Amid new COVID-19 wave, FDA places millions at risk by restricting access to vaccines

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In a significant shift in COVID-19 vaccination policy, the Food and Drug Administration (FDA) announced plans this week to limit access to future vaccine doses in the United States. Under the new regulatory framework, outlined by FDA officials Drs. Vinay Prasad and Martin A. Makary in the *New England Journal of Medicine*, annual COVID-19 booster shots will primarily be available to older adults—typically those over 65—and to individuals aged 6 months and older with underlying medical conditions that put them at high risk for severe COVID-19 outcomes.

This policy marks a major departure from previous policy. It is being promoted as a way to further normalize the ongoing COVID-19 pandemic and treat SARS-CoV-2 as just another respiratory virus among the many that sicken the population each year.

The Centers for Disease Control and Prevention (CDC) defines eligible high-risk conditions broadly, including obesity, mental health conditions like depression, asthma, cancer, heart disease and diabetes. FDA officials estimate that, under the new strategy, between 100 million and 200 million Americans—roughly 30 to 60 percent of the US population—will remain eligible for vaccines. However, this framework would leave many healthy Americans, including younger adults and children, potentially ineligible for routine vaccination, despite the risks posed by Long COVID, which affects 4-10 percent of the US population. Roughly 1 in 10 adults who have had COVID-19 develop this debilitating condition.

For healthy individuals between 6 months and 64 years old without risk factors, the FDA now requires randomized, controlled trial data evaluating clinical outcomes before granting Biologics License Applications for vaccines in this group. This demand for more robust evidence exceeds previous authorization processes for updated boosters, which often relied on immunogenicity data.

In their NEJM article, Prasad and Makary cynically argue that these policy changes aim to prevent further declines in immunization rates caused by eroding public trust in vaccination. They reference declining MMR vaccination rates for measles, correctly noting that these vaccines are safe and protective. However, they do not acknowledge that mistrust in vaccines has been fueled by the very individuals and institutions now shaping public health policy, who have promoted conspiracies and alternative treatments instead of sound scientific advice.

Prasad and Makary themselves have a well-documented history of undermining public health measures and promoting pseudoscientific positions. Both have been outspoken critics of previous FDA policies, with Prasad labeling the agency a “failure” and calling annual COVID-19 boosters “a public health disaster the likes of which we’ve never seen before.” Makary, meanwhile, has repeatedly minimized the dangers of COVID-19, falsely predicting the pandemic would be “mostly gone” by April 2021, and has lent credibility to the Wuhan Lab Lie conspiracy theory, despite a lack of supporting evidence.

Their rhetoric mirrors that of the anti-vaccine movement, recycling arguments long used by opponents of science-based medicine. During the pandemic, Prasad in particular became a prominent critic of mask mandates, lockdowns and efforts to speed the deployment of vaccines, aligning himself with reactionary figures and platforms that have consistently opposed effective public health interventions.

Neither Makary nor Prasad are experts in infectious diseases or vaccinology, yet they have maneuvered themselves into positions of authority over the nation’s vaccine policy. Their approach is not rooted in advancing public health but in furthering a right-wing agenda that seeks to dismantle the very infrastructure needed to respond to a global health crisis. Their NEJM article, which claims to defend “public trust,” is a smokescreen for policies that will deepen vaccine hesitancy and leave the population exposed to preventable illness and death.

The policy shift comes as COVID-19 continues to cause

significant morbidity and mortality across the US and internationally, with an estimated 30,000-50,000 people having died from COVID-19 in the US since last October.

Recent CDC data shows that more than 300 people died each week from COVID-19 last month, down from nearly 1,000 weekly deaths in January. However, the Pandemic Mitigation Collaborative reports weekly excess deaths at 600 to 1,100—a figure 2-4 times higher than the CDC's weekly death toll. Wastewater surveillance indicates that about 250,000 people are contracting COVID-19 daily. Health authorities expect another wave of infections in July or August, followed by a winter surge.

While the FDA restricts vaccine access and may slow the approval process for future vaccines in healthy populations, the virus continues to evolve. The LP.8.1 strain, a descendant of the JN.1 variant, is currently dominant in the US, accounting for 70 percent of cases in early May.

Meanwhile, new variants are emerging elsewhere. The NB.1.8.1 variant is linked to a large surge in China and is rising in parts of Asia. Hong Kong has reported COVID-19 rates not seen in at least a year, with a significant increase in emergency room visits and hospitalizations. Taiwan has also reported more severe cases and deaths, prompting officials to stockpile vaccines and antiviral treatments. The CDC has detected NB.1.8.1 cases in the US among international travelers and through local health authorities in several states.

Scientists are raising concerns about NB.1.8.1. A preprint study led by Yunlong Cao found that NB.1.8.1 has a growth advantage over the previously dominant LP.8.1.1. Preliminary data suggest that while NB.1.8.1 may not evade the immune system better than other rising strains, it binds more effectively to human cells, indicating it could be more transmissible. The study notes that NB.1.8.1 demonstrates a "balanced profile of ACE2 binding and immune evasion, supporting its potential for future prevalence."

The vaccine policy shift aligns with broader fascistic attacks on science and public health by the Trump administration, whose Health and Human Services (HHS) department has declared the pandemic "over" and replaced the federal COVID-19 resource hub with a website promoting the Wuhan Lab Lie theory.

Many public health officials view these actions as part of a push to normalize the virus and dismantle public health infrastructure, despite ongoing viral mutation and public health impact. Requiring lengthy clinical trials for previously tested vaccines is seen by experts as a barrier to using life-saving treatments. Given the virus's rapid mutation, a vaccine based on an earlier strain could become obsolete by the time trials are completed, wasting valuable resources.

Amid these policy changes and the emergence of new variants, the leadership of key US health institutions is cementing policies that will undermine scientific research and public health preparedness.

The National Institutes of Health (NIH), now led by Dr. Jay Bhattacharya, a health economist rather than a virologist, has become a focal point for these concerns. Bhattacharya has played a prominent role in the administration's efforts to restrict research funding and promote quack theories.

At his first staff town hall on Monday, Bhattacharya promoted the Wuhan Lab Lie, claiming the NIH may have funded research that caused the pandemic. Bhattacharya stated, "It's possible that the pandemic was caused by research conducted by human beings, and it is also possible that the NIH partly sponsored that research." He added, "I've looked at the scientific evidence and I believe it," endorsing the lab leak theory.

These anti-scientific statements prompted a walkout of dozens of NIH staffers, who were applauded by many of their remaining colleagues, indicating the growing opposition among NIH and other public health workers.

Bhattacharya's support for the Wuhan Lab Lie is longstanding. He was part of Biosafety Now, a group that opposed gain-of-function research and called for the retraction of papers supporting a natural origin. He also co-authored the Great Barrington Declaration, which advocated for a "herd immunity" strategy through widespread infection. His embrace of the lab leak theory has always aimed to provide a pretext for attacking perceived enemies and dismantling public health infrastructure.

Under Bhattacharya's leadership, the NIH has seen significant cuts and restructuring. Thousands of staff have been laid off or induced to leave. Over 2,500 grant applications have been rejected, more than 800 existing grants terminated and research funds frozen. The administration has proposed a 37 percent cut to the NIH budget for 2026. Funding categories for increasing vaccine uptake and training diverse researchers have been discontinued. Research into Long COVID and next-generation vaccines has been cut or terminated. Bhattacharya himself stated he signed off on cutting over $1.8 billion in research grants.