I

117TH CONGRESS
1ST SESSION

H. R. 5585

To establish the Advanced Research Projects Agency–Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 15, 2021

Ms. ESHOO introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To establish the Advanced Research Projects Agency–Health, and for other purposes.

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 Agency–Health Act'' or the ''ARPA–H Act''.

SEC. 2. ADVANCED RESEARCH PROJECTS AGENCY–HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"PART J—ADVANCED RESEARCH PROJECTS AGENCY–HEALTH

"SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY–HEALTH.

''(a) ESTABLISHMENT.—There is established the Advanced Research Projects Agency–Health (in this part referred to as 'ARPA–H') within the Department of Health and Human Services.

''(b) GOALS AND ACTIVITIES.—

''(1) GOALS.—The goals of ARPA–H shall be to—

''(A) foster the development of new, breakthrough capabilities, technologies, systems, and platforms to accelerate innovations in health and medicine;

''(B) revolutionize diagnosis, mitigation, prevention, and treatment of diseases through the development of transformative health technologies and high-need cures;

''(C) promote high-risk, high-reward innovation to develop high-need cures; and

''(D) ensure the United States maintains—

''(i) global leadership in science and innovation; and

"(ii) the highest quality of life and health for its citizens.

"(2) MEANS.—ARPA–H shall achieve the goals under paragraph (1) by—

"(A) identifying and promoting revolutionary advances in health sciences;

"(B) translating scientific discoveries into technological innovations and high-need cures;

"(C) providing resources and support to create platform capabilities that draw on multiple disciplines;

"(D) delivering advanced proofs of concept that demonstrate clinically meaningful advances;

"(E) accelerating transformational technological advances in areas with limited funding or technical certainty; and

"(F) prioritizing investments based on such considerations as—

"(i) scientific opportunity and uniqueness of fit to the strategies and operating practices of ARPA–H;

"(ii) the effect on disease burden, including unmet patient need and the fiscal

liability of the Federal Government with respect to health care; and

"(iii) potential opportunities to advance health equity.

"(c) DIRECTOR.—

"(1) IN GENERAL.—The President shall appoint in the Department of Health and Human Services a director of ARPA–H (in this section referred to as the 'Director').

"(2) QUALIFICATIONS.—The Director shall be an individual who, by reason of professional background and experience, is especially qualified to manage—

"(A) research and advanced development programs; and

"(B) large-scale, high-risk initiatives with respect to health research across multiple sectors, including generating high-need cures.

"(3) RELATIONSHIP TO SECRETARY.—The Director shall report to the Secretary.

"(4) DUTIES.—The duties of the Director shall include the following:

"(A) Approve and terminate the projects and programs of ARPA–H.

"(B) Set research and development priorities with respect to the goals under subsection (b) and manage the budget of ARPA–H.

"(C) Develop funding criteria and assess the success of programs through the establishment of technical milestones.

"(D) Advance the goals under subsection (b), through consideration of the advice of the ARPA–H Interagency Advisory Committee established under subsection (l).

"(E) Solicit data, as needed, from the National Institutes of Health and other relevant Federal agencies, private entities, academia, nonprofit organizations, and international organizations.

"(F) Coordinate with the Director of the National Institutes of Health to ensure that the programs of ARPA–H build on and are informed by scientific research supported by the National Institutes of Health.

"(G) Coordinate with the heads of Federal agencies and, to the extent practicable, ensure that the activities of ARPA–H supplement (and do not supplant) the efforts of other Federal agencies.

''(5) TERM.—The Director—

''(A) shall be appointed for a 5-year term; and

''(B) may be reappointed for 1 consecutive term.

''(6) AUTONOMY OF AGENCY REGARDING RECOMMENDATIONS AND TESTIMONY.—No officer or agency of the United States shall have any authority to require the Director or any other officer of ARPA–H to submit legislative recommendations, or testimony or comments on legislation, to any officer or agency of the United States for approval, comments, or review prior to the submission of such recommendations, testimony, or comments to the Congress, if such recommendations, testimony, or comments to the Congress include a statement indicating that the views expressed therein are those of the Director or such officer, and do not necessarily reflect the views of the President or another agency.

''(7) DELEGATION OF AUTHORITY.—The Director may delegate to any duly authorized employee, representative, or agent any power vested in the Director or ARPA–H by law, except that the Director may not delegate the power to appoint the Deputy Director under paragraph (8).

''(8) DEPUTY DIRECTOR.—The Director shall appoint a deputy director to serve as acting Director in the absence or unavailability of the Director (notwithstanding section 3345 of title 5, United States Code).

''(d) APPLICATION OF PAPERWORK REDUCTION ACT.—The Director may waive the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the 'Paperwork Reduction Act') with respect to the activities described under subsection (c)(3)(F).

''(e) PARTNERSHIPS.—In carrying out this section, the Director may partner with public and private entities, including—

''(1) other Federal agencies;

''(2) institutions of higher education;

''(3) private or public research institutions;

''(4) federally funded research and development centers;

''(5) private entities, including biotechnology, and pharmaceutical, medical device, and other health entities; and

''(6) nonprofit organizations, including patient advocacy groups.

''(f) COORDINATION ON HIGH-NEED CURES.—The Director shall coordinate with the Commissioner of Food and Drugs and the Administrator of the Centers for Medicare & Medicaid Services to expedite the development, application, coverage, and implementation of high-need cures.

''(g) AWARDS.—In carrying out this section, the Director may make awards in the form of grants, contracts, cooperative agreements, prizes, and other transactions, including—

''(1) grants and cooperative agreements subject to the uniform administrative requirements, cost principles, and audit requirements for Federal awards contained in part 200 of title 2 of the Code of Federal Regulations;

''(2) contracts subject to chapter 1 of title 48, Code of Federal Regulations (or successor regulations) (commonly referred to as the 'Federal Acquisition Regulation') but exempt from the regulations specified in chapter 3 of title 48, Code of Federal Regulations (or successor regulations);

''(3) multi-year contracts under section 3903 of title 41, United States Code;

''(4) prize competitions; and

''(5) other transactions or prototype projects that are directly relevant to enhancing such goals.

''(h) FACILITIES AUTHORITY.—The Director may—

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

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

''(i) PERSONNEL.—

''(1) IN GENERAL.—The Director of ARPA–H shall have the authority to—

''(A) hire personnel under section 207(f) and establish governing criteria to recruit, appoint, and compensate personnel under this section without regard to any provision in title 5, United States Code, governing appointments under the civil service laws and 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, notwithstanding section 202 of the Department of Health and Human Services Ap-

propriations Act, 1993 (Public Law 102–394) or any provision of title 5, United States Code, governing the rates of pay or classification of employees in the executive branch;

''(B) make additional appointments of scientific, medical, and professional personnel under this section without regard to any provision in title 5, United States Code, governing appointments under the civil service laws and 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, notwithstanding section 202 of Department of Health and Human Services Appropriations Act, 1993 (Public Law 102–394) or any provision of title 5, United States Code, governing the rates of pay or classification of employees in the executive branch; and

''(C) make appointments to positions of administration or management of ARPA–H without regard to any provision in title 5, United States Code, governing appointments under the civil service laws and fix the com-

pensation 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, notwithstanding section 202 of Department of Health and Human Services Appropriations Act, 1993 (Public Law 102–394) or any provision of title 5, United States Code, governing the rates of pay or classification of employees in the executive branch.

''(2) ADDITIONAL STAFF.—The Director of ARPA–H may use all authorities in existence on the date of enactment of this section that are provided to the Secretary to hire administrative, financial, legal, contracts, legislative affairs, and information technology staff, and such other staff as may be identified by the Director as necessary to carry out this section.

''(3) ADDITIONAL CONSIDERATIONS.—In appointing qualified personnel under this subsection, the Director—

''(A) may contract with private entities; and

''(B) shall make efforts to recruit and retain a diverse workforce, including individuals

underrepresented in science and medicine and racial and ethnic minorities.

''(4) ADDITIONAL HIRING AUTHORITY.—To the extent needed to carry out the duties in paragraph (1), the Director is authorized to utilize hiring authorities under section 3372 of title 5, United States Code, to staff ARPA–H with employees from other Federal agencies, State and local governments, Indian Tribes and Tribal organizations, institutions of higher education, and other organizations, as described in that section, in the same manner and subject to the same conditions, that apply to such individuals utilized to accomplish other purposes.

''(5) EXISTING AUTHORITIES.—The authorities granted by this section are—

''(A) in addition to existing authorities granted to the Secretary; and

''(B) are not intended to supersede or modify any existing authorities.

''(j) PROGRAM MANAGERS.—

''(1) IN GENERAL.—The Director shall designate employees of ARPA–H to serve as program managers for the programs carried out by ARPA–H.

''(2) DUTIES.—A program manager shall—

"(A) establish research and development goals for programs in accordance with guidance from the Director;

"(B) collaborate with experts from the National Institutes of Health and other Federal agencies and experts in relevant scientific fields to identify research and development opportunities;

"(C) convene workshops, as needed, with relevant Federal agencies, institutions of higher education, nonprofit research institutions, companies, venture capital firms, and nonprofit organizations for the development of high-need cures;

"(D) issue funding opportunity announcements;

"(E) select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA–H, taking into consideration—

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

"(ii) the demonstrated capabilities of the applicants to successfully carry out the proposed project;

"(iii) the unmet needs within patient populations;

"(iv) the consideration by the applicant of future commercial applications of the project, including the feasibility of partnering with one or more commercial entities; and

"(v) such other criteria as are established by the Director;

"(F) identify milestones and monitor progress of such milestones with respect to each project;

"(G) provide recommendations to the Director with respect to advancing the goals under subsection (b);

"(H) identify opportunities for the commercial application of successful projects, including through the establishment of partnerships between or among awardees; and

"(I) provide recommendations to expand, restructure, or terminate research partnerships or projects.

"(3) TERM.—A program manager may serve not greater than 2 terms for a period of 3 years each.

''(k) REPORTS AND EVALUATION.—

''(1) ANNUAL REPORT.—

''(A) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of this section, and each fiscal year thereafter, the Director shall submit a report on the actions undertaken, and results generated, by ARPA–H, including—

''(i) a description of projects supported by ARPA–H in the previous fiscal year and whether such projects are meeting the goals developed by the Director pursuant to subsection (c)(4)(C);

''(ii) a description of projects terminated in the previous fiscal year, and the reason for such termination;

''(iii) a description of projects starting in the next fiscal year, as available;

''(iv) activities conducted in coordination with other Federal agencies; and

''(v) an analysis of the extent of coordination conducted pursuant to subsections (c)(4)(F) and (f), including successes and barriers with respect to achieving the goals under subsection (b).

''(B) SUBMISSION TO CONGRESS.—The report under subsection (a) shall be submitted to—

''(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

''(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate.

''(2) EVALUATION.—

''(A) IN GENERAL.—Not later than 8 years after the date of the enactment of this section, the Secretary shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to study and evaluate whether ARPA–H has met the goals under subsection (b).

''(B) SUBMISSION OF RESULTS.—The agreement entered into under subparagraph (A) shall require the National Academies of Sciences, Engineering, and Medicine to submit the results of the evaluation conducted under such agreement to the Secretary, the Committee on Energy and Commerce of the House

of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

''(l) STRATEGIC PLAN.—Not later than 1 year after the date of the enactment of this section, and every 4 years thereafter, the Director shall provide to the relevant committees of Congress a strategic plan describing how ARPA–H will carry out investments each fiscal year in the next 4-year period.

''(m) ADDITIONAL ADVICE.—In carrying out this section, the Director may seek advice from—

''(1) the President's Committee of Advisors on Science and Technology;

''(2) peers in the scientific community, including academia and industry;

''(3) experts in other Federal agencies;

''(4) any professional or scientific organization with expertise technologies under development by ARPA–H or a relevant scientific discipline; and

''(5) representatives of patient communities.

''(n) ARPA–H ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Director shall establish an interagency advisory committee to be known as the ARPA–H Interagency Advisory Committee (re-

ferred to in this subsection as the 'Advisory Committee').

''(2) MEMBERSHIP.—The Advisory Committee may include any or all of the following members, or designees:

''(A) The Director of the National Institutes of Health.

''(B) The Director of National Center for Advancing Translational Sciences.

''(C) The Director of Office of Science and Technology Policy.

''(D) The Commissioner of the Food and Drug Administration.

''(E) The Director of the Biomedical Advanced Research and Development Authority.

''(F) The Director of the Centers for Disease Control and Prevention.

''(G) The Administrator of the Centers for Medicare & Medicaid Services.

''(H) The Director of the Agency for Healthcare Research and Quality.

''(I) The Director of the Office of Minority Health.

''(J) The Administrator of the Health Resources and Services Administration.

''(K) The Director of the Defense Advanced Research Projects Agency.

''(L) The Director of the National Science Foundation.

''(M) The Director of the Office of Science of the Department of Energy.

''(N) Representatives of any Federal agency with subject matter expertise that the Director of ARPA–H determines is necessary for the successful completion of a project carried out pursuant to this section.

''(3) DUTIES.—The Advisory Committee shall advise the Director, including by—

''(A) making recommendations on—

''(i) research priorities that will provide the greatest return on investment with respect to improving human health;

''(ii) avoiding duplication of efforts in the Federal Government; and

''(iii) improving coordination with other Federal agencies; and

''(B) identifying and developing strategies to address market barriers to commercialization or adoption of high-need cures.

''(4) NON-APPLICABILITY OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

''(5) ADVISORY NATURE.—The function of the Committee shall be advisory in nature. Nothing in this section shall be construed as giving the Committee authority over the activities authorized under this section.

''(o) RULE OF CONSTRUCTION.—The authorities under this section, with respect to the Director, are additional authorities that do not supersede or modify any existing authorities.

''(p) DEFINITIONS.—In this section:

''(1) ADVANCED PROOFS OF CONCEPT.—The term 'advanced proofs of concept' means data, a prototype, or other experimental evidence that—

''(A) may precede the development of a high-need cure or health technology; and

''(B) demonstrates the feasibility of a new concept.

''(2) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 262 of the Federal Food, Drug, and Cosmetic Act.

''(3) DRUG.—The term 'drug' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(4) DEVICE.—The term 'device' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(5) FEDERAL ACQUISITION REGULATION.—The term 'Federal Acquisition Regulation' means the Federal Acquisition Regulation issued pursuant to section 1303(a)(1) of title 41, United States Code.

''(6) HIGH-NEED CURE.—The term 'high-need cure' means a drug, biological product, or device—

''(A) that should be prioritized to detect, diagnose, mitigate, prevent, or treat any disease or medical condition; and

''(B) for which incentives in commercial market are unlikely to result in the adequate or timely development of such drug, biological product, or device.

''(7) PRIZE COMPETITIONS.—The term 'prize competitions' has the meaning given such term in section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719).

"SEC. 499B. HEALTH ADVANCED RESEARCH AND DEVELOPMENT FUND.

''(a) ESTABLISHMENT.—There is established in the Treasury a fund to be known as the Health Advanced Research and Development Fund (in this section referred to as the 'Fund') which shall be administered by the Director of ARPA–H for the purposes of carrying out section 499A.

''(b) SEPARATE BUDGET REQUEST.—The annual budget request for ARPA–H shall be separate from the rest of the budget for the Department of Health and Human Services. The Director of ARPA–H shall prepare and submit directly to the President for review and transmittal to Congress, an annual budget for ARPA–H after reasonable opportunity for comment (but without change) by the Secretary.

''(c) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to the Fund, $3,000,000,000 for fiscal year 2022, to remain available until expended.

''(2) ADVANCE APPROPRIATIONS.—For each fiscal year beginning with fiscal year 2022, discretionary new budget authority provided in an appropriations Act for ARPA–H shall—

''(A) be made available for that fiscal year; and

"(B) include advance discretionary new budget authority that first becomes available for the first fiscal year following the budget year.

"(3) SEPARATE APPROPRIATIONS.—Appropriations to the Fund shall be separate and distinct from other appropriations for the Department.".

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