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117TH CONGRESS
1ST SESSION

H. R. 5745

To clarify Medicare coverage for COVID–19 testing and to provide support for cellular immune response research for COVID–19, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 2021

Mr. DUNN (for himself and Mr. JACKSON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

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A BILL

To clarify Medicare coverage for COVID–19 testing and to provide support for cellular immune response research for COVID–19, and for 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 "COVID–19 Access to Testing and Support for Immune Response Research Act of 2021".

SEC. 2. FINDINGS.

Congress finds the following:

(1) A public health emergency regarding the COVID–19 pandemic was first declared on January 31, 2020, and has been subsequently renewed repeatedly, most recently on July 19, 2021, by the Secretary of Health and Human Services under both Republican and Democratic administrations.

(2) In the spring of 2020, the only tests available to determine whether a person had a recent or prior infection of SARS–CoV–2 were serology tests which could identify whether a person had antibodies specific to the SARS–CoV–2 virus.

(3) On May 8, 2020, the Centers for Medicare & Medicaid Services (CMS), citing the ongoing COVID–19 public health emergency, issued an interim final rule which recognized on an interim basis that certain Food and Drug Administration-authorized serology tests fall under the Medicare benefit category for diagnostic laboratory tests.

(4) On March 5, 2021, the Food and Drug Administration issued the first authorization for the emergency use of a cellular (T-cell) immune response COVID–19 test intended for use as an aid in identifying individuals with an adaptive T-cell immune response to SARS–CoV–2, indicating recent or prior infection with SARS–CoV–2.

(5) CMS has yet to update its May 8, 2020, interim final rule or provide separate guidance to clarify that Medicare coverage extends to other Food and Drug Administration-authorized tests, including T-cell tests, that are intended for diagnosing recent or prior infection with SARS–CoV–2.

(6) In research and development related to infectious diseases and vaccines, including SARS–CoV–2, historically the antibody response, which is only half of the adaptive immune system, has been the primary tool for assessment.

(7) The other half of the adaptive immune response, the T-cell response, has historically been more difficult to assess, but scientific and technological advances now allow for standardized and sensitive methods to measure T-cells.

(8) The National Institutes of Health have integrated T-cell testing into certain studies regarding the impact of T-cells in detecting and defending against SARS–CoV–2 variants, and there exist additional research opportunities regarding the cellular immune response to SARS–CoV–2, including—

(A) identifying the type and duration of T-cell response that confers immunity (including

to variants) following natural infection, vaccination, or both;

(B) understanding the T-cell response in different populations, including children, the elderly, and immunocompromised individuals; and

(C) understanding the T-cell response in patients facing long-term COVID–19 symptoms.

(9) Evidence shows T-cells play an important role in the immune response to COVID–19 and points to the need for a concerted research effort, which could have profound consequences on public health, such as policies on boosters or the development of therapeutics for patients suffering from post-acute sequelae of COVID–19 infection.

SEC. 3. CLARIFYING MEDICARE COVERAGE OF COVID–19 DIAGNOSTIC LABORATORY TESTS.

(a) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall by interim rule, subregulatory guidance, or otherwise, provide for coverage of T-cell diagnostic laboratory tests furnished during the period beginning on January 1, 2022, and ending on the last date of the public health emergency period (described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))) for beneficiaries with current

or known prior COVID–19 infection or suspected current or suspected past COVID–19 infection.

(b) T-CELL DIAGNOSTIC LABORATORY TEST DEFINED.—For purposes of subsection (a), the term ''T-cell diagnostic laboratory test'' means a clinical laboratory test that is—

(1) intended to identify an adaptive T-cell immune response to SARS–CoV–2 indicative of recent or prior infection with SARS–CoV–2; and

(2) cleared, approved, or otherwise authorized pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 4. NATIONAL STRATEGY FOR COVID–19 CELLULAR IMMUNE RESPONSE RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'')—

(1) shall—

(A) expand, intensify, and coordinate the programs and activities of the National Institutes of Health and the Centers for Disease Control and Prevention with respect to scientific and clinical research on the cellular immune response related to COVID–19;

(B) develop and implement a national strategy to research the cellular immune response to SARS–CoV–2, which shall include research on—

(i) the type and duration of T-cell responses to COVID–19 vaccines and how such responses confer immunity and contribute to protection from infection with SARS–CoV–2 variants of concern;

(ii) the type and duration of T-cell responses in patients who have recovered from COVID–19 and how such responses may confer immunity;

(iii) the type and duration of T-cell immune responses in patients facing long-term COVID–19 symptoms; and

(iv) the type and duration of T-cell responses to vaccination and natural infection in certain populations, such as children, the elderly, and immunocompromised individuals; and

(C) update the strategy under subparagraph (B) as appropriate; and

(2) subject to the availability of appropriations, may make grants to States, political subdivisions,

public-private partnerships, academic institutions, and other public entities to carry out scientific and clinical research on the cellular immune response related to COVID–19 and to implement the strategy under paragraph (2).

(b) CONSULTATION.—In carrying out subsection (a), the Secretary shall consult with relevant individuals, as appropriate, such as—

(1) clinicians, public health professionals, and others with expertise in cellular immune response;

(2) representatives of patient advocacy and research organizations with interest in cellular immune research;

(3) researchers with expertise in cellular immunology; and

(4) epidemiologists with experience in cellular immune response.

(c) PUBLIC MEETING.—Not later than 3 months after the date of the enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health, shall convene a public meeting composed of subject matter experts and stakeholders to identify research needs and opportunities.

(d) PUBLICATION OF STRATEGY.—The Secretary shall make public the strategy under subsection (a)(1)(B),

including initial funding opportunity announcements, within 6 months of the date of enactment of this Act.

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