

# Drug Company Contracted to Produce Covid Vaccines Hid Evidence of Quality Issues



A nurse draws from a vial of the Johnson & Johnson coronavirus vaccine in Los Angeles, Calif., March 25, 2021. (Lucy Nicholson/Reuters)none

Emergent BioSolutions, a company contracted to produce Covid vaccine doses, hid evidence of the contamination of vaccines from the Food and Drug Administration, a new report reveals.

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The report, released on Tuesday by the Congressional House Select Subcommittee on the Coronavirus Crisis, alleges that 400 million vaccine doses produced by Emergent had to be destroyed. Though no contaminated doses were ever released to the public, the destruction came as the U.S.

vaccine rollout was underway, when doses were in high demand as people sought to get inoculated. Emergent had previously lined up \$1.8 billion in contracts to produce vaccines, including those made by Johnson & Johnson and AstraZeneca.

The report alleges that Emergent neglected to ensure its quality control systems were adequate to ensure Covid vaccines were healthy and safe to be administered to patients. Its Bayview plant in Baltimore, Md., which has since been shut down, was the focus of the report.

Internal emails between executives, documents, and interviews requested by the committee via subpoena showed that the company's executives were doubtful of their vaccine quality control yet declined to take measures to resolve the issue.

The report also described attempts to delude visiting FDA regulators, which involved deliberately mislabeling vials and removing yellow warning tags from poor quality vaccine samples when regulators were on premises.

"Shame on us for thinking that [Emergent's] experience in manufacturing would mean they would be able to move ahead and make the vaccines in a high-quality manner that we would expect for an experienced vaccine manufacturer," said Dr Peter Marks, the FDA's director for Biologics Evaluation and Research, in testimony to Congress.

The report also describes how government officials treated Emergent with leniency or did not investigate claims of poor quality. The report noted that officials from the Trump Administration's Operation Warp Speed, a task force to expedite vaccine production, expressed their concerns to the FDA about Emergent in 2020. Once the FDA was notified of these quality problems, however, the report alleges that Emergent was granted lenient treatment in order to achieve compliance.

In March of 2021, Emergent discovered mass contamination of its doses resulting from its quality control practices and notified the FDA. These doses were later destroyed. The Biden Administration terminated their vaccine contract in November of 2021, which led to Emergent receiving a \$320 million severance payment.

Despite these issues, Emergent – a long-time federal contractor – still produces many biological products for the government, including federal anthrax vaccines.

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