.....

(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to establish a National Institute for Biomedical Research and Development, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. TLAIB introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to establish a National Institute for Biomedical Research and Development, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicines for the People Act''.

SEC. 2. ESTABLISHMENT.

(a) IN GENERAL.—Part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

"Subpart 21—National Institute for Biomedical Research and Development

"SEC. 464z–11. PURPOSE AND FUNCTIONS OF INSTITUTE.

''(a) IN GENERAL.—The general purposes of the National Institute for Biomedical Research and Development (referred to in this subpart as the 'Institute') are—

''(1) to engage in full-cycle development of drugs, devices, and biological products to promote long-term access to medicines, foster innovation, and ensure prioritization of public health needs; and

''(2) to make such drugs, devices, and biological products available to the public at equitable and accessible prices.

''(b) RESEARCH AND DEVELOPMENT PROGRAM.—

''(1) IN GENERAL.—The Director of the Institute (referred to in this subpart as the 'Director') shall carry out a program for the research and development of drugs, devices, and biological products for approval, licensure, clearance, or authorization under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

''(2) ACTIVITIES.—The Director shall carry out the program described in paragraph (1) through—

''(A) managing direct research and development at Federal laboratories of the National Institutes of Health;

''(B) contracting with public or private entities for research and development;

''(C) acquisition of research and development, including technologies and related scientific data, from public or private entities;

''(D) licensing of patents under subsection (f);

''(E) establishment of separate facilities to conduct the work of the Institute, including, at the discretion of the Director, the construction of facilities and the acquisition of land, for the purposes of the establishment or operation of the Institute;

''(F) sharing scientific data in a timely manner for use by research communities and Federal and State agencies;

''(G) coordinating the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies;

''(H) conducting or sponsoring research necessary to obtain approval from the Food and Drug Administration, including clinical trials to generate safety and effectiveness data and information;

''(I) conducting health technology assessments in accordance with paragraph (3) for drug, devices, and biological products the research or development of which is conducted or funded under this section;

''(J) carrying out any other activities necessary for the successful commercialization of drugs, devices, and biological products the research or development of which is conducted or funded under this section; and

''(K) implementing goals, priorities, objectives, policies, and procedures established by the Board.

''(3) REQUIREMENTS FOR HEALTH TECHNOLOGY ASSESSMENTS.—

''(A) IN GENERAL.—In conducting health technology assessments of drugs, devices, and biological products for purposes of paragraph (2)(I), the Director shall ensure that such health technology assessments—

''(i) are conducted in a formal, systematic, and transparent manner;

''(ii) use state-of-the-art methods to consider the best available evidence;

''(iii) examine the direct, intended consequences and indirect, unintended consequences of the use of the applicable drug, device, or biological product, as compared to existing alternatives; and

''(iv) consider factors such as clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, and implications for patients, relatives, caregivers, and the broader public.

''(B) DEFINITION OF HEALTH TECHNOLOGY ASSESSMENT.—In this section, the term 'health technology assessment' means a multidisciplinary process that uses explicit methods to determine the value of a drug, device, or biological product.

''(c) RESEARCH MONITORING; ACQUISITION.—

''(1) IN GENERAL.—The Director shall monitor the results of research conducted or supported by

the National Institutes of Health and by other appropriate public and private entities, such as the Biomedical Advanced Research and Development Authority of the Department of Health and Human Services or the Walter Reed Pilot Bioproduction Facility of the Department of Defense, to identify inventions that, if subjected to appropriate research and development activities, may be suitable for approval, licensure, clearance, or authorization under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act as a drug, biological product, or device.

''(2) ACQUISITION.—Notwithstanding chapter 18 of title 35, United States Code, the Director may acquire, and shall have the right of first refusal for, the rights to an invention identified under paragraph (1) that is the result of research conducted or supported by the National Institutes of Health.

''(d) PRIORITIZATION.—In allocating the resources of the Institute, the Board shall establish priorities for research and development that reflect the magnitude of the potential public health impact, unmet needs in current product development, and the potential for scientific breakthrough.

''(e) TRANSPARENCY.—

''(1) IN GENERAL.—The Director shall ensure that the Institute adheres to the highest standards of transparency by—

''(A) sharing with researchers, manufacturers, and the public preclinical and clinical trial data and data on costs in an open and timely manner, which data—

''(i) shall include all safety and effectiveness data and information that has been submitted in an application to the Food and Drug Administration, including an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act; and

''(ii) shall be deidentified to protect patient privacy, but may not otherwise be withheld from disclosure on any basis;

''(B) making information regarding activities carried out by the Institute publicly available online, including—

''(i) information regarding research and development that is receiving priority;

''(ii) all data developed in carrying out research and development activities;

''(iii) summary findings made in carrying out such activities; and

''(iv) copies of all licensing agreements and contracts entered into with public and private entities; and

''(C) requiring any entity that conducts research funded by the Institute—

''(i) to share scientific data generated from such research not later than the earlier of the date of the first associated publication or the end of the period of the award of such funds;

''(ii) when selecting a repository, to give priority to—

''(I) data repositories supported by or affiliated with the National Institutes of Health; and

''(II) data repositories that—

''(aa) assign datasets unique persistent identifiers;

''(bb) provide free and easy access to datasets and their metadata;

"(cc) make datasets and metadata available for broad reuse;

"(dd) have capabilities for ensuring confidentiality for sensitive data;

"(ee) have documented security and integrity measures; and

"(ff) have documented procedures to restrict dataset access and use that are consistent with participant consent and changes in consent, in the case of human participant data;

"(iii) to take reasonable steps to ensure data is made available for as long as such data may be useful for the larger research community, institutions, or the public; and

"(iv) on acceptance for publication and consistent with applicable copyright law, to submit, or have submitted on their behalf, to the PubMed Central database of the National Library of Medicine (or any successor archive or database), an elec-

tronic version of the final, peer-reviewed manuscript describing such research, which manuscript shall be made publicly available by the National Library of Medicine not later than 1 year after the date on which such manuscript is officially published.

''(2) DEFINITION OF SCIENTIFIC DATA.—In this subsection, the term 'scientific data' means data commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.

''(f) PATENTS AND TRADE SECRETS.—

''(1) IN GENERAL.—Notwithstanding chapter 18 of title 35, United States Code, the Director shall ensure that the Federal Government owns the rights to any patents and trade secrets relating to drugs, devices, and biological products the research or development of which is conducted or funded under this section, including any research or development conducted through contracting with a private entity or acquired from a private entity under this section.

''(2) MANAGEMENT.—The Director shall manage the patents and trade secrets relating to re-

search and development conducted or funded under this section in the public-interest.

''(3) PATENTS.—

''(A) IN GENERAL.—The Director shall obtain patents, as appropriate, for inventions resulting from research and development conducted or funded under this section.

''(B) STANDARD PATENT LICENSING POLICY.—Unless otherwise determined by the Director, patents held by the Institute shall be licensed to the Medicines Patent Pool.

''(C) ACCESS.—Notwithstanding chapter 18 of title 35, United States Code, the Director shall ensure public interest access, in terms of both price and supply, considered independently, including in low and middle income country markets, to patents and trade secrets relating to drugs, devices, and biological products the research or development of which is conducted or funded under this section, including through—

''(i) stipulating, as a condition of receipt of Federal extramural biomedical research funding awarded through the Department of Health and Human Services,

that the Institute shall be granted rights to all the data and technical information developed under a contract, including all necessary intellectual property, technology, know-how, and other information (including master batch records, standard operating procedures, quality assurance and quality control information, detailed bill of materials for the drug, device, or biological product and other manufacturing documentation) relating to the drug, device, or biological product necessary for operationalizing technology transfer;

''(ii) at the discretion of the Director, stipulating in any contract the Institute enters into with an extramural party that such party will provide commercially reasonable support for technology transfer activities; and

''(iii) non-exclusive licensing to public, nonprofit, and for-profit entities under subparagraph (D).

''(D) LICENSING.—In any license of the rights to a patent held by the Institute, the Director shall license patents—

"(i) to public entities, free of cost;

"(ii) to nonprofit organizations, free of cost; and

"(iii) to for-profit entities with terms that protect the public interest, including non-exclusivity provisions, cost-plus pricing terms, and reciprocity rules.

"(4) TRADE SECRETS AND CONFIDENTIAL COMMERCIAL INFORMATION.—

"(A) IN GENERAL.—The Director may not claim trade secrets or confidential commercial information with respect to any drugs, devices, or biological products the research or development of which is conducted or funded under this section, including any research or development conducted through contracting with a private entity or acquired from a private entity under this section.

"(B) CONFIDENTIAL COMMERCIAL INFORMATION DEFINED.—In this paragraph, the term 'confidential commercial information' means information that contains material exempt from disclosure under subsection (b)(4) of section 552 of title 5, United States Code (commonly known as the 'Freedom of Information Act').

''(g) PUBLIC AND PRIVATE MANUFACTURING; LICENSING; ROYALTIES.—

''(1) IN GENERAL.—With respect to a drug, biological product, or device the patent for which is held by the Federal Government under this section and that is approved, licensed, cleared, or authorized under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act, the Director shall provide for—

''(A) the public manufacturing of such drug, biological product, or device, if practicable; and

''(B) such drugs, biological products, and devices so manufactured to be sold at cost.

''(2) LICENSING; ROYALTIES.—If the Director determines that public manufacturing for a drug, biological product, or device described in paragraph (1) is not practicable, the Director—

''(A) may license the patent for such drug, biological product, or device to a private entity, based on the value established by a health technology assessment conducted under subsection (b)(2)(I);

''(B) shall give preference to the manufacturing of such drug, biological product, or de-

vice, by a nonprofit organization before seeking any manufacturing by for-profit companies;

''(C) shall, consistent with section 14 of the Stevenson-Wydler Technology Innovation Act of 1980, reinvest the royalties received from such licensing into research and development under this section; and

''(D) may consider the need for diversified, regional production of medicines to ensure access, or for other purposes, when granting licenses.

''(h) SUPERVISION.—The work of the Director shall be directed and supervised by the Secretary, who shall have the authority, after consulting with the voting members of the Board, to remove the Director.

''(i) USE OF EXISTING RESOURCES.—In providing for the establishment and operations of the Institute, the Director of NIH may, on request of the Director of the Institute—

''(1) transfer to the Institute such personnel of the National Institutes of Health as the Director of NIH determines to be appropriate;

''(2) allow the Institute to use such facilities of the National Institutes of Health as the Director of NIH determines to be appropriate; and

''(3) obtain administrative support for the Institute from the other agencies of the National Institutes of Health, including the other national research institutes.

"SEC. 464z–12. GOVERNING BOARD.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Medicines for the People Act, the Secretary shall establish a governing board (referred to in this subpart as the 'Board') to assist the Secretary in establishing high-level policy, conducting long-term planning, and providing overall direction for the Institute.

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—The Board shall consist of 15 voting members, to be appointed by the Secretary, including—

''(A) not fewer than 2 civil society representatives with a background in identifying and addressing barriers to the ability of individuals and populations to acquire medicines needed to achieve health;

''(B) not fewer than 2 patient advocates from independent patient organizations that take no funding from for-profit companies (or foundations or nonprofit organizations affiliated with for-profit companies) involved in the pro-

duction or sale of any drug, biological product, or device and do not have executives from such companies (or affiliated foundations or non-profit organizations) on their governing boards;

''(C) not fewer than 2 current or former public health officials;

''(D) not fewer than 2 current or former members of the Institute, except in the case of the initial membership of the Board; and

''(E) such other members as the Secretary determines appropriate.

''(2) CHAIR.—The members of the Board shall elect from among such members a Chair of the Board.

''(3) NONVOTING MEMBERS.—The Secretary may, after consulting with the voting members of the Board, appoint not more than 4 nonvoting members of the Board. Such nonvoting members shall have relevant experience or expertise not already represented on the Board.

''(4) TERMS.—

''(A) MEMBERS.—The term of each member of the Board shall be not more than 6 years, and the Secretary shall designate staggered terms for the members first appointed.

Members may serve 1 additional term at the discretion of the Secretary.

''(B) CHAIR.—The term of the position of Chair of the Board shall not exceed 6 years.

''(5) LIMITATIONS.—In appointing members under paragraph (1), the Secretary shall ensure that—

''(A) not more than 5 members are from the for-profit sector;

''(B) no member is, or has been during the 6-year period preceding the date of appointment, a lobbyist, as defined in section 3 of the Lobbying Disclosure Act of 1995, registered under section 4 of that Act for a for-profit pharmaceutical manufacturer;

''(C) no member is a current or former senior executive officer of a covered entity;

''(D) no member is a current or former senior executive officer of a covered entity during the 6-year period beginning on the later of—

''(i) the date of a Federal settlement relating to a violation of sections 3729 through 3733 of title 31, United States Code (commonly known as the 'False

Claims Act'), the Federal Food, Drug, and Cosmetic Act, including a Federal consent decree, the Sherman Act, the Clayton Act, or the Federal Trade Commission Act that was entered into by the relevant covered entity; and

''(ii) the date on which an enforcement action relating to a violation by the covered entity of sections 3729 through 3733 of title 31, United States Code (commonly known as the 'False Claims Act'), the Federal Food, Drug, and Cosmetic Act, the Sherman Act, the Clayton Act, or the Federal Trade Commission Act in a court of the United States or by an Executive agency has concluded; and

''(E) no member during the time period described in paragraph (6), with the intent to influence or with the intent to gain information for use in analyzing securities or commodities markets or in informing investment decisions in any securities or commodities market of the United States, makes any communication to or appearance before the former public office or Executive agency of the member for compensa-

tion, provided that any such violation shall be subject to the penalties set forth in section 216 of title 18, United States Code.

''(6) TIME PERIOD.—The time period described in this paragraph is as follows:

''(A) With respect to an officer or employee of an Executive agency, the later of—

''(i) the date on which a President other than the President serving at the time of the termination of service or employment of the officer or employee takes office; and

''(ii) the date on which the 2-year period beginning on the date of the termination of service or employment as an officer or employee expires.

''(B) With respect to an officer or employee of an Executive agency who becomes a corporate lobbyist, the later of—

''(i) the date on which a President other than the President serving at the time of the termination of service or employment of the officer or employee takes office; and

''(ii) the date on which the 6-year period beginning on the date of the termination of service or employment as an officer or employee expires.

''(c) DUTIES.—The Board, subject to the supervision of the Secretary under subsection (e), shall—

''(1) establish goals, priorities, objectives, policies, and procedures relating to the operation and development of the Institute, including identifying promising inventions under subsection (c)(1) of section 464z–11;

''(2) ensure that the Institute effectively carries out the purposes specified in section 464z–11(a), including that drugs, devices, or biological products the research or development of which is conducted or funded under section 464z–11 are successfully commercialized and available to the public;

''(3) establish such committees or bodies as may be necessary to facilitate or carry out the duties of the Board; and

''(4) perform such other duties and responsibilities as may be necessary to carry out this section.

''(d) DEFINITIONS.—In this section:

''(1) CORPORATE LOBBYIST.—The term 'corporate lobbyist' means a lobbyist, as defined in sec-

tion 3 of the Lobbying Disclosure Act of 1995, who is registered under section 4 of that Act and who is employed by a corporation, as defined in section 101(9) of title 11, United States Code.

''(2) COVERED ENTITY.—The term 'covered entity' means any entity that is—

''(A)(i) a for-profit company; or

''(ii) a bank holding company, a savings and loan holding company, or any other financial institution; and

''(B)(i) operating under a Federal settlement relating to a violation of sections 3729 through 3733 of title 31, United States Code (commonly known as the 'False Claims Act'), the Federal Food, Drug, and Cosmetic Act, including a Federal consent decree, the Sherman Act, the Clayton Act, or the Federal Trade Commission Act; or

''(ii) the subject of an enforcement action relating to a violation of sections 3729 through 3733 of title 31, United States Code (commonly known as the 'False Claims Act'), the Federal Food, Drug, and Cosmetic Act, the Sherman Act, the Clayton Act, or the Federal Trade

Commission Act in a court of the United States or by an Executive agency.

''(3) EXECUTIVE AGENCY.—The term 'Executive agency'—

''(A) has the meaning given the term in section 105 of title 5, United States Code; and

''(B) includes—

''(i) the Executive Office of the President and all components thereof, including the White House Office; and

''(ii) the Office of the Vice President.

''(4) RIGHTS TO AN INVENTION.—The term 'rights to an invention' includes all rights, title, and interests in an invention, including—

''(A) any sale, assignment, or other transfer of a patent on the invention, United States or foreign; and

''(B) any exclusive license to a patent on an invention, United States or foreign.

''(e) SUPERVISION.—The work of the Board shall be directed and supervised by the Secretary who shall—

''(1) consult with the Board;

''(2) have the authority to review, approve, modify, or reject any decision the Board makes pur-

suant to the duties of the Board under subsection (c); and

''(3) make public any reasons why the Secretary rejected or materially modified the decisions of the Board pertaining to such duties.

''(f) POWERS.—

''(1) HEARINGS AND SESSIONS.—The Board may, for the purpose of carrying out this section, hold hearings, sit and act at times and places, take testimony, administer oaths or affirmations to witnesses appearing before the Board, and receive evidence as the Board considers appropriate.

''(2) OBTAINING OFFICIAL DATA.—The Board may secure directly from any department or agency of the United States information necessary to enable the Board to carry out the duties of the Board under this section.

''(3) ADMINISTRATIVE SUPPORT SERVICES.—On request of the Board, the Administrator of the General Services Administration shall provide to the Board, on a reimbursable basis, the administrative support services necessary for the Board to carry out the duties of the Board under this section.

''(4) STAFF.—On request of the Board and on a reimbursable basis, for the purpose of assisting the

Board in carrying out the duties of the Board, the Secretary may detail to the Board any personnel of their department.

''(g) TERMS OF OFFICE.—

''(1) VACANCIES.—A member appointed by the Secretary to fill a vacancy on the Board occurring before the expiration of the term for which the predecessor of the member was appointed shall be appointed for the remainder of such term.

''(2) REMOVAL.—A member may be removed from the Board by the Secretary only for inefficiency, neglect of duty, or malfeasance in office.

''(h) PAY.—

''(1) RATES OF PAY.—Members of the Board shall each be entitled to receive the daily equivalent of the annual rate of basic pay for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such members are engaged in the performance of duties of the Board.

''(2) PROHIBITION OF COMPENSATION OF FEDERAL EMPLOYEES.—Notwithstanding paragraph (1), the members of the Board who are full-time officers or employees of the United States for purposes of title 5, United States Code, may not receive addi-

tional pay, allowances, or benefits by reason of their service on the Board.

''(3) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

''(i) APPLICATION OF FEDERAL ADVISORY COMMITTEE ACT.—The Board shall be subject to chapter 10 of title 5, United States Code (commonly referred to as the 'Federal Advisory Committee Act'), except that section 1013(a)(2) of such title shall not apply.

''SEC. 464z–13. EVALUATION; REPORTS.

''(a) IN GENERAL.—Not later than 5 years after the date of enactment of the Medicines for the People Act, and annually thereafter, the Director shall evaluate the activities of the Institute. Such evaluation shall include the following metrics:

''(1) Number of applications or submissions under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

''(2) Number of clinical trial data sets published in the public domain.

''(3) Number of new drugs, biological products, and devices developed or brought to market, directly or indirectly.

''(4) Number of licenses acquired from public, nonprofit, and for-profit entities.

''(5) Number of patents licensed, disaggregated by public, nonprofit, or private entity.

''(6) Number of patents filed.

''(7) Number of patents purchased or acquired.

''(8) Estimated savings to public health care programs due to the activities of the Institute.

''(b) ANNUAL REPORTS.—Not later than 5 years after the date of enactment of the Medicines for the People Act, and annually thereafter, the Director shall submit to Congress, and make publicly available, a report describing the results of the applicable annual evaluation carried out under subsection (a), including, for patents licensed, filed, purchased, or acquired, the patent application numbers, filing dates, names of licensees, dates of licenses, and where license agreements may be found.

''SEC. 464z–14. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to carry out this subpart $90,000,000,000 for fiscal year 2027, to remain available until expended.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 401 of the Public Health Service Act (42 U.S.C. 281) is amended—

(A) in subsection (b)—

(ii) by redesignating paragraph (25) as paragraph (26); and

(iii) by inserting after paragraph (24) the following:

''(25) The National Institute for Biomedical Research and Development.''; and

(B) in subsection (d)(1), by striking ''27'' and inserting ''28''.

(2) Section 405 of the Public Health Service Act (42 U.S.C. 284) is amended—

(A) in subsection (b)(2)(B)(ii), by inserting ''or governing board'' after ''advisory council''; and

(B) in subsection (c)(3), by inserting ''or governing board'' after ''advisory council''.

(c) PENALTIES AND INJUNCTIONS.—Section 216 of title 18, United States Code, is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by inserting ''or section 464z–12 of the Public Health Service Act'' after ''of this title'';

(2) in subsection (b), by inserting ''or section 464z–12 of the Public Health Service Act'' after ''of this title''; and

(3) in subsection (c), by inserting ''or section 464z–12 of the Public Health Service Act'' after ''of this title''.