Week in Review: 22 – 26 February 2021

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

FDA issues new guidance on developing vaccines that cover variants.

This week the US Food and Drug Administration (FDA) issued a new policy for companies who manufacture tests, therapies, and any preventive medications that applies to companies submitting changes to existing products in response to the emerging coronavirus variants. Under normal circumstances, new submissions require submission of extensive clinical data and production plans, but in response to the mounting and potentially pandemic-elongating mutations, the FDA has published an expedited review pathways for public opinion and contribution.

For pharmaceutical companies producing vaccines, there are no anticipated changes to manufacturing requirements should changes need to be made to cover variants, but additional clinical information in the form of "immunogenicity studies" will need to support any changes. Unlike a full clinical trial, such studies are designed to demonstrate patients' immune response to new formulations compared to authorized vaccines, similar to how annual influenza vaccines are evaluated. Applicants are also being encouraged to compare the response of unvaccinated individuals and those who have been previously inoculated against the virus.

Monoclonal antibodies, which despite mixed evidence still have potential to help some patients, have been shown to be less effective in targeting variant strains. The FDA guidelines provide a pathway for expedited generation of the required clinical and non-clinical data required for approval of modified submissions. Similarly, the recommendations for the broader therapeutics market focused on the composition of Phase II and Phase III clinical trials and the changing variables of vaccine availability and viral makeup.

Tests are also a concern. With the accuracy of many tests relying on the genetic makeup of the virus for adequate detection, the FDA included a list of products known to be affected by existing mutations. This portion of the publication focused on the Administration's efforts to study and catalogue the variants. It also highlights the importance of monitoring how any variants in the future may affect the reliability of existing products.

Collectively this report aims to empower companies to continue developing products related to combatting the pandemic with prevention, detection, and treatment, by providing guidance on an evolving enemy and how to swiftly and effectively respond to changing response requirements. *The Food and Drug Administration. 26 February 2021.*

—Brief19 Policy Team

New guidelines for payment protection program.

The Paycheck Protection Program (PPP) is a program that was created under the Coronavirus Aid, Relief, Economic Security (CARES) Act that aimed to help small businesses through the turmoil of covid-19. While its rollout has been far from perfect, it has maintained bipartisan support, and President Biden has announced changes to the qualifications to straighten out the ship.

Unfortunately, since the earliest days of the PPP, large conglomerates found ways to use their corporate structures to qualify for payouts, with $243.4 million of the initial $349 billion going to publicly-traded companies. While many of these entities elected to return the ill-gotten

funds after being publicly identified, not all did. Despite the problems in vetting applicants in this first-come, first-served program, its filing deadline was extended due to unused funds, and additional stimulus packages continued to refill the coffers. Further, though the House and Senate were very much divided on the size and content of subsequent stimulus packages, both parties have supported the PPP and it continues to disburse loans.

Starting this week, President Biden is charting a new course, having announced that for the next two weeks, the only businesses that can apply for funding are those with fewer than twenty employees. Specific pools will be set aside for sole ownership entities as well as businesses owned by women and people of color. The new guidelines will also include legal US residents who are *not* citizens, a group that was excluded under the previous application cycles. Also included are felons whose charges do not include fraud. In addition, those with student loan debt delinquency will no longer be disqualified. *Various*. *24 February 2021*.

—Brief19 Policy Team

UK eases restrictions as new data hint at decreased risk of hospitalization after coronavirus vaccination.

New information out of the United Kingdom on Monday suggests that the impressive vaccination effort undertaken there has reduced hospitalizations by a large margin. Citing data that has not yet been published or peer-reviewed, UK Prime Minister Boris Johnson announced the data stemming from the ongoing study and monitoring of infections at several locations across the country.

The UK has been one of the leaders worldwide in vaccinating the eligible population, with more than one-third of all adults having already received at least one dose of an authorized vaccine. Caution should be used in interpreting these announcements as scientific proof of vaccine effectiveness on a population-wide level, however, as the data are observational in nature and have not yet been reviewed by the scientific community for publication. However, the news that the Pfizer vaccine reduced hospitalization by 85 percent and the Oxford-AstraZeneca vaccine showed a 94 percent reduction in hospitalization is welcome news nearly a year into the covid-19 pandemic.

The UK has been on widespread lockdowns for the better part of the last two months, in part due to the novel variant of SARS-CoV-2 found there, which is believed to be more infectious than previously known versions of the virus, and possibly more virulent. With these findings, the Prime Minister also announced the easing of some restrictions currently in place. *23 February 2021*.

—Jordan M. Warchol, MD, MPH

Editor's note: Here at Brief19, we are committed to fighting medical disinformation, one briefing at a time. But what are the heavy-hitters of the internet and social media space doing to stop harmful stories from going viral? To learn more, we invited two Misinformation Policy Managers at Facebook to brief us on what they are doing to promote reliable health, science, and medical information during the pandemic.

—Jeremy Samuel Faust MD, MS

Facebook's approach to covid-19 and vaccine misinformation.

Since covid-19 was declared a public health emergency almost a year ago, Facebook has been working to connect people to reliable information and limit misinformation about the

pandemic. We have recently expanded these efforts to address concerns around vaccine hesitancy and covid-19.

A key part of our strategy to combat misinformation is to promote authoritative information. We have connected over 2 billion people from 189 countries to information from the World Health Organization (WHO) and other health authorities through our COVID-19 Information Center and messages in people's feeds. Facebook is now running the largest worldwide campaign to promote authoritative information about covid-19 vaccines, including promoting authoritative results in searches and giving $120 million in ad credits to national health ministries, NGOs, and UN agencies.

Connecting people to reliable information is only half the challenge. To limit misinformation, our covid-19 policies aim to minimize health harm while still allowing people to discuss, debate, and share personal experiences, opinions, and news. We remove content with claims that health authorities have confirmed are both (a) false and (b) would likely contribute to imminent physical harm—including increased likelihood of exposure to or transmission of the virus, or adverse effects on the public health system. For example, "vitamin C cures COVID-19," or "hospitals kill patients to increase their COVID numbers!" We also may remove Pages, Groups, and Instagram accounts that repeatedly share such information.

Building on these policies, we are now removing more misinformation to address vaccine hesitancy during the pandemic. Since December, we've removed false information about covid-19 vaccines, including claims that they contain a microchip, change DNA, or were designed for population control. Earlier this month, following consultations with health organizations like the WHO, we began removing additional debunked theories about vaccines in general, including claims that they are toxic or cause autism. We also began removing other common covid-19 hoaxes debunked by multiple of our independent fact-checking partners, including that covid-19 is man-made, patented, or not new.

For other content, we reduce distribution of posts rated false by one of our 80-plus independent fact-checking partners (covering over 60 languages), and we display a warning label with more context, prohibit it in ads, and further restrict repeat offenders. Under these policies, between March and October 2020, we removed more than 12 million pieces of content on Facebook and Instagram and displayed warnings on about 167 million pieces of content on Facebook. Expanding these efforts will help us continue to take aggressive action against misinformation about covid-19 and vaccines. As the situation evolves, we'll continue to review content on our platforms and engage with experts to provide additional policy guidance. *22 February 2021*.

—Aaron Berman and Krista Cox, Misinformation Policy Managers, Facebook

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Brief19 is a daily executive summary of covid-19-related medical research, news, and public policy. It was founded and created by frontline emergency medicine physicians with expertise in medical research critique, health policy, and public policy.