

**Auto Casualty** 

# Drug of the Month: Insights Into COVID-19 Vaccines and Workers' Comp

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COVID-19 vaccination efforts continue to progress, after the <a href="Emergency Use Authorization (EUA)">Emergency Use Authorization (EUA)</a> of two COVID-19 vaccines by the Food and Drug Administration (FDA) in late 2020. In late February 2021, a <a href="third">third</a> vaccine was given approval to begin distribution. As the U.S. works to distribute these vaccines and restore normalcy to everyday life, what key information do you need to know? This Drug of the Month article will cover the following:

- Overview of the three COVID-19 vaccines authorized for use and distribution as of early 2021.
- How these vaccines work.
- The potential impact of the COVID-19 vaccines on the workers' compensation industry.

#### Overview of the COVID-19 Vaccines and How They Work

The first two SARS CoV2 vaccines authorized for use and distributed in the U.S. are also the first vaccine products of a new, synthetic messenger RNA (mRNA) production technology. Pfizer-BioNTech and Moderna vaccines, FDA authorized in mid-December 2020 and shipping for first use, are both products of this technology. Researchers in the early 1990's first discovered that mRNA, which carries coded instructions for making proteins in cells, might be used to carry programmed instruction for the production of specific proteins into human cells and create those "in vivo", or in the body. The mRNA vaccine, encoded for production of the SARS CoV2 spike protein, enters a cell which then produces and releases the spike protein, prompting host immune system recognition and mobilization of an immune response. The vaccinated individual is then protected from next encounters with the SARS CoV2 virus in the "wild", by immune recognition of the identifying spike protein. Because mRNA is easily degraded in the body before it enters the cell, developers built a carrier, called a lipid nanoparticle, which shields the mRNA and carries it "safely" across the cell wall. The progress of early research and speed with which mRNA can be produced have both contributed to the accelerated development timeline and deployment of the much needed, first synthetic mRNA vaccines. Influenza, pneumonia, smallpox, shingles and most other legacy vaccines are produced as live attenuated,

inactivated, subunit or toxoid vaccine types. Several additional SARS CoV2 vaccines in development (from Astra Zeneca/Oxford and Janssen) will be live-attenuated vaccines, more like legacy vaccines for other infectious illnesses than the newer mRNA types. The safety and effectiveness of both new synthetic mRNA vaccines were evaluated by independent expert panels advising the FDA on their requests for emergency use authorization in mid-December 2020. Interim data from near complete (phase 3) clinical trials of Pfizer-BioNTech and Moderna vaccines indicated effectiveness in preventing COVID-19, in persons 18 years of age or older, of around 95%. Observed adverse events and side effects were similar to that of other viral vaccines. The Pfizer-BioNTech and Moderna vaccines each require two doses (21 and 28 days apart, respectively) to provide targeted immunity. Both manufacturers are projecting an additional 100 million doses to deliver by the close of Quarter 1, 2021, and these are expected to be joined by other vaccines approaching the FDA to request authorization. The Center for Disease Control and Prevention (CDC) has published a set of recommendations to lead states and municipalities in their prioritization of vaccine administrations. The CDC recommends that initial supplies of COVID-19 vaccine (Phase 1a) be allocated to healthcare personnel and long-term care facility residents. Experts advising the CDC have also described additional cautions related to vaccinating the following groups:

- Pregnant and lactating persons.
- Persons with allergies.
- Children and young teens (below age 16).
- Persons with HIV.
- Persons taking immunosuppressant therapy.
- Persons who have recently received or plan to soon receive another vaccination.

The rapid development and market arrival of synthetic mRNA vaccines in December 2020, followed closely by others early this year, offers some much-awaited promise for relief from the continuing pressures of the COVID-19 pandemic in the U.S. How well the progress of scaled-up manufacture, targeted distribution, priority allocations and actual vaccinations is executed will be an important feature in stemming the spread of illness.

## Johnson & Johnson Vaccine Overview

The most recent COVID-19 vaccine approved for use differs from the first two vaccines in several ways. <u>Developed by Johnson & Johnson</u> (J&J), the vaccine follows legacy technology, using a "viral vector". This is similar to how the influenza and a number of other vaccines work. The J&J vaccine has a few advantages over the mRNA vaccines:

- Requires only one injection versus two, eliminating some logistical issues relating to second doses and potential for "incomplete" target immunity.
- Has less stringent cold chain storage requirements, allowing for conventional refrigeration versus the ultracold storage needed for Moderna and Pfizer vaccines and simplifying distribution needs.

The J&J vaccine has a lower demonstrated effectiveness against SARS-COV2 and emerging strains than the Moderna or Pfizer vaccines. The FDA states, "the vaccine was approximately 67% effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days after vaccination and 66% effective in preventing moderate to severe/critical COVID-19 occurring at least 28 days after vaccination." However, the vaccine appears to be more effective in preventing severe disease, showing "77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination. The expert panel shows no serious safety concerns and mild side effects from the J&J vaccine, including pain at the injection site, headache and fatigue.

With an additional vaccine approved, distribution and inoculation efforts should continue to ramp up. We will continue to monitor the approval of these vaccines and potential additional approvals as they occur.

### **COVID-19 Vaccines: Potential Impact on Workers' Compensation**

How might the approval of the COVID-19 vaccines affect the workers' compensation industry? As of now, the true impact is unknown. However, there may be specific instances to take into account and future considerations to make. While vaccines are not routinely covered in workers compensation benefits, there may be specific exceptions, such as healthcare employers, where the risk of infections in workplace settings might be greater and they opt to include vaccine coverage. Other considerations for the workers' compensation industry include:

- Wider vaccination coverage—who pays?
- Whether companies can/should mandate the COVID-19 vaccine or treat it like the flu shot with incentives.
  - Considerations about how to know if a worker is vaccinated (and how to follow HIPAA guidelines).
- Post-vaccination return to work strategies, including providing a safe and healthy work environment if a vaccine is not mandated, and workers returning to the office after a prolonged work from home period.
- ADA considerations—if a person cannot get the vaccine, are they required to work from home?
- Worker vaccination opt-out strategies.
  - Will COVID still be covered by workers' comp if a worker opts out of receiving the vaccine?
- Long-term vaccination policies and plans.
  - Federal, state, and local regulations such as OSHA.
  - o Civil liability risks for the business.

As vaccine development, distribution and education continues to change rapidly, we will attempt to keep you updated on any new developments. For breaking updates, visit our COVID-19 updates channel on Mitchell.com.



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