AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

(no.) _____

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Biomedical Research and Public Health for Patients Act''.

SEC. 2. TRIENNIAL REPORTS OF DIRECTOR OF NIH.

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

(1) in the heading, by striking ''**BIENNIAL**'' and inserting ''**TRIENNIAL**''; and

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''biennial'' and inserting ''triennial'';

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

''(3) A description of intra-NIH activities, including identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers and recommendations for promoting coordination of information among the centers of excellence.'';

(C) in paragraph (4)—

(i) in subparagraph (B), by striking ''demographic variables and other variables'' and inserting ''demographic variables, including biological and social variables and relevant age categories, and determinants of health''; and

(ii) in subparagraph (C)(v)—

(I) by striking ''demographic variables and such'' and inserting ''demographic variables, including rel-

evant age categories, information submitted by each national research institute and national center to the Director of NIH under section 492B(f), and such''; and

(II) by striking ''(regarding inclusion of women and minorities in clinical research)'' and inserting ''and other applicable requirements regarding inclusion of demographic groups''; and

(D) in paragraph (6)—

(i) in the matter preceding subparagraph (A), by striking ''the following:'' and inserting ''the following—'';

(ii) in subparagraph (A)—

(I) by striking ''An evaluation'' and inserting ''an evaluation''; and

(II) by striking the period and inserting ''; and'';

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

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

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

SEC. 3. ADMINISTRATIVE BURDEN ON INVESTIGATORS.

(a) DISCLOSURE OF FINANCIAL CONFLICTS OF INTEREST.—

(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—

(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

(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.

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

(A) modifying the timelines for the reporting of financial conflicts of interest to just in time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

(B) ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term ''investigator''; and

(C) updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

(b) MONITORING OF SUBRECIPIENTS OF FUNDING FROM THE NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate—

(1) an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that—

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

(B) the primary awardee conducts a formal or informal evaluation of each subrecipient's risk of noncompliance with Federal statutes and regulations, and the conditions of the subaward; and

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

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

(c) REPORTING OF FINANCIAL EXPENDITURES.—The Secretary, in consultation with the Director of the National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients.

(d) ANIMAL CARE AND USE IN RESEARCH.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director shall seek the input of experts, as appropriate. The Director shall—

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

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

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

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

ments under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

(f) RESEARCH POLICY BOARD.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the ''Research Policy Board'' (referred to in this subsection as the ''Board''), to provide the Director and other members of the Federal Government with information on the effects of regulations related to Federal research requirements.

(2) MEMBERSHIP.—

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

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

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

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) NON-FEDERAL MEMBERS.—The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates—

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

(ii) procedures to fill membership positions vacated before the end of a member's term.

(3) PURPOSE AND RESPONSIBILITIES.—The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include—

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

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

prove coordination of regulation and policy related to research;

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

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) EXPERT SUBCOMMITTEES.—The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including those emerging from new scientific advances.

(5) REPORTING REQUIREMENTS.—Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant

Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

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

(7) GAO REPORT.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board's activities with respect to the responsibilities described in paragraph (3).

SEC. 4. REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS.

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

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

(A) by redesignating such matter as subsection (f)(1); and

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

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

''(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

''(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.''.

SEC. 5. STREAMLINING NIH REPORTING REQUIREMENTS.

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

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

''(B) REPORTING.—Not later than 2 years after the date of enactment of Promoting Biomedical Research and Public Health for Patients Act, the head of each national research institute or national center shall submit to the Director of NIH a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.''; and

(2) in subparagraphs (D) and (E) by striking ''(B)(i)'' each place it appears and inserting ''(B)''.

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

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b); and

(3) in subsection (b) (as so redesignated), by striking ''subsections (a) and (b)'' and inserting ''subsection (a)''.

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

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

(1) by striking subsection (b); and

(2) by striking ''(a) DEVELOPMENT OF NEW VACCINES.—The Secretary'' and inserting ''The Secretary''.

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

(1) in the subsection heading, by striking ''ANNUAL'' and inserting ''BIENNIAL''; and

(2) in the matter preceding paragraph (1), by striking ''an annual report'' and inserting ''a report on a biennial basis''.

(f) REVIEW OF CENTERS OF EXCELLENCE.—

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

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

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

(1) by striking paragraph (2); and

(2) by redesignating paragraph (3) as paragraph (2).

(h) BIENNIAL REPORT.—

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

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

SEC. 6. NATIONAL VACCINE INJURY COMPENSATION PROGRAM.

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

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

tration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.''.

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

''(f) MATERNAL IMMUNIZATION.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

''(2) DEFINITION.—As used in this subsection, the term 'child' shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term 'include' in subsection (a) of such section were replaced with the term 'mean'.''.

(c) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding ''A covered vaccine administered to a pregnant woman shall constitute more than one administra-

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

SEC. 7. VACCINE MEETINGS; REPORT ON VACCINE INNOVATION.

(a) VACCINE MEETINGS.—The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.

(b) REPORT ON VACCINE INNOVATION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in collaboration with appropriate agencies or offices within the Department of Health and Human Services, including the National Institute of Allergy and Infectious Diseases and the Biomedical Advanced Research and Development Authority, shall issue to the Committee on Health, Education, Labor, and Pensions of the Sen-

ate and the Committee on Energy and Commerce of the House of Representatives, and post publicly on the Internet website of the Department of Health and Human Services, a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease.

(2) CONTENTS.—The report described in paragraph (1) shall review the current status of vaccine development and, as appropriate—

(A) consider the optimal process to determine which vaccines would be beneficial and how information on such vaccines is disseminated to key stakeholders;

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

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

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

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

partment of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

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

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

SEC. 8. TECHNICAL UPDATES TO CLINICAL TRIALS DATABASE.

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

(1) in clause (ii)(I), by inserting before the semicolon ‘‘, unless the responsible party affirmatively requests that the Director of NIH publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval’’; and

(2) by adding at the end the following:

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

form responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

''(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

''(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

''(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.''.

SEC. 9. COMPLIANCE ACTIVITIES REPORTS.

(a) DEFINITIONS.—In this section:

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

(2) DIRECTOR OF NIH.—The term ''Director of NIH'' means the Director of the National Institutes of Health.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Humans Services.

(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLIANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of NIH and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes education and outreach, guidance, enforcement, and other activities undertaken to encourage compliance with section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(c) REPORTS ON CLINICAL TRIALS.—

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

years, the Secretary, acting through the Director of NIH and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing—

(A) the total number of applicable clinical trials with complete data bank registration information registered during the period for which the report is being prepared (broken down by each year of such reporting period);

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

(C) the activities undertaken by the Secretary during the period for which the report is being prepared to educate responsible persons about data bank registration and results submission requirements, including through issuance of guidance documents, informational meetings, and training sessions; and

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

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

SEC. 10. APPOINTMENT OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.

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

''(a) APPOINTMENT.—

''(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes and centers shall be appointed by the Secretary, acting through the Director of NIH. Each Director of a national research institute or national center shall report directly to the Director of NIH.

''(2) APPOINTMENT.—

''(A) TERM.—A Director of a national research institute or national center who is ap-

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

''(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or national center, the Director may be reappointed. There shall be no limit on the number of terms that a Director may serve.

''(C) VACANCIES.—If the office of a Director of a national research institute or national center becomes vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

''(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the Promoting Biomedical Research and Public Health for Patients Act shall be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

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

nate the appointment of such Director of a national research institute or center prior to the expiration of such Director's 5-year term.

''(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.''.

SEC. 11. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

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

(1) in paragraph (1), by striking ''phase IIA'' and inserting ''phase IIB''; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking ''phase IIB'' and inserting ''phase III'';

(B) in subparagraph (A), by striking ''phase IIB'' and inserting ''phase III'';

(C) in subparagraph (B), by striking ''phase IIA'' and inserting ''phase IIB''; and

(D) in subparagraph (C), by striking ''phase IIB'' and inserting ''phase III''.