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Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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April 22, 2020

Mr. Jason Feldman
Co-Founder and Chief Executive Officer
Vault Health Inc.
22 W 23rd Street, 5th Floor
New York, NY 10010

Dear Mr. Feldman:

The Subcommittee on Economic and Consumer Policy requests information about Vault Health Inc.'s at-home diagnostic test for the novel coronavirus SARS-CoV-2. There are questions about whether your distribution of the test and claims your company made about it could be in violation of federal law.

Your company's website claims that consumers can purchase a test for $150 that is the "first FDA EUA-approved saliva test – for COVID-19." According to your website, you "have teamed up with RUCDR Infinite Biologics to offer medically-supervised telehealth testing in your home for the novel coronavirus." Under Vault's testing protocol, a "physician-ordered test" is sent to a patient's home, the patient self-collects a saliva sample during a telehealth video call, and then the patient ships the sample overnight to a lab for analysis.[1]

Under the March 16, 2020, policy from the Food and Drug Administration (FDA), at-home sample collection is not authorized unless specifically authorized by an Emergency Use Authorization (EUA).[2] Under this policy, RUCDR's saliva-based test has not been authorized for at-home sample collection. Rather, the EUA provides:

> Collection of saliva specimens is limited to patients with symptoms of COVID-19 and should be ***performed in a healthcare setting under the supervision of a trained healthcare provider*** using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated."[3]

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[1] Vault Health, *COVID-19 Testing* (online at www.vaulthealth.com/covid/) (accessed Apr. 20, 2020).

[2] Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency* (Mar. 16, 2020) (online at www.fda.gov/media/135659/download).

[3] Food and Drug Administration, *Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay EUA Summary* (emphasis added) (online at www.fda.gov/media/136875/download).

For these reasons, the Subcommittee requests responses to the following questions regarding your company's at-home coronavirus test by April 27, 2020:

1. How many tests have been ordered from Vault, sample collection kits sent to customers, samples received by the laboratory, and results returned to patients?

2. What screening does Vault perform before providing a test to a consumer, including written questionnaires or consultation with a healthcare provider by telehealth, and how does Vault determine who gets a test?

3. Have Vault patients been provided with the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device for at-home sample collection?

4. What reasons do you have to believe that at-home telehealth sample collection is allowed under RUCDR's EUA's requirement that collection be "performed in a healthcare setting under the supervision of a trained healthcare provider"?

5. What instructions are given to patients during at-home sample collection? Please provide all documents provided for telehealth providers and patients regarding at-home sample collection.

6. What reasons do you have to believe that test results are reliable when samples are collected at home and packaged and shipped by a patient?

7. What information does Vault give to its patients with their test results? Please provide a generic copy or template for all documents given to patients regarding test results at any point from ordering the test to receiving results.

8. Under what circumstances does Vault recommend or refer the patient for additional testing with an alternative specimen?

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

cc: The Honorable Michael Cloud, Ranking Member