

## ADVANCED RESEARCH PROJECTS AGENCY–HEALTH ACT

JUNE 13, 2022.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,  
submitted the following

## REPORT

[To accompany H.R. 5585]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5585) to establish the Advanced Research Projects Agency-Health, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

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Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

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This Act may be cited as the “Advanced Research Projects 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, as an independent operating division within the Department of Health and Human Services, the Advanced Research Projects Agency—Health (in this part referred to as ‘ARPA—H’). Not later than 180 days after the date of enactment of this part, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health within the National Institutes of Health, as in existence on the date of enactment of this part, to ARPA—H established by the preceding sentence.

**“(b) GOALS AND METHODS.—**

“(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 that are not being met by Federal programs or private entities;

“(B) revolutionize detection, diagnosis, mitigation, prevention, treatment, and curing of serious diseases and medical conditions through the development of transformative health technologies;

“(C) promote high-risk, high-reward innovation for the development and translation of transformative health technologies; and

“(D) contribute to ensuring the United States maintains—

“(i) global leadership in science and innovation;

“(ii) the highest quality of life and health for its citizens; and

“(iii) an aggressive agenda for innovations to address global health threats that place United States citizens at risk.

“(2) METHODS.—ARPA—H shall achieve the goals specified in paragraph (1) by—

“(A) discovering, identifying, and promoting revolutionary advances in health sciences;

“(B) translating scientific discoveries into transformative health technologies;

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

“(D) using researchers in a wide range of disciplines, including the life sciences, the physical sciences, engineering, and the computational sciences;

“(E) delivering advanced proofs of concept that demonstrate potentially clinically meaningful advances;

“(F) developing new capabilities, advanced computational tools, predictive models, or analytical techniques to identify potential targets and technological strategies for early disease detection and intervention;

“(G) accelerating transformational technological advances in areas with limited technical certainty; and

“(H) 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, quality and disparity gaps, and the potential to preempt progression of serious disease; and

“(iii) the effect on the fiscal liability of the Federal Government with respect to health care and the ability to reduce the cost of care through innovation.

**“(c) DIRECTOR.—**

“(1) IN GENERAL.—The President shall appoint with the advice and consent of the Senate, a director of ARPA—H (in this part 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 and technology development across multiple sectors, including generating transformative health technologies and improving health outcomes for patients.

“(3) RELATIONSHIP TO SECRETARY.—The Director shall report directly 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 specified in 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 Research Council established under subsection (q).
- “(E) Solicit data, as needed, from the National Institutes of Health and other relevant entities.
- “(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.
- “(H) Ensure ARPA–H does not provide funding for a project unless the program manager determines that the project meets the goals described in subsection (b)(1).

“(5) TERM.—The Director—

- “(A) shall be appointed for a 5-year term; and
- “(B) may be reappointed for 1 consecutive 5-year 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 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 the first assistant to the office.

“(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 methods described in subsection (b)(2).

“(e) PROTECTION OF INFORMATION.—The following types of information collected by ARPA–H from recipients of financial assistance awards shall be considered commercial and financial information obtained from a person and privileged or confidential and not subject to disclosure under section 552(b)(4) of title 5, United States Code:

- “(1) Plans for commercialization of technologies developed under the award, including business plans, technology-to market plans, market studies, and cost and performance models.
- “(2) Investments provided to an awardee from third parties (such as venture capital firms, hedge funds, and private equity firms), including amounts and the percentage of ownership of the awardee provided in return for the investments.
- “(3) Additional financial support that the awardee—
  - “(A) plans to invest or has invested in the technology developed under the award; or
  - “(B) is seeking from third parties.
- “(4) Revenue from the licensing or sale of new products or services resulting from research conducted under the award.

“(f) SHARING INFORMATION WITH THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—The Director shall timely share relevant information with the Administrator of the Centers for Medicare & Medicaid Services that may help to expedite determinations of coverage of transformative health technologies developed by ARPA–H.

“(g) EXPEDITING BREAKTHROUGHS THROUGH COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION.—

- “(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Director, may take actions to facilitate translation of transformative health technology into tangible solutions for patients and to expedite development of drugs, devices, and biological products, including through—

“(A) helping to ensure that drug, device, or biological product development programs, in as efficient a manner as possible, gather the nonclinical and clinical data necessary to advancing the development of such products and to obtaining their approval, licensure, or clearance, as applicable, by the Food and Drug Administration under sections 505, 510(k), and 515 of the Federal Food, Drug, and Cosmetic Act and section 351 of this Act;

“(B) expediting review of investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act, review of investigational device exemptions under section 520(g) of such Act, and review of applications for approval, licensure, and clearance of drugs, devices, or biological products under sections 505, 510(k), and 515 of such Act, and section 351 of this Act; and

“(C) meeting at appropriate intervals with the Director and any member of the ARPA-H Interagency Research Council to discuss the development status of drugs, devices, or biological products and projects that are the highest priorities to ARPA-H, unless the Director and the Commissioner of Food and Drugs determine that any such meetings are not necessary.

“(2) RELATION TO OTHERWISE AUTHORIZED ACTIVITIES OF THE FDA.—The authority specified in paragraph (1) shall not be construed as limiting the authority of the Secretary, acting through the Commissioner of Food and Drugs, with respect to the review and approval, clearance, authorization for emergency use, or licensure of drugs, devices, or biological products under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

“(3) REIMBURSEMENT.—The Director, using funds made available to ARPA-H, may reimburse the Food and Drug Administration for expenditures made by the Food and Drug Administration for activities carried out under this section that have been identified by the Commissioner of Food and Drugs and the Director as being carried out by the Food and Drug Administration.

“(h) AWARDS.—

“(1) IN GENERAL.—In carrying out this section, the Director may make awards including—

“(A) grants and cooperative agreements, which shall—

“(i) be subject to the uniform administrative requirements, cost principles, and audit requirements for Federal awards contained in part 200 of title 2, Code of Federal Regulations (or successor regulations); and

“(ii) include the total line-item and itemized indirect facilities and administrative costs that shall be made publicly available and published in a machine-readable format;

“(B) contracts subject to the Federal Acquisition Regulation;

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

“(D) prizes; and

“(E) other transactions.

“(2) EXEMPTIONS FOR CERTAIN REQUIREMENTS.—Research funded by ARPA-H shall not be subject to the requirements of section 406(a)(3)(A)(ii) or section 492.

“(i) FACILITIES AUTHORITY.—

“(1) IN GENERAL.—The Director may acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as may be necessary to carry out this section.

“(2) LEASE OF NONEXCESS PROPERTY.—The Director may enter into a lease under this section with any person or entity (including another department or agency of the Federal Government or an entity of a State or local government) with regard to any nonexcess real property and related personal property under the jurisdiction of the Director.

“(3) UTILIZATION OF LEASE FUNDS.—

“(A) IN GENERAL.—The Director may utilize, without further appropriation, amounts of cash consideration received for a lease entered into under this subsection to cover the full costs to ARPA-H in connection with the lease. Funds received as such cash consideration shall remain available until expended.

“(B) CAPITAL REVITALIZATION AND IMPROVEMENTS.—Of any amounts of cash consideration received under this subsection that are not utilized in accordance with subparagraph (A), without further appropriation—

“(i) 35 percent shall—

“(I) be deposited in a capital asset account to be established by the Director;

“(II) be available for maintenance, capital revitalization, and improvements of the real property assets and related personal property under the jurisdiction of the Director; and

“(III) remain available until expended; and

“(ii) the remaining 65 percent shall be available to the respective center or facility of ARPA–H engaged in the lease of nonexcess real property, and shall remain available until expended for maintenance, capital revitalization, and improvements of the real property assets and related personal property at the respective center or facility subject to the concurrence of the Director.

“(C) NO UTILIZATION FOR DAILY OPERATING COSTS.—Amounts utilized under subparagraph (B) may not be utilized for daily operating costs.

“(4) LOCATIONS.—

“(A) IN GENERAL.—ARPA–H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

“(B) CONSIDERATIONS.—In determining the location of facilities, the Director shall make a fair and open consideration of—

“(i) the characteristics of the intended location; and

“(ii) the extent to which such location will facilitate advancement of the goals and methods specified in subsection (b).

“(j) PERSONNEL.—

“(1) IN GENERAL.—The Director may—

“(A) make and rescind appointments of scientific, engineering, medical, and professional personnel, which may include temporary or time-limited appointments as determined by the Director to fulfill the mission of ARPA–H, without regard to any provision in title 5, United States Code, governing appointments and removals under the civil service laws, and fix the base pay 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; and

“(B) contract with private recruiting firms for the hiring of qualified staff referenced in subparagraph (A).

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

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

“(A) may contract with private entities;

“(B) shall make efforts to recruit and retain a diverse workforce, including individuals underrepresented in science and medicine and racial and ethnic minorities (as long as such efforts comply with applicable Federal civil rights law); and

“(C) shall recruit program managers with expertise in a wide range of relevant disciplines, including life sciences, the physical sciences, engineering, and the computational sciences.

“(4) ADDITIONAL HIRING AUTHORITY.—To the extent needed to carry out the authorities vested by paragraph (1), the Director may utilize hiring authorities under sections 3371 through 3376 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 such sections.

“(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.

“(6) AUTHORITY TO ACCEPT FEDERAL DETAILEES.—The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

“(k) PROGRAM MANAGERS.—

“(1) IN GENERAL.—The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 consecutive 3-year term) for the programs carried out by ARPA–H.

“(2) DUTIES.—A program manager shall—

“(A) establish, in consultation with the Director or Deputy Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

“(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 gaps and opportunities;

“(C) convene workshops and meetings, as needed, with entities such as patients, patient advocacy groups, practitioners, professional societies, and other stakeholders to solicit input on programs and goals;

“(D) manage applications and proposals, through the appropriate officials for making grants, cooperative agreements, contracts, prizes, and other transaction awards for advanced research that may show particular promise, especially in areas in which the private sector and the Federal Government have not undertaken sufficient research;

“(E) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

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

“(i) the scientific and technical merit of the proposed project;

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

“(iii) the unmet needs or ability to improve health outcomes within patient populations;

“(iv) future commercial applications of the project or the feasibility of partnering with one or more commercial entities;

“(v) the potential for interdisciplinarity of the approach of the project; and

“(vi) such other criteria as established by the Director;

“(G) conduct project reviews within 18 months of funding awards to identify milestones and monitor progress of such milestones with respect to each project and prior to disbursement of new funds;

“(H) provide recommendations to the Director with respect to advancing the goals specified in subsection (b);

“(I) cultivate opportunities for the commercial application or community use of successful projects, including through the establishment of partnerships between or among awardees;

“(J) identify innovative cost-sharing arrangements for ARPA–H projects;

“(K) provide recommendations to expand, restructure, or terminate research partnerships or projects; and

“(L) ensure that—

“(i) animal studies meet the Federal animal research requirements pursuant of the Public Health Service Policy on Humane Care and Use of Laboratory Animals; and

“(ii) applications apply statistical modeling approaches and appropriately justify animal sample sizes to meet project goals.

“(I) REPORTS AND EVALUATION.—

“(1) ANNUAL REPORT.—

“(A) IN GENERAL.—Beginning not later than 1 year after the date of 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 programs starting in the next fiscal year, as available;

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

“(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);

“(vi) a description of the demographic (including racial and gender) diversity if available of direct recipients and performers in funded projects and of the ARPA–H workforce; and

“(vii) a disclosure by the award recipients of whether the principal investigators named on the award participate in foreign talent programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documenta-

tion related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded.

“(B) SUBMISSION TO CONGRESS.—The report under subparagraph (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 5 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 under which the National Academies agree to study and evaluate whether ARPA–H is meeting the goals specified in 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.

“(m) STRATEGIC PLAN.—Not later than 1 year after the date of the enactment of this section, and every 3 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 following 3-year period.

“(n) INDEPENDENT REVIEW.—Not later than 1 year after the date of the enactment of this section, and every 3 years thereafter, the Comptroller General of the United States shall conduct an independent review of the research portfolio of the Department of Health and Human Services, including ARPA–H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

“(1) to assess the degree of unnecessary duplication of existing Federal programs and projects; and

“(2) to make recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

“(o) PRIORITIZATION.—The Director shall—

“(1) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to domestic recipients conducting the research on transformative health technology in the United States;

“(2) as appropriate and practicable, ensure that nondomestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section are conducting research in collaboration with a domestic recipient;

“(3) not award any grants, cooperative agreements, contracts, prizes, and other transactions to nondomestic recipients subject to malign foreign influence or organized under the laws of a malign foreign country; and

“(4) in accordance with the requirements of chapter 33 of title 41, United States Code, and the Federal Acquisition Regulation, only award grants, cooperative agreements, contracts, prizes, and other transactions to individual persons that do not have more than 3 ongoing concurrent grants, cooperative agreements, contracts, prizes, and other transactions under this section.

“(p) ADDITIONAL CONSULTATION.—In carrying out this section, the Director may consult with—

“(1) the President’s Council of Advisors on Science and Technology;

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

“(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

“(4) a new interagency research council organized to support the programs of ARPA–H and to provide advice and assistance on—

“(A) specific program tasks; or

“(B) the overall direction of ARPA–H; and

“(5) any other entity the Director may deem appropriate.

“(q) ARPA–H INTERAGENCY RESEARCH COUNCIL.—

“(1) IN GENERAL.—The Director shall establish an interagency advisory committee to be known as the ARPA–H Interagency Research Council (referred to in this subsection as the ‘Research Council’).

“(2) MEMBERSHIP.—The Research Council 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 Food and Drugs.
- “(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) The Director of the Advanced Research Projects Agency-Energy.
- “(O) The Assistant Secretary for Preparedness and Response.
- “(P) Representatives of any Federal agency with subject matter expertise that the Director determines is necessary for the successful completion of a project carried out pursuant to this section.
- “(Q) Any other entity the Director may deem appropriate.

“(3) DUTIES.—The Research Council 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 regulatory, reimbursement, and market barriers to commercialization or adoption of transformative health technologies, including technologies intended to preempt serious disease.

“(4) ADVISORY NATURE.—The function of the Research Council shall be advisory in nature. Nothing in this subsection shall be construed as granting the Research Council authority over any activities or functions of ARPA-H.

“(5) MEETINGS.—Not later than 1 year after the date of the enactment of this section, and every fiscal year thereafter, the Director shall convene meetings of the Research Council, including conferences or workshops, as needed. The Research Council may function through established or ad hoc committees, task forces, or interagency groups to—

- “(A) share information on health innovations funded by ARPA-H; and
- “(B) receive input on areas of particular promise for ARPA-H projects.

“(r) TECHNOLOGY TRANSFER OFFICE.—The Director may establish within ARPA-H an Office of Technology Transfer to facilitate, where appropriate, the transfer of federally-owned or federally-originated technology to recipients of an award under this section (other than Federal Government entities).

“(s) FOLLOW-ON PRODUCTION AWARD AUTHORITY.—

- “(1) IN GENERAL.—An other transaction entered into by the Director under subsection (h)(1) for a project may provide for the award of a follow-on production contract or transaction to the participants in the transaction by ARPA-H or another Federal agency. For purposes of this paragraph, such an other transaction includes all individual subprojects awarded under the transaction to a consortium of United States industry and academic institutions.
- “(2) RELATION TO COMPETITIVE PROCEDURES.—A follow-on production contract or transaction under paragraph (1) may be awarded to the participants in the transaction without the use of competitive procedures (as defined in section 152 of title 41, United States Code), notwithstanding the requirements of division C of subtitle I of such title 41, if—
  - “(A) competitive procedures were used for the selection of parties for participation in the other transaction; and
  - “(B) the participants in the other transaction successfully completed the project provided for in the transaction.
- “(3) PRECONDITION.—A follow-on production contract or transaction may be awarded pursuant to this subsection when the Director determines that an individual project or subproject as part of a consortium is successfully completed by the participants.
- “(4) CLARIFICATION.—Award of a follow-on production contract or transaction pursuant to this subsection shall not be made contingent upon the successful completion of all activities within a consortium as a condition for an award for follow-on production of a successfully completed project or subproject within that consortium.

“(5) OTHER AUTHORITIES.—Contracts and transactions entered into by ARPA–H pursuant to this subsection may be awarded pursuant to division C of subtitle I of title 41, United States Code, or under such procedures, terms, and conditions as the Director or head of such agency may establish by regulation.

“(t) 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.

“(u) DEFINITIONS.—In this part:

“(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 transformative health technologies; and

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

“(2) BIOLOGICAL PRODUCT.—The term ‘biological product’ has the meaning given such term in section 351(i).

“(3) DEPARTMENT.—The term ‘Department’ means the Department of Health and Human Services.

“(4) DRUG; DEVICE.—The terms ‘drug’ and ‘device’ have the meanings given such terms 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) FEDERAL AGENCY.—The term ‘Federal agency’ has the meaning given such term in section 3371 of title 5, United States Code.

“(7) PRIZE.—The term ‘prize’ means a prize as such term is used in section 24 of the Stevenson-Wydler Technology Innovation Act of 1980.

“(8) TRANSFORMATIVE HEALTH TECHNOLOGY.—The term ‘transformative health technology’ means a drug, biological product, intervention, platform, tool, or device—

“(A) that should be prioritized to detect, diagnose, mitigate, prevent, cure, or treat a serious disease or medical condition for which there are unmet needs; and

“(B) for which—

“(i) significant scientific uncertainty and regulatory risk exist; or

“(ii) incentives in the commercial market are unlikely to result in the adequate or timely development of such drug, biological product, intervention, platform, tool, or device.

“(v) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated \$500,000,000 for each of fiscal years 2023 through 2027, to remain available until expended.”.

## I. PURPOSE AND SUMMARY

H.R. 5585, the “Advanced Research Project Agency-Health Act” or the “ARPA–H Act,” authorizes the Advanced Research Projects Agency for Health (ARPA–H) within the Department of Health and Human Services (HHS) with the objective of accelerating innovation in health and medicine in order to foster the development of innovative transformative health technologies that are not being developed by existing federal programs or the private sector. The bill establishes a defined mission for the new agency, along with specific goals and methods to address that mission, defines the role and authorities of the director and program managers, creates a research council and reporting mechanisms to determine whether projects are meeting the agency’s goals, and authorizes hiring, awards, cooperative agreements, and other transactions, among other authorities. The bill authorizes appropriations of \$500 million for each of the fiscal years 2023 through 2027 to remain available until expended.

## II. BACKGROUND AND NEED FOR LEGISLATION

The American biomedical research enterprise is supported by the world’s leading academic institutions, scientists, and commercial

industries.<sup>1</sup> The development of vaccines through the joint public-private partnerships orchestrated by Operation Warp Speed to respond to the coronavirus disease of 2019 (COVID-19) pandemic is an example of America's biomedical research leadership. Prior to Operation Warp Speed, the fastest timeline for the development of any vaccine from viral sampling to approval was four years.<sup>2</sup> Developing multiple vaccines within one year to effectively prevent serious illness and death from COVID-19 infection was unprecedented.<sup>3</sup> This outcome was made possible by significant federal investment and extensive collaboration with the private sector.<sup>4</sup> For example, years of fundamental research on related coronaviruses that caused severe acute respiratory syndrome and Middle East respiratory syndrome, funded by the National Institutes of Health (NIH) and biotechnology companies, played a major role in the development of COVID-19 vaccines.<sup>5 6</sup>

However, barriers and gaps exist within the public and private biomedical research ecosystem, which can lead to the stalling or failure of innovative projects.<sup>7</sup> The priorities of the academic and commercial sectors may result in ideas not being pursued that are considered too high-risk, have a significant cost, or where the potential commercial market would not support the cost, among other reasons.<sup>8</sup> H.R. 5585 seeks to address this gap by establishing a new entity, ARPA-H, that will accelerate biomedical innovation in health and medicine by supporting high-risk, high-reward research projects. Projects taken on by ARPA-H will be subject to time-limited goals, benchmarks, and accountability initiatives.

ARPA-H is inspired by and builds on the model of the Defense Advanced Research Projects Agency (DARPA).<sup>9</sup> DARPA was launched in 1958 with the goal of making pivotal investments in breakthrough technologies for national security.<sup>10</sup> Some of DARPA's important achievements include the development of the internet, stealth aircraft, miniaturized Global Positioning System technologies, flat-screen displays, and more.<sup>11</sup> There are key features of DARPA that have facilitated its success and that are included in the design of ARPA-H, including its flexible hiring and contracting authorities, streamlined and efficient leadership organization, milestone-based review, and focused mission.<sup>12</sup>

<sup>1</sup> White House Office of Science and Technology Policy, *Advanced Research Project Agency for Health (ARPA-H): Concept Paper* (June 2021) [www.whitehouse.gov/wpcontent/uploads/2021/06/ARPA-H-Concept-Paper.pdf](http://www.whitehouse.gov/wpcontent/uploads/2021/06/ARPA-H-Concept-Paper.pdf).

<sup>2</sup> *Id.*  
<sup>3</sup> Philip Ball, *The Lightning-Fast Quest for COVID Vaccines—and What It Means for Other Diseases*, *Nature* (Dec. 18, 2020) ([doi.org/10.1038/d41586-020-03626-1](https://doi.org/10.1038/d41586-020-03626-1)).

<sup>4</sup> *Id.*  
<sup>5</sup> *Id.*  
<sup>6</sup> Amber Dance, *Coronavirus Vaccines Get a Biotech Boost*, *Nature* (July 21, 2020) ([doi.org/10.1038/d41586-020-02154-2](https://doi.org/10.1038/d41586-020-02154-2)).

<sup>7</sup> Francis S. Collins et al., *ARPA-H: Accelerating Biomedical Breakthroughs*, *Science*, 373 (July 9, 2021) ([doi.org/10.1126/science.abj8547](https://doi.org/10.1126/science.abj8547)).

<sup>8</sup> *Id.*  
<sup>9</sup> Congressional Research Service, *Advanced Research Agency for Health (ARPA-H): Potential Questions for Consideration* (Sept. 23, 2021). ([www.crs.gov/Reports/R46901?source=search&guid=c6ee36775a9 c4ed8a9239b678b 393e61&in dex=0](http://www.crs.gov/Reports/R46901?source=search&guid=c6ee36775a9 c4ed8a9239b678b 393e61&in dex=0)).

<sup>10</sup> Defense Advanced Research Projects Agency, *About DARPA* ([www.darpa.mil/aboutus/about-darpa](http://www.darpa.mil/aboutus/about-darpa)) (accessed Jan. 30, 2022).

<sup>11</sup> Defense Advanced Research Projects Agency, *Innovation at DARPA* (July 2016) ([www.darpa.mil/attachments/ DARPA\\_Innovation\\_2016.pdf](http://www.darpa.mil/attachments/ DARPA_Innovation_2016.pdf)).

<sup>12</sup> Defense Advanced Research Projects Agency, *Contracting Managing* ([www.darpa.mil/with-us/contract-management](http://www.darpa.mil/with-us/contract-management)) (accessed Jan. 30, 2022).

### III. COMMITTEE HEARINGS

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearing was used to develop or consider H.R. 5585:

The Subcommittee on Health held a hearing on February 8, 2022. The hearing was entitled, “ARPA-H: The Next Frontier of Biomedical Research.” The Subcommittee received testimony from the following witnesses:

- Keith R. Yamamoto, Vice Chancellor for Science Policy and Strategy, University of California San Francisco;
- Esther Krofah, Executive Director, FasterCures and Center for Public Health at the Milken Institute;
- Geoffrey Shiu Fei Ling, CEO, On Demand Pharmaceuticals, and Professor of Neurology, Johns Hopkins Medicine;
- Admiral Brett P. Giroir, Former Assistant Secretary for Health, U.S. Department of Health and Human Services; and
- Brian James Miller, Professor of Medicine John Hopkins Medicine.

### IV. COMMITTEE CONSIDERATION

H.R. 5585, the “Advanced Research Project Agency-Health Act” or the “ARPA-H Act,” was introduced on October 15, 2021, by Representative Anna Eshoo (D-CA) and was referred to the Committee on Energy and Commerce. Subsequently, on October 18, 2021, the bill was referred to the Subcommittee on Health.

On May 11, 2022, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 5585 and five other bills. During consideration of the bill, no amendments were offered. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, without amendment, by a voice vote.

On May 18, 2022, the full Committee met in open markup session, pursuant to notice, to consider H.R. 5585 and five other bills. An amendment in the nature of a substitute (AINS), offered by Representative Eshoo, was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Representative Pallone, Chairman of the Committee, to order H.R. 5585 reported favorably to the House, amended, by a roll call vote of 53 yeas to 3 nays.

### V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there was one record vote taken on H.R. 5585, including a motion by Mr. Pallone ordering H.R. 5585 favorably reported to the House, amended. The motion on final passage of the bill was approved by a record vote of 53 yeas to 3 nays. The following are the record votes taken during Committee consideration, including the names of those members voting for and against:

Committee on Energy and Commerce  
117<sup>th</sup> Congress

**Full Committee**

*(ratio: 32-26)*

ROLL CALL VOTE #127

Bill: **H.R. 5585**, the “Advanced Research Project Agency-Health Act” or “ARPA-H Act”

Vote: Final Passage

Disposition: **AGREED TO** by a roll call vote of 53 yeas to 3 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers	X		
Mr. Rush	X			Mr. Upton	X		
Ms. Eshoo	X			Mr. Burgess	X		
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta	X		
Ms. Schakowsky	X			Mr. Guthrie	X		
Mr. Butterfield	X			Mr. McKinley	X		
Ms. Matsui	X			Mr. Kinzinger			
Ms. Castor	X			Mr. Griffith	X		
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. McNerney	X			Mr. Johnson	X		
Mr. Welch	X			Mr. Long		X	
Mr. Tonko	X			Mr. Bueshon	X		
Ms. Clarke	X			Mr. Mullin	X		
Mr. Schrader	X			Mr. Hudson	X		
Mr. Cárdenas	X			Mr. Walberg	X		
Mr. Ruiz	X			Mr. Carter	X		
Mr. Peters	X			Mr. Duncan			
Mrs. Dingell	X			Mr. Palmer	X		
Mr. Veasey	X			Mr. Dunn	X		
Ms. Kuster	X			Mr. Curtis		X	
Ms. Kelly	X			Ms. Lesko		X	
Ms. Barragán	X			Mr. Pence	X		
Mr. McEachin	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Mr. Soto	X			Mr. Armstrong	X		
Mr. O’Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

## VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

## VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

## VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to authorize ARPA-H within HHS to accelerate innovation in health and medicine by investing in high-risk, high-reward research projects. The bill authorizes appropriations of \$500 million for each of the fiscal years 2023 through 2027 to remain available until expended.

## X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5585 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

## XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5585 contains no earmarks, limited tax benefits, or limited tariff benefits.

### XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

### XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

### XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

#### *Section. 1. Short title*

Section 1 designates that the short title may be cited as the “Advanced Research Projects Agency–Health Act” or the “ARPA–H Act.”

#### *Sec. 2. Advanced Research Projects Agency–Health*

Section 2 amends Title IV of the Public Health Service Act to establish ARPA–H as an independent operating division within HHS. This section establishes the goals of ARPA–H to foster the development of new, breakthrough capabilities, technologies, systems, and platforms to accelerate innovations in health and medicine that are not being met by existing federal programs or private entities to ensure the United States maintains global leadership in science and the highest quality of life and health for its citizens. This section also includes the methods by which ARPA–H shall achieve these goals, including identifying, translating, accelerating, prioritizing, and delivering transformative health technologies. This section also specifies that investments will be prioritized based on scientific opportunity, the effect on disease burden, including unmet patient need, and the ability to reduce the cost of care through innovation.

This section creates the position of a presidentially-appointed, Senate-confirmed Director who shall report to the Secretary of HHS and perform the duties of approving, setting, developing, and advancing the goals and priorities of the Agency; coordinate with NIH and other federal agencies, private entities, academia, non-profit organizations, and international organizations to solicit data, build on scientific research, and ensure that efforts supplement (and do not supplant) those of other federal agencies; and appoint a deputy director.

Under this section, the Director is authorized to submit autonomous agency recommendations and testimony to Congress, protect certain ARPA–H information from disclosure, share information with the Centers for Medicare and Medicaid Services, expedite breakthroughs through cooperation with the Food and Drug Administration, lease facilities and determine the location of ARPA–H’s headquarters, hire personnel, and appoint program managers. This section instructs the Director to prioritize awarding ARPA–H funding to domestic recipients conducting research in the United States. As appropriated and practicable, this section also specifies that the Director shall ensure that nondomestic recipients conduct research in collaboration with a domestic recipient and shall not

award any funding to nondomestic recipients subject to malign foreign influence or organized under the laws of a malign foreign country.

This section requires the Director to submit reports on the actions, results, and forthcoming strategic plans of ARPA-H to the Congressional Committees in the House and Senate with appropriate jurisdiction. It also permits the Director to seek advice from outside entities and to establish the ARPA-H Interagency Research Council. Under this section, the Director may establish an Office of Technology Transfer with ARPA-H to facilitate the transfer of federally owned or originated technology to recipients of ARPA-H funding.

Under this section, the Comptroller General is required to conduct an independent review of the research portfolio of HHS, including ARPA-H, to assess the degree of unnecessary duplication and to make recommendations regarding potential reorganization, coordination, or termination of such programs.

This section authorizes appropriations of \$500 million for each of the fiscal years 2023 through 2027 to remain available until expended.

#### XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

#### PUBLIC HEALTH SERVICE ACT

\* \* \* \* \*

#### TITLE IV—NATIONAL RESEARCH INSTITUTES

\* \* \* \* \*

#### **PART J—ADVANCED RESEARCH PROJECTS AGENCY—HEALTH**

##### **SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY—HEALTH.**

(a) *ESTABLISHMENT.*—There is established, as an independent operating division within the Department of Health and Human Services, the Advanced Research Projects Agency—Health (in this part referred to as “ARPA-H”). Not later than 180 days after the date of enactment of this part, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health within the National Institutes of Health, as in existence on the date of enactment of this part, to ARPA-H established by the preceding sentence.

(b) *GOALS AND METHODS.*—

(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 that are not being met by Federal programs or private entities;

- (B) revolutionize detection, diagnosis, mitigation, prevention, treatment, and curing of serious diseases and medical conditions through the development of transformative health technologies;
- (C) promote high-risk, high-reward innovation for the development and translation of transformative health technologies; and
- (D) contribute to ensuring the United States maintains—
  - (i) global leadership in science and innovation;
  - (ii) the highest quality of life and health for its citizens; and
  - (iii) an aggressive agenda for innovations to address global health threats that place United States citizens at risk.

(2) *METHODS.*—ARPA-H shall achieve the goals specified in paragraph (1) by—

- (A) discovering, identifying, and promoting revolutionary advances in health sciences;
- (B) translating scientific discoveries into transformative health technologies;
- (C) providing resources and support to create platform capabilities that draw on multiple disciplines;
- (D) using researchers in a wide range of disciplines, including the life sciences, the physical sciences, engineering, and the computational sciences;
- (E) delivering advanced proofs of concept that demonstrate potentially clinically meaningful advances;
- (F) developing new capabilities, advanced computational tools, predictive models, or analytical techniques to identify potential targets and technological strategies for early disease detection and intervention;
- (G) accelerating transformational technological advances in areas with limited technical certainty; and
- (H) 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, quality and disparity gaps, and the potential to preempt progression of serious disease; and
  - (iii) the effect on the fiscal liability of the Federal Government with respect to health care and the ability to reduce the cost of care through innovation.

(c) *DIRECTOR.*—

- (1) *IN GENERAL.*—The President shall appoint with the advice and consent of the Senate, a director of ARPA-H (in this part 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 and technology development across multiple sectors, including generating transformative health technologies and improving health outcomes for patients.

(3) *RELATIONSHIP TO SECRETARY.*—The Director shall report directly 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 specified in 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 Research Council established under subsection (q).

(E) Solicit data, as needed, from the National Institutes of Health and other relevant entities.

(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.

(H) Ensure ARPA-H does not provide funding for a project unless the program manager determines that the project meets the goals described in subsection (b)(1).

(5) *TERM.*—The Director—

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

(B) may be reappointed for 1 consecutive 5-year 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 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 the first assistant to the office.

(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 methods described in subsection (b)(2).

(e) *PROTECTION OF INFORMATION.*—The following types of information collected by ARPA–H from recipients of financial assistance awards shall be considered commercial and financial information obtained from a person and privileged or confidential and not subject to disclosure under section 552(b)(4) of title 5, United States Code:

- (1) Plans for commercialization of technologies developed under the award, including business plans, technology-to market plans, market studies, and cost and performance models.
- (2) Investments provided to an awardee from third parties (such as venture capital firms, hedge funds, and private equity firms), including amounts and the percentage of ownership of the awardee provided in return for the investments.
- (3) Additional financial support that the awardee—
  - (A) plans to invest or has invested in the technology developed under the award; or
  - (B) is seeking from third parties.
- (4) Revenue from the licensing or sale of new products or services resulting from research conducted under the award.

(f) *SHARING INFORMATION WITH THE CENTERS FOR MEDICARE & MEDICAID SERVICES.*—The Director shall timely share relevant information with the Administrator of the Centers for Medicare & Medicaid Services that may help to expedite determinations of coverage of transformative health technologies developed by ARPA–H.

(g) *EXPEDITING BREAKTHROUGHS THROUGH COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION.*—

(1) *IN GENERAL.*—The Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Director, may take actions to facilitate translation of transformative health technology into tangible solutions for patients and to expedite development of drugs, devices, and biological products, including through—

(A) helping to ensure that drug, device, or biological product development programs, in as efficient a manner as possible, gather the nonclinical and clinical data necessary to advancing the development of such products and to obtaining their approval, licensure, or clearance, as applicable, by the Food and Drug Administration under sections 505, 510(k), and 515 of the Federal Food, Drug, and Cosmetic Act and section 351 of this Act;

(B) expediting review of investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act, review of investigational device exemptions under section 520(g) of such Act, and review of applications for approval, licensure, and clearance of drugs, devices, or biological products under sections 505, 510(k), and 515 of such Act, and section 351 of this Act; and

(C) meeting at appropriate intervals with the Director and any member of the ARPA–H Interagency Research Council to discuss the development status of drugs, devices, or biological products and projects that are the highest priorities to ARPA–H, unless the Director and the Commissioner of Food and Drugs determine that any such meetings are not necessary.

(2) *RELATION TO OTHERWISE AUTHORIZED ACTIVITIES OF THE FDA.*—The authority specified in paragraph (1) shall not be construed as limiting the authority of the Secretary, acting through the Commissioner of Food and Drugs, with respect to the review and approval, clearance, authorization for emergency use, or licensure of drugs, devices, or biological products under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

(3) *REIMBURSEMENT.*—The Director, using funds made available to ARPA-H, may reimburse the Food and Drug Administration for expenditures made by the Food and Drug Administration for activities carried out under this section that have been identified by the Commissioner of Food and Drugs and the Director as being carried out by the Food and Drug Administration.

(h) *AWARDS.*—

(1) *IN GENERAL.*—In carrying out this section, the Director may make awards including—

- (A) grants and cooperative agreements, which shall—
  - (i) be subject to the uniform administrative requirements, cost principles, and audit requirements for Federal awards contained in part 200 of title 2, Code of Federal Regulations (or successor regulations); and
  - (ii) include the total line-item and itemized indirect facilities and administrative costs that shall be made publicly available and published in a machine-readable format;
- (B) contracts subject to the Federal Acquisition Regulation;
- (C) multi-year contracts under section 3903 of title 41, United States Code;
- (D) prizes; and
- (E) other transactions.

(2) *EXEMPTIONS FOR CERTAIN REQUIREMENTS.*—Research funded by ARPA-H shall not be subject to the requirements of section 406(a)(3)(A)(ii) or section 492.

(i) *FACILITIES AUTHORITY.*—

(1) *IN GENERAL.*—The Director may acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as may be necessary to carry out this section.

(2) *LEASE OF NONEXCESS PROPERTY.*—The Director may enter into a lease under this section with any person or entity (including another department or agency of the Federal Government or an entity of a State or local government) with regard to any nonexcess real property and related personal property under the jurisdiction of the Director.

(3) *UTILIZATION OF LEASE FUNDS.*—

(A) *IN GENERAL.*—The Director may utilize, without further appropriation, amounts of cash consideration received for a lease entered into under this subsection to cover the full costs to ARPA-H in connection with the lease. Funds received as such cash consideration shall remain available until expended.

(B) *CAPITAL REVITALIZATION AND IMPROVEMENTS.*—Of any amounts of cash consideration received under this sub-

section that are not utilized in accordance with subparagraph (A), without further appropriation—

(i) 35 percent shall—

(I) be deposited in a capital asset account to be established by the Director;

(II) be available for maintenance, capital revitalization, and improvements of the real property assets and related personal property under the jurisdiction of the Director; and

(III) remain available until expended; and

(ii) the remaining 65 percent shall be available to the respective center or facility of ARPA-H engaged in the lease of nonexcess real property, and shall remain available until expended for maintenance, capital revitalization, and improvements of the real property assets and related personal property at the respective center or facility subject to the concurrence of the Director.

(C) NO UTILIZATION FOR DAILY OPERATING COSTS.—

Amounts utilized under subparagraph (B) may not be utilized for daily operating costs.

(4) LOCATIONS.—

(A) IN GENERAL.—ARPA-H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

(B) CONSIDERATIONS.—In determining the location of facilities, the Director shall make a fair and open consideration of—

(i) the characteristics of the intended location; and

(ii) the extent to which such location will facilitate advancement of the goals and methods specified in subsection (b).

(j) PERSONNEL.—

(1) IN GENERAL.—The Director may—

(A) make and rescind appointments of scientific, engineering, medical, and professional personnel, which may include temporary or time-limited appointments as determined by the Director to fulfill the mission of ARPA-H, without regard to any provision in title 5, United States Code, governing appointments and removals under the civil service laws, and fix the base pay 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; and

(B) contract with private recruiting firms for the hiring of qualified staff referenced in subparagraph (A).

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

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

(A) may contract with private entities;

(B) shall make efforts to recruit and retain a diverse workforce, including individuals underrepresented in science and medicine and racial and ethnic minorities (as long as such efforts comply with applicable Federal civil rights law); and

(C) shall recruit program managers with expertise in a wide range of relevant disciplines, including life sciences, the physical sciences, engineering, and the computational sciences.

(4) ADDITIONAL HIRING AUTHORITY.—To the extent needed to carry out the authorities vested by paragraph (1), the Director may utilize hiring authorities under sections 3371 through 3376 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 such sections.

(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.

(6) AUTHORITY TO ACCEPT FEDERAL DETAILEES.—The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

(k) PROGRAM MANAGERS.—

(1) IN GENERAL.—The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 consecutive 3-year term) for the programs carried out by ARPA-H.

(2) DUTIES.—A program manager shall—

(A) establish, in consultation with the Director or Deputy Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

(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 gaps and opportunities;

(C) convene workshops and meetings, as needed, with entities such as patients, patient advocacy groups, practitioners, professional societies, and other stakeholders to solicit input on programs and goals;

(D) manage applications and proposals, through the appropriate officials for making grants, cooperative agreements, contracts, prizes, and other transaction awards for advanced research that may show particular promise, especially in areas in which the private sector and the Federal Government have not undertaken sufficient research;

(E) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

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

- (i) the scientific and technical merit of the proposed project;
- (ii) the capabilities of the applicants to successfully carry out the proposed project;
- (iii) the unmet needs or ability to improve health outcomes within patient populations;
- (iv) future commercial applications of the project or the feasibility of partnering with one or more commercial entities;
- (v) the potential for interdisciplinarity of the approach of the project; and
- (vi) such other criteria as established by the Director;

(G) conduct project reviews within 18 months of funding awards to identify milestones and monitor progress of such milestones with respect to each project and prior to disbursement of new funds;

(H) provide recommendations to the Director with respect to advancing the goals specified in subsection (b);

(I) cultivate opportunities for the commercial application or community use of successful projects, including through the establishment of partnerships between or among awardees;

(J) identify innovative cost-sharing arrangements for ARPA-H projects;

(K) provide recommendations to expand, restructure, or terminate research partnerships or projects; and

(L) ensure that—

- (i) animal studies meet the Federal animal research requirements pursuant of the Public Health Service Policy on Humane Care and Use of Laboratory Animals; and

- (ii) applications apply statistical modeling approaches and appropriately justify animal sample sizes to meet project goals.

(l) REPORTS AND EVALUATION.—

(1) ANNUAL REPORT.—

(A) IN GENERAL.—Beginning not later than 1 year after the date of 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 programs starting in the next fiscal year, as available;

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

(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);

(vi) a description of the demographic (including racial and gender) diversity if available of direct recipients and performers in funded projects and of the ARPA-H workforce; and

(vii) a disclosure by the reward recipients of whether the principal investigators named on the award participate in foreign talent programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded.

(B) SUBMISSION TO CONGRESS.—The report under subparagraph (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 5 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 under which the National Academies agree to study and evaluate whether ARPA-H is meeting the goals specified in 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.

(m) STRATEGIC PLAN.—Not later than 1 year after the date of the enactment of this section, and every 3 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 following 3-year period.

(n) INDEPENDENT REVIEW.—Not later than 1 year after the date of the enactment of this section, and every 3 years thereafter, the Comptroller General of the United States shall conduct an independent review of the research portfolio of the Department of Health and Human Services, including ARPA-H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

(1) to assess the degree of unnecessary duplication of existing Federal programs and projects; and

(2) to make recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

(o) **PRIORITIZATION.**—The Director shall—

(1) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to domestic recipients conducting the research on transformative health technology in the United States;

(2) as appropriate and practicable, ensure that nondomestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section are conducting research in collaboration with a domestic recipient;

(3) not award any grants, cooperative agreements, contracts, prizes, and other transactions to nondomestic recipients subject to malign foreign influence or organized under the laws of a malign foreign country; and

(4) in accordance with the requirements of chapter 33 of title 41, United States Code, and the Federal Acquisition Regulation, only award grants, cooperative agreements, contracts, prizes, and other transactions to individual persons that do not have more than 3 ongoing concurrent grants, cooperative agreements, contracts, prizes, and other transactions under this section.

(p) **ADDITIONAL CONSULTATION.**—In carrying out this section, the Director may consult with—

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

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

(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

(4) a new interagency research council organized to support the programs of ARPA-H and to provide advice and assistance on—

(A) specific program tasks; or

(B) the overall direction of ARPA-H; and

(5) any other entity the Director may deem appropriate.

(q) **ARPA-H INTERAGENCY RESEARCH COUNCIL.**—

(1) **IN GENERAL.**—The Director shall establish an interagency advisory committee to be known as the ARPA-H Interagency Research Council (referred to in this subsection as the “Research Council”).

(2) **MEMBERSHIP.**—The Research Council 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 Food and Drugs.

(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) The Director of the Advanced Research Projects Agency-Energy.
- (O) The Assistant Secretary for Preparedness and Response.
- (P) Representatives of any Federal agency with subject matter expertise that the Director determines is necessary for the successful completion of a project carried out pursuant to this section.
- (Q) Any other entity the Director may deem appropriate.

(3) **DUTIES.**—The Research Council 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 regulatory, reimbursement, and market barriers to commercialization or adoption of transformative health technologies, including technologies intended to preempt serious disease.

(4) **ADVISORY NATURE.**—The function of the Research Council shall be advisory in nature. Nothing in this subsection shall be construed as granting the Research Council authority over any activities or functions of ARPA-H.

(5) **MEETINGS.**—Not later than 1 year after the date of the enactment of this section, and every fiscal year thereafter, the Director shall convene meetings of the Research Council, including conferences or workshops, as needed. The Research Council may function through established or ad hoc committees, task forces, or interagency groups to—

- (A) share information on health innovations funded by ARPA-H; and
- (B) receive input on areas of particular promise for ARPA-H projects.

(r) **TECHNOLOGY TRANSFER OFFICE.**—The Director may establish within ARPA-H an Office of Technology Transfer to facilitate, where appropriate, the transfer of federally-owned or federally-originated technology to recipients of an award under this section (other than Federal Government entities).

## (s) FOLLOW-ON PRODUCTION AWARD AUTHORITY.—

(1) *IN GENERAL.*—An other transaction entered into by the Director under subsection (h)(1) for a project may provide for the award of a follow-on production contract or transaction to the participants in the transaction by ARPA-H or another Federal agency. For purposes of this paragraph, such an other transaction includes all individual subprojects awarded under the transaction to a consortium of United States industry and academic institutions.

(2) *RELATION TO COMPETITIVE PROCEDURES.*—A follow-on production contract or transaction under paragraph (1) may be awarded to the participants in the transaction without the use of competitive procedures (as defined in section 152 of title 41, United States Code), notwithstanding the requirements of division C of subtitle I of such title 41, if—

- (A) competitive procedures were used for the selection of parties for participation in the other transaction; and
- (B) the participants in the other transaction successfully completed the project provided for in the transaction.

(3) *PRECONDITION.*—A follow-on production contract or transaction may be awarded pursuant to this subsection when the Director determines that an individual project or subproject as part of a consortium is successfully completed by the participants.

(4) *CLARIFICATION.*—Award of a follow-on production contract or transaction pursuant to this subsection shall not be made contingent upon the successful completion of all activities within a consortium as a condition for an award for follow-on production of a successfully completed project or subproject within that consortium.

(5) *OTHER AUTHORITIES.*—Contracts and transactions entered into by ARPA-H pursuant to this subsection may be awarded pursuant to division C of subtitle I of title 41, United States Code, or under such procedures, terms, and conditions as the Director or head of such agency may establish by regulation.

(t) *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.

## (u) DEFINITIONS.—In this part:

(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 transformative health technologies; and
- (B) demonstrates the feasibility of a new concept.

(2) *BIOLOGICAL PRODUCT.*—The term “biological product” has the meaning given such term in section 351(i).

(3) *DEPARTMENT.*—The term “Department” means the Department of Health and Human Services.

(4) *DRUG; DEVICE.*—The terms “drug” and “device” have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

(5) *FEDERAL ACQUISITION REGULATION.*—The term “Federal Acquisition Regulation” means the Federal Acquisition Regula-

*tion issued pursuant to section 1303(a)(1) of title 41, United States Code.*

(6) *FEDERAL AGENCY.*—The term “Federal agency” has the meaning given such term in section 3371 of title 5, United States Code.

(7) *PRIZE.*—The term “prize” means a prize as such term is used in section 24 of the Stevenson-Wydler Technology Innovation Act of 1980.

(8) *TRANSFORMATIVE HEALTH TECHNOLOGY.*—The term “transformative health technology” means a drug, biological product, intervention, platform, tool, or device—

(A) that should be prioritized to detect, diagnose, mitigate, prevent, cure, or treat a serious disease or medical condition for which there are unmet needs; and

(B) for which—

(i) significant scientific uncertainty and regulatory risk exist; or

(ii) incentives in the commercial market are unlikely to result in the adequate or timely development of such drug, biological product, intervention, platform, tool, or device.

(v) *AUTHORIZATION OF APPROPRIATIONS.*—There is authorized to be appropriated \$500,000,000 for each of fiscal years 2023 through 2027, to remain available until expended.

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