

FDA advisory panel deals a blow to Biden's COVID-19 vaccine booster plans

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On Friday, September 17, the scientific advisory committee of the US Food and Drug Administration (FDA) voted 16-2 against Pfizer's application to offer a third dose of their COVID-19 vaccine to all eligible recipients, 16 years old or over. The decision came only three days before the scheduled launch of Biden's announced plan to begin offering COVID-19 vaccine boosters to all those previously vaccinated.

The advisory panel reconvened in the afternoon to vote on a revised booster question. It unanimously supported offering a third jab to those 65 years or older or at higher risk of developing severe COVID-19. Though not taking a formal vote, the panel was polled on which groups might be considered for a booster. All agreed that health care workers or those at high risk of occupational exposure should be given such considerations. The panel's decision does not bind the FDA, but it usually follows the recommendations.

The advisory panel did not discuss how high-risk occupational exposures would be defined, given the high rates of community transmission. Many workers in factories, teachers at schools, and those working gig jobs have told the WSWs that there have been widespread COVID-19 infections in their workplaces.

The scientists and public health experts on the advisory panel appear to have been following the data they were presented, which demonstrated a substantial benefit from booster shots, particularly for the elderly and those at higher health risk. They clearly were not simply following orders from the White House, since their recommendation disrupted the administration's planned September 20 booster shot launch.

That said, neither the panel nor the FDA considered the only real strategy for ending the pandemic, which is to implement a society-wide program of elimination and eradication. Booster shots are actually an indication

of the failure of the Biden administration's claims that vaccination in and of itself would be enough to halt the pandemic. Instead, they buy a bit more time for those most vulnerable, while the coronavirus continues its rampage and is given more leeway to mutate and potentially evolve into even more dangerous variants.

Evidence has been mounting that the immunity generated from the vaccines, both Pfizer and Moderna, begins to wane over time, leading to a higher risk among the vaccinated to developing breakthrough infections and severe disease. Most of this data comes out of Israel, where after a high rate of vaccination in the first months of 2021, the complete abandonment of public health measures has led to a resurgence of infections with the highly transmissible Delta variant, for which the booster campaign has become a stop-gap measure. There has been an appreciable decline in infection rates and disease severity among elderly people in Israel who have received the third shot.

The observation study coming out of Israel demonstrated a significant decline in infections among those receiving a booster, compared to vaccinated groups within several days, reaching a 10-fold factor in the reduction. The third dose also reduced the chance of severe COVID-19 illness by 95 percent compared to those only fully vaccinated.

The Biden administration's pledge to begin offering coronavirus booster shots to the eligible population by the week of September 20 was first announced in mid-August. On August 25, Pfizer submitted a supplement to their Biologics License Application (BLA) seeking approval to offer a booster dose six months after completing the primary two-shot series. It can only be assumed that these events were coordinated.

Soon after, two senior scientists, Dr. Philip Krause and Dr. Marion Gruber, announced their resignation

from the FDA in opposition to a policy of giving boosters to all those previously vaccinated against COVID-19, rather than restricting them to the elderly and vulnerable.

In a critique published in *The Lancet*, they objected to the claim that enhancing immunity in all vaccinated people will reduce the number of COVID-19 cases, writing, “Most of the observational studies on which this conclusion is based are, however, preliminary and difficult to interpret precisely due to potential confounding and selective reporting. ... Current evidence does not appear to show a need for boosting in the general population, in which efficacy against severe disease remains high ... the limited supply of these vaccines will save the most lives if made available to people who are at appreciable risk of serious disease and have not yet received any vaccine.”

The Centers for Disease Control and Prevention (CDC) recently published a series of studies evaluating the impact of vaccination on the population. Vaccine effectiveness in preventing COVID-19 hospitalization was 86 percent but much lower among those 75 years old or higher (at 76 percent). The estimates were similar between Pfizer and Moderna.

Another study found that though vaccination appeared to confer a more than 10 times decreased risk of COVID-19-related deaths during the period from April 4 to July 17, when the study period was split in halves, COVID-19 deaths among the small fraction of vaccinated individuals who suffered breakthrough symptomatic infections rose from eight percent in the earlier half to 16 percent in the latter half, essentially doubling. The implication here is that not only Delta’s greater ferocity but also declining immunity led to these differences.

In a Tweet released by Dr. Ahmed Elbanna, which epidemiologist Dr. Eric Feigl-Ding highlighted, noted that once vaccinated individuals suffered breakthrough symptomatic infections, the case hospitalization ratio or case fatality ratio were not hugely different to the unvaccinated group.

This suggests that, contrary to much published commentary, the main advantage conferred by vaccination, as the efficacy begins to wane after six months or more, is that it still greatly reduces the likelihood of contracting infection at all, or of that infection becoming symptomatic. If, however,

vaccinated individuals become infected and begin to show symptoms, they suffer morbidities and mortalities similar to those of the unvaccinated.

Dr. Feigl-Ding also showed that several months after being fully vaccinated, antibody titers (a type of blood test that determines the presence and level [titer] of antibodies in the blood) fall from a peak geometric mean of 762 to only 136. Once the booster shots were administered, the titers climbed to 1,419 by day seven and nearly 2,400 after a month. Given that a significant number of the population are now reaching the six-month window from completing their vaccinations, these findings have considerable implications in the Biden’s vaccine-only response to the pandemic.

As Dr. Malgorzata Gasperowicz, a developmental biologist and activist for Zero COVID in Canada, recently said in an interview with the WSWS, “There is this dangerous idea being perpetuated by those relying on vaccines when they say they want to decouple infections from disease severity. These decision-makers suggest that it is acceptable to let the virus spread because it won’t harm us if we are vaccinated.”

She went on to add that though the current vaccines are helping avert severe disease, if the virus continues to evolve, the new variants can develop sufficient immune-escape capabilities that the next time a vaccinated person becomes infected with these new strains, the derived immunity from vaccines may not protect them.

Dr. Malgorzata concluded, “The Delta variant has been the most dangerous strain of the coronavirus. ... I was afraid it would be more difficult to bend the Delta curve because it was more transmissible than the Alpha or the original variant. Now, however, we have seen exponential declines [as noted in New Zealand] are possible, and they would be possible everywhere. But taking that decision to eradicate is the most important. And once we take it, in only several weeks, we would stop all community transmission. And if in every region community transmission is contained, then we won’t have a big problem anymore.”



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