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# COVID-19 Update

## *A Look at the Numbers*

As of April 1, 2021, the Centers for Disease Control and Prevention (CDC) estimate that more than 548,000 deaths have been attributed to the COVID-19 virus with an estimated 30.2 million confirmed positive cases since the start of the pandemic.<sup>1</sup>

Although more than a hundred years have passed since the world experienced its more severe pandemic in recent history, the COVID-19 pandemic has reignited discussions over the preparedness of world powers in containing and ultimately mitigating infectious outbreaks that threaten humans around the world.

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<sup>1</sup>United States COVID-19 Cases and Deaths by State. Centers for Disease Control and Prevention. Accessed April 1, 2021. [https://covid.cdc.gov/covid-data-tracker/#cases\\_casesper100klast7days](https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days)

<sup>2</sup>Federal Food, Drug, and Cosmetic Act (FD&C Act). United States Food and Drug Administration. Accessed April 1, 2021. <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>

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## FDA Authorization and Approvals

### *Understanding the Background*

Despite these sobering statistics, future generations will likely judge the world's response by focusing on the tremendous efforts that have been made to curtail the continued spread of the potentially deadly virus.

Since December 2020, the United State Food and Drug Administration (FDA) has provided Emergency Use Authorizations (EUA) to both Pfizer/BioNTech and Moderna in a preventative approach to allow their respective mRNA-based vaccines to enter the market. Although not the same as an official FDA approval and born out of section 564 of the Federal Food, Drug, and Cosmetic Act<sup>2</sup> (FD&C Act), the Emergency Use Authorization authority grants the FDA Commissioner with the ability to allow unapproved medications onto the market to serve a significant healthcare need in the absence of FDA approved alternatives.

# 548k

### *Deaths Attributed to COVID-19 Virus*

As of April 1, 2021

# 30.2m

### *Confirmed Positive Cases Since Start*

As of April 1, 2021

# Vaccine Concerns and Manufacturer Contributions

## *Vaccine Distribution*

The introduction of these vaccines has not been without their fair share of concern, however. Product specific storage requirements and concerns regarding the need for a second dose have exposed potential pitfalls in the United States distribution plan for these vaccines.

To date, Pfizer/BioNTech have supplied the United States with roughly 200 million vaccine doses with over a billion doses total projected by the end of 2021; Moderna expects an output of 100 million additional doses by this summer. Several additional manufacturers (e.g. Janssen, AstraZeneca, Sanofi/GSK, etc.) currently have their vaccine candidates in phase 3 clinical trials with the goal of formal FDA approval during the 2021 calendar year. Many of these manufacturers have already secured contracts with the federal government to supply hundreds of millions of doses if approved.

**200m** *Vaccines  
Provided by  
Pfizer/BioNTech*

**1b+** *Total Doses Projected  
for Distribution  
by the End of 2021*

**100m** *Additional  
Moderna Doses  
by Summer 2021*

## Healthcare Community Takes Action

### *What to Expect Moving Forward*

From a treatment perspective, the FDA has similarly granted Emergency Use Authorizations to several monoclonal antibodies (e.g. bamlanivimab, LY-CoV555; Lilly) to assist in the treatment of active COVID-19 infections in patients who would likely to progress to more severe disease or require hospitalization.

Coupled with continued approval of COVID-19 testing, and a line of additional vaccine manufacturers eminently waiting for EUAs, the world has taken an “all hands on deck” approach to slow down the spread of the virus and virus-related deaths.

As a healthcare community, we are still in the learning phase of exactly how the 2019 SARS-CoV-2 virus affects the human body from a long-term perspective. Anecdotal accounts from around the world have taught us to expect the unexpected with this pandemic; it may be years before we know its full effect.

Despite these facts and as new details emerge, it is important that health systems remain nimble to ensure that every possible attempt to save human lives is carried out. The coming months will help us better understand if our efforts have been successful and hopefully prepare us a global community in preventing future outbreaks.