

Suspend the Rules and Pass the Bill, H.R. 4373, with an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

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:

1 (1) Cellular and molecular processes may be
2 used, mimicked, or redesigned to develop new prod-
3 ucts, processes, and systems that improve societal
4 well-being, strengthen national security, and con-
5 tribute to the economy.

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

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

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

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

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

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

14 **SEC. 3. DEFINITIONS.**

15 In this Act:

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

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

1 ural systems and to enable novel or optimize func-
2 tions and capabilities.

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

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

10 **SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND**
11 **DEVELOPMENT INITIATIVE.**

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

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

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

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

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

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

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

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

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

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

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

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

4 (B) projects funded under joint sollicita-
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 and

24 (C) support for the development of com-
25 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 OFFICE.—

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

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

21 (B) serve as the point of contact on Fed-
22 eral engineering biology activities for govern-
23 ment organizations, academia, industry, profes-
24 sional societies, State governments, interested

1 citizen groups, and others to exchange technical
2 and programmatic information;

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

8 (D) conduct public outreach, including dis-
9 semination of findings and recommendations of
10 the advisory committee established under sec-
11 tion 6, as appropriate; and

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

18 (2) FUNDING.—The Director of the Office of
19 Science and Technology Policy shall develop an esti-
20 mate of the funds necessary to carry out the activi-
21 ties of the Initiative Coordination Office, including
22 an estimate of how much each participating agency
23 described in subsection (a) will contribute to such
24 funds, and submit such estimate to Congress no
25 later than 90 days after the enactment of this Act.

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

8 **SEC. 6. ADVISORY COMMITTEE.**

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

18 (b) **ASSESSMENT.**—The advisory committee shall as-
19 sess—

20 (1) the current state of United States competi-
21 tiveness in engineering biology, including the scope
22 and scale of United States investments in engineer-
23 ing biology research and development in the inter-
24 national context;

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

4 (3) progress made in implementing the Initia-
5 tive;

6 (4) the need to revise the Initiative;

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

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

13 (7) the management, coordination, implementa-
14 tion, and activities of the Initiative; and

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

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

1 (1) the findings of the advisory committee's as-
2 sessment under subsection (b); and

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

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

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

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

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

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

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

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

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

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

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

18 **SEC. 8. AGENCY ACTIVITIES.**

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

21 (1) support basic research in engineering biol-
22 ogy through individual grants and through inter-
23 disciplinary research centers;

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

1 (3) provide support for research instrumenta-
2 tion for engineering biology disciplines, including
3 support for research, development, optimization and
4 validation of novel technologies to enable the dy-
5 namic study of molecular processes in situ;

6 (4) support curriculum development and re-
7 search experiences for secondary, undergraduate,
8 and graduate students in engineering biology and
9 biomanufacturing; and

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

14 (b) DEPARTMENT OF COMMERCE.—As part of the
15 Initiative, the Director of the National Institute of Stand-
16 ards and Technology shall—

17 (1) establish a bioscience research program to
18 advance the development of standard reference ma-
19 terials and measurements and to create new data
20 tools, techniques, and processes necessary to advance
21 engineering biology and biomanufacturing;

22 (2) provide access to user facilities with ad-
23 vanced or unique equipment, services, materials, and
24 other resources to industry, institutions of higher

1 education, nonprofit organizations, and government
2 agencies to perform research and testing; and

3 (3) provide technical expertise to inform the po-
4 tential development of guidelines or safeguards for
5 new products, processes, and systems of engineering
6 biology.

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

9 (1) conduct and support research, development,
10 demonstration, and commercial application activities
11 in engineering biology, including in the areas of syn-
12 thetic biology, advanced biofuel development,
13 biobased materials, and environmental remediation;

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

18 (3) provide access to user facilities with ad-
19 vanced or unique equipment, services, materials, and
20 other resources, as appropriate, to industry, institu-
21 tions of higher education, nonprofit organizations,
22 and government agencies to perform research and
23 testing.

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

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

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

15 (e) ENVIRONMENTAL PROTECTION AGENCY.—As
16 part of the Initiative, the Environmental Protection Agen-
17 cy shall support research on how products, processes, and
18 systems of engineering biology will affect or can protect
19 the environment.