

NEWS BRIEF

Provided by: Hodge, Hart & Schleifer

FDA Issues Emergency Use Authorization for Johnson & Johnson COVID-19 Vaccine

The U.S. Food and Drug Administration (FDA) recently [issued](#) an Emergency Use Authorization (EUA) for Johnson & Johnson's COVID-19 vaccine to be distributed in the United States for use by individuals 18 years of age and older.

This authorization follows a recommendation from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) to issue a EUA for the vaccine, and confirms that Americans will have access to a third effective coronavirus vaccine that will allow states to increase distribution.

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"The authorization of this vaccine expands the availability of vaccines, the best medical prevention method for COVID-19, to help us in the fight against this pandemic, which has claimed over half a million lives in the United States."

- *Acting FDA Commissioner Dr. Janet Woodcock*

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According to the FDA, the effectiveness data to support its EUA includes an analysis of participants who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. This ongoing study is being conducted in South Africa, certain countries in South America, Mexico and the United States. Overall, the vaccine was found to be approximately

67% effective in preventing moderate to severe COVID-19 cases occurring at least 14 days after vaccination and 85% effective in preventing moderate to severe COVID-19 cases occurring at least 28 days after vaccination. Additionally, the FDA has not identified any specific safety concerns, and the agency says the vaccine meets its rigorous standards for safety.

Overview of the Johnson & Johnson COVID-19 Vaccine

The Johnson & Johnson COVID-19 vaccine was developed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson, and importantly, requires only one dose, as opposed to the Moderna and Pfizer-BioNTech vaccines which require two doses. The vaccine can also be stored at standard refrigeration temperatures for at least three months, while other vaccines approved for emergency use have stricter refrigeration and storage requirements.

Next Steps

There are around 4 million doses of this vaccine ready to be distributed, and shipments of the vaccine are set to begin immediately. Distribution of the vaccine could begin as soon as Tuesday, March 2. Johnson & Johnson plans on providing up to 20 million shots in the next month and 100 million over the summer.

Employers should continue to monitor updates from local officials for vaccine availability. Hodge, Hart & Schleifer will keep you updated on any noteworthy developments.

