

# **LEGISLATIVE OVERSIGHT & INVESTIGATIONS COMMITTEE**

## **Minutes of the 7th Meeting of the 2021 Interim**

**December 16, 2021**

### **Call to Order and Roll Call**

The 7th meeting of the Legislative Oversight & Investigations Committee was held on Thursday, December 16, 2021, at 1:00 PM, in Room 131 of the Capitol Annex. Senator Danny Carroll, Chair, called the meeting to order, and the secretary called the roll.

Present were:

Members: Senator Danny Carroll, Co-Chair; Jason Howell, Vice-Chair, Morgan McGarvey, Michael J. Nemes, Wil Schroder, Brandon J. Storm, and Reginald Thomas; Representatives Lynn Bechler, Vice-Chair, John Blanton, Ken Fleming, Angie Hatton, Joni L. Jenkins, Steve Riley, and Scott Sharp.

Guests: Dr. Steven Stack, Commissioner, Department for Public Health; Mike Tuggle, Assistant Director, Department for Public Health.

LRC Staff: Gerald W. Hoppmann, Committee Staff Administrator; Committee Analysts William Spears, Jacob Blevins, Joel Thomas, Jeremy Skinner, Shane Stevens, Chris Hall, Ryan Brown, Taylor Johnston, McKenzie Ballard; and Ashley Taylor, Committee Assistant.

### **Minutes for November 10th, 2021**

Upon motion by Representative Blanton and second by Senator Nemes, the minutes for the November 10th, 2021, meeting were approved without objection.

Senator Carroll spoke about the devastating tornados and their impact on the state of Kentucky. He gave a special thanks to the people of our state and country for their support. Senator Carroll also commented on how proud he is of our Governor for his support and how he has handled the disaster. Senator Howell and Representative Bechler provided updates on the tornado damage and relief efforts in each of their districts. Senator Carroll shared his plans to file a bill during the upcoming session that will enhance penalties for crimes that are committed during states of emergency.

Senator Carroll noted the committee hoped to have Department of Corrections (DOC) officials in attendance to testify regarding the commutation and release of inmates

during the pandemic, but due to miscommunication they were not able to attend. He discussed two separate requests he made to DOC for details related to good time credits that inmates received as part of their commutations. He explained that the agency has sent back very minimal information and he expects the committee will be utilizing subpoena power to get previously requested information and testimony. Senator Carroll hopes it is simply an honest oversight, but is concerned that we are having so much trouble receiving detailed responses. He also stated it is difficult to believe that DOC would release inmates without knowing in detail whether they met the qualifications for release under the conditions set by the Governor.

### **COVID-19 Testing and Vaccine Administration**

Senator Carroll asked the Commissioner for the Department of Public Health to introduce himself for the record and to provide an overview of contracts, processes, and vendors used during the pandemic related to testing and vaccinations. Dr. Stack introduced himself and also shared his condolences for those living in the tornado impacted areas.

Dr. Stack explained that when the pandemic first began in early 2020, the only place that could provide COVID-19 testing was the Center for Disease Control and Prevention (CDC). By late February through mid-March, the state public health lab could only do a small volume of testing. By the beginning of April however, testing was expanded to highly sophisticated molecular diagnostic labs. These types of labs are customized and have to go through a number of enhanced regulatory approvals because of the very precise nature of what they do. Although the availability to test expanded to the community, testing remained scarce given very few labs with proper capacity. As a result, emergency procurement was used to establish a partnership with Gravity Diagnostics, which was able to procure and obtain necessary testing materials through intense efforts. The company ended up being able to provide testing for hospitals and nursing homes throughout the state. The state also partnered with the Kroger Corporation, who volunteered their services without charge for providing communities with access to testing, including drive-through options.

A multi-provider open Request for Proposal (RFP) was used to assist with providing testing to nursing homes and elderly communities across the state. The specifications of the contract were defined and made available to any laboratory who met them. Fourteen or more labs have supported nursing homes and elderly communities with assistance provided from the multi-provider contract, which is currently still open. Arrangements were also made with public universities, specifically the University of Kentucky and the University of Louisville to assist with increased testing during the summer surge. The University of Louisville used Gravity Diagnostics to process the specimens, while the University of Kentucky sub-contracted with Wild Heath, Inc.

The Federal government provided almost 1.3 million BinaxNOW™ COVID-19 Ag Cards, which are used for antigen detection. The cards were distributed widely across the state, without a contract. A wide array of different settings received the cards for at-risk and vulnerable populations. The state also uses a federal contract to purchase the BinaxNOW cards at a discounted rate of \$5 per test.

In the spring of 2021 the state received a new federal grant to provide testing at K-12 schools. Using the open RFP process and with multiple labs participating, testing at just under 1,300 schools across the state is being done. There are 25 vendors participating in this contract, with 9-10 labs doing the majority of testing.

Dr. Stack stated there is one contract with two iterations related to COVID-19 vaccinations, although there were three vendors that offered proposals. One of the vendors was a Fortune 500 company and the second was an established testing company, both of which required guaranteed minimums and high rates. The pricing that Wild Health, Inc. offered in contrast, did not include guaranteed minimums and offered lower rates. The first iteration of the contract was used through the end of the fiscal year.

Dr. Stack encouraged everyone to show gratitude to local health department leaders for all they have done in response to COVID-19, including contact tracing, testing and vaccinations. He explained there is a variety of means that can be used to help local health departments such as emergency procurement and open RFPs. The Finance and Administration Cabinet is also in the process of issuing a regular RFP as a competitive bid. He stated that a variety of other tools have been used like university exclusions and memoranda of agreement with non-profits in order to provide testing efficiently, equitably, and transparently.

In response to a question from Senator Carroll, Dr. Stack explained that one type of BinaxNOW cards are designed to take at home. They are packaged for the consumer and come with instructions on how to use them and can be bought at stores like Walgreens for \$24. The other cards are packaged for medical professionals and they come with forty tests per box. These tests were sent out to locations such as homeless shelters, health departments, nursing homes, jails, and universities. They can be used as long as access to a laboratory provider exists, in order to ensure they are administered properly.

The federal government plans to purchase over 300 million Ellume COVID-19 tests by early next year. These point-of-care tests will be distributed to vulnerable populations but will also be available to the public. The federal government wants these tests to be available for people to test themselves at home without associated healthcare costs.

Dr. Stack responded to Senator Carroll concerning accuracy of the tests by discussing the Ellume test. This test requires a person to download an app onto their

smartphone, which will then provide instructions on how to administer the test. After 15 minutes from the time someone swabs their nose, the app on their smartphone will provide a positive or negative test result and will advise the individual what actions should be taken. However, the Ellume tests are not as reliable as the PCR tests and may miss people who are very early or very late in the illness.

In response to a question from Senator Carroll, Dr. Stack explained that Wild Health, Inc. was picked for vaccine distribution because when lined up with the other two opportunities it was preferable. Since Wild Health, Inc. handles lifestyle, health, and personal wellness medicine, they already have a laboratory that does molecular diagnostic testing. The University of Kentucky also sub-contracts with Wild Health, Inc., for testing. Dr. Stack responded to Senator Carroll that he was not aware if Wild Health, Inc., is owned by the son of a former Governor.

In response to Senator Carroll's question, Dr. Stack agreed that getting vaccines to primary care physicians who can then administer to patients is definitely a high priority. One of the challenges at the very beginning of the pandemic was the limited supply of vaccines being shipped to local communities. Wide spread distribution was not possible, since there were some hospitals not able to get the vaccines. Another issue was having the proper storage available for the vaccines. The more evident problem currently is the federal government's very specific requirements for vaccine sites. The federal requirements are very burdensome, so much that small physician practices may not be able to meet them, thus preventing their participation.

In response to a question from Representative Fleming about future preparedness, Dr. Stack stated he believes messaging has been inconsistent based on various sources. He does not believe the science or the medicine is the problem, rather the challenge is human behavior. He made a point to express gratitude to the state employees that essentially had to build an entire testing infrastructure for a single disease that did not exist before. The infrastructure had to evolve over times of scarcity and differential funding sources, testing, and settings.

Vaccine deployment was the biggest challenge, given limited supplies of vaccines. Another challenge was to find a way not to make personal or political some of the basics of public health science, according to Dr. Stack. Representative Fleming stated that the distribution network was difficult with respect to getting vaccines out, but appreciates the effort that was taken to communicate information to the public. He added that in the future he believes a better environment will exist to get testing completed and vaccines administered.

Senator Carroll asked about positivity rates and numbers at the beginning of the pandemic, as well as incomplete or missing laboratory test results at that time. He

inquired about whether the incomplete or missing results were from out-of-state labs and asked Dr. Stack to discuss the difficulty receiving complete results.

Dr. Stack replied that a lot of Kentucky's labs were not set up with the Kentucky Health Information Exchange, which allows the electronic submission of laboratory results. Instead, many lab results were coming in via fax or e-fax. This resulted in people having to type in manual information, which is difficult to handle with hundreds, thousands, or tens of thousands of results. It is much more efficient for information to come in electronically for computer-to-computer analysis.

The cabinet in response to these challenges on-boarded scores of labs to the exchange. These labs now submit results electronically. As part of the current RFP process, successful vendors are also required to submit data electronically through the exchange, which has improved the process. So, during the next crisis, labs will already be part of the exchange, which will allow for quicker results and improved interactions with local health departments.

Senator Carroll switched to the topic of monoclonal anti-bodies and recent discussion about whether this treatment is underutilized, a topic which was addressed during the recent special session. He cited the example of a woman from Bowling Green who was very sick with COVID-19, but not given the option of monoclonal treatment. After receiving the treatment, the woman improved after 24-48 hours. Senator Carroll asked for Dr. Stack's perspective on monoclonal treatment, including its politicization, priority for the state, as well as federal control over supply.

Although monoclonals have been useful, Dr. Stack discussed concern that people viewed the treatment as an alternative to vaccine. He added that by waiting to get sick, a person's overall risk increases. He also touched on the cost effectiveness of vaccines at \$40 per person versus \$2,100 per dose for monoclonal anti-bodies.

Availability of vaccines versus the monoclonals is also a concern. According to Dr. Stack, from May through July when cases of the Delta variant were climbing, we started consuming so much of the treatment that in a matter of 4-6 weeks the federal government intervened by taking away sites that could order monoclonal anti-bodies directly from distributors. This occurred in September, after which the federal government took full control of the supply. As a result, states were required to ration limited amounts of the treatment.

Dr. Stack also discussed recent appropriations that allowed for the creation of a website to show sites where the public can request treatments. He commented on one two-week period where sites requested 10,000 treatments, but Kentucky's allocation was only 4,000. He also discussed improvements to the infrastructure that allows for coordination meetings between the state, distributors, and hospitals. Unfortunately

though, a lot of people meet the criteria but there is not enough product, which requires the sites to prioritize based on the highest risk.

Senator Carroll asked if it takes a long time to produce the monoclonal treatments. Dr. Stack answered that monoclonal anti-bodies are complex synthetic proteins with high demand, but only three treatments exist and are very costly. He discussed how FEMA funding was available early on, but it was too restrictive. For example, it requires daily inspections for all sites, which is resource intensive. Dr. Stack added that he does not discount the effectiveness of monoclonal anti-body treatments. For example, prior to September of this year, there were already 104 sites offering this treatment, but not in a high-profile manner.

Senator Carroll commented that he believes the monoclonal anti-body treatments could have been promoted more, which may have resulted in additional lives being saved. He also commented that the fear of people choosing to opt for getting sick instead of taking a vaccination may have been a reason that more emphasis was not placed on the treatments.

He also stated that monoclonal anti-body treatments should be a major priority for the state, then requested information on how long it takes to produce whatever number of monoclonal antibody treatments are needed for those who meet the eligibility criteria. Dr. Stack stated he will have to request this information from the CDC and Department of Health and Human Services since he does not have access to it.

Senator Carroll asked about the chemical makeup and effectiveness of the Merc and Pfizer antiviral pills. Dr. Stack answered that they are quite different from the monoclonal anti-bodies because the pills block a specific cell that works with the virus. He also commented that the pills vary in effectiveness. For example, the Merc pill only reduces the risk of hospitalization to 50%, while the monoclonal treatments have a 75% rate. He also said the Pfizer pill is closer to 89% effective at preventing hospitalizations, but that it has to be taken within three days after onsite of the virus. The Merc pill has to be given within five days. There are also other concerns with both pills such as negative interactions with certain medications and pregnancy risks.

Representative Jenkins thanked Dr. Stack for his leadership. She asked about Omicron and the things they should be prepared for in the future and whether current treatments will be effective. Dr. Stack stated that while Omicron at this point is not a big concern in Kentucky, it could become problematic. He said that 3% of all cases are the Omicron variant, whereas before Delta was 99% of all cases. However, with the faster spreading variant, Omicron could soon account for one-quarter of all cases.

He also stated that if a person is fully vaccinated or boosted, there is protection against severe disease and death. But, one could still contract the virus, which means the

disease can continue to spread. As far as the monoclonals are concerned, the new variant could undermine their effectiveness. The cabinet is watching the federal government for firm decisions in that respect.

Dr. Stack said that although family outings or gatherings can occur, people should be careful not to knowingly spread disease. He also said that masks are helpful by reducing the risk of spreading disease.

Representative Bechler stated that his understanding is the majority of individuals with Omicron are vaccinated. Dr. Stack stated this could be true, since 60% of Kentuckians are vaccinated. Representative Bachler followed up with a question about whether vaccination rates are at a sufficient level. Dr. Stack responded that we need a higher vaccination rate, since the virus still has chances to mutate significantly given the unvaccinated. Theoretically, he stated if higher percentages were vaccinated, the virus could be shut down. Dr. Stack followed up with additional data showing that those under 60 who have died since July 1<sup>st</sup> were 95% unvaccinated. Over age 60, 73% of the deaths were the unvaccinated.

Senator Carroll asked about recent testimony in front of the Interim Joint Health, Welfare, and Family Services Committee about testing for neutralizing antibodies. He heard that CDC does not recommend relying on these tests instead of getting vaccinated. Senator Carroll then asked if at some point measuring these antibodies will be beneficial, as opposed to relying on boosters. For example, with Hepatitis B where an individual can get tested to see if they are adequately protected.

Dr. Stack stated he is not sure what type of data scientists need in order to make such a determination, since we are less than two years from the start of the virus and one year from the first vaccine. He also stated that it may be more cost effective to boost a patient for example with tetanus, instead of testing for antibodies. Senator Carroll stated that he wished people were as comfortable with the COVID-19 vaccine as they are with tetanus boosters. However, with much of the population that type of trust does not exist.

Senator Thomas complimented Dr. Stack's leadership during the pandemic and commented on the positive feedback he has received from people. He then asked a question about when we can expect to see an end to the pandemic and what information is coming from the CDC in this regard. Dr. Stack said that he has not lost confidence that things will become more normalized moving forward. He then discussed the need for continued vaccinations, since the variants thrive because of the unvaccinated. The concern is not only local, but also global. He mentioned the continent of Africa as an example, since variants are originating there.

Dr. Stack also commented on the benefits of vaccination coupled with the protective value from people already having the disease. He went on to say that as a

result of this combination, over time the population will develop enough of a reservoir of protection where hospitals are not being overcrowded. He gave the example of the flu, where tens of thousands of people may die each year, but that risk of death is tolerated. So, the answer according to Dr. Stack, is to push ahead with increased vaccinations to get through the pandemic. He also commented that much of the challenge may not be evident to the public. For example, he used the example of people watching a University of Kentucky game at Kroger Stadium, but not knowing that across the street the National Guard is present to help sustain the hospital's work.

Senator Carroll stated this is the last committee meeting of the year and thanked staff for its work. He said that more than likely the committee will meet during the session in order to consider additional topics. He asked that members bring ideas to the co-chairs. He also stated that during the next interim the committee will be getting more into the investigations side of things and that he looks forward to digging into certain issues as a result of changes made to the committee's authority. He also asked that everybody keep those who are in need in Kentucky in their prayers.

Prior to adjourning the meeting, Senator Carroll requested that CHFS provide a list of owners and investors in Wild Health, Inc.