110TH CONGRESS
2D SESSION

S. 2988

To amend the Public Health Service Act to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2008

Mr. LIEBERMAN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases.

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 ''Accelerating Cures Act of 2008''.

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SEC. 3. FINDINGS; PURPOSE.

(a) FINDINGS.—Congress finds the following:

(1) The National Institutes of Health (referred to in this section as the ''NIH'') is the United States premier biomedical research investment with annual appropriations exceeding $29,200,000,000.

(2) The goals of the NIH are to—

(A) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to significantly advance the Nation's capacity to protect and improve health;

(B) develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capacity to prevent disease;

(C) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and

(D) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

(3) Thus, the NIH is tasked with applying basic science discoveries to protect and improve health. This includes, translational research, which is the scientific work necessary to develop a clinical application from a basic science discovery.

(4) The United States translational research investment will be key to the Nation responding effectively—

(A) to public and population health threats;

(B) to the complex nature of chronic diseases, which are responsible for 7 out of 10 deaths in the United States, for 75 percent of

the $2,300,000,000,000 spent annually on healthcare in the United States, and for 16 percent of gross domestic product;

(C) to research and development vacuums in the private for-profit market, such as in the fields of vaccine and antibiotic production, drugs for Third World diseases, orphan drugs, and medical tools for pediatric populations; and

(D) to facilitate the process of converting medical innovations into commercial products.

(5) Key components of the translational research process include research prioritization, a strengthening and maintenance of an expert workforce, multidisciplinary collaborative work, strategic risk taking, support of small innovative businesses caught along common pathways in the research and development Valley of Death, simplification and promotion of the clinical research endeavor, and early involvement of private entities that are skilled in the manufacturing and marketing process in the translational research endeavor.

(6) A National Academy of Sciences/Institute of Medicine report made recommendations for reorganizing NIH to meet new challenges facing the biomedical research endeavor. The committee report

contained specific recommendations aimed at strengthening clinical and translational research including: increasing trans-NIH research, promoting innovation and risk taking in intramural research, creating a ''special projects'' program, and increasing funding for research management and support.

(7) The Government Accountability Office reported that although the pharmaceutical industry has increased its research and development investment by 147 percent from 1993 to 2004, new drug applications to the Food and Drug Administration have only increased by 39 percent; thus, the productivity of the industry's research and development expenditures is declining. The report cited that a limited scientific understanding of how to translate research discoveries into safe and effective drugs is contributing to the problem and recommended that training researchers who can translate drug discoveries into effective medicines is necessary.

(8) It is estimated to take 17 years for a science discovery to be translated from the point of proof of concept to clinical application. The percent of physicians engaged in research has declined steadily from a peak of 4.6 percent in 1985 to 1.8 percent in 2003.

(9) A report by the Infectious Disease Society of America cited concerns with the lack of new antibiotics to treat infectious diseases. The report commended the NIH Roadmap, but also recommended that NIH aggressively expand the translational research components of the Roadmap, increase grants to small businesses, universities, and nonprofits working in antibiotics research and development, and seek more opportunities to partner with pharmaceutical and biotech companies.

(10) Clinical effectiveness results provide patients, payers, and clinicians with tools to evaluate the benefits versus risks of the ever evolving number of prevention, diagnosis, and treatment strategies available.

(11) The Common Fund is an annual set aside account created from an agreed upon percentage of the annual budget that supports innovative and trans-NIH initiatives to improve and accelerate research to impact health.

(12) The ''Valley of Death'' is a stage in biomedical development between research and commercialization where the success of a product is dependent on its profitability.

(b) PURPOSE.—The purpose of this Act is to create a new pathway to curing disease by enhancing public and private research to translate new discoveries from bench to bedside.

SEC. 4. ACCELERATING CURES ACT OF 2008.

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—ACCELERATING CURES

"Subpart 1—Pathways to Cures Subcommittee

"SEC. 499A. PATHWAYS TO CURES SUBCOMMITTEE.

''(a) DEFINITION OF TRANSLATIONAL RESEARCH.—In this section, the term 'translational research' means research that transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical application to reduce disease incidence, morbidity, and mortality.

''(b) ESTABLISHMENT OF PATHWAYS TO CURES SUBCOMMITTEE.—There is established a Pathways to Cures Subcommittee within the Council of Councils of the Office of Portfolio Analysis and Strategic Initiatives of the National Institutes of Health that shall convene not less frequently than twice a year to help advise and direct the translational research priorities of the Office of Portfolio

Analysis and Strategic Initiatives (referred to in this part as the 'OPASI').

''(c) MEMBERSHIP.—

''(1) IN GENERAL.—The subcommittee established under subsection (b) may be composed of the following members:

''(A) The Director of NIH and the Director of OPASI who shall be subcommittee co-chairs.

''(B) The heads of the institutes and centers of the National Institutes of Health.

''(C) Heads from Federal agencies, including—

''(i) the Administrator for the Substance Abuse and Mental Health Services Administration;

''(ii) the Under Secretary for Science and Technology of the Department of Homeland Security;

''(iii) the Commanding General for the United States Army Medical Research and Materiel Command;

''(iv) the Director of the Centers for Disease Control and Prevention;

''(v) the Commissioner of Food and Drugs;

''(vi) the Director of the Office of Science of the Department of Energy;

''(vii) the President of the Institute of Medicine;

''(viii) the Director of the Agency for Healthcare Research and Quality; and

''(ix) the Director of the Defense Advanced Research Projects Agency.

''(2) OTHER MEMBERS.—The subcommittee established under subsection (b) shall also include not fewer than 3 leaders from the small business medical research community, 3 leaders from large pharmaceutical or biotechnology companies, and 3 leaders from academia and patient advocacy organizations, all of whom shall be appointed by the Director of NIH.

''(d) RECOMMENDATIONS; COORDINATION; FUNDING.—

''(1) SETTING PRIORITIES.—The subcommittee established under subsection (b) shall make recommendations to assist the Director of OPASI in setting translational research priorities.

''(2) RECOMMENDATIONS.—In making recommendations, the subcommittee shall—

''(A) consider risk and burden of disease as well as lines of research uniquely poised to deliver effective diagnostics and therapies; and

''(B) be mission-driven and identify research that shows specific promise for a new treatment or cure for a disease.

''(3) COORDINATION.—The subcommittee shall ensure sharing of research agendas among the institutes and centers of the National Institutes of Health for the purpose of coordinating translational research priorities, where appropriate, across such institutes and centers.

''(4) FUNDING.—The subcommittee and the Director of OPASI—

''(A) shall identify research with application or commercialization potential; and

''(B) may fund such research

''(e) REPORT.—The subcommittee established under subsection (b) shall submit an annual report to Congress on progress towards finding new treatments and cures.

"Subpart 2—Clinical Effectiveness; FFRDC

"SEC. 499B. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER.

''(a) ESTABLISHMENT OF CENTER.—

''(1) IN GENERAL.—The Director of NIH, in conjunction with the Director of the Agency for Healthcare Research and Quality (referred to in this subpart as the 'AHRQ'), shall establish a Federally Funded Research and Development Center (referred to in this subpart as the 'FFRDC') on clinical effectiveness research.

''(2) DEFINITION OF CLINICAL EFFECTIVENESS RESEARCH.—In this section, the term 'clinical effectiveness research' means research that—

''(A) provides information for health care decision makers, including patients, providers, and public and private payers, to make evidence-based decisions about the delivery of health care; and

''(B) considers specific subpopulations.

''(3) DIRECTOR OF THE FFRDC.—The Director of NIH, in conjunction with the Director of the AHRQ, shall appoint a Director of the FFRDC.

''(b) DUTIES OF THE DIRECTOR OF THE FFRDC.—The Director of the FFRDC shall—

''(1) review, synthesize, and disseminate clinical effectiveness research;

''(2) set priorities for, and fund, trials, such as randomized controlled trials, adaptive trials, and practical trials, observational studies, secondary data analysis in areas of clinical effectiveness research where evidence is lacking, systematic reviews of existing research, as necessary, and cost-effectiveness studies;

''(3) make recommendations regarding the findings of paragraphs (1) and (2);

''(4) study the differential outcomes of interventions on subpopulations within diseases;

''(5) use competitive award processes, including, but not solely, competitive peer review, and examine methods of rapid review cycles to reduce delays in funding decisions;

''(6) encourage the development and use of electronic health data to conduct clinical effectiveness research for the goal of improving clinical care delivery;

''(7) support the development of methodological standards to be used when conducting studies of clinical effectiveness and value in order to help en-

sure accurate and effective comparisons and update such standards not less frequently than annually;

''(8) include, and collaborate and consult with, as necessary, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine, as well as private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, professional societies, hospitals, academic institutions, and health foundations;

''(9) establish a public review or hearing process, which includes the Food and Drug Administration, to examine findings of studies;

''(10) determine the best approach to make available the findings resulting from subparagraphs (A) and (B) to relevant Federal agencies, private and public stakeholders in the health care system, and consumers;

''(11) provide a public forum for addressing conflicting guidelines and recommendations; and

''(12) submit annual reports to Congress on the research activities and findings of the FFRDC.

''(c) CLINICAL EFFECTIVENESS ADVISORY BOARD.—

''(1) ESTABLISHMENT AND FUNCTION.—The Director of the FFRDC shall establish, in conjunction with the Director of NIH and the Director of the AHRQ, an independent Clinical Effectiveness Advisory Board (referred to in this section as the 'Advisory Board'), to include not more than 20 appointed members, in order to provide expert advice and guidance on the research priorities of the FFRDC.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—Membership on the Advisory Board shall be comprised of—

''(i) representatives of the National Institutes of Health, the AHRQ, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine; and

''(ii) private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, profes-

sional societies, hospitals, academic institutions, and health foundations.

''(B) EXPERTS.—Membership on the Advisory Board shall consist of leading experts from diverse disciplinary areas, including physicians, social scientists, statisticians, health services researchers, economists, and other health care professionals.

''(C) TERMS.—Terms for members of the Advisory Board shall be fixed, multiyear, and staggered.

''(D) APPOINTMENT.—The members of the Advisory Board who are described in subparagraph (A)(ii) shall be appointed by the Director of the FFRDC, the Director of NIH, and the Director of the AHRQ.

''(E) CHAIR.—The Director of the AHRQ shall be chair of the Advisory Board.

''(3) CONFLICTS OF INTEREST.—Members of the Advisory Board shall disclose any financial, political, or organizational conflicts of interest in conducting the work of the Advisory Board.

''(4) DUTIES.—The Advisory Board shall—

''(A) recommend priorities for clinical effectiveness research to be undertaken by the

FFRDC, taking into consideration significant gaps in clinical effectiveness research, including research needs for information on subpopulations and diverse populations, including women, children, and racial and ethnic minorities, and on individuals with comorbid diseases;

''(B) identify existing and novel research designs and methods that may be considered by the FFRDC in conducting clinical effectiveness research;

''(C) review clinical effectiveness research methods;

''(D) review the FFRDC processes to determine whether the research conducted is objective, credible, developed through a transparent process that includes consultations with appropriate stakeholders, including consumers, patient organizations, and the public, and is clinically relevant;

''(E) make recommendations to the AHRQ and the National Institutes of Health for the effective dissemination of the findings of the FFRDC supported research to clinicians, payers, and consumers, and patient organizations; and

''(F) following the first year, review current and previous research agendas and make recommendations regarding research agendas.

''(5) INITIAL MEETING.—The initial meeting of the Advisory Board shall be no later than 6 months after the date of enactment of the Accelerating Cures Act of 2008.

''(6) ADVISORY NATURE OF BOARD.—The recommendations of the Advisory Board shall not be binding, but shall be considered by the Director of the FFRDC when developing the clinical effectiveness research agenda.

''(d) RESEARCH AGENDA.—The Director of the FFRDC shall establish the research agenda of the FFRDC, based on the priorities established by the Advisory Board, and shall update such agenda not less frequently than annually, and shall—

''(1) focus on—

''(A) identifying gaps in clinical effectiveness research relating to medical procedures, medical technologies, pharmaceuticals, health information technologies, and other relevant services and products that significantly contribute to health care outcomes and expenditures;

''(B) funding trials, studies, and reviews, and coordinating these efforts with ongoing research efforts in the Federal Government, academic institutions, and private entities to fill gaps identified under subparagraph (A);

''(C) synthesizing and reviewing clinical effectiveness research to fill gaps identified under subparagraph (A); and

''(D) supporting the development of an evidence base for the development of clinical care guidelines based on the results of clinical effectiveness research;

''(2) convene such working groups on clinical effectiveness research as the Director of the FFRDC determines necessary;

''(3) meet with members representing the National Institutes of Health, the AHRQ, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other Federal agencies, and the Institute of Medicine, as well as private payers, insurers, pharmaceutical and device companies, patient advocacy and public interest groups, professional societies, hospitals, academic in-

stitutions, practice based research networks health foundations, and the general public to promote communication and transparency; and

''(4) notify the public well in advance of any public meetings.

''(e) REPORTS.—

''(1) GUIDANCE OR RECOMMENDATIONS.—The Director of the FFRDC, in conjunction with the Director of NIH and the Director of the AHRQ, shall provide, not less frequently than annually, guidance or recommendations to health care providers, payers, and consumers, and Congressional committees of jurisdiction on the comparative effectiveness of health care services.

''(2) STATUS REPORTS.—The Director of the FFRDC shall provide annual status reports on the work of the FFRDC to Congressional committees of jurisdiction.

''(f) AVAILABILITY OF RESEARCH FINDINGS.—The Director of the FFRDC shall develop and identify efficient and effective methods of disseminating the findings of the clinical effectiveness assessments of medical procedures, technologies, and therapeutics, including by making these available on the Internet. Any relevant reports (including interim progress reports, draft final clinical effectiveness

reviews, and final progress reports on new research submitted for publication) on the results of clinical effectiveness research supported by the FFRDC shall be made available on the Internet, not later than 90 days after the report is completed.

''(g) EVALUATIONS AND REPORTS OF FFRDC.—The Director of NIH, in conjunction with the Director of the AHRQ, shall enter into regular agreements with entities, such as the Institute of Medicine, to—

''(1) evaluate the FFRDC and its functioning; and

''(2) produce reports on priority setting for the FFRDC, and on research methods developed and employed by the FFRDC, among other purposes.

"Subpart 3—Health Advanced Research Projects Program

"SEC. 499C. HEALTH ADVANCED RESEARCH PROJECTS PROGRAM.

''(a) ESTABLISHMENT.—There is established within the OPASI, a Health Advanced Research Projects Program (referred to in this section as the 'Research Projects Program') that shall be headed by a Director of the Research Projects Program who is appointed by the Director of NIH.

''(b) COMPOSITION.—The Research Projects Program shall be composed of portfolio managers in key health areas, which are determined by the Director of the Research Projects Program in conjunction with the Director of OPASI, the Director of NIH, and the Pathways to Cures Subcommittee established under section 499A.

''(c) GUIDANCE.—The Research Projects Program shall be guided by and shall undertake grand challenges that encourage innovative, multidisciplinary, and collaborative research across institutes and centers of the National Institutes of Health, across Federal agencies, and between public and private partners of the National Institutes of Health.

''(d) MANAGEMENT GUIDANCE.—The Research Projects Program shall be guided by the following management and organizing principles in directing the Research Projects Program:

''(1) Keep the Research Projects Program small, flexible, entrepreneurial, and non-hierarchical, and empower portfolio managers with substantial autonomy to foster research opportunities with freedom from bureaucratic impediments in administering the manager's portfolios.

''(2) Seek to employ the strongest scientific and technical talent in the Nation in research fields in which the Research Projects Program is working.

''(3) Rotate a significant portion of the staff after 3 to 5 years of experience to ensure continuous entry of new talent into the Research Projects Program.

''(4) Use, whenever possible, research and development investments by the Research Projects Program to leverage comparable matching investment and coordinated research from other institutes and centers of the National Institutes of Health, from other Federal agencies, and from the private and nonprofit research sectors.

''(5) Utilize supporting technical, contracting, and administrative personnel from other institutes and centers of the National Institutes of Health in administering and implementing research efforts to encourage participation, collaboration, and cross-fertilization of ideas across the National Institutes of Health.

''(6) Utilize a challenge model in Research Projects Program research efforts, creating a translational research model that supports fundamental research breakthroughs, early and late stage

applied development, prototyping, knowledge diffusion, and technology deployment.

''(7) Establish metrics to evaluate research success and periodically revisit ongoing research efforts to carefully weigh new research opportunities against ongoing research.

''(8) Support risk-taking in research pursuits and tolerate productive failure.

''(9) Ensure that revolutionary and breakthrough technology research dominates the Research Projects Program's research agenda and portfolio.

''(e) ACTIVITIES.—Using the funds and authorities provided to the Director of NIH, the Research Projects Program shall carry out the following activities:

''(1) The Research Projects Program shall support basic and applied health research to promote revolutionary technology changes that promote health.

''(2) The Research Projects Program shall advance the development, testing, evaluation, prototyping, and deployment of critical health products.

''(3) The Research Projects Program, consistent with recommendations of the Pathways to Cures Subcommittee established under section 499A, with the priorities of OPASI, and with the grand

challenges that encourage innovative, multidisciplinary, and collaborative research, shall emphasize—

"(A) translational research efforts, including efforts conducted through collaboration with the private sector, that pursue—

"(i) innovative health products that could address acute health threats such as a flu pandemic, spread of antibiotic resistant hospital acquired infections, or other comparable problems;

"(ii) remedies for diseases afflicting lesser developed countries;

"(iii) remedies for orphan diseases for which the for-profit sector is not finding new treatments;

"(iv) alternative technologies with significant health promise that are not well-supported in the system of health research, such as adjuvant technology or technologies for vaccines based on the innate immunological response; and

"(v) fast track development, including development through accelerated completion of animal and human clinical trials,

for emerging remedies for significant public health problems; and

''(B) other appropriate translational research efforts for critical health issues.

''(4) The Research Projects Program shall utilize funds to provide support to outstanding research performers in all sectors and encourage cross-disciplinary research collaborations that will allow scientists from fields such as information and computer sciences, nanotechnology, chemistry, physics, and engineering to work alongside top researchers with more traditional biomedical backgrounds.

''(5) The Research Projects Program shall provide selected research projects with single-year or multiyear funding and require researchers for such projects to provide interim progress reports, including milestones on progress, to the Research Projects Program on not less frequently than a biannual basis.

''(6) The Research Projects Program shall award competitive, merit-reviewed grants, cooperative agreements, or contracts to public or private entities, including businesses, federally funded research and development centers, and universities.

''(7) The Research Projects Program shall provide advice to the Director of OPASI concerning funding priorities.

''(8) The Research Projects Program may solicit proposals for competitions to address specific health vulnerabilities identified by the Director of NIH and the Director of OPASI and award prizes for successful outcomes.

''(9) The Research Projects Program shall periodically hold health research and technology demonstrations to improve contact among researchers, technology developers, vendors, and acquisition personnel.

''(10) The Research Projects Program shall carry out other activities determined appropriate by the Director of NIH.

''(f) EMPLOYEES.—

''(1) HIRING.—The Director of the Research Projects Program, in hiring employees for positions with the Research Projects Program, shall have the same hiring and management authorities as described in section 1101 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (5 U.S.C. 3104 note).

''(2) TERM.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term of such appointments for employees of the Research Projects Program may not exceed 5 years.

''(B) EXTENSION.—The Director of the Research Projects Program may, in the case of a particular employee of the Research Projects Program, extend the term to which employment is limited under subparagraph (A) by not more than 2 years if the Director of the Research Projects Program determines that such action is necessary to promote the efficiency of the Research Projects Program.

''(g) FLEXIBILITY.—The Director of the Research Projects Program shall have the authority to flexibly fund projects, including the prompt awarding, releasing, enhancing, or withdrawal of monies in accordance with the assessment of the Research Projects Program and project manager.

"Subpart 4—Clinical Trials

"SEC. 499D. GRANTS FOR QUALITY CLINICAL TRIAL DESIGN AND EXECUTION.

''The Director of OPASI—

''(1) shall award grants for clinical trial design and execution to academic centers and practice-

based research networks to fund multidisciplinary clinical research teams, which clinical research teams may be composed of members who include project managers, clinicians, epidemiologists, social scientists, and clinical research coordinators; and

''(2) may award grants for clinical trial design and execution to researchers.

"SEC. 499D–1. STREAMLINING THE REGULATORY PROCESS GOVERNING CLINICAL RESEARCH.

''(a) ESTABLISHMENT OF CENTRALIZED INSTITUTIONAL REVIEW BOARDS.—

''(1) IN GENERAL.—

''(A) ESTABLISHMENT AND OVERSIGHT.—The Director of OPASI shall appoint a Director of Centralized Institutional Review Boards (referred to in this part as the 'Director of CIRBs') who shall establish and oversee the functioning and progress of a series of Centralized Institutional Review Boards (referred to in this part as 'CIRBs') to serve as human subject safety and well-being custodians for multi-institutional clinical trials that are funded partially or in full by public research dollars.

''(B) WORK WITH FDA.—The Director of CIRBs shall work with the Commissioner of

Food and Drugs to make regulations governing multi-site clinical trials and the regulatory requirements of the Food and Drug Administration more consistent in order to reduce barriers to commercialization of new treatments.

''(2) EXISTING GUIDELINES AND BEST PRACTICES.—CIRBs shall be established in accordance with professional best practices and Good Clinical Practice (GCP) guidelines so that institutions involved in multi-institutional studies may—

''(A) use joint review;

''(B) rely upon the review of another qualified institutional review board; or

''(C) use similar arrangements to avoid duplication of effort and to assure a high-quality of expert oversight.

''(b) HOUSED.—Each CIRB shall be housed—

''(1) at the institute or center of the National Institutes of Health with expertise on the subject of the clinical trial; or

''(2) at a public or private institution with comparable organizational capacity, such as the Department of Veterans Affairs.

''(c) SERVICE.—The use of CIRBs shall be available, as appropriate, at the request of public or private institu-

tions and shall be funded through user fees of the CIRBs or the National Institutes of Health's funds.

''(d) REVIEW PROCESS.—

''(1) IN GENERAL.—Each CIRB shall review research protocols and subject informed consent forms to ensure the protection of safety and well-being of research participants enrolled in multi-institutional clinical trials.

''(2) PROCESS.—The CIRB review process shall consist of contractual agreements between the CIRB and the study sites of multi-institutional clinical trials. The CIRB shall act on behalf, in whole or in part, of the bodies ordinarily responsible for the safety of research subjects in a locality. In the case in which a locality does not have such a body, the locality shall depend solely on the CIRB to oversee the protection of human subjects and the CIRB shall assume responsibility for ensuring adequate assessment of the local research context.

''(e) RESEARCH APPLICATIONS.—

''(1) IN GENERAL.—Each CIRB shall review and package research applications for facilitated electronic review by local institutional review boards participating in a multi-institutional clinical trial.

''(2) CIRB REVIEW.—A local institutional review board may accept or reject a CIRB review. In the case in which a local institutional review board accepts a CIRB review, the CIRB shall assume responsibility for annual, amendment, and adverse event reviews. If a local institutional review board elects to decline participation in the CIRB, the local institutional review board shall appoint a liaison to the CIRB.

''(f) WORK IN CONCERT.—In the case in which a local institutional review board works in concert with a CIRB, the local institutional review board shall be responsible for taking into consideration local characteristics (including ethnicity, educational level, and other demographic characteristics) of the population from which research subjects will be drawn, which influence, among other things, whether there is sound selection of research subjects or whether adequate provision is made to minimize risks to vulnerable populations.

''(g) COMMUNICATION OF IMPORTANT INFORMATION.—Each CIRB shall regularly communicate important information in electronic form to the local institutional review boards or, in cases where a local institutional review board does not exist, to the principal investigator,

including regular safety updates or requirements to change a research protocol in order to improve safety.

''(h) COORDINATION.—Each CIRB shall fully coordinate with the institute or center of the National Institutes of Health that has specialized knowledge of the research area of the clinical trial. Other Federal agencies and private entities undertaking clinical trials may contract with the National Institutes of Health to use a CIRB.

''SEC. 499D–2. CLINICAL RESEARCH STUDY AND CLINICAL TRIAL.

''(a) IN GENERAL.—The Director of NIH shall—

''(1) commission the Institute of Medicine to study the rules that protect patient safety and anonymity so that in a contemporary clinical research context, a better balance can be achieved between clinical research promotion and regulatory requirements governing research subject safety and privacy;

''(2) examine informed consent processes; and

''(3) request that the Institute of Medicine issue a written report not later than 18 months after the date of enactment of the Accelerating Cures Act of 2008 that shall—

''(A) consider changes to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) and the amendments

made by such Act that further promote the clinical research endeavor; and

''(B) include recommendations for changes that shall not be limited to legislation but shall include changes to healthcare systems, including health information technology, and to researcher practice that facilitate the clinical research endeavor.

''Subpart 5—Training Clinical and Translational Researchers of the Future

''SEC. 499E. TRAINING TRANSLATIONAL AND CLINICAL RESEARCHERS OF THE FUTURE.

''(a) IN GENERAL.—

''(1) ESTABLISHMENT OF PROGRAM.—The Director of OPASI shall establish training programs to increase the number of, and maintain existing, translational and clinical researchers, including researchers trained in community-based research.

''(2) PURPOSE.—The purpose of the training programs described in paragraph (1) shall be to train a cadre of researchers in core competencies in the translational and clinical sciences for the ultimate goal of improving healthcare delivery, healthcare options to the public, the use of healthcare by patients, and healthcare outcomes.

''(b) GRANTS.—

''(1) IN GENERAL.—The Director of OPASI shall award grants to, and enter into contracts with, public and nonprofit educational entities to establish, strengthen, or expand training programs for researchers to be trained in the translational and clinical sciences.

''(2) AWARDING OF GRANTS.—The Director of OPASI shall award grants to, and enter into contracts with, applicants that—

''(A) support multidisciplinary approaches in training;

''(B) utilize collaborative strategies for conducting research across various disciplines to translate basic science discoveries; and

''(C) train researchers focused on improving care and patient outcomes.

''(3) REQUIRED USE OF FUNDS.—The Director of OPASI shall award grants to, and enter into contracts with, entities for the following purposes:

''(A) To establish training programs for M.D. and Ph.D. researchers in translational or clinical research.

''(B) To establish training programs for individuals at predoctoral levels, including those

in medical school, and for allied health professionals, in translational or clinical research.

"(C) To establish training programs for nurses in translational and clinical research.

"(D) To strengthen or expand existing training programs for translational or clinical researchers.

"(E) To establish a wide range of training programs, including one-year training programs, summer programs, pre- and postdoctoral clinical or translational research fellowships, and advanced research training programs for mid-career researchers and clinicians.

"(F) To provide stipends and allowances, including for travel and subsistence expenses, in amounts the Director of OPASI determines appropriate, to support the training of translational or clinical researchers.

"(G) To provide financial assistance to public and nonprofit educational entities for the purpose of supporting the training of translational or clinical researchers, through clinical education, curricula, and technological support, and other measures.

''(H) To measure the impact of the translational and clinical research training programs on the biomedical sciences and on clinical practice.

''(c) FUNDS AVAILABLE.—The Director of OPASI may make funds available to support training programs for translational or clinical researchers at the National Institutes of Health for entities awarded grants or contracts under subsection (b).

''(d) NOVEL AND BEST PRACTICES.—The Director of OPASI shall convene, on not less frequently than a biannual basis, members of training institutions to share novel and best practices in training translational or clinical researchers.

''(e) TRAINING.—A trainee of a program funded under a grant or contract awarded under this section may conduct part of the trainee's training at the Health Advanced Research Projects Program.

''(f) CONSISTENT DEFINITIONS AND METHODOLOGIES.—For the purposes of funding training programs for clinical researchers, the Director of NIH shall develop consistent definitions and methodologies to classify and report clinical research.

"SEC. 499E–1. TRANSLATIONAL RESEARCH TRAINING PROGRAM.

''The Director of NIH shall ensure that each institute and center of the National Institutes of Health has established, or contracted for the establishment of, a translational research training program at the institute or center.

"Subpart 6—The 'Valley of Death'

"SEC. 499F. SMALL BUSINESS PARTNERSHIPS.

''(a) IN GENERAL.—An independent advisory board shall be established at the National Academy of Sciences to conduct periodic evaluations of the Small Business Innovation Research program (referred to in this subpart as the 'SBIR program') and the Small Business Technology Transfer program (referred to in this subpart as the 'STTR program') of the Office of Extramural Research in the Office of the Director of the National Institutes of Health for the purpose of improving management of the programs through data-driven assessment. The advisory board shall consist of the Director of NIH, the Director of the SBIR program, senior National Institutes of Health agency managers, university and industry experts, and program stakeholders.

''(b) SBIR AND STTR GRANTS AND CONTRACTS.—

''(1) IN GENERAL.—

"(A) PROGRAM MANAGERS WITH SUFFICIENT EXPERTISE.—Not less than 25 percent of the grants and contracts awarded by each of the SBIR and STTR programs shall be awarded on a competitive basis by an SBIR or STTR program manager who has sufficient managerial, technical, and translational research expertise to expertly assess the quality of a SBIR or STTR proposal.

"(B) EXPERIENCE OF PROGRAM MANAGERS.—In hiring new SBIR or STTR program managers, the Director of NIH shall consider experience in commercialization or industry.

"(C) EMPHASIS ON GRANT AND CONTRACT AWARDS.—In awarding grants and contracts under the SBIR program and the STTR program—

"(i) each SBIR and STTR program manager shall place an emphasis on applications that identify from the onset products with commercial potential to prevent, diagnose, and treat diseases, as well as promote health and well-being; and

''(ii) risk-taking shall be supported and productive failure shall be tolerated.

''(2) EXAMINATION OF COMMERCIALIZATION AND OTHER METRICS.—The independent advisory board described in subsection (a) shall evaluate the success of the requirement under paragraph (1)(A) by examining increased commercialization and other metrics, to be determined and collected by SBIR and STTR programs.

''(3) SUCCESS.—Each recipient of a SBIR or STTR grant or contract, as a condition of receiving such grant or contract, shall report to the SBIR or STTR program—

''(A) whether there was eventual commercial success of the product developed with the assistance of the grant or contract; and

''(B) on other metrics as determined by the SBIR or STTR program to capture broader measures of success.

''(c) POTENTIAL PURCHASERS OR INVESTORS.—The SBIR and STTR programs shall administer nonpeer review grants and contracts pursuant to this section through program managers who shall place special emphasis on partnering grantees and entities awarded contracts from the very beginning of the research and development proc-

ess with potential purchasers or investors of the product, including large pharmaceutical or biotechnology companies, venture capital firms, and Federal agencies (including the National Institutes of Health).

''(d) PHASE I AND II.—The SBIR and STTR programs shall reduce the time period between Phase I and Phase II funding of grants and contracts under the SBIR and STTR programs to—

''(1) 6 months; or

''(2) less than 6 months if the grantee or entity awarded a contract demonstrates that the grantee or entity awarded a contract has interest from third parties to buy or fund the product development with the grant or contract.

''(e) PHASE III.—A SBIR or STTR program manager may petition the Director of NIH for Phase III funding of a grant or contract for a project that requires a boost to finalize procurement of a product. The maximum funding for Phase III funding shall be $2,000,000 for each of a maximum of 2 years. Such Phase III funding may come from the Common Fund of the NIH.

''(f) EVALUATION AND REPORTING REQUIREMENTS.—In order to enhance the evidence base guiding SBIR and STTR program decisions and changes, the SBIR and STTR programs shall—

''(1) conduct regular internal and external evaluations of the program;

''(2) review current data collection methods for the purpose of identifying gaps and deficiencies, and develop a formal plan for evaluation and assessment of program success, including operational benchmarks for success; and

''(3) conduct a review on the number of SBIR and STTR awards made to women and minorities and develop outreach and review strategies to increase the number of awards to women and minorities.

''(g) PILOT PROGRAMS.—

''(1) IN GENERAL.—The SBIR and STTR programs may initiate pilot programs, based on the development of a formal mechanism for designing, implementing, and evaluating pilot programs, to spur innovation and to test new strategies that may enhance the effectiveness of the program.

''(2) CONSIDERATIONS.—The SBIR and STTR programs shall consider, among other issues, conducting pilot programs on including individuals with commercialization experience in study sections, hiring individuals with industry experience for staff positions, separating the commercial and scientific re-

view processes, and examining the impact of the trend toward larger awards on the overall program.

''(h) ELECTRONIC RECORDS.—

''(1) IN GENERAL.—The SBIR and STTR programs shall keep a publicly accessible electronic record of all SBIR or STTR investments in research and development.

''(2) CONTENT OF RECORD.—The record described in paragraph (1) shall include, at a minimum, the following information:

''(A) The grantee or entity awarded a grant or contract.

''(B) A description of the research being funded.

''(C) The amount of money awarded in each phase of SBIR or STTR funding.

''(D) If applicable, the purchaser of the product, current use of the product, and estimated annual revenue resulting from the procurement.

''(E) Dates of Phases I, II, and III awards, as applicable.

''(F) Other metrics as determined by the SBIR or STTR programs.

''(i) MEETING.—The Director of NIH shall convene a meeting, not less frequently than annually, consisting of the National Institutes of Health SBIR/STTR program coordinator or manager and each institute and center of the National Institutes of Health to share best practices, report on program activities, and review existing policies.

''(j) REPORT TO CONGRESS.—The Director of NIH shall submit an annual report to Congress and the independent advisory board described in subsection (a) on the SBIR and STTR programs' activities.

"SEC. 499F–1. RAPID ACCESS TO INTERVENTION DEVELOPMENT.

''(a) IN GENERAL.—The Director of OPASI shall expand the existing Rapid Access to Intervention Development Program (referred to in this subpart as the 'RAID') that—

''(1) is designed to assist the translation of promising, novel, and scientifically meritorious therapeutic interventions to clinical use by helping investigators navigate the product development pipeline;

''(2) shall aim to remove barriers between laboratory discoveries and clinical trials of new molecular therapies, technologies, and other clinical interventions;

''(3) shall aim to progress, augment, and complement the innovation and research conducted in private entities to reduce duplicative and redundant work using public funds;

''(4) shall coordinate with the offices of the National Institutes of Health that promote translational research in the pre-clinical phase across the National Institutes of Health;

''(5) shall identify, for the OPASI, those research projects with promise for clinical application or commercialization; and

''(6) shall, in collaboration with the Translational Development Program for New Innovations, facilitate the translation of new innovations through the development process.

''(b) PROJECTS.—

''(1) IN GENERAL.—The RAID, in collaboration with the Director of OPASI, shall carry out a program that shall select, in accordance with paragraph (2), projects of eligible entities to receive access to laboratories, facilities, and other support resources of the National Institutes of Health for the preclinical development of drugs, biologics, diagnostics, and devices.

''(2) SELECTION.—Not less than 25 percent of the projects selected under paragraph (1) shall be selected on a competitive basis—

''(A) by a program manager with sufficient managerial, technical, and translational research expertise to adequately assess the quality of a project proposal; or

''(B) from a peer review process.

''(3) ELIGIBLE ENTITIES.—In this subsection, the term 'eligible entity' means—

''(A) a university researcher;

''(B) a nonprofit research organization; or

''(C) a firm of less than 100 employees in collaboration with 1 or more universities or nonprofit organizations such as a community health center.

''(4) DISCONTINUE SUPPORT.—The RAID may discontinue support of a project if the project fails to meet commercialization success criteria established by the RAID.

''(c) DISCOVERIES FROM LAB TO CLINICAL PRACTICE.—The program under subsection (b) shall accelerate the process of bringing discoveries in medical technology and drugs from the laboratory to the clinic.

''(d) ONGOING REVIEW.—The RAID shall review, on an ongoing basis, potential products and may not support products past the proof-of-principle stage.

"SEC. 499F–2. TRANSLATIONAL DEVELOPMENT PROGRAM FOR NEW INNOVATIONS.

''(a) IN GENERAL.—The Director of OPASI shall develop a Translational Development Program for New Innovations to guide institutions of higher education, small businesses, for-profits, nonprofits, or other such entities through the translational research development process by facilitating the following:

''(1) Triage screening of applications for promising innovations expected to reduce disease incidence, morbidity, and mortality.

''(2) Outlining the tasks, timelines, and costs required to navigate and complete the development process for such innovations.

''(3) Providing project management support for the recommended development tasks.

''(4) Interfacing with the Food and Drug Administration and the entity to devise a plan that safely and rapidly brings new drugs, biologics devices, diagnostics, and other interventions to approval.

''(b) COORDINATION.—The Translational Development Program for New Innovations shall—

''(1) collaborate with the RAID; and

''(2) be comprised of personnel with extensive experience with investigational new drug applications and in commercialization.

"Subpart 7—Translational Research Fund

"SEC. 449G. TRANSLATIONAL RESEARCH FUND.

''(a) ACCOUNT.—There is established an account to be known as the Translational Research Fund that shall consist of amounts appropriated for translational research priorities as described in subsection (b). Such account shall not be funded from amounts otherwise provided to the National Institutes of Health.

''(b) AUTHORIZATION OF APPROPRIATIONS.—For each fiscal year, there is authorized to be appropriated for the Translational Research Fund to carry out the activities under this part an amount equal to the amount set aside for the Common Fund for such fiscal year.

''(c) ALLOTMENT TO HEALTH ADVANCED RESEARCH PROJECTS PROGRAM.—Not less than half of the annual amount appropriated for the Translational Research Fund shall be allotted to the Health Advanced Research Projects Program.''.

SEC. 5. APPLICATION OF RESEARCH REQUIREMENT.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404I. APPLICATION OF RESEARCH REQUIREMENT.

''Each application for, and summary of, a project, grant, or contract from the National Institutes of Health, shall include a statement on the possible application of the research for detecting, treating, or curing a health condition or disease state.''.

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