Fall COVID-19 booster campaign begins in the US as CDC approves bivalent vaccines with limited data

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The Biden administration and corporate media have sought to cultivate a celebratory mood to the kickoff of the new anti-COVID-19 vaccine booster campaign that has commenced after the Labor Day weekend. Despite the fact that they have not completed any clinical trials to prove their benefit, the newly formulated bivalent vaccines from Pfizer and Moderna, which contain a formula tailored to both the ancestral variant and the Omicron BA.4 and BA.5 subvariants, are being touted as the next best defense against the coronavirus.

Meanwhile, access to free COVID-19 tests from the federal government has ended, masking and social distancing are not mandated or encouraged in any state, and dashboards tracking COVID-19 infections have been largely dismantled. With K-12 schools and college campuses back in full swing, the number of COVID-19 infections has exploded in these settings without anywhere near adequate testing or data reporting.

Worst of all, the daily average for COVID-19 deaths remains stubbornly high at around 500, with barely a mention in the press on the ongoing horrific scale of death across the US. Approximately 37,000 Americans have died during this summer from COVID-19 and 220,000 since January 1. By the end of the year, the official number of deaths from COVID-19 will surpass 1.1 million.

After a White House summit on the future of COVID-19 vaccines in late July, the decision was made to purchase bivalent vaccines for this fall, but only if they incorporated the dominant strains of the Omicron subvariants, BA.4 and BA.5. Initially, when the vaccine manufacturers began designing their Omicron-relevant COVID-19 vaccines, they targeted the original subvariants, BA.1 and BA.2.

Based on the favorable neutralization titer levels with the BA.1/BA.2 bivalent vaccines, the Food and Drug Administration (FDA) advisory panel assumed these would also hold true for BA.4/BA.5 versions. They gave their surest endorsement, and the Biden administration ordered the vaccine manufacturers to make the necessary adjustments and have them ready before Labor Day so their regulatory agencies could sign off on them.

Given the sobering estimates at the time that this fall and winter would see over 100 million infections and tens of thousands more deaths, the White House needed to save face. With what remained of the limited COVID-19 funds, 105 million doses of the Pfizer and 66 million doses of the Moderna bivalent COVID-19 boosters were purchased.

At the eleventh hour, last Thursday the FDA granted emergency use authorization for the bivalent COVID-19 vaccine boosters. On Saturday, September 3, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) gave a near-unanimous approval, and CDC Director Rochelle Walensky signed off on the recommendation.

Pediatrician Dr. Pablo J. Sanchez at Ohio State University's Nationwide Children's Hospital in Columbus was the lone dissenting member of the ACIP, who voted "no" because there was insufficient relevant clinical data to guide these recommendations. He explained, "I voted no because I really feel that we need the human data, and to me, that's really important—it's a new vaccine, it's a new platform. There's a lot of vaccine hesitancy already." Dr. Sanchez added, "Personally, I'm in the age group where I'm at high risk and I'm almost sure that I will receive it. I just feel that this was a bit premature, and I wish we had seen that data. Having said that, I am comfortable that the vaccine will likely be safe like the others."

According to the CDC, individuals must have completed the initial COVID-19 vaccine series to be eligible for the bivalent boosters. To receive the Pfizer booster, one must be 12 years or older, while for Moderna's, the lower age limit is 18. Additionally, it is recommended that at least two months have passed from completing the initial vaccine series or receiving the last booster to take the bivalent vaccines.

As mentioned before, there is no human trial data on the specific COVID-19 booster formulations that have been authorized. Dr. Ashish Jha, the White House Coronavirus Response Coordinator, mentioned last month during a press brief on the forthcoming boosters that data would be available as soon as mid-September. However, Dr. Peter Marks, who heads the FDA office that reviews vaccines, recently told CNBC that it may take at least another couple of months.

Without a doubt, the Biden administration has chosen expediency over data. It remains unclear how much more protection these new bivalent boosters can offer the population over the original boosters. Vaccine scientist John Moore at Weill Cornell Medicine in New York City told *Nature*, "This is not some kind of super-shield against infection compared to what you could have got two weeks ago or a month ago."

The *Nature* report notes that previous large-scale efficacy trials that had shown significant reduction in severe disease "are no longer practical, possible, or ethical in 2022." To gauge efficacy, scientists have turned to measuring immune responses with the latest formulations and comparing them to responses achieved when the original vaccines were administered.

One recent study published on August 26, 2022, titled "Predicting

the efficacy of variant-modified COVID-19 vaccine boosters," attempted to provide some context to the question. The authors found that the variant-modified vaccines, on average, produced 1.51-fold higher titers than the equivalent ancestral-based vaccine.

In their attempt to estimate the clinical benefits of the 1.5-fold improvement, they modeled the correlating neutralization titers with observed clinical protection based on previous phase 3 clinical trials. This translates to protection against symptomatic infection from 50 percent (immunity presently from vaccines received six months prior) to 85.6 percent for the original booster and to 90.2 percent for the variant-modified jab. Against severe disease, protection would rise to 98 percent with the original booster and 98.8 percent for the bivalent boosters, or "an additional 0.8 percentage points of protection on average from severe COVID-19 compared to an ancestral-based booster."

The authors conclude, "A large proportion of the benefit comes from receiving any booster at all (including an ancestral-based booster). Use of a variant-modified vaccine is expected to provide a modest increase in protection, which may be slightly greater in cases where the vaccine immunogen is more antigenically related to the circulating variant or if immunity has waned." As the study underscores, the absolute clinical benefit for bivalent boosters compared to the original strains remains unclear.

The Biden administration has spent the last of its COVID-19 funding to procure these next-generation COVID-19 vaccine boosters. Once these run out, the cost for additional vaccines will be deferred to an individual's insurance plan. Because these boosters are intended as annual vaccines in line with influenza vaccines, paying for another jab six months later when immunity has waned will be an out-of-pocket cost.

It is essential that workers and the general public reject the propaganda of the political establishment and corporate media, which falsely present COVID-19 as harmless to vaccinated people, and remain vigilant in wearing well-fitting N95 respirators and social distance to the greatest extent possible in order to prevent the spread of COVID-19. The risks of developing Long-COVID, which can cause crippling debilitation, are only slightly reduced by vaccines, and the same will likely hold for the latest bivalent vaccines. As of yet, there are no treatments proven to mitigate the impacts of Long COVID, which can affect nearly every organ in the body.

The essence of the COVID-19 vaccine booster with Omicron-specific subvariant formulations is to deepen the vaccine-only strategy of the Biden administration, which has openly embraced a criminal policy of "forever COVID-19" in which no efforts will be made to eliminate or even reduce viral transmission.

The latest vaccines change nothing about the nature of the coronavirus and the waning of the population's immunity that will most assuredly occur over a few months. World Health Organization (WHO) Director-General Dr. Tedros Adhanom Ghebreyesus recently warned once again of the possibility of the emergence of deadlier and more infectious variants and the need to take appropriate precautions. However, for Biden and the short-sighted bureaucrats heading the COVID Response Team, in particular Drs. Ashish Jha and Rochelle Walensky, the official epidemiologic statistics on the pandemic read like quarterly financial statements without a thought to the future.

Since hosting a "Summit on the Future of COVID-?19 Vaccines" in late July, the COVID Response Team has issued barely a word on the need to fast-track the development of sterilizing mucosal vaccines. Last month, noted Yale immunologist Dr. Akiko Iwasaki, who participated in the White House summit, gave the *New York Times* the following prognosis for the development of mucosal vaccines in the US: "Nasal vaccines will not be available this winter, but if there is government support and coordination, they can be available in the near future, potentially in a couple of years."

The Western media has been almost entirely silent on the fact that on Sunday China approved the world's first inhaled vaccine against the SARS-CoV-2 coronavirus. *Fortune* magazine ran the story on Monday that CanSino Biologics had been granted regulatory approval for their "needle-free" vaccine, Convidecia Air. It is inhaled through the mouth using a nebulizer to convert the liquid form of the vaccine into an aerosol. According to a preprint study, participants who had completed the two-dose Sinovac vaccine series and were given the inhaled booster showed a tremendous immune response within four weeks, even to Omicron. By contrast, those receiving the third Sinovac dose did not show an immune response against Omicron.

Another scientific study out of Russia found that the intranasally delivered Sputnik V vaccine induced robust systemic and local immune responses in mice for up to 180 days. Also, on Tuesday Health Minister Mansukh Mandaviya, Drugs Controller General of India, approved Bharat Biotech's recombinant nasal vaccine for restricted use in India.

These advances in mucosal vaccines against SARS-CoV-2, as well as similar vaccines being developed far more slowly in the US and EU, could tremendously benefit the fight against the pandemic. But without the resources directed to producing these critical therapeutics and quickly distributing them globally, these crucial breakthroughs will linger on laboratory work benches collecting the proverbial dust.

The nature of world capitalism, in which rival nation states are pitted against one another in ruthless competition, prevents a rational and scientific approach to addressing a pandemic that has killed upwards of 23 million people and debilitated over 100 million more.

It is essential that the international working class take up the fight for a Zero-COVID global elimination strategy, using every public health measure known to reduce viral transmission, in order to bring the pandemic to an end. The collaboration of scientists, if empowered to work together to address humanity's needs, would provide a tremendous boost to the health of the world's population and massively expand life expectancy for all.