Week in Review: 11-15 May 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Rapid SARS-CoV-2 test used by White House may miss half of cases. Throughout this pandemic, the FDA has issued a number of emergency use authorizations. One issue with EUAs is that products are not subject to the same testing as under normal approval processes, so accuracy is not guaranteed. A pre-print published on May 14 found that a rapid SARS-CoV-2 test that was approved under EUA failed to diagnose 48% of confirmed infections. That means for every two patients with the virus, approximately one would test negative. Perhaps the bigger issue with this finding is that this rapid test is the test being used by the White House to test employees and visitors. If these findings are confirmed, that would constitute a huge risk of virus transmission within the White House, especially since masking only became protocol within the last week after two staffers tested positive. This study is a pre-print which means the submission has not been accepted for publication yet. *CNBC. 15 May 2020. –Kimi Chernoby, MD, JD Policy Section Editor*

Details of Operation Warp Speed Concern Scientists. The White House is expected to announce details about its project Operation Warp Speed, its effort to rapidly develop and deploy a coronavirus vaccine. In the meantime, a government official shared details with *Science*. The program has three teams, focused on development, supply and manufacturing, and distribution. The development team will winnow the more than 100 different candidates to the most likely 8, with the hope of starting human trials in July while simultaneously conducting large-scale animal safety reviews. At the same time, the supply and manufacturing group will lay the groundwork to enable large scale production of up to 4 different vaccines. Experts expressed concern about several aspects of the program, from its goal to produce 100 million doses by November and 300 million total by January, a target many said was unrealistic, to the decision to exclude any vaccine candidates from China and to focus on producing vaccines for Americans first. Some experts said even the program's name was problematic, as it might undermine confidence in the safety of vaccines ultimately produced. *Science. 14 May 2020.* *–Joshua Lesko, MD*

Senate hearing paints dark picture of the coming months. The Senate Committee on Health, Education, Labor, and Pensions hearing on May 14 on safely getting back to work and school ironically took place largely over video. Chairman Lamar Alexander announced that he had decided to remain under self-quarantine instead of returning to Washington this week after a member of his staff tested positive for SARS-CoV-2. Three of the key witnesses—CDC director Dr. Robert Redfield, FDA Commissioner, Dr. Stephen Hahn, and Dr. Anthony Fauci, the federal government's top infectious-disease experts—are also self-quarantining. Together, the doctors painted a picture of the next few months that was much darker than that portrayed by President Trump. They expressed concern about the lack of adequate testing, a proven therapy, or vaccine, and described the country's public health infrastructure as needing major investment. Dr. Fauci said that a vaccine would almost certainly not be ready by the start of the new school year. *New York Times. 13 May 2020.* *–Jordan M. Warchol, MD, MPH*

Rural hospitals sue for support. Hospitals across the country have been losing millions of dollars every week due largely to cancelled elective procedures and closed clinics. The Small

Business Administration (SBA) Paycheck Protection Program (PPP), part of the CARES Act, sought to mitigate the effect of this lost income, but under the PPP, bankrupt entities cannot receive loans due to their high risk of failure. Now some bankrupt rural hospitals, for whom the pandemic's toll came on top of years of financial hardship, are suing the SBA over being denied the funding. Judges in Maine and Vermont have recently ruled in favor of the hospitals, but lengthy legal proceedings may outlast the finite funding. *Various. 12 May 2020.*

Looking inside the Democrats' Proposed New Relief Package. On Tuesday, House Speaker Nancy Pelosi introduced HR6800, known as "The Heroes Act," a $3 trillion bill that would represent a fifth round of economic stimulus. Here are the major elements of this 1800-page package: *Healthcare*: $100 billion to the Provider Relief Fund and a new formula to determine allocation of grants; reinstituting of the Advance Payment Program with a lower interest rate; creation of The Heroes' Fund, a grant program for frontline healthcare workers to receive hazard pay; new requirements for nursing facilities to provide residents with reasonable access to telephone and internet services, delineation of the process to be designated a covid-19 treatment center, the disclosures required, and the ability to transfer residents not eligible for such specific care; *Public Health:* increased regulation of the contents and quality of the National Stockpile; process to ensure supply chain integrity; increased funding for the Medical Reserve Corps; establishment of a research network. *Insurance:* increased Medicaid funding; broader access to Affordable Care Act plans; waivers of co-pays for coronavirus-associated medical expenses; subsidies to cover COBRA premiums for newly-unemployed; *Small Business Administration:* $10 billion for the Economic Injury Disaster Loan program; granular definitions of qualified businesses for the Paycheck Protection Program. *Local Support:* $75 billion for contact tracing and testing; $1 trillion in funding to state and local governments. In addition, package would: extend the $600 weekly federal unemployment supplement through January 2021 (currently it is set to expire in July); extend all expiring visas until ninety days after cessation of the public health emergency; increase protections against foreclosure and eviction proceedings; invest $175 billion in housing assistance, and increase food program funding. *The House of Representatives. Abbreviated from Brief19 for 14 May 2020.* *–Joshua Lesko, MD*

More than just the medication. Concerns are rising that producing drugs and vaccines against SARS-CoV-2 may be more difficult than discovering them. Specific regulations governing production, transportation, and storage can cause delays. It is unclear what modifications, if any, the FDA will make to its guidance. For example, the glass used to make vaccine bottles is already in shortage, though a coronavirus vaccine does not yet exist. Production of drugs themselves is also presenting challenges. Although the FDA granted an EUA for remdesivir, its manufacturer has had to find ways to produce the complex drug quickly. The global economic crisis poses problems, since many drugmakers rely on a vast network of partners to produce a drug. *Various. 12 May 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.