Congress of the United States
Washington, DC 20515

June 16, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

As medical professionals and Members of Congress, we applaud the FDA's investment in antigen tests and polymerase chain reaction (PCR) tests, which played a key role in the COVID-19 pandemic response. Now that COVID-19 infections nationwide have substantially decreased, and continue to fall, due in large part to the widespread availability of vaccines, we ask that you review applications for tests measuring the presence of T cell mediated immunity to COVID-19. Tests measuring T cells could provide better detection of immunity in those naturally infected and could also be pivotal in tracking immunity after vaccination.

While antigen and PCR tests are diagnostics for active infections, diagnostics for the immune system after viraemia are essential for tracking immune response via prior infection or vaccination, and will be of increasing utility as we transition to the closing phases of the COVID-19 pandemic. Antibody levels are primarily helpful for detecting antibody presence in the short window immediately after the initial infection but may quickly decline. Additionally, infection may not always produce measurable antibodies.

Measuring T cell response allows better detection of patients who have been previously infected and have an adaptive immune response. A test to measure the T cell response would give healthcare providers a tool to measure if a COVID-19 vaccine available under an Emergency Use Authorization is appropriate for their patients. Providing a measure to determine if a patient has previously been infected, and to what degree they have a natural immune response, will give patients more information as they consult with their healthcare provider and make a decision with respect to vaccination. This would be especially helpful for individuals who have experienced adverse reactions to vaccines in the past or other populations with other conditions that may affect their risk profile. Additionally, if a patient's test reveals they do not have an adaptive immune response, that may encourage them to get vaccinated even if they had previously tested COVID-19 positive.

Measuring T cell response would also provide a way to measure immunity after vaccination. The testing can inform ongoing vaccine research to allow measurement of the duration of vaccine

immunity over time and against various strains of the virus. Measuring vaccine-induced immunity will be a critical factor in ending the COVID-19 pandemic.

We applaud the FDA for granting an Emergency Use Authorization (EUA) for T-DETECT COVID, a T cell test that screens for a T cell signal; however, we encourage the FDA to also consider T cell tests that measure T cell responses to spike and nucleocapsid proteins, which are most related to this disease. The spike protein is involved in measurement of T cell response from vaccination while the nucleocapsid protein is involved with T cell response from natural infection. Tests that measure T cell responses to spike and nucleocapsid proteins for COVID-19 are available in Europe. We would appreciate your review of these tests in the United States.

It has come to our attention that the FDA previously acknowledged that it isn't prioritizing T-cell tests because it is prioritizing applications for rapid diagnosis, point-of-care diagnostics and variant diagnostics. While this may have been appropriate at the peak of the pandemic, the mitigation efforts must shift from triage to long-term, to include measuring vaccine-induced immunity and natural immune response. We ask that you reevaluate these priorities to consider long-term mitigation of COVID-19. For over a decade, the FDA has approved tests measuring T cells to diagnose tuberculosis, another dangerous respiratory disease. We have seen the advantage of using T cell technology in gauging TB vaccine efficacy and testing accuracy. We encourage you to consider the benefits of the technology for combating COVID-19.

Measuring T cell response could significantly improve medical decisions and vaccine research as we aim to end the COVID-19 pandemic. We appreciate the work the FDA has done to review applications for antigen, PCR, and antibody tests, and encourage the Administration to also review applications for tests measuring T cells. We appreciate your attention to this matter.

Sincerely,

Andy Harris, M.D.
Member of Congress

Roger Marshall, M.D.
United States Senator

Rand Paul, M.D.
United States Senator

Neal P. Dunn, M.D.
Member of Congress

Ronny L. Jackson, M.D.
Member of Congress

Mariannette Miller-Meeks, M.D.
Member of Congress