NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Health Service Regulation

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DATE: December 9, 2020

TO: EMS Professionals

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SUBJECT: COVID-19 Vaccine Safety

The purpose of this memo is to briefly describe the process vaccines must go through to prove they are safe and effective. We also want to emphasize how important vaccination will be to end this pandemic. There must be widespread vaccination for our society to return to normal and end the current pandemic. We are now in the middle of the biggest public health crisis since 1918. The entire healthcare system, and especially prehospital providers, has been under great strain. The process of vaccine development and administration has a long and proven track record of safety in our country.

In the United States, vaccines must go through a thorough vetting process to prove they are safe and effective; this is a multi-step process which is monitored throughout for safety. At the end of this process, the Food and Drug Administration reviews all the data before approving the vaccine for public distribution. Each vaccine candidate must go through several phases of trials which are numbered sequentially, #1 through #3.

As mentioned above, a candidate vaccine must go through an approval process which involves three different phases. Each phase is larger and more complex than the phase before it. Phase #1 trials typically have 20-100 participants; this phase is meant to determine if the vaccine generates an immune response and if there are any initial safety concerns. It also is meant to help determine the best dosing. Phase #2 trials are larger and have hundreds of participants. The purpose of phase #2 is to assess safety and determine how much of an immune response is generated by the vaccine. Phase #3 trials include the largest number of participants; normally tens of thousands of participants. A phase #3 trial is meant to determine how well the vaccine protects people from the disease and looks for more rare adverse reactions. Phase #3 trials

follow patients for several months. The full multi-phase process is important to ensure the vaccine is safe and effective.

Vaccine development for COVID-19 has moved very quickly; some are concerned too quickly. That being said, there has also been no time in history when so many financial resources, people and countries, with the technology capable of producing these vaccines, were all working to the same common goal. Operation Warp Speed was a US public-private partnership to promote the development and mass production of vaccines with almost $18 billion dollars spent towards this initiative. To put this amount of money in perspective, the US government spends approximately $3 billion dollars for the entire US Park Service budget each year.

The United States has not permitted any shortcuts in the development of a COVID vaccine. Some countries have cleared vaccines for deployment to the general population without undergoing the final phase #3 trial; this is not the case in the United States. In the US, vaccines must go through the full three phase processes, which is very important. Phase #3 testing, with 30,000 or more subjects, ensures that we will have a safe and effective vaccine. Currently, there are two candidate vaccines going to the FDA for possible authorization. Both vaccine candidates have undergone full phase #3 testing. These vaccines are being developed by Pfizer and Moderna, respectively. The data from these vaccine trials is very encouraging. You are not acting as a test subject by receiving the vaccination after FDA authorization. Tens of thousands of individuals have already volunteered for the clinical trial to prove the safety and efficacy of these vaccines. It is from their courage in participating in the process that we, as a population, stand to gain the benefit from these safe vaccinations.

The Pfizer vaccine started Phase 3 testing on July 17 and final data was ready on November 18. There were 43,000 participants in the Pfizer Phase 3 trial. There were 162 cases of COVID in the placebo group and 8 cases in the group which received the vaccine. There was a total of 10 severe cases of COVID in the trial, 9 of which occurred in the placebo group. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%). In fact, having mild symptoms following any vaccine is a sign that the body is creating an immune response. The biggest challenge with the Pfizer vaccine will be that it must be stored and transported at negative 94 degrees Fahrenheit.

The Moderna vaccine started phase 3 testing on July 17. Preliminary data was analyzed on November 16 and final data was ready on November 30. There were more than 30,000 participants at 100 clinical sites. In all, there were 196 patients in the study who got COVID-19; of the subjects that got COVID 185 were in the placebo group. There were 11 cases of COVID in the group which received the vaccine; of the 11 people in the vaccine group who contracted COVID none had severe symptoms. There were no serious adverse reactions in the group which received the vaccine. The main adverse events noted included injection site pain, fatigue, muscle aches, joint pains, headache, and redness at the injection sites.

Some might ask, “if we already know that these vaccines are safe, why aren’t we advocating to give them to children as well?” At this time, we can only be sure that these vaccines are safe in the population that were part of the clinical trials. Children were not included in the 3 phases of the clinical trial for these two vaccines; for this reason, until further trials are performed to include children, children will not be included in this vaccination program until we are sure it is safe and effective for them.

The only way to end the pandemic is for greater than 70% of the population to be vaccinated. We must get our society back to normal. We must also protect ourselves, our families, and our

patients from COVID. We are lucky that we have a very robust healthcare system in this country which can rapidly develop safe and effective vaccines. Candidate vaccines are undergoing a rigorous multi-phase process to insure they are safe and effective. Should the FDA review the final data and give approval, we will have safe and effective vaccines which will allow our society to heal and return to normal.

Link to NC DHHS Vaccine website
https://covid19.ncdhhs.gov/vaccines

NCDHHS COVID-19 Vaccine Frequently Asked Questions
https://covid19.ncdhhs.gov/vaccines/frequently-asked-questions