Top FDA Officials Counter Politicians on Booster Shots, While Pfizer Product's Approval Continues to Face Questions

TrialSite Staff, September 6, 2021

By way of background, TrialSite has chronicled how the FDA skipped advisory committee hearings and public comments in granting the alleged "full approval" for the Pfizer vaccine. The agency says that it did not go through the committee process as there were no "controversial issues" involved. Further, the efficacy analysis of the FDA was based on old data. It mainly focused on early strains of SARS-CoV-2, while we reported that "it is quite clear that the vaccine is much less effective in preventing infection by the currently circulating strain (Delta)." The agency even notes that the vaccine has myocarditis and pericarditis risks that need further evaluation. Also, Pfizer's vaccine is known as "BioNTech" under the full approval, but the original EUA product is still in stock. So, in the face of new mandates, many may be misled into thinking they are not taking an EUA product when they get the backstock.

Experts Say More Data Needed for Boosters

Now, on September 3, the *New York Times* reports that "Health Officials Advise White House to Scale Back Booster Plan for Now." Top regulators warned late last week that they don't have the data to recommend boosters except for "certain recipients" of Pfizer's vaccine. The officials are telling the White House to "scale back" booster shot plans until more data can be collected and analyzed. Dr. Janet Woodcock, acting FDA commissioner, and Dr. Rochelle P. Walensky, who leads at CDC, said the agencies "may" be able to determine if boosters are recommended in the next few weeks. This relates to the Pfizer-BioNTech product only. The arguments were made in a meeting with White House pandemic coordinator Jeffrey D. Zients. He has "insisted" for many months that the White House will go with the advice of the government's scientists, "wherever it leads." Only three weeks prior, President Biden offered that, pending FDA approval, boosters would begin the week of September 20 for adults who had their last Pfizer or Moderna shot at least eight months prior.

POTUS Versus Science

Biden has emphasized that boosters are an important tool in our national pandemic and for the Delta variant. "The plan is for every adult to get a booster shot eight months after you got your second shot," he opined on August 18. He

continued, “It will make you safer, and for longer. And it will help us end the pandemic faster.” Yet setting a September date “set off alarm bells inside FDA” and played a role in the recent resignations of two head vaccine regulators. Doctors Woodcock and Walensky helped create the booster plan and endorsed it to the public. Some experts think this created undue pressure on scientists to “go along” with the policy when weighing evidence. University of Pennsylvania professor of medical ethics and health policy Dr. Steven Joffe notes, “Now those agencies are in a box—We want doctors and scientists and the public to trust in the recommendations and decisions that are made, to be able to point to the FDA and CDC doing their due diligence.”

FDA Vaccines Director Quits

In private, Woodcock had posited that it was too risky to set a booster timeline prior to regulators being able to “thoroughly review the data.” And new challenges have come up since the August announcement about boosters. Among other things, regulators need time to figure out a proper dosage for a third Moderna shot, and their application contained “insufficient data.” Also, the FDA has not looked at the raw data from Israel, which they have been requesting. That nation’s experts are saying that a third Pfizer shot is helpful, but the FDA “wants to see the underlying data, to make sure it backs up summaries that the Israeli government has provided.” Confusion about the boosters may “create a perception that federal vaccine policy is in some degree of disarray. But some public health experts will most likely welcome it.” The two who resigned, Dr. Marion Gruber, director of FDA’s vaccines office, along with deputy Dr. Phillip Krause, have said that “there was not nearly enough data to justify offering extra shots to the general population starting in just weeks.” Now, the FDA’s advisory committee is set to publicly review Pfizer’s booster data on September 17. A key member of the committee, Dr. Paul Offit, director at the Vaccine Education Center at Children’s Hospital in Philadelphia, offers that boosters are “premature.” He noted, “There is no compelling reason to get a third dose” at this time.