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Risk-Benefit Analysis of The FDA's Decision to Pause J&J Vaccine - BLOG

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INTRODUCTION

On April 23rd, the FDA and CDC released a joint statement lifting the recommended pause on the Johnson & Johnson (Janssen) COVID-19 Vaccine (1). This came ten days after the agencies imposed the recommended pause, on April 13th.

The pause was recommended as the CDC and FDA reviewed six reported cases in the U.S. of a rare and severe type of blood clot, cerebral venous sinus thrombosis, in combination with low levels of blood platelets, this condition is known as thrombosis-thrombocytopenia syndrome (TTS)(2). According to the initial statement, these six cases occurred among women between the ages of 18 and 48; their symptoms occurred 6 to 13 days after vaccination with the Janssen vaccine. This temporary suspension was recommended out of an abundance of caution to allow for a thorough safety review.

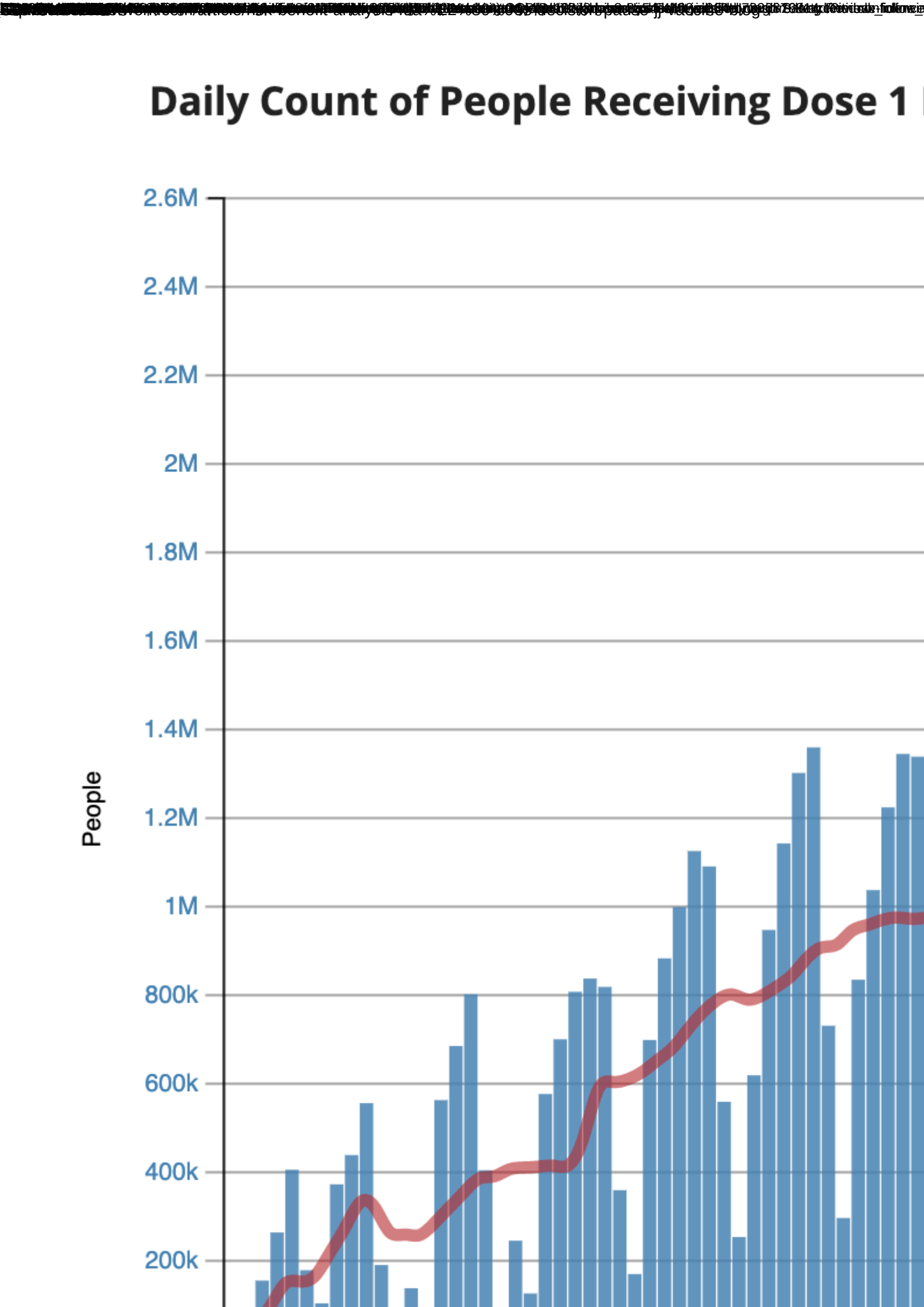
FDA RESPONSE

The FDA analyzed the data from these cases. In addition, the CDC convened two meetings of the Advisory Committee on Immunization Practices (ACIP) to further review the instances, discuss the latest data on TTS, listened to statements from Janssen (the vaccine manufacturer) and the COVID-19 Vaccine Safety Technical (VaST) Subgroup, and handled a risk benefit analysis. The teams at the agencies conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse effects and how to properly manage and recognize these events.

Ultimately, the two agencies determined that the use of the Janssen COVID-19 vaccine should be resumed in the US expressing confidence that the vaccine is safe and effective in preventing COVID-19. The FDA determined the available data demonstrates that the vaccine's known and potential benefits outweigh the known and potential risks for individuals 18 and older, thereby passing the benefit-risk analysis with the risk control measure and updating the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) as well as adding the risk of Thrombosis with Thrombocytopenia to Post-Authorization Experience(3).

While both agencies assert the Janssen vaccine is safe and effective and understanding the pause to be illustrative of the FDA's and CDC's commitment to safety, the pause has had significant consequences with blowback from an already mistrusting public about the handling of the COVID-19 pandemic . According to a Post-ABC poll, less than 1 in 4 unvaccinated Americans are willing to get the Johnson & Johnson vaccine (4). But the hesitancy is not reserved for the J&J vaccine -- From the same poll, only about half of unvaccinated Americans think the Moderna and Pfizer vaccines are safe.

Recommending the pause has led to criticism and frustration among some who have supported vaccination efforts and wish instead, the FDA had done this without sounding the alarm. Now Americans who were skeptical of the vaccine's effectiveness, uncomfortable with the timeline of the vaccines' development, or looking to wait a few months feel their qualms with being vaccinated were validated and have decided not to get vaccinated at all. While some countries are experiencing vaccine shortages, in the US, businesses and employers are supplying incentives, in the form of food, beer, paid time off, and money in efforts to increase the percentage of vaccinated Americans and achieve herd immunity. Yet, the graph of Trends in Number of COVID-19 Vaccinations in the US from the CDC's COVID Data Tracker shows how the general public feels about getting vaccinated before and after the FDA and CDC released their joint statement recommending the pause on the Janssen COVID-19 vaccine (5). As of today, the trendline is steeply declining from where it was the day the statement was released.


Daily Count of People Receiving Dose 1
2.6M
2.4M
2.2M
2M
1.8M
1.6M
1.4M
1.2M
1M
800k
600k
400k
200k
People