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Jeff Zmuda, Secretary

Laura Kelly, Governor

To: Juvenile and Adult Facility Residents and Family Members

From: Jeff Zmuda, Secretary

Date: December 16, 2020

Re: Coronavirus Updates

Our residents who have been housed at the Saguaro Correctional Center in Eloy, Arizona returned to Lansing Correction Facility (LCF) yesterday. The 118 individuals cleared all COVID-19 testing protocols prior to their return to Kansas. To further protect the health of all involved, they will remain in quarantine for 21 days at LCF before being dispersed to other KDOC facilities.

In October 2019, we transferred those individuals to the private prison in Arizona under a contract with Nashville-based CoreCivic. This was done to manage overcapacity challenges in Kansas prisons and anticipated growth in numbers. We had planned to return these folks to Kansas by the end of June 2020. However, this plan was disrupted by the pandemic. We continued to revisit the original plan and have determined returning our residents at this time is in the best interest of all those involved. CoreCivic provided transportation from the Arizona facility to Kansas for the medium- and maximum- custody residents.

We are working with Governor Kelly's office and the Kansas Department of Health and Environment (KDHE) on details regarding access to COVID-19 vaccines. Planning is underway for staff and our residents, and we anticipate more information on the subject to be available as soon as this afternoon. For the most up to date information, Governor Kelly provides weekly updates at her press conferences every Wednesday at 4 p.m., and weekly updates are also available on the KDHE website: COVID-19 Vaccine | KDHE COVID-19 (kdheks.gov).

As vaccines becomes available, we encourage everyone to learn more about them. Attached are two documents, one provides information about COVID-19 vaccines and the other provides some explanation as to process regarding Emergency Use Authorization of the vaccines. I have included just below this paragraph a couple of links to related information about the COVID-19 vaccines, and also included two documents that provide background details. Additional information will be made available in all facilities for both residents and staff. It is certainly great news that vaccines are starting to become available, but they will not replace the need to wear masks, socially distance wherever and whenever possible and follow all other public health recommendations for the foreseeable future.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits/facts.html)

https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)

We recently looked at our positive COVID-19 numbers within KDOC and I thought you might find this of interest. As you can see from the following information, the number of current positive cases among our residents hit a high in early November and has since declined. The number of current positive cases among staff hit a high in early December and has decrease somewhat over the last two weeks. There could be many explanations for the higher numbers, including more frequent testing. Whatever the reason, I am so encouraged to see the numbers going down! Please continue to do your part to stop the spread!

- Oct. 7, 2020: 171 Resident Current Cases; 27 Staff Current Cases
- November 4, 2020: 585 Resident Current Cases; 90 Staff Current Cases
- December 7, 2020: 407 Resident Current Cases; 152 Staff Current Cases
- December 10, 2020: 387 Resident Current Cases; 146 Staff Current Cases
- December 14, 2020: 342 Resident Current Cases; 131 Staff Current Cases

All resident and staff COVID-19 positive cases are posted twice a week on our website, Mondays and Thursdays by 5 p.m.at https://www.doc.ks.gov/kdoc-coronavirus-updates/kdoc-covid-19-status .

(See next page for start of information from the CDC and FDA.)

Emergency Use Authorization for Vaccines Explained

Español (https://www.fda.gov/vaccines-blood-biologics/vaccines/explicacion-de-la-autorizacion-de-uso-de-emergencia-para-las-vacunas)

FDA is globally respected for its scientific standards of vaccine safety, effectiveness and quality. The agency provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information through all phases of clinical trials, which continues after a vaccine has been approved by FDA or authorized for emergency use.

FDA recognizes the gravity of the current public health emergency and the importance of facilitating availability, as soon as possible, of vaccines to prevent COVID-19 - vaccines that the public will trust and have confidence in receiving.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.

Once submitted, FDA will evaluate an EUA request and determine whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to FDA.

Are the COVID-19 vaccines rigorously tested?

Yes. Clinical trials are evaluating investigational COVID-19 vaccines in tens of thousands of study participants to generate the scientific data and other information needed by FDA to determine safety and effectiveness. These clinical trials are being conducted according to the rigorous standards set forth by the FDA.

Initially, in phase 1, the vaccine is given to a small number of generally healthy people to assess its safety at increasing doses and to gain early information about how well the vaccine works to induce an immune response in people. In the absence of safety concerns from phase 1 studies, phase 2 studies include more people, where various dosages are tested on hundreds of people with typically varying health statuses and from different demographic groups, in randomized-controlled studies. These studies provide additional safety information on common short-term side effects and risks, examine the relationship between the dose administered and the immune response, and may provide initial information regarding the effectiveness of the vaccine. In phase 3, the vaccine is generally administered to thousands of people in randomized, controlled studies involving broad demographic groups (i.e., the population intended for use of the vaccine) and generates critical information on effectiveness and additional important safety data. This phase provides additional information about the immune response in people who receive the vaccine compared to those who receive a control, such as a placebo.

What safety and effectiveness data are required to be submitted to FDA for an EUA request for a vaccine intended to prevent COVID-19?

COVID-19 vaccines are undergoing a rigorous development process that includes tens of thousands of study participants to generate the needed non-clinical, clinical, and manufacturing data. FDA will undertake a comprehensive evaluation of this information submitted by a vaccine manufacturer.

For an EUA to be issued for a vaccine, for which there is adequate manufacturing information to ensure quality and consistency, FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine. An EUA request for a COVID-19 vaccine can be submitted to FDA based on a final analysis of a phase 3 clinical efficacy trial or an interim analysis of such trial, i.e., an analysis performed before the planned end of the trial once the data have met the pre-specified success criteria for the study's primary efficacy endpoint.

From a safety perspective, FDA expects an EUA submission will include all safety data accumulated from phase 1 and 2 studies conducted with the vaccine, with an expectation that phase 3 data will include a median follow-up of at least 2-months (meaning that at least half of vaccine recipients in phase 3 clinical trials have at least 2 months of follow-up) after completion of the full vaccination regimen. In

addition, FDA expects that an EUA request will include a phase 3 safety database of well over 3,000 vaccine recipients, representing a high proportion of participants enrolled in the phase 3 study, who have been followed for serious adverse events and adverse events of special interest for at least one month after completion of the full vaccination regimen.

Part of FDA's evaluation of an EUA request for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls information for the vaccine. Sufficient data should be submitted to ensure the quality and consistency of the vaccine product. FDA will use all available tools and information, including records reviews, site visits, and previous compliance history, to assess compliance with current good manufacturing practices.

What is the process that manufacturers are following to potentially make a COVID-19 vaccine available by EUA?

- Vaccine manufacturers are undertaking a development process that includes tens of thousands of study participants to generate non-clinical, clinical, and manufacturing information needed by FDA for the agency to determine whether the known and potential benefits outweigh the known and potential risks of a vaccine for the prevention of COVID-19.
- When the phase 3 portion of the human clinical trial reaches a predetermined point that informs how well a vaccine prevents COVID-19, as discussed and agreed to in advance with FDA, an independent group (called a data safety monitoring board) will review the data and inform the manufacturer of the results. Based on the data and the interpretation of the data by this group, manufacturers decide whether and when to submit an EUA request to FDA, taking into consideration input from FDA.
- After FDA receives an EUA request, our career scientists and physicians will evaluate all of the information included in the manufacturer's submission.
- While FDA's evaluation is ongoing, we will also schedule a public meeting of our Vaccines and Related Biological Products Advisory Committee, which is made up of external scientific and public health experts from throughout the country. During the meeting, these experts, who are carefully screened for any potential conflicts of interest, will discuss the safety and effectiveness data so that the public and scientific community will have a clear understanding of the data and information that FDA is evaluating to make a decision whether to authorize a COVID-19 vaccine for emergency use.
- Following the advisory committee meeting, FDA's career professional staff will consider the input of the advisory committee members and continue their evaluation of the submission to determine whether the available safety and effectiveness and manufacturing data support an emergency use authorization of the specific COVID-19 vaccine in the United States.

Who are the FDA career professionals evaluating EUAs for vaccines?

The FDA staff are career scientists and physicians who have globally recognized expertise in the complexity of vaccine development and in evaluating the safety and effectiveness of all vaccines intended to prevent infectious diseases. These FDA professionals are committed to decision-making based on scientifically driven evaluation of data. FDA staff are like your family - they are fathers, mothers, daughters, sons, sisters, brothers and more. They and their families are also directly impacted by the work that they do, and are exactly who you want making these important public health decisions for the United States.

What are the plans for continued monitoring of COVID-19 vaccines authorized by FDA for emergency use?

FDA expects vaccine manufacturers to include in their EUA requests a plan for active follow-up for safety, including deaths, hospitalizations, and other serious or clinically significant adverse events, among individuals who receive the vaccine under an EUA, to inform ongoing benefit-risk determinations to support continuation of the EUA.

FDA also expects manufacturers who receive an EUA to continue their clinical trials to obtain additional safety and effectiveness information and pursue licensure (approval).

Post-authorization vaccine safety monitoring is a federal government responsibility shared primarily by FDA and the U.S. Centers for Disease Control and Prevention (CDC), along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There will be multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post-authorization/post-approval vaccine safety monitoring infrastructure that will be scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – will use multiple existing vaccine safety

monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative, and Medicare claims data.

How will vaccine recipients be informed about the benefits and risks of any vaccine that receives an EUA?

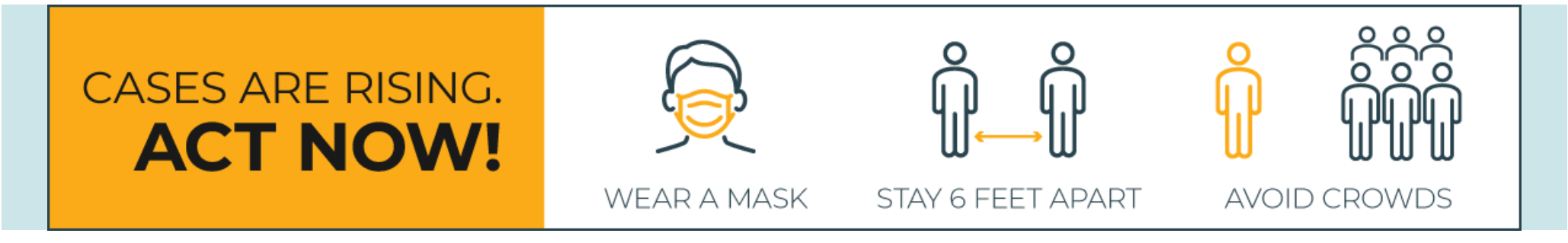
FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. Typically, this information is communicated in a patient "fact sheet." The FDA posts these fact sheets on our website.

How is it that COVID-19 vaccines have been developed so quickly?

In public health emergencies, such as a pandemic, the development process may be atypical. For example, as demonstrated by the response to the COVID-19 pandemic, the U.S. government has coalesced government agencies, international counterparts, academia, nonprofit organizations and pharmaceutical companies to develop a coordinated strategy for prioritizing and speeding development of the most promising vaccines. In addition, the federal government has made investments in the necessary manufacturing capacity at its own risk, giving companies confidence that they can invest aggressively in development and allowing faster distribution of an eventual vaccine. However, efforts to speed vaccine development to address the ongoing COVID-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety.

Recognizing the urgent need for safe and effective vaccines, FDA is utilizing its various authorities and expertise to facilitate the expeditious development and availability of vaccines that have met the agency's rigorous and science-based standards for quality, safety, and effectiveness. Early in a public health crisis, FDA provides clear communication to the pharmaceutical industry pertaining to the scientific data and information needed to ensure development of vaccines and works quickly to provide advice on their proposed development plans and assessment of the data that are generated.

Centers for Disease Control and Prevention



Facts about COVID-19 Vaccines

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COVID-19 (Coronavirus Disease)

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Now that there's an authorized and recommended COVID-19 vaccine in the United States, accurate vaccine information is critical.

FACT: COVID-19 vaccines will not give you COVID-19

None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. There are several different types of vaccines in development. However, the goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity. Learn more about how COVID-19 vaccines work.

It typically takes a few weeks for the body to build immunity after vaccination. That means it's possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and get sick. This is because the vaccine has not had enough time to provide protection.

FACT: COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests

Vaccines currently in clinical trials in the United States won't cause you to test positive on viral tests, which are used to see if you have a **current infection**.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a **previous infection** and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

FACT: People who have gotten sick with COVID-19 may still benefit from getting vaccinated

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before.

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

We won't know how long immunity produced by vaccination lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

FACT: Getting vaccinated can help prevent getting sick with COVID-19

While many people with COVID-19 have only a mild illness, others may get a severe illness or they may even die. There is no way to know how COVID-19 will affect you, even if you are not at increased risk of severe complications. If you get sick, you also may spread the disease to friends, family, and others around you while you are sick. COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness. Learn more about how COVID-19 vaccines work.

FACT: Receiving an mRNA vaccine will not alter your DNA

mRNA stands for messenger ribonucleic acid and can most easily be described as instructions for how to make a protein or even just a piece of a protein. mRNA is not able to alter or modify a person's genetic makeup (DNA). The mRNA from a COVID-19 vaccine never enter the nucleus of the cell, which is where our DNA are kept. This means the mRNA does not affect or interact with our DNA in any way. Instead, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop protection (immunity) to disease. Learn more about how COVID-19 mRNA vaccines work.

How do I know which sources of COVID-19 vaccine information are accurate?

It can be difficult to know which sources of information you can trust. Learn more about finding credible vaccine information.

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