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1ST SESSION

H. R. 4373

IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2019

Received; read twice and referred to the Committee on Commerce, Science,
and Transportation

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Engineering Biology
3 Research and Development Act of 2019”.

4 **SEC. 2. FINDINGS.**

5 The Congress makes the following findings:

6 (1) Cellular and molecular processes may be
7 used, mimicked, or redesigned to develop new prod-
8 ucts, processes, and systems that improve societal
9 well-being, strengthen national security, and con-
10 tribute to the economy.

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

15 (3) Long-term research and development is nec-
16 essary to create breakthroughs in engineering biol-
17 ogy. Such research and development requires govern-
18 ment investment as many of the benefits are too dis-
19 tant or uncertain for industry to support alone.

20 (4) Research is necessary to inform evidence-
21 based governance of engineering biology and to sup-
22 port the growth of the engineering biology industry.

23 (5) The Federal Government can play an im-
24 portant role by facilitating the development of tools
25 and technologies to further advance engineering biol-
26 ogy, including user facilities, by facilitating public-

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

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

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

18 **SEC. 3. DEFINITIONS.**

19 In this Act:

20 (1) **BIOMANUFACTURING.**—The term “bio-
21 manufacturing” means the utilization of biological
22 systems to develop new and advance existing prod-
23 ucts, tools, and processes at commercial scale.

24 (2) **ENGINEERING BIOLOGY.**—The term “engi-
25 neering biology” means the application of engineer-

1 ing design principles and practices to biological sys-
2 tems, including molecular and cellular systems, to
3 advance fundamental understanding of complex nat-
4 ural systems and to enable novel or optimize func-
5 tions and capabilities.

6 (3) INITIATIVE.—The term “Initiative” means
7 the National Engineering Biology Research and De-
8 velopment Initiative established under section 4.

9 (4) OMICS.—The term “omics” refers to the
10 collective technologies used to explore the roles, rela-
11 tionships, and actions of the various types of mol-
12 ecules that make up the cells of an organism.

13 **SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND**
14 **DEVELOPMENT INITIATIVE.**

15 (a) IN GENERAL.—The President, acting through the
16 Office of Science and Technology Policy, shall implement
17 a National Engineering Biology Research and Develop-
18 ment Initiative to advance societal well-being, national se-
19 curity, sustainability, and economic productivity and com-
20 petitiveness through—

21 (1) advancing areas of research at the intersec-
22 tion of the biological, physical, chemical, and infor-
23 mation sciences and engineering to accelerate sci-
24 entific understanding and technological innovation in
25 engineering biology;

1 (2) advancing areas of biomanufacturing re-
2 search to optimize, standardize, scale, and deliver
3 new products and solutions;

4 (3) supporting social and behavioral sciences
5 and economics research that advances the field of
6 engineering biology and contributes to the develop-
7 ment and public understanding of new products,
8 processes, and technologies;

9 (4) supporting risk research, including under
10 subsection (d);

11 (5) supporting the development of novel tools
12 and technologies to accelerate scientific under-
13 standing and technological innovation in engineering
14 biology;

15 (6) expanding the number of researchers, edu-
16 cators, and students with engineering biology train-
17 ing, including from traditionally underserved popu-
18 lations;

19 (7) accelerating the translation and commer-
20 cialization of engineering biology research and devel-
21 opment by the private sector; and

22 (8) improving the interagency planning and co-
23 ordination of Federal Government activities related
24 to engineering biology.

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

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

5 (A) grants to individual investigators and
6 teams of investigators, including interdiscipli-
7 nary teams;

8 (B) projects funded under joint sollicita-
9 tions by a collaboration of no fewer than two
10 agencies participating in the Initiative; and

11 (C) interdisciplinary research centers that
12 are organized to investigate basic research
13 questions, carry out technology development
14 and demonstration activities, and increase un-
15 derstanding of how to scale up engineering biol-
16 ogy processes, including biomanufacturing;

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

19 (A) support for curated genomics,
20 epigenomics, and all other relevant omics data-
21 bases, including plant and microbial databases,
22 that are available to researchers to carry out
23 engineering biology research;

1 (B) development of standards for such
2 databases, including for curation, interoper-
3 ability, and protection of privacy and security;

4 (C) support for the development of com-
5 putational tools, including artificial intelligence
6 tools, that can accelerate research and innova-
7 tion using such databases; and

8 (D) an inventory and assessment of all
9 Federal government omics databases to identify
10 opportunities for consolidation and inform in-
11 vestment in such databases as critical infra-
12 structure for the engineering biology research
13 enterprise;

14 (3) sustained support for the development, opti-
15 mization, and validation of novel tools and tech-
16 nologies to enable the dynamic study of molecular
17 processes in situ, including through grants to inves-
18 tigators at institutions of higher education and other
19 nonprofit research institutions, and through the
20 Small Business Innovation Research Program and
21 the Small Business Technology Transfer Program,
22 as described in section 9 of the Small Business Act
23 (15 U.S.C. 638);

24 (4) education and training of undergraduate
25 and graduate students in engineering biology, in bio-

1 manufacturing, in bioprocess engineering, and in
2 areas of computational science applied to engineer-
3 ing biology;

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

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

10 (A) identifying precompetitive research op-
11 portunities;

12 (B) facilitating public-private partnerships
13 in engineering biology research and develop-
14 ment;

15 (C) connecting researchers, graduate stu-
16 dents, and postdoctoral fellows with entrepre-
17 neurship education and training opportunities;
18 and

19 (D) supporting proof of concept activities
20 and the formation of startup companies includ-
21 ing through programs such as the Small Busi-
22 ness Innovation Research Program and the
23 Small Business Technology Transfer Program.

24 (c) EXPANDING PARTICIPATION.—The Initiative
25 shall include, to the maximum extent practicable, outreach

1 to primarily undergraduate and minority-serving institu-
2 tions about Initiative opportunities, and shall encourage
3 the development of research collaborations between re-
4 search-intensive universities and primarily undergraduate
5 and minority-serving institutions.

6 (d) ETHICAL, LEGAL, ENVIRONMENTAL, SAFETY,
7 SECURITY, AND SOCIETAL ISSUES.—Initiative activities
8 shall take into account ethical, legal, environmental, safe-
9 ty, security, and other appropriate societal issues by—

10 (1) supporting research, including in the social
11 sciences, and other activities addressing ethical,
12 legal, environmental, and other appropriate societal
13 issues related to engineering biology, including inte-
14 grating research on such topics with the research
15 and development in engineering biology, and ensur-
16 ing that the results of such research are widely dis-
17 seminated, including through interdisciplinary engi-
18 neering biology research centers described in sub-
19 section (b)(1);

20 (2) supporting research and other activities re-
21 lated to the safety and security implications of engi-
22 neering biology, including outreach to increase
23 awareness among federally-funded researchers at in-
24 stitutions of higher education about potential safety

1 and security implications of engineering biology re-
2 search, as appropriate;

3 (3) ensuring that input from Federal and non-
4 Federal experts on the ethical, legal, environmental,
5 security, and other appropriate societal issues re-
6 lated to engineering biology is integrated into the
7 Initiative; and

8 (4) ensuring, through the agencies and depart-
9 ments that participate in the Initiative, that public
10 input and outreach are integrated into the Initiative
11 by the convening of regular and ongoing public dis-
12 cussions through mechanisms such as workshops,
13 consensus conferences, and educational events, as
14 appropriate.

15 **SEC. 5. INITIATIVE COORDINATION.**

16 (a) INTERAGENCY COMMITTEE.—The President, act-
17 ing through the Office of Science and Technology Policy,
18 shall designate an interagency committee to coordinate en-
19 gineering biology, which shall be co-chaired by the Office
20 of Science and Technology Policy, and include representa-
21 tives from the National Science Foundation, the Depart-
22 ment of Energy, the National Aeronautics and Space Ad-
23 ministration, the National Institute of Standards and
24 Technology, the Environmental Protection Agency, the
25 Department of Agriculture, the National Institutes of

1 Health, the Bureau of Economic Analysis, and any other
2 agency that the President considers appropriate (in this
3 section referred to as the “interagency committee”). The
4 Director of the Office of Science and Technology Policy
5 shall select an additional co-chairperson from among the
6 members of the Interagency Committee. The Interagency
7 Committee shall oversee the planning, management, and
8 coordination of the Initiative. The Interagency Committee
9 shall—

10 (1) provide for interagency coordination of Fed-
11 eral engineering biology research, development, and
12 other activities undertaken pursuant to the Initia-
13 tive;

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

16 (3) develop, not later than 12 months after the
17 date of enactment of this Act, and update every 3
18 years, a strategic plan that—

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

23 (B) describes—

- 1 (i) the Initiative’s support for long-
2 term funding for interdisciplinary engineer-
3 ing biology research and development;
- 4 (ii) the Initiative’s support for edu-
5 cation and public outreach activities;
- 6 (iii) the Initiative’s support for re-
7 search and other activities on ethical, legal,
8 environmental, safety, security, and other
9 appropriate societal issues related to engi-
10 neering biology;
- 11 (iv) how the Initiative will move re-
12 sults out of the laboratory and into appli-
13 cation for the benefit of society and United
14 States competitiveness; and
- 15 (v) how the Initiative will measure
16 and track the contributions of engineering
17 biology to United States economic growth
18 and other societal indicators;
- 19 (4) develop a national genomic sequencing
20 strategy to ensure engineering biology research fully
21 leverages plant, animal, and microbe biodiversity to
22 enhance long-term innovation and competitiveness in
23 engineering biology in the United States;
- 24 (5) propose an annually coordinated interagency
25 budget for the Initiative that is intended to ensure—

1 (A) the maintenance of a robust engineer-
2 ing biology research and development portfolio;
3 and

4 (B) that the balance of funding across the
5 Initiative is sufficient to meet the goals and pri-
6 orities established for the Program;

7 (6) develop a plan to utilize Federal programs,
8 such as the Small Business Innovation Research
9 Program and the Small Business Technology Trans-
10 fer Program as described in section 9 of the Small
11 Business Act (15 U.S.C. 638), in support of the ac-
12 tivities described in section 4(b)(3); and

13 (7) in carrying out this section, take into con-
14 sideration the recommendations of the advisory com-
15 mittee established under section 6, the results of the
16 workshop convened under section 7, existing reports
17 on related topics, and the views of academic, State,
18 industry, and other appropriate groups.

19 (b) ANNUAL REPORT.—Beginning with fiscal year
20 2020, not later than 90 days after submission of the Presi-
21 dent’s annual budget request and each fiscal year there-
22 after, the interagency committee shall prepare and submit
23 to the Committee on Science, Space, and Technology of
24 the House of Representatives and the Committee on Com-

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

3 (1) a summarized agency budget in support of
4 the Initiative for the fiscal year to which such budg-
5 et request applies, and for the then current fiscal
6 year, including a breakout of spending for each
7 agency participating in the Program and for the de-
8 velopment and acquisition of any research facilities
9 and instrumentation; and

10 (2) an assessment of how Federal agencies are
11 implementing the plan described in subsection
12 (a)(3), and a description of the amount and number
13 of awards made under the Small Business Innova-
14 tion Research Program and the Small Business
15 Technology Transfer Program (as described in sec-
16 tion 9 of the Small Business Act (15 U.S.C. 638))
17 in support of the Initiative.

18 (c) INITIATIVE OFFICE.—

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

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

1 (B) serve as the point of contact on Fed-
2 eral engineering biology activities for govern-
3 ment organizations, academia, industry, profes-
4 sional societies, State governments, interested
5 citizen groups, and others to exchange technical
6 and programmatic information;

7 (C) oversee interagency coordination of the
8 Initiative, including by encouraging and sup-
9 porting joint agency solicitation and selection of
10 applications for funding of activities under the
11 Initiative;

12 (D) conduct public outreach, including dis-
13 semination of findings and recommendations of
14 the advisory committee established under sec-
15 tion 6, as appropriate; and

16 (E) promote access to, and early applica-
17 tion of, the technologies, innovations, and ex-
18 pertise derived from Initiative activities to agen-
19 cy missions and systems across the Federal
20 Government, and to United States industry, in-
21 cluding startup companies.

22 (2) FUNDING.—The Director of the Office of
23 Science and Technology Policy shall develop an esti-
24 mate of the funds necessary to carry out the activi-
25 ties of the Initiative Coordination Office, including

1 an estimate of how much each participating agency
2 described in subsection (a) will contribute to such
3 funds, and submit such estimate to Congress no
4 later than 90 days after the enactment of this Act.

5 (3) **TERMINATION.**—The Initiative Coordination
6 Office established under this subsection shall termi-
7 nate on the date that is 10 years after the date of
8 the enactment of this Act, unless a determination is
9 made by the President that such Office is necessary
10 to meet the economic or national security goals of
11 the Program.

12 **SEC. 6. ADVISORY COMMITTEE.**

13 (a) **IN GENERAL.**—The President, acting through the
14 Office of Science and Technology Policy, shall designate
15 or establish an advisory committee on engineering biology
16 research and development (in this section referred to as
17 the “advisory committee”) to be composed of not fewer
18 than 12 members, including representatives of research
19 and academic institutions, industry, and nongovernmental
20 entities, who are qualified to provide advice on the Initia-
21 tive.

22 (b) **ASSESSMENT.**—The advisory committee shall as-
23 sess—

24 (1) the current state of United States competi-
25 tiveness in engineering biology, including the scope

1 and scale of United States investments in engineer-
2 ing biology research and development in the inter-
3 national context;

4 (2) current market barriers to commercializa-
5 tion of engineering biology products, processes, and
6 tools in the United States;

7 (3) progress made in implementing the Initia-
8 tive;

9 (4) the need to revise the Initiative;

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

12 (6) whether the strategic plan developed or up-
13 dated by the interagency committee established
14 under section 5 is helping to maintain United States
15 leadership in engineering biology;

16 (7) the management, coordination, implementa-
17 tion, and activities of the Initiative; and

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

21 (c) REPORTS.—Beginning not later than 2 years
22 after the date of enactment of this Act, and not less fre-
23 quently than once every 3 years thereafter, the advisory
24 committee shall submit to the President, the Committee
25 on Science, Space, and Technology of the House of Rep-

1 representatives, and the Committee on Commerce, Science,
2 and Transportation of the Senate, a report on—

3 (1) the findings of the advisory committee’s as-
4 sessment under subsection (b); and

5 (2) the advisory committee’s recommendations
6 for ways to improve the Initiative.

7 (d) APPLICATION OF FEDERAL ADVISORY COM-
8 MITTEE ACT.—Section 14 of the Federal Advisory Com-
9 mittee Act (5 U.S.C. App.) shall not apply to the Advisory
10 Committee.

11 **SEC. 7. EXTERNAL REVIEW OF ETHICAL, LEGAL, ENVIRON-**
12 **MENTAL, AND SOCIETAL ISSUES.**

13 (a) IN GENERAL.—Not later than 6 months after the
14 date of enactment of this Act, the Director of the National
15 Science Foundation shall enter into an agreement with the
16 National Academies of Sciences, Engineering, and Medi-
17 cine to conduct a review, and make recommendations with
18 respect to, the ethical, legal, environmental, and other ap-
19 propriate societal issues related to engineering biology re-
20 search and development. The review shall include—

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

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

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

4 (4) recommendations on how engineering biol-
5 ogy researchers can best incorporate considerations
6 of ethical, legal, environmental, and other societal
7 issues into the development of research proposals
8 and the conduct of research.

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

13 (1) submit to the Committee on Science, Space,
14 and Technology of the House of Representatives and
15 the Committee on Commerce, Science, and Trans-
16 portation of the Senate a report containing the find-
17 ings and recommendations of the review conducted
18 under subsection (a); and

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

21 **SEC. 8. AGENCY ACTIVITIES.**

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

1 (1) support basic research in engineering biol-
2 ogy through individual grants and through inter-
3 disciplinary research centers;

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

6 (3) provide support for research instrumenta-
7 tion for engineering biology disciplines, including
8 support for research, development, optimization and
9 validation of novel technologies to enable the dy-
10 namic study of molecular processes in situ;

11 (4) support curriculum development and re-
12 search experiences for secondary, undergraduate,
13 and graduate students in engineering biology and
14 biomanufacturing; and

15 (5) award grants, on a competitive basis, to en-
16 able institutions to support graduate students and
17 postdoctoral fellows who perform some of their engi-
18 neering biology research in an industry setting.

19 (b) DEPARTMENT OF COMMERCE.—As part of the
20 Initiative, the Director of the National Institute of Stand-
21 ards and Technology shall—

22 (1) establish a bioscience research program to
23 advance the development of standard reference ma-
24 terials and measurements and to create new data

1 tools, techniques, and processes necessary to advance
2 engineering biology and biomanufacturing;

3 (2) provide access to user facilities with ad-
4 vanced or unique equipment, services, materials, and
5 other resources to industry, institutions of higher
6 education, nonprofit organizations, and government
7 agencies to perform research and testing; and

8 (3) provide technical expertise to inform the po-
9 tential development of guidelines or safeguards for
10 new products, processes, and systems of engineering
11 biology.

12 (c) DEPARTMENT OF ENERGY.—As part of the Ini-
13 tiative, the Secretary of Energy shall—

14 (1) conduct and support research, development,
15 demonstration, and commercial application activities
16 in engineering biology, including in the areas of syn-
17 thetic biology, advanced biofuel development,
18 biobased materials, and environmental remediation;

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

23 (3) provide access to user facilities with ad-
24 vanced or unique equipment, services, materials, and
25 other resources, as appropriate, to industry, institu-

1 tions of higher education, nonprofit organizations,
2 and government agencies to perform research and
3 testing.

4 (d) NATIONAL AERONAUTICS AND SPACE ADMINIS-
5 TRATION.—As part of the Initiative, the National Aero-
6 nautics and Space Administration shall—

7 (1) conduct and support basic and applied re-
8 search in engineering biology, including in synthetic
9 biology, and related to Earth and space sciences,
10 aeronautics, space technology, and space exploration
11 and experimentation, consistent with the priorities
12 established in the National Academies' decadal sur-
13 veys; and

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

18 (e) ENVIRONMENTAL PROTECTION AGENCY.—As
19 part of the Initiative, the Environmental Protection Agen-
20 cy shall support research on how products, processes, and

- 1 systems of engineering biology will affect or can protect
- 2 the environment.

Passed the House of Representatives December 9,
2019.

Attest: CHERYL L. JOHNSON,
Clerk.