[Discussion Draft]

AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5585

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

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 en-

actment 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.

''(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 Com-

mittee 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 mar-

ket 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 re-

cipients 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 addi-

tional 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.''.

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