Discover & Deliver: First FDA-Authorized Coronavirus Vaccine Poised for Approval

Today, all eyes were on a little-known 23-member Food and Drug Advisory (FDA) meeting. While it may not have been on the formal agenda, the meeting was closely monitored to see if the committee could deliver one thing that has seemed out of reach in 2020: a light at the end of the tunnel.

The meeting of the FDA's Vaccines and Related Biological Products Advisory Committee discussed the emergency use authorization (EUA) for Pfizer's COVID-19 vaccine, the first shown to be safe and effective against the coronavirus.

Here is what we know:

The vote: Over the course of the nine-hour meeting, the advisory committee considered whether there was sufficient data to grant an EUA for the vaccine. At the end of meeting, the committee held a vote **recommending Emergency Use Authorization** for people age 16 and older by a vote of 17 in favor, 4 against, with one abstention. While the committee's vote is non-binding, the FDA is likely to move forward with their recommendation to issue the EUA as soon as Friday.

Distribution begins: Once the EUA is issued, the vaccine distribution can begin within 24 hours, and "we will start to have shots in arms within 96 hours" according to the Gustave Perna, the chief operations officer of Operation Warp Speed.

First recipients: Last week, the Center for Disease Control (CDC) Prevention Committee on Immunization practices recommended that front-line healthcare workers and residents of long-term care facilities – group 1a – receive the first doses of the coronavirus vaccine once the EUA is issued. The states subsequently submitted vaccine distribution plans and will now have to decide how to distribute the initial, limited batch of doses to group 1a recipients.

The unknowns: While today marks a tremendous step forward, as with any truly innovative medicine, there are still unknowns. Dr. Nancy Messonnier with the CDC notes that we don't yet know whether the vaccine is "infection-blocking" or "disease-blocking." We also don't know how long immunity will last, making it all the more important that the rigorous clinical studies continue even after the EUA is granted.

What's next: On December 17, the FDA Advisory Committee will meet again to discuss the EUA application for Moderna's COVID-19 vaccine, meaning that before year's end we may have authorized vaccines to combat COVID-19.

Thanks to the tremendous work of our brightest scientific minds and most innovative companies, there is cause for hope that brighter days lay ahead in 2021.

—Kelly Anderson, Senior Director, Health & Drug Policy, Global Innovation Policy Center