Week in Review: 20-24 April 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Reopening drama continues. Last week, President Trump claimed that the decision to re-open our communities for business was a decision reserved for the federal government and his administration, not state governors. This came in contrast to the way shelter in place orders rolled out, which was state by state. A few days later, he backpedaled and acknowledged that the decision to re-open was in fact a state decision, and one that governors were empowered to make. Last week, more overt civil unrest over shelter in place orders began to materialize. First in Michigan, then in other states, citizens began to publicly demand that governments re-open communities for business. In response to these protests, President Trump issued a series of tweets advocating for governors to "Liberate Michigan" or "Liberate Minnesota." When Georgia Governor Brian Kemp announced earlier this week that Georgia would become one of the first states to re-open, many expected President Trump to be supportive. Afterall, Governor Kemp declared the decision came in response to Trump's Opening Up America Again plan, stating Georgia had met the Phase 1 criteria for reopening. However, on April 22, in an apparent about-face, President Trump announced that he "totally disagrees" with Governor Kemp's decision, and that it may be wiser to wait until Phase 2 before re-opening. *23 April 2020*.

–Kimi Chernoby, MD, JD, Policy Section Editor.

Reimbursement for uninsured care. The US Department of Health and Human Services (HHS) has announced more details on reimbursing healthcare providers treating patients without insurance for covid-19. Citing an undisclosed portion of the $100 billion Provider Relief Fund that was established as part of the CARES Act, providers will be able to directly bill to the federal government for reimbursement at Medicare rates. Registration for the program will begin on April 27 at coviduninsuredclaim.hrsa.gov and claims may be submitted in early May, "subject to available funding." *The Department of Health and Human Services. 24 April 2020.*

–Joshua Lesko, MD

New stimulus package by the numbers. On April 21, the US Senate voted to approve an additional $484 billion stimulus package to reinvigorate the Paycheck Protection Program (PPP) and provide additional funding for national testing programs. The initial $350 billion set aside for PPP in the second stimulus package was quickly claimed. This new bill allocates a further $310 billion to replenish the program. Of these funds, $60 billion has been reserved for under-banked and rural areas, $60 billion is directed to the Economic Injury Disaster Loan (EIDL) program, with up to $10 billion of the EIDL allocation available as grants. The package reserves an additional $75 billion to reimburse healthcare entities for expenses and losses associated with covid-19, and directs $25 billion to bolster national testing, with explicit instructions on distribution between federal and local entities. *US Senate. 22 April 2020.* *–Joshua Lesko, MD*

Changes in testing policy. The Laboratory Corporation of America (Labcorp) has become the first company permitted to provide at-home test kits for the coronavirus. In a statement this week, the Food and Drug Administration (FDA) reissued the Emergency Use Authorization (EUA) to permit the personal use of Labcorp's Pixel test. The first-of-its-kind allowance was granted after the test demonstrated equality of accuracy and safety at-home to that of in-office

testing. Labcorp has stated that the test will be made available in the coming weeks, initially for healthcare workers and first responders. A physician's order will be required. Collected samples will be shipped directly to Labcorp. Results will be viewable to patients through a secure portal online. Kits will not be available in Maryland, New Jersey, New York, and Rhode Island, due to state laws prohibiting such unmonitored testing. *Various. 24 April 2020.* *–Joshua Lesko, MD*

Was the Bright light snuffed out? In an update to prior news that the director of the federal government's Biomedical Advanced Research and Development Authority (BARDA) Rick Bright was pushed out of his job, the former official released a statement today stating that he believes he was removed from his post in response to his insistence that "science-- not politics or cronyism-- [had] to lead the way" in combating the SARS-CoV-2. Bright, who is an expert in vaccine development, specifically called out his hesitation around the administration's push of hydroxychloroquine and chloroquine as a central reason for his ouster. Reportedly, Bright became aware of the change only when he was locked out of his agency email account and his name was removed from the official BARDA website. He has called for an investigation into the Department of Health and Human Services' politicization of the work for which the agency is responsible. This includes medical countermeasures to pandemics and other health threats. Alternate reports have stated that Bright's move was over a year in the making. *Axios, Politico. 23 April 2020.* *–Jordan Warchol, MD, MPH.*

Emergency use authorization leaves quality by the wayside. One way that the Food and Drug Administration has been dealing with the covid-19 pandemic is by issuing emergency use authorizations (EUA) for different devices. Examples include ventilators, testing swabs, and antibody testing. An EUA allows a product to enter the marketplace without having to go through standard testing usually required of new products. The benefit is that new products get to market sooner. The downside is that scientists and researchers may not have not fully validated the accuracy or safety of these products. Over the course of the pandemic, the FDA has approved over ninety covid-19 antibody tests. Knowledge of people's immunity status against SARS-CoV-2 has been billed as essential to opening up the country. However, emerging evidence shows that these new antibody tests are variable and unreliable. It is unclear whether some or all of these tests would meet normal FDA guidelines. What is clear, though, is that re-opening the country based on inaccurate testing could prove very dangerous. *New York Times. 20 April 2020.*
–Kimi Chernoby, MD JD, Policy Section Editor.

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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.