

117TH CONGRESS
1ST SESSION

H. R. 4521

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

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2021

Ms. JOHNSON of Texas (for herself and Mr. LUCAS) introduced the following bill; which was referred to the Committee on Science, Space, and Technology, and in addition to the Committees on Agriculture, and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 “Bioeconomy Research
5 and Development Act of 2021”.

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 has an obligation
19 to ensure that ethical, legal, environmental, safety,
20 security, and societal implications of its science and
21 technology research and investment follows policies
22 of responsible innovation and fosters public trans-
23 parency.

24 (6) The Federal Government can play an im-
25 portant role by facilitating the development of tools

1 and technologies to further advance engineering biology,
2 including user facilities, by facilitating public-
3 private partnerships, by supporting risk research,
4 and by facilitating the commercial application in the
5 United States of research funded by the Federal
6 Government.

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

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

19 **SEC. 3. DEFINITIONS.**

20 In this Act:

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

(2) ENGINEERING BIOLOGY.—The term “engineering biology” means the application of engineering design principles and practices to biological systems, including molecular and cellular systems, to advance fundamental understanding of complex natural systems and to enable novel or optimize functions and capabilities.

11 (4) OMICS.—The term “omics” refers to the
12 collective technologies used to explore the roles, rela-
13 tionships, and actions of the various types of mol-
14 ecules 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 Develop-
20 ment Initiative to advance societal well-being, national se-
21 curity, sustainability, and economic productivity and com-
22 petitiveness through—

23 (1) advancing areas of research at the intersec-
24 tion of the biological, physical, chemical, data, and
25 computational and information sciences and engi-

1 engineering to accelerate scientific understanding and
2 technological innovation in engineering biology;

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

15 (5) supporting research relating to the risks
16 and benefits of engineering biology, including under
17 subsection (d);

18 (6) supporting the development of novel tools
19 and technologies to accelerate scientific under-
20 standing and technological innovation in engineering
21 biology;

(7) expanding the number of researchers, educators, and students and a retooled workforce with engineering biology training, including from tradit-

1 tionally underrepresented and underserved popu-
2 lations;

3 (8) accelerating the translation and commer-
4 cialization of engineering biology and biomanufac-
5 turing research and development by the private sec-
6 tor; and

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

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

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

14 (A) grants to fund the work of individual
15 investigators and teams of investigators, includ-
16 ing interdisciplinary teams;

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

20 (C) interdisciplinary research centers that
21 are organized to investigate basic research
22 questions, carry out technology development
23 and demonstration activities, and increase un-
24 derstanding of how to scale up engineering biol-
25 ogy processes, including biomanufacturing;

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

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

15 (C) support for the development of com-
16 putational tools, including artificial intelligence
17 tools, that can accelerate research and innova-
18 tion using such databases; and

1 bases as critical infrastructure for the engineer-
2 ing biology research enterprise;

3 (3) sustained support for the development, optimi-
4 zation, and validation of novel tools and tech-
5 nologies to enable the dynamic study of molecular
6 processes in situ, including through—

7 (A) research conducted at Federal labora-
8 tories;

9 (B) grants to fund the work of investiga-
10 tors at institutions of higher education and
11 other nonprofit research institutions;

12 (C) incentivized development of retooled in-
13 dustrial sites across the country that foster a
14 pivot to modernized engineering biology initia-
15 tives; and

16 (D) awards under the Small Business In-
17 novation Research Program and the Small
18 Business Technology Transfer Program, as de-
19 scribed in section 9 of the Small Business Act
20 (15 U.S.C. 638);

21 (4) support for education and training of un-
22 dergraduate and graduate students in engineering
23 biology, biomanufacturing, bioprocess engineering,
24 and computational science applied to engineering bi-

1 ology and in the related ethical, legal, environmental,
2 safety, security, and other societal domains;

3 (5) activities to develop robust mechanisms for
4 documenting and quantifying the outputs and eco-
5 nomic 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 develop-
13 ment;

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

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

23 (c) EXPANDING PARTICIPATION.—The Initiative
24 shall include, to the maximum extent practicable, outreach
25 to primarily undergraduate and minority-serving institu-

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

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

9 (1) supporting research, including in the social
10 sciences, and other activities addressing ethical,
11 legal, environmental, and other appropriate societal
12 issues related to engineering biology, including inte-
13 grating research on such topics with the research
14 and development in engineering biology, and encour-
15 aging the dissemination of the results of such re-
16 search, including through interdisciplinary engineer-
17 ing biology research centers described in subsection
18 (b)(1);

19 (2) supporting research and other activities re-
20 lated to the safety and security implications of engi-
21 neering biology, including outreach to increase
22 awareness among Federal researchers and Federally-
23 funded researchers at institutions of higher edu-
24 cation about potential safety and security implica-
25 tions of engineering biology research, as appropriate;

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

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

13 (5) complying with all applicable provisions of
14 Federal law.

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 ac-
19 tivities of the Initiative as appropriate, which shall be co-
20 chaired by the Office of Science and Technology Policy,
21 and include representatives from the National Science
22 Foundation, the Department of Energy, the National Aer-
23 onautics and Space Administration, the National Institute
24 of Standards and Technology, the Environmental Protec-
25 tion Agency, the National Oceanic and Atmospheric Ad-

1 ministration, the Department of Agriculture, the Depart-
2 ment of Health and Human Services, the Bureau of Eco-
3 nomic Analysis, and any other agency that the President
4 considers appropriate (in this section referred to as the
5 “Interagency Committee”). The Director of the Office of
6 Science and Technology Policy shall select an additional
7 co-chairperson from among the members of the Inter-
8 agency Committee. The Interagency Committee shall over-
9 see the planning, management, and coordination of the
10 Initiative. The Interagency Committee shall—

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

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

17 (3) develop, not later than 12 months after the
18 date of the enactment of this Act, and update every
19 3 years thereafter, a strategic plan submitted to the
20 Committee on Science, Space, and Technology and
21 the Committee on Energy and Commerce of the
22 House of Representatives and the Committee on
23 Commerce, Science, and Transportation and the
24 Committee on Health, Education, Labor, and Pen-
25 sions of the Senate that—

- 1 (A) guides the activities of the Initiative
2 for purposes of meeting the goals and priorities
3 established under (and updated pursuant to)
4 paragraph (2); and
5 (B) describes—
6 (i) the Initiative’s support for long-
7 term funding for interdisciplinary engineer-
8 ing biology research and development;
9 (ii) the Initiative’s support for edu-
10 cation and public outreach activities;
11 (iii) the Initiative’s support for re-
12 search and other activities on ethical, legal,
13 environmental, safety, security, and other
14 appropriate societal issues related to engi-
15 neering biology including—
16 (I) an applied biorisk manage-
17 ment research plan;
18 (II) recommendations for inte-
19 grating security into biological data
20 access and international reciprocity
21 agreements;
22 (III) recommendations for manu-
23 facturing restructuring to support en-
24 gineering biology research, develop-
25 ment, and scaling-up initiatives; and

(IV) an evaluation of existing

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

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

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

24 (5) develop a plan to utilize Federal programs,
25 such as the Small Business Innovation Research

1 Program and the Small Business Technology Transfer
2 Program as described in section 9 of the Small
3 Business Act (15 U.S.C. 638), in support of the ac-
4 tivities described in section 4(b)(3); and

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

11 (b) TRIENNIAL REPORT.—Beginning with fiscal year
12 2022 and ending in fiscal year 2028, not later than 90
13 days after submission of the President’s annual budget re-
14 quest and every third fiscal year thereafter, the Inter-
15 agency Committee shall prepare and submit to the Com-
16 mittee on Science, Space, and Technology of the House
17 of Representatives and the Committee on Commerce,
18 Science, and Transportation of the Senate a report that
19 includes—

20 (1) a summarized agency budget in support of
21 the Initiative for the fiscal year to which such budg-
22 et request applies, for the following 2 fiscal years,
23 for the then current fiscal year, including a breakout
24 of spending for each agency participating in the Pro-

1 gram, and for the development and acquisition of
2 any research facilities and instrumentation; and

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

6 (A) a description of the amount and num-
7 ber of awards made under the Small Business
8 Innovation Research Program and the Small
9 Business Technology Transfer Program (as de-
10 scribed in section 9 of the Small Business Act
11 (15 U.S.C. 638)) in support of the Initiative;

12 (B) a description of the amount and num-
13 ber of projects funded under joint solicitations
14 by a collaboration of no fewer than 2 agencies
15 participating in the Initiative; and

16 (C) a description of the effect of the newly
17 funded projects by 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 Federal
2 engineering biology activities for government organizations, academia, industry, professional societies, State governments, interested citizen groups, and others to exchange technical and programmatic information;
- 7 (C) oversee interagency coordination of the Initiative, including by encouraging and supporting joint agency solicitation and selection of applications for funding of activities under the Initiative, as appropriate;
- 12 (D) conduct public outreach, including dissemination of findings and recommendations of the advisory committee established under section 6, as appropriate;
- 16 (E) serve as the coordinator of ethical, legal, environmental, safety, security, and other appropriate societal input; and
- 19 (F) promote access to, and early application of, the technologies, innovations, and expertise derived from Initiative activities to agency missions and systems across the Federal Government, and to United States industry, including startup companies.

1 (2) FUNDING.—The Director of the Office of
2 Science and Technology Policy, in coordination with
3 each participating Federal department and agency,
4 as appropriate, shall develop and annually update an
5 estimate of the funds necessary to carry out the ac-
6 tivities of the Initiative Coordination Office and sub-
7 mit such estimate with an agreed summary of con-
8 tributions from each agency to Congress as part of
9 the President's annual budget request to Congress.

10 (3) TERMINATION.—The Initiative Coordination
11 Office established under this subsection shall termi-
12 nate on the date that is 10 years after the date of
13 the enactment of this Act.

14 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to alter the policies, processes, or
16 practices of individual Federal agencies in effect on the
17 day before the date of the enactment of this Act relating
18 to the conduct of biomedical research and advanced devel-
19 opment, including the solicitation and review of extra-
20 mural research proposals.

21 **SEC. 6. ADVISORY COMMITTEE.**

22 (a) IN GENERAL.—The agency co-chair of the inter-
23 agency committee established in section 5 shall, in con-
24 sultation with the Office of Science and Technology Policy,
25 designate or establish an advisory committee on engineer-

1 ing biology research and development (in this section re-
2 ferred to as the “advisory committee”) to be composed of
3 not fewer than 12 members, including representatives of
4 research and academic institutions, industry, and non-
5 governmental entities, who are qualified to provide advice
6 on the Initiative.

7 (b) ASSESSMENT.—The advisory committee shall as-
8 sess—

9 (1) the current state of United States competi-
10 tiveness in engineering biology, including the scope
11 and scale of United States investments in engineer-
12 ing biology research and development in the inter-
13 national context;

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

17 (3) progress made in implementing the Initia-
18 tive;

19 (4) the need to revise the Initiative;

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

22 (6) whether the strategic plan developed or up-
23 dated by the interagency committee established
24 under section 5 is helping to maintain United States
25 leadership in engineering biology;

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

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

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

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

21 (e) TERMINATION.—The advisory committee estab-
22 lished under subsection (a) shall terminate on the date
23 that is 10 years after the date of the enactment of this
24 Act.

1 **SEC. 7. EXTERNAL REVIEW OF ETHICAL, LEGAL, ENVIRON-**
2 **MENTAL, SAFETY, SECURITY, AND SOCIETAL**
3 **ISSUES.**

4 (a) IN GENERAL.—Not later than 6 months after the
5 date of enactment of this Act, the Director of the National
6 Science Foundation shall seek to enter into an agreement
7 with the National Academies of Sciences, Engineering,
8 and Medicine to conduct a review, and make recommenda-
9 tions with respect to, the ethical, legal, environmental,
10 safety, security, and other appropriate societal issues re-
11 lated to engineering biology research and development.

12 The review shall include—

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

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

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

20 (4) recommendations on how researchers en-
21 gaged in engineering biology can best incorporate
22 considerations of ethical, legal, environmental, safe-
23 ty, security, and other societal issues into the devel-
24 opment of research proposals and the conduct of re-
25 search.

1 (b) REPORT TO CONGRESS.—The agreement entered
2 into under subsection (a) shall require the National Acad-
3 emies of Sciences, Engineering, and Medicine to, not later
4 than 2 years after the date of the enactment of this Act—
5 (1) submit to the Committee on Science, Space,
6 and Technology of the House of Representatives and
7 the Committee on Commerce, Science, and Trans-
8 portation of the Senate a report containing the find-
9 ings and recommendations of the review conducted
10 under subsection (a); and
11 (2) make a copy of such report available on a
12 publicly accessible website.

13 **SEC. 8. AGENCY ACTIVITIES.**

14 (a) NATIONAL SCIENCE FOUNDATION.—As part of
15 the Initiative, the National Science Foundation shall—
16 (1) support research in engineering biology
17 through individual grants, collaborative grants, and
18 through interdisciplinary research centers;
19 (2) support research on the environmental,
20 legal, ethical, and social implications of engineering
21 biology;
22 (3) provide support for research instrumenta-
23 tion, equipment, and cyberinfrastructure for engi-
24 neering biology disciplines, including support for re-
25 search, development, optimization and validation of

1 novel technologies to enable the dynamic study of
2 molecular processes in situ;

3 (4) support curriculum development and re-
4 search experiences for secondary, undergraduate,
5 and graduate students in engineering biology and
6 biomanufacturing, including through support for
7 graduate fellowships and traineeships in engineering
8 biology; and

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

13 (b) DEPARTMENT OF COMMERCE.—

14 (1) NATIONAL INSTITUTE OF STANDARDS AND
15 TECHNOLOGY.—As part of the Initiative, the Direc-
16 tor of the National Institute of Standards and Tech-
17 nology shall—

18 (A) establish a bioscience research pro-
19 gram to advance the development of standard
20 reference materials and measurements and to
21 create new data tools, techniques, and processes
22 necessary to advance engineering biology and
23 biomanufacturing;

24 (B) provide access to user facilities with
25 advanced or unique equipment, services, mate-

1 rials, and other resources to industry, institu-
2 tions of higher education, nonprofit organiza-
3 tions, and government agencies to perform re-
4 search and testing; and

5 (C) provide technical expertise to inform
6 the potential development of guidelines or safe-
7 guards for new products, processes, and sys-
8 tems of engineering biology.

9 (2) NATIONAL OCEANIC AND ATMOSPHERIC AD-
10 MINISTRATION.—As part of the initiative, the Ad-
11 ministrator of the National Oceanic and Atmos-
12 pheric Administration shall—

13 (A) conduct and support research in omics
14 and associated bioinformatic sciences and de-
15 velop tools and products to improve ecosystem
16 stewardship, monitoring, management, assess-
17 ments and forecasts, consistent with the mis-
18 sion of the agency; and

19 (B) collaborate with other agencies to un-
20 derstand potential environmental threats and
21 safeguards related to engineering biology.

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

24 (1) conduct and support research, development,
25 demonstration, and commercial application activities

1 in engineering biology, including in the areas of synthetic
2 biology, advanced biofuel and bioproduct development,
3 biobased materials, and environmental remediation;

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

9 (3) provide access to user facilities with advanced or unique equipment, services, materials, and other resources, including secure access to high-performance computing, as appropriate, to industry, institutions of higher education, nonprofit organizations, and government agencies to perform research and testing; and

16 (4) strengthen collaboration between the Office of Science and the Energy Efficiency and Renewable Energy Office to help transfer fundamental research results to industry and accelerate commercial applications.

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

24 (1) conduct and support research in engineering biology, including in synthetic biology, and related to

1 Earth and space sciences, aeronautics, space technology,
2 and space exploration and experimentation,
3 consistent with the priorities established in the National Academies' decadal surveys; and
4

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

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

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

14 (2) award grants through the National Institute
15 of Food and Agriculture and the Agriculture Advanced Research and Development Authority; and
16

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

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

24 (g) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—As part of the Initiative, the Secretary of Health

1 and Human Services, as appropriate and consistent with
2 activities of the Department of Health and Human Serv-
3 ices in effect on the day before the date of the enactment
4 of this Act, shall—

- 5 (1) support research and development to ad-
6 vance the understanding and application of engineer-
7 ing biology for human health;
8 (2) support relevant interdisciplinary research
9 and coordination; and
10 (3) support activities necessary to facilitate
11 oversight of relevant emerging biotechnologies.

12 **SEC. 9. RULE OF CONSTRUCTION.**

13 Nothing in this Act shall be construed to require pub-
14 lic disclosure of information that is exempt from manda-
15 tory disclosure under section 552 of title 5, United States
16 Code.

