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ONE HUNDRED SIXTEENTH CONGRESS

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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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March 3, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

The Committee on Oversight and Reform requests documents and information on the efforts of the Department of Health and Human Services (HHS) and its sub-agencies, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), to develop, authorize, and distribute testing procedures for the novel coronavirus disease (COVID-19), which you declared a public health emergency on January 31, 2020.

COVID-19 is poised to become an international pandemic. An essential part of readiness is the ability to diagnose the disease efficiently and accurately so patients can receive the appropriate treatment and our government can mount an effective response.

Although the World Health Organization (WHO) began efforts to make diagnostic tests available across the globe by the first week of February, reports indicate that the United States has declined to utilize these tests.[1]

At this time, there is no FDA-approved diagnostic for COVID-19. On February 4, 2020, however, FDA authorized emergency use of a CDC-developed 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel.[2] CDC and certain qualified labs began to utilize these test kits, but other labs or hospitals that wanted to employ a diagnostic, whether similar to CDC's or not, still had to receive emergency use authorization from FDA.[3]

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[1] World Health Organization, *2019 Novel Coronavirus (2019-nCoV): Strategic Preparedness and Response Plan* (Feb. 3, 2020) (online at www.who.int/docs/default-source/coronaviruse/srp-04022020.pdf); *As Coronavirus Numbers Rise, C.D.C. Testing Comes Under Fire*, New York Times (Mar. 2, 2020) (online at www.nytimes.com/2020/03/02/health/coronavirus-testing-cdc.html).

[2] Food and Drug Administration, *Novel Coronavirus (COVID-19)* (updated Feb. 27, 2020) (online at www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-covid-19).

[3] Food and Drug Administration, *Press Release: FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic* (Feb. 4, 2020) (online at www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first).

State and local labs have expressed doubts about the accuracy of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. New York officials declined to use the test kit that they received from CDC due to their concerns about its accuracy.[4] Flawed components in the CDC test kits prompted the CDC to ship replacement kits to public health laboratories after several weeks' delay.[5] It has been reported that there were contamination issues at the lab that was manufacturing the CDC test kits, and FDA Commissioner Stephen Hahn stated that FDA and CDC have discovered "that problems with certain test components were due to a manufacturing issue."[6]

While the testing efforts of state and local labs were hampered by these technical problems, the testing conducted by CDC itself also appears to have been limited by its own narrow and strict criteria. Reportedly, to be tested by CDC, a patient with suspected novel coronavirus must have recently traveled to China or been in contact with another infected individual.[7] As of Saturday, February 29, 2020, CDC had only tested 472 patients.[8]

Ultimately, to speed up availability of field testing, on February 29, 2020, FDA announced new guidance permitting COVID-19 testing at certain labs that have pending applications for emergency use authorization.[9] The impact of this new policy is unknown.

In order to assist the Committee in its review of this matter, please provide the following documents and information by 12:00 p.m., on March 9, 2020:

1. An accounting of all individuals for whom CDC has been requested to perform COVID-19 tests, including date of each request, whether testing was conducted, the date(s) any testing was conducted, the result of any testing, the requesting entity, and the state where the request originated;

2. An accounting of all COVID-19 testing CDC has conducted, broken down by state and requesting entity, the date(s) the testing was conducted, and the results of each test;

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[4] *Key Missteps at the CDC Have Set Back Its Ability to Detect the Potential Spread of Coronavirus*, ProPublica (Feb. 28, 2020) (online at www.propublica.org/article/cdc-coronavirus-covid-19-test).

[5] *As Coronavirus Numbers Rise, C.D.C. Testing Comes Under Fire*, New York Times (Mar. 2, 2020) (online at www.nytimes.com/2020/03/02/health/coronavirus-testing-cdc.html).

[6] *Scoop: Lab for Coronavirus Test Kits May Have Been Contaminated*, Axios (Mar. 1, 2020) (online at www.axios.com/cdc-lab-coronavirus-contaminated-6dc9726d-dea3-423f-b5ad-eb7b1e44c2e2.html).

[7] *Id.*

[8] *See* Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID – 19) in the U.S.* (accessed Feb. 29, 2020) (archived online at web.archive.org/web/20200301233711/https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html).

[9] Food and Drug Administration, *Press Release: Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics* (Feb. 29, 2020) (online at www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics).

3. A list identifying all labs, including contact information, that have received a test kit for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, including the date the test kit was sent;

4. To the extent that CDC is aware of COVID-19 testing being performed by other entities, including state, university, or private laboratories, the number of individuals for whom COVID-19 testing has been requested, broken down by entity and state, and the results of such testing (i.e., positive or negative) broken down by entity and state;

5. A list of all applications submitted for emergency use authorization for a diagnostic test for COVID-19, including who submitted the application, the applicant's location and contact information, the date of submission, and the status;

6. A list of all entities who have applied to use diagnostic tests for COVID-19 under the February 29, 2020, FDA policy allowing certain labs to begin using diagnostics before FDA completes its review of their emergency use authorization requests; and

7. Documents sufficient to demonstrate any shortfalls with respect to cleanliness, safety, contamination, or other quality issue for facilities at which test kits for CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel were manufactured, including inspection records and related complaints.

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. An attachment to this letter provides additional instructions for responding to the Committee's request.

If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Stephen F. Lynch
Chairman
Subcommittee on National Security

Gerald E. Connolly
Chairman
Subcommittee on Government Operations

Enclosure

cc: The Honorable Jim Jordan, Ranking Member
Committee on Oversight and Reform

The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

The Honorable Jody B. Hice, Ranking Member
Subcommittee on National Security

The Honorable Mark Meadows, Ranking Member
Subcommittee on Government Operations

Responding to Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committees.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committees' preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committees should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committees should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committees' letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee on Oversight and Reform, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a

part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term "including" shall be construed broadly to mean "including, but not limited to."

5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.

7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term "individual" means all natural persons and all persons or entities acting on their behalf.