AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 2713

To provide for the implementation of a Precision Medicine Initiative.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advancing Precision Medicine Act of 2016''.

SEC. 2. PRECISION MEDICINE INITIATIVE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') is encouraged to establish and carry out an initiative, to be known as the ''Precision Medicine Initiative'', to augment efforts to address disease prevention, diagnosis, and treatment.

(b) COMPONENTS.—The Initiative described under subsection (a) may include—

(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

(3) applying genomic technologies to provide data on the molecular basis of disease;

(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

(5) other activities determined appropriate by the Secretary to advance the goals of the Initiative.

(c) AUTHORITY OF THE SECRETARY.—In carrying out this section, the Secretary may—

(1) coordinate with the Secretary of Energy, private industry, and others determined appropriate by the Secretary to identify and address the advanced supercomputing needs for the Initiative described under subsection (a);

(2) develop and utilize public-private partnerships; and

(3) leverage existing data sources.

(d) REQUIREMENTS.—In the implementation of the Initiative under subsection (a), the Secretary shall—

(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, and the Office of the National Coordinator for Health Information Technology;

(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data; and

(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities.

SEC. 3. PROTECTION OF IDENTIFIABLE, SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

''(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

''(A) an individual is identified; or

''(B) there is a risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

''(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

''(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

''(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.''.

SEC. 4. DATA SHARING.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking ''and'' at the end;

(2) in paragraph (24), by striking the period and inserting ''; and''; and

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

''(25) may require recipients of NIH grants or cooperative agreements to share scientific data, to the extent feasible, generated from such NIH grants or cooperative agreements in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

''(A) human research participants, including with respect to privacy, security, informed consent, and protected health information;

''(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient; and

''(C) national, homeland, and economic security interests.''.

SEC. 5. HIGH-RISK, HIGH-REWARD RESEARCH.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following:

''(m) HIGH-RISK, HIGH-REWARD RESEARCH.—

''(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program offices within the Office of the Director, to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders.

''(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high-impact, cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

''(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including

why the use of such authority is essential to promoting the success of the project;

''(B) receives approval for the use of such authority from the Director of NIH; and

''(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.''.

(b) REPORT TO CONGRESS.—Not later than September 30, 2020, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct an evaluation of the activities under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by subsection (a), and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation.

(c) DUTIES OF DIRECTORS OF INSTITUTES.—Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) by redesignating subparagraphs (C) through (L) as subparagraphs (D) through (M), respectively; and

(2) by inserting after subparagraph (B), the following:

''(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;''.