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116TH CONGRESS *2d Session*	SENATE	REPORT 116–330

BIOECONOMY RESEARCH AND DEVELOPMENT ACT OF 2020

R E P O R T

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ON

S. 3734

DECEMBER 15, 2020.—Ordered to be printed

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BIOECONOMY RESEARCH AND DEVELOPMENT ACT OF 2020

DECEMER 15, 2020.—Ordered to be printed

Mr. WICKER, from the Committee on Commerce, Science, and Transportation, submitted the following

R E P O R T

[To accompany S. 3734]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 3734) to provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology, having considered the same, reports favorably thereon with an amendment (in the nature of a substitute) and recommends that the bill (as amended) do pass.

PURPOSE OF THE BILL

The purpose of this bill is to provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology and continued growth in the U.S. bioeconomy.

BACKGROUND AND NEEDS

In their recent report entitled "Safeguarding the Bioeconomy," the National Academy of Sciences defined the U.S. bioeconomy as the "economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences."[1] Using this definition, the Academy estimated the bioeconomy contributed $959.2 billion (5.1 percent of gross domestic product) to the U.S. economy in 2016.[2]

[1] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).
[2] Ibid.

Although advances in engineering and computer and information sciences have helped support the bioeconomy, advances in biotechnology have been the most transformative. Biotechnology is the use of living organisms to create products. One of the simplest examples of biotechnology is the use of yeast to make bread or brew beer. More advanced techniques can be used to produce medicine or genetically modify organisms.[3] Synthetic biology, sometimes referred to as "engineering biology," is a subset of biotechnology in which organisms are modified to create a desired product or outcome.[4] For example, bacterial genomes can be modified to produce medicine, help clean pollutants, and reduce chemical production costs.

Agriculture, Biomedical, and Bioindustrial Biotechnology

The challenges of feeding a growing global population can, in part, be reduced by advances in biotechnology. Advanced selective breeding techniques and gene editing have the potential to create an increase in agricultural yield similar to what was seen during what is referred to as the "Green Revolution," which started in the late 1960s.[5] During the Green Revolution, selective breeding and synthetic fertilizer use more than doubled some crop yields. These increased crop yields decreased cases of malnutrition globally. However, challenges remain in meeting global micronutrient requirements and developing agricultural methods that are less energy intensive.[6]

With synthetic biology, several of the downsides of the Green Revolution can be mitigated—crops can be developed to meet micronutrient needs and use fewer resources. For example, what is referred to as "golden rice" was created by adding the gene that produces vitamin A to conventional rice. The resulting rice contains enough vitamin A to prevent the host of diseases that can result from vitamin A deficiency.[7] The need for synthetic fertilizers may be reduced by adding nitrogen-fixing genes to bacteria that live on the roots of corn and other crops. Much like how the bacteria work that live on a soybean plant's roots, this would allow the crops to effectively absorb the much needed nitrogen nutrient without the need for industrially manufactured nitrogen fertilizer.[8]

Advances in biotechnology are also creating opportunities to advance medicine and keep people healthy. For example, penicillin, an antibacterial drug produced by a fungus, was discovered in

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[3] Norwegian University of Science and Technology, "What Is Biotechnology?" (https://www.ntnu.edu/ibt/about-us/what-is-biotechnology) (accessed Sep. 17, 2020).

[4] Engineering Biology Research Consortium, "What Is Synthetic/Engineering Biology?" (https://ebrc.org/what-is-synbio/) (accessed Sep. 17, 2020); National Academies of Sciences, Engineering, and Medicine, *Biodefense in the Age of Synthetic Biology* (Washington, DC: The National Academies Press, 2018). Available online (https://www.ncbi.nlm.nih.gov/books/NBK535871/) (accessed Sep. 17, 2020).

[5] Julia Bailey-Serres et al., "Genetic Strategies for Improving Crop Yields," *Nature*, 575(7781):109–118, (Nov. 6, 2019) (doi: 10.1038/s41586-019-1679-0) (accessed Sep. 17, 2020).

[6] Prabhu L. Pingali, "Green Revolution: Impacts, Limits, and the Path Ahead," *PNAS*, 109:12302–12308 (Jul. 31, 2012). Available online (https://www.pnas.org/content/109/31/12302) (accessed Sep. 17, 2020).

[7] Guangwen Tang et al., "Golden Rice Is an Effective Source of Vitamin A," *The American Journal of Clinical Nutrition*, vol. 89:6 (2009). Available online (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2682994/) (accessed Sep. 17, 2020).

[8] Min-Hyung Ryu et al., "Control of Nitrogen Fixation in Bacteria That Associate With Cereals," *Nature Microbiology*, Dec. 16, 2019 (doi: 10.1038/s41564-019-0631-2) (accessed Sep. 17, 2020).

1928, but large-scale production of the drug was difficult[9] until the 1940s when scientists developed a process to ferment the drug in 10,000-gallon tanks,[10] saving millions of lives.[11] Influenza vaccines have historically been grown in chicken eggs, but this process is relatively slow and the drug cannot be taken by people with egg allergies.[12] Cell-based flu vaccines are beginning to allow for more controlled, larger, and faster growing batches of vaccine, similar to a technique used for diseases like polio and retrovirus for many years.[13] New biotechnologies are allowing scientists to use cells to produce more effective and increasingly targeted drugs faster. One tool, clustered regularly interspaced short palindromic repeats (CRISPR), enables scientists to edit the genome.[14] CRISPR has been used to edit animal genes so that they produce useful drugs, such as a goat that produces an anticlotting protein in its milk and a chicken that produces eggs containing a drug that fights cholesterol diseases.[15] It also has the potential to edit human cells and repair genetic mutations that cause deadly diseases, such as amyotrophic lateral sclerosis (ALS) and Duchenne muscular dystrophy,[16] though this application currently carries a host of safety and ethical issues.[17] Genetically engineered T-cells can be used to attack cancer cells, in a therapy which has been approved by the Food and Drug Administration.[18] Further advances in biotechnology will likely help cure diseases and decrease human suffering.

Previous Government Actions

The 2012 National Bioeconomy Blueprint identified efforts supporting the bioeconomy in many departments and agencies.[19] Though there are necessary sector-specific activities, the Government Accountability Office found that the Federal Government could better manage synthetic biology research by assigning roles

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[9] Milton Wainwright, "The History of the Therapeutic Use of Crude Penicillin," *Medical History*, 31:1 (1987). Available online (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1139683/pdf/medhist00068-0045.pdf) (accessed Sep. 17, 2020)

[10] John Patrick Swann, "The Search for Synthetic Penicillin During World War II," *The British Journal for the History of Science*, 16:2 (1983).

[11] Dr. David Ho, "Bacteriologist Alexander Fleming," *Time*, 153:12 (Mar. 29, 1999). Available online by subscription (http://content.time.com/time/magazine/article/0,9171,990612,00.html) (accessed Sep. 17, 2020).

[12] Michel Lombard et al., "A Brief History of Vaccines and Vaccination," *Revue Scientifique et Technique-Office International des Epizooties*, 26:1 (May 2007). Available for article download (https://www.researchgate.net/publication/6205699_A_brief_history_of_vaccines_and_vaccination) (accessed Sep. 17, 2020).

[13] Andy Extance, "Cell-based Flu Vaccines Ready for US Prime Time," *Nature*, 10:246 (Apr. 8, 2011). Available online (https://www.nature.com/articles/nrd3414) (accessed Sep. 17, 2020).

[14] National Institutes of Health, "What Are Genome Editing and CRISPR-Cas9?," Feb. 21, 2020 (https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/) (accessed Sep. 17, 2020).

[15] Sara Reardon, "Welcome to the CRISPR Zoo," *Nature*, 531:7593 (Mar. 9, 2016). Available online (https://www.nature.com/news/welcome-to-the-crispr-zoo-1.19537) (accessed Sep. 17, 2020).

[16] Chengzu Long et al., "Genome Editing of Monogenic Neuromuscular Diseases: A Systematic Review," *Jama Neurol*, 73(11):1349–1355 (Nov. 2016). Available online (doi:10.1001/jamaneurol.2016.3388) (accessed Sep. 17, 2020).

[17] Hopkins Bloomberg Public Health Magazine, "Should CRISPR Be Used to Edit Human Genes to Treat Genetic Diseases?," Spring 2019 (https://magazine.jhsph.edu/2019/should-crispr-be-used-edit-human-genes-treat-genetic-diseases) (accessed Sep. 17, 2020).

[18] Tristen S. Park, Steven A. Rosenberg, and Richard A. Morgan, "Treating Cancer With Genetically Engineered T-cells," *Trends in Biotechnology*, 29:11 (Nov. 1, 2011). Available online by subscription (http://doi.org/10.1016/j.tibtech.2011.04.009) (accessed Sep. 17, 2020)

[19] The White House, *National Bioeconomy Blueprint*, Apr. 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf) (accessed Sep. 17, 2020).

and responsibilities.[20] In October 2019, the White House hosted the Summit on America's Bioeconomy. The primary goals highlighted by the summit included improving our workforce to support the bioeconomy, promoting and safeguarding critical infrastructure and data, leveraging the U.S. innovative ecosystem, and identifying and reducing regulatory challenges.[21]

Currently, there is not a breakdown of Federal funding for activities that support the bioeconomy, but in fiscal year 2015 the Government spent approximately $30.5 billion on life sciences. Much of this research directly or indirectly supports the bioeconomy. The bulk of this Federal funding goes through the Department of Health and Human Services.[22]

In addition to direct funding, Federal agencies can provide tools to support the bioeconomy. One such example is the National Institute of Standards and Technology's Living Measurement Systems Foundry. The goal of this program is to provide testing and measurements of engineered microbes.[23] Additionally, as engineered microbes become more ubiquitous in everything from medicine to manufacturing, creating testing that allows for effective, efficient quality assurance is critical, as are investments in additional bioeconomy research infrastructure.[24]

Competitiveness and Security Concerns

There are two primary security and competitiveness concerns with respect to the bioeconomy. The first is whether the United States will continue to lead in both research and commercialization in the bioeconomy. The second is the potential for the nefarious use of the techniques for and products of synthetic biology.

Some indicators suggest that the United States is losing some of its dominance in the bioeconomy. For example, while the United States still produces the most publications in the biological and medical sciences, China has been rapidly increasing the number of papers it produces, particularly on key topics such as research on CRISPR, therapeutic antibodies, and metabolic engineering.[25] With respect to patents, the United States is still the global leader, but its dominance has slipped. For example, in 2001, the United States produced approximately 40 percent of the international patents in biotechnology; by 2014, the number had dropped to less than 35 percent. With respect to patents just filed in the United States or China, China overtook the United States in 2011. It is, however,

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[20] U.S. Government Accountability Office, *Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Billions in Financial Benefits*, GAO–19–285SP, May 21, 2019 (https://www.gao.gov/products/gao-19-285sp?utm_source=blog&utm_medium=social&utm_campaign=watchblog) (accessed Sep. 17, 2020).

[21] Office of Science and Technology Policy, *Summary of the 2019 White House Summit on America's Bioeconomy*, Oct. 7, 2019 (https://www.whitehouse.gov/wp-content/uploads/2019/10/Summary-of-White-House-Summit-on-Americas-Bioeconomy-October-2019.pdf) (accessed Sep. 17, 2020).

[22] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).

[23] National Institute of Standards and Technology, "NIST Living Measurement Systems Foundry" (https://www.nist.gov/programs-projects/nist-living-measurement-systems-foundry) (accessed Sep. 17, 2020).

[24] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).

[25] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).

unclear as to whether these country-specific patents will result in robust commercialization on China's part.[26] It should also be noted that despite the United States having the most synthetic biology companies in the world, some of the most productive firms, based on number of patents, are in Europe.[27]

The Department of Defense, Department of State, Department of Homeland Security, and the Office of the Director of National Intelligence have all identified synthetic biology as an emerging threat. For example, synthetic biology could be used to make novel biological or chemical weapons or enhance the performance of military personnel.[28] So called dual use research of concern (DURC) is research that could be reasonably used for nefarious purposes. The Federal Government has certain rules for DURC. The rules do not prohibit research, but do assign clear roles and responsibilities for the institutes and researchers. Currently, the rules cover research involving 15 agents and toxins and seven categories of experiments.[29] The specificity of the categories simplifies the application of the rules, but may also miss potentially dangerous research, particularly in emerging fields.

There are also concerns about asymmetric sharing of data. For example, China has a very large genetic database, but does not make it available to researchers outside the country. When a country like the United States openly shares genetic data, China is able to start a database of genetic data from U.S. sources. While not currently possible, technological advances could theoretically allow an adversary to use one's genetic code to gain insight into personality traits. The Chinese have used their large genetic database to target ethnic minorities, most notably, Uighurs.[30]

Ethical and Safety Concerns

The advent of new techniques to manipulate natural systems or living organisms requires careful consideration of the safe and ethical use of such technologies. While gene editing techniques have been around for decades, the development of new, more precise techniques like CRISPR require researchers and policymakers to carefully consider when and how they are used, including how genetic modifications may propagate or impact the environment.[31] Bioethicist Dr. Jeffrey Kahn notes that there are three areas of concern related to gene editing: (1) modifying genetic material that can be passed down to offspring (germline modifications); (2) the possibility of cosmetic or otherwise unnecessary genetic modifications; and (3) the implications of human interference in natural

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[26] Ibid.
[27] Ibid.
[28] Government Accountability Office, "Long-Range Emerging Threats Facing the United States As Identified by Federal Agencies," Dec. 2018 (https://www.gao.gov/assets/gao-19-204sp.pdf) (accessed Sep. 17, 2020).
[29] National Institutes of Health, "Dual Use Research of Concern" (https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/) (accessed Sep. 17, 2020).
[30] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).
[31] David Baltimore et al, "A Prudent Path Forward for Genomic Engineering and Germline Gene Modification," *Science,* vol. 348:6230, Apr. 3, 2015, https://science.sciencemag.org/content/348/6230/36.full.

processes.[32] Further research is needed to mitigate these concerns.[33]

One area of controversy surrounds the use of gene editing on germline cells, which would change the genes passed on to offspring and future generations. There may be some cases in which germline editing to remove hereditary diseases could be beneficial, though a consensus study on the topic published by the NASEM notes the significant and complex social, ethical, technical, and religious concerns about the appropriateness of such intervention.[34] There are also concerns about how such techniques could be weaponized against vulnerable populations or used without consent.[35] In the United States, there is a moratorium on human germline editing, including editing the DNA of human embryos.[36]

SUMMARY OF PROVISIONS

If enacted, S. 3734, the Bioeconomy Research and Development Act of 2020, would do the following:

- Establish a Federal engineering biology research initiative and require a national strategy for Federal agency investments and a framework for interagency coordination.
- Support the creation of bioeconomy-relevant databases and tools.
- Expand public-private partnerships and education and training for the next generation of engineering biology researchers.
- Provide direction for mission-relevant activities in engineering biology for several Federal agencies.
- Mandate an independent review of current policies and create a presidential advisory committee tasked with providing assessments and analyses of policy.
- Ensure that the authorized initiative would address potential ethical, legal, environmental, safety and security issues associated with engineering biology research.

LEGISLATIVE HISTORY

S. 3734, the Bioeconomy Research and Development Act of 2020, was introduced on May 14, 2020, by Senator Gillibrand (for herself and Senators Markey, Rubio, and Gardner) and referred to the Committee on Commerce, Science, and Transportation of the Senate. On May 20, 2020, the Committee met in open Executive Session and, by voice vote, ordered S. 3734 reported favorably with an amendment (in the nature of a substitute).

A related bill, H.R. 4373, the Engineering Biology Research and Development Act of 2019, was introduced on September 18, 2019,

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[32] Dr. Jeffrey P. Kahn, "Testimony to the House Committee on Science, Space, and Technology," June 16, 2015, (https://republicans-science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-114-SY15-WState-JKahn-20150616.pdf) (accessed Sep. 17, 2020).

[33] National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020). Available online (https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy) (accessed Sep. 17, 2020).

[34] "Human Genome Editing: Science, Ethics, and Governance," National Academy of Sciences, 2017, (https://www.nap.edu/download/24623#) (accessed Sep. 17, 2020).

[35] Heidi Howard et al, "One Small Edit for Humans, One Giant Edit for Humankind?" *European Journal of Human Genetics*, January 26, 2018 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5839051/) (accessed Sep. 17, 2020).

[36] Francis S. Collins, "Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos," National Institutes of Health, April 28, 2015 (https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos) (accessed Sep. 17, 2020).

by Representative Eddie Bernice Johnson (for herself and Representatives James F. Sensenbrenner, Zoe Lofgren, and Frank D. Lucas) and referred to the Committee on Science, Space, and Technology of the House of Representatives. On December 9, 2019, H.R. 4373, as amended, passed the House of Representatives.

Another related bill, S. 3191, the Industries of the Future Act of 2020, was introduced on January 14, 2020, by Senators Wicker (for himself and Senators Gardner, Baldwin, and Peters) and referred to the Committee on Commerce, Science, and Transportation of the Senate. On March 11, 2020, the Committee met in open Executive Session and, by voice vote, ordered S. 3191 reported favorably with an amendment. S. 3191 would increase the capacity of research and development programs of the Federal Government that focus on industries of the future, including engineering biology.

Hearing

The Committee's Subcommittee on Science, Oceans, Fisheries, and Weather held a related hearing entitled "Securing U.S. Leadership in the Bioeconomy," on March 3, 2020. That hearing examined the Federal Government's role in the bioeconomy. The Committee received testimony from Dr. Timothy Donohue, Director of the Great Lakes Bioenergy Research Center at the University of Wisconsin-Madison; Mr. Jason Gammack, Chief Commercial Officer of Inscripta Inc.; Dr. Jason Kelly, Co-Founder and Chief Executive Officer of Ginkgo Bioworks; and Dr. Megan Palmer, Senior Research Scholar at the Center for International Security and Cooperation at Stanford University.

ESTIMATED COSTS

In compliance with subsection (a)(3) of paragraph 11 of rule XXVI of the Standing Rules of the Senate, the Committee states that, in its opinion, it is necessary to dispense with the requirements of paragraphs (1) and (2) of that subsection in order to expedite the business of the Senate.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported:

Number of Persons Covered

S. 3734, as reported, would not impose any new significant regulatory requirements, and, therefore, would not subject any individuals or businesses to new significant regulations.

Economic Impact

Enactment of S. 3734 is not expected to have any significant adverse impacts on the Nation's economy. S. 3734 would serve to drive technology transfer to the private sector, ensuring optimal return on Federal investment, and support research that will lead to continued economic strength.

Privacy

S. 3734, as reported, would not have any adverse impact on the privacy of individuals.

Paperwork

S. 3734 would not impose a substantial paperwork burden on individuals or businesses. S. 3734 would require two reports from the committees that would be created by this bill. The first report would be from the interagency committee to the Committee on Science, Space, and Technology of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate within 90 days after the President's annual budget request, produced triennially, summarizing agency budgets in support of the Bioeconomy Initiative and an assessment of how Federal agencies are implementing the Initiative. The second report would be from the advisory committee to the Committee on Science, Space, and Technology of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate to provide an assessment of U.S. competitiveness in engineering biology, progress made on implementing the Initiative, and recommendations to improve the Initiative. The advisory committee report would be prepared triennially, and the reporting requirement would terminate after 10 years. The National Academies of Sciences, Engineering, and Medicine would also submit a report to Congress to review and make recommendations with respect to the ethical, legal, environmental, safety, security, and other appropriate societal issues related to engineering biology research and development.

CONGRESSIONALLY DIRECTED SPENDING

In compliance with paragraph 4(b) of rule XLIV of the Standing Rules of the Senate, the Committee provides that no provisions contained in the bill, as reported, meet the definition of congressionally directed spending items under the rule.

SECTION-BY-SECTION ANALYSIS

Section. 1. Short title.

This section would provide that the bill may be cited as the "Bioeconomy Research and Development Act of 2020".

Section 2. Findings.

This section would highlight the importance of engineering biology to societal well-being, national security, and the economy, as well as how the Federal Government can play an important role in maintaining U.S. leadership in engineering biology research and development.

Section 3. Definitions.

This section define the terms "biomanufacturing", "engineering biology", "Initiative", and "omics" as used in the bill.

Section 4. National Engineering Biology Research and Development Initiative.

Subsection (a) would establish the National Engineering Biology Research and Development Initiative to do the following:

- Advance engineering biology research, including social science, biomanufacturing, and economic research relating to the field.
- Improve public understanding of engineering biology.

- Support risk research to address ethical, safety, security and other societal implications of engineering biology.
- Support the development of tools and technologies to accelerate engineering biology research.
- Expand the engineering biology workforce, to include traditionally underrepresented and underserved populations.
- Accelerate technology transfer and commercialization of engineering biology research.
- Improve interagency planning and coordination of Federal engineering biology activities.

Subsection (b) outlines the specific activities of the Initiative, including support for research grants, research at Federal and non-Federal laboratories, omics databases and related tools, novel tools and technologies to accelerate research, interdisciplinary education and training of undergraduate and graduate students, development of metrics to understand and assess the outputs and economic benefits of engineering biology, and technology transfer activities.

Subsection (c) would require the Initiative to engage in outreach to undergraduate and minority-serving institutions, encouraging research collaborations among these institutions and research-intensive universities.

Subsection (d) would direct the Initiative to take into account ethical, legal, environmental, safety, security, and societal issues by: (1) supporting research related to these concerns associated with engineering biology; (2) integrating input from Federal and non-Federal experts on these topics; and (3) engaging in public outreach to incorporate public input into Initiative activities.

Section 5. Initiative coordination.

This section would require the President, acting through the Office of Science and Technology Policy, to designate an interagency committee that would oversee the planning, management, and coordination of the Initiative. The interagency committee would do the following:

- Develop and regularly update a strategic plan to meet the goals and priorities of the Initiative, which would be submitted to Congress no later than 12 months after the date of enactment and updated triennially thereafter.
- Develop a national genomic sequencing strategy.
- Develop a plan to utilize Federal programs, such as those described in the Small Business Act.
- Submit a triennial budget report to Congress beginning with fiscal year 2022 and ending in fiscal year 2028 that summarizes spending of participating Federal agencies and provides an assessment of how Federal agencies are implementing the plan.
- Establish and update goals and priorities for the interagency committee.
- Coordinate Federal activities related to engineering biology.

This section would also direct the President to establish an Initiative Coordination Office, with a Director and full-time staff, to provide support to the interagency committee and the advisory committee established in section 6. The Office of Science and Technology Policy is directed to draft a cost estimate for the Initiative Coordination Office, along with a plan for how participating agen-

cies should contribute to that cost estimate for Congress' review. The Office would be terminated 10 years after enactment.

Section 6. Advisory committee.

This section would authorize the head of the interagency committee co-chair agency, in consultation with the Office of Science and Technology Policy, to designate or establish an advisory committee of qualified non-Federal members to provide advice on the Initiative. The advisory committee would assess the following:

- the state of U.S. competitiveness in engineering biology;
- current market barriers to commercialization of engineering biology products, processes, and tools;
- progress made by the Initiative;
- whether the Initiative requires any revisions;
- balance of activities and funds across the Initiative;
- whether the Initiative's strategic plan is effective;
- management, coordination, implementation, and activities of the Initiative; and
- whether ethical, legal, environmental, safety, security, and other appropriate societal issues are adequately addressed by the Initiative.

The advisory committee would report their findings and recommendations to the President and Congress no later than 2 years after the date of enactment of the Act, and at least every 3 years thereafter. The advisory committee would terminate after 10 years.

Section 7. External review of ethical, legal, environmental, safety, security, and societal issues.

This section would direct the National Science Foundation to, not later than 6 months after the date of enactment of this Act, seek to engage the National Academies of Sciences, Engineering, and Medicine to conduct a review of the ethical, legal, environmental, security, safety, and other societal concerns related to engineering biology research and development. This review will note research gaps in these areas, recommend actions the Initiative can take to address said gaps, and recommend ways engineering biology researchers can take the societal concerns identified in this section into account as they develop proposals and conduct research. The National Academies of Sciences, Engineering, and Medicine are directed to submit this report to Congress within 2 years after the date of enactment of this Act, as well as make the report publicly available.

Section 8. Agency activities.

This section outlines agency-specific activities and the responsibilities that agencies would be required to undertake as part of the Initiative. This list includes activities and responsibilities at the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Department of Defense, the National Aeronautics and Space Administration, the Department of Agriculture, the Environmental Protection Agency, the National Institutes of Health, and the Food and Drug Administration.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee states that the bill as reported would make no change to existing law.

○