

## J&J COVID-19 Vaccine - ACIP Recommends Continued Use

- On April 23, 2021, the <u>CDC's Advisory Committee on Immunization Practices (ACIP) convened an emergency meeting</u> to reassess the risk benefit profile of the Johnson & Johnson (J&J) coronavirus vaccine.
- After reviewing the current data, hearing from J&J, and deliberating on different options, they
  decided to reaffirm their original recommendations for the vaccine for ages and genders. The
  recommendation is:
  - The Janssen (J&J) COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.
- There were 10 votes in favor to 4 votes against and 1 abstaining (due to conflict of interest).
   Dissenting members were in favor of an alternative option that specifically described the risk of clotting in women age < 50 years and that they may choose an alternative. After considerable discussion the ACIP felt that the recommendation should be clear, simple, and unambiguous to facilitate communication and implementation.</p>
- The J&J COVID-19 vaccine will remain on the U.S. Market
- Additional risk information will be added to the J&J vaccine label in the form of a boxed warning, and
  the patient fact sheet will include new language advising of the risk of blood clots in women less than
  50 years old.
- Additional communications are expected from the FDA and CDC early next week, including updated clinical considerations for use which will describe the risks in more detail.
- To date, <u>7.98 million doses</u> of the J&J vaccine have been administered and 15 cases of an atypical
  clotting event (thrombosis and thrombocytopenia syndrome) have been detected. No cases have
  been detected with the mRNA vaccines from Pfizer/BioNTech and Moderna.



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