109TH CONGRESS
1ST SESSION

S. 2104

To amend the Public Health Service Act to establish the American Center for Cures to accelerate the development of public and private research efforts towards tools and therapies for human diseases with the goal of early disease detection, prevention, and cure, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 14, 2005

Mr. REID (for Mr. LIEBERMAN (for himself, Mr. COCHRAN, Mr. CARPER, and Mrs. HUTCHISON)) 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 establish the American Center for Cures to accelerate the development of public and private research efforts towards tools and therapies for human diseases with the goal of early disease detection, prevention, and cure, 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 ''American Center for Cures Act of 2005''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. 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 $28,000,000,000.

(2) The mission of the NIH is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

(3) The pace of knowledge application to promote health and reduce disease can be influenced through strategic funding and reorganization of some aspects of the traditional research endeavor. This process is known as translational research investment.

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

(A) to acute man-made or natural health threats;

(B) to the complexity and multi-disciplinary nature of chronic diseases, which are responsible for 7 out of every 10 deaths in the United States and for more than 70 percent of

the $1,700,000,000,000 spent in the United States on health care each year; and

(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, and medical tools for pediatric populations.

(5) Key components of the translational research process include research prioritization, an expert workforce, multi-disciplinary collaborative work, facilitated information exchange, 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 involvement of private entities early on in the translational research endeavor that are skilled in the manufacturing and marketing process.

SEC. 4. AMERICAN CENTER FOR CURES.

(a) AMERICAN CENTER FOR CURES.—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—AMERICAN CENTER FOR CURES

"SEC. 499A. DEFINITIONS.

''In this part:

''(1) CENTER.—The term 'Center' means the American Center for Cures established under section 499B.

''(2) COUNCIL.—The term 'Council' means the Cures Council established under section 499B.

''(3) DIRECTOR.—The term 'Director' means the Director of the American Center for Cures.

''(4) INCUBATOR.—The term 'incubator' means an economic development organization designed to accelerate the growth and success of entrepreneurial individuals, concepts, and companies.

''(5) RESEARCH TOOL.—The term 'research tool' means a resource that scientists use in their laboratories that has no immediate therapeutic or diagnostic value, including cell lines, monoclonal antibodies, reagents, laboratory equipment and machines, databases, and computer software.

''(6) TEST BED.—The term 'test bed' means the pilot environment to prototype innovation.

''(7) TRANSLATIONAL RESEARCH.—The term 'translational research' means investigation in which knowledge obtained from fundamental research such as with genes, cells, or animals, is transformed through early and late stage development prototyping and testing into diagnostic or therapeutic

interventions that can be applied to the treatment or prevention of disease or frailty.

"SEC. 499B. ESTABLISHMENT OF AMERICAN CENTER FOR CURES.

"(a) IN GENERAL.—There is established within the National Institutes of Health an American Center for Cures—

"(1) whose mission shall be to increase the capacity of the National Institutes of Health to promote translational research, including between the institutes and centers of the National Institutes of Health, between the National Institutes of Health and other Federal agencies, and between grantees and business partners of the National Institutes of Health, so as to speed the development of effective therapies, diagnostics, and cures essential to human health and well being;

"(2) that shall formulate and implement a strategy for the Nation's translational research investment, which strategy shall include—

"(A) a prioritization of biomedical research on diseases based on disease burden and research promise; and

"(B) funding for innovative, multidisciplinary, and collaborative research across the

institutes and centers of the National Institutes of Health, across Federal agencies, and between public and private partners of the National Institutes of Health;

''(3) that shall be guided, in part, by a series of 'Grand Challenges' formulated through collaboration between the Director of Cures and the Council, that shall be strategic challenges that direct the public and private health research community towards collaborative multi-staged projects that have the potential to transform the healthcare environment, such as—

''(A) the creation of laboratory diagnostics that enable the Nation to detect quickly and accurately acute health threats such as an avian flu pandemic or a bioterrorism attack;

''(B) a focus on therapeutic delivery systems targeting individual viruses or hard to reach cells in the body, such as the brain, using advances in nanotechnology;

''(C) accelerated research into the potential of stem cells to replace the form and function of tissues lost to patients suffering from diseases such as spinal cord injury, Parkinson's disease, and insulin-dependent diabetes;

''(D) creation of a biomedical informatics infrastructure that can organize the human genome and the proteins for which the genome codes in ways that scientists can better understand the genetic contribution to phenotypic disease;

''(E) the elaboration of adjuvant technology that can bolster the effectiveness of vaccines;

''(F) development of antigen sparing vaccines such as those based on triggering the innate immune response;

''(G) development of rapid vaccine manufacturing capacity from new production methods such as viral cell culture or bioengineering technology;

''(H) creation of a fast track clinical trial infrastructure that incorporates a national doctor and patient registry, centralized investigational review boards, electronic medical records, and other health information technologies;

''(I) a focus on addressing less profitable conditions for which research and development efforts are insufficient, such as—

''(i) orphan, small population, and third world diseases;

''(ii) antibiotic resistance;

''(iii) a threat of a flu epidemic or pandemic;

''(iv) diseases associated with social stigma such as depression and seizure disorders; or

''(v) other comparable problems;

''(J) a commitment by researchers and manufacturers from all sectors to develop vaccines for the world's most deadly infectious diseases, including HIV, tuberculosis, and malaria; and

''(K) other appropriate challenges; and

''(4) that shall have other appropriate purposes.

''(b) DIRECTOR OF THE CENTER AND THE DIRECTOR OF NIH.—

''(1) IN GENERAL.—The Center shall be administered by a Director of Cures who shall be appointed by the President with the advice and consent of the Senate. The Director of the NIH, in consultation with the Council, shall recommend candidates for the Director of Cures to the President.

''(2) ACTIVITIES.—

''(A) DIRECTOR OF NIH.—The Director of NIH shall—

''(i) work with the Director of Cures to promote translational research efforts; and

''(ii) serve as a co-chair of the Council.

''(B) DIRECTOR OF CURES.—

''(i) ACCELERATION FUND.—

''(I) IN GENERAL.—The Director of Cures shall have at the Director's disposal an annual acceleration fund to provide support for research and development of breakthrough biomedical discoveries and to carry out the purpose of the Center. Amounts in the fund may be available through grants, contracts, and cooperative agreements to public sector entities, private sector entities, and non-governmental organizations. The Director of Cures shall allocate not less than ½ of the acceleration funds to the Health Advanced Research Projects Agency described in subpart 2. The

remainder of such funds shall be available to the Federally Funded Research and Development Centers described in subpart 1 and other activities of the Center.

''(II) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to fund the acceleration fund under subclause (I) $5,000,000,000 for fiscal year 2007 and each succeeding fiscal year.

''(ii) DIRECT OTHER OFFICES.—The Director of Cures shall direct other offices within the Center that are established under this part.

''(c) COUNCIL.—

''(1) ESTABLISHMENT.—There is established within the Center a Cures Council that shall convene not less frequently than twice a year to help advise and direct the translational research efforts of the Center.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The Council shall be composed of the following members:

''(i) The Director of NIH and the Director of Cures who shall be Council co-chairs.

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

''(iii) Heads from not less than 9 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.

''(B) OTHER MEMBERS.—Membership of the Council shall also include not fewer than 3 leaders from the small business community, 3 leaders from large pharmaceutical or biotechnology companies, and 3 leaders from academia, all of whom shall be appointed by the President.

''(3) SUBCOMMITTEES.—The Council or the Council co-chairs may form subcommittees of the Council as needed.

''(4) RECOMMENDATIONS; COORDINATION.—The Council shall make recommendations that help the Director of Cures set research priorities for the Center. In making recommendations, the Council shall consider risk and burden of disease as well as lines of research uniquely poised to deliver effective diagnostics and therapies. The Council shall also coordinate research priorities in, and ensure sharing of

research agendas among, the institutes and centers of the National Institutes of Health.

''(5) OFFICE OF INTRAMURAL RISK OPPORTUNITY AND MAPPING.—The Council shall be aided by the Office of Intramural Risk Opportunity and Mapping of the Office of Technology Transfer of the Center established in subpart 5.

''(6) ANNUAL ASSESSMENT.—The Council shall make an annual assessment of the priorities and progress of the Center and shall make the assessment available to the public in written and electronic form.

''(d) BUDGET AND FUNDS.—The Director of Cures shall—

''(1) prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the Center, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Council; and

''(2) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Center.

"Subpart 1—Federally Funded Research and Development Centers

"SEC. 499C. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS.

''(a) IN GENERAL.—The Director of Cures is authorized to establish 1 or more Federally Funded Research and Development Centers that shall carry out activities related to the mission of the Center, as described in section 499B(a)(1).

''(b) DUTIES.—

''(1) IN GENERAL.—The Federally Funded Research and Development Centers shall serve as sites for the performance of multidisciplinary and cross-disciplinary research and shall—

''(A) establish, as appropriate, technology test beds and incubators;

''(B) utilize cooperative agreements with the private sector; and

''(C) conduct large-scale multidisciplinary translational research projects in health or disease areas that are essential to medical advancement but lack adequate private sector funding.

''(2) CONSULTATION.—In carrying out the duties described in paragraph (1), the Federally Funded Research and Development Centers shall consult

widely with representatives from private industry, institutions of higher education, nonprofit institutions, other Federal governmental agencies, and other federally funded research and development centers.

''(c) COMPETITION.—The Director of Cures shall ensure that competitive mechanisms are used to select and to promote the ongoing quality and performance of the Federally Funded Research and Development Centers.

''(d) TERM OF FUNDING.—Federally Funded Research and Development Centers shall be funded for not more than 7 years, after which time the Federally Funded Research and Development Centers' re-funding shall be contingent upon approval by the Director of Cures and the Council.

''(e) REPORTS.—Each Federally Funded Research and Development Center receiving funding under this section shall submit a biannual report to the Director and the appropriate committees of Congress on the activities carried out by the Federally Funded Research and Development Center under this section.

''(f) FUNDING FOR SUPPORT.—For any fiscal year, the Director of Cures may use not more than 25 percent of the funds available to the Director under the acceleration fund under section 499B(b)(2)(B)(i)(II) to establish

Federally Funded Research and Development Centers under this section.

"Subpart 2—Health Advanced Research Projects

"SEC. 499D. HEALTH ADVANCED RESEARCH PROJECTS AGENCY.

''(a) ESTABLISHMENT.—There is established within the Center a Health Advanced Research Projects Agency (referred to in this section as the 'Research Projects Agency') that shall—

''(1) carry out activities related to the mission of the Center, as described in section 499B(a)(1); and

''(2) be headed by a Director of the Research Projects Agency who is appointed by the Director of Cures.

''(b) COMPOSITION.—The Research Projects Agency shall be composed of not more than 100 portfolio managers in key health areas, which areas are determined by the Director of the Research Projects Agency in conjunction with the Director of Cures and the Council.

''(c) GUIDANCE.—The Research Projects Agency shall be guided by and shall undertake grand challenges formulated by the Center that encourage innovative, multi-disciplinary, 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 Agency shall be guided by the following management and organizing principles in directing the Research Projects Agency:

''(1) Keep the Research Projects Agency 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 Agency 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 Agency.

''(4) Use whenever possible research and development investments by the Research Projects Agency 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 non-profit 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 effort to encourage participation, collaboration, and cross-fertilization of ideas across the National Institutes of Health.

''(6) Utilize a challenge model in Research Projects Agency 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) Tolerate risk-taking in research pursuits.

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

''(e) ACTIVITIES.—Using the funds and authorities provided to the Director of Cures, and the authorities pro-

vided to the Director of NIH, the Research Projects Agency shall carry out the following activities:

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

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

''(3) The Research Projects Agency, consistent with recommendations of the Council, with the priorities of the Director of Cures, and with the need to discuss challenges described in section 499B(a)(3), shall emphasize—

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

''(i) innovative health products that could significantly and promptly 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 and small population diseases;

''(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 Agency 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 Agency shall provide selected research projects with single-year or

multi-year funding and require researchers for such projects to provide interim progress reports to the Research Projects Agency on not less frequently than a biannual basis.

''(6) The Research Projects Agency 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 Agency shall provide advice to the Director of Cures concerning funding priorities.

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

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

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

''(f) EMPLOYEES.—

''(1) HIRING.—The Research Projects Agency, in hiring employees for positions with the Research Projects Agency, 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 Agency may not exceed 5 years.

''(B) EXTENSION.—The Director of the Research Projects Agency may, in the case of a particular employee of the Research Projects Agency, extend the term to which employment is limited under subparagraph (A) by up to 2 years if the Director of the Research Projects Agency determines that such action is necessary to promote the efficiency of the Research Projects Agency.

''(g) FLEXIBILITY.—The Research Projects Agency 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 Agency and project manager.

''(h) FUNDING.—The Research Projects Agency shall utilize funds received from the acceleration fund, described in section 499B(b)(2)(B)(i), for the Agency's research and development activities. There is authorized to be appropriated from such fund $2,500,000,000 to carry out the activities of the Research Projects Agency.

''Subpart 3—Clinical Trials

''SEC. 499E. INCREASING RESEARCH STUDY PARTICIPATION.

''The Director of NIH shall establish a national clinical study registry within the National Library of Medicine of the National Institutes of Health in accordance with section 499H. The Center shall publicize the registry, with attention given to minority groups that are frequently underrepresented in clinical trials.

''SEC. 499E–1. GRANTS FOR QUALITY CLINICAL TRIAL DESIGN AND EXECUTION.

''The Director of Cures—

''(1) shall award grants for clinical trial design and execution to academic centers to fund multi-disciplinary clinical research teams, which clinical research teams may be composed of members who in-

clude project managers, clinicians, epidemiologists, social scientists, and nursing staff; and

''(2) may award grants for clinical trial design and execution to researchers from small firms with highly promising novel therapeutic entities.

''SEC. 499E–2. STREAMLINING THE REGULATORY PROCESS GOVERNING CLINICAL RESEARCH.

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

''(1) IN GENERAL.—The Director of Cures shall establish a series of Centralized institutional Review Boards (referred to in this section 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.

''(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 aimed 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 institutions and shall be funded through user fees of the CIRBs or the Center's funds.

''(d) REVIEW PROCESS.—

''(1) IN GENERAL.—Each CIRB shall review research protocols and informed consent to ensure the protection and safety 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) LOCAL REVIEW.—Local institutional review board review may be performed by a subcommittee of the local institutional review board that is empowered to make decisions in a timely manner.

''(3) 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.

''(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 changes in research protocol 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 Center to use a CIRB.

''SEC. 499E–3. TRAINING CLINICAL RESEARCHERS OF THE FUTURE.

''The Center shall augment the National Institutes of Health's investment into programs dedicated to developing the clinical research workforce for tomorrow. The programs shall include:

''(1) The National Institutes of Health's Mentored Patient-Oriented Research Career Development Award to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research.

''(2) The National Institutes of Health's award to encourage mentorship among particularly talented early- and mid-career investigators doing clinical research who want to train new investigators.

''(3) The National Institutes of Health grants to help institutions develop curricula for clinical researchers leading to a clinical science certificate or master's degree.

''(4) The National Institutes of Health grants to fund participants in clinical science programs, including clinical science certificates or clinical science masters' degrees.

''SEC. 499E–4. CLINICAL RESEARCH STUDY AND CLINICAL TRIAL.

''The Director of NIH shall—

''(1) commission the Institute of Medicine of the National Academies 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 requirement governing research subject safety and privacy; and

''(2) request that the Institute of Medicine issue a written report not later than 18 months after the date of enactment of this part 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 health care systems and to researcher practice that facilitate the clinical research endeavor.

''SEC. 499E–5. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i)—

''(1) $100,000,000 to carry out section 499E–1(1) for fiscal year 2007 and each succeeding fiscal year;

''(2) $50,000,000 to carry out section 499E–2 for fiscal year 2007 and each succeeding fiscal year;

''(3) $200,000,000 to carry out section 499E–3 for fiscal year 2007 and each succeeding fiscal year; and

''(4) $2,500,000 to carry out section 499E–4.

''Subpart 4—Valley of Death

''SEC. 499F. SMALL BUSINESS PARTNERSHIPS.

''(a) ESTABLISHMENT OF THE OFFICE OF BIOSCIENTIFIC ENTERPRISE DEVELOPMENT.—

''(1) ESTABLISHMENT.—There is established within the Office of Technology Transfer of the Center (as established in subpart 5) an Office of Bioscientific Enterprise Development (referred to in the subpart as the 'OBED').

''(2) TRANSFERS.—

''(A) IN GENERAL.—The OBED shall include the functions (including related personnel and resources) of the following programs of the Office of Extramural Research in the Office of the Director of the National Institutes of Health:

''(i) The Small Business Innovation Research program (referred to in this subpart as the 'SBIR').

''(ii) The Small Business Technology Transfer program (referred to in this subpart as the 'STTR').

''(B) TIME FOR TRANSFERS.—The Secretary shall ensure that the programs described in subparagraph (A) are transferred to the OBED not later than 6 months after the date of enactment of this part.

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

''(1) IN GENERAL.—Not less than 35 percent of the grants and contracts awarded by the SBIR and STTR shall be awarded on a competitive basis by an OBED program manager with sufficient managerial, technical, and translational research expertise to expertly assess the quality of a SBIR or STTR proposal. The OBED, through such project manager, shall place special emphasis on SBIR and STTR grant and contract applications that identify from the onset products with commercial potential that influence human health.

''(2) POTENTIAL PURCHASERS OR INVESTORS.—The OBED shall administer non-peer reviewed grants and contracts under this subsection through program managers who shall place special emphasis on partnering grantees and entities award-

ed contracts from the very beginning of the research and development process with potential purchasers or investors of the products, including large pharmaceutical or biotechnology companies, venture capital firms, and Federal agencies (including the National Institutes of Health).

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

''(A) 6 months; or

''(B) 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 developed with the grant or contract.

''(4) PHASE III.—

''(A) FUNDING.—A program manager under this subsection may petition the Director of Cures for Phase III funding of the grant or contract for a project that requires a boost to finalize procurement of a product. The maximum funding for Phase III funding of a project shall be $2,000,000 for a maximum of 2 years. Such Phase III funding shall come

from the acceleration fund, as described in section 499B(b)(2)(B)(i), of the Director of Cures.

''(B) REPORT SUCCESS.—Each recipient of a SBIR or STTR grant or contract, as a condition of receiving such grant or contract, shall report to the OBED whether there was eventual commercial success of the product developed with the assistance of the grant or contract.

''(5) RECORD.—

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

''(B) CONTENTS.—The record described in subparagraph (A) shall include, at minimum, the following information:

''(i) The grantee or entity awarded a contract.

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

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

''(iv) If applicable, the purchaser of the product, current use of the product,

and estimated annual revenue resulting from the procurement.

''(6) BONUS.—For each fiscal year, for the non-peer reviewed SBIR and STTR grants or contracts, the 2 program managers who are most successful in terms of the number of grantees or entities awarded a contract who complete Phase III shall each be awarded a $10,000 bonus.

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

''(a) ESTABLISHMENT OF OFFICE.—The Office of Technology Transfer of the Center shall establish an Office of Rapid Access to Intervention Development (referred to in this subpart as the 'RAID') that—

''(1) is designed to assist translating promising, novel, and scientifically meritorious therapeutic interventions to clinical use by providing support to help 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; and

''(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.

''(b) PROJECTS.—

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

''(2) SELECTION.—Not less than 35 percent of the projects selected under paragraph (1) shall be selected on a competitive basis by a program manager with sufficient managerial, technical, and translational research expertise to adequately assess the quality of a project proposal. Projects under paragraph (1) may also be selected 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.

''(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 CLINIC.—The program under subsection (b) shall accelerate the process of bringing discoveries from the laboratory to the clinic through—

''(1) the development of pharmacological assays;

''(2) the scale-up of production from lab scale to clinical-trials scale;

''(3) the development of suitable formulations;

''(4) the evaluation of chemical stability;

''(5) the evaluation of materials testing for durability or reactivity;

''(6) undertaking initial toxicology studies;

''(7) planning clinical trials; and

''(8) advice regarding the investigational new drug or investigational new device filing with the Food and Drug Administration.

''(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. TOXICITY STUDIES.

''(a) ONGOING RESEARCH.—The Center shall support ongoing research into the most efficient methods of screening for in vivo toxicity, including using cell-based and animal model technologies.

''(b) OFFER OF STUDIES.—The Director of Cures shall direct the Office of Technology Transfer of the Center to offer toxicity studies as an available feature to precede completion of licensing agreement contracts because toxicity studies are expensive and rate-limiting barriers to the licensing of intellectual property from the National Institutes of Health.

''SEC. 499F–3. ADDITIONAL FUNDING SOURCES AND MODELS.

''The Director of Cures may provide acceleration funds, described in section 499B(b)(2)(B)(i), for innovative custom contracts for translational research development to entities that license intellectual property from the National Institutes of Health where such contracts support innovation and new models of cooperation and commercialization.

"SEC. 499F–4. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i)—

"(1) $400,000,000 to carry out section 499F for fiscal year 2007 and each succeeding fiscal year; and

"(2) $100,000,000 to carry out section 499F–1 for fiscal year 2007 and each succeeding fiscal year.

"Subpart 5—Office of Technology Transfer

"SEC. 499G. RESTRUCTURING.

"(a) ESTABLISHMENT.—There is established within the Center an Office of Technology Transfer (referred to in this subpart as the 'OTT').

"(b) TRANSFERS.—The OTT shall include the functions (and related personnel and resources) of the Office of Technology Transfer in the Office of the Director of the National Institutes of Health.

"SEC. 499G–1. MARKETING FUNCTION.

"(a) IN GENERAL.—The OTT shall establish a program that—

"(1) cultivates industry interest in funded research of the National Institutes of Health;

"(2) reaches out to potential industry partners;

''(3) coordinates patents from the other institutes and centers of the National Institutes of Health; and

''(4) manages Cooperative Research and Development Agreements, biological licensing agreements, material transfer agreements, and intellectual property licensing.

''(b) PROMOTION.—The program under subsection (a) shall assist in promoting the success of government and industry partnerships for the development of new technologies by soliciting involvement of the private sector from the beginning of the translational research process, including by creating an electronic database within the National Library of Medicine, which shall be updated regularly, that tabulates translational research efforts occurring at the National Institutes of Health. The OTT shall hold an annual national translational research conference that brings together researchers and industry representatives from across fields from both the private and public sectors.

''(c) TRANSFER MANAGEMENT AND SUPPORT.—The OTT shall develop a program for transfer management and support that is familiar with the National Institutes of Health's intramural and extramural research portfolio, which program's mission is to reach out to potential indus-

try partners to cultivate interest in collaboration with public researchers with the goal of product development and procurement. For those Institutes or Centers with their own Office of Technology Transfer Offices, the OTT shall work closely with those offices to coordinate industry outreach efforts. Those offices, on a biannual basis, shall meet with the OTT and shall submit a report to the OTT describing the translational research efforts of the Center or Institute and corresponding efforts to attract commercial interest in their research portfolio.

''(d) MANAGEMENT.—

''(1) IN GENERAL.—The OTT shall manage the Cooperative Research and Development Agreements between industry and public research partners.

''(2) REGISTRATION.—The OTT shall—

''(A) as appropriate, register the agreements within a publicly accessible electronic database maintained by the National Library of Medicine of the National Institutes of Health; and

''(B) oversee the collaborative process in terms of pre-determined outputs, negotiating problems that may occur between collaborating entities, and assuring intellectual property pro-

tections necessary for successful product development.

"SEC. 499G–2. OFFICE OF INTRAMURAL RISK OPPORTUNITY AND MAPPING.

"(a) ESTABLISHMENT.—There is established in the Office of Technology Transfer of the Center, an Office of Intramural Risk Opportunity and Mapping that shall oversee the intramural research programs of the National Institutes of Health to be certain they are complementary and distinct from extramural and private programs.

"(b) REVIEWS AND REPORTS.—The Office of Intramural Risk Opportunity and Mapping shall—

"(1) conduct regular reviews of the intramural research programs of the National Institutes of Health; and

"(2) report every 2 years on such reviews.

"(c) HEALTH RISKS AND OPPORTUNITIES.—The Office of Intramural Risk Opportunity and Mapping shall—

"(1) identify and map public health risks and scientific opportunities and keep data on such topics current and updated; and

"(2) provide the information described in paragraph (1) to the Council on a biannual basis to help the Council prioritize the Nation's translation research investment.

''(d) TRANS-NIH COLLABORATIVE RESEARCH.—

''(1) IN GENERAL.—The Office of Intramural Risk Opportunity and Mapping shall make, in coordination with the Director of Cures and the Director of NIH, funds available to groups of institutes and centers of the National Institutes of Health to promote engagement in multi-institute projects that focus on translational research endeavors.

''(2) FUNDING.—Funding levels and periods of funding under paragraph (1) shall be flexible as necessary to achieve trans-institute project objectives. Preference for funding shall be given to projects that promote high levels of cross-disciplinary collaboration, that address diseases with the greatest burden or research promise, and that are most likely to result in the development of a diagnostic or therapeutic prototype.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out this subsection $150,000,000.

"SEC. 499G–3. PATENTING AND LICENSING INCENTIVES.

"(a) IN GENERAL.—The OTT shall make every effort to increase licensing throughput in order to stimulate the availability of useful products for patients.

"(b) INCENTIVES.—The OTT shall develop incentives that create private sector, financial, commercial, and academic interest in the National Institutes of Health's intellectual property portfolio, which incentives may include the following:

"(1) The patent extension of National Institutes of Health's health patents, in which there is an extension of the time during which the licensee has exclusive right to the intellectual property.

"(2) The patent restoration of National Institutes of Health's health patents, in which there is restoration of the full patent life, or another agreed upon term, of a technology to the licensee from the time of Food and Drug Administration passage or other agreed upon milestone.

"(3) Partnering options, which are options to pursue exclusive and nonexclusive licensing to 1 or more partners in the government, industrial, or academic sectors.

"(c) CUSTOMIZED MODELS.—The Director of Cures shall encourage the OTT to cultivate customized models

for contracts that fulfill the needs of industry and the public.

"SEC. 499G–4. TRANSLATIONAL RESEARCHER DEVELOPMENT.

''(a) IN GENERAL.—The Director of Cures shall oversee the development of a curriculum for internships in interdisciplinary research that will encompass rotations through multiple institutes and centers of the National Institutes of Health (including the National Library of Medicine), the clinical trial design process, and other related disciplines with an emphasis on practical experience.

''(b) TUITION GRANTS.—The Director of Cures shall award tuition grants for extramural interdisciplinary research programs.

''(c) TRAINING.—The Center shall train interdisciplinary scientists in the science and art of risk analysis and mapping through a program of internships and fellowships.

"SEC. 499G–5. 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—Developing Information Systems

"SEC. 499H. ADVANCING NATIONAL HEALTH INFORMATION INFRASTRUCTURE.

''(a) GENOMIC DATA.—

''(1) IN GENERAL.—The National Center for Biotechnology Information of the National Library of Medicine of the National Institutes of Health shall develop new computational methods to aid in the processing of genomic data by novice and experienced researchers.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out paragraph (1) $8,000,000, of which—

''(A) $2,500,000 is authorized to be appropriated to support the program's computational infrastructure; and

''(B) $5,500,000 is authorized to be appropriated for hiring biologists and computer scientists who are trained in bioinformatics.

''(b) DATABASE.—The Secretary, acting through the Director of NIH, shall undertake, in collaboration with the National Library of Medicine of the National Institutes of Health, construction of a clinical study registry and re-

sults database that may expand upon the National Library of Medicine's information system and database.

"(c) CLINICAL TRIAL INFORMATION.—

"(1) IN GENERAL.—

"(A) IN GENERAL.—The clinical study registry and results database, described in subsection (b), shall consist of a registry of phase III clinical trials taking place in the United States and a database of their results.

"(B) CLINICAL STUDY REGISTRY.—Participation in the clinical study registry shall be mandatory for both public and private entities.

"(C) RESULTS DATABASE.—Participation in the clinical trial results database shall be mandatory for both public and private entities. The clinical trial results database shall include even negative studies, which demonstrate no therapeutic effect.

"(2) REGISTRY OF CLINICAL TRIALS.—The registry of clinical trials shall include not less than the following:

"(A) The clinical trial title.

"(B) A description of the product under study.

"(C) The hypothesis to be tested.

''(D) The intervention.

''(E) The study design, methodology, duration, and location.

''(F) Participation criteria.

''(G) Contact information.

''(H) Sponsoring organization.

''(3) CLINICAL TRIAL RESULTS.—The database of clinical trial results shall consist of not less than the following:

''(A) The trial start date and completion date.

''(B) A summary of the results of the trial in a standard, non-promotional summary format.

''(C) Summary data tables with respect to the primary and secondary outcome measures.

''(D) Information on the statistical significance of the results and publications in peer reviewed journals relating to the trial, with, when available, an electronic link to the journal article.

''(E) A description of the process used to review the results of the trial, including a statement about whether the results have been peer

reviewed by reviewers independent of the trial sponsor.

''(F) Safety data concerning the trial, including a summary of all adverse events specifying the number and type of events.

''(G) Reference information to the clinical trial in the clinical registry.

''(d) REGISTRATION OF TRIALS AND REPORTING OF RESULTS.—

''(1) WEBSITE PUBLICATION.—Each principal investigator of a public clinical trial or responsible person for a private clinical trial shall register phase III clinical trials in accordance with paragraph (2) and report phase III clinical trial results in accordance with paragraph (2) with the National Library of Medicine of the National Institutes of Health. The National Library of Medicine shall make the information available for viewing on the Library's Website, www.clinicaltrials.gov. The National Library of Medicine shall electronically link each registered clinical trial with its database of results and link each database of results with its registered clinical trial.

''(2) TIMELINE OF REGISTRATION.—

"(A) IN GENERAL.—An entity described in paragraph (1) shall register a clinical trial not later than 3 months after the Food and Drug Administration has approved the entity's clinical trial protocol and report clinical trial results not later than 3 months after completing the clinical trial, which shall be defined as the point where the specified trial duration has been surpassed and the analysis of the data is complete or the trial is stopped because of vital positive or negative findings, or as the point determined by the judgment of the Secretary. All information submitted to the National Library of Medicine shall be accurate and updated.

"(B) LOSS OF FUNDING.—In the case in which an entity described in paragraph (1) does not register a clinical trial or report on clinical trial results in accordance with subparagraph (A), the Secretary may—

"(i) not award a grant, contract, cooperative agreements, or any other award to the principal investigators of such entity until the principal investigators comply with the requirements under subparagraph (A); and

"(ii) in the case of an entity that does not receive Federal funding for the clinical trial, fine the entity $10,000 a day for a sum not to exceed $2,000,000 until the responsible person for the clinical trial complies with the requirements under subparagraph (A).

"(C) WAIVER.—The Secretary may waive the requirements of subparagraph (A) upon a written request from the responsible person if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public's interest or consistent with the protection of public health.

"SEC. 499H–1. PUBLIC ACCESS REQUIREMENT FOR RESEARCH.

"(a) IN GENERAL.—The Secretary shall require all funded investigators, whether direct employees of the Department of Health and Human Services or recipients of grants, contracts, or other support of the National Institutes of Health, the Centers for Disease Control and Prevention, or the Agency for Healthcare Research and Quality, to submit to the National Library of Medicine of the National Institutes of Health (referred to in this section as the 'National Library of Medicine'), upon acceptance

for publication in a journal or other publication included in the PubMed directory, final manuscripts resulting from research in which direct costs are supported in whole or in part by the National Institutes of Health, the Centers for Disease Control and Prevention, or the Agency for Healthcare Research and Quality.

''(b) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—The National Library of Medicine shall include all such manuscripts described in subsection (a), after peer review, for display in the National Library of Medicine's digital library archive, PubMed Central. The copyright holder of a manuscript described in subsection (a) may request the author's manuscript be replaced with final published text.

''(2) TIMELINE.—A manuscript described in subsection (a) shall become publicly available on the Internet through PubMed Central not later than 6 months after the date of publication of the manuscript.

''(3) LOSS OF FUNDING FOR FAILURE TO SUBMIT ON TIME.—Failure to submit required information under this section to the National Library of Medicine within 6 months of the date of publication of the manuscript involved shall be considered by the

Secretary in the context of grant compliance review and may result in the loss of public funding for the investigators involved as determined appropriate by the agency involved.

"SEC. 499H–2. INFORMATICS TRAINING AND WORKFORCE DEVELOPMENT.

''(a) IN GENERAL.—The Director of NIH shall develop a multi-faceted approach to increasing the number of persons trained in clinical bioinformatics by implementing appropriate programs, including the programs described in subsection (b).

''(b) PROGRAMS.—The programs under this subsection are the following:

''(1) K–12 SCIENCE PROGRAM.—The National Library of Medicine of the National Institutes of Health shall develop with the National Science Foundation a kindergarten through grade 12 clinical informatics education curriculum that shall include an assessment component. The National Library of Medicine shall award not more than 500 schools each $30,000 to implement the curriculum.

''(2) UNDERGRADUATE DEGREE PROGRAMS IN BIOINFORMATICS.—The National Library of Medicine of the National Institutes of Health shall—

"(A) award grants to academic health centers and graduate training programs to collaborate with an undergraduate institution of higher education's department of biology, chemistry, or computer science to develop curricula leading to a bachelor's degree in bioinformatics; and

"(B) encourage grantees to form an interinstitutional consortium.

"(3) INCREASING THE NUMBER OF NIH BIOINFORMATICS GRADUATE TRAINING PROGRAMS.—The National Library of Medicine of the National Institutes of Health shall increase the number of bioinformatics graduate training programs through funding existing graduate training programs of the National Institutes of Health to meet the expanding needs for training and outreach to the biomedical community. The programs shall focus on the skills needed to apply bioinformatics methods specifically to problems of human health and disease. The Director of NIH shall hire 12 individuals with a doctorate in molecular biology and expertise in training and developing educational programs to assist in carrying out the programs under this paragraph.

''(4) CENTERS OF EXCELLENCE IN CLINICAL BIOINFORMATICS.—The National Library of Medicine of the National Institutes of Health, through the Center, shall establish Centers of Excellence in Clinical Bioinformatics that shall have state-of-the-art computational methods and tools applicable to human disease prevention, diagnosis, and treatment. The Centers of Excellence in Clinical Bioinformatics shall provide graduate student and postdoctoral support, through distinguished faculty, in order to contribute to the highest level of training in the bioinformatics workforce pipeline.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, from the acceleration fund of the Director of Cures described in section 499B(b)(2)(B)(i), to carry out this section $50,000,000 for fiscal year 2007 and each succeeding fiscal year of which—

''(1) $15,000,000 is authorized to be appropriated for fiscal year 2007 and each succeeding fiscal year to carry out subsection (b)(1); and

''(2) $2,000,000 is authorized to be appropriated to carry out subsection (b)(3).

"SEC. 499H–3. NATIONAL LIBRARY OF MEDICINE EXPANSION OF FACILITIES.

''(a) SENSE OF CONGRESS.—It is the sense of Congress that Congress should make special effort to fund the expansion of facilities of the National Library of Medicine of the National Institutes of Health. These facilities are essential to the National Library of Medicine being able to fulfill its many informatics functions, which include providing essential informational resources to scientists worldwide and advancing the underpinning of much of the National Institutes of Health conducted biomedical research.

''(b) REPORT.—The Director shall request that the Institute of Medicine of the National Academies report to Congress on the impact of not providing funding for the expansion of facilities described in subsection (a).

"Subpart 7—Research Tools

"SEC. 499I. NIH RESEARCH TOOL INVENTORY.

''(a) ANNUAL REVIEW.—The Director of NIH shall direct the head of each institute and center of the National Institutes of Health to perform an annual review of the institute or center's research tool inventory for the specific purpose of enabling each institute or center to understand the research tool distribution, frequency of use, intellectual property status, and utility. Each institute and center of the National Institutes of Health shall describe in the in-

stitute or center's annual review the type and quantity of research tools the institute or center desires to obtain to better fulfill the institute or center's research and development goals.

''(b) DATABASE.—The Director of Cures shall—

''(1) enter the information obtained from the annual review under subsection (a) into an electronic research tool database; and

''(2) use such database to oversee the prioritization and funding of new projects to fulfill pressing needs and promising technologies.

''SEC. 499I–1. EXCEPTIONS TO TOOL GUIDELINES.

''The Director of Cures may advise the Office of Technology Transfer of the Center to provide exceptions to prohibitions against patenting and licensing research tools under some circumstances of customized contracts when exclusive or non-exclusive licensing provides the swiftest and most efficacious final development of an important health care technology.''.

(b) CONFORMING AMENDMENT.—Section 401(b)(1) of the Public Health Service Act (42 U.S.C. 281(b)(1)) is amended by adding at the end the following:

''(S) The American Center for Cures.''.

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