

## **BRIEF19**

*A daily review of covid-19 research and policy.*

### **POLICY BRIEFING**

#### **Biden administration moves to financially incentive vaccination.**

One of the difficulties in reaching herd immunity via vaccination is finding the motivation to do so. Tying vaccination to freedom of movement can [exacerbate](#) societal divisions, especially given that not everyone has equal access. On the other hand, healthcare employers [mandating](#) vaccination makes sense, given that patients expect to be protected when seeking medical care. But broader adoption of mandates seems unlikely, at least in the United States. The Biden Administration has instead [launched](#) a variety of societal programs aimed at outreach and fighting vaccine hesitancy and nudging those considering vaccination (i.e. “the movable middle”) in the right direction.

Now the administration has decided to wade into financial incentivization. Aimed at small businesses, a new [initiative](#) is a tax credit to cover sick leave for vaccination and potential days off from vaccine side effects. All businesses with fewer than five hundred employees are eligible. The effort is [funded](#) by the [American Rescue Plan](#), the \$1.9 trillion stimulus package passed last month, and is meant to lower or remove yet another barrier for vaccine holdouts. In his announcement of the program, President Biden encouraged large businesses to provide similar benefits and education to their employees. *Various. 23 April 2021.*

—*Brief19 Policy Team*

#### **FDA finds unsanitary conditions at Emergent BioSolutions plant, a Johnson & Johnson vaccine production site.**

This week, the US Food and Drug Administration said that a Baltimore plant run by Emergent BioSolutions, which ruined millions of Johnson & Johnson covid-19 vaccine doses, maintained conditions that were unsanitary and unsuitable for manufacturing. The FDA had asked Emergent BioSolutions to temporarily stop producing materials for covid-19 vaccines earlier this month after the agency initiated an inspection of the plant. FDA investigators found that the firm had “failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross-contamination of bulk drug substances.” In its 13-page report, the FDA cited the plant for having “peeling paint” and black and brown residue on the walls that could affect the plant’s “ability to adequately clean and disinfect.” The report noted that the facility was “not maintained in a clean and sanitary condition [and] was not of suitable size, design and location to facilitate cleaning, maintenance and proper operations.”

The FDA, which inspected the plant over the course of eight days, said that it would work with Emergent BioSolutions to address the findings from the inspection. Production of Johnson & Johnson’s vaccine at the Emergent plant has been paused, and the FDA has said that it “will not allow the release of any product until we feel confident that it meets our expectations for quality.” Emergent said it was committed to working with the FDA and Johnson & Johnson to fix the problems identified, saying, “while we are never satisfied to see shortcomings in our manufacturing facilities or process, they are correctable and we will take swift action to remedy them.”

A Congressional investigation is now underway to determine how this Baltimore drug manufacturer won the federal contract to produce the Johnson & Johnson vaccine in the United States. On April 19, Representatives Carolyn Maloney and James Clyburn sent a letter to the top

executives of Emergent BioSolutions, Inc. to launch an investigation into whether Emergent leveraged its relationship with the Trump Administration to profit from federal contracts despite a track record of raising prices and failing to meet contract requirements, and whether these actions impeded the nation's response to the coronavirus pandemic. [22 April 2021](#).

—Miranda Yaver, PhD

### **Coverage from above for coronavirus vaccines.**

Surprise billing has long been a pain point for patients. Surprise billing occurs when a patient's insurance does not pay for the full cost of a medical therapy that was seemingly "covered" by the plan, and the remainder of the balance charged by the healthcare provider is billed to patient directly. The CARES Act forbade collection of expenses incurred relating to the coronavirus, with the caveat that the patient must have had a positive screening test, a loophole [used](#) by insurance companies. If a patient have all the signs of covid-19, but never got a positive test (which was not uncommon early in the pandemic before widespread testing became available), insurance companies could throw surprise bills at patients without recourse. The Trump administration previously [announced](#) an initiative to address this problem but never provided a resolution process for violation complaints.

This week the US Department of Health and Human Services (HHS) sought to [address](#) another aspect of surprise billing: vaccination. According to the memo, as a result of all vaccines currently being distributed in the United States falling under the auspices of the US Centers for Disease Control and Prevention (CDC)'s COVID-19 Vaccination Program, no office visit or additional fees may be charged to patients if the sole intent of the interaction was vaccination. Despite this, the HHS Office of the Inspector General (OIG) acknowledged multiple complaints of just such instances occurring. Unfortunately, this requirement only applies to Medicare, Medicaid, the Health Resources and Services Administration's (HRSA's) COVID-19 Uninsured Program, and insurance plans funded by the Affordable Care Act. Similarly, while providers cannot bill a patient directly, they can bill third-party payers for administrative fees that may then ultimately be charged to the patient.

Both the Trump and Biden administrations stated that US residents should pay out-of-pocket to be vaccinated or receive care for covid-19 illnesses. The Biden administration is now working to close the gaps between theory and reality, as they become apparent. *Various*. [21 April 2021](#).

—Brief19 Policy Team

### **US Centers for Disease Control and Prevention investigating breakthrough infections.**

We have known since data from the various vaccine trials were released that very few people would develop severe covid-19 illnesses but that some people would still become infected with asymptomatic or mild cases of SARS-CoV-2, despite vaccination. The question was: just how effective are the vaccines in preventing all infection. This was not measured in any of the major trials, as it would have required serial testing of tens of thousands of test subjects for weeks and months.

A few months into the vaccination campaign, we can take a look at [the numbers](#) (as of April 13th, according to the US Centers for Disease Control and Prevention's). Data on "breakthrough infections," (i.e. individuals who tested positive for SARS-CoV-2 after completing a vaccination regimen), are accumulating. Here are the facts:

- At least 75 million individuals in the United States have been fully vaccinated.
- There have been 5,814 reported cases of breakthrough infections.
- 2,622 (45 percent) were age 60 or older.

- 3,752 (65 percent) were female.
- 1,695 (29 percent) were asymptomatic cases. These cases were picked up in situations such as required testing prior to elective medical procedures or other required testing.
- 396 (7 percent) were hospitalized and 74 (1.3 percent) died (note: individuals hospitalized for reasons other than covid-19 were still counted as breakthrough cases if they were fully vaccinated and later tested positive; around 12 percent of the “covid-19” deaths were actually considered not related to covid-19. However, out of caution, those numbers were included in the statistics).

What is the takeaway? First, it is important to know that the vaccines are not 100 percent effective; breakthrough cases were always seen as a likely scenario. What is less certain, however, is how accurate these numbers are in reflecting larger trends, as these data are reliant on voluntary reporting from state health departments, and without serial universal screening, asymptomatic breakthrough cases are especially likely to be undercounted. This means that the number of asymptomatic or mild cases is likely far higher. That’s actually “ok” in a sense. If the vaccines mean that people who get infected with SARS-CoV-2 do not even notice it, we can assume that the vaccines are doing their job—which is to keep people from experiencing substantial illness, disability, or death. On the other hand, a higher number of breakthrough infections also begs the frequently asked question: are vaccinated people with breakthrough infections contagious? That remains unknown. This major unknown is why the CDC has maintained guidance that essentially says that vaccinated people can get together with relatively few restrictions, while vaccinated and unvaccinated persons still need to be more careful.

For its part, the CDC continues to emphasize that the vaccines are still largely effective and that everyone who is eligible should get vaccinated at their earliest opportunity. Because breakthrough cases can happen, it is also important to maintain physical distancing and masking policies, especially around unvaccinated and incompletely vaccinated individuals, until the data supports a universal relaxation in protective measures. *The Centers for Disease Control and Prevention*. [19 April 2021](#).

—Brief19 Policy Team

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

*Kane Elfman PhD, Publishing and design.*

*Anna Fang, Week in Review.*

*Jeremy Samuel Faust MD MS, Editor-in-Chief.*

<http://www.brief19.com/>

Twitter: [@brief\\_19](#)

[submissions@brief19.com](mailto:submissions@brief19.com)

*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.