# U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

#### **HEARING CHARTER**

The New Normal: Preparing for and Adapting to the Next Phase of COVID-19

Thursday, March 31, 2021 10:00 a.m. EDT – 12:00 p.m. EDT Zoom

#### **PURPOSE**

The purpose of this hearing is to discuss how research, data, and coordination efforts must evolve as COVID-19 surges ebb and flow. The hearing will examine existing gaps in data and public health preparedness as we enter the third year of the pandemic in the United States. Members and witnesses will discuss how the federal government can scale up data collection and communication to detect surges and variants as early as possible, and how federal guidance can best reflect the evolving threat of COVID-19 while minimizing social disruption.

### **WITNESSES**

- Dr. Ezekiel Emanuel, Vice Provost for Global Initiatives, Co-Director of the Healthcare Transformation Institute, and Levy University Professor at the Perelman School of Medicine and The Wharton School of the University of Pennsylvania
- Ms. Karen Ayala, Executive Director of DuPage County Board of Health
- Dr. Lucy McBride, Practicing Primary Care Physician in Washington, DC
- Dr. Mariana Matus, Co-Founder, Biobot Analytics

## **OVERARCHING QUESTIONS**

- What research and data gaps have emerged as we enter the third year of the pandemic, and how can federal resources best be leveraged to close these gaps?
- What are the most useful metrics to judge whether a particular municipality, state, or nation should implement increased protective measures?
- How can data collection and communication be improved to get information to public health decision makers across the country?

## "Endemic" COVID-19?

In recent months, conversation around the transition to the next phase of the pandemic has invoked the concept of COVID-19 as "endemic." Endemicity has been posed as a potentially permanent offramp from current pandemic COVID. The Centers for Disease Control (CDC) classifies endemic levels of disease as the constant or usual presence of an infectious agent in a particular area. The recent omicron surge and current rising COVID levels in Europe and Asia have made it clear that we are not at a point where disease levels are constant and predictable. COVID infection and mortality rates are also tied to external factors such as vaccination rate, protective measures such as masking, and hospital capacity, which vary from community to community and will have differing impacts on unpredictable future variants. It may be years before COVID-19 meets the CDC definition of endemic.

Even diseases that have been circulating for decades are perhaps inappropriate to classify as endemic. While tuberculosis, HIV/AIDS, and malaria are at low levels or nonexistent in wealthy countries, they remain at pandemic levels around the world.<sup>3</sup> The COVID-19 pandemic has emphasized the importance of a global perspective in fighting infectious disease.

While "endemic COVID" has been used as a shorthand in discussions of the new normal of living with COVID-19, the term is imprecise and unlikely to apply to a virus that continues to mutate unpredictably. This hearing will therefore focus on the steps that must be taken to prepare for and adapt to the likely scenario that COVID-19 levels will continue to ebb and flow across the country and the globe.

#### **Vaccines**

In the past two years, a growing understanding of the virus has allowed public health entities to determine what metrics give us the best understanding of a particular individual's risk of contracting, suffering from, and dying from COVID-19. Early on, it was clear that age and underlying health conditions contributed to the risk of severe illness and death. Eighty-one percent of those who have died from the virus were aged 65 and older; and underlying lung, heart, and autoimmune conditions, among others, increase the likelihood of developing severe illness.<sup>4</sup>

Vaccines were rolled out to the general population of the United States in the first half of 2021. All three vaccines granted Emergency Use Authorization by the Food and Drug Administration by spring 2021 were at least 85 percent effective at preventing serious illness within a month of receiving the recommended doses.<sup>5</sup> Getting vaccinated is an incredibly important step to reducing risk at the individual level – during the omicron surge, unvaccinated individuals were

<sup>&</sup>lt;sup>1</sup> https://www.wired.com/story/covid-will-become-endemic-the-world-must-decide-what-that-means/

<sup>&</sup>lt;sup>2</sup> https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html

<sup>&</sup>lt;sup>3</sup> https://www.statnews.com/2021/07/06/why-arent-diseases-like-hiv-and-malaria-which-still-kill-millions-of-people-a-year-called-

pandemics/#:~:text=HIV%20and%20AIDS%2C%20tuberculosis%2C%20and%20malaria%20shouldn't%20be,been %20beaten%20in%20rich%20countries.

<sup>4</sup> https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-who-is-at-risk/art-20483301

<sup>&</sup>lt;sup>5</sup> https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19-vaccines

23 times more likely to be hospitalized than those who had received booster shots, and 5.3 times more likely than those who had been vaccinated but not boosted. However, data on infectiousness, hospitalization, and death during the omicron surge showed that vaccine efficacy declined compared to previous surges, including the delta wave. Furthermore, we have fallen short on both national and international vaccination goals, due to a combination of widespread misinformation and, in low- and middle-income countries, production and distribution issues. An under-vaccinated population puts both vaccinated and unvaccinated individuals at higher risk as the ground remains fertile for new variants to proliferate.

Confronting the problem of an under-vaccinated population in the United States will require an understanding of vaccine hesitancy in populations that are persuadable and investing in public health communication to meet individuals where they are. Despite ongoing questions about the ideal dosing, booster sequencing, and how efficacy differs across different populations and against new variants, it is incontrovertible that vaccines improve an individual's likelihood of avoiding severe or fatal COVID.

## **Testing**

The landscape of COVID-19 testing has changed dramatically in the past two years. Americans now have access to tests through a combination of test centers, pharmacies, hospitals, and antigen tests available over the counter and from the U.S. government. <sup>10</sup> Due to falling case numbers and individuals' increasing preference for at-home antigen tests, many local and state governments are shuttering mass testing sites. <sup>11</sup> While PCR tests have been considered the gold standard for much of the pandemic, antigen tests offer some advantages – test results are available immediately, and offer a better indication of contagiousness, while PCR test results take hours, if not days, and can remain positive past the point of contagiousness. <sup>12</sup>

Despite the convenience of antigen tests, accuracy remains a problem to the point that the CDC recommends taking multiple tests within a relatively short timeframe for more reliable results. <sup>13</sup> In addition, antigen test results are decoupled from virus surveillance networks. This prevents public health authorities from getting a full understanding of the prevalence of COVID-19 in the community, potentially delaying a timely and comprehensive response. It also creates a barrier for individuals who test positive and need to seek treatment. Investing in a robust reporting

<sup>9</sup> https://www.nature.com/articles/s41591-022-01713-6

<sup>&</sup>lt;sup>6</sup> <u>https://www.fiercehealthcare.com/providers/unvaccinated-23-times-more-likely-boosted-be-hospitalized-during-omicron-wave</u>

<sup>&</sup>lt;sup>7</sup> https://www.washingtonpost.com/health/interactive/2022/vaccine-omicron-effectiveness/?itid=hp pandemic&itid=lk inline manual 3

<sup>8</sup> https://www.covidroadmap.org/roadmap

https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/

https://www.nytimes.com/live/2022/03/20/world/covid-19-mandates-cases-vaccine#some-states-in-the-us-are-closing-virus-testing-sites-despite-fears-of-a-new-surge, https://www.axios.com/local/austin/2022/03/21/austin-covid-testing-sites-shutter, https://www.axios.com/local/twin-cities/2022/03/21/minnesota-tim-walz-to-close-testing-vaccine-sites

<sup>12</sup> https://www.washingtonpost.com/opinions/2022/01/26/use-rapid-antigen-tests-instead-of-pcr/

<sup>13</sup> https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

system for positive antigen tests can bolster public health response, improve individual outcomes, and expand the reach of clinical trials of new treatments. <sup>14</sup>

Epidemiologists have suggested that a more robust testing infrastructure should incorporate a test-to-treat model, connecting those who test positive to health professionals who can assess any relevant underlying conditions, prescribe appropriate therapeutics, offer enrollment in relevant clinical trials, and provide advice on protecting patients and their families. <sup>15</sup> A scaled-up test-to-treat paradigm, in concert with scaled up genomic sequencing to shorten the lag between sample collection and variant identification, could also inform treatment options, as treatments successful against delta have been shown to be less effective against omicron. <sup>16</sup>

Gaps in data collection of positive test results also has the potential to underestimate the number of people who have some level of COVID-19 immunity. Infection with COVID-19 confers a level of immunity against re-infection. <sup>17</sup> Antibody levels are even more durable amongst those who received two doses of mRNA vaccines either before <sup>18</sup> or after infection. <sup>19</sup> Infection-induced immunity appears to wane more quickly than vaccine-induced immunity, <sup>20</sup> but a full understanding of the level of COVID resistance in a community requires a better accounting of the virus's permeation among vaccinated and unvaccinated people alike. More robust reporting structures for positive PCR and antigen tests will improve our ability to make informed decisions on protective measures, facilitate broader genomic sequencing of samples, and allow better forecasts of future surges.

## **CDC Community Levels Dashboard**

On February 25<sup>th</sup> the CDC deployed the Community Levels Dashboard. Previous community recommendations were based on the number of new cases and the percent of positive tests, which the CDC felt did not sufficiently capture the risk levels for omicron community spread.<sup>21</sup> The number of cases was maintained as a metric, and two new metrics, hospital admissions and percent of hospital beds in use by COVID patients, were added to shift the focus towards where omicron was most burdening the healthcare system.<sup>22</sup>

Though the metrics did not always reflect it, mortality rates have been tied to hospital capacity since the beginning of the pandemic.<sup>23</sup> Rural areas in particular are vulnerable to severe surges, because rural hospitals have been closing at an accelerating rate over the past decade and rural

<sup>16</sup> https://www.statnews.com/2022/03/25/fda-limits-therapy-ineffective-against-ba2-variant-omicron/

<sup>&</sup>lt;sup>14</sup> https://www.covidroadmap.org/roadmap

<sup>15</sup> Ibid

<sup>&</sup>lt;sup>17</sup> https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-natural-immunity-what-you-need-to-know

<sup>18</sup> https://www.hopkinsmedicine.org/news/newsroom/news-releases/in-covid-19-vaccinated-people-those-with-prior-infection-likely-to-have-more-antibodies

<sup>19</sup> https://www.nejm.org/doi/full/10.1056/NEJMc2201607

<sup>&</sup>lt;sup>20</sup> <a href="https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-natural-immunity-what-you-need-to-know">https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-natural-immunity-what-you-need-to-know</a>

<sup>21</sup> https://www.cnn.com/2022/02/23/health/cdc-covid-metrics/index.html

<sup>&</sup>lt;sup>22</sup> https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html#anchor 82254

<sup>&</sup>lt;sup>23</sup> https://news.yale.edu/2021/02/01/lack-icu-beds-tied-thousands-excess-covid-19-deaths

areas have mortality rates almost double those of metropolitan areas.<sup>24</sup> Incorporating hospital capacity and resources into the CDC Community Levels Dashboard allows for a more nuanced prediction of the impact of a COVID surge on both urban and rural populations.

To power the Dashboard, case rate data is collected by hospitals, healthcare providers, and laboratories, which then communicate it to a public health authority for aggregation and transmission to the CDC. The other two metrics are drawn from the Department of Health and Human Services Unified Hospital Data Surveillance System.<sup>25</sup> The process of transmitting data from the frontlines to the CDC is far from simple. Though the CDC corroborates the data where possible, both the CDC and public health officials acknowledge that the data can be incomplete.<sup>26</sup> Data reporting can be especially strained when the demands of a spike in cases detracts from hospital staff's ability to enter timely health data into their system.

Once data are put into the Dashboard, there are clear thresholds for each metric which combine to produce a green, yellow, or red rating for a county depending on the level of risk. Each level then corresponds to individual and community level recommendations. Green counties are simply encouraged to have residents stay up to date with vaccines, while red counties are encouraged to deploy indoor masking, and significant testing<sup>27</sup>. Tangible recommendations based on local risk level are key to navigating a new normal, where precautions will need to scale up and ease back based on the best available information, rather than come to an end altogether.

#### **Wastewater Surveillance**

By the time positive tests, hospital strain, and mortality begin to rise in a particular area, COVID has been spreading at elevated levels in that community for days or even weeks.<sup>28</sup> Wastewater surveillance offers an opportunity to detect COVID-19 spikes days before the impact is seen at testing centers and hospitals.

In November 2021, the omicron variant was detected in wastewater across the nation 11 days before it was detected in a test sample.<sup>29</sup> Wastewater surveillance works by sampling wastewater from sewers and treatment plants to detect virus RNA secreted by those infected with the virus. Many states and municipalities stood up wastewater surveillance programs in the past two years, and as of February 4, 2022, the CDC has published wastewater data from 672 participating sites.<sup>30</sup>

In addition to serving as a leading indicator of COVID surges, wastewater surveillance can provide researchers with a wealth of data on emerging and potential variants. Researchers have

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 $<sup>\</sup>frac{^{24} \ https://www.politico.com/news/2022/03/19/covid-closed-rural-hospitals-tennessee-deaths-anti-vax-conspiracies-00018204}{}$ 

<sup>25</sup> https://covid.cdc.gov/covid-data-tracker/#county-view Footnotes

<sup>26</sup> https://www.cdc.gov/coronavirus/2019-ncov/covid-data/faq-surveillance.html

<sup>&</sup>lt;sup>27</sup> https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html

<sup>&</sup>lt;sup>28</sup> https://www.hawaiidata.org/news/2020/8/4/importance-of-leading-lagging-indicators-monitoring-hawaii-covid19

<sup>&</sup>lt;sup>29</sup> https://www.scientificamerican.com/article/wastewater-monitoring-offers-powerful-tool-for-tracking-covid-and-other-diseases/

<sup>&</sup>lt;sup>30</sup> https://covid.cdc.gov/covid-data-tracker/#wastewater-surveillance

identified variants in wastewater that have never been detected in human samples, which can provide insight into how the virus might mutate into another variant and inform how particular sequences might contribute to the virus's ability to evade the human immune system response.<sup>31</sup>

The Department of Health and Human Services and the CDC lead a National Sewage Surveillance Interagency Leadership Committee that consists of representatives from nine federal agencies and to collect and analyze COVID wastewater data and communicate with state and local partners. <sup>32</sup> Continued investment to expand the scope of surveillance efforts can help in the fight against COVID-19 as it ebbs and flows, and the infrastructure put in place can provide a wealth of public health information beyond the current pandemic.

#### The Next COVID Wave

There are early indicators that another wave of COVID may be on its way in the US. This wave would be driven by the BA.2 variant of omicron, which is about 30 percent more infectious than BA.1.1 omicron variant which caused the previous domestic spike<sup>33</sup>. BA.2 is already present in the United States and has steadily grown to 35 percent of U.S. COVID cases as of the week ending on March 19<sup>th</sup>. Europe, which has repeatedly been a leading indicator for U.S. cases, has seen BA.2 dominate other variants, including BA.1.1, and cases are slowing in their descent or rising in France, the United Kingdom, and Italy. Additionally, wastewater data in the United States, a leading indicator as discussed above, has begun to show spikes in certain regions of the country, though with cases low overall in the United States it is difficult to separate signal from noise. In the United States in the United States it is difficult to separate signal from noise.

These alarming indicators come as large numbers of U.S. citizens abandon the individual behaviors previously employed to contain the pandemic. Mask mandates and proof of vaccine requirements have been lifted across the United States,<sup>37</sup> and the availability of tests, treatments, and vaccines is expected to decline.<sup>38</sup> Both factors may exacerbate the severity of the next COVID wave.

Despite the concerning indicators, another spike in cases is not necessarily imminent. White House Chief Medical Adviser Dr. Anthony Fauci has said that while there may be an uptick in cases, a full surge is unlikely.<sup>39</sup> Countries such as Austria, Germany, and Greece are already seeing a decline in case counts following the spike due to BA.2.<sup>40</sup> Moreover, early studies

<sup>&</sup>lt;sup>31</sup> https://www.nytimes.com/2022/02/03/health/coronavirus-wastewater-new-york.html

<sup>32 &</sup>lt;a href="https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/federal-coordination-partnering-wastewater-surveillance.html">https://www.cdc.gov/healthywater/surveillance/wastewater-surveillance/federal-coordination-partnering-wastewater-surveillance.html</a>

<sup>&</sup>lt;sup>33</sup> https://www.medrxiv.org/content/10.1101/2022.01.28.22270044v1

<sup>34</sup> https://covid.cdc.gov/covid-data-tracker/#variant-proportions

<sup>35</sup> https://ourworldindata.org/explorers/coronavirus-data-explorer?facet=none&Metric=Confirmed+cases&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=ITA~GBR~FRA

<sup>&</sup>lt;sup>36</sup> https://covid.cdc.gov/covid-data-tracker/#wastewater-surveillance

<sup>&</sup>lt;sup>37</sup> https://www.nytimes.com/explain/2022/03/01/us/mask-mandates-us

<sup>&</sup>lt;sup>38</sup> https://www.nytimes.com/2022/03/25/opinion/covid-funding-congress-biden.html

<sup>&</sup>lt;sup>39</sup> https://www.cnbc.com/2022/03/23/covid-omicron-bapoint2-subvariant-will-soon-dominate-in-us-but-fauci-doesnt-expect-another-surge.html

<sup>40</sup> https://ourworldindata.org/explorers/coronavirus-data-explorer?facet=none&Metric=Confirmed+cases&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=DEU~GRC~AUT

suggest that a BA1.1 omicron infection does provide protection from BA.2, so the recent wave of cases may protect against a BA.2-fueled wave. <sup>41</sup> Finally, the warming weather and current decrease in time spent inside in close quarters may also play a part in decreasing the impact of BA.2 in the United States. 42 However, even if another spike in COVID cases is not imminent, it is still likely over a longer time frame.

https://www.nature.com/articles/d41586-022-00558-w
https://www.theatlantic.com/health/archive/2022/03/omicron-subvariant-new-covid-wave/627094/