ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

> Majority (202) 225-2927 Minority (202) 225-3641

July 22, 2020

The Honorable Stephen M. Hahn, M.D. Commissioner of Food and Drugs Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

We write regarding troubling reports about fraudulent antibody test scams occurring in the marketplace. Throughout the coronavirus disease of 2019 (COVID-19) pandemic, scammers have capitalized on consumers' fear and uncertainty at every turn, including by selling fraudulent treatments and cures, offering sham tests and vaccines, and posing as government officials to obtain money and personal information. Although we do not yet know the degree to which COVID-19 antibodies provide protection against infection, there is now reportedly a significant demand for antibody tests among consumers who wish to return to their everyday activities against the advice of public health experts. It is no surprise that scammers are seeking to take advantage of this demand and are reportedly engaging in fraudulent antibody test scams.

Last month, the Federal Bureau of Investigation (FBI) warned that scammers are marketing fraudulent and/or unapproved antibody tests to consumers.³ The reported goal of such scams is to obtain sensitive personal information, such as Social Security numbers, dates of birth, and insurance information, which can then later be used in identity theft or insurance theft schemes.⁴ The FBI's warning indicates that scammers may advertise these fraudulent tests online, such as through social media platforms, or through more direct consumer interactions,

¹ Bogus Vaccines. Fake Testing Sites. Virus Frauds Are Flourishing, The New York Times (Apr. 17, 2020).

² Hype and science collide as FDA tries to rein in 'wild West' of COVID-19 blood tests, Los Angeles Times (June 3, 2020).

³ The Federal Bureau of Investigation, *FBI Warns of Potential Fraud in Antibody Testing for COVID-19* (June 26, 2020) (press release).

⁴ F.B.I Warns of Fraudulent Coronavirus Antibody Tests, The New York Times (June 29, 2020).

The Honorable Stephen M. Hahn, M.D. July 22, 2020 Page 2

such as emails and telephone calls.⁵ Concerningly, it appears the scammers may be incentivizing consumers to interact with them by offering money and even deceiving consumers into believing the tests are required by posing as government officials.⁶

These scams are dangerous not only because of the potential for identity or insurance theft, but also because of their potential to provide a false sense of security to individuals who wish to return to their everyday lives. The FBI warned that these scams may provide its victims with false test results. A false positive antibody test result could lead individuals to believe they are immune from COVID-19 and therefore do not need to take certain precautions, such as wearing masks and engaging in social distancing. This jeopardizes the health and well-being of not only those that are scammed, but also the communities in which the individuals live, work, and socialize.

Given that it remains unclear whether the presence of antibodies provides a level of protection against re-infection, ⁸ it is imperative that your agency takes steps to ensure consumers are protected from scams that may affect their financial and physical well-being. In an effort to understand how the Food and Drug Administration (FDA) is responding to these scams, the Committee requests responses to the following by August 5, 2020:

- 1. Has FDA determined the extent to which fraudulent antibody test scams as described above are occurring in the marketplace? If so, please provide information regarding the quantity of these scams, types of methods deployed by scammers, and, if known, the consequences to consumers.
- 2. What resources is FDA employing to monitor the marketplace to determine whether scams related to COVID-19 are occurring? Please indicate the frequency with which such monitoring occurs.
- 3. If FDA receives indications that a scam is occurring, what criteria does it use to determine whether to launch an investigation into the potential scam? If FDA confirms a scam is being perpetrated, what resources can it employ to address the scam and protect consumers?

⁵ The Federal Bureau of Investigation, *FBI Warns of Potential Fraud in Antibody Testing for COVID-19* (June 26, 2020) (press release).

⁶ F.B.I Warns of Fraudulent Coronavirus Antibody Tests, The New York Times (June 29, 2020).

⁷ The Federal Bureau of Investigation, *FBI Warns of Potential Fraud in Antibody Testing for COVID-19* (June 26, 2020) (press release).

⁸ Centers for Disease Control and Prevention, *Test for Past Infection (Antibody Test)* (June 30, 2020) (www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html).

The Honorable Stephen M. Hahn, M.D. July 22, 2020 Page 3

- 4. Has FDA already taken action against any entities engaging in fraudulent antibody test scams as those scams are described above? If so, please provide further details about these actions, including the number of actions taken, the type of actions taken, and the organizations subject to these actions.
- 5. Please describe any information sharing and other coordination efforts between FDA and other federal and state entities to monitor the marketplace, identify scams related to COVID-19, and hold entities involved in such scams accountable.

Thank you for your prompt attention to our request. For any questions, please contact Manmeet Dhindsa, Lisa Goldman, and Stephen Holland of the Majority staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.

Trank Pallar. p.

Chairman

Diana DeGette

Chair

Subcommittee on Oversight and Investigations

Paus Dollate

Anna G. Eshoo Chairwoman

Subcommittee on Health

Jan Schakowsky

Chair

Subcommittee on Consumer Protection

and Commerce