

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advanced Research
5 Project Agency–Health Act” or the “ARPA–H Act”.

6 **SEC. 2. ADVANCED RESEARCH PROJECTS AGENCY–**
7 **HEALTH.**

8 Title IV of the Public Health Service Act (42 U.S.C.
9 281 et seq.) is amended by adding at the end the fol-
10 lowing:

1 **“PART J—ADVANCED RESEARCH PROJECTS**

2 **AGENCY–HEALTH**

3 **“SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY–**
4 **HEALTH.**

5 “(a) ESTABLISHMENT.—There is established the Ad-
6 vanced Research Projects Agency–Health (in this part re-
7 ferred to as ‘ARPA–H’) within the Department of Health
8 and Human Services.

9 “(b) GOALS AND ACTIVITIES.—

10 “(1) GOALS.—The goals of ARPA–H shall be
11 to—

12 “(A) foster the development of new, break-
13 through capabilities, technologies, systems, and
14 platforms to accelerate innovations in health
15 and medicine;

16 “(B) revolutionize diagnosis, mitigation,
17 prevention, and treatment of diseases through
18 the development of transformative health tech-
19 nologies and high-need cures;

20 “(C) promote high-risk, high-reward inno-
21 vation to develop high-need cures; and

22 “(D) ensure the United States main-
23 tains—

24 “(i) global leadership in science and
25 innovation; and

1 “(ii) the highest quality of life and
2 health for its citizens.

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

5 “(A) identifying and promoting revolu-
6 tionary advances in health sciences;

7 “(B) translating scientific discoveries into
8 technological innovations and high-need cures;

9 “(C) providing resources and support to
10 create platform capabilities that draw on mul-
11 tiple disciplines;

12 “(D) delivering advanced proofs of concept
13 that demonstrate clinically meaningful ad-
14 vances;

15 “(E) accelerating transformational techno-
16 logical advances in areas with limited funding
17 or technical certainty; and

18 “(F) prioritizing investments based on
19 such considerations as—

20 “(i) scientific opportunity and unique-
21 ness of fit to the strategies and operating
22 practices of ARPA–H;

23 “(ii) the effect on disease burden, in-
24 cluding unmet patient need and the fiscal

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

3 “(iii) potential opportunities to ad-
4 vance health equity.

5 “(c) DIRECTOR.—

6 “(1) IN GENERAL.—The President shall ap-
7 point in the Department of Health and Human
8 Services a director of ARPA–H (in this section re-
9 ferred to as the ‘Director’).

10 “(2) QUALIFICATIONS.—The Director shall be
11 an individual who, by reason of professional back-
12 ground and experience, is especially qualified to
13 manage—

14 “(A) research and advanced development
15 programs; and

16 “(B) large-scale, high-risk initiatives with
17 respect to health research across multiple sec-
18 tors, including generating high-need cures.

19 “(3) RELATIONSHIP TO SECRETARY.—The Di-
20 rector shall report to the Secretary.

21 “(4) DUTIES.—The duties of the Director shall
22 include the following:

23 “(A) Approve and terminate the projects
24 and programs of ARPA–H.

1 “(B) Set research and development prior-
2 ities with respect to the goals under subsection
3 (b) and manage the budget of ARPA–H.

4 “(C) Develop funding criteria and assess
5 the success of programs through the establish-
6 ment of technical milestones.

7 “(D) Advance the goals under subsection
8 (b), through consideration of the advice of the
9 ARPA–H Interagency Advisory Committee es-
10 tablished under subsection (l).

11 “(E) Solicit data, as needed, from the Na-
12 tional Institutes of Health and other relevant
13 Federal agencies, private entities, academia,
14 nonprofit organizations, and international orga-
15 nizations.

16 “(F) Coordinate with the Director of the
17 National Institutes of Health to ensure that the
18 programs of ARPA–H build on and are in-
19 formed by scientific research supported by the
20 National Institutes of Health.

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

1 “(5) TERM.—The Director—

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

3 and

4 “(B) may be reappointed for 1 consecutive
5 term.

6 “(6) AUTONOMY OF AGENCY REGARDING REC-
7 COMMENDATIONS AND TESTIMONY.—No officer or
8 agency of the United States shall have any authority
9 to require the Director or any other officer of
10 ARPA–H to submit legislative recommendations, or
11 testimony or comments on legislation, to any officer
12 or agency of the United States for approval, com-
13 ments, or review prior to the submission of such rec-
14 ommendations, testimony, or comments to the Con-
15 gress, if such recommendations, testimony, or com-
16 ments to the Congress include a statement indi-
17 cating that the views expressed therein are those of
18 the Director or such officer, and do not necessarily
19 reflect the views of the President or another agency.

20 “(7) DELEGATION OF AUTHORITY.—The Direc-
21 tor may delegate to any duly authorized employee,
22 representative, or agent any power vested in the Di-
23 rector or ARPA–H by law, except that the Director
24 may not delegate the power to appoint the Deputy
25 Director under paragraph (8).

1 “(8) DEPUTY DIRECTOR.—The Director shall
2 appoint a deputy director to serve as acting Director
3 in the absence or unavailability of the Director (not-
4 withstanding section 3345 of title 5, United States
5 Code).

6 “(d) APPLICATION OF PAPERWORK REDUCTION
7 ACT.—The Director may waive the requirements of sub-
8 chapter I of chapter 35 of title 44, United States Code
9 (commonly referred to as the ‘Paperwork Reduction Act’)
10 with respect to the activities described under subsection
11 (c)(3)(F).

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

15 “(1) other Federal agencies;

16 “(2) institutions of higher education;

17 “(3) private or public research institutions;

18 “(4) federally funded research and development
19 centers;

20 “(5) private entities, including biotechnology,
21 and pharmaceutical, medical device, and other health
22 entities; and

23 “(6) nonprofit organizations, including patient
24 advocacy groups.

1 “(f) COORDINATION ON HIGH-NEED CURES.—The
2 Director shall coordinate with the Commissioner of Food
3 and Drugs and the Administrator of the Centers for Medi-
4 care & Medicaid Services to expedite the development, ap-
5 plication, coverage, and implementation of high-need
6 cures.

7 “(g) AWARDS.—In carrying out this section, the Di-
8 rector may make awards in the form of grants, contracts,
9 cooperative agreements, prizes, and other transactions, in-
10 cluding—

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

16 “(2) contracts subject to chapter 1 of title 48,
17 Code of Federal Regulations (or successor regula-
18 tions) (commonly referred to as the ‘Federal Acqui-
19 sition Regulation’) but exempt from the regulations
20 specified in chapter 3 of title 48, Code of Federal
21 Regulations (or successor regulations);

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

24 “(4) prize competitions; and

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

3 “(h) FACILITIES AUTHORITY.—The Director may—

4 “(1) acquire (by purchase, lease, condemnation
5 or otherwise), construct, improve, repair, operate,
6 and maintain such real and personal property nec-
7 essary to carry out this section; and

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

11 “(i) PERSONNEL.—

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

14 “(A) hire personnel under section 207(f)
15 and establish governing criteria to recruit, ap-
16 point, and compensate personnel under this sec-
17 tion without regard to any provision in title 5,
18 United States Code, governing appointments
19 under the civil service laws and fix the com-
20 pensation of such personnel at a rate to be de-
21 termined by the Director, up to the amount of
22 annual compensation (excluding expenses) spec-
23 ified in section 102 of title 3, United States
24 Code, notwithstanding section 202 of the De-
25 partment of Health and Human Services Ap-

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

5 “(B) make additional appointments of sci-
6 entific, medical, and professional personnel
7 under this section without regard to any provi-
8 sion in title 5, United States Code, governing
9 appointments under the civil service laws and
10 fix the compensation of such personnel at a rate
11 to be determined by the Director, up to the
12 amount of annual compensation (excluding ex-
13 penses) specified in section 102 of title 3,
14 United States Code, notwithstanding section
15 202 of Department of Health and Human Serv-
16 ices Appropriations Act, 1993 (Public Law
17 102–394) or any provision of title 5, United
18 States Code, governing the rates of pay or clas-
19 sification of employees in the executive branch;
20 and

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

1 pensation of such personnel at a rate to be de-
2 termined by the Director, up to the amount of
3 annual compensation (excluding expenses) spec-
4 ified in section 102 of title 3, United States
5 Code, notwithstanding section 202 of Depart-
6 ment of Health and Human Services Appro-
7 priations Act, 1993 (Public Law 102–394) or
8 any provision of title 5, United States Code,
9 governing the rates of pay or classification of
10 employees in the executive branch.

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

19 “(3) ADDITIONAL CONSIDERATIONS.—In ap-
20 pointing qualified personnel under this subsection,
21 the Director—

22 “(A) may contract with private entities;
23 and

24 “(B) shall make efforts to recruit and re-
25 tain a diverse workforce, including individuals

1 underrepresented in science and medicine and
2 racial and ethnic minorities.

3 “(4) ADDITIONAL HIRING AUTHORITY.—To the
4 extent needed to carry out the duties in paragraph
5 (1), the Director is authorized to utilize hiring au-
6 thorities under section 3372 of title 5, United States
7 Code, to staff ARPA–H with employees from other
8 Federal agencies, State and local governments, In-
9 dian Tribes and Tribal organizations, institutions of
10 higher education, and other organizations, as de-
11 scribed in that section, in the same manner and sub-
12 ject to the same conditions, that apply to such indi-
13 viduals utilized to accomplish other purposes.

14 “(5) EXISTING AUTHORITIES.—The authorities
15 granted by this section are—

16 “(A) in addition to existing authorities
17 granted to the Secretary; and

18 “(B) are not intended to supersede or
19 modify any existing authorities.

20 “(j) PROGRAM MANAGERS.—

21 “(1) IN GENERAL.—The Director shall des-
22 ignate employees of ARPA–H to serve as program
23 managers for the programs carried out by ARPA–
24 H.

25 “(2) DUTIES.—A program manager shall—

1 “(A) establish research and development
2 goals for programs in accordance with guidance
3 from the Director;

4 “(B) collaborate with experts from the Na-
5 tional Institutes of Health and other Federal
6 agencies and experts in relevant scientific fields
7 to identify research and development opportuni-
8 ties;

9 “(C) convene workshops, as needed, with
10 relevant Federal agencies, institutions of higher
11 education, nonprofit research institutions, com-
12 panies, venture capital firms, and nonprofit or-
13 ganizations for the development of high-need
14 cures;

15 “(D) issue funding opportunity announce-
16 ments;

17 “(E) select, on the basis of merit, each of
18 the projects to be supported under a program
19 carried out by ARPA-H, taking into consider-
20 ation—

21 “(i) the novelty and scientific and
22 technical merit of the proposed projects;

23 “(ii) the demonstrated capabilities of
24 the applicants to successfully carry out the
25 proposed project;

1 “(iii) the unmet needs within patient
2 populations;

3 “(iv) the consideration by the appli-
4 cant of future commercial applications of
5 the project, including the feasibility of
6 partnering with one or more commercial
7 entities; and

8 “(v) such other criteria as are estab-
9 lished by the Director;

10 “(F) identify milestones and monitor
11 progress of such milestones with respect to each
12 project;

13 “(G) provide recommendations to the Di-
14 rector with respect to advancing the goals
15 under subsection (b);

16 “(H) identify opportunities for the com-
17 mercial application of successful projects, in-
18 cluding through the establishment of partner-
19 ships between or among awardees; and

20 “(I) provide recommendations to expand,
21 restructure, or terminate research partnerships
22 or projects.

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

1 “(k) REPORTS AND EVALUATION.—

2 “(1) ANNUAL REPORT.—

3 “(A) IN GENERAL.—Beginning not later
4 than 1 year after the date of the enactment of
5 this section, and each fiscal year thereafter, the
6 Director shall submit a report on the actions
7 undertaken, and results generated, by ARPA-
8 H, including—

9 “(i) a description of projects sup-
10 ported by ARPA-H in the previous fiscal
11 year and whether such projects are meet-
12 ing the goals developed by the Director
13 pursuant to subsection (c)(4)(C);

14 “(ii) a description of projects termi-
15 nated in the previous fiscal year, and the
16 reason for such termination;

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

19 “(iv) activities conducted in coordina-
20 tion with other Federal agencies; and

21 “(v) an analysis of the extent of co-
22 ordination conducted pursuant to sub-
23 sections (c)(4)(F) and (f), including suc-
24 cesses and barriers with respect to achiev-
25 ing the goals under subsection (b).

1 “(B) SUBMISSION TO CONGRESS.—The re-
2 port under subsection (a) shall be submitted
3 to—

4 “(i) the Committee on Energy and
5 Commerce and the Committee on Appro-
6 priations of the House of Representatives;
7 and

8 “(ii) the Committee on Health, Edu-
9 cation, Labor, and Pensions and the Com-
10 mittee on Appropriations of the Senate.

11 “(2) EVALUATION.—

12 “(A) IN GENERAL.—Not later than 8 years
13 after the date of the enactment of this section,
14 the Secretary shall enter into an agreement
15 with the National Academies of Sciences, Engi-
16 neering, and Medicine to study and evaluate
17 whether ARPA–H has met the goals under sub-
18 section (b).

19 “(B) SUBMISSION OF RESULTS.—The
20 agreement entered into under subparagraph (A)
21 shall require the National Academies of
22 Sciences, Engineering, and Medicine to submit
23 the results of the evaluation conducted under
24 such agreement to the Secretary, the Com-
25 mittee on Energy and Commerce of the House

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

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

10 “(m) ADDITIONAL ADVICE.—In carrying out this sec-
11 tion, the Director may seek advice from—

12 “(1) the President’s Committee of Advisors on
13 Science and Technology;

14 “(2) peers in the scientific community, includ-
15 ing academia and industry;

16 “(3) experts in other Federal agencies;

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

20 “(5) representatives of patient communities.

21 “(n) ARPA–H ADVISORY COMMITTEE.—

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

1 ferred to in this subsection as the ‘Advisory Com-
2 mittee’).

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

6 “(A) The Director of the National Insti-
7 tutes of Health.

8 “(B) The Director of National Center for
9 Advancing Translational Sciences.

10 “(C) The Director of Office of Science and
11 Technology Policy.

12 “(D) The Commissioner of the Food and
13 Drug Administration.

14 “(E) The Director of the Biomedical Ad-
15 vanced Research and Development Authority.

16 “(F) The Director of the Centers for Dis-
17 ease Control and Prevention.

18 “(G) The Administrator of the Centers for
19 Medicare & Medicaid Services.

20 “(H) The Director of the Agency for
21 Healthcare Research and Quality.

22 “(I) The Director of the Office of Minority
23 Health.

24 “(J) The Administrator of the Health Re-
25 sources and Services Administration.

1 “(K) The Director of the Defense Ad-
2 vanced Research Projects Agency.

3 “(L) The Director of the National Science
4 Foundation.

5 “(M) The Director of the Office of Science
6 of the Department of Energy.

7 “(N) Representatives of any Federal agen-
8 cy with subject matter expertise that the Direc-
9 tor of ARPA–H determines is necessary for the
10 successful completion of a project carried out
11 pursuant to this section.

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

14 “(A) making recommendations on—

15 “(i) research priorities that will pro-
16 vide the greatest return on investment with
17 respect to improving human health;

18 “(ii) avoiding duplication of efforts in
19 the Federal Government; and

20 “(iii) improving coordination with
21 other Federal agencies; and

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

1 “(4) NON-APPLICABILITY OF FACa.—The Fed-
2 eral Advisory Committee Act (5 U.S.C. App.) shall
3 not apply to the Advisory Committee.

4 “(5) ADVISORY NATURE.—The function of the
5 Committee shall be advisory in nature. Nothing in
6 this section shall be construed as giving the Com-
7 mittee authority over the activities authorized under
8 this section.

9 “(o) RULE OF CONSTRUCTION.—The authorities
10 under this section, with respect to the Director, are addi-
11 tional authorities that do not supersede or modify any ex-
12 isting authorities.

13 “(p) DEFINITIONS.—In this section:

14 “(1) ADVANCED PROOFS OF CONCEPT.—The
15 term ‘advanced proofs of concept’ means data, a
16 prototype, or other experimental evidence that—

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

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

21 “(2) BIOLOGICAL PRODUCT.—The term ‘bio-
22 logical product’ has the meaning given such term in
23 section 262 of the Federal Food, Drug, and Cos-
24 metic Act.

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

4 “(4) DEVICE.—The term ‘device’ has the mean-
5 ing given such term in section 201 of the Federal
6 Food, Drug, and Cosmetic Act.

7 “(5) FEDERAL ACQUISITION REGULATION.—
8 The term ‘Federal Acquisition Regulation’ means
9 the Federal Acquisition Regulation issued pursuant
10 to section 1303(a)(1) of title 41, United States
11 Code.

12 “(6) HIGH-NEED CURE.—The term ‘high-need
13 cure’ means a drug, biological product, or device—

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

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

21 “(7) PRIZE COMPETITIONS.—The term ‘prize
22 competitions’ has the meaning given such term in
23 section 24 of the Stevenson-Wydler Technology In-
24 novation Act of 1980 (15 U.S.C. 3719).

1 **“SEC. 499B. HEALTH ADVANCED RESEARCH AND DEVELOP-**
2 **MENT FUND.**

3 “(a) ESTABLISHMENT.—There is established in the
4 Treasury a fund to be known as the Health Advanced Re-
5 search and Development Fund (in this section referred to
6 as the ‘Fund’) which shall be administered by the Director
7 of ARPA–H for the purposes of carrying out section
8 499A.

9 “(b) SEPARATE BUDGET REQUEST.—The annual
10 budget request for ARPA–H shall be separate from the
11 rest of the budget for the Department of Health and
12 Human Services. The Director of ARPA–H shall prepare
13 and submit directly to the President for review and trans-
14 mittal to Congress, an annual budget for ARPA–H after
15 reasonable opportunity for comment (but without change)
16 by the Secretary.

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—

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

21 “(2) ADVANCE APPROPRIATIONS.—For each fis-
22 cal year beginning with fiscal year 2022, discre-
23 tionary new budget authority provided in an appro-
24 priations Act for ARPA–H shall—

25 “(A) be made available for that fiscal year;

26 and

1 “(B) include advance discretionary new
2 budget authority that first becomes available
3 for the first fiscal year following the budget
4 year.

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

○