

Union Calendar No. 277

117TH CONGRESS
2^D SESSION

H. R. 5585

[Report No. 117-365]

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

JUNE 13, 2022

Additional sponsors: Ms. LOFGREN, Ms. ROYBAL-ALLARD, Mr. THOMPSON of California, Mr. HUFFMAN, Mr. COSTA, Mr. SUOZZI, Ms. JOHNSON of Texas, Mr. MICHAEL F. DOYLE of Pennsylvania, Ms. WASSERMAN SCHULTZ, Mr. MCGOVERN, Mr. CARTWRIGHT, Mrs. FLETCHER, Mr. CÁRDENAS, Ms. CRAIG, Mrs. TRAHAN, Mr. PASCRELL, Mr. COURTNEY, Mr. PERLMUTTER, Ms. ROSS, Mr. MCNERNEY, Mrs. NAPOLITANO, Mr. PETERS, Ms. BARRAGÁN, Mr. LEVIN of California, Mr. TONKO, Ms. SCHRIER, Ms. BLUNT ROCHESTER, Mr. KHANNA, Ms. CHU, Mr. DESAULNIER, Mr. SCHIFF, Ms. SPEIER, Mr. AGUILAR, Mr. TRONE, Ms. MCCOLLUM, Mr. SCHRADER, Ms. JACOBS of California, Mr. QUIGLEY, Mr. MOULTON, Mr. WELCH, Mr. RUSH, Ms. SCHAKOWSKY, Ms. KUSTER, Ms. KELLY of Illinois, Mrs. DINGELL, Ms. MATSUI, Ms. CASTOR of Florida, Mr. O'HALLERAN, Ms. DEGETTE, Mr. UPTON, Ms. SEWELL, Mr. SARBANES, Ms. CLARKE of New York, Mr. MORELLE, Mr. GRIJALVA, Mr. NADLER, Mr. MCEACHIN, Mr. SOTO, Mr. CARBAJAL, Mr. BISHOP of Georgia, Mr. FITZPATRICK, Mr. LAWSON of Florida, Mr. BURGESS, Mr. COHEN, Ms. WILLIAMS of Georgia, and Ms. BROWN of Ohio

JUNE 13, 2022

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on October 15, 2021]

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 *Projects Agency–Health Act” or the “ARPA–H Act”.*

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

7 *Title IV of the Public Health Service Act (42 U.S.C.*
8 *281 et seq.) is amended by adding at the end the following:*

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

10 **AGENCY–HEALTH**

11 **“SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY–**

12 **HEALTH.**

13 *“(a) ESTABLISHMENT.—There is established, as an*
14 *independent operating division within the Department of*
15 *Health and Human Services, the Advanced Research*
16 *Projects Agency–Health (in this part referred to as ‘ARPA–*
17 *H’). Not later than 180 days after the date of enactment*
18 *of this part, the Secretary shall transfer all functions, per-*
19 *sonnel, missions, activities, authorities, and funds of the*
20 *Advanced Research Projects Agency for Health within the*
21 *National Institutes of Health, as in existence on the date*
22 *of enactment of this part, to ARPA–H established by the*
23 *preceding sentence.*

24 *“(b) GOALS AND METHODS.—*

1 “(1) *GOALS.—The goals of ARPA-H shall be*
2 *to—*

3 “(A) *foster the development of new, break-*
4 *through capabilities, technologies, systems, and*
5 *platforms to accelerate innovations in health and*
6 *medicine that are not being met by Federal pro-*
7 *grams or private entities;*

8 “(B) *revolutionize detection, diagnosis,*
9 *mitigation, prevention, treatment, and curing of*
10 *serious diseases and medical conditions through*
11 *the development of transformative health tech-*
12 *nologies;*

13 “(C) *promote high-risk, high-reward inno-*
14 *vation for the development and translation of*
15 *transformative health technologies; and*

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

18 “(i) *global leadership in science and*
19 *innovation;*

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

22 “(iii) *an aggressive agenda for innova-*
23 *tions to address global health threats that*
24 *place United States citizens at risk.*

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

3 “(A) *discovering, identifying, and pro-*
4 *moting revolutionary advances in health*
5 *sciences;*

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

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

11 “(D) *using researchers in a wide range of*
12 *disciplines, including the life sciences, the phys-*
13 *ical sciences, engineering, and the computational*
14 *sciences;*

15 “(E) *delivering advanced proofs of concept*
16 *that demonstrate potentially clinically meaning-*
17 *ful advances;*

18 “(F) *developing new capabilities, advanced*
19 *computational tools, predictive models, or ana-*
20 *lytical techniques to identify potential targets*
21 *and technological strategies for early disease de-*
22 *tection and intervention;*

23 “(G) *accelerating transformational techno-*
24 *logical advances in areas with limited technical*
25 *certainty; and*

1 “(H) prioritizing investments based on such
2 considerations as—

3 “(i) scientific opportunity and unique-
4 ness of fit to the strategies and operating
5 practices of ARPA–H;

6 “(ii) the effect on disease burden, in-
7 cluding unmet patient need, quality and
8 disparity gaps, and the potential to pre-
9 empt progression of serious disease; and

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

14 “(c) DIRECTOR.—

15 “(1) IN GENERAL.—The President shall appoint
16 with the advice and consent of the Senate, a director
17 of ARPA–H (in this part referred to as the ‘Direc-
18 tor’).

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

22 “(A) research and advanced development
23 programs; and

24 “(B) large-scale, high-risk initiatives with
25 respect to health research and technology develop-

1 *ment across multiple sectors, including gener-*
2 *ating transformative health technologies and im-*
3 *proving health outcomes for patients.*

4 “(3) *RELATIONSHIP TO SECRETARY.*—*The Direc-*
5 *tor shall report directly to the Secretary.*

6 “(4) *DUTIES.*—*The duties of the Director shall*
7 *include the following:*

8 “(A) *Approve and terminate the projects*
9 *and programs of ARPA–H.*

10 “(B) *Set research and development prior-*
11 *ities with respect to the goals specified in sub-*
12 *section (b) and manage the budget of ARPA–H.*

13 “(C) *Develop funding criteria and assess the*
14 *success of programs through the establishment of*
15 *technical milestones.*

16 “(D) *Advance the goals under subsection*
17 *(b), through consideration of the advice of the*
18 *ARPA–H Interagency Research Council estab-*
19 *lished under subsection (g).*

20 “(E) *Solicit data, as needed, from the Na-*
21 *tional Institutes of Health and other relevant en-*
22 *tities.*

23 “(F) *Coordinate with the Director of the*
24 *National Institutes of Health to ensure that the*
25 *programs of ARPA–H build on, and are in-*

1 *formed by, scientific research supported by the*
2 *National Institutes of Health.*

3 “(G) *Coordinate with the heads of Federal*
4 *agencies and, to the extent practicable, ensure*
5 *that the activities of ARPA–H supplement (and*
6 *do not supplant) the efforts of other Federal*
7 *agencies.*

8 “(H) *Ensure ARPA–H does not provide*
9 *funding for a project unless the program man-*
10 *ager determines that the project meets the goals*
11 *described in subsection (b)(1).*

12 “(5) *TERM.—The Director—*

13 “(A) *shall be appointed for a 5-year term;*
14 *and*

15 “(B) *may be reappointed for 1 consecutive*
16 *5-year term.*

17 “(6) *AUTONOMY OF AGENCY REGARDING REC-*
18 *COMMENDATIONS AND TESTIMONY.—No officer or agen-*
19 *cy of the United States shall have any authority to*
20 *require the Director or any other officer of ARPA–H*
21 *to submit legislative recommendations, or testimony*
22 *or comments on legislation, to any officer or agency*
23 *of the United States for approval, comments, or re-*
24 *view prior to the submission of such recommenda-*
25 *tions, testimony, or comments to the Congress, if such*

1 *recommendations, testimony, or comments to the Con-*
2 *gress include a statement indicating that the views*
3 *expressed therein are those of the Director or such offi-*
4 *cer, and do not necessarily reflect the views of the*
5 *President or another agency.*

6 “(7) *DELEGATION OF AUTHORITY.—The Director*
7 *may delegate to any duly authorized employee, rep-*
8 *resentative, or agent any power vested in the Director*
9 *by law, except that the Director may not delegate the*
10 *power to appoint the Deputy Director under para-*
11 *graph (8).*

12 “(8) *DEPUTY DIRECTOR.—The Director shall ap-*
13 *point a deputy director to serve as the first assistant*
14 *to the office.*

15 “(d) *APPLICATION OF PAPERWORK REDUCTION*
16 *ACT.—The Director may waive the requirements of sub-*
17 *chapter I of chapter 35 of title 44, United States Code (com-*
18 *monly referred to as the ‘Paperwork Reduction Act’) with*
19 *respect to the methods described in subsection (b)(2).*

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

1 “(1) *Plans for commercialization of technologies*
2 *developed under the award, including business plans,*
3 *technology-to market plans, market studies, and cost*
4 *and performance models.*

5 “(2) *Investments provided to an awardee from*
6 *third parties (such as venture capital firms, hedge*
7 *funds, and private equity firms), including amounts*
8 *and the percentage of ownership of the awardee pro-*
9 *vided in return for the investments.*

10 “(3) *Additional financial support that the*
11 *awardee—*

12 “(A) *plans to invest or has invested in the*
13 *technology developed under the award; or*

14 “(B) *is seeking from third parties.*

15 “(4) *Revenue from the licensing or sale of new*
16 *products or services resulting from research conducted*
17 *under the award.*

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

1 “(g) *EXPEDITING BREAKTHROUGHS THROUGH CO-*
2 *OPERATION WITH THE FOOD AND DRUG ADMINISTRA-*
3 *TION.—*

4 “(1) *IN GENERAL.—The Secretary, acting*
5 *through the Commissioner of Food and Drugs and in*
6 *consultation with the Director, may take actions to*
7 *facilitate translation of transformative health tech-*
8 *nology into tangible solutions for patients and to ex-*
9 *pedite development of drugs, devices, and biological*
10 *products, including through—*

11 “(A) *helping to ensure that drug, device, or*
12 *biological product development programs, in as*
13 *efficient a manner as possible, gather the non-*
14 *clinical and clinical data necessary to advancing*
15 *the development of such products and to obtain-*
16 *ing their approval, licensure, or clearance, as*
17 *applicable, by the Food and Drug Administra-*
18 *tion under sections 505, 510(k), and 515 of the*
19 *Federal Food, Drug, and Cosmetic Act and sec-*
20 *tion 351 of this Act;*

21 “(B) *expediting review of investigational*
22 *new drug applications under section 505(i) of*
23 *the Federal Food, Drug, and Cosmetic Act, re-*
24 *view of investigational device exemptions under*
25 *section 520(g) of such Act, and review of appli-*

1 *cations for approval, licensure, and clearance of*
2 *drugs, devices, or biological products under sec-*
3 *tions 505, 510(k), and 515 of such Act, and sec-*
4 *tion 351 of this Act; and*

5 “(C) *meeting at appropriate intervals with*
6 *the Director and any member of the ARPA–H*
7 *Interagency Research Council to discuss the de-*
8 *velopment status of drugs, devices, or biological*
9 *products and projects that are the highest prior-*
10 *ities to ARPA–H, unless the Director and the*
11 *Commissioner of Food and Drugs determine that*
12 *any such meetings are not necessary.*

13 “(2) *RELATION TO OTHERWISE AUTHORIZED AC-*
14 *TIVITIES OF THE FDA.—The authority specified in*
15 *paragraph (1) shall not be construed as limiting the*
16 *authority of the Secretary, acting through the Com-*
17 *missioner of Food and Drugs, with respect to the re-*
18 *view and approval, clearance, authorization for emer-*
19 *gency use, or licensure of drugs, devices, or biological*
20 *products under the Federal Food, Drug, and Cosmetic*
21 *Act or section 351 of this Act.*

22 “(3) *REIMBURSEMENT.—The Director, using*
23 *funds made available to ARPA–H, may reimburse the*
24 *Food and Drug Administration for expenditures*
25 *made by the Food and Drug Administration for ac-*

1 *tivities carried out under this section that have been*
2 *identified by the Commissioner of Food and Drugs*
3 *and the Director as being carried out by the Food and*
4 *Drug Administration.*

5 “(h) AWARDS.—

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

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

10 “(i) *be subject to the uniform adminis-*
11 *trative requirements, cost principles, and*
12 *audit requirements for Federal awards con-*
13 *tained in part 200 of title 2, Code of Fed-*
14 *eral Regulations (or successor regulations);*
15 *and*

16 “(ii) *include the total line-item and*
17 *itemized indirect facilities and administra-*
18 *tive costs that shall be made publicly avail-*
19 *able and published in a machine-readable*
20 *format;*

21 “(B) *contracts subject to the Federal Acqui-*
22 *sition Regulation;*

23 “(C) *multi-year contracts under section*
24 *3903 of title 41, United States Code;*

25 “(D) *prizes; and*

1 “(E) other transactions.

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

6 “(i) *FACILITIES AUTHORITY.—*

7 “(1) *IN GENERAL.—The Director may acquire*
8 *(by purchase, lease, condemnation, or otherwise), con-*
9 *struct, improve, repair, operate, and maintain such*
10 *real and personal property as may be necessary to*
11 *carry out this section.*

12 “(2) *LEASE OF NONEXCESS PROPERTY.—The Di-*
13 *rector may enter into a lease under this section with*
14 *any person or entity (including another department*
15 *or agency of the Federal Government or an entity of*
16 *a State or local government) with regard to any non-*
17 *excess real property and related personal property*
18 *under the jurisdiction of the Director.*

19 “(3) *UTILIZATION OF LEASE FUNDS.—*

20 “(A) *IN GENERAL.—The Director may uti-*
21 *lize, without further appropriation, amounts of*
22 *cash consideration received for a lease entered*
23 *into under this subsection to cover the full costs*
24 *to ARPA–H in connection with the lease. Funds*

1 *received as such cash consideration shall remain*
2 *available until expended.*

3 “(B) *CAPITAL REVITALIZATION AND IM-*
4 *PROVEMENTS.—Of any amounts of cash consid-*
5 *eration received under this subsection that are*
6 *not utilized in accordance with subparagraph*
7 *(A), without further appropriation—*

8 *“(i) 35 percent shall—*

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

12 *“(II) be available for mainte-*
13 *nance, capital revitalization, and im-*
14 *provements of the real property assets*
15 *and related personal property under*
16 *the jurisdiction of the Director; and*

17 *“(III) remain available until ex-*
18 *pended; and*

19 *“(ii) the remaining 65 percent shall be*
20 *available to the respective center or facility*
21 *of ARPA-H engaged in the lease of non-*
22 *excess real property, and shall remain*
23 *available until expended for maintenance,*
24 *capital revitalization, and improvements of*
25 *the real property assets and related personal*

1 *property at the respective center or facility*
2 *subject to the concurrence of the Director.*

3 “(C) *NO UTILIZATION FOR DAILY OPER-*
4 *ATING COSTS.—Amounts utilized under subpara-*
5 *graph (B) may not be utilized for daily oper-*
6 *ating costs.*

7 “(4) *LOCATIONS.—*

8 “(A) *IN GENERAL.—ARPA–H, including its*
9 *headquarters, shall not be located on any part of*
10 *the existing National Institutes of Health cam-*
11 *puses.*

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

15 “(i) *the characteristics of the intended*
16 *location; and*

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

20 “(j) *PERSONNEL.—*

21 “(1) *IN GENERAL.—The Director may—*

22 “(A) *make and rescind appointments of sci-*
23 *entific, engineering, medical, and professional*
24 *personnel, which may include temporary or*
25 *time-limited appointments as determined by the*

1 *Director to fulfill the mission of ARPA–H, with-*
2 *out regard to any provision in title 5, United*
3 *States Code, governing appointments and remov-*
4 *als under the civil service laws, and fix the base*
5 *pay compensation of such personnel at a rate to*
6 *be determined by the Director, up to the amount*
7 *of annual compensation (excluding expenses)*
8 *specified in section 102 of title 3, United States*
9 *Code; and*

10 *“(B) contract with private recruiting firms*
11 *for the hiring of qualified staff referenced in sub-*
12 *paragraph (A).*

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

22 *“(3) ADDITIONAL CONSIDERATIONS.—In ap-*
23 *pointing personnel under this subsection, the Direc-*
24 *tor—*

25 *“(A) may contract with private entities;*

1 “(B) shall make efforts to recruit and retain
2 a diverse workforce, including individuals under-
3 represented in science and medicine and racial
4 and ethnic minorities (as long as such efforts
5 comply with applicable Federal civil rights law);
6 and

7 “(C) shall recruit program managers with
8 expertise in a wide range of relevant disciplines,
9 including life sciences, the physical sciences, en-
10 gineering, and the computational sciences.

11 “(4) *ADDITIONAL HIRING AUTHORITY.*—To the
12 extent needed to carry out the authorities vested by
13 paragraph (1), the Director may utilize hiring au-
14 thorities under sections 3371 through 3376 of title 5,
15 United States Code, to staff ARPA–H with employees
16 from other Federal agencies, State and local govern-
17 ments, Indian Tribes and Tribal organizations, insti-
18 tutions of higher education, and other organizations,
19 as described in such sections.

20 “(5) *EXISTING AUTHORITIES.*—The authorities
21 granted by this section are—

22 “(A) in addition to existing authorities
23 granted to the Secretary; and

24 “(B) are not intended to supersede or mod-
25 ify any existing authorities.

1 “(6) *AUTHORITY TO ACCEPT FEDERAL*
2 *DETAILEES.—The Director may accept officers or em-*
3 *ployees of the United States or members of the uni-*
4 *formed service on a detail from an element of the Fed-*
5 *eral Government on a reimbursable or a nonreimburs-*
6 *able basis, as jointly agreed to by the heads of the re-*
7 *ceiving and detailing elements, for a period not to ex-*
8 *ceed 3 years.*

9 “(k) *PROGRAM MANAGERS.—*

10 “(1) *IN GENERAL.—The Director shall appoint*
11 *program managers for 3-year terms (and may re-*
12 *appoint such program managers for 1 consecutive 3-*
13 *year term) for the programs carried out by ARPA—*
14 *H.*

15 “(2) *DUTIES.—A program manager shall—*

16 “(A) *establish, in consultation with the Di-*
17 *rector or Deputy Director, research and develop-*
18 *ment goals for programs, including timelines*
19 *and milestones, and make such goals available to*
20 *the public;*

21 “(B) *collaborate with experts from the Na-*
22 *tional Institutes of Health and other Federal*
23 *agencies and experts in relevant scientific fields*
24 *to identify research and development gaps and*
25 *opportunities;*

1 “(C) convene workshops and meetings, as
2 needed, with entities such as patients, patient
3 advocacy groups, practitioners, professional soci-
4 eties, and other stakeholders to solicit input on
5 programs and goals;

6 “(D) manage applications and proposals,
7 through the appropriate officials for making
8 grants, cooperative agreements, contracts, prizes,
9 and other transaction awards for advanced re-
10 search that may show particular promise, espe-
11 cially in areas in which the private sector and
12 the Federal Government have not undertaken
13 sufficient research;

14 “(E) issue funding opportunity announce-
15 ments, using uniform administrative processes,
16 as appropriate;

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

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

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

1 “(iii) *the unmet needs or ability to im-*
2 *prove health outcomes within patient popu-*
3 *lations;*

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

7 “(v) *the potential for*
8 *interdisciplinarity of the approach of the*
9 *project; and*

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

12 “(G) *conduct project reviews within 18*
13 *months of funding awards to identify milestones*
14 *and monitor progress of such milestones with re-*
15 *spect to each project and prior to disbursement*
16 *of new funds;*

17 “(H) *provide recommendations to the Direc-*
18 *tor with respect to advancing the goals specified*
19 *in subsection (b);*

20 “(I) *cultivate opportunities for the commer-*
21 *cial application or community use of successful*
22 *projects, including through the establishment of*
23 *partnerships between or among awardees;*

24 “(J) *identify innovative cost-sharing ar-*
25 *rangements for ARPA–H projects;*

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

4 “(L) ensure that—

5 “(i) animal studies meet the Federal
6 animal research requirements pursuant of
7 the Public Health Service Policy on Hu-
8 mane Care and Use of Laboratory Animals;
9 and

10 “(ii) applications apply statistical
11 modeling approaches and appropriately jus-
12 tify animal sample sizes to meet project
13 goals.

14 “(l) *REPORTS AND EVALUATION.*—

15 “(1) *ANNUAL REPORT.*—

16 “(A) *IN GENERAL.*—Beginning not later
17 than 1 year after the date of enactment of this
18 section, and each fiscal year thereafter, the Di-
19 rector shall submit a report on the actions un-
20 dertaken, and results generated, by ARPA–H, in-
21 cluding—

22 “(i) a description of projects supported
23 by ARPA–H in the previous fiscal year and
24 whether such projects are meeting the goals

1 *developed by the Director pursuant to sub-*
2 *section (c)(4)(C);*

3 *“(ii) a description of projects termi-*
4 *nated in the previous fiscal year, and the*
5 *reason for such termination;*

6 *“(iii) a description of programs start-*
7 *ing in the next fiscal year, as available;*

8 *“(iv) activities conducted in coordina-*
9 *tion with other Federal agencies;*

10 *“(v) an analysis of the extent of coordi-*
11 *nation conducted pursuant to subsections*
12 *(c)(4)(F) and (f), including successes and*
13 *barriers with respect to achieving the goals*
14 *under subsection (b);*

15 *“(vi) a description of the demographic*
16 *(including racial and gender) diversity if*
17 *available of direct recipients and performers*
18 *in funded projects and of the ARPA-H*
19 *workforce; and*

20 *“(vii) a disclosure by the reward re-*
21 *cipients of whether the principal investiga-*
22 *tors named on the award participate in for-*
23 *ign talent programs, including the provi-*
24 *sion of copies of all grants, contracts, or*
25 *other agreements related to such programs,*

1 *and other supporting documentation related*
2 *to such programs, as a condition of receipt*
3 *of Federal extramural biomedical research*
4 *funding awarded.*

5 “(B) *SUBMISSION TO CONGRESS.*—*The re-*
6 *port under subparagraph (A) shall be submitted*
7 *to—*

8 “(i) *the Committee on Energy and*
9 *Commerce and the Committee on Appro-*
10 *priations of the House of Representatives;*
11 *and*

12 “(ii) *the Committee on Health, Edu-*
13 *cation, Labor, and Pensions and the Com-*
14 *mittee on Appropriations of the Senate.*

15 “(2) *EVALUATION.*—

16 “(A) *IN GENERAL.*—*Not later than 5 years*
17 *after the date of the enactment of this section, the*
18 *Secretary shall enter into an agreement with the*
19 *National Academies of Sciences, Engineering,*
20 *and Medicine under which the National Acad-*
21 *emies agree to study and evaluate whether*
22 *ARPA–H is meeting the goals specified in sub-*
23 *section (b).*

24 “(B) *SUBMISSION OF RESULTS.*—*The agree-*
25 *ment entered into under subparagraph (A) shall*

1 *require the National Academies of Sciences, En-*
2 *gineering, and Medicine to submit the results of*
3 *the evaluation conducted under such agreement*
4 *to the Secretary, the Committee on Energy and*
5 *Commerce of the House of Representatives, and*
6 *the Committee on Health, Education, Labor, and*
7 *Pensions of the Senate.*

8 “(m) *STRATEGIC PLAN.*—Not later than 1 year after
9 the date of the enactment of this section, and every 3 years
10 thereafter, the Director shall provide to the relevant commit-
11 tees of Congress a strategic plan describing how ARPA–H
12 will carry out investments each fiscal year in the following
13 3-year period.

14 “(n) *INDEPENDENT REVIEW.*—Not later than 1 year
15 after the date of the enactment of this section, and every
16 3 years thereafter, the Comptroller General of the United
17 States shall conduct an independent review of the research
18 portfolio of the Department of Health and Human Services,
19 including ARPA–H, the National Institutes of Health, the
20 Food and Drug Administration, and the Biomedical Ad-
21 vanced Research and Development Authority—

22 “(1) *to assess the degree of unnecessary duplica-*
23 *tion of existing Federal programs and projects; and*

1 “(2) to make recommendations regarding any
2 potential reorganization, consolidation, or termi-
3 nation of such programs and projects.

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

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

10 “(2) as appropriate and practicable, ensure that
11 nondomestic recipients of any grants, cooperative
12 agreements, contracts, prizes, and other transactions
13 under this section are conducting research in collabo-
14 ration with a domestic recipient;

15 “(3) not award any grants, cooperative agree-
16 ments, contracts, prizes, and other transactions to
17 nondomestic recipients subject to malign foreign in-
18 fluence or organized under the laws of a malign for-
19 eign country; and

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

1 *agreements, contracts, prizes, and other transactions*
2 *under this section.*

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

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

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

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

12 “(4) *a new interagency research council orga-*
13 *nized to support the programs of ARPA–H and to*
14 *provide advice and assistance on—*

15 “(A) *specific program tasks; or*

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

17 “(5) *any other entity the Director may deem ap-*
18 *propriate.*

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

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

1 “(2) *MEMBERSHIP.*—*The Research Council may*
2 *include any or all of the following members, or des-*
3 *ignees:*

4 “(A) *The Director of the National Institutes*
5 *of Health.*

6 “(B) *The Director of National Center for*
7 *Advancing Translational Sciences.*

8 “(C) *The Director of Office of Science and*
9 *Technology Policy.*

10 “(D) *The Commissioner of Food and Drugs.*

11 “(E) *The Director of the Biomedical Ad-*
12 *vanced Research and Development Authority.*

13 “(F) *The Director of the Centers for Disease*
14 *Control and Prevention.*

15 “(G) *The Administrator of the Centers for*
16 *Medicare & Medicaid Services.*

17 “(H) *The Director of the Agency for*
18 *Healthcare Research and Quality.*

19 “(I) *The Director of the Office of Minority*
20 *Health.*

21 “(J) *The Administrator of the Health Re-*
22 *sources and Services Administration.*

23 “(K) *The Director of the Defense Advanced*
24 *Research Projects Agency.*

1 “(L) *The Director of the National Science*
2 *Foundation.*

3 “(M) *The Director of the Office of Science*
4 *of the Department of Energy.*

5 “(N) *The Director of the Advanced Research*
6 *Projects Agency–Energy.*

7 “(O) *The Assistant Secretary for Prepared-*
8 *ness and Response.*

9 “(P) *Representatives of any Federal agency*
10 *with subject matter expertise that the Director*
11 *determines is necessary for the successful comple-*
12 *tion of a project carried out pursuant to this sec-*
13 *tion.*

14 “(Q) *Any other entity the Director may*
15 *deem appropriate.*

16 “(3) *DUTIES.—The Research Council shall ad-*
17 *vice the Director, including by—*

18 “(A) *making recommendations on—*

19 “(i) *research priorities that will pro-*
20 *vide the greatest return on investment with*
21 *respect to improving human health;*

22 “(ii) *avoiding duplication of efforts in*
23 *the Federal Government; and*

24 “(iii) *improving coordination with*
25 *other Federal agencies; and*

1 “(B) identifying and developing strategies
2 to address regulatory, reimbursement, and mar-
3 ket barriers to commercialization or adoption of
4 transformative health technologies, including
5 technologies intended to preempt serious disease.

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

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

18 “(A) share information on health innova-
19 tions funded by ARPA–H; and

20 “(B) receive input on areas of particular
21 promise for ARPA–H projects.

22 “(r) *TECHNOLOGY TRANSFER OFFICE.*—The Director
23 may establish within ARPA–H an Office of Technology
24 Transfer to facilitate, where appropriate, the transfer of fed-
25 erally-owned or federally-originated technology to recipients

1 *of an award under this section (other than Federal Govern-*
2 *ment entities).*

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

4 “(1) *IN GENERAL.—An other transaction entered*
5 *into by the Director under subsection (h)(1) for a*
6 *project may provide for the award of a follow-on pro-*
7 *duction contract or transaction to the participants in*
8 *the transaction by ARPA–H or another Federal agen-*
9 *cy. For purposes of this paragraph, such an other*
10 *transaction includes all individual subprojects award-*
11 *ed under the transaction to a consortium of United*
12 *States industry and academic institutions.*

13 “(2) *RELATION TO COMPETITIVE PROCE-*
14 *DURES.—A follow-on production contract or trans-*
15 *action under paragraph (1) may be awarded to the*
16 *participants in the transaction without the use of*
17 *competitive procedures (as defined in section 152 of*
18 *title 41, United States Code), notwithstanding the re-*
19 *quirements of division C of subtitle I of such title 41,*
20 *if—*

21 “(A) *competitive procedures were used for*
22 *the selection of parties for participation in the*
23 *other transaction; and*

1 “(B) *the participants in the other trans-*
2 *action successfully completed the project provided*
3 *for in the transaction.*

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

9 “(4) *CLARIFICATION.—Award of a follow-on pro-*
10 *duction contract or transaction pursuant to this sub-*
11 *section shall not be made contingent upon the success-*
12 *ful completion of all activities within a consortium as*
13 *a condition for an award for follow-on production of*
14 *a successfully completed project or subproject within*
15 *that consortium.*

16 “(5) *OTHER AUTHORITIES.—Contracts and*
17 *transactions entered into by ARPA–H pursuant to*
18 *this subsection may be awarded pursuant to division*
19 *C of subtitle I of title 41, United States Code, or*
20 *under such procedures, terms, and conditions as the*
21 *Director or head of such agency may establish by reg-*
22 *ulation.*

23 “(t) *RULE OF CONSTRUCTION.—The authorities under*
24 *this section, with respect to the Director, are additional au-*

1 *thorities that do not supersede or modify any existing au-*
2 *thorities.*

3 “(u) *DEFINITIONS.—In this part:*

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

7 “(A) *may precede the development of trans-*
8 *formative health technologies; and*

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

11 “(2) *BIOLOGICAL PRODUCT.—The term ‘biologi-*
12 *cal product’ has the meaning given such term in sec-*
13 *tion 351(i).*

14 “(3) *DEPARTMENT.—The term ‘Department’*
15 *means the Department of Health and Human Serv-*
16 *ices.*

17 “(4) *DRUG; DEVICE.—The terms ‘drug’ and ‘de-*
18 *vice’ have the meanings given such terms in section*
19 *201 of the Federal Food, Drug, and Cosmetic Act.*

20 “(5) *FEDERAL ACQUISITION REGULATION.—The*
21 *term ‘Federal Acquisition Regulation’ means the Fed-*
22 *eral Acquisition Regulation issued pursuant to sec-*
23 *tion 1303(a)(1) of title 41, United States Code.*

1 “(6) *FEDERAL AGENCY.*—*The term ‘Federal*
2 *agency’ has the meaning given such term in section*
3 *3371 of title 5, United States Code.*

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

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

11 “(A) *that should be prioritized to detect, di-*
12 *agnose, mitigate, prevent, cure, or treat a serious*
13 *disease or medical condition for which there are*
14 *unmet needs; and*

15 “(B) *for which—*

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

18 “(ii) *incentives in the commercial*
19 *market are unlikely to result in the ade-*
20 *quate or timely development of such drug,*
21 *biological product, intervention, platform,*
22 *tool, or device.*

23 “(v) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
24 *authorized to be appropriated \$500,000,000 for each of fis-*

1 *cal years 2023 through 2027, to remain available until ex-*
2 *pended.”.*

Union Calendar No. 277

117TH CONGRESS
2^D SESSION

H. R. 5585

[Report No. 117-365]

A BILL

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

JUNE 13, 2022

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed