.....

(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. _____

To amend the Public Health Service Act to authorize and provide for the expansion, intensification, and coordination of the programs and activities of the National Institutes of Health with respect to post-viral chronic neuroimmune diseases, specifically myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), to support the COVID–19 response, and other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. RASKIN introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to authorize and provide for the expansion, intensification, and coordination of the programs and activities of the National Institutes of Health with respect to post-viral chronic neuroimmune diseases, specifically myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), to support the COVID–19 response, and other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Understanding COVID–19 Subsets and ME/CFS Act'' or the ''U.C.S. ME/CFS Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) As of May 27, 2020, the virus that causes COVID–19 has infected 1.7 million Americans, many of whom may never recover, and has caused over 100,000 deaths.

(2) Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a serious, chronic, and multisystemic disease associated with survivors of viral infections.

(3) Subsets of COVID–19 patients are presenting with ME/CFS symptoms, such as brain inflammation, and experts expect a significant increase of ME/CFS cases in the next two years in the United States following the COVID–19 epidemic.

(4) ME/CFS is characterized by chronic or lifelong symptoms across multiple body systems including post-exertional malaise (PEM), brain inflammation, fever, pain, neurological, immune and cognitive dysfunction, and swollen glands or tender lymph nodes which are most likely to appear following a

viral infection, like coronaviruses, Epstein-Barr, or Q–River fever.

(5) The severity of both COVID–19 and ME/CFS ranges from mild to completely debilitating and in some cases can be lethal.

(6) The cause of ME/CFS is unknown. There is no diagnostic test for ME/CFS, and there is no treatment for ME/CFS that is approved by the Food and Drug Administration.

(7) Physicians are not sufficiently educated on the proper diagnosis of COVID–19 subsets, ME/CFS, or current treatments for ME/CFS. This leads to excess health care costs, errors in treatments, and harm to patients.

(8) Patients with ME/CFS frequently suffer for years before receiving an accurate diagnosis and are often given harmful treatment recommendations exposing them to unnecessary and costly tests and procedures, as well as needless suffering and expense.

(9) The economic impact of ME/CFS is high. The annual cost in the United States for ME/CFS is estimated to be between $17,000,000,000 and $24,000,000,000 in medical expenditures and lost productivity. The overwhelming majority of people with ME/CFS are unable to work.

(10) ME/CFS symptoms are consistent with other neuroimmune diseases, such as Gulf War Illness, and are recognized as a serious and disabling issue for military veterans, particularly those who have been deployed in war zones and experience foreign toxic or viral exposure.

(11) ME/CFS affects individuals of every age, racial, ethnic, and socioeconomic group, including children. Research shows that ME/CFS is two to four times more likely to occur in women than men.

(12) The National Institute of Neurological Disorders and Stoke of the National Institutes of Health unanimously accepted the recent report of the National Advisory Neurological Disorders and Stroke (NANDS) Council Working Group for ME/CFS which identifies research gaps and opportunities ready for investment.

SEC. 3. RESEARCH ON COVID–19 SUBSETS AND POST-VIRAL CHRONIC NEUROIMMUNE DISEASES.

Subpart 7 of part C of title IV of the Public Health Service Act (42 U.S.C. 285g et seq.) is amended by adding at the end the following:

"SEC. 452H. RESEARCH ON COVID–19 SUBSETS AND POST-VIRAL CHRONIC NEUROIMMUNE DISEASES.

"(a) IN GENERAL.—The Director of NIH, in coordination with or acting through the Director of the Institute, shall conduct and support research and related activities concerning the diagnosis, treatment, and risk factors of post-viral chronic neuroimmune diseases, specifically myalgic encephalomyelitis/chronic fatigue syndrome (in this section referred to as 'ME/CFS'), COVID–19 patients exhibiting ME/CFS symptoms, and survivors of COVID–19 with ME/CFS. Such research shall attempt to better understand the underlying cause or causes of ME/CFS to reduce the rate of onset of ME/CFS in COVID–19 survivors or identify effective treatments and improve outcomes for COVID–19 survivors with ME/CFS.

"(b) DATA COLLECTION.—In carrying out subsection (a), the Director of NIH shall implement a system to collect data on ME/CFS, which can be contributed to and utilized by research partners, and which provides for the collection of such data including—

"(1) epidemiologic information with respect to the incidence, prevalence, and impact of ME/CFS in the United States, COVID–19 patients exhibiting ME/CFS symptoms, and survivors of COVID–19 with ME/CFS;

''(2) primary data on ME/CFS natural history and symptom progress, including related data on the post-viral nature, risk factors, and various conditions known to be comorbid with ME/CFS;

''(3) the availability of medical and social services for individuals with ME/CFS and their families; and

''(4) the disaggregation of such data by population and geographical region.

''(c) COLLABORATIVE RESEARCH CENTERS.—In carrying out subsection (a), the Director of NIH shall award grants and contracts to public or nonprofit private entities to pay all or part of the cost of establishing or expanding collaborative research centers for ME/CFS, including the costs of stakeholder engagement and patient outreach programs.

''(d) DEVELOPING RESEARCH AGENDA.—The Director of NIH, in coordination with the Director of the Institute, the Trans-NIH ME/CFS Working Group, interagency partners, stakeholders, and disease experts, shall develop a research agenda—

''(1) drawing from the September 2019 report of the National Advisory Neurological Disorders and Stroke Council Working Group for ME/CFS; and

''(2) prioritizing outcomes for COVID–19 patients exhibiting ME/CFS symptoms and survivors of COVID–19 with ME/CFS.

''(e) RESEARCH PROGRAM.—In carrying out subsection (b), the Director of NIH, in coordination with the Director of the Institute and the directors of other national research institutes and centers, and utilizing the National Institutes of Health's process of scientific peer review, shall—

''(1) prioritize opportunities that accelerate diagnosis and identify effective treatments for COVID–19 patients exhibiting ME/CFS symptoms and survivors of COVID–19 with ME/CFS;

''(2) prioritize projects with new and early career researchers;

''(3) expand ME/CFS research programs including the continuation of existing studies, remote convenings with stakeholders, and new ME/CFS disease specific funding announcements, including set-aside funds; and

''(4) explore opportunities to partner with the Department of Defense and the Department of Veterans Affairs to increase research and improve patient care regarding ME/CFS that commonly impact veterans and active duty military personnel.

''(f) REPORT TO CONGRESS.—Not later than 24 months after the date of enactment of the Understanding COVID–19 Subsets and ME/CFS Act, the Director of NIH shall submit a report to Congress on the progress made in gathering data and expanding research on the onset and clinical care of COVID–19 survivors with ME/CFS, including the rate at which COVID–19 survivors are diagnosed with ME/CFS. Such report shall summarize the grants and research funded, by year, under this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2020 through 2024.''.

SEC. 4. PROMOTING PUBLIC AWARENESS OF POST-VIRAL CHRONIC NEUROIMMUNE DISEASES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by adding at the end the following:

''SEC. 320B. PUBLIC AWARENESS OF POST-VIRAL CHRONIC NEUROIMMUNE DISEASES.

''(a) IN GENERAL.—The Secretary may engage in public awareness and education activities to increase understanding and recognition of post-viral chronic neuroimmune diseases, specifically myalgic encephalomyelitis/chronic fatigue syndrome (in this section referred to as 'ME/CFS').

''(b) ACTIVITIES INCLUDED.—Activities under subsection (a) may include the distribution of print, film, and web-based materials targeting health care providers and the public and prepared and disseminated in conjunction with patient organizations that conduct research on or treat ME/CFS.

''(c) EMPHASIS.—The information expressed through activities under subsection (a) shall emphasize—

''(1) basic information on ME/CFS, the symptoms, prevalence, and frequently co-occurring conditions; and

''(2) the importance of early diagnosis, and prompt and accurate treatment of ME/CFS, including most recent treatment recommendations.''.