CAROLYN B. MALONEY CHAIRWOMAN ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051 MINORITY (202) 225–5074 http://oversight.house.gov

March 24, 2020

Mr. Eren Bali Chief Executive Officer Carbon Health Medical Group, Inc. 55 Pacific Avenue, Suite 100 San Francisco, CA 94104

Dear Mr. Bali:

The Subcommittee on Economic and Consumer Policy requests information about your company's at-home coronavirus test kits.

On March 20, 2020, the Food and Drug Administration (FDA) cautioned against using at-home testing kits as their accuracy has yet to be clearly determined.¹ On March 21, 2020, FDA made clear that its Emergency Use Authorization Guidelines bar the use of at-home sample collection, and that it "has not authorized any test that is available for purchase for testing yourself at home for COVID-19."²

Given FDA's statements on this issue, the Subcommittee requests that you respond to the following questions by March 27, 2020, regarding your company's at home coronavirus tests:

- 1. When did your company start offering at-home coronavirus test kits for sale to consumers, and when did you stop?
- 2. How many at-home coronavirus test kits did your company sell, how much did you charge, and how many consumers returned test kits with their samples?
- 3. Do you intend to destroy all consumer samples received, and if so, when and how will you do so?

¹ Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits* (Mar. 20, 2020) (online at www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits).

² Food and Drug Administration, *FAQs on Diagnostic Testing for SARS-CoV-2* (Mar. 21, 2020) (online at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2).

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- 4. Do you intend to refund all consumers all amounts they paid for at-home coronavirus test kits, and if so, when and how you will you do so?
- 5. How many nasopharyngeal swabs does your company possess, and will you donate them for use with FDA-approved coronavirus tests?

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi Chairman Subcommittee on Economic and Consumer Policy

Katie Porter Member of Congress

cc: The Honorable Michael Cloud, Ranking Member