ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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June 8, 2021

Rochelle P. Walensky, M.D., M.P.H. Director Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329

Dear Director Walensky:

We write to request information and a briefing from the U.S. Centers for Disease Control and Prevention (CDC) that will assist us in our inquiry into the origins of SARS-CoV-2, the virus that causes COVID-19. As Republican leaders of the Committee on Energy and Commerce, the Congressional Committee with jurisdiction over public health, we strongly support an independent, comprehensive investigation into the origins of the COVID-19 pandemic, including the possibility of an accidental laboratory leak.

In investigating the origin of the pandemic, it is essential to uncover the most accurate information necessary to determine when the first case of SARS-CoV-2 occurred. According to the March 2021 joint World Health Organization-China study, Chinese records had established 174 confirmed COVID-19 cases in December 2019, with the first case of infection on December 8, 2019. However, a March 2020 article in the South China Morning Post reported the first case in China was actually on November 17, 2019, according to government data reviewed by the

World Health Organization, WHO-convened global study of origins of SARS-CoV-2: China Part, Publications Overview (Mar. 30, 2021) available at https://www.who.int/publications/i/item/who-convened-global-study-of-origins-of-sars-cov-2-china-part.

reporter.² The same article stated that Chinese authorities had identified at least 266 people who were infected in November and December 2019.³

Both December case counts appear to be severe undercounts and, notably, not consistent with the reproductive rate of the virus. The reproductive rate of the virus was an estimated 4 to 5 cases from each case at the beginning of the pandemic.⁴ Thus, there should have been a much higher progression of cases reported for December after the date of the first case. Further, the date of the first case in the China–World Health Organization study does not appear to be consistent with findings from the November 2020 study that the CDC conducted with the American Red Cross (ARC) on archived blood donations to see if there were indications of SARS-CoV-2 infections earlier in the U.S. than January 2020.⁵ Since the Chinese government continues to block access to pertinent data on cases in China, examination of possible evidence in the United States could shed light on the timing of when the earliest cases in China occurred.

The first case of SARS-CoV-2 infection was reported in the United States on January 19, 2020, and confirmed by CDC using its RT-PCR diagnostic assay on January 20, 2020. CDC conducted work to see if there were indications of earlier, undetected SARS-CoV-2 infections prior to January 19, 2020. In November 2020, CDC and the ARC published a study that tested archived blood donations from donors in nine states between December 13, 2019 and January 17, 2020. The results of the study indicated that it is possible the virus may have been present in California, Oregon, and Washington as early as December 13-16, 2019, and in Connecticut, Iowa, Massachusetts, Michigan, Rhode Island, and Wisconsin as early as December 30, 2019 -

² Josephine Ma, Coronavirus: China's first confirmed Covid-19 case traced back to November 17, South China Morning Post (Mar. 13, 2020) available at https://www.scmp.com/news/china/society/article/3074991/coronavirus-chinas-first-confirmed-covid-19-case-traced-back. The possibility of early cases in November in China is further raised by a recent report. A Chinese medical researcher's inadvertent disclosure may have indicated two early suspected COVID cases on November 14 and 21. One of the suspect cases showed a patient who lived about a mile from Wuhan's main coronavirus research laboratories. Ian Birrell, Is 'Patient Su' Covid's Patient Zero?, Daily Mail (May 29, 2021) available at https://www.dailymail.co.uk/news/article-9632921/Is-Patient-Su-Covids-Patient-Zero-asks-IAN-BIRRELL.html.

³ Id.

⁴ Kevin Linka *et al, The reproduction number of COVID-19 and its correlation with public health interventions*, Computational Mechanics (July 28, 2020) *available at* https://link.springer.com/article/10.1007/s00466-020-01880-8.

⁵ Sridhar V Basavaraju, et al, Serologic Testing of US Blood Donations to Identify Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)—Reactive Antibodies: December 2019—January 2020, Clinical Infectious Diseases (Nov. 30, 2020) available at https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1785/6012472.

⁶ U.S. Centers for Disease Control and Prevention, First Travel-related Case of 2019 Novel Coronavirus Detected in the United States, Press Release, (Jan. 21, 2020) available at https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-

case.html#:~:text=First%20Travel%2Drelated%20Case%20of%202019%20Novel%20Coronavirus%20Detected%20in%20United%20States,-

Press%20Release&text=The%20Centers%20for%20Disease%20Control,in%20the%20state%20of%20Washington. ⁷ Sridhar V Basavaraju, *et al*, *Serologic Testing of US Blood Donations to Identify Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)—Reactive Antibodies: December 2019—January 2020*, Clinical Infectious Diseases (Nov. 30, 2020) *available at* https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1785/6012472.

January 17, 2020. Although antibodies that reacted to the SARS-CoV-2 virus were detected in blood donations from all nine states included in the study, the percentage of blood samples with these antibodies was very low (about 1.4 percent, with slightly higher positive rates for the West Coast states) - indicating that if the virus was circulating in the U.S., it was not widespread at that time.

The study reported that it could not be determined whether the samples that indicated antibody responses from undetected SARS-CoV-2 infections were community or travelassociated. The tests used in the study's evaluation were designed to detect antibodies to SARS-CoV-2. The study noted that there is some limited similarity between SARS-CoV-2 and other, more common coronaviruses, so cross reactivity could not be ruled out completely. However, additional evidence, including microneutralization, detection of both SARS-CoV-2—specific IgG and IgM, and SARS-CoV-2 S1-specific Ig reactivity, made it very unlikely that all reactive specimens represented false positives. We understand the study may not be conclusive enough for CDC to modify its stance on the date of the first diagnosed COVID-19 case in the U.S. as being January 19, 2020, even though the findings suggest that SARS-CoV-2 may have been introduced into the United States prior to January 19, 2020. We request that the CDC provide a staff briefing to discuss the study further.

We note that the study did not test samples earlier than December 13, 2019, or later than January 17, 2020. The CDC needs to conduct additional studies to test more samples, throughout the United States, including samples several months before December 13, 2019, to gather more data to indicate how early the first case appeared in the U.S. CDC should use the best testing assays available, with assays specific to SARS-CoV-2, and with molecular or serologic methods for corroboration. Testing samples earlier in time will provide a control period to use in comparison to the period of positive samples, and gauge if a possible cross-reactivity signal is present during months when we would not have expected cases. In addition, the CDC needs to test samples after January 17, 2020 until January 31, 2020, to see if the number of additional cases found would be consistent with an earlier date for the first case. Accordingly, we request that the CDC conduct another study to test samples from blood donations further back in time to at least July 2019 through January 31, 2020, using the most effective test methods to reduce or eliminate substantially any concerns over false positives for other coronaviruses. Accordingly we request that the CDC conduct another study to test samples from blood donations further back in time to at least July 2019 through January 31, 2020, using the most effective test methods to reduce or eliminate substantially any concerns over false positives for other coronaviruses.

⁸ Id.

⁹ Id.

¹⁰ Id.

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ U.S. Food and Drug Administration, Coronavirus (COVID-19) Update: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study, FDA News Release (June 4, 2020) available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-publicly-shares-antibody-test-performance-data-kits-part-validation.

In preparation for the briefing, please provide written responses to the following:

- 1. The CDC and ARC researchers employed orthogonal assays, which is a requirement for chem-bio forensics analyses. The researchers reported a specificity rate of 99.3 percent and sensitivity rate of 96 percent for the assays used in the study. Please provide the validation data of the assays used, the data that support these numbers, the Limit of Detection (LOD), and the Limit of Quantitation (LOQ).
- 2. IgM is the first antibody to be produced in response to any antigen. IgG is the main type of antibody found in the blood and usually appears between 10 and 20 days after a patient has recovered from infection. It is odd that positive/negative IgM and IgG results varied among samples, raising questions about the validity of the results. Is this due to the timing of the blood collections and virus exposure as IgM typically rises early and then declines as IgG rises and stabilizes? Please explain this variation.
- 3. Only serum samples were serologically tested. Is it possible to also test corresponding positive polymerase chain reaction in whole blood or tissue samples?
- 4. Emerging pathogens are identified by recognition of a novel syndrome. Only then can a causal agent be identified, and tests developed. How should serosurveys be designed to see how long an emerging virus may have been present?
- 5. According to an article in the San Jose Mercury News, ¹⁵ "months after the virus became widespread, pathologists in many parts of the country re-examined unexplained deaths from before the pandemic by testing lab samples for signs of COVID-19, the same way [Patricia] Dowd's case was confirmed in Santa Clara County." Has the CDC coordinated with the states that have re-examined unexplained deaths for signs of COVID-19? If so, which states have conducted re-examinations and how far back in time did they go?
- 6. According to the same article in the San Jose Mercury News, ¹⁶ provisional death data compiled by the CDC's National Center on Health Statistics (NCHS) show five deaths attributed to COVID-19 in January 2020. The site shows at least one death each in California, Illinois, Wisconsin, and Tennessee. Robert Anderson, chief of the Mortality Statistics Branch at NCHS stated: "It's either clearly an error or something we didn't know about before." As of early April 2021, the CDC was still investigating at least five deaths nationwide that appear in its records in the first weeks of 2020.¹⁷ What is the status of this investigation?

¹⁷ Id.

¹⁵ Harriet Blair Rowan, *Mysterious COVID data: Was San Jose woman really first U.S. death?*, San Jose Mercury (April 8, 2021), *available at* https://www.mercurynews.com/2021/04/08/covid-cdc-exploring-whether-reports-of-january-2020-deaths-real-or-data-glitches/.

¹⁶ Id.

Please make arrangements to schedule the briefing for Committee staff by June 22, 2021. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers

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Republican Leader

Committee on Energy and Commerce

John Man Lodger

Fred Upton

Republican Leader

Subcommittee on Energy

Fred lepte

Bob Latta

Republican Leader

Subcommittee on Communications and

Technology

Brett Guthrie

Republican Leader

Subcommittee on Health

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Steve Scaline

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Bill Johnson Member of Congress

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Member of Congress

Greg Pence

Member of Congress

Dan Crenshaw

Member of Congress

John Joyce, M.D.

Member of Congress

Kelly Armstrong

Member of Congress

CC: The Honorable Frank Pallone, Chairman

The Honorable Anna Eshoo, Chair, Subcommittee on Health

The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations