Week in Review: 7 – 11 December 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

One giant leap for humankind. The promise of vaccines becomes a reality, the United Kingdom begins to vaccinate its population.

Editor's note: December 8 was a momentous day. In a global first, people in the United Kingdom received vaccinations against SARS-CoV-2 outside of a clinical trial. It is worth stopping to marvel at this achievement. One year ago, SARS-CoV-2 began circulating in humans, changing life as we knew it in a matter of months. The disease it causes, covid-19, has the ability to cause life-threatening pneumonia, first reported in late December. By early January, scientists in China had already sequenced the genetic material of the virus and shared it with scientists around the world. A mere two months later, vaccines encoding the virus's surface spike protein had been genetically engineered and delivered to the early phase I trial patients. Now, less than nine months after covid-19 was declared pandemic, the first safe and effective vaccine has arrived. On Brief19 we assess new clinical trial data, and hear from two vaccine experts, both of whom provide important critiques while overall being optimistic about the prospects for the vaccines which are now poised to change the course of this pandemic. *9 December 2020.*

—Jeremy Samuel Faust MD MS

FDA set to make EUA recommendation for Pfizer/BioNTech vaccine.

In the wake of multiple countries including the U.K. and Canada approving the covid-19 vaccine manufactured by Pfizer and BioNTech, Americans have been awaiting the Food and Drug Administration's (FDA) final determination regarding Emergency Use Authorization (EUA). The EUA request was sent on November 20, and the FDA's vaccine advisory committee met on December 10 to make its final recommendation. Ahead of its meeting, the FDA released its analysis on Tuesday, suggesting that the EUA would be forthcoming.

In its analysis, the FDA discusses the ongoing safety and efficacy data being collected as part of the phase 3 randomized double-blinded and placebo-controlled trial. Thus far, the data from ~36,000 participants randomized to receive either a two-part vaccine or placebo, has suggested a 95 percent efficacy in preventing covid-19. Plus, the vaccine has been shown to decrease severe illnesses and reduce rates of symptomatic disease even after just one dose.

Furthermore, they remarked that the safety profile of the vaccine suggests, "no specific safety concerns identified that would preclude issuance of an EUA." The most common adverse reactions reported were injection site reactions, fatigue, headache, muscle pain, chills, joint pain and fever. Severe adverse reactions were recorded in 0 to 4.6% of participants, and were more common after the second dose. Serious adverse reactions were noted to be less than 0.5%.

The meeting was an open forum, during which the FDA asked its committee to recommend whether they think the potential benefits of the vaccine outweigh its risks based on the available scientific evidence and suggest possible follow up studies. Of note, their recommendations were be made only for Americans ages 16 and older.

Though safety and efficacy data will be collected for many months to come, it is clear that this and the other candidates, such as those from Moderna and AstraZeneca, boast strong safety and efficacy profiles. While we may yet learn of rare complications resulting from the new mRNA technology used by Pfizer and Moderna, we also know that the possibility of covid-19 infection leading to death is at least an order of magnitude greater than the flu and countless recovered patients are still suffering from long term symptoms. *Various*. *10 December 2020.* ***Update: The FDA issued an Emergency Use Authorization for the COVID-19 Vaccine on 11 December 2020.***

—Fred Milgrim, MD

A look at the new proposed bipartisan Senate stimulus package.

Passage of additional coronavirus aid has faced a stalemate for approximately five months in Congress, since the May passage of the HEROES Act by the House of Representatives (seen as too expansive by the Senate) and the July passage of the HEALS Act by the Senate (seen as too limited by the House). Now, however, bipartisan momentum seems to be building for a new $900 billion package proposed by the Senate. One-hundred eighty billion dollars would be used to establish a federal unemployment benefit of $300 billion through March, $25 billion in housing assistance, $45 billion for transportation industry support and $82 billion for education. The plan would inject another $288 billion into the Paycheck Protection Program and $160 billion for state and local government support.

While Senate Majority Leader Mitch McConnell (R-Kentucky) has publicly opposed the effort, and Speaker of the House Nancy Pelosi (D-California) has called any package under $1 trillion a non-starter. As a result, rank-and-file support and public pressure for Congress to act before the winter recess may break the logjam that has plagued the process so far. *Various. 7 December 2020.*

—Joshua Lesko, MD

President-Elect Biden announces Becerra as pick to lead HHS. Who is he and why does Donald Trump dislike him so much?

California Attorney General Xavier Becerra has been tapped by President-Elect Joe Biden's to be the next Secretary of Health and Human Services (HHS), a role that would be at once novel and familiar to him. Despite never having worked in healthcare before, his acumen has garnered him significant praise from health policy leaders given his past work. Notably, he first helped steer the Affordable Care Act (ACA) in 2009 and 2010 as a member of the House of Representatives and his commitment to protecting the ACA has continued since. This past November, he argued for the preservation of the ACA before the Supreme Court in *California v. Texas*, with particular attention paid to covid-19 constituting a pre-existing condition.

In addition to the expected ongoing work defending the ACA as the HSS Secretary, Becerra will work on the administration's response to covid-19. Last month he again outlined the importance of the ACA: "covid-19 has made one thing undeniable; we must safeguard the Affordable Care Act—lives depend on it." His record in the healthcare sphere has been widely recognized, as he was called, "perhaps the biggest thorn in President Trump's side on the ACA, reproductive health and immigrant rights," by Larry Levitt, Executive Vice President of the Kaiser Family Foundation.

In addition to Becerra's healthcare policy background, he has proven an outspoken opponent of the Trump administration's immigration agenda. In light of the covid-19 pandemic, he also called on the Trump Administration to release immigrants without significant criminal histories from detention centers, to prioritize those in poor health and to take other affirmative steps so as to reduce the spread of covid-19 in immigrant detention facilities.

Of particular note, Becerra would be making history as the first Hispanic/Latinx HHS Secretary if confirmed. This equity milestone is further underscored by the fact that the Hispanic/Latinx community has been disproportionately affected by the covid-19 pandemic. His voice and representation would be a welcome advocate to the Biden-Harris cabinet. *7 December 2020.*

—Miranda Yaver, PhD

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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.