117TH CONGRESS
2D SESSION

S. _____

To establish an Advanced Research Projects Authority for Health within the National Institutes of Health.

IN THE SENATE OF THE UNITED STATES

Mrs. MURRAY (for herself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To establish an Advanced Research Projects Authority for Health within the National Institutes of Health.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advanced Research Project Authority for Health Act'' or the ''ARPA–H Act''.

SEC. 2. ADVANCED RESEARCH PROJECTS AUTHORITY FOR HEALTH.

Part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by inserting after subpart 2 of such part the following:

"Subpart 3—Advanced Research Projects Authority for Health

"SEC. 483. ADVANCED RESEARCH PROJECTS AUTHORITY FOR HEALTH.

''(a) DEFINITIONS.—In this section:

''(1) ARPA–H.—The term 'ARPA–H' means the Advanced Research Projects Authority for Health established under subsection (b).

''(2) DIRECTOR.—The term 'Director' means the Director of ARPA–H appointed under subsection (c).

''(3) OTHER TRANSACTIONS.—The term 'other transactions' has the meaning given such term in section 319L(a)(3).

''(b) ESTABLISHMENT OF THE ADVANCED RESEARCH PROJECTS AUTHORITY FOR HEALTH.—There is established within the National Institutes of Health the Advanced Research Projects Authority for Health, for purposes of—

''(1) supporting high-impact, cutting-edge research in biomedicine and broadly applicable breakthrough technologies that have the potential to significantly transform and advance areas of biomedical science and medicine in a manner that cannot readily be accomplished through traditional biomedical research or commercial activity; and

''(2) overcoming long-term and significant technological and scientific barriers to advancing such technologies in order to improve the prevention, diagnosis, mitigation, treatment, and cure of health conditions.

''(c) DIRECTOR.—

''(1) IN GENERAL.—ARPA–H shall be headed by a Director, who shall be appointed by the President. The Director shall report to the Director of NIH.

''(2) QUALIFICATIONS.—The Director shall be an individual who, by reason of professional background and experience, is especially qualified to advise the Secretary on, and manage, research programs that advance the purposes of ARPA–H in promoting biomedical and novel technology innovation pursuant to this section, and who has a demonstrated ability to identify and develop partnerships to address strategic needs in meeting such purposes.

''(3) APPOINTMENT.—Notwithstanding section 405(a)(2), the Director shall be appointed for a period of 4 years. The President may extend the term of a Director for a period of up to 4 additional years.

''(4) DUTIES.—The Director shall—

"(A) establish strategic goals, objectives, and priorities for ARPA–H, pursuant to the purposes of ARPA–H described in subsection (b);

"(B) approve all new programs within ARPA–H and terminate any program within ARPA–H that is not achieving its goals;

"(C) establish criteria for funding and assessing the success of programs through the establishment of technical milestones;

"(D) ensure that applications for funding disclose current and previous research and development efforts, and identify any challenges associated with such efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing sources of funding, as applicable and appropriate, in pursuit of the technology area for which funding is requested;

"(E) facilitate coordination between the Department of Health and Human Services, relevant agencies within such Department, and other relevant Federal departments and agencies, with respect to research supported by ARPA–H;

"(F) support transformative, translational, applied, and advanced research in areas of biomedical science to address specific technical or scientific questions by —

"(i) prioritizing investments based on scientific potential and impact on the field of biomedicine, as described in subsection (b), especially in areas that require public-private partnerships in order to effectively advance research and development activities;

"(ii) translating scientific discoveries and cutting-edge innovation into technological advancements;

"(iii) encouraging opportunities to develop broadly applicable technologies, using a multi-disciplinary approach; and

"(iv) making investments in high-risk, high-reward research related to broadly applicable technologies, capabilities, and platforms that may have an application for medicine and health;

"(G) encourage strategic collaboration and partnerships with a broad range of entities, including institutions of higher education, indus-

try, nonprofit organizations, or consortia of such entities, which may include federally-funded research and development centers; and

"(H) ensure that the United States maintains global leadership in researching and developing health technologies.

"(d) PERSONNEL.—

"(1) IN GENERAL.—The Director shall establish and maintain within ARPA–H a staff with appropriate qualifications and expertise to enable ARPA–H to carry out the responsibilities under this section.

"(2) PROGRAM MANAGERS.—

"(A) IN GENERAL.—The Director shall designate employees to serve as program managers for the programs established or supported pursuant to subsection (c)(4).

"(B) RESPONSIBILITIES.—A program manager shall—

"(i) establish, in consultation with the Director, research and development goals for the program, including timelines and milestones, and make such goals available to the public;

"(ii) provide project oversight and management of strategic initiatives to advance the purpose of the program;

"(iii) encourage research collaborations, including by identifying and supporting applicable public-private partnerships;

"(iv) select the projects to be supported under the program after considering—

"(I) the novelty, scientific, and technical merit of the proposed projects;

"(II) the demonstrated capabilities of the applicants to successfully carry out the proposed project and achieve designated milestones within the applicable timeline;

"(III) the potential future commercial applications of the project proposed by the applicant;

"(IV) the degree to which the project addresses a scientific or technical question pursuant to subsection (c)(4)(F) and has the potential to

transform biomedicine, as described in subsection (b); and

''(V) other criteria as established by the Director;

''(v) recommend program restructure, expansion, or termination of research projects or whole projects, as necessary and appropriate; and

''(vi) communicate with leaders in the health care and biomedical research and development fields, including from both the public and private sectors, representatives of patient organizations, institutions of higher education, and nonprofit organizations, to identify areas of need and scientific opportunity with the potential to transform biomedicine as described in subsection (b).

''(C) TERM.—The term of a program manager shall be not more than 3 years, and, at the discretion of the Director, may be renewed for one additional period of up to 3 years.

''(3) CONSIDERATIONS.—The Director—

''(A) in designating employees to serve as program managers under paragraph (1), shall

consider, as appropriate, individuals with demonstrated scientific expertise and management skills required to advance the purposes of ARPA–H, and who represent a diverse set of professional experiences or backgrounds, including individuals with experience in academia, industry, government, nonprofit organizations, or other sectors; and

''(B) in making appointments of personnel to staff or support ARPA–H, may consider other factors, as appropriate, such as populations that are traditionally underrepresented in the biomedical research enterprise.

''(4) HIRING.—

''(A) IN GENERAL.—The Director may—

''(i) make or rescind appointments of scientific, medical, and professional personnel, without regard to any provision of title 5, United States Code governing appointments under the civil service laws and notwithstanding section 202 of the Department of Health and Human Services Appropriations Act, 1993 (Public Law 102–394); and

"(ii) fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

"(B) REPORTING.—The Director shall establish and maintain records regarding the use of the authority under subparagraph (A)(i), including—

"(i) the number of positions filled through such authority;

"(ii) the types of appointments of such positions;

"(iii) the titles, occupational series, and grades of such positions;

"(iv) the number of positions publicly noticed to be filled under such authority;

"(v) the number of qualified applicants who apply for such positions;

"(vi) the qualification criteria for such positions; and

"(vii) the demographic information of individuals appointed to such positions.

"(C) REPORTS TO CONGRESS.—Not later than one year after the date of enactment of

the Advanced Research Project Authority for Health Act, and annually thereafter for each fiscal year in which such authority is used, the Director 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 the total number of appointments filled under this subsection within the fiscal year and how the positions relate to the purposes of ARPA–H.

''(D) PRIVATE RECRUITING FIRMS.—The Director may contract with private recruiting firms for the hiring of qualified technical staff to carry out this section.

''(E) CLARIFICATIONS.—

''(i) PREVIOUS POSITIONS.—The Director shall ensure that the personnel who are appointed to staff or support ARPA–H are individuals who, at the time of appointment and for 3 years prior to such appointment, were not employed by the National Institutes of Health.

''(ii) NUMBER OF PERSONNEL.—The Director may appoint not more than 120

personnel under this section. The Director shall submit a notification to Congress if the Director determines that additional personnel are required to carry out this section.

''(F) GAO REPORT.—Not later than 2 years after the date of enactment of the Advanced Research Project Authority for Health Act, the Comptroller General of the United States 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 on the use of the authority provided under subparagraph (A)(i). Such report shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include information on—

''(i) the number of positions publicly noticed and filled under the authority under this subsection;

''(ii) the occupational series, grades, and types of appointments of such positions;

''(iii) how such positions related to advancing the purposes of ARPA–H;

''(iv) how the Director made appointment decisions under this subsection;

''(v) sources used to identify candidates for filling such positions;

''(vi) the number of individuals appointed;

''(vii) aggregated demographic information related to individuals appointed; and

''(viii) any challenges, limitations, or gaps related to the use of the authority under this subsection and any related recommendations to address such challenges, limitations, or gaps.

''(e) FUNDING AWARDS.—

''(1) IN GENERAL.—In carrying out this section, the Director may award grants, contracts, cooperative agreements, cash prizes, and enter into other transactions, as described in paragraph (2).

''(2) OTHER TRANSACTIONS.—

''(A) LIMITATIONS ON ENTERING INTO OTHER TRANSACTIONS.—

"(i) IN GENERAL.—To the maximum extent practicable, competitive procedures shall be used when entering into other transactions to carry out projects under this section.

"(B) WRITTEN DETERMINATIONS REQUIRED.—The authority of this paragraph may be exercised for a project if the project manager—

"(i) submits a proposal to the Director for each individual use of such authority before conducting or supporting a project, including why the use of such authority is essential to promoting the success of the project;

"(ii) receives approval for the use of such authority from the Director; and

"(iii) for each year in which the program manager has used such authority in accordance with this paragraph, submits a report to the Director on the activities of the program relating to such project.

"(3) PRIZE COMPETITIONS.—The Director may utilize the authorities and processes established under section 24 of the Stevenson-Wydler Tech-

nology Innovation Act of 1980 (15 U.S.C. 3719) to support prize competitions, in accordance with this section.

''(4) FEDERAL DEMONSTRATION OF TECHNOLOGIES.—The Director may seek opportunities to partner with procurement programs of Federal agencies to demonstrate technologies resulting from activities funded through ARPA–H.

''(5) CLARIFICATIONS.—Research supported by this section shall not be subject to the requirements of section 406(a)(3)(A)(ii) or 492.

''(f) COORDINATION, COLLABORATION, NONDUPLICATION, AND CONSULTATION.—

''(1) COORDINATION.—To the maximum extent practicable, the Director shall ensure that the activities of ARPA–H are coordinated with, and do not duplicate the efforts of—

''(A) other programs within, or research conducted or supported by, the Department of Health and Human Services, including the National Institutes of Health and the Biomedical Advanced Research and Development Authority; and

''(B) other relevant efforts or research and development programs operated or overseen by

other departments, agencies, or offices of the Federal Government.

''(2) FUNDING DETERMINATIONS.—The Director shall ensure that ARPA–H does not provide funding for a research program or project unless the applicant for such funding demonstrates that—

''(A)(i) such applicant has made sufficient unsuccessful attempts to secure private financing, and that there is a lack of significant private support for the program or project; or

''(ii) such program or project is in the best interests of the United States; and

''(B) such program or project has the potential to significantly transform and advance the field of biomedicine, as described in subsection (b).

''(3) CONSULTATION.—In carrying out this section, the Director may seek input from—

''(A) the President's Council of Advisors on Science and Technology;

''(B) representatives of professional or scientific organizations with expertise in specific technologies under consideration or development by ARPA–H; and

"(C) representatives of patient organizations, public health, innovators, and other public and private entities.

"(4) ENHANCED COLLABORATION AND COMMUNICATION.—

"(A) IN GENERAL.—In order to facilitate enhanced collaboration and communication with respect to the most current priorities of ARPA–H, the Food and Drug Administration may meet with ARPA–H and any other appropriate Federal partners, such as the Biomedical Advanced Research and Development Authority, at appropriate intervals, to discuss the development status, and actions that may be taken to facilitate the development, of medical products and projects that are the highest priorities to ARPA–H.

"(B) RELATION TO OTHERWISE AUTHORIZED ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.—Utilizing interagency agreements or other appropriate resource allocation mechanisms available, the Director shall reimburse the Food and Drug Administration, as appropriate, for activities identified by the Commissioner of Food and Drugs and the Di-

rector as being conducted by the Food and Drug Administration under the authority of this section, using funds made available to ARPA–H.

''(g) ADVISORY COMMITTEE.—

''(1) IN GENERAL.—There is established an ARPA–H Interagency Advisory Committee (referred to in this subsection as the 'Advisory Committee') to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA–H.

''(2) MEMBERS.—The Advisory Committee established under paragraph (1) shall consist of the heads of the following agencies or their designees:

''(A) The National Institutes of Health.

''(B) The Centers for Disease Control and Prevention.

''(C) The Food and Drug Administration.

''(D) The Office of the Assistant Secretary for Preparedness and Response.

''(E) The Office of the Assistant Secretary of Health.

''(F) The Defense Advanced Research Projects Agency.

''(G) The Office of Science of the Department of Energy.

''(H) The National Science Foundation.

''(I) Any other agency with subject matter expertise that the Director of ARPA–H determines appropriate to advance programs or projects under this section.

''(3) NONAPPLICABILITY OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

''(4) ADVISORY NATURE.—The functions of the Advisory Committee shall be advisory in nature, and nothing in this subsection shall be construed as granting such Committee authority over the activities authorized under this section.

''(5) PERFORMANCE MEASURES FRAMEWORK.—The Director, in consultation with the Advisory Committee, shall develop a performance measures framework for programs or projects supported by ARPA–H in order to inform and facilitate the evaluation required under subsection (m), including identification of any data needed to perform such evaluation, consistent with subsection (l).

''(h) FACILITIES.—

''(1) AUTHORITIES.—The Director is authorized to—

''(A) acquire (by purchase, lease, condemnation or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary to carry out this section; and

''(B) lease an interest in property for not more than 20 years, notwithstanding section 1341(a)(1) of title 31, United States Code.

''(2) LOCATIONS.—

''(A) IN GENERAL.—ARPA–H, including its headquarters, shall not be located, including headquartered, inside of, or in close proximity to, the National Capital region, and shall not be located on any part of the National Institutes of Health campuses.

''(B) CONSIDERATIONS.—In determining the location of facilities, the Director shall consider the characteristics of the intended location and the extent to which such location will facilitate advancement of the ARPA–H purposes pursuant to subsection (b).

''(i) RULE OF CONSTRUCTION.—The authorities granted by this section—

"(1) are in addition to existing authorities granted to the Secretary; and

"(2) shall not be construed to modify or supersede any existing authorities.

"(j) PROTECTION OF INFORMATION.—

"(1) IN GENERAL.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(2) REPORTING.—One year after the date of enactment of the Advanced Research Project Authority for Health Act, and annually thereafter, the Director shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

"(A) the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure; and

"(B) the nature of any request under section 552 of title 5, United States Code, or sec-

tion 1905 of title 18, United States Code, that was denied using such authority.

''(k) REPORTS AND STRATEGIC PLANS.—

''(1) ANNUAL REPORT.—As part of the annual budget request submitted for each fiscal year, the Director shall provide to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that describes—

''(A) projects supported by ARPA–H during the previous fiscal year, and, with respect to each such project, the stage of development and details as to whether the project is meeting project milestones;

''(B) projects supported by ARPA–H in the previous fiscal year that were terminated, and the reasons for termination;

''(C) projects supported by ARPA–H during the previous fiscal year that examine topics and technologies closely related to other activities funded by the Department of Health and Human Services, including an analysis of whether in supporting such projects, the Direc-

tor is in compliance with the requirements of this section; and

"(D) current, proposed, and planned projects to be carried out.

"(2) STRATEGIC PLAN.—Not later than 180 days after the appointment of the first Director pursuant to subsection (c), and every 4 years thereafter, the Director shall provide to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a plan describing the strategic plan that ARPA–H will use to guide future investments over the following 4 fiscal years. Every 2 years after the date of submission of the initial plan, the Director shall submit a supplemental strategic plan that details any changes to such strategic vision, as appropriate. The requirements regarding individual institute and center strategic plans under section 402(m), including paragraph (3) of such subsection, shall not apply to ARPA–H.

"(l) NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE EVALUATION.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Advanced Research Project Authority for Health Act, the Director shall seek to enter into a contract with the National Academies of Sciences, Engineering, and Medicine under which the National Academies conducts an evaluation of ARPA–H regarding the goals and purposes of ARPA–H and the degree to which the activities of ARPA–H support, and align with, such goals and purposes.

''(2) INCLUSIONS.—The evaluation under paragraph (1) may include—

''(A) recommendations on how to improve upon the operation of, and projects carried out by, ARPA–H, which may include lessons learned from other advanced research and development agencies or authorities within the Department of Health and Human Services and in other departments, agencies, or offices of the Federal Government;

''(B) a description of lessons learned from the establishment and operation of ARPA–H, and the manner in which those lessons may apply to the operation of other programs of the

Department of Health and Human Services; and

''(C) an analysis of whether any projects supported by ARPA–H were duplicative of other research programs supported by the Department of Health and Human Services or other another relevant Federal department or agency.

''(3) AVAILABILITY.—Upon completion of the evaluation, the evaluation shall be submitted by the Director to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and made publicly available.

''(m) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2023 through 2027.

''(n) ADDITIONAL BUDGET CLARIFICATION.—Any budget request for ARPA–H shall be separate from the other budget requests of the National Institutes of Health.''.