Week in Review: 3 – 7 May 2021

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Biden administration in favor of loosening patent protections for coronavirus vaccines.

In a reversal of decades of American policy positions, earlier this week the Biden administration said it now favors loosening intellectual property protections on covid-19 vaccines in an effort to speed the end of the pandemic. Pressure had been mounting on the United States and other advanced economies to share the knowledge and supplies for creating these vaccines in order to help other nations that continue to struggle with vaccinating their populations. Recent surges in cases in countries such as India and South Africa could have been prevented, or at least the effects lessened, if vaccine rollouts in those nations had been further along before the outbreaks occurred.

The decision came with mixed reviews from other world leaders. Chancellor Angela Merkel of Germany expressed significant concern regarding the relaxation of these IP rights, which are held by companies and in most instances honored internationally. However, officials from other regional partners, including in Italy and Australia, praised the move. Others commented that patent protections are not the most pressing hurdle being faced with respect to mass production and distribution of vaccines throughout the world.

Significant challenges remain in many countries, regardless of the Biden policy. Existing infrastructure will not suffice in most areas. That means finding or developing the infrastructure necessary to produce vaccines (*e.g.* standing up manufacturing facilities capable of the sophisticated processes required to make the physical product) is a priority. In addition, supply chain issues and shortages of raw ingredients owing to the pandemic have also made manufacturing considerably more difficult across the world. Meetings of the World Trade Organization are ongoing to further discuss the patent easing proposals, and these surrounding issues. *Various. 7 May 2021*.

—Jordan M. Warchol, MD, MPH

US Food and Drug Administration set to expand Pfizer/BioNtech vaccine to adolescents ages 12-15.

As the US approaches 250 million doses of coronavirus vaccines administered to nearly 150 million residents (over 44 percent of all residents and nearly 83 percent of adults 65 years and older), the US Food and Drug Administration is about to expand the pool of available recipients. It is reported that an Emergency Use Authorization may come next week that would open the vaccine to 12 to 15-year old persons.

The reports come at a time when vaccine equity is being discussed widely. While immunizing children is seen as an important step in reaching herd immunity (so that new variants do not emerge that breakthrough vaccines), the reality is that there are literally billions of adults around the world who do not yet have access.

The Biden administration, the WHO, and the vaccine companies itself are working to increase access. The Trump administration's America First approach did not provide a running start. But changing priorities now does not mean that vaccines can suddenly be delivered magically. As we have learned, both the Pfizer/BioNtech and Moderna vaccines require extremely cold storage. The chain of delivery therefore presents one logistical problem and storage once the vaccines once they have reached their destination is another. Some of these problems will be solved in an *ad hoc* manner. But as ever, this pandemic has revealed the inequities in health delivery systems both in the US and around the world. *4 May 2021*.

—Jeremy Samuel Faust, MD MS

New goal set for US vaccinations: 70 percent by the Fourth of July.

Nothing would say freedom like herd immunity. With that in mind, President Biden today announced a new goal for the country. By Independence Day (July 4), he wants 70 percent of the total population vaccinated. While it is unclear whether this would constitute "herd immunity," it certainly would represent progress towards it.

To achieve this, 100 million more shots will need to be administered in just 60 days. This comes as daily vaccine rates have declined from their zenith in early April (the peak was April 1st, when 4.2 million doses were given; the latest 7-day average is approximately 2.45 million).

The number of available doses is no longer seen as the bottleneck. Now it's about access and interest. To address that, President Biden says that the administration will work to increase the number of pharmacies that can vaccinate the communities they serve and to send doses to pediatricians. The latter is key as vaccine eligibility extends to younger and younger Americans. Many parents will seek the counsel of trusted pediatricians. Giving doses to these frontline doctors directly will be key then, as some parents who were willing to go to mass vaccination sites might not feel as confident about doing the same with their kids.

Making the process of finding places that vaccinate has also become a priority. People on US soil can now text "438829" (GetVax) to get and toll-free number to call or a link to Vaccines.gov, a new website that helps people find a place to get their shot. *5 May 2021*.

—Jeremy Samuel Faust, MD MS

Eli Lilly facing staff complaints at its drug manufacturing sites.

In the haste to beat back the ever-advancing covid-19 pandemic over the past year, scientists, researchers, and pharmaceutical companies have had to work at breakneck speed—occasionally to the detriment of quality. Examples of this came in the form of at least some less-than-high-quality journal articles, and some questionable manufacturing practices at the one of the facilities making the Johnson & Johnson vaccine. Now, Eli Lilly seems to be facing some similar challenges with respect to quality control.

According to employees at the company, a factory executive in Branchburg, New Jersey may have altered government-required documents in order to downplay quality control problems at the plant where Lilly's monoclonal antibody treatment, bamlanivimab, was being manufactured. Per *Reuters*, the internal complaint from early April asserts that the executive rewrote findings by Lilly's technical experts at the plant to make more favorable conclusions, which were then shared with the US Food and Drug Administration (FDA) as part of its investigation of the site.

The complaint was filed by more than 10 employees, including managers, who claimed they saw the findings before and after they were allegedly edited to paint a rosier view. A Lilly spokesman confirmed the employees' complaint and said that the company takes all reports of improper or inappropriate conduct seriously.

Separately in March, FDA inspectors identified numerous manufacturing lapses at another Lilly facility, in Indianapolis, with respect to substandard sanitation and quality control procedures of bottles of its covid-19 therapy and other drugs. The troubles at these factories, in addition to numerous internal complaints in recent years, deepen the challenges facing one of the nation's largest drug producers. *6 May 2021*.

—Miranda Yaver, PhD

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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.