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Is the FDA's Accelerated Approval of Molnupiravir Setting a Pharmaceutical Standard?

By Justin Honore
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Ira Leiderman, Cassel Salpeter

In late December, the U.S. Food and Drug Administration approved Emergency Use Authorization of Pfizer's Paxlovid, a pill to help treat COVID-19. The next day another pill, Merck's Molnupiravir, was approved. This marked a big step in the fight against COVID-19, especially with these pills now available in several states. The pace at which these drugs were given the green light, though, is giving medical professionals questions and concerns. Will Molnupiravir's and Paxlovid's accelerated production set a new standard for pharmaceutical pill production, for better or for worse?

Dr. Kishor Wasan, Chief Medical & Scientific Officer at Skymount Medical U.S., has vast experience with drug development. He is an award-winning pharmaceutical scientist and he has published over 240 peer reviewed articles on lipid-based drug delivery and lipoprotein-drug interactions. Dr. Wasan says this accelerated approval and production isn't a new process for the FDA or pharmaceutical researchers. So why is it drawing so much attention?

“It’s been around. The FDA is not actually skirting their processes: They’re just saying, ‘Hey, use this process.’ What is happening is this authorization is now being used a lot,” said Dr. Wasan. “The general public probably didn’t even know about it because it was probably only used in varying situations people probably didn’t know about.”

Since the initial vaccine was first made readily accessible to Americans, two variants have spread relentlessly, with the current dominant variant, Omicron, overwhelming hospitals. With these compounding factors at play, has there been a forced standard change for drug approval, one that will guide future authorization? Dr. J. Wes Ulm, a physician, medical researcher, and clinical genetics resident at the University of Pittsburgh Medical Center, who has a focus in translational medicine and has applied data-mining tools toward drug discovery and repositioning said, simply, “no.” However, according to Dr. Ulm, the FDA has been willing to shift aspects of its approval approach because of COVID’s public health urgency.

“It’s not only mortality from COVID 19 that’s been so high, but mortality from heart attacks, mortality and morbidity from strokes, from gallstones, from car accidents, from sports injuries, that’s gone up significantly because we just don’t have the staff to care for people,” said Dr. Ulm. “That’s the sort of public health emergency overwhelming hospitals that has led to a genuine rethink at the very least in the EUA process and even potentially for full approval or in the steps leading up to it.”

The key to enabling a fast-tracked approval process lies in Emergency Use Authorization that the FDA has at its disposal. Ira Leiderman, Managing Director at Cassel Salpeter and Company, said this emergency use authorization is one of many tools in the FDA’s tool belt. We asked him why, then, the FDA has been using this approach, and why it could be effective for these different forms of COVID-19 treatments.

“The FDA uses the data collected by the developers of the products looking at safety and efficacy from Phase 1 studies and ultimate efficacy from large Phase 3 studies to grant this emergency use authorization which will allow these companies to sell the products and at the same time allow them to continue collecting data and continue their filing process to get full product licensure,” said Leiderman. “This is not a cutback in quality, it is just the stop gap measure that is one of the tools the FDA has to expedite approval of products that are important and in need for public health purposes.”

At first glance it sounds like steps are being skipped when authorizing "emergency use," but Dr. Wasan said the benefit risk analysis is heavily weighed. According to Dr. Wasan, all COVID treatments have had a limited number of patients because of the urgency of the decision, but as more data comes in, how the pill is prescribed could change. This limited data was one of the concerns in the Molnupiravir approval process which saw the FDA vote 13-10 in it's initial recommendation.

"The initial data looked really great, it looked like it was really safe and that it seemed to have significant efficacy, but as they started to get more and more patients, they found that the efficacy actually started to go down and there were safety concerns," said Dr. Wasan.

Moving forward Dr. Wasan can envision other cases where developers utilize already developed drugs and then modify them like they did for the COVID-19 pill as well as start the conversation with the FDA about the drug approval process before they present it to them.