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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR,
AND PENSIONS

WASHINGTON, DC 20510-6300

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www.help.senate.gov

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Dear Long COVID Stakeholder:

As Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee, it is my strong belief that the crisis of Long COVID is a public health emergency that we can no longer ignore.

As you know all too well, Long COVID is an infection-associated chronic condition where individuals experience chronic or relapsing symptoms after an acute COVID-19 infection. These symptoms can impact anyone who has previously been exposed to COVID-19, regardless of age or severity of the initial infection. In America today, about 22 million adults have Long COVID, though this is likely an underestimate. People with Long COVID experience a variety of symptoms from cognitive impairment and extreme fatigue, to life-threatening cardiovascular and neurological challenges.

In January 2024, the HELP Committee held a hearing on the topic of Long COVID where experts underscored the urgent need to aggressively find approved treatments for this terrible disease, to better educate medical professionals on how to diagnose Long COVID, to better understand the risks associated with Long COVID and to identify potential therapeutic options, among many other things.

As part of the Committee's ongoing work to address the crisis of Long COVID, Chairman Sanders has released a draft legislative proposal on this important issue.

This draft proposal would:

- **Provide \$1 billion in mandatory funding per year for 10 years to the National Institutes of Health (NIH) to respond to the Long COVID crisis with the sense of urgency that it demands.**

- **Create a centralized coordinating entity** for the majority of Long COVID research activities at NIH, with a clear leadership structure that includes patients who have lived experience with Long COVID.
- **Require NIH to establish a new grant process** for clinical trials related to Long COVID. These grants would be reviewed more quickly than traditional grants and prioritize funding for studies that test non-behavioral therapeutic and preventative interventions in patients with Long COVID, including but not limited to repurposing existing pharmaceutical interventions.
- **Establish an NIH research advisory board** made up of scientists, health care providers, and patients who have lived experience with Long COVID and other COVID-induced chronic conditions. The goal of the research advisory board would be to provide advice on research funding.
- **Require NIH to establish a Long COVID database** for the storage and dissemination of de-identified patient data to make Long COVID research more accessible.
- **Require federal entities to provide continued education and support** to patients, providers, and the public about the ongoing risks of Long COVID, as well as how to identify and address it.

We invite your input on the more detailed proposal ([HERE](#)). Please submit your comments to the Committee by email at LongCOVIDComments@help.senate.gov no later than the close of business on Tuesday, April 23, 2024.

Thank you in advance for your feedback. We appreciate your input on this important matter and look forward to working with all of you to address this important public health issue.

Sincerely,



Bernard Sanders
Chair
Senate HELP Committee

Addendum

Establish a Long COVID Research Program at the National Institutes of Health (NIH)

- Require the NIH Director to establish a Long COVID Research Program to create a centralized, coordinating structure for the majority of Long COVID research and clinical activities at NIH.
 - The NIH Director will appoint a Director to oversee the Long COVID Research Program and establish a strategic research plan that would expand, intensify, expedite, and coordinate NIH's Long COVID activities. This plan would be published within 6 months of the development of this research program and be updated annually.
 - The Director of the Long COVID Research Program must be someone who has experience directing a research program on Long COVID or other infection-associated chronic conditions. Preference must be given to individuals who have previously demonstrated commitment to Long COVID and other COVID-induced infection associated chronic conditions. As part of the hiring process, the NIH shall seek recommendations from Long COVID patient advocacy organizations.
- The purpose of the program would be to:
 - Investigate the etiology, pathophysiology, risk factors, and pathology of Long COVID; explore best ways to prevent, detect, monitor, treat, and cure Long COVID and other COVID-induced conditions; and contribute knowledge to the understanding, prevention, mitigation, and treatment of Long COVID and other COVID-induced conditions; and
 - Develop and facilitate both intramural and extramural programs on clinical and fundamental aspects of Long COVID and other COVID-induced conditions.
- As part of the new Long COVID Research Program, the NIH shall develop a new Scientific Research Group composed of individuals represented by leading Long COVID researchers and patient advocates for the purposes of evaluating Long COVID research grant applications.

Expedite Long COVID Research

- The NIH Director shall establish a fast track mechanism for seeking, evaluating through a peer-review process, and funding research grants relating to Long COVID. Grant requests will receive higher priority if they

demonstrate the ability to begin interventions in a timely manner and if they have letters of support from patient organizations with a history of Long COVID advocacy.

- Grant funding announcements must be made in a way that provides potential applicants at least four weeks to prepare and submit their application.
- The NIH must ensure that authors receive a final decision on their grant applications within 120 days. For those proposals that are denied, the NIH must provide an explanation.
- These grants shall prioritize funding for studies that test outcomes of pharmaceutical interventions in patients with Long COVID, with an emphasis on drugs and interventions that are currently being utilized by patients and providers off-label. These grants can also be used to aid in the development of new pharmaceutical interventions that have strong evidence to suggest effect in treating or curing Long COVID.
- The NIH shall also provide guidance to recipients of these grants on how to contact patients for potential clinical trials.
- There shall also be grant funds set-aside for evaluating the impact and accessibility of programs and interventions regarding health-related social needs, such as community health worker and peer support, occupational and physical therapy, and home and community-based services.

Establish Research Advisory Board

- The NIH Director shall initiate procedures to contract with an independent, nonprofit, outside entity, such as the National Academies of Sciences, Engineering, and Medicine, to establish and support a Long COVID Research Advisory Board (the Board). The contract will facilitate the Board's establishment and ongoing functioning to ensure the Long COVID Research Program's transparency, accountability, and communication of results to the public.
- The purpose of the Board is to provide guidance to the Director of the Long COVID Research Program on the following --
 - Appropriate research activities to be undertaken with respect to clinical treatment of Long COVID. This includes but is not limited to:
 - Research on medical interventions for preventing, treating, and understanding the mechanisms of Long COVID and COVID-induced conditions;

- Research on effectiveness of treating Long COVID with drugs that are not yet FDA approved for the treatment of Long COVID and COVID-induced conditions;
 - Review ongoing publicly and privately supported research on clinical treatments for Long COVID and COVID-induced conditions;
 - Issue and make available to health care professionals and the public, reports describing and evaluating such research; and
 - Convene accessible meetings for the purpose of determining the recommendations which may inform development of clinical guidelines by health care provider organizations.
 - Contribute to the NIH's overall research priorities related to Long COVID and COVID-induced conditions.
- On appropriate and effective actions to ensure the accountability, transparency, and communication of results of the Long COVID Research Program.
- The contracted entity will conduct a nomination process that allows for public input on nominees and facilitate member selection to seat a new Board within six months of contract award. The composition of the Board shall be the following with consideration from diverse backgrounds:
 - 6 non-federal members from among scientists, health care providers, and other health professionals or researchers who have primary expertise in Long COVID;
 - 5 non-federal members from the public with lived experience with Long COVID;
 - 2 members nominated by the NIH Director or the Director of the Long COVID Research Program from among NIH personnel who have expertise in Long COVID research; and
 - Ex officio members to include Institute Directors at NIH whose institutes are engaged in conducting or funding Long COVID research.
- The contracted entity will convene and otherwise support the Board in executing its responsibilities.
- The Board composition should reflect the diversity of the Long COVID population, with an emphasis on those who face the highest disease burden.

Establish Data System and Information Hub

- The Director of the Long COVID Research Program shall establish a Long COVID Data System for the collection, storage, analysis, retrieval, and dissemination of primary data, including tissue samples, derived from patient populations with Long COVID.
- The Director of the Long COVID Research Program shall establish a Long COVID Information Hub to facilitate and enhance, through dissemination of information, knowledge and understanding of Long COVID by health professionals, patients, industry, and the public.
- The NIH shall form a committee of NIH researchers specializing in Long COVID and other COVID-induced chronic infections for the purpose of evidence synthesis. The committee will be responsible for issuing an annual report detailing the major findings from clinical studies conducted within the year.
- The NIH will also establish a biological data bank of clinical information from patients enrolled in federally funded Long COVID research. This information must be disseminated to patients, other members of the public, health care providers, and researchers while ensuring patient privacy is strictly maintained. As part of this process, the NIH shall establish an external advisory committee to establish the parameters for the data elements that will be included.
 - In establishing this data bank, the NIH shall engage closely with other entities that have established patient registries for Long COVID.

Public Education and Outreach Campaign

- The Centers for Disease Control and Prevention (CDC), in coordination with the Long COVID Research Program, the Research Advisory Board, and the Office of the Assistant Secretary of Health, along with state, local and Tribal health departments, shall develop a public education campaign with materials for patients, families and caregivers on the risks of developing Long COVID, recognizing the signs and symptoms of Long COVID, and information on how to prevent and seek treatment for Long COVID.
 - This awareness campaign will include educational materials on self-management tools and support services.
 - Additionally, the campaign will include information on Long COVID in children and adults.
 - This information must be available in multiple languages, including American Sign Language, and be provided to Medicare and Medicaid beneficiaries, State Medicaid agencies, and health plans.

- Additionally, grants will be provided to health departments to work in conjunction with community-based organizations to reach populations most affected by Long COVID and COVID-19.

Provider Education

- The Long COVID Research Program will work with the CDC and Office of Long COVID Research and Practice to provide information and continuing education programs for health care providers and allied health professionals who will provide care for patients with Long COVID (primary care providers, specialists, community health centers, community health workers, Long COVID Clinics, etc). This education should cover:
 - How to screen for and diagnose Long COVID and common new-onset conditions or comorbid conditions, including differences in symptomology by gender, race, ethnicity, age, disability and preexisting conditions;
 - How to inform patients of the risks of developing Long COVID and the risks of reinfection for those with Long COVID;
 - Supportive treatment and symptom management options, lifestyle modifications, and other resources that exist for Long COVID and common new-onset conditions or comorbid conditions; and
 - When to refer patients to specialists (when needed).
- NIH can also make grants to establish projects to develop patient-centered model protocols for the clinical care of individuals with Long COVID. The NIH will prioritize grant requests that emphasize patient access to multidisciplinary care as well as specific care for underserved communities.
- NIH will also create professional education modules specifically for a community-based health workforce so that information about Long COVID is delivered in culturally and linguistically appropriate ways.
- To support education of providers, the NIH will hold an annual conference of clinicians, researchers, patients, and government partners to share information on Long COVID. These conferences will include virtual options and plain language summaries that enable participation by those most affected by Long COVID.
- The NIH will host a conference with Long COVID experts to build consensus on clinical terms, definitions, and clinical endpoints for Long COVID studies and to share the state of the science in this multidisciplinary field.

Report

- The Director of the Long COVID Research Program must provide an annual public report on expenditures in the previous year with respect to Long COVID. Must include for each program, project, or activity:
 - A specification of the amount obligated for each activity;
 - Summary description of each project, program, or activity; and
 - Summary of progress made by each program, project or activity with respect to increased knowledge of etiology, detection, treatment, and prevention of Long COVID.
- This report must be made available to the public on the agency website.
- This report must also be shared with the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce.

Authorization of Appropriations

\$1 billion in mandatory funding per year for 10 years to address the Long COVID crisis.