

# Full FDA authorization of the Pfizer COVID vaccine: No panacea for the COVID catastrophe

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On Monday, the US Food and Drug Administration (FDA) announced that Pfizer's COVID-19 mRNA vaccine was granted full authorization for the prevention of COVID-19 disease in people 16 years of age or older. The vaccine, now being marketed under the new name Comirnaty, will still be available to those aged 12 through 15 under the initial emergency use authorization.

In the press brief announcing the approval, acting FDA commissioner Dr. Janet Woodcock said, "The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."

In concert with the FDA announcement, President Joe Biden released a statement from the White House urging business leaders, as well as state and local officials, to begin mandating vaccines for their employees. The Pentagon followed suit hours later declaring they would now enforce the vaccine mandates for 1.4 million soldiers and another million civilian employees.

Dr. Georges Benjamin, executive director of the American Public Health Association, told the *Los Angeles Times*, "You're going to see a lot more groups being more comfortable saying a shot is required. They'll be more firm about helping people understand that, pure and simple, it is much safer to get the vaccine than to get the disease."

As important as the vaccines have been to stem severe disease and death from COVID-19 infections, the FDA's full approval for Pfizer does not mean any real progress in ending the pandemic. Vaccination alone is not enough; it must be combined with a massive public health campaign, including lockdowns as well as masking and social distancing, with the goal of eradication, not mitigation of SARS-CoV-2.

At the recent event hosted by the *World Socialist Web Site*, "For a Global Strategy to Stop the Pandemic and Save Lives," Dr. Michael Baker, renowned epidemiologist with the University of Otago in New Zealand, warned, "We cannot

vaccinate our way out of the pandemic. Even if we had global vaccine access and high coverage, we would still have circulating virus. So, we need to combine vaccine with public health measures."

Given the contagiousness of the Delta variant, vaccination will have little impact in suppressing the growth of the "circulating virus."

Critical modeling analysis conducted by Dr. Malgorzata Gasperowicz, a developmental biologist and researcher at the University of Calgary, Canada, demonstrated that given the present efficacy of the vaccines against the Delta variant, only in combination with moderate public health measures could the growth of the pandemic in the US be brought under one, where, over a period of several weeks, the community outbreaks would be brought to zero.

In the current formulation by the White House, the CDC, and the entire political spectrum, the vaccine-only mandate gives free rein to the virus, which will have the final say on the matter, acting on the basis of well-known epidemiological laws. Whether it is the let-it-rip approach advocated by Republican governors, or the mitigation but not eradication approach of Biden and the Democrats, the virus will be able to expand exponentially, as will hospitalizations and deaths.

In two short months since the US saw the lowest case and death count, the seven-day moving average has now climbed to 150,000 infections per day with more than 850 people dying each day. On August 24, more than 1,100 people succumbed to the infection.

And the current drive to fully open all schools for in-class instruction will only accelerate the present massive surge of infections. The week ending August 19 saw 180,000 COVID-19 cases among children, a 50 percent increase over the previous week, and coming weeks will surpass the highs of the winter, when more than 211,000 children were infected in the week ending January 14, 2021. As evidence through the last 18 months has now clearly demonstrated, children in schools function as a primary catalyst for the waves of infections within communities.

Equally concerning is the mounting evidence that over time

the COVID-19 vaccines, and in particular, the Pfizer jab, are demonstrating waning efficacy after a few short months. A recent study from the University of Oxford, in the UK, using data obtained from the Office for National Statistics, found that three months after vaccination, the efficacy against symptomatic infections for the Pfizer vaccine had slipped from the mid-90s to 75 percent. The efficacy of AstraZeneca's COVID-19 vaccine dropped but at a much slower rate. Extrapolating the data, Oxford projected that Pfizer's efficacy would eventually drop below 50 percent, the level typically required to win FDA approval in the first place.

The threat the Delta variant poses is best exemplified by the present experiences in Israel, which has fully vaccinated more than 60 percent of its population. It is currently facing a surge of new infections that are also matching previous winter highs. And with these infections, the death toll appears to be keeping pace with trends during previous waves.

A spokesman for Pfizer, in response to a question from the press, declared, "These latest data from Israel are consistent with the epidemiological trends we have been observing and reinforce the need for a booster dose to re-establish maximum protective efficacy."

Since the Israeli government launched a campaign to offer those aged 60 and older a third shot on July 30, approximately 60 percent in this group have received the booster. In the older group, it appears the rates of infection are declining once more, making many in the media and other countries take notice. Yesterday, Israel extended the eligibility for a third dose to those 30 years and older who had received the second dose at least five months prior.

With the granting of full approval, the FDA helps clear the way for an influx of people clamoring for booster shots, as physicians will now have more discretion to offer COVID-19 vaccines.

While little has been said in the American media or by the Biden administration, when such additional vaccination campaign measures are implemented across the US and Europe, many middle- and low-income nations will be left in the lurch, as they are once more pushed to the back of the line, unable to give most of their citizens even a first shot while people in the wealthy countries get a third one.

On September 20, the Biden administration will begin offering boosters for fully vaccinated individuals who received their second dose more than eight months before. However, the current approval, plans for mandates, and then boosters, will do little to stem the present disastrous wave as schools are beginning to admit students by the millions for in-person instruction. No vaccine campaign can win a foot race against the Delta variant without strict mitigation measures and lockdowns to check its spread.

Troubling evidence has only confirmed the dangers this virus poses. In a recent analysis conducted by investigators during of the outbreak in Guangdong, China in May, and June of 2021,

they found that those infected with Delta strain are more likely to infect others before they become symptomatic than people infected with the earlier version that first emerged in Wuhan.

People infected with Delta shed viral particles for almost two days before developing symptoms. Previous data placed the window for asymptomatic shedding at less than one day. Additionally, a recent study from South Korea confirmed that the viral load shed by infected individuals when they first develop symptoms was 300 times higher than with the original virus and remained higher throughout the window of communicability.

The rise in the number of breakthrough infections suggests that the neutralizing antibodies in people who are fully immunized are not providing sufficient protection against the Delta variant. The main target for the Pfizer COVID-19 vaccines is the receptor binding domain (RBD) and the N-terminal domain (NTD) in the virus's spike protein.

A just published study from Osaka, Japan, suggested that if the Delta variant acquires additional mutations beyond the ones it already possessed, it could develop the ability to escape vaccine-induced immunity. The acquisition of other mutations is expected, highlighting the importance of tracking these mutations where they start.

According to a report providing explanation of the Osaka study published yesterday in *News - Medical*, "Additional mutations ... of the Delta variants may make it fully resistant to the immune sera of vaccinated individuals. ... Thus, the Delta variant is likely to acquire further mutations with increased infectivity and resistance."

The authors concluded that though "a third round of booster immunization with the SARS-CoV-2 vaccine is currently under consideration, our data suggest that repeated immunization with the wild-type spike may not be effective in controlling the emerging Delta variants." They call for the development of a new vaccine directed against the spike protein of the Delta strain.

The implication of these findings means the need to rewind the pandemic clock and develop and produce new vaccines against the Delta variant and once more initiate a new vaccination campaign—in other words, vaccination without an all-encompassing public health response can become a never-ending treadmill, with new vaccinations required to guard against ever more virulent and dangerous variants of the virus.



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