Week in Review: 24-28 August 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

New options created by ACA protect the newly unemployed from losing health insurance.

The United States Supreme Court announced that it will again hear oral arguments on the Constitutionality of the Affordable Care Act (ACA, or "Obamacare") on November 10, one week after Election Day. The newest challenge to the ACA is led by a contingent of 18 Republican state attorneys-general and is supported by the Trump administration. However, amid the covid-19 pandemic that has led to widespread layoffs (and possibly permanent job losses), the uniquely American system in which a high number of people get their health insurance through their employers now threatens to cut millions of people off from their insurance plans. In that context, it is important to recognize the new options created by the ACA for health insurance that are unrelated to employment. These include more generous Medicaid eligibility criteria in the 36 states that chose to expand their programs, extension of dependent coverage to 26 years of age, and insurance Marketplaces supported by consumer protections and premium tax credits.

In a recent article in the New England Journal of Medicine, my colleague Benjamin Sommers and I quantified the ACA's effect on changes in health insurance coverage after job losses. We used national data from the Medical Expenditure Panel Survey. We compared the trajectories in coverage for nonelderly adults who lost their jobs before 2014—the year the law's Medicaid and Marketplace provisions went into full effect—with the trajectories of those who lost their jobs after 2014. As expected, there were large drops in employer-sponsored insurance after job losses (more than 12 percent), whether a job loss occurred before or after 2014. However, after implementation of the ACA, there were large gains in Medicaid (8.9 percent) and Marketplace coverage (2.6 percent) that fully offset the reduction in employer-sponsored insurance for people who left or lost their jobs. These results suggest that the ACA will play a critical role in alleviating coverage losses related to the covid-19 recession. In the context of millions of Americans losing their jobs in a short period of time, and an ongoing pandemic, overturning the ACA would likely be devastating to patients, clinicians, hospitals, and state economies. The very virus that has brought about record unemployment levels is the same agent that makes health insurance—and the new options created under the ACA—more important than ever. *25 August 2020.* *—Sumit Agarwal, MD MPH*

Emergency use authorization for convalescent plasma granted over experts' concerns.

On Sunday, the U.S. Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for convalescent plasma as a treatment for covid-19. On Friday, *Brief19* covered a developing story in which a group of experts from the National Institutes of Health (NIH) and National Institutes of Allergy and Infectious Disease (NIAID) including Dr. Anthony Fauci and Dr. Francis Collins opposed this designation due to insufficient evidence demonstrating benefit. But on Sunday the administration moved forward. The White House Chief of Staff hailed the move, saying that the FDA had been made by President Trump and his team to "see the light." Under the Authorization, the FDA determined that the potential gains of plasma outweighs the known and potential risks. The premise behind the use of such plasma is that individuals who have recovered from the coronavirus have circulating antibodies that may be able to stimulate the recipient's immune system into mounting a more effective defense. However, the FDA's decision memorandum relies mainly on retrospective data. In a press briefing, it was claimed that plasma was associated with a 35 percent lowering of the death rate from covid-19. This is a misleading claim. In a subset of a subset (patients under 80 years old who received plasma in the first three days of hospitalization, who were

not on mechanical ventilators), death rates fell from around 10 percent to around 6.5 percent. Even if those data are found in a true trial, this implies that nearly 30 such patients would need to be treated to save one life. Nevertheless, that would be a significant victory, if it were found to be true in a clinical trial. Meanwhile, the only two randomized clinical trials studying the effect of plasma in treating covid-19 have been disappointing. Both showed no statistical benefit. *The FDA. 24 August 2020.* *—Joshua Lesko, MD*

Operation Warp Speed becomes more transparent, but questions still remain.

A pair of researchers involved in Operation Warp Speed (OWS) penned an editorial in the *New England Journal of Medicine* published yesterday, exposing some of the inner workings of government's groundbreaking push to create and distribute a vaccine to fight the SARS-CoV-2 infection responsible for covid-19. Initially announced on May 15, 2020, OWS was a new partnership created between the Department of Defense, Department of Health and Human Services, and the private sector, and the medical community has been clamoring for more details about its progress and goals. Leadership within OWS is drawing upon experience from working for many high-level health organizations such as the National Institutes of Health (NIH) and is taking a page out of the Zika and Ebola response playbooks, but with even more ambitious initiatives.

In the article, the authors describe concrete steps being taken by OWS to develop and deploy hundreds of millions of vaccine doses to the American public by the middle of 2021. They discuss the four types of vaccine platforms which have been chosen as the basis for the vaccine candidates currently being investigated and note that they were chosen not only for their ability to be rapidly developed and manufactured, but also because these methods of immunization are generally known to be safe and effective. To encourage broader chances of success, OWS also plans to support two vaccine candidates in each of the four categories and will further delineate which candidate will best serve various at-risk populations as more data is obtained and becomes available.

Many critics of OWS have raised concerns that the project might forego safety for the sake of speed. The authors attempt to allay these fears by describing the "harmonized end-points" across all Phase 3 trials, as well as the steps that have been taken to give those trials as much time to progress as possible. This includes extensive investment in the infrastructure required to produce and distribute a vaccine as quickly as possible, including building the physical plants, vials, and retaining the workforce necessary to manufacture the eventual vaccines even before any single candidate is approved by the Food and Drug Administration. This will allow vaccine production to occur as soon as possible once a candidate's safety and efficacy are determined. The authors also note that OWS will continue to monitor the long-term safety of any vaccines produced by the project using comprehensive surveillance strategies.

Despite this cursory look into the workings of this extensive and expensive endeavor, it is unlikely to answer all of the questions outside experts will have, not least of which will be expected costs of the vaccine candidates. Other questions remain surrounding regulations imposed on more traditionally developed pharmaceuticals such as how patent protections and exclusivities will be applied. *27 August 2020.* *—Jordan M. Warchol, MD, MPH*

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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.