BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

FDA cracks down on fraudulent coronavirus cures.

Wherever there is fear or uncertainty, unscrupulous individuals will seek to profit. The covid-19 pandemic is no exception. In response to this, the US Food and Drug Administration (FDA) maintains an up-to-date list of products on its website that fraudulently claim to prevent, treat, mitigate, diagnose or cure the disease. Reassuringly, a total of 146 products had been listed since last March, and as of this writing, only seven are still on the market.

The FDA has the authority to intercede when patients are at risk, using a range of options from warning letters, product seizures, injunctions, or even criminal prosecution depending on the degree of dereliction.

The site also includes a link that enables members of the general public to report any suspicious or concerning products that may not have yet caught the agency's attention. The long and short of it is that if a product makes claims that are too good to be true, they likely are. That's also why when the FDA has granted emergency authorization to medications for which the evidence is slim-to-none, such decisions undermine other more well-considered guidance. It's no wonder that the public does not always know what to make of many recommendations from the FDA. Similar problems have mounted in other areas of the US federal government. While the new administration has said it is committed to science over politics, regaining public confidence will not happen overnight. *19 February 2021*.

—Brief19 Policy Team

Will Texas storm cause a covid-19 spike?

In the wake of the winter storm that plowed through Texas, power outages have plagued the state. An unexpected consequence is that Texas could now be facing another covid-19 spike resulting. With hundreds of thousands losing heat and electricity, many Texans have flocked to crowded hotels and shelters, or have been forced to seek heat and shelter in the homes of friends and relatives that still have power.

Conditions favoring spread of SARS-CoV-2 are only worsening. Grocery store lines are longer than ever. Many hotels are full—with reported instances of price gouging given the growing demand, driving people into increasingly crowded conditions. It is unlikely that physical distancing can be reasonably maintained amid these crowded conditions, making it a matter of time before the risk of viral transmission rises to dangerous levels. Moreover, Texas has pushed back against mask mandates and physical distancing measures despite the gravity of the covid-19 pandemic, which means a surge now stands to be all that much worse.

This deteriorating situation clearly has far reaching implications, and Texas' leaders have not taken effective action—more inclined to blame the situation on the Green New Deal (which has yet to be implemented) than enacting policies that could actually help the immediate situation. To make matters worse, the delivery of hundreds of thousands of vaccines will be delayed by the storm.

The Texas crisis is just the latest example of our country's need to invest in infrastructure, disaster preparedness, and to take climate change seriously. Preventing emergencies like this takes foresight, time, and effort. But once they've occurred, gaining immediate control of the consequences becomes impossible. *18 February 2021*.

—Miranda Yaver, PhD

CDC releases guidance on opening schools.

On Friday the US Centers for Disease Control and Prevention (CDC) released updated guidelines on school reopenings. The opening statements stress the importance of these decisions being made on a local level, using community transmission information. A companion Operational Strategy for K-12

Schools through Phased Mitigation outlines the essential elements for safe in-person teaching—strategies to reduce transmission using community transmission indicators, and changes to instructional and testing modalities intended to limit SARS-CoV-2 spread. This strategy also addresses the inherent concerns of continued remote education and potential health inequities that this alternative use has created or worsened.

These community indicators serve as a modification to the Dynamic School Decision Making indicators, using new epidemiologic data and simplifying the criteria to create new risk-based thresholds hinging on total new cases per 100,000 people and the percentage of positive tests over the previous week (see the Table below).

Over the past several days, criticism of the CDC's new guideline has come from all sides, despite the fact that it provides far more evidence-based policy than previous statements on the topic from the agency. One on extreme, some feel that any opening of schools before all teachers have been vaccinated is too soon. On the other end of the spectrum, some point to the fact that even in areas of high transmission, schools have not been shown to be drivers of community spread. These observers also note that the standards put forth by the CDC imply that school is unlikely to open for the remainder of the year, which they see as untenable. *The Centers for Disease Control and Prevention*.

Indicator	Lowest Transmission	Low Transmission Blue	Moderate Transmission Yellow	Substantial Transmission Orange	High Transmission Red
Total new cases per 100,000 persons in the past 7 days**	Category no longer exists. It has been merged into one low transmission (blue) category.	0-9	10-49	50-99	≥100
Percentage of NAATs that are positive in the past 7 days***		<5.0%	5.0%-7.9%	8.0%-9.9%	≥10.0%

Note: NAAT is an abbreviation for nucleic acid amplification test, and refers to tests that search for the genetic material of a micrbobe—in this case SARS-CoV-2. *15 February 2021*. *—Brief19 Policy Team*

Polar vortex storms delay vaccine distribution.

Although Tuesday the Biden team announced an increase in covid-19 vaccine distribution week over week by 23 percent, shipments for this week have been significantly delayed by winter storms affecting major hubs.

A polar vortex has swept the middle of the country from Minnesota down through Texas with sub-zero temperatures, resulting in dangerous conditions at FedEx warehouses which ship the vaccine in Memphis and Louisville. The US Centers for Disease Control and Prevention is working with federal and local agencies as well as private industry to attempt to minimize the delays in vaccine distribution. Many of the areas affected by the winter storms have also had to cancel vaccine clinics due to hazardous weather conditions. It is not yet clear how long the delays are expected to continue but it comes at a time when case counts have finally begun to drop to levels now seen since October. *17 February 2021*.

—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.