible parties of the option to  
8 request that clinical trial information for  
9 an applicable device clinical trial be pub-  
10 licly posted prior to the date of clearance  
11 or approval, in accordance with clause  
12 (ii)(I).

13 “(iv) COMBINATION PRODUCTS.—An  
14 applicable clinical trial for a product that  
15 is a combination of drug, device, or biologi-  
16 cal product shall be considered—

17 “(I) an applicable drug clinical  
18 trial, if the Secretary determines  
19 under section 503(g) of the Federal  
20 Food, Drug, and Cosmetic Act that  
21 the primary mode of action of such  
22 product is that of a drug or biological  
23 product; or

24 “(II) an applicable device clinical  
25 trial, if the Secretary determines

1                   under such section that the primary  
2                   mode of action of such product is that  
3                   of a device.”.

4 **SEC. 9. COMPLIANCE ACTIVITIES REPORTS.**

5       (a) DEFINITIONS.—In this section:

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

10          (2) DIRECTOR OF NIH.—The term “Director of  
11       NIH” means the Director of the National Institutes  
12       of Health.

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

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

1 (c) REPORTS ON CLINICAL TRIALS.—

2 (1) IN GENERAL.—Not later than 2 years after  
3 the final compliance date under the final rule imple-  
4 menting section 402(j) of the Public Health Service  
5 Act, and every 2 years thereafter for the next 4  
6 years, the Secretary, acting through the Director of  
7 NIH and in collaboration with the Commissioner of  
8 Food and Drugs, shall submit to the Committee on  
9 Health, Education, Labor, and Pensions of the Sen-  
10 ate and the Committee on Energy and Commerce of  
11 the House of Representatives, a report describing—

12 (A) the total number of applicable clinical  
13 trials with complete data bank registration in-  
14 formation registered during the period for  
15 which the report is being prepared (broken  
16 down by each year of such reporting period);

17 (B) the total number of applicable clinical  
18 trials registered during the period for which the  
19 report is being prepared for which results have  
20 been submitted to the data bank (broken down  
21 by each year of such reporting period);

22 (C) the activities undertaken by the Sec-  
23 retary during the period for which the report is  
24 being prepared to educate responsible persons  
25 about data bank registration and results sub-

1 mission requirements, including through  
 2 issuance of guidance documents, informational  
 3 meetings, and training sessions; and

4 ~~(D)~~ the activities described in the report  
 5 submitted under subsection (b).

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

14 **SEC. 10. APPOINTMENT OF DIRECTORS OF NATIONAL RE-**  
 15 **SEARCH INSTITUTES AND NATIONAL CEN-**  
 16 **TERS.**

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

19 “(a) APPOINTMENT.—

20 “(1) IN GENERAL.—The Director of the Na-  
 21 tional Cancer Institute shall be appointed by the  
 22 President and the Directors of the other national re-  
 23 search institutes and centers shall be appointed by  
 24 the Secretary, acting through the Director of NIH.  
 25 Each Director of a national research institute or na-



1 tional center shall report directly to the Director of  
2 NIH.

3 ~~“(2) APPOINTMENT.—~~

4 ~~“(A) TERM.—A Director of a national re-~~  
5 ~~search institute or national center who is ap-~~  
6 ~~pointed by the Secretary, acting through the~~  
7 ~~Director of NIH, shall be appointed for 5 years.~~

8 ~~“(B) REAPPOINTMENT.—At the end of the~~  
9 ~~term of a Director of a national research insti-~~  
10 ~~tute or national center, the Director may be re-~~  
11 ~~appointed. There shall be no limit on the num-~~  
12 ~~ber of terms that a Director may serve.~~

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

19 ~~“(D) CURRENT DIRECTORS.—Each Direc-~~  
20 ~~tor of a national research institute or national~~  
21 ~~center who is serving on the date of enactment~~  
22 ~~of the Promoting Biomedical Research and~~  
23 ~~Public Health for Patients Act shall be deemed~~  
24 ~~to be appointed for a 5-year term under this~~

1 subsection beginning on such date of enact-  
2 ment.

3 “(E) **RULE OF CONSTRUCTION.**—Nothing  
4 in this subsection shall be construed to limit the  
5 ability of the Director of NIH or a Director of  
6 a national research institute or center to termi-  
7 nate the appointment of such Director of a na-  
8 tional research institute or center prior to the  
9 expiration of such Director’s 5-year term.

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

19 **SEC. 11. NATIONAL CENTER FOR ADVANCING**  
20 **TRANSLATIONAL SCIENCES.**

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

23 (1) in paragraph (1), by striking “phase HA”  
24 and inserting “phase HB”; and

25 (2) in paragraph (2)—

1           (A) in the matter preceding subparagraph  
2           (A), by striking “phase HB” and inserting  
3           “phase III”;

4           (B) in subparagraph (A), by striking  
5           “phase HB” and inserting “phase III”;

6           (C) in subparagraph (B), by striking  
7           “phase HA” and inserting “phase HB”; and

8           (D) in subparagraph (C), by striking  
9           “phase HB” and inserting “phase III”.

10 **SECTION 1. SHORT TITLE.**

11           *This Act may be cited as the “Promoting Biomedical*  
12 *Research and Public Health for Patients Act”.*

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

14           *Section 403 of the Public Health Service Act (42*  
15 *U.S.C. 283) is amended—*

16           (1) *in the section heading, by striking “BIEN-*  
17 *NIAL” and inserting “TRIENNIAL”; and*

18           (2) *in subsection (a)—*

19           (A) *in the matter preceding paragraph (1),*  
20 *by striking “biennial” and inserting “triennial”;*

21           (B) *by amending paragraph (3) to read as*  
22 *follows:*

23           “(3) *A description of intra-NIH activities, in-*  
24 *cluding identification of the percentage of funds made*  
25 *available by each national research institute and na-*

1        *tional center with respect to each applicable fiscal*  
2        *year for conducting or supporting research that in-*  
3        *volves collaboration between the institute or center*  
4        *and 1 or more other national research institutes or*  
5        *national centers and recommendations for promoting*  
6        *coordination of information among the centers of ex-*  
7        *cellence.”;*

8                *(C) in paragraph (4)—*

9                    *(i) in subparagraph (B), by striking*  
10                  *“demographic variables and other vari-*  
11                  *ables” and inserting “demographic vari-*  
12                  *ables, including biological and social vari-*  
13                  *ables and relevant age categories, and deter-*  
14                  *minants of health”;* and

15                  *(ii) in subparagraph (C)(v)—*

16                    *(I) by striking “demographic*  
17                    *variables and such” and inserting “de-*  
18                    *mographic variables, including rel-*  
19                    *evant age categories, information sub-*  
20                    *mitted by each national research insti-*  
21                    *tute and national center to the Direc-*  
22                    *tor of NIH under section 492B(f), and*  
23                    *such”;* and

24                    *(II) by striking “(regarding inclu-*  
25                    *sion of women and minorities in clin-*

1           ical research)” and inserting “and  
2           other applicable requirements regard-  
3           ing inclusion of demographic groups”;  
4           and

5           (D) in paragraph (6)—

6           (i) in the matter preceding subpara-  
7           graph (A), by striking “the following:” and  
8           inserting “the following—”;

9           (ii) in subparagraph (A)—

10           (I) by striking “An evaluation”  
11           and inserting “an evaluation”; and

12           (II) by striking the period and in-  
13           serting “; and”;

14           (iii) by striking subparagraphs (B)  
15           and (D);

16           (iv) by redesignating subparagraph (C)  
17           as subparagraph (B); and

18           (v) in subparagraph (B), as redesi-  
19           gnated by clause (iv), by striking “Rec-  
20           ommendations” and inserting “rec-  
21           ommendations”.

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

23           (a) **DISCLOSURE OF FINANCIAL CONFLICTS OF INTER-**  
24 **EST.**—

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

5                   (A) lead a review by research funding agen-  
6                   cies of all regulations and policies related to the  
7                   disclosure of financial conflicts of interest, in-  
8                   cluding the minimum threshold for reporting fi-  
9                   nancial conflicts of interest; and

10                   (B) make revisions, as appropriate, to har-  
11                   monize existing policies and reduce administra-  
12                   tive burden on researchers while maintaining the  
13                   integrity and credibility of research findings and  
14                   protections of human participants.

15           (2) *CONSIDERATIONS.*—In updating policies  
16           under paragraph (1)(B), the Secretary shall con-  
17           sider—

18                   (A) modifying the timelines for the report-  
19                   ing of financial conflicts of interest to just in  
20                   time information by institutions receiving grant  
21                   or cooperative agreement funding from the Na-  
22                   tional Institutes of Health;

23                   (B) ensuring that financial interest disclo-  
24                   sure reporting requirements are appropriate for,  
25                   and relevant to, awards that will directly fund

1           *research, which may include modification of the*  
2           *definition of the term “investigator”; and*

3                   *(C) updating any applicable training mod-*  
4           *ules of the National Institutes of Health related*  
5           *to Federal financial interest disclosure.*

6           ***(b) MONITORING OF SUBRECIPIENTS OF FUNDING***  
7           ***FROM THE NATIONAL INSTITUTES OF HEALTH.—The Di-***  
8           ***rector of the National Institutes of Health shall implement***  
9           ***measures to reduce the administrative burdens related to***  
10           ***monitoring of subrecipients of grants by primary awardees***  
11           ***of funding from the National Institutes of Health, which***  
12           ***may incorporate findings and recommendations from exist-***  
13           ***ing and ongoing activities. Such measures may include, as***  
14           ***appropriate—***

15                   ***(1) an exemption from subrecipient monitoring***  
16           ***requirements, upon request from the primary award-***  
17           ***ees, provided that—***

18                           ***(A) the subrecipient is subject to Federal***  
19           ***audit requirements pursuant to the Uniform***  
20           ***Guidance of the Office of Management and***  
21           ***Budget;***

22                           ***(B) the primary awardee conducts a formal***  
23           ***or informal evaluation of each subrecipient’s risk***  
24           ***of noncompliance with Federal statutes and reg-***

1            *ulations, and the conditions of the subaward;*  
2            *and*

3            *(C) such exemption does not absolve the pri-*  
4            *mary awardee of liability for misconduct by sub-*  
5            *recipients; and*

6            *(2) the implementation of alternative grant*  
7            *structures that obviate the need for subrecipient moni-*  
8            *toring, which may include collaborative grant models*  
9            *allowing for multiple primary awardees.*

10          *(c) REPORTING OF FINANCIAL EXPENDITURES.—The*  
11          *Secretary, in consultation with the Director of the National*  
12          *Institutes of Health, shall evaluate financial expenditure re-*  
13          *porting procedures and requirements for recipients of fund-*  
14          *ing from the National Institutes of Health and take action,*  
15          *as appropriate, to avoid duplication between department*  
16          *and agency procedures and requirements and minimize*  
17          *burden to funding recipients.*

18          *(d) ANIMAL CARE AND USE IN RESEARCH.—Not later*  
19          *than 2 years after the date of enactment of this Act, the*  
20          *Director of the National Institutes of Health, in collabora-*  
21          *tion with the Secretary of Agriculture and the Commis-*  
22          *sioner of Food and Drugs, shall complete a review of appli-*  
23          *cable regulations and policies for the care and use of labora-*  
24          *tory animals and make revisions, as appropriate, to reduce*  
25          *administrative burden on investigators while maintaining*



1 *the integrity and credibility of research findings and pro-*  
2 *tection of research animals. In carrying out this effort, the*  
3 *Director shall seek the input of experts, as appropriate. The*  
4 *Director shall—*

5           (1) *identify ways to ensure such regulations and*  
6 *policies are not inconsistent, overlapping, or unneces-*  
7 *sarily duplicative, including with respect to inspec-*  
8 *tion and review requirements by Federal agencies and*  
9 *accrediting associations;*

10           (2) *take steps to eliminate or reduce identified*  
11 *inconsistencies, overlap, or duplication among such*  
12 *regulations and policies; and*

13           (3) *take other actions, as appropriate, to im-*  
14 *prove the coordination of regulations and policies*  
15 *with respect to research with laboratory animals.*

16           (e) *DOCUMENTATION OF PERSONNEL EXPENSES.—The*  
17 *Secretary shall clarify the applicability of the requirements*  
18 *under the Office of Management and Budget Uniform Guid-*  
19 *ance for management and certification systems adopted by*  
20 *entities receiving Federal research grants through the De-*  
21 *partment of Health and Human Services regarding docu-*  
22 *mentation of personnel expenses, including clarification of*  
23 *the extent to which any flexibility to such requirements*  
24 *specified in such Uniform Guidance applies to entities re-*

1 *ceiving grants through the Department of Health and*  
2 *Human Services.*

3 *(f) RESEARCH POLICY BOARD.—*

4 *(1) ESTABLISHMENT.—Not later than 1 year*  
5 *after the date of enactment of this Act, the Director*  
6 *of the Office of Management and Budget shall estab-*  
7 *lish an advisory committee, to be known as the “Re-*  
8 *search Policy Board” (referred to in this subsection as*  
9 *the “Board”), to provide the Director and other mem-*  
10 *bers of the Federal Government with information on*  
11 *the effects of regulations related to Federal research*  
12 *requirements.*

13 *(2) MEMBERSHIP.—*

14 *(A) IN GENERAL.—The Board shall include*  
15 *not more than 10 Federal members, including*  
16 *each of the following Federal members or their*  
17 *designees:*

18 *(i) The Administrator of the Office of*  
19 *Information and Regulatory Affairs of the*  
20 *Office of Management and Budget.*

21 *(ii) The Director of the Office of*  
22 *Science and Technology Policy.*

23 *(iii) The Secretary of Health and*  
24 *Human Services.*

1                   (iv) *The Director of the National*  
2                   *Science Foundation.*

3                   (v) *The secretaries and directors of*  
4                   *other departments and agencies that sup-*  
5                   *port or regulate scientific research, as deter-*  
6                   *mined by the Director of the Office of Man-*  
7                   *agement and Budget.*

8                   (B) *NON-FEDERAL MEMBERS.*—*The Board*  
9                   *shall be comprised of not less than 9 and not*  
10                  *more than 12 representatives of academic re-*  
11                  *search institutions, other private, nonprofit re-*  
12                  *search institutions, or other nonprofit organiza-*  
13                  *tions with relevant expertise. Such members shall*  
14                  *be appointed by a formal process, to be estab-*  
15                  *lished by the Director of the Office of Manage-*  
16                  *ment and Budget, in consultation with the Fed-*  
17                  *eral membership, and that incorporates—*

18                         (i) *nomination by members of the non-*  
19                         *profit scientific research community, in-*  
20                         *cluding academic research institutions; and*

21                         (ii) *procedures to fill membership posi-*  
22                         *tions vacated before the end of a member's*  
23                         *term.*

24                   (3) *PURPOSE AND RESPONSIBILITIES.*—*The*  
25                   *Board shall make recommendations regarding the*

1        *modification and harmonization of regulations and*  
2        *policies having similar purposes across research fund-*  
3        *ing agencies to ensure that the administrative burden*  
4        *of such research policy and regulation is minimized*  
5        *to the greatest extent possible and consistent with*  
6        *maintaining responsible oversight of federally funded*  
7        *research. Activities of the Board may include—*

8                *(A) providing thorough and informed anal-*  
9                *ysis of regulations and policies;*

10               *(B) identifying negative or adverse con-*  
11               *sequences of existing policies and making action-*  
12               *able recommendations regarding possible im-*  
13               *provement of such policies;*

14               *(C) making recommendations with respect*  
15               *to efforts within the Federal Government to im-*  
16               *prove coordination of regulation and policy re-*  
17               *lated to research;*

18               *(D) creating a forum for the discussion of*  
19               *research policy or regulatory gaps, challenges,*  
20               *clarification, or harmonization of such policies*  
21               *or regulation, and best practices; and*

22               *(E) conducting ongoing assessment and*  
23               *evaluation of regulatory burden, including devel-*  
24               *opment of metrics, periodic measurement, and*

1           *identification of process improvements and pol-*  
2           *icy changes.*

3           (4) *EXPERT SUBCOMMITTEES.*—*The Board may*  
4           *form temporary expert subcommittees, as appropriate,*  
5           *to develop timely analysis on pressing issues and as-*  
6           *ist the Board in anticipating future regulatory chal-*  
7           *lenges, including those emerging from new scientific*  
8           *advances.*

9           (5) *REPORTING REQUIREMENTS.*—*Not later than*  
10          *2 years after the date of enactment of this Act, and*  
11          *once thereafter, the Board shall submit a report to the*  
12          *Director of the Office of Management and Budget, the*  
13          *Administrator of the Office of Information and Regu-*  
14          *latory Affairs of the Office of Management and Budg-*  
15          *et, the Director of the Office of Science and Tech-*  
16          *nology Policy, the heads of relevant Federal depart-*  
17          *ments and agencies, the Committee on Health, Edu-*  
18          *cation, Labor, and Pensions of the Senate, and the*  
19          *Committee on Energy and Commerce of the House of*  
20          *Representatives containing formal recommendations*  
21          *on the conceptualization, development, harmonization,*  
22          *and reconsideration of scientific research policy, in-*  
23          *cluding the regulatory benefits and burdens.*

24          (6) *SUNSET.*—*The Board shall terminate on*  
25          *September 30, 2020.*

1           (7) *GAO REPORT.*—Not later than 4 years after  
 2     the date of enactment of this Act, the Comptroller  
 3     General of the United States shall conduct an inde-  
 4     pendent evaluation of the activities carried out by the  
 5     Board pursuant to this subsection and submit to the  
 6     appropriate committees of Congress a report regard-  
 7     ing the results of the independent evaluation. Such re-  
 8     port shall review and assess the Board’s activities  
 9     with respect to the responsibilities described in para-  
 10    graph (3).

11 **SEC. 4. REIMBURSEMENT FOR RESEARCH SUBSTANCES**  
 12                                   **AND LIVING ORGANISMS.**

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

15           (1) in the flush matter at the end of subsection  
 16     (a)—

17                   (A) by redesignating such matter as sub-  
 18     section (f)(1); and

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

21           (2) in subsection (f) (as so redesignated), by add-  
 22     ing at the end the following:

23     “(2) Where research substances and living organisms  
 24     are made available under paragraph (1) through contrac-  
 25     tors, the Secretary may direct such contractors to collect

1 *payments on behalf of the Secretary for the costs incurred*  
2 *to make available such substances and organisms and to*  
3 *forward amounts so collected to the Secretary, in the time*  
4 *and manner specified by the Secretary.*

5 “(3) *Amounts collected under paragraph (2) shall be*  
6 *credited to the appropriations accounts that incurred the*  
7 *costs to make available the research substances and living*  
8 *organisms involved, and shall remain available until ex-*  
9 *pendent for carrying out activities under such accounts.”.*

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

11 (a) *TRANS-NIH RESEARCH REPORTING.*—Section  
12 *402A(c)(2) of the Public Health Service Act (42 U.S.C.*  
13 *282a(c)(2)) is amended—*

14 (1) *by amending subparagraph (B) to read as*  
15 *follows:*

16 “(B) *REPORTING.*—*Not later than 2 years*  
17 *after the date of enactment of Promoting Bio-*  
18 *medical Research and Public Health for Patients*  
19 *Act, the head of each national research institute*  
20 *or national center shall submit to the Director of*  
21 *NIH a report, to be included in the triennial re-*  
22 *port under section 403, on the amount made*  
23 *available by the institute or center for con-*  
24 *ducting or supporting research that involves col-*  
25 *laboration between the institute or center and 1*

1           *or more other national research institutes or na-*  
2           *tional centers.”; and*

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

5           *(b) FRAUD AND ABUSE REPORTING.—Section 403B of*  
6           *the Public Health Service Act (42 U.S.C. 283a-1) is amend-*  
7           *ed—*

8           *(1) by striking subsection (b);*

9           *(2) by redesignating subsection (c) as subsection*  
10          *(b); and*

11          *(3) in subsection (b) (as so redesignated), by*  
12          *striking “subsections (a) and (b)” and inserting “sub-*  
13          *section (a)”.*

14          *(c) DOCTORAL DEGREES REPORTING.—Section*  
15          *403C(a)(2) of the Public Health Service Act (42 U.S.C.*  
16          *283a-2(a)(2)) is amended by striking “(not including any*  
17          *leaves of absence)”.*

18          *(d) VACCINE REPORTING.—Section 404B of the Public*  
19          *Health Service Act (42 U.S.C. 283d) is amended—*

20                 *(1) by striking subsection (b); and*

21                 *(2) by striking “(a) DEVELOPMENT OF NEW*  
22                 *VACCINES.—The Secretary” and inserting “The Sec-*  
23                 *retary”.*



1           (e)       NATIONAL       CENTER       FOR       ADVANCING  
2   *TRANSLATIONAL SCIENCES.*—Section 479(c) of the Public  
3   Health Service Act (42 U.S.C. 287(c)) is amended—

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

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

9           (f) *REVIEW OF CENTERS OF EXCELLENCE.*—

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

12                   (2)       CONFORMING       AMENDMENT.—Section  
13   399EE(c) of the Public Health Service Act (42 U.S.C.  
14   280i–4(c)) is amended by striking “399CC, 404H,”  
15   and inserting “399CC”.

16           (g) *RAPID HIV TEST REPORT.*—Section 502(a) of the  
17   Ryan White CARE Act Amendments of 2000 (42 U.S.C.  
18   300cc note) is amended—

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

20                   (2) by redesignating paragraph (3) as para-  
21   graph (2).

22           (h) *BIENNIAL REPORT.*—

23                   (1) *REPEAL.*—Section 464Y of the Public Health  
24   Service Act (42 U.S.C. 285q–3) is repealed.





1 *ordinate with respect to the public health needs, epidemi-*  
2 *ology, and program planning and implementation consid-*  
3 *erations related to immunization, including with regard to*  
4 *meetings with stakeholders related to such topics.*

5 *(b) REPORT ON VACCINE INNOVATION.—*

6 *(1) IN GENERAL.—Not later than 1 year after*  
7 *the date of enactment of this Act, the Secretary of*  
8 *Health and Human Services (referred to in this sec-*  
9 *tion as the “Secretary”), in collaboration with appro-*  
10 *priate agencies or offices within the Department of*  
11 *Health and Human Services, including the National*  
12 *Institutes of Health, the Centers for Disease Control*  
13 *and Prevention, and the Biomedical Advanced Re-*  
14 *search and Development Authority, shall issue to the*  
15 *Committee on Health, Education, Labor, and Pen-*  
16 *sions of the Senate and the Committee on Energy and*  
17 *Commerce of the House of Representatives, and post*  
18 *publicly on the Internet website of the Department of*  
19 *Health and Human Services, a report on ways to*  
20 *promote innovation in the development of vaccines*  
21 *that minimize the burden of infectious disease.*

22 *(2) CONTENTS.—The report described in para-*  
23 *graph (1) shall review the current status of vaccine*  
24 *development and, as appropriate—*

1           (A) consider the optimal process to deter-  
2           mine which vaccines would be beneficial and how  
3           information on such vaccines is disseminated to  
4           key stakeholders;

5           (B) examine and identify whether obstacles  
6           exist that inhibit the development of beneficial  
7           vaccines; and

8           (C) make recommendations about how best  
9           to remove any obstacles identified under sub-  
10          paragraph (B) in order to promote and  
11          incentivize vaccine innovation and development.

12          (3) CONSULTATION.—In preparing the report  
13          under this subsection, the Secretary may consult  
14          with—

15               (A) representatives of relevant Federal agen-  
16               cies and departments, including the Department  
17               of Defense and the Department of Veterans Af-  
18               fairs;

19               (B) academic researchers;

20               (C) developers and manufacturers of vac-  
21               cines;

22               (D) medical and public health practitioners;

23               (E) representatives of patient, policy, and  
24               advocacy organizations; and

1                   (F) representatives of other entities, as the  
2                   Secretary determines appropriate.

3 **SEC. 8. TECHNICAL UPDATES TO CLINICAL TRIALS DATA-**  
4                   **BASE.**

5                   Section 402(j)(2)(D) of the Public Health Service Act  
6 (42 U.S.C. 282(j)(2)(D)) is amended—

7                   (1) in clause (ii)(I), by inserting before the semi-  
8                   colon “, unless the responsible party affirmatively re-  
9                   quests that the Director of NIH publicly post such  
10                  clinical trial information for an applicable device  
11                  clinical trial prior to such date of clearance or ap-  
12                  proval”; and

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

14                               “(iii) **OPTION TO MAKE CERTAIN CLIN-**  
15                               **ICAL TRIAL INFORMATION AVAILABLE EAR-**  
16                               **LIER.**—The Director of NIH shall inform  
17                               responsible parties of the option to request  
18                               that clinical trial information for an appli-  
19                               cable device clinical trial be publicly posted  
20                               prior to the date of clearance or approval,  
21                               in accordance with clause (ii)(I).

22                               “(iv) **COMBINATION PRODUCTS.**—An  
23                               applicable clinical trial for a product that  
24                               is a combination of drug, device, or biologi-  
25                               cal product shall be considered—

1                   “(I) an applicable drug clinical  
2                   trial, if the Secretary determines under  
3                   section 503(g) of the Federal Food,  
4                   Drug, and Cosmetic Act that the pri-  
5                   mary mode of action of such product is  
6                   that of a drug or biological product; or

7                   “(II) an applicable device clinical  
8                   trial, if the Secretary determines under  
9                   such section that the primary mode of  
10                  action of such product is that of a de-  
11                  vice.”.

12 **SEC. 9. COMPLIANCE ACTIVITIES REPORTS.**

13           (a) *DEFINITIONS.*—In this section:

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

18                   (2) *DIRECTOR OF NIH.*—The term “Director of  
19                   NIH” means the Director of the National Institutes  
20                   of Health.

21                   (3) *SECRETARY.*—The term “Secretary” means  
22                   the Secretary of Health and Human Services.

23           (b) *REPORT ON ACTIVITIES TO ENCOURAGE COMPLI-*  
24 *ANCE.*—Not later than 2 years after the date of enactment  
25 *of this Act, the Secretary, acting through the Director of*

1 *NIH and in collaboration with the Commissioner of Food*  
2 *and Drugs, shall submit to the Committee on Health, Edu-*  
3 *cation, Labor, and Pensions of the Senate and the Com-*  
4 *mittee on Energy and Commerce of the House of Represent-*  
5 *atives, a report that describes education and outreach, guid-*  
6 *ance, enforcement, and other activities undertaken to en-*  
7 *courage compliance with section 402(j) of the Public Health*  
8 *Service Act (42 U.S.C. 282(j)).*

9 *(c) REPORTS ON CLINICAL TRIALS.—*

10 *(1) IN GENERAL.—Not later than 2 years after*  
11 *the final compliance date under the final rule imple-*  
12 *menting section 402(j) of the Public Health Service*  
13 *Act, and every 2 years thereafter for the next 4 years,*  
14 *the Secretary, acting through the Director of NIH and*  
15 *in collaboration with the Commissioner of Food and*  
16 *Drugs, shall submit to the Committee on Health,*  
17 *Education, Labor, and Pensions of the Senate and the*  
18 *Committee on Energy and Commerce of the House of*  
19 *Representatives, a report describing—*

20 *(A) the total number of applicable clinical*  
21 *trials with complete data bank registration in-*  
22 *formation registered during the period for which*  
23 *the report is being prepared (broken down by*  
24 *each year of such reporting period);*



1           (B) the total number of applicable clinical  
2 trials registered during the period for which the  
3 report is being prepared for which results have  
4 been submitted to the data bank (broken down by  
5 each year of such reporting period);

6           (C) the activities undertaken by the Sec-  
7 retary to educate responsible persons about data  
8 bank registration and results submission require-  
9 ments, including through issuance of guidance  
10 documents, informational meetings, and training  
11 sessions; and

12           (D) the activities described in the report  
13 submitted under subsection (b).

14           (2) *ACTIONS TO ENFORCE COMPLIANCE.*—After  
15 the Secretary has undertaken the educational activi-  
16 ties described in paragraph (1)(C), the Secretary shall  
17 include in subsequent reports submitted under para-  
18 graph (1) the number of actions taken by the Sec-  
19 retary during the period for which the report is being  
20 prepared to enforce compliance with data bank reg-  
21 istration and results submission requirements.

1 **SEC. 10. APPOINTMENT OF DIRECTORS OF NATIONAL RE-**  
2 **SEARCH INSTITUTES AND NATIONAL CEN-**  
3 **TERS.**

4 *Subsection (a) of section 405 of the Public Health*  
5 *Service Act (42 U.S.C. 284) is amended to read as follows:*

6 “(a) *APPOINTMENT.—*

7 “(1) *IN GENERAL.—The Director of the National*  
8 *Cancer Institute shall be appointed by the President,*  
9 *and the Directors of the other national research insti-*  
10 *tutes and centers shall be appointed by the Secretary,*  
11 *acting through the Director of NIH. Each Director of*  
12 *a national research institute or national center shall*  
13 *report directly to the Director of NIH.*

14 “(2) *APPOINTMENT.—*

15 “(A) *TERM.—A Director of a national re-*  
16 *search institute or national center who is ap-*  
17 *pointed by the Secretary, acting through the Di-*  
18 *rector of NIH, shall be appointed for 5 years.*

19 “(B) *REAPPOINTMENT.—At the end of the*  
20 *term of a Director of a national research insti-*  
21 *tute or national center, the Director may be re-*  
22 *appointed. There shall be no limit on the number*  
23 *of terms that a Director may serve.*

24 “(C) *VACANCIES.—If the office of a Director*  
25 *of a national research institute or national cen-*  
26 *ter becomes vacant before the end of such Direc-*

1            *tor's term, the Director appointed to fill the va-*  
2            *cancy shall be appointed for a 5-year term start-*  
3            *ing on the date of such appointment.*

4            *“(D) CURRENT DIRECTORS.—Each Director*  
5            *of a national research institute or national cen-*  
6            *ter who is serving on the date of enactment of the*  
7            *Promoting Biomedical Research and Public*  
8            *Health for Patients Act shall be deemed to be ap-*  
9            *pointed for a 5-year term under this subsection*  
10           *beginning on such date of enactment.*

11           *“(E) RULE OF CONSTRUCTION.—Nothing in*  
12           *this subsection shall be construed to limit the*  
13           *ability of the Director of NIH or a Director of*  
14           *a national research institute or center to termi-*  
15           *nate the appointment of such Director of a na-*  
16           *tional research institute or center prior to the ex-*  
17           *piration of such Director's 5-year term.*

18           *“(3) NONAPPLICATION OF CERTAIN PROVISION.—*  
19           *The restrictions contained in section 202 of the De-*  
20           *partments of Labor, Health and Human Services,*  
21           *and Education, and Related Agencies Appropriations*  
22           *Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note)*  
23           *related to consultants and individual scientists ap-*  
24           *pointed for limited periods of time shall not apply to*  
25           *Directors appointed under this subsection.”.*

1 **SEC. 11. NATIONAL CENTER FOR ADVANCING**  
2 **TRANSLATIONAL SCIENCES.**

3 (a) *IN GENERAL.*—Section 479(b) of the Public Health  
4 Service Act (42 U.S.C. 287(b)) is amended—

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

7 (2) in paragraph (2)—

8 (A) in the matter preceding subparagraph  
9 (A), by striking “phase IIB” and inserting  
10 “phase III”;

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

13 (C) in subparagraph (B), by striking  
14 “phase IIA” and inserting “phase IIB”; and

15 (D) in subparagraph (C), by striking  
16 “phase IIB” and inserting “phase III”.

17 (b) *INCREASED TRANSPARENCY.*—Section 479 of the  
18 Public Health Service Act (42 U.S.C. 287) is amended—

19 (1) in subsection (c)—

20 (A) in paragraph (4)(D), by striking “and”  
21 at the end;

22 (B) in paragraph (5), by striking the period  
23 and inserting a semicolon; and

24 (C) by adding at the end the following:

1           “(6) *the methods and tools, if any, that have*  
2           *been developed since the last biennial report was pre-*  
3           *pared; and*

4           “(7) *the methods and tools, if any, that have*  
5           *been developed and are being utilized by the Food and*  
6           *Drug Administration to support medical product re-*  
7           *views.”; and*

8           (2) *by adding at the end the following:*

9           “(d) *INCLUSION OF LIST.—The first biennial report*  
10          *submitted under this section after the date of enactment of*  
11          *this subsection shall include a complete list of all of the*  
12          *methods and tools, if any, which have been developed by*  
13          *research supported by the Center.*

14          “(e) *RULE OF CONSTRUCTION.—Nothing in this sec-*  
15          *tion shall be construed as authorizing the Secretary to dis-*  
16          *close any information that is a trade secret, or other privi-*  
17          *leged or confidential information subject to section*  
18          *552(b)(4) of title 5, United States Code, or section 1905*  
19          *of title 18, United States Code.”.*

Calendar No. 429

114<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 2742**

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**A BILL**

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

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APRIL 18, 2016

Reported with an amendment