

The Times Weekly

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COVID-19 Vaccine Approval Still a Go for Those Over 5

On Feb. 11, Pfizer postponed the request for the FDA to approve the vaccine for those under the age of 5. Although, this was not an ideal decision as it means that children younger than 4 years are still unable to get the vaccine. The announcement should not be seen as a reason for vaccine skepticism but instead as proof that no decision is made until safety is ensured.

In fact, the FDC and CDC take vaccine safety and precaution very seriously, and the creation of the COVID-19 vaccine was no different. In an ongoing 5 step process; initial development, clinical trials, authorization, manufacturing, and monitoring. The vaccines were closely observed and examined to ensure safety for all.

In the initial development stage, the vaccines were developed in laboratories throughout the U.S. Although the strain that causes infection from COVID-19 recently surfaced, according to the CDC scientists have been working for numerous years to create new vaccines that will protect the body from coronaviruses. This past knowledge was applied to the current vaccines and is what allowed for the COVID-19 vaccine to be produced quickly.

After the vaccine was created clinical trials began and each vaccine went through all three phases to ensure that the vaccine was safe and effective. Performing various clinical trials that featured those of all ages, races, genders, and ethnicities data was collected and analyzed so it was

understood how everyone would react to the vaccine. Each age group was placed into different age brackets to ensure that each group received a dose that was right for them. These clinical trials showed with overwhelming data that the COVID-19 vaccine was indeed safe and effective for those over the age of 5. Showing no serious safety concerns within 8 weeks of vaccination. Past these 8 weeks it is highly unusual for adverse effects to take place.

After these clinical trials were complete before anyone in the community had access to the vaccines the FDA assessed the data from the trials. The FDA then decided that it was safe to authorize an Emergency Use Authorization which allowed for quick distribution while safety standards were reached. When it comes to the distribution of the vaccine the U.S. government invested resources that allowed for manufacturing of the vaccine. These resources allowed for the vaccines to be created when the clinical trials were in the final stages, allowing each consumer to get the shot as soon as it was deemed safe and effective.

Although, the EUAs were approved, CDC and FDA constantly monitor the vaccines and tracks to ensure that they remain safe. Now that hundreds of millions of vaccinations have been given, the vaccines still prove to be safe. In fact, after further studies were conducted, full approval was awarded to the Pfizer-BioNTech vaccine for everyone 16 years and older. This approval reestablished the high safety standards, effectiveness, and extraordinary quality the vaccine has. Allowing everyone who received the vaccine to feel protected as they return to normal life.

When it comes to COVID-19 cases in children, the positivity rate is still alarming. According to the American Academy of Pediatrics for over 27 weeks in a row COVID-19 cases in children are

above 100,000 reported cases. Many of these cases could be prevented if more children were vaccinated for COVID-19. As detailed throughout this article the vaccine was created with safety and effectiveness at the core. The postponed request does not mean that the vaccine is unsafe for those over the age of 5 years old. Instead, it simply means that the data needs to be looked at before it is approved for the smallest age group.

Many children have never had a normal school year, and only know the pandemic world as normal. To change this, it is essential to get them vaccinated. The vaccines were safely created and have been tested and monitored to make sure that a positive impact is had. To better protect the community and those in it anyone older than 5 years of age should make an appointment to get vaccinated as soon as possible.

Published by Chad Kodiak, CEO of local pharmacy KodoCare. Kodiak wants to remind all members of the community to get vaccinated.