GlobalResearch
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US: FDA Asks J&J To Discard Millions of COVID-19 Vaccine Doses

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Global Research, June 13, 2021
TeleSur

Region: USA
Theme: Science and Medicine

The U.S. Food & Drug Administration on Friday said Johnson & Johnson (JNJ.N) must dump millions of doses of its COVID-19 vaccine manufactured at a Baltimore factory plagued with sanitary problems.
While the federal agency cleared about 10 million doses, The New York Times reported that the batches being discarded are around 60 million doses.

Without confirming the number of vaccine doses, the FDA said in a news release that it had authorized two batches for use, that several other batches were not suitable for use and that others were being evaluated.

The agency said it could not yet authorize Emergent BioSolutions Inc's (EBS.N) plant for manufacturing the J&J vaccine, as production at its Baltimore site was halted by U.S. authorities in April and J&J was put in charge of manufacturing at the plant.

The J&J doses from this site expected to be exported to other countries and are already in vials and ready for use.

Safety concerns about the J&J vaccine together with with slow U.S. demand for vaccinations in general have limited rollout of the one-shot vaccine to a standstill. Nearly half of the 21 million doses produced for the United States remain unused.

The FDA said its decision permits the J&J doses to be used in the United States or exported, and the FDA will share relevant information about the doses' manufacture with regulators where the vaccine is shipped.

J&J confirmed that the FDA authorized two batches, but was silent about the doses regulators decided to toss.

"Today's decisions represent progress in our continued efforts to make a difference in this pandemic on a global scale," Kathy Wengel, J&J's chief global supply chain officer, said in the statement.

Last month, Emergent Chief Executive Robert Kramer said he believed there were 100 million doses of J&J's vaccine ready for review and that regulators had already begun the process.

The April pause followed a discovery that ingredients from AstraZeneca's COVID-19 vaccine, also being produced at the plant, actually contaminated a batch of J&J's vaccine. AstraZeneca's jab is no longer being produced at that plant.

Specifically, an FDA inspection found a considerable list of sanitary problems and bad manufacturing practices at Emergent's plant.

Europe's drug regulator also said Friday that batches of the J&J vaccine made for Europe at the time the contamination issues were found at the Baltimore plant would not be used.

The EMA did not say how many shots were affected, but Reuters believes it to be millions of doses, making it harder for J&J to meet obligations to deliver 55 million doses to Europe by the end of June.

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