



U.S. FDA Backs J@J COVID-19 Vaccine Boosters



On Friday, 15 October, a U.S. FDA advisory committee unanimously recommended that all adults that received the Johnson & Johnson (J&J) COVID-19 vaccine get a booster shot at least two months after their first shot. J&J now joins Pfizer and Moderna in gaining an FDA recommendation for a booster.

Unlike the Pfizer and Moderna recommendations which only cover vulnerable groups, the FDA advisory committee advocates that all adult J&J recipients receive the booster. J&J said receiving the booster dose two months after initial vaccination increases protection but also that receiving it six months after may work better. The committee cited growing evidence that J&J recipients are less protected than Pfizer or Moderna recipients, and that COVID-19 protection wanes with time: many J&J recipient were vaccinated months ago. Much of the discussion centred on whether the J&J vaccine should even be considered as a single dose vaccine given its lower protection efficacy when compared to the Pfizer and Moderna vaccines. Others complained about the low number of trial participants in J&J's trials.

FDA adviser, Dr Paul Offit of Children's Hospital of Philadelphia, added: 'I think this frankly was always a two-dose vaccine... It would be hard to recommend this as a single-dose vaccine at this point.'

Given the public health concerns over the vaccine's long-term efficacy, the committee unanimously approved the booster dose for all J&J recipients aged 18 and older at least two months after their first dose. Although not required to, the FDA generally follows advisory committee recommendations. Once the FDA gives official approval, the U.S. Centers for Disease Control and Prevention will make specific guidelines on who should receive the boosters. CDC advisers are scheduled to meet to discuss this.

Meanwhile, the EU EMA is awaiting mature clinical trial data package from J&J to support authorization of a booster dose. Focused discussion will be on the time interval between the two vaccine doses.

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