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Congress of the United States
House of Representatives
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April 22, 2020

Dr. Jay A. Tischfield
Founder, Chief Executive Officer, and Scientific Director
RUCDR Infinite Biologics
145 Bevier Road
Piscataway, NJ 08854

Dear Dr. Tischfield:

The Subcommittee on Economic and Consumer Policy requests information about RUCDR Infinite Biologics's testing for the novel coronavirus SARS-CoV-2 of samples collected through Vault Health, Inc.'s telehealth testing process. There are questions about whether Vault's distribution of the test and claims made about it could be in violation of federal law.

Vault's website claims that consumers can purchase a test for $150 that is the "first FDA EUA-approved saliva test – for COVID-19." Vault claims that they "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, your 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]

For these reasons, the Subcommittee requests responses to the following questions regarding your SARS-CoV-2 saliva test by April 27, 2020:

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[1] Vault Health, *COVID-19 Testing* (online at www.vaulthealth.com/covid/) (accessed Apr. 17, 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).

1. How many saliva samples have you received from Vault or its patients for testing? How many tests have you performed?

2. What did you tell Vault about how to collect samples for your saliva test?

3. What did Vault tell you about its testing process, including sample collection?

4. What steps have you taken to ensure that Vault and other providers comply with the EUA's requirements regarding saliva specimen collection, including:

   a. limitation to patients with symptoms of COVID-19;

   b. performance in a healthcare setting under the supervision of a trained healthcare provider; and

   c. use of the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device?

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

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

7. What information do you provide with test results, and do you send these test results to Vault or directly to patients? Please provide a generic copy or template for all documents regarding test results and how to interpret them that you have provided to Vault or Vault's patients. Does this information and delivery differ for providers other than Vault?

8. How do you ensure that negative results for SARS-CoV-2 RNA from saliva are confirmed by testing of an alternative specimen type when clinically indicated?

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