

116TH CONGRESS
1ST SESSION

H. R. 4373

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2019

Ms. JOHNSON of Texas (for herself, Mr. SENSENBRENNER, Ms. LOFGREN,
and Mr. LUCAS) introduced the following bill; which was referred to the
Committee on Science, Space, and Technology

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. FINDINGS.**

7 The Congress makes the following findings:

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

1 ucts, processes, and systems that improve societal
2 well-being, strengthen national security, and con-
3 tribute to the economy.

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

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

13 (4) Research is necessary to inform evidence-
14 based governance of engineering biology and to sup-
15 port the growth of the engineering biology industry.

16 (5) The Federal Government can play an im-
17 portant role by facilitating the development of tools
18 and technologies to further advance engineering biol-
19 ogy, including user facilities, by facilitating public-
20 private partnerships, by supporting risk research,
21 and by facilitating the commercial application in the
22 United States of research funded by the Federal
23 Government.

24 (6) The United States led the development of
25 the science and engineering techniques that created

1 the field of engineering biology, but due to increas-
2 ing international competition, the United States is
3 at risk of losing its competitive advantage if it does
4 not invest the necessary resources and have a na-
5 tional strategy.

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

12 **SEC. 3. DEFINITIONS.**

13 In this Act:

14 (1) BIOMANUFACTURING.—The term “bio-
15 manufacturing” means the utilization of biological
16 systems to develop new and advance existing prod-
17 ucts, tools, and processes at commercial scale.

18 (2) ENGINEERING BIOLOGY.—The term “engi-
19 neering biology” means the application of engineer-
20 ing design principles and practices to biological sys-
21 tems, including molecular and cellular systems, to
22 advance fundamental understanding of complex nat-
23 ural systems and to enable novel functions and capa-
24 bilities.

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

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

8 **SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND**
9 **DEVELOPMENT INITIATIVE.**

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

16 (1) advancing areas of research at the intersec-
17 tion of the biological, physical, chemical, and infor-
18 mation sciences and engineering to accelerate sci-
19 entific understanding and technological innovation in
20 engineering biology;

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

24 (3) supporting social and behavioral sciences
25 and economics research that advances the field of

1 engineering biology and contributes to the develop-
2 ment and public understanding of new products,
3 processes, and technologies;

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

6 (5) supporting the development of novel tools
7 and technologies to accelerate scientific under-
8 standing and technological innovation in engineering
9 biology;

10 (6) expanding the number of researchers, edu-
11 cators, and students with engineering biology train-
12 ing, including from traditionally underserved popu-
13 lations;

14 (7) accelerating the translation and commer-
15 cialization of engineering biology research and devel-
16 opment by the private sector; and

17 (8) improving the interagency planning and co-
18 ordination of Federal Government activities related
19 to engineering biology.

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

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

1 (A) grants to individual investigators and
2 teams of investigators, including interdisdiscipli-
3 nary teams;

4 (B) projects funded under joint solicita-
5 tions by a collaboration of no fewer than two
6 agencies participating in the Initiative; and

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

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

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

20 (B) development of standards for such
21 databases, including for curation, interoper-
22 ability, and protection of privacy and security;

23 (C) support for the development of com-
24 putational tools, including artificial intelligence

1 tools, that can accelerate research and innova-
2 tion using such databases; and

3 (D) an inventory and assessment of all
4 Federal government omics databases to identify
5 opportunities for consolidation and inform in-
6 vestment in such databases as critical infra-
7 structure for the engineering biology research
8 enterprise;

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

19 (4) education and training of undergraduate
20 and graduate students in engineering biology, in bio-
21 manufacturing, in bioprocess engineering, and in
22 areas of computational science applied to engineer-
23 ing biology;

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

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

7 (A) identifying precompetitive research op-
8 portunities;

9 (B) facilitating public-private partnerships
10 in engineering biology research and develop-
11 ment;

12 (C) connecting researchers, graduate stu-
13 dents, and postdoctoral fellows with entrepre-
14 neurship education and training opportunities;
15 and

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

21 (c) EXPANDING PARTICIPATION.—The Initiative
22 shall include, to the maximum extent practicable, outreach
23 to primarily undergraduate and minority-serving institu-
24 tions about Initiative opportunities, and shall encourage
25 the development of research collaborations between re-

1 search-intensive universities and primarily undergraduate
2 and minority-serving institutions.

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

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

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

24 (3) ensuring that input from Federal and non-
25 Federal experts on the ethical, legal, environmental,

1 security, and other appropriate societal issues re-
2 lated to engineering biology is integrated into the
3 Initiative; and

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

11 **SEC. 5. INITIATIVE COORDINATION.**

12 (a) INTERAGENCY COMMITTEE.—The President, act-
13 ing through the Office of Science and Technology Policy,
14 shall designate an interagency committee to coordinate en-
15 gineering biology, which shall be co-chaired by the Office
16 of Science and Technology Policy, and include representa-
17 tives from the National Science Foundation, the Depart-
18 ment of Energy, the National Aeronautics and Space Ad-
19 ministration, the National Institute of Standards and
20 Technology, the Environmental Protection Agency, the
21 Department of Agriculture, the National Institutes of
22 Health, the Bureau of Economic Analysis, and any other
23 agency that the President considers appropriate (in this
24 section referred to as the “interagency committee”). The
25 Director of the Office of Science and Technology Policy

1 shall select an additional co-chairperson from among the
2 members of the Interagency Committee. The Interagency
3 Committee shall oversee the planning, management, and
4 coordination of the Initiative. The Interagency Committee
5 shall—

6 (1) provide for interagency coordination of Fed-
7 eral engineering biology research, development, and
8 other activities undertaken pursuant to the Initia-
9 tive;

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

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

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

19 (B) describes—

20 (i) the Initiative's support for long-
21 term funding for interdisciplinary engineer-
22 ing biology research and development;

23 (ii) the Initiative's support for edu-
24 cation and public outreach activities;

1 (iii) the Initiative's support for re-
2 search and other activities on ethical, legal,
3 environmental, safety, security, and other
4 appropriate societal issues related to engi-
5 neering biology;

6 (iv) how the Initiative will move re-
7 sults out of the laboratory and into appli-
8 cation for the benefit of society and United
9 States competitiveness; and

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

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

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

21 (A) the maintenance of a robust engineer-
22 ing biology research and development portfolio;
23 and

1 (B) that the balance of funding across the
2 Initiative is sufficient to meet the goals and pri-
3 orities established for the Program;

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

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

16 (b) ANNUAL REPORT.—Beginning with fiscal year
17 2020, not later than 90 days after submission of the Presi-
18 dent’s annual budget request and each fiscal year there-
19 after, the interagency committee shall prepare and submit
20 to the Committee on Science, Space, and Technology of
21 the House of Representatives and the Committee on Com-
22 merce, Science, and Transportation of the Senate a report
23 that includes—

24 (1) a summarized agency budget in support of
25 the Initiative for the fiscal year to which such budg-

1 et request applies, and for the then current fiscal
2 year, including a breakout of spending for each
3 agency participating in the Program and for the de-
4 velopment and acquisition of any research facilities
5 and instrumentation; and

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

14 (c) INITIATIVE STAFFING.—The President shall en-
15 sure adequate staffing for the Initiative, including full-
16 time staff within the Office of Science and Technology
17 Policy, who shall—

18 (1) provide technical and administrative support
19 to the interagency committee and the advisory com-
20 mittee established under section 6;

21 (2) serve as the point of contact on Federal en-
22 gineering biology activities for government organiza-
23 tions, academia, industry, professional societies,
24 State governments, interested citizen groups, and

1 others to exchange technical and programmatic in-
2 formation;

3 (3) oversee interagency coordination of the Ini-
4 tiative, including by encouraging and supporting
5 joint agency solicitation and selection of applications
6 for funding of activities under the Initiative;

7 (4) conduct public outreach, including dissemi-
8 nation of findings and recommendations of the advi-
9 sory committee established under section 6, as ap-
10 propriate; and

11 (5) promote access to, and early application of,
12 the technologies, innovations, and expertise derived
13 from Initiative activities to agency missions and sys-
14 tems across the Federal Government, and to United
15 States industry, including startup companies.

16 **SEC. 6. ADVISORY COMMITTEE.**

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

1 (b) ASSESSMENT.—The advisory committee shall as-
2 sess—

3 (1) the current state of United States competi-
4 tiveness in engineering biology, including the scope
5 and scale of United States investments in engineer-
6 ing biology research and development in the inter-
7 national context;

8 (2) current market barriers to commercializa-
9 tion of engineering biology products, processes, and
10 tools in the United States;

11 (3) progress made in implementing the Initia-
12 tive;

13 (4) the need to revise the Initiative;

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

16 (6) whether the strategic plan developed or up-
17 dated by the interagency committee established
18 under section 5 is helping to maintain United States
19 leadership in engineering biology;

20 (7) the management, coordination, implementa-
21 tion, and activities of the Initiative; and

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

1 (c) REPORTS.—Beginning not later than 2 years
2 after the date of enactment of this Act, and not less fre-
3 quently than once every 3 years thereafter, the advisory
4 committee shall submit to the President, the Committee
5 on Science, Space, and Technology of the House of Rep-
6 resentatives, and the Committee on Commerce, Science,
7 and Transportation of the Senate, a report on—

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

10 (2) the advisory committee’s recommendations
11 for ways to improve the Initiative.

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

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

18 (a) IN GENERAL.—Not later than 12 months after
19 the date of enactment of this Act, the Director of the Na-
20 tional Science Foundation shall enter into an agreement
21 with the National Academies to convene a workshop to
22 review the ethical, legal, environmental, and other appro-
23 priate societal issues related to engineering biology re-
24 search and development. The goals of the workshop shall
25 be to—

- 1 (1) assess the current research on such issues;
- 2 (2) evaluate the research gaps relating to such
- 3 issues; and
- 4 (3) provide recommendations on how the Initia-
- 5 tive can address the research needs identified.

6 (b) REPORT TO CONGRESS.—Not later than 2 years
7 after the date of enactment of this Act, the Director of
8 the National Science Foundation shall transmit to the
9 Committee on Science, Space, and Technology of the
10 House of Representatives and the Committee on Com-
11 merce, Science, and Transportation of the Senate a sum-
12 mary report containing the findings of the workshop con-
13 vened under this section.

14 **SEC. 8. AGENCY ACTIVITIES.**

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

- 17 (1) support basic research in engineering biol-
- 18 ogy through individual grants and through inter-
- 19 disciplinary research centers;
- 20 (2) support research on the environmental,
- 21 legal, and social implications of engineering biology;
- 22 (3) provide support for research instrumenta-
- 23 tion for engineering biology disciplines, including
- 24 support for research, development, optimization and

1 validation of novel technologies to enable the dy-
2 namic study of molecular processes in situ; and

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

7 (b) DEPARTMENT OF COMMERCE.—As part of the
8 Initiative, the Director of the National Institute of Stand-
9 ards and Technology shall—

10 (1) establish a bioscience research program to
11 advance the development of standard reference ma-
12 terials and measurements and to create new data
13 tools, techniques, and processes necessary to advance
14 engineering biology and biomanufacturing;

15 (2) provide access to user facilities with ad-
16 vanced or unique equipment, services, materials, and
17 other resources to industry, institutions of higher
18 education, nonprofit organizations, and government
19 agencies to perform research and testing; and

20 (3) provide technical expertise to inform the po-
21 tential development of guidelines or safeguards for
22 new products, processes, and systems of engineering
23 biology.

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

1 (1) conduct and support basic research, devel-
2 opment, demonstration, and commercial application
3 activities in engineering biology, including in the
4 areas of synthetic biology, advanced biofuel develop-
5 ment, biobased materials, and environmental remedi-
6 ation;

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

11 (3) provide access to user facilities with ad-
12 vanced or unique equipment, services, materials, and
13 other resources, as appropriate, to industry, institu-
14 tions of higher education, nonprofit organizations,
15 and government agencies to perform research and
16 testing.

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

20 (1) conduct and support basic and applied re-
21 search in engineering biology, including in synthetic
22 biology, and related to Earth and space sciences,
23 aeronautics, space technology, and space exploration
24 and experimentation, consistent with the priorities

1 established in the National Academies' decadal sur-
2 veys; and

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

7 (e) ENVIRONMENTAL PROTECTION AGENCY.—As
8 part of the Initiative, the Environmental Protection Agen-
9 cy shall support research on how products, processes, and
10 systems of engineering biology will affect or can protect
11 the environment.

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