

As the J&J COVID-19 Vaccine Administration is Paused for Safety Concerns: What is the Impact on South Carolina and its Citizens?

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On April 13, 2020, the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) issued a Joint Statement on the Johnson and Johnson (J&J) COVID-19 Vaccine. The CDC and FDA are recommending a pause in the use of the J&J vaccine as the agencies investigate six reported cases of serious blood clots occurring in individuals vaccinated with the J&J product.

In turn, South Carolina's Department of Environmental Control (DHEC) placed an immediate pause on the distribution of the J&J vaccine in South Carolina on the same day and is contacting healthcare providers to alert them of this development.

The CDC and FDA state that more than 6.8 million doses of the J&J vaccine have been administered in the United States. Of the 6.8 million doses, the CDC and FDA are recommending a pause in administration of the use of the J&J vaccine while it examines six reported cases of a rare type of blood clot called the "cerebral venous thrombosis" which has occurred in combination of low levels of blood platelets. All six cases occurred among women 6 to 13 days after the vaccination.

It appears that the rare blood clotting side effect may be connected to the type of vaccine J&J has developed, an "adenovirus vector vaccine," which is a different type than the Pfizer and Moderna vaccines (both mRNA vaccines). The FDA stated in a briefing on April 13 that it has not seen the blood clotting complications with the Pfizer or Moderna vaccines.

What is important to note for individuals and medical professionals, is that this specific type of blood clot ("cerebral venous thrombosis") cannot be treated the same way as other types of blood clots. Typically, an anticoagulant called heparin is used, but this can be dangerous in treating the type of blood clot caused by the J&J vaccine.

The good news is the adverse events in the form of the blood clots appear to be extremely rare, and the CDC and FDA's actions to pause the vaccine to examine the rare occurrence signals the government's focus on vaccine safety. The CDC and FDA confirm that vaccine safety is a "top priority" for the federal government.

South Carolina DHEC also reiterated that its top priority "is protecting the health and safety of the public" and that this pause is evidence of the very close monitoring of vaccine safety.

In addition, J&J announced its support of the pause and its commitment to safety.

What does that mean for South Carolina and its vaccine supply and should South Carolina citizens be concerned? As far as the availability of COVID-19 vaccinations, fortunately, South Carolina has been receiving only a small amount of the J&J vaccine – only 7,000 doses a week – as compared to 40,000 doses each of the Pfizer or Moderna vaccines. Therefore, the impact on the availability of COVID-19 vaccines in South Carolina during the pause of the J&J vaccine should be minimal.

As noted by DHEC, millions of people have received COVID-19 vaccines during the pandemic with very little side effects. With this assurance, DHEC encourages South Carolinians to get vaccinated in order to protect themselves and others.

If health problems do occur from a vaccination, DHEC reminds people who have side effects to contact their healthcare provider. Consultation with a healthcare provider can aide in treatment of the side effects and, as noted for the J&J blood clots, the side effects from a vaccine may need a specific type of treatment rather than the normal treatment course.

The pause of the J&J vaccinations may only last a matter of days this time, but the actual time frame depends on what the CDC and FDA learns from its investigation of the blood clot side effect in the next few days.

For those who have received the J&J vaccine before the new pause, if you received the vaccine more than a month ago, the CDC says the risk of blood clots is very low. But for those who have received the vaccine in the last couple of weeks, the CDC says to look out for any symptoms of side effects, and if you experience severe headache, abdominal pain, leg pain, or shortness of breath, you should contact your healthcare provider and seek medical treatment immediately.

For now, the CDC and FDA are working to reschedule people with J&J appointments to have one of the two other vaccines, Pfizer or Moderna, but admits this process will be "bumpy." The agencies also anticipate providing regular updates on the J&J pause.

In the meantime, the FDA is reiterating its commitment to vaccination and stressed at the April 13 briefing that "it is a really important tool to get this pandemic under control." The FDA confirmed it has "real world evidence" of the vaccines' effectiveness in the United States and encouraged everyone to get vaccinated, given the significant risks from the COVID-19 virus.