Section-by-Section Summary of the Accelerating Cures Act of 2008

A bill to enhance public and private research efforts to develop new tools and therapies that prevent, detect, and cure diseases more quickly from bench to bedside.

Background

The National Institutes of Health (NIH), comprised of 27 major institutes and centers, receives the world's largest public source of biomedical research funding with an annual budget of over $29 billion. The NIH produces new discoveries in cancer, cardiovascular, infectious disease and allergy advancements for health promotion and relief from the burdens of disease. Its mission is science in the 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.

Need

The public investment in basic science research at the NIH has provided countless new discoveries and has led to new treatments and therapies for diseases that afflict millions of Americans. However, studies estimate that on average, it takes 17 years for a laboratory discovery to move from bench to bedside.

To accelerate the pace of biomedical research and development, this legislation would provide new authorities and funding in support of the NIH's goal to "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." Specifically, the legislation aims to strengthen and promote the translational and clinical sciences, which are critical to the advancement of basic science discoveries to clinical care. The Accelerating Cures Act would accomplish this by creating new programs that fund high-risk, high-reward research, to oversee and direct promising avenues of translational research, to increase the translational and clinical research workforce, and to provide new funds and authorities to evaluate the clinical effectiveness of various treatments and procedures at the NIH.

The provisions outlined above are based on the work of experts in the biomedical research enterprise in the United States, and from reports, such as the 2003 National Academy of Sciences Report, "Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges."

A section by section summary of the legislation is included below.

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SUBPART 1 – PATHWAYS TO CURES SUBCOMMITTEE
Section 499A: Pathways to Cures Subcommittee

Section 499A defines translational research as research that transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical application to reduce disease incidence, morbidity, and mortality.

This section establishes a 'Pathways to Cures Subcommittee' within the Council of Councils of the Office of Portfolio Analysis and Strategic Initiatives (OPASI) to provide advice on, and direct, translational research priorities while considering risk and burden of disease with an emphasis on delivering effective diagnostics and therapies. The subcommittee will evaluate research agendas among the NIH institutes and centers in order to coordinate cross-intramural research efforts. The subcommittee would be comprised of the Director of NIH, Director of OPASI, heads of the NIH institutes and centers, heads of several Federal agencies, and leaders from the small business community, large pharmaceutical and biotechnology companies, and academia.

SUBPART 2 – CLINICAL EFFECTIVENESS; FFRDC
Section 499B: Federally funded research and development center

Section 499B would authorize the joint establishment of a Federally Funded Research and Development Center (FFRDC) between the NIH and the Agency for Healthcare Research and Quality (AHRQ) to conduct clinical effectiveness research. Clinical effectiveness research is defined as research that 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, including information on specific subpopulations.

The FFRDC would be charged with prioritizing, overseeing, competitively funding, and disseminating results of clinical effectiveness research through an advisory board and working groups comprised of private and public sector participants.

SUBPART 3 – HEALTH ADVANCED RESEARCH PROJECTS PROGRAM
Section 499C: Health Advanced Research Projects Program

Section 499C establishes a Health Advanced Research Projects Program (Research Projects Program) to support innovative multi- and cross-disciplinary collaborative and high-risk research between NIH Institutes and Centers, NIH and other federal agencies, and NIH grantees and business partners. The Research Projects Program would be modeled after the Defense Advanced Research Projects Agency (DARPA). It would support fundamental research breakthroughs, early and late stage applied development, prototyping, knowledge diffusion, and technology deployment.

The Research Projects Program funds would be awarded to those projects with potential for significant health impact. Specifically, awards would be focused on projects pursuing high-risk

biomedical research, such as accelerated trials with technological and scientific innovation for emerging public and population health consequences. The program would be small, flexible, entrepreneurial, and non-hierarchical for the purpose of empowering portfolio managers to foster research opportunities free from bureaucratic impediments.

SUBPART 4 – CLINICAL TRIALS
Section 499D: Grants for quality clinical trial design and execution

Section 499D would award grants to academic centers, practice-based research networks, and small firms with multidisciplinary clinical research teams and novel clinical trial designs.

Section 499D – 1: Streamlining the regulatory process governing clinical research

Section 499K-1 establishes Centralized Institutional Review Boards (CIRBs) to streamline regulatory processes for multicenter clinical trials within the NIH or at a private or public institution with an established organizational capacity. A CIRB would work in concert with local institutional review boards (IRBs) and communicate with them regularly in order to reduce the administrative burden on individual IRBs and to accelerate the pace of initiating and conducting multicenter clinical trials.

Section 499D – 2: Clinical research study and clinical trial

Section 499D-2 commissions the Institute of Medicine (IOM) to evaluate the extent to which a balance can be achieved between clinical research promotion and regulatory requirements that govern research safety and privacy and, if deemed necessary, consider changes to the Health Insurance Portability and Accountability Act (HIPPA) of 1996 to better facilitate both ethical and efficient clinical research endeavors.

SUBPART 5 – TRAINING CLINICAL AND TRANSLATIONAL RESEARCHERS OF THE FUTURE
Section 499E: Training translational and clinical researchers of the future

Section 499E requires the Director of OPASI to continue to establish training programs to increase and maintain the translational and clinical research pool targeted at those with MDs and PhDs, as well as predoctoral, medical, nursing, and allied health professions' students. The Director would award monies to public and nonprofit educational entities to foster multidisciplinary and interdisciplinary research collaborations through internships, fellowships, and sabbaticals. In turn, these institutions will be required to share novel ideas and best practices in the training of translational and clinical researchers.

Section 499E – 1: Translational research training program
Section 499E-1 requires the Director of the NIH to ensure that each institute and center has or will establish a translational research training program for intramural research personnel.

SUBPART 6 – THE "VALLEY OF DEATH"
Section 499F: Small business partnerships

Section 499F establishes an advisory board at the National Academy of Sciences consisting of the Directors of the NIH and Small Business Innovation Research (SBIR) program, senior agency managers at the NIH, university and industry experts, and other program stakeholders to provide regular assessments of program management and effectiveness.

The SBIR and Small Business Technology Transfer Research (STTR) programs will be required to award at least 25% of grants and contracts on a competitive basis by a program manager with experience in commercialization and industry for the purpose of identifying products with commercial potential to prevent, diagnose, and cure diseases.
In addition, the SBIR and STTR programs shall also place emphasis on partnering awardees and grantees with potential purchasers or investors such as pharmaceutical or biotechnology companies, venture capital firms, or Federal agencies from the outset. The program will also reduce the time period between Phase I and Phase II to no more than six months and allow funding to be awarded for Phase III purposes through NIH program funds following approval by the Director of the NIH.

The SBIR and STTR programs will be required to conduct regular internal and external evaluations of the programs and to incorporate data collection methods in order to set operational benchmarks for success, including strategies to increase the number of awards to women and minorities. This section also encourages the use of pilot programs by the SBIR and STTR programs to support innovation in program management and commercialization of funded products. The SBIR and STTR programs will be required to maintain publically accessible electronic records of all investments made in research and development.

Section 499F – 1: Rapid access to intervention development

Section 499F-1 authorizes the Director of OPASI to expand the existing Rapid Access to Intervention Development (RAID) program to assist investigators with promising interventions in navigating the product pipeline. Assistance ranges from the removal of barriers between laboratory discoveries and clinical trials, reduction of duplicative and redundant work, sharing of resources, and coordination with NIH offices that promote translational research in pre-clinical phases. The Director of OPASI and the RAID initiative will select entities such as Universities and nonprofit organizations, which would benefit from access to laboratories, facilities, and other support resources at the NIH, through a competitive and peer review processes.

Section 499F – 2: Translational Development Program for New Innovations

Section 499F-2 authorizes the Director of OPASI to develop a Translational Development Program that will collaborate with RAID to streamline and accelerate the translational research development process for bringing new innovations to commercialization by triaging applications for innovation potential, outlining tasks and timelines, providing project management support, and interfacing with the FDA to safely and rapidly bring new drugs, biologics, diagnostics, medical devices and other interventions to approval.

SUBPART 7 – TRANSLATIONAL RESEARCH FUND
Section 499G: Translational Research Fund

Section 499G authorizes the establishment of a Translational Research Fund that is equal to the amount set aside for the NIH Common Fund annually and no less than half of this amount shall be allotted to the Health Advanced Research Projects Program.

Sec. 404I: Application of Research Requirement

Section 404I requires that each applicant for a project, grant, or contract from the NIH must include a statement on the potential application of the research for detecting, treating, or curing a health condition or disease state.