116TH CONGRESS
2D SESSION

S. _____

To provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology.

IN THE SENATE OF THE UNITED STATES

Mrs. GILLIBRAND (for herself, Mr. MARKEY, Mr. RUBIO, and Mr. GARDNER) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology.

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 ''Bioeconomy Research and Development Act of 2020''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) Cellular and molecular processes may be used, mimicked, or redesigned to develop new prod-

ucts, processes, and systems that improve societal well-being, strengthen national security, and contribute to the economy.

(2) Engineering biology relies on a workforce with a diverse and unique set of skills combining the biological, physical, chemical, and information sciences and engineering.

(3) Long-term research and development is necessary to create breakthroughs in engineering biology. Such research and development requires government investment as many of the benefits are too distant or uncertain for industry to support alone.

(4) Research is necessary to inform evidence-based governance of engineering biology and to support the growth of the engineering biology industry.

(5) The Federal Government has an obligation to ensure that ethical, legal, environmental, safety, security, and societal implications of its science and technology research and investment follows policies of responsible innovation and fosters public transparency.

(6) The Federal Government can play an important role by facilitating the development of tools and technologies to further advance engineering biology, including user facilities, by facilitating public-

private partnerships, by supporting risk research, and by facilitating the commercial application in the United States of research funded by the Federal Government.

(7) The United States led the development of the science and engineering techniques that created the field of engineering biology, but due to increasing international competition, the United States is at risk of losing its competitive advantage if does not invest the necessary resources and have a national strategy.

(8) A National Engineering Biology Initiative can serve to establish new research directions and technology goals, improve interagency coordination and planning processes, drive technology transfer to the private sector, and help ensure optimal returns on the Federal investment.

SEC. 3. DEFINITIONS.

In this Act:

(1) BIOMANUFACTURING.—The term ''biomanufacturing'' means the utilization of biological systems to develop new and advance existing products, tools, and processes at commercial scale.

(2) ENGINEERING BIOLOGY.—The term ''engineering biology'' means the application of engineer-

ing design principles and practices to biological systems, including molecular and cellular systems, to advance fundamental understanding of complex natural systems and to enable novel or optimize functions and capabilities.

(3) INITIATIVE.—The term ''Initiative'' means the National Engineering Biology Research and Development Initiative established under section 4.

(4) OMICS.—The term ''omics'' refers to the collective technologies used to explore the roles, relationships, and actions of the various types of molecules that make up the cells of an organism.

SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND DEVELOPMENT INITIATIVE.

(a) IN GENERAL.—The President, acting through the Office of Science and Technology Policy, shall implement a National Engineering Biology Research and Development Initiative to advance societal well-being, national security, sustainability, and economic productivity and competitiveness through—

(1) advancing areas of research at the intersection of the biological, physical, chemical, data, and computational sciences and engineering to accelerate scientific understanding and technological innovation in engineering biology;

(2) advancing areas of biomanufacturing research to optimize, standardize, scale, and deliver new products and solutions;

(3) supporting social and behavioral sciences and economics research that advances the field of engineering biology and contributes to the development and public understanding of new products, processes, and technologies;

(4) improving the understanding of engineering biology of the scientific and lay public and supporting greater evidence-based public discourse about its benefits and risks;

(5) supporting risk research, including under subsection (d);

(6) supporting the development of novel tools and technologies to accelerate scientific understanding and technological innovation in engineering biology;

(7) expanding the number of researchers, educators, and students with engineering biology training, including from traditionally underrepresented and underserved populations;

(8) accelerating the translation and commercialization of engineering biology research and development by the private sector; and

(9) improving the interagency planning and coordination of Federal Government activities related to engineering biology.

(b) INITIATIVE ACTIVITIES.—The activities of the Initiative shall include—

(1) sustained support for engineering biology research and development through—

(A) grants to individual investigators and teams of investigators, including interdisciplinary teams;

(B) projects funded under joint solicitations by a collaboration of no fewer than two agencies participating in the Initiative; and

(C) interdisciplinary research centers that are organized to investigate basic research questions, carry out technology development and demonstration activities, and increase understanding of how to scale up engineering biology processes, including biomanufacturing;

(2) sustained support for databases and related tools, including—

(A) support for curated genomics, epigenomics, and all other relevant omics databases, including plant and microbial databases,

that are available to researchers to carry out engineering biology research;

(B) development of standards for such databases, including for curation, interoperability, and protection of privacy and security;

(C) support for the development of computational tools, including artificial intelligence tools, that can accelerate research and innovation using such databases; and

(D) an inventory and assessment of all Federal government omics databases to identify opportunities for consolidation and inform investment in such databases as critical infrastructure for the engineering biology research enterprise;

(3) sustained support for the development, optimization, and validation of novel tools and technologies to enable the dynamic study of molecular processes in situ, including through—

(A) research conducted at Federal laboratories;

(B) grants to investigators at institutions of higher education and other nonprofit research institutions; and

(C) through the Small Business Innovation Research Program and the Small Business Technology Transfer Program, as described in section 9 of the Small Business Act (15 U.S.C. 638);

(4) education and training of undergraduate and graduate students in engineering biology, in biomanufacturing, in bioprocess engineering, and in areas of computational science applied to engineering biology and in the related ethical, legal, environmental, safety, security, and other societal issues;

(5) activities to develop robust mechanisms for tracking and quantifying the outputs and economic benefits of engineering biology; and

(6) activities to accelerate the translation and commercialization of new products, processes, and technologies by—

(A) identifying precompetitive research opportunities;

(B) facilitating public-private partnerships in engineering biology research and development;

(C) connecting researchers, graduate students, and postdoctoral fellows with entrepre-

neurship education and training opportunities; and

(D) supporting proof of concept activities and the formation of startup companies including through programs such as the Small Business Innovation Research Program and the Small Business Technology Transfer Program.

(c) EXPANDING PARTICIPATION.—The Initiative shall include, to the maximum extent practicable, outreach to primarily undergraduate and minority-serving institutions about Initiative opportunities, and shall encourage the development of research collaborations between research-intensive universities and primarily undergraduate and minority-serving institutions.

(d) ETHICAL, LEGAL, ENVIRONMENTAL, SAFETY, SECURITY, AND SOCIETAL ISSUES.—Initiative activities shall take into account ethical, legal, environmental, safety, security, and other appropriate societal issues by—

(1) supporting research, including in the social sciences, and other activities addressing ethical, legal, environmental, and other appropriate societal issues related to engineering biology, including integrating research on such topics with the research and development in engineering biology, and ensuring that the results of such research are widely dis-

seminated, including through interdisciplinary engineering biology research centers described in subsection (b)(1);

(2) supporting research and other activities related to the safety and security implications of engineering biology, including outreach to increase awareness among Federal researchers and Federally-funded researchers at institutions of higher education about potential safety and security implications of engineering biology research, as appropriate;

(3) ensuring that input from Federal and non-Federal experts on the ethical, legal, environmental, safety, security, and other appropriate societal issues related to engineering biology is integrated into the Initiative; and

(4) ensuring, through the agencies and departments that participate in the Initiative, that public input and outreach are integrated into the Initiative by the convening of regular and ongoing public discussions through mechanisms such as workshops, consensus conferences, and educational events, as appropriate.

SEC. 5. INITIATIVE COORDINATION.

(a) INTERAGENCY COMMITTEE.—The President, acting through the Office of Science and Technology Policy,

shall designate an interagency committee to coordinate engineering biology, which shall be co-chaired by the Office of Science and Technology Policy, and include representatives from the National Science Foundation, the Department of Energy, the Department of Defense, the National Aeronautics and Space Administration, the National Institute of Standards and Technology, the Environmental Protection Agency, the Department of Agriculture, the National Institutes of Health, the Bureau of Economic Analysis, and any other agency that the President considers appropriate (in this section referred to as the ''interagency committee''). The Director of the Office of Science and Technology Policy shall select an additional co-chairperson from among the members of the Interagency Committee. The Interagency Committee shall oversee the planning, management, and coordination of the Initiative. The Interagency Committee shall—

(1) provide for interagency coordination of Federal engineering biology research, development, and other activities undertaken pursuant to the Initiative;

(2) establish and periodically update goals and priorities for the Initiative;

(3) develop, not later than 12 months after the date of enactment of this Act, and update every 3

years, a strategic plan submitted to the Committee on Science, Space, and Technology of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate that—

(A) guides the activities of the Initiative for purposes of meeting the goals and priorities established under (and updated pursuant to) paragraph (2); and

(B) describes—

(i) the Initiative's support for long-term funding for interdisciplinary engineering biology research and development;

(ii) the Initiative's support for education and public outreach activities;

(iii) the Initiative's support for research and other activities on ethical, legal, environmental, safety, security, and other appropriate societal issues related to engineering biology including—

(I) an applied biorisk management research plan;

(II) recommendations for integrating security into biological data access and international reciprocity agreements; and

(III) an evaluation of existing biosecurity governance policies, guidance, and directives for the purposes of creating a unified, adaptable, evidence-based framework to respond to emerging biosecurity challenges created by advances in engineering biology;

(iv) how the Initiative will move results out of the laboratory and into application for the benefit of society and United States competitiveness; and

(v) how the Initiative will measure and track the contributions of engineering biology to United States economic growth and other societal indicators;

(4) develop a national genomic sequencing strategy to ensure engineering biology research fully leverages plant, animal, and microbe biodiversity to enhance long-term innovation and competitiveness in engineering biology in the United States;

(5) propose an annually coordinated interagency budget for the Initiative that is intended to ensure—

(A) the maintenance of a robust engineering biology research and development portfolio; and

(B) that the balance of funding across the Initiative is sufficient to meet the goals and priorities established for the Program;

(6) develop a plan to utilize Federal programs, such as the Small Business Innovation Research Program and the Small Business Technology Transfer Program as described in section 9 of the Small Business Act (15 U.S.C. 638), in support of the activities described in section 4(b)(3); and

(7) in carrying out this section, take into consideration the recommendations of the advisory committee established under section 6, the results of the workshop convened under section 7, existing reports on related topics, and the views of academic, State, industry, and other appropriate groups.

(b) ANNUAL REPORT.—Beginning with fiscal year 2020, not later than 90 days after submission of the President's annual budget request and each fiscal year thereafter, the interagency committee shall prepare and submit to the Committee on Science, Space, and Technology of the House of Representatives and the Committee on Com-

merce, Science, and Transportation of the Senate a report that includes—

(1) a summarized agency budget in support of the Initiative for the fiscal year to which such budget request applies, and for the then current fiscal year, including a breakout of spending for each agency participating in the Program and for the development and acquisition of any research facilities and instrumentation; and

(2) an assessment of how Federal agencies are implementing the plan described in subsection (a)(3), including—

(A) a description of the amount and number of awards made under the Small Business Innovation Research Program and the Small Business Technology Transfer Program (as described in section 9 of the Small Business Act (15 U.S.C. 638)) in support of the Initiative; and

(B) a description of the amount and number of projects funded under joint solicitations by a collaboration of no fewer than 2 agencies participating in the Initiative.

(c) INITIATIVE OFFICE.—

(1) IN GENERAL.—The President shall establish an Initiative Coordination Office, with a Director and full-time staff, which shall—

(A) provide technical and administrative support to the interagency committee and the advisory committee established under section 6;

(B) serve as the point of contact on Federal engineering biology activities for government organizations, academia, industry, professional societies, State governments, interested citizen groups, and others to exchange technical and programmatic information;

(C) oversee interagency coordination of the Initiative, including by encouraging and supporting joint agency solicitation and selection of applications for funding of activities under the Initiative;

(D) conduct public outreach, including dissemination of findings and recommendations of the advisory committee established under section 6, as appropriate;

(E) serve as the coordinator of ethical, legal, environmental, safety, security, and other appropriate societal input; and

(F) promote access to, and early application of, the technologies, innovations, and expertise derived from Initiative activities to agency missions and systems across the Federal Government, and to United States industry, including startup companies.

(2) FUNDING.—The Director of the Office of Science and Technology Policy shall develop an estimate of the funds necessary to carry out the activities of the Initiative Coordination Office, including an estimate of how much each participating agency described in subsection (a) will contribute to such funds, and submit such estimate to Congress no later than 90 days after the enactment of this Act.

(3) TERMINATION.—The Initiative Coordination Office established under this subsection shall terminate on the date that is 10 years after the date of the enactment of this Act, unless a determination is made by the President that such Office is necessary to meet the economic or national security goals of the Program.

SEC. 6. ADVISORY COMMITTEE.

(a) IN GENERAL.—The President, acting through the Office of Science and Technology Policy, shall designate or establish an advisory committee on engineering biology

research and development (in this section referred to as the ''advisory committee'') to be composed of not fewer than 12 members, including representatives of research and academic institutions, industry, and nongovernmental entities, who are qualified to provide advice on the Initiative.

(b) ASSESSMENT.—The advisory committee shall assess—

(1) the current state of United States competitiveness in engineering biology, including the scope and scale of United States investments in engineering biology research and development in the international context;

(2) current market barriers to commercialization of engineering biology products, processes, and tools in the United States;

(3) progress made in implementing the Initiative;

(4) the need to revise the Initiative;

(5) the balance of activities and funding across the Initiative;

(6) whether the strategic plan developed or updated by the interagency committee established under section 5 is helping to maintain United States leadership in engineering biology;

(7) the management, coordination, implementation, and activities of the Initiative; and

(8) whether ethical, legal, environmental, safety, security, and other appropriate societal issues are adequately addressed by the Initiative.

(c) REPORTS.—Beginning not later than 2 years after the date of enactment of this Act, and not less frequently than once every 3 years thereafter, the advisory committee shall submit to the President, the Committee on Science, Space, and Technology of the House of Representatives, and the Committee on Commerce, Science, and Transportation of the Senate, a report on—

(1) the findings of the advisory committee's assessment under subsection (b); and

(2) the advisory committee's recommendations for ways to improve the Initiative.

(d) APPLICATION OF FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

SEC. 7. EXTERNAL REVIEW OF ETHICAL, LEGAL, ENVIRONMENTAL, SAFETY, SECURITY, AND SOCIETAL ISSUES.

(a) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Director of the National

Science Foundation shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a review, and make recommendations with respect to, the ethical, legal, environmental, safety, security, and other appropriate societal issues related to engineering biology research and development. The review shall include—

(1) an assessment of the current research on such issues;

(2) a description of the research gaps relating to such issues;

(3) recommendations on how the Initiative can address the research needs identified pursuant to paragraph (2); and

(4) recommendations on how engineering biology researchers can best incorporate considerations of ethical, legal, environmental, safety, security, and other societal issues into the development of research proposals and the conduct of research.

(b) REPORT TO CONGRESS.—The agreement entered into under subsection (a) shall require the National Academy of Sciences, Engineering, and Medicine to, not later than 2 years after the date of the enactment of this Act—

(1) submit to the Committee on Science, Space, and Technology of the House of Representatives and

the Committee on Commerce, Science, and Transportation of the Senate a report containing the findings and recommendations of the review conducted under subsection (a); and

(2) make a copy of such report available on a publicly accessible website.

(c) ALTERNATE CONTRACT SCIENTIFIC ORGANIZATION.—

(1) IN GENERAL.—If the Director is unable to enter into an agreement described in subsection (a) with the National Academy of Sciences before the date specified in such subsection on terms acceptable to the Director, the Director shall seek to enter into such an agreement with another appropriate scientific organization that—

(A) is not part of the Government;

(B) operates as a not-for-profit entity; and

(C) has expertise and objectivity comparable to that of the National Academy of Sciences.

(2) TREATMENT.—If the Director enters into an agreement with another organization as described in paragraph (1), any reference in this subsection to the National Academy of Sciences shall be treated as a reference to the other organization.

SEC. 8. AGENCY ACTIVITIES.

(a) NATIONAL SCIENCE FOUNDATION.—As part of the Initiative, the National Science Foundation shall—

(1) support basic research in engineering biology through individual grants and through interdisciplinary research centers;

(2) support research on the environmental, legal, ethical, and social implications of engineering biology;

(3) provide support for research instrumentation for engineering biology disciplines, including support for research, development, optimization and validation of novel technologies to enable the dynamic study of molecular processes in situ;

(4) support curriculum development and research experiences for secondary, undergraduate, and graduate students in engineering biology and biomanufacturing; and

(5) award grants, on a competitive basis, to enable institutions to support graduate students and postdoctoral fellows who perform some of their engineering biology research in an industry setting.

(b) DEPARTMENT OF COMMERCE.—As part of the Initiative, the Director of the National Institute of Standards and Technology shall—

(1) establish a bioscience research program to advance the development of standard reference materials and measurements and to create new data tools, techniques, and processes necessary to advance engineering biology and biomanufacturing;

(2) provide access to user facilities with advanced or unique equipment, services, materials, and other resources to industry, institutions of higher education, nonprofit organizations, and government agencies to perform research and testing; and

(3) provide technical expertise to inform the potential development of guidelines or safeguards for new products, processes, and systems of engineering biology.

(c) DEPARTMENT OF ENERGY.—As part of the Initiative, the Secretary of Energy shall—

(1) conduct and support research, development, demonstration, and commercial application activities in engineering biology, including in the areas of synthetic biology, advanced biofuel development, biobased materials, and environmental remediation;

(2) support the development, optimization and validation of novel, scalable tools and technologies to enable the dynamic study of molecular processes in situ; and

(3) provide access to user facilities with advanced or unique equipment, services, materials, and other resources, as appropriate, to industry, institutions of higher education, nonprofit organizations, and government agencies to perform research and testing.

(d) DEPARTMENT OF DEFENSE.—As part of the Initiative, the Secretary of Defense shall—

(1) conduct and support research and development in engineering biology and associated data and information sciences;

(2) support curriculum development and research experiences in engineering biology and associated data and information sciences across the military education system, to include service academies, professional military education, and military graduate education; and

(3) assess risks of potential national security and economic security threats relating to engineering biology.

(e) NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.—As part of the Initiative, the National Aeronautics and Space Administration shall—

(1) conduct and support basic and applied research in engineering biology, including in synthetic

biology, and related to Earth and space sciences, aeronautics, space technology, and space exploration and experimentation, consistent with the priorities established in the National Academies' decadal surveys; and

(2) award grants, on a competitive basis, that enable institutions to support graduate students and postdoctoral fellows who perform some of their engineering biology research in an industry setting.

(f) DEPARTMENT OF AGRICULTURE.—As part of the Initiative, the Secretary of Agriculture shall—

(1) support research and development in engineering biology, including in synthetic biology and biomaterials;

(2) award grants through the National Institute of Food and Agriculture; and

(3) support development conducted by the Agricultural Research Service.

(g) ENVIRONMENTAL PROTECTION AGENCY.—As part of the Initiative, the Environmental Protection Agency shall support research on how products, processes, and systems of engineering biology will affect or can protect the environment.

(h) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

(1) NATIONAL INSTITUTES OF HEALTH.—As part of the Initiative, the Director of the National Institutes of Health shall—

(A) support research and development to advance the understanding and application of engineering biology for human health, including in synthetic biology, cell and tissue engineering, computational biology, and artificial intelligence;

(B) support and accelerate the application of biomedical research and technologies through cross-disciplinary collaboration and training programs;

(C) support research on ethical, legal, safety, and societal implications of emerging biotechnologies; and

(D) award grants on a competitive basis, that enable institutions to support graduate students and postdoctoral fellows who perform some of their engineering biology research across multiple disciplinary departments.

(2) FOOD AND DRUG ADMINISTRATION.—As part of the Initiative, the Commissioner of Food and Drugs shall—

(A) support research and evaluation of safety, potency, and efficacy of novel biologic products and biomanufacturing technologies; and

(B) ensure the timely development of screening methods to evaluate safety and security of new biological products and processes.