PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE

Minutes of the 3rd Meeting of the 2020 Interim

August 13, 2020

Call to Order and Roll Call

The 3rd meeting of the Program Review and Investigations Committee was held on Thursday, August 13, 2020, at 1:00 PM, in Room 171 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; Representative Lynn Bechler, Co-Chair; Senators Karen Berg, Tom Buford, Michael J. Nemes, Reginald Thomas, Whitney Westerfield, and Phillip Wheeler; Representatives Al Gentry, Ruth Ann Palumbo, Steve Riley, Rob Rothenburger, and Walker Thomas.

Guests: Steven Stack, MD, Commissioner, Department for Public Health; Doug Thoroughman, PhD, United States Public Health Service and Acting State Epidemiologist, Department for Public Health.

LRC Staff: Tom Hewlett, Committee Staff Administrator, Licensing, Occupations, and Administrative Regulations; William Spears; Joel Thomas; and Elizabeth Hardy, Committee Assistant.

Minutes for July 23, 2020

Upon motion by Senator Nemes and second by Representative Rothenburger, minutes for the July 23, 2020, meeting were approved without objection.

Review of COVID-19 Testing and Statistics

Senator Carroll administered the oath to Dr. Stack and Dr. Thoroughman. Both affirmed that they would tell the truth.

Dr. Stack and Dr. Thoroughman reviewed the testing and reporting process for COVID-19 in Kentucky. Dr. Thoroughman indicated that all 120 counties have had at least one case. He stated that the rate of cases and deaths in Kentucky had continued to increase, but mortality in Kentucky has been consistently about 1 percentage point lower than the national average. The increases appear to have reached a plateau after imposition of the mask mandate, so it appears the mandate has helped reduce the number of cases, but it will take some time to see whether the trend continues.

Dr. Thoroughman explained the public health regulations that apply to COVID-19, particularly 902 KAR 2:020 Sections 2, 5, and 10. The regulations require health professionals, facilities, and laboratories to report cases immediately to both the local and state health department. There are several paths for reporting, including electronic and fax. The same case might be reported by more than one entity—for example, a doctor and a laboratory—but the department has a process to remove duplicates.

Dr. Thoroughman described two types of COVID-19 tests: Virus detection tests and blood tests. Virus detection tests check for viral genes or antigens, which are proteins from the virus, are likely to indicate whether there is an active infection. It is possible to have virus present after the active phase of the disease, when the person is no longer infectious. Blood testing detects antibodies that the body has produced and is likely to show past infections.

Dr. Thoroughman explained that the preferred electronic reporting method is the Kentucky Health Information Exchange (KHIE). Many providers and labs were already using KHIE, but those that were not face a lengthy process to be enrolled. The other ways to report include the federal system, fax, or electronic spreadsheet. There are a number of new "pop-up" labs providing testing and new tests that can be performed in a clinic with no lab. Some of the new labs and providers do not know about reporting requirements. Regulations only require reporting of positive results, but the department is asking for all results, and some labs are resisting because it is not legally required.

In response to a question from Senator Carroll regarding the reason to report inaccurate numbers, Dr. Thoroughman stated there was a public demand for that information and the federal positivity rate for Kentucky was about 2 to 3 percentage points higher than what the department calculated. They were able to determine that the federal system was missing a lot of negative tests. Dr. Stack explained that the demands of the public and federal requirements force the state to participate in a system that it does not control, but the state's decision making is not based on a single number but rather on a combination of factors. Dr. Thoroughman said that an important factor is the case incidence rate. The positivity rate, though not accurate, is consistent and so reliably shows trends up or down.

In response to a question from Senator Berg, Dr. Thoroughman explained that positive cases but not the negative cases from KHIE go to the federal system. Some older laboratories like Quest and LabCorp that have been grandfathered in use only the federal system, but some newer laboratories like Gravity use KHIE, and others submit data via spreadsheets. He has not been able to determine the relative numbers from each source yet. Dr. Thoroughman estimated that the federal system and KHIE are about evenly split and together cover about 60 percent of testing. The rest are in separate data systems.

Dr. Thoroughman said that all types of test results are reportable, but not all tests results are correct. The FDA is responsible for validating lab tests, but the state has validated some at the request of local health departments. He said that Dr. Stack intervened with one lab that did not meet standards. There are many factors that affect how to interpret a test result, such as whether the test was given early or late in the disease. Outside factors can affect the accuracy, such as obtaining a good specimen at the beginning, then how long it takes to get to the lab and how well the specimens are preserved during shipment. Some kinds of test equipment can give inaccurate results if not cleaned thoroughly between tests. This is especially the case for antigen testing.

Dr. Thoroughman explained the reporting process for COVID-19 cases. They must meet Kentucky's case definition, which is based on the federal definition, in order to be counted. Four factors are considered. Clinically, do the symptoms fit COVID-19 with no other likely diagnosis? What type of testing was done? Was the person in close contact with another confirmed or likely case or in a group that was likely to be exposed? If the person died, was COVID-19 listed as the primary or contributing cause? These four factors together determine whether a case is confirmed, probable, or suspect. Both confirmed and probable cases are counted in the department's number of positive cases, but suspect cases are not counted. The goal is to combine clinician reports with lab data and remove duplicates daily. This level of data processing would normally take 2 weeks, but the department is doing it daily.

Dr. Thoroughman indicated that the governor receives reports each afternoon that include case numbers and mortality rates, lab testing numbers, patient disposition counts, race and ethnicity distributions, and statistics for new cases and deaths. Public health officials and other cabinet officials receive a document highlighting key data points.

Dr. Thoroughman explained that all COVID-19 deaths meeting the state's case definition are counted. There is a committee that reviews all questionable deaths. Some deaths are not reported based on the medical record and other evidence.

In response to a question from Senator Carroll regarding the total number of death reviews and the number that were determined questionable, Dr. Thoroughman indicated that there were two to four reviews per week, but he would get the numbers. Senator Carroll inquired how the committee members were chosen. Dr. Stack responded that the Division of Epidemiology organized it.

In response to a question from Senator Carroll, Dr. Stack provided the number of cases in Kentucky from the official website as of August 12: 36,945 confirmed positives (2,530 probable and 34,415 confirmed) and 790 deaths (5 probable and 785 confirmed).

Dr. Thoroughman discussed counting people who have recovered. It is difficult to count the number of people who have recovered, and the number is underestimated. He also discussed the daily reporting of COVID-19 cases. Both confirmed cases and probable

cases are counted on the day they are reported, which is not a true count of daily incidence, but other measures are also inaccurate or incomplete. He explained some unusual spikes of cases.

Dr. Stack stated that all the daily numbers are true new positive cases, and spikes in the data are highlighted along with their causes. The day-to-day variation might not truly be representative. For decision making, they often use rolling averages that flatten out the variation, typically 7 days, up to 14 days.

Dr. Thoroughman compared the flu and COVID-19. Flu tests used to be unreliable because of the type of testing, but they have improved. The testing for COVID-19 is more reliable, and people are more likely to be tested for COVID-19 than for flu. There have been approximately 35,000 COVID-19 cases in 5 months this year and approximately 27,500 cases of the flu in 7 months last season. The mortality rate for COVID-19 is higher with 772 COVID-19-related deaths as of August 8 and 767 flu-related deaths in the last 4 years combined. The death count is more accurate than the case count. Nationally, there have been approximately 160,000 COVID-19-related deaths in 6 months and 26,000 to 35,000 flu-related deaths annually.

Dr. Thoroughman explained that some people may be ill with COVID-19 for a long time before dying, which causes a lag between the case count and death count. However, the most likely factor might be the change in the mix of people getting sick. Younger people are more likely to become ill and to be tested but less likely to have severe illness, and older people are more protected now. The counts show an increase in the number of young people getting the virus, especially in the 16 to 20 age group. There has been a slight rise in the overall number of deaths in Kentucky due to COVID-19.

Dr. Thoroughman explained that rapid testing platforms are available, but test supplies are scarce and the machines can be expensive. The federal government is investing a lot of money in vaccine research, but only time will tell if an effective vaccine is developed. He had no information about a reported testing flaw at the University of Kentucky. There are any number of explanations for the positive and then negative tests of the Ohio governor.

In response to a question from Senator Carroll regarding the number of Kentucky children who have died from the flu and COVID-19, Dr. Thoroughman indicated that he would get the number for the flu. He said he was aware of one child death related to COVID-19. The autopsy did not show anything, but the child was positive with COVID-19. Senator Carroll asked if more children die from the flu, and Dr. Thoroughman confirmed that more children have died from the flu. He said the seasonal flu tends to affect young adults, the very young, and very old; however, the pandemic flu affects middle-aged people more.

In response to a question from Senator Thomas about the effect of re-opening schools, bars, and sporting events, Dr. Stack said the mortality rate is better in Kentucky than in other southern states because Kentucky took action early to prevent an initial exponential spread, which is difficult to contain. When they noticed an increase, they implemented a mask mandate and followed federal advice on closing bars and reducing restaurants' capacity to blunt the second surge, which is much lower than the number of cases in states like Louisiana, Georgia, and Texas. He said that masks and social distancing are among the most powerful public health tools available, but recognized that social distancing especially and masks somewhat are disruptive to normal life.

In response to a question from Senator Thomas about health inequities and the upcoming flu season, Dr. Stack recommended that people get a flu vaccine. This year, it will be particularly bad to get a respiratory illness that could be confused with COVID-19, which could lead to incorrect treatment. A bad flu season by itself can fill hospitals, and coupled with COVID-19 this could lead to a real crisis. There are health inequities in Black and minority communities. The department's Health Equity Branch has been working to find ways to eliminate inequities as much as possible.

In response to Representative Bechler's question about the mortality rate, Dr. Stack stated that the rate is declining. The mortality rate is estimated to be between 0.7 percent and 1.5 percent. If there are no barriers to care, the estimated mortality rate is approximately 1 percent, which is 10 times the mortality rate of the flu. It is correct that 99 percent of people who get it will likely survive. This means that 3.3 million people could die nationally, but at least 98 or 99 percent would survive. Dr. Thoroughman added that not reducing the transmission of COVID-19 could cause the hospitals to be overrun and more people would be lost. Representative Bechler asked if Kentucky was able to flatten the curve in order to not overwhelm the hospitals. Dr. Stack responded yes, for the initial surge, and probably the current surge. A couple of hospitals were at or near capacity. Some eastern Kentucky hospitals have stopped doing elective surgeries to be sure there is enough capacity for COVID-19. It is difficult to find the exact number of preventive measures needed to keep the curve below capacity. Dr. Thoroughman said that if the public takes masks, social distancing, and other measures seriously, then the economy can remain open.

In response to a question from Senator Carroll regarding the mortality rate excluding nursing homes, Dr. Thoroughman responded that nursing homes account for two-thirds of the mortality rate. Females have been affected more because they tend to live longer and more of them live in nursing homes. Most of the people who died also had comorbidities.

In response to a question from Representative Bechler regarding false positive and negative results, Dr. Thoroughman said that every lab test has a false positivity rate and false negativity rate. The population being tested also affects a test's accuracy. If there is no one with the disease, any positives will be false, but if there are a lot of people with the disease, then most of the positive results will be correct. Public health officials take positive

results seriously. Dr. Stack added that the public should make use of health care providers to interpret test results. A positive viral gene test is incredibly reliable and, therefore, does not require a clinician order. Antigen and antibody tests do require clinician orders so that properly trained medical professionals can decide if the test is appropriate.

In response to a question from Representative Bechler about the administration's consideration of the consequences of implementing the economic shutdown, Dr. Stack stated that potential consequences and competing interests were taken into account. Kentucky followed and is still following most of the recommendations from the White House, such as masks; restrictions on bars, restaurants, and other places likely to spread disease; and aggressive steps like the healthy at home initiative followed by a phased reopening. Similar steps have worked well in other countries where the measures were followed more carefully than in the United States. Considering restrictions by zip code or county, people and viruses do not respect lines on a map. In the United States, there is nothing to stop people from crossing boundaries. Substance abuse, mental health, suicide, heart disease, and other problems are public health issues that have to be balanced against other undesirable outcomes. There are no clear-cut answers.

In response to Representative Bechler's question about herd immunity, Dr. Thoroughman said that herd immunity is currently not happening but would be a good thing. Dr. Stack said he believed that approximately 5 percent of the Kentucky population has been infected with COVID-19, while New York is near 20 percent. Herd immunity probably would require about 60 to 70 percent of the population to have been infected. Dr. Thoroughman responded that with COVID-19, it was probably 95 percent. Dr. Stack estimated that 100 percent infected would lead to approximately 45,000 deaths in Kentucky. In response to Representative Bechler's reference to Sweden, Dr. Stack stated that Sweden's gross domestic product fell almost 9 percent and its mortality rate is higher than nearby countries.

In response to a question from Senator Carroll about positivity rates by county, Dr. Thoroughman said at this time it is not feasible, but if all the labs were using KHIE, it would be possible. Dr. Stack said he would like to have a real-time online dashboard available to the public. There are currently more than 15 people trying to get numbers for the governor daily. It is a very difficult task.

In response to Representative Rothenburger's question about getting an idea of how many people have been infected and whether they can get the disease again, Dr. Thoroughman said that some organizations like the American Red Cross are trying to get people tested using antibody testing. There will not be mass antibody testing because it is invasive and expensive, but testing a sample of people could give an estimate. He indicated that immunity to COVID-19 is unknown past the first 3 months. Dr. Stack added that the FDA approved over 100 tests using relaxed standards, which means many are not reliable.

He recommended against individuals getting an antibody test unless a clinician recommends it for a specific reason.

In response to a question from Representative Rothenburger about stockpiles of personal protective equipment (PPE), Dr. Stack responded that they are concerned about the number of PPE available because supplies are falling again. Kentucky increased warehouse space for PPE to keep 2 to 3 months of supply, and hospitals are required to have 14 days' supply of PPE. This is more than surrounding states. Models suggest that that is enough for first responders and hospitals to get by but not enough for the entire health care system.

In response to a question from Senator Carroll about basing their decisions on closing schools and businesses on the number of cases in nursing homes, Dr. Thoroughman responded that two-thirds of deaths but approximately 18 percent of cases were in long-term care facilities. Dr. Stack said that decisions were based on the best information available at the time, and he would not change anything in retrospect. He acknowledged the harms and said that they are attempting to be better calibrated, limiting fewer activities without causing further harm. But where schools have opened, many of them are closing in 1 to 2 weeks, and hundreds of people are in quarantine. Children go home from school to parents and grandparents, and just one person can infect a whole floor of a nursing home.

In response to questions from Senator Carroll, Dr. Stack expressed support for the decision to delay school openings, saying it would be better to use nontraditional instruction first and let other states try in-person school. He said he supported the earlier plan as well, but then Kentucky reached an all-time high in the number of COVID-19 cases and was experiencing exponential growth on track to become another hot spot. All the advice was to take aggressive steps to reduce its spread. He stated that despite White House encouragement to open schools, there is no evidence that children do not spread the virus. Dr. Stack stated that he wants to prevent the disease from spreading on a massive scale.

In response to a question from Senator Berg about reported cases for daycares and schools, Dr. Thoroughman explained that there is no mechanism for daycares to report cases directly to the Department for Public Health. He is aware of 13 clusters at daycares, mostly involving staff members infecting other staff members. Many facilities had a staff member or child with a positive test but no transmission via the facility. There has been a chilling effect with some daycares and long-term care facilities unwilling to report cases. Dr. Stack provided an example of pastors telling parishioners and businesses telling employees to not get tested or talk to the department. Contact tracing could work but not if undermined this way. He reiterated the department's obligation to protect people and their privacy when tracing contacts.

In response to Representative Riley's question about when schools can resume in person, Dr. Stack said the exit strategy is a vaccine. The federal government is investing in

potential vaccines. A vaccine could be developed by next year at the earliest. Having a safe vaccine is important because there are a lot of people skeptical about vaccines in general.

Representative Riley commented that a significant number of students in his district do not have internet access and asked about the greater damage from closing schools. Dr. Stack responded that there was a middle path, where students and teachers wear masks and socially distance, but many people don't believe in those measures. If other states are successful at opening with masks and distancing, perhaps it will convince Kentuckians to do so.

Senator Carroll commented that children who do not go to school go back to daycare where they mix with other children.

Senator Nemes asked about the average age of death for people with COVID-19. Dr. Stack said the average death age is 77.4 years.

Senator Westerfield said that he has emailed several questions to the department. He asked, in relation to schools, whether the administration considered factors like child abuse referrals, drug overdoses, and academic performance. Dr. Stack said that those factors were considered by his department and by the Department of Education. He has heard sincerely held but erroneous beliefs about how COVID-19 is spread, resulting in people do not understand why they need to follow public health guidelines.

In response to a question from Senator Carroll about the believability of public health advice and the political aspects of the issue, Dr. Stack said that differences of opinion and political disagreements have been present for a long time, but he is not a political advisor and has given public health advice, not political advice.

In response to comments by Senator Carroll about not seeking input from the legislature, Dr. Stack said he is part of a group of other state health officials that has worked with the United States surgeon general, other federal officials, county judges/executive, college presidents, school superintendents, and local public health officials. He spends most of his day in dialogue with other people.

In response to Senator Carroll's question about individuals in quarantine having to inform the health department before calling an ambulance, Dr. Stack said that is not a general practice now but it was practiced in the beginning when they were worried about the contagion. Dr. Thoroughman confirmed that there had been several large-scale exposures of coronavirus in hospitals because someone came in who was infected. He mentioned that a similar practice was used with Ebola.

In response to a question from Senator Berg about exponential growth and implementation of the mask mandate, Dr. Thoroughman referred to the weekly COVID-19 rate with June 8-14 as the low point before exponentially growing through the week of

July 13-19. Exponential growth means growing more each week rather than the same amount each week. He said that the evidence strongly suggests that the mask mandate on July 10 has worked.

The meeting adjourned at 3:38 p.m.