“Johnson & Johnson’s COVID vaccine is safe and effective”, says the FDA

From the IN CASE YOU HADN’T HEARD department . . .

Facing almost 20,000 lawsuits by women who blame Johnson & Johnson’s talcum powder for causing cancer finally has a $100 million settlement from the manufacturer. The company agreed to settle 1,000 of these cases in bulk. ***Despite growing concerns*** *of carcinogenic agents,* ***the products giant continued to market and sell its baby powder to Black and Hispanic women****.*
J&J SEGMENTED ITS MARKETING CAMPAIGN WITHOUT PROPER DISCLOSURE TO THE PUBLIC THAT ITS PRODUCT COULD POTENTIALLY CAUSE CANCER.

USA TODAY (2/24 / 21) reported detailed information on a Johnson & Johnson candidate vaccine for COVID-19 raises no safety concerns, according to a report released early Wednesday. The Food and Drug Administration advisory committee is holding an all-day meeting Friday to review the data and is likely to give the vaccine a thumbs up, likely leading to an FDA authorization for the vaccine within the next few days.

The J&J vaccine differs from the two already authorized; only one shot is recommended, instead of two. The FDA advisory committee, called the Vaccines and Related Biological Products Advisory Committee or VRBPAC, is expected to sign off on the vaccine because it **seems ???** to have met all the criteria for authorization.

Like the Moderna and Pfizer-BioNTech vaccines, the one from J&J held a large clinical trial showing its safety and effectiveness, and the company has proven it can manufacture the vaccine in a safe and consistent manner.

J&J has agreed to provide 100 million doses of its vaccine in the United States by June, including 20 million by the end of March. Those doses will add to the 300 million doses Pfizer-BioNTech and Moderna each have promised to deliver to the U.S. government by the end of July.

COVID vaccines, tests work well now, but variants have FDA preparing for a future when they may not.

In terms of demographics, 38% of participants were over 60 and 55% were male. **Of the nearly 20,000 participants in the U.S., 74% were white, 15% Hispanic, 13% Black, 6% Asian and ,1% were Native American.**

More than 40% of the trial participants globally had medical conditions putting them at higher risk for severe COVID, including obesity, type 2 diabetes, hypertension or HIV.

In new safety information released Wednesday on 6,736 trial participants, nearly 49% had pain at their injection site, 39% developed a headache after the shot, 38% were tired and 33% had muscle pain. Nearly all these symptoms were considered mild or moderate and resolved in one or two days. People who received the vaccine were more likely to suffer from hives, blood clots and ringing in their ears.

The J&J vaccine can be stored in a refrigerator for three months and in a freezer for up to two years, making it relatively easy to distribute through typical medical supply systems.

The FDA is awarding COVID vaccines emergency use authorizations rather than full approvals.

Although all the testing to date has been comparable to tests required for full approval, **The vaccines have not been required to show longer-term data, WHICH WOULD DELAY THEIR DISTRIBUTION.**

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