

**FOR IMMEDIATE RELEASE**

**December 11, 2020**

## **Department of Health: Emergency Use Authorizations for Vaccines are Critical, Beneficial in Public Health Emergencies**

**Harrisburg, PA** – Secretary of Health Dr. Rachel Levine today informed Pennsylvanians about the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) process for COVID-19 vaccines and outlined the importance of this process in public health emergencies.

“The creation of a COVID-19 vaccine is a crucial development in the fight against COVID-19, both nationwide and in Pennsylvania,” Dr. Levine said. “I want to stress that in order for an EUA to be issued for a vaccine, the FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine. With advanced technology available today, the FDA is able to expedite its review process of thoroughly analyzing the safety and efficacy results of clinical trials. We all want the pandemic to end, and a COVID-19 vaccine is the next tool in our COVID-19 toolkit to achieve that goal.”

An EUA is used by the FDA to approve the use of safe and effective medical products during a public health emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions. An EUA can be used to approve a number of medical products, including vaccines. All vaccines must undergo the EUA approval process before being fully licensed.

After being approved and licensed, the [FDA continues to oversee its production](#) to ensure continued safety. Monitoring of the vaccine and its production activities must continue as long as the manufacturer holds a license for the vaccine product.

Currently, U.S. drug manufacturers are conducting clinical trials to create a safe and effective COVID-19 vaccine through clinical trials, including:

- Pfizer;
- Moderna;
- AstraZeneca;
- Johnson & Johnson;
- Inovio; and
- Novavax.

On Friday, November 20, Pfizer and BioNTech announced their plan to [submit](#) their vaccine to the FDA for EUA approval. The FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) [voted in favor](#) to recommend that the FDA issue an EUA on Thursday, December 10. In order for the FDA to grant an EUA, the vaccine needs to go through a number of different approval processes to ensure the vaccine is safe and effective. The next step is for the FDA to grant an EUA for the Pfizer

vaccine. Then, the U.S. Centers for Disease Control and Prevention (CDC) can approve the vaccine.

On November 30, Moderna announced its plan to [submit](#) its vaccine to the FDA for approval. Next week, this vaccine will undergo the same review process as the Pfizer vaccine.

Vaccine manufacturers are following similar processes to make a COVID-19 vaccine available through an EUA:

1. Manufacturers start the clinical trial, or development process that includes tens of thousands of participants to gather nonclinical, clinical and manufacturing information needed by the FDA to determine if the known and potential benefits outweigh the known and potential risks of a vaccine to prevent COVID-19.
2. The manufacturers get enough information on how well the vaccine prevents COVID-19, the manufacturer will discuss with the FDA and data safety monitoring board will review the data. Based on this data, and additional input from the FDA, manufacturers will then decide whether and when they should submit an EUA request to the FDA.
3. After the FDA receives an EUA request, scientists and physicians will examine all of the information included in the submission.
4. While the FDA reviews the submission, it will schedule a public meeting among its Vaccines and Related Biological Products Advisory Committee where experts will discuss the safety and efficacy data so the public and scientific community can clearly understand what data is being used to make a decision.
5. After the advisory committee meeting, the FDA will use the advisory's input and continue to evaluate the submission to determine if the available data support an EUA of a COVID-19 vaccine.
6. The vaccine will be available after the FDA approves the EUA for the COVID-19 vaccine.

It is important to remember that in public health emergencies, such as a pandemic, the development process may not follow routine timelines. However, it's important to remember that these COVID-19 vaccines have been produced according to rigorous standards set by the FDA and are safe for people to get when available. The COVID-19 vaccine will help to prevent the virus or lessen the severity of the symptoms if someone does get it.

More information about the COVID-19 vaccine can be found [here](#).

**The Wolf Administration stresses the role Pennsylvanians play in helping to reduce the spread of COVID-19:**

- Wash your hands with soap and water for at least 20 seconds or use hand sanitizer if soap and water are not available.
- Cover any coughs or sneezes with your elbow, not your hands.

- Clean surfaces frequently.
- Stay home to avoid spreading COVID-19, especially if you are unwell.
- If you must go out, you are required to wear a mask when in a business or where it is difficult to maintain proper social distancing.
- Download the COVID Alert PA app and make your phone part of the fight. The free app can be found in the [Google Play Store](#) and the [Apple App Store](#) by searching for “covid alert pa”.

### **Updated Coronavirus Links: Press Releases, State Lab Photos, Graphics**

- [Daily COVID-19 Report](#)
- [Press releases regarding coronavirus](#)
- [Latest information on the coronavirus](#)
- [Photos of the state’s lab in Exton](#) (for download and use)
- [Coronavirus and preparedness graphics](#) (located at the bottom of the page)
- [Community preparedness and procedures materials](#)

All Pennsylvania residents are encouraged to sign up for AlertPA, a text notification system for health, weather, and other important alerts like COVID-19 updates from commonwealth agencies. Residents can sign up online at [www.ready.pa.gov/BeInformed/Signup-For-Alerts](http://www.ready.pa.gov/BeInformed/Signup-For-Alerts)