

Union Calendar No. 215

116TH CONGRESS
1ST SESSION

H. R. 4373

[Report No. 116–270]

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

NOVEMBER 5, 2019

Additional sponsors: Ms. HILL of California, Mr. FOSTER, Mr. FITZPATRICK,
Miss GONZÁLEZ-COLÓN of Puerto Rico, Mr. BEYER, Ms. KENDRA S.
HORN of Oklahoma, and Mr. CASTEN of Illinois

NOVEMBER 5, 2019

Reported with an amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on September 18, 2019]

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-*
10 *ucts, processes, and systems that improve societal*
11 *well-being, strengthen national security, and con-*
12 *tribute to the economy.*

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

17 (3) *Long-term research and development is nec-*
18 *essary to create breakthroughs in engineering biology.*
19 *Such research and development requires government*
20 *investment as many of the benefits are too distant or*
21 *uncertain for industry to support alone.*

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

1 (5) *The Federal Government can play an impor-*
2 *tant role by facilitating the development of tools and*
3 *technologies to further advance engineering biology,*
4 *including user facilities, by facilitating public-private*
5 *partnerships, by supporting risk research, and by fa-*
6 *cilitating the commercial application in the United*
7 *States of research funded by the Federal Government.*

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

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

20 **SEC. 3. DEFINITIONS.**

21 *In this Act:*

22 (1) *BIOMANUFACTURING.*—*The term “biomanu-*
23 *facturing” means the utilization of biological systems*
24 *to develop new and advance existing products, tools,*
25 *and processes at commercial scale.*

1 (2) *ENGINEERING BIOLOGY.*—The term “engi-
2 neering biology” means the application of engineering
3 design principles and practices to biological systems,
4 including molecular and cellular systems, to advance
5 fundamental understanding of complex natural sys-
6 tems and to enable novel or optimize functions and
7 capabilities.

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

11 (4) *OMICS.*—The term “omics” refers to the col-
12 lective technologies used to explore the roles, relation-
13 ships, and actions of the various types of molecules
14 that make up the cells of an organism.

15 **SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND**
16 **DEVELOPMENT INITIATIVE.**

17 (a) *IN GENERAL.*—The President, acting through the
18 Office of Science and Technology Policy, shall implement
19 a National Engineering Biology Research and Development
20 Initiative to advance societal well-being, national security,
21 sustainability, and economic productivity and competitive-
22 ness through—

23 (1) *advancing areas of research at the intersec-*
24 *tion of the biological, physical, chemical, and infor-*
25 *mation sciences and engineering to accelerate sci-*

1 *entific understanding and technological innovation in*
2 *engineering biology;*

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

6 (3) *supporting social and behavioral sciences*
7 *and economics research that advances the field of en-*
8 *gineering biology and contributes to the development*
9 *and public understanding of new products, processes,*
10 *and technologies;*

11 (4) *supporting risk research, including under*
12 *subsection (d);*

13 (5) *supporting the development of novel tools and*
14 *technologies to accelerate scientific understanding and*
15 *technological innovation in engineering biology;*

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

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

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

1 (b) *INITIATIVE ACTIVITIES.*—*The activities of the Ini-*
2 *tiative shall include—*

3 (1) *sustained support for engineering biology re-*
4 *search 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 solicitations*
9 *by a collaboration of no fewer than two agencies*
10 *participating in the Initiative; and*

11 (C) *interdisciplinary research centers that*
12 *are organized to investigate basic research ques-*
13 *tions, carry out technology development and*
14 *demonstration activities, and increase under-*
15 *standing of how to scale up engineering biology*
16 *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 en-*
23 *gineering biology research;*

1 (B) development of standards for such data-
2 bases, including for curation, interoperability,
3 and protection of privacy and security; and

4 (C) support for the development of computa-
5 tional 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 Fed-
9 eral government omics databases to identify op-
10 portunities for consolidation and inform invest-
11 ment in such databases as critical infrastructure
12 for the engineering biology research enterprise;

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

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

1 *areas of computational science applied to engineering*
2 *biology;*

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

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

9 *(A) identifying precompetitive research op-*
10 *portunities;*

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

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

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

22 *(c) EXPANDING PARTICIPATION.—The Initiative shall*
23 *include, to the maximum extent practicable, outreach to*
24 *primarily undergraduate and minority-serving institutions*
25 *about Initiative opportunities, and shall encourage the de-*

1 *velopment of research collaborations between research-inten-*
2 *sive universities and primarily undergraduate and minor-*
3 *ity-serving institutions.*

4 (d) *ETHICAL, LEGAL, ENVIRONMENTAL, SAFETY, SE-*
5 *CURITY, AND SOCIETAL ISSUES.—Initiative activities shall*
6 *take into account ethical, legal, environmental, safety, secu-*
7 *rity, and other appropriate societal issues by—*

8 (1) *supporting research, including in the social*
9 *sciences, and other activities addressing ethical, legal,*
10 *environmental, and other appropriate societal issues*
11 *related to engineering biology, including integrating*
12 *research on such topics with the research and develop-*
13 *ment in engineering biology, and ensuring that the*
14 *results of such research are widely disseminated, in-*
15 *cluding through interdisciplinary engineering biology*
16 *research centers described in subsection (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 aware-*
20 *ness among federally-funded researchers at institu-*
21 *tions of higher education about potential safety and*
22 *security implications of engineering biology research,*
23 *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 related
2 to engineering biology is integrated into the Initia-
3 tive; 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, con-
9 sensus conferences, and educational events, as appro-
10 priate.

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

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

1 *co-chairperson from among the members of the Interagency*
2 *Committee. The Interagency Committee shall oversee the*
3 *planning, management, and coordination of the Initiative.*

4 *The Interagency Committee shall—*

5 *(1) provide for interagency coordination of Fed-*
6 *eral engineering biology research, development, and*
7 *other activities undertaken pursuant to the Initiative;*

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

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

13 *(A) guides the activities of the Initiative for*
14 *purposes of meeting the goals and priorities es-*
15 *tablished under (and updated pursuant to) para-*
16 *graph (2); and*

17 *(B) describes—*

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

21 *(ii) the Initiative's support for edu-*
22 *cation and public outreach activities;*

23 *(iii) the Initiative's support for re-*
24 *search and other activities on ethical, legal,*
25 *environmental, safety, security, and other*

1 *appropriate societal issues related to engi-*
2 *neering biology;*

3 *(iv) how the Initiative will move re-*
4 *sults out of the laboratory and into applica-*
5 *tion for the benefit of society and United*
6 *States competitiveness; and*

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

11 *(4) develop a national genomic sequencing strat-*
12 *egy to ensure engineering biology research fully*
13 *leverages plant, animal, and microbe biodiversity to*
14 *enhance long-term innovation and competitiveness in*
15 *engineering biology in the United States;*

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

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

20 *(B) that the balance of funding across the*
21 *Initiative is sufficient to meet the goals and pri-*
22 *orities established for the Program;*

23 *(6) develop a plan to utilize Federal programs,*
24 *such as the Small Business Innovation Research Pro-*
25 *gram and the Small Business Technology Transfer*

1 *Program as described in section 9 of the Small Busi-*
2 *ness Act (15 U.S.C. 638), in support of the activities*
3 *described in section 4(b)(3); and*

4 *(7) in carrying out this section, take into consid-*
5 *eration the recommendations of the advisory com-*
6 *mittee established under section 6, the results of the*
7 *workshop convened under section 7, existing reports*
8 *on related topics, and the views of academic, State,*
9 *industry, and other appropriate groups.*

10 *(b) ANNUAL REPORT.—Beginning with fiscal year*
11 *2020, not later than 90 days after submission of the Presi-*
12 *dent’s annual budget request and each fiscal year thereafter,*
13 *the interagency committee shall prepare and submit to the*
14 *Committee on Science, Space, and Technology of the House*
15 *of Representatives and the Committee on Commerce,*
16 *Science, and Transportation of the Senate a report that in-*
17 *cludes—*

18 *(1) a summarized agency budget in support of*
19 *the Initiative for the fiscal year to which such budget*
20 *request applies, and for the then current fiscal year,*
21 *including a breakout of spending for each agency par-*
22 *ticipating in the Program and for the development*
23 *and acquisition of any research facilities and instru-*
24 *mentation; and*

1 (2) *an assessment of how Federal agencies are*
2 *implementing the plan described in subsection (a)(3),*
3 *and a description of the amount and number of*
4 *awards made under the Small Business Innovation*
5 *Research Program and the Small Business Tech-*
6 *nology Transfer Program (as described in section 9 of*
7 *the Small Business Act (15 U.S.C. 638)) in support*
8 *of the Initiative.*

9 (c) *INITIATIVE STAFFING.—The President shall ensure*
10 *adequate staffing for the Initiative, including full-time staff*
11 *within the Office of Science and Technology Policy, who*
12 *shall—*

13 (1) *provide technical and administrative support*
14 *to the interagency committee and the advisory com-*
15 *mittee established under section 6;*

16 (2) *serve as the point of contact on Federal engi-*
17 *neering biology activities for government organiza-*
18 *tions, academia, industry, professional societies, State*
19 *governments, interested citizen groups, and others to*
20 *exchange technical and programmatic information;*

21 (3) *oversee interagency coordination of the Ini-*
22 *tiative, including by encouraging and supporting*
23 *joint agency solicitation and selection of applications*
24 *for funding of activities under the Initiative;*

1 (4) *conduct public outreach, including dissemi-*
 2 *nation of findings and recommendations of the advi-*
 3 *sory committee established under section 6, as appro-*
 4 *priate; and*

5 (5) *promote access to, and early application of,*
 6 *the technologies, innovations, and expertise derived*
 7 *from Initiative activities to agency missions and sys-*
 8 *tems across the Federal Government, and to United*
 9 *States industry, including startup companies.*

10 **SEC. 6. ADVISORY COMMITTEE.**

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

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

21 (1) *the current state of United States competi-*
 22 *tiveness in engineering biology, including the scope*
 23 *and scale of United States investments in engineering*
 24 *biology research and development in the international*
 25 *context;*

1 (2) *current market barriers to commercialization*
2 *of engineering biology products, processes, and tools*
3 *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 under*
11 *section 5 is helping to maintain United States leader-*
12 *ship 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 after*
19 *the date of enactment of this Act, and not less frequently*
20 *than once every 3 years thereafter, the advisory committee*
21 *shall submit to the President, the Committee on Science,*
22 *Space, and Technology of the House of Representatives, and*
23 *the Committee on Commerce, Science, and Transportation*
24 *of the Senate, a report on—*

1 (1) *the findings of the advisory committee’s as-*
 2 *essment under subsection (b); and*

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

5 (d) *APPLICATION OF FEDERAL ADVISORY COMMITTEE*
 6 *ACT.—Section 14 of the Federal Advisory Committee Act*
 7 *(5 U.S.C. App.) shall not apply to the Advisory Committee.*

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

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

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

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

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

1 (4) *recommendations on how engineering biology*
2 *researchers can best incorporate considerations of eth-*
3 *ical, legal, environmental, and other societal issues*
4 *into the development of research proposals and the*
5 *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 Transpor-*
13 *tation of the Senate a report containing the findings*
14 *and recommendations of the review conducted under*
15 *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 the*
20 *Initiative, the National Science Foundation shall—*

21 (1) *support basic research in engineering biology*
22 *through individual grants and through interdisdisci-*
23 *nary research centers;*

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

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

6 (4) *support curriculum development and re-*
7 *search experiences for secondary, undergraduate, and*
8 *graduate students in engineering biology and bio-*
9 *manufacturing; 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 Ini-*
15 *tiative, the Director of the National Institute of Standards*
16 *and Technology shall—*

17 (1) *establish a bioscience research program to ad-*
18 *vance the development of standard reference materials*
19 *and measurements and to create new data tools, tech-*
20 *niques, and processes necessary to advance engineer-*
21 *ing 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 edu-*

1 *cation, 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 Initia-*
8 *tive, 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, biobased*
13 *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 ADMINISTRA-*
2 *TION.—As part of the Initiative, the National Aeronautics*
3 *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, aero-*
7 *navitics, space technology, and space exploration and*
8 *experimentation, consistent with the priorities estab-*
9 *lished in the National Academies’ decadal surveys;*
10 *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 part*
16 *of the Initiative, the Environmental Protection Agency shall*
17 *support research on how products, processes, and systems*
18 *of engineering biology will affect or can protect the environ-*
19 *ment.*

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