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House panel probes vaccine makers' oversight of Emergent plant

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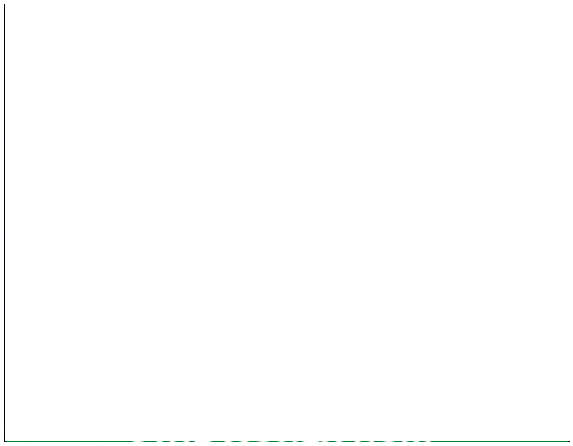
BY **SARAH OWERMOHLE** | 06/23/2021 11:08 AM EDT

The exterior view of the Emergent BioSolutions plant in Baltimore, Md.| Tasos Katopodis/Getty Images

Two House panels are asking Johnson & Johnson and AstraZeneca to lay out their agreements with Emergent BioSolutions to produce coronavirus vaccines in an effort to understand how the contractor contaminated and destroyed millions of shots.

The committees' Tuesday letters to the two pharmaceutical companies' chief executives broaden their probe into the embattled Maryland contract manufacturer, which until April had deals with each company to produce their Covid-19 vaccines. The Biden administration asked AstraZeneca to leave the plant after Emergent ruined 15 million J&J doses. Millions more doses made at the facility have not been cleared for release yet.



"Evidence recently released by the Committees shows that Emergent was warned multiple times that serious manufacturing problems and deficient controls at the Bayview facility could lead to contamination but that Emergent failed to act," House Oversight Chair Carolyn Maloney (D-N.Y.) and House Coronavirus Crisis Chair Jim Clyburn (D-S.C.) wrote a letter asking AstraZeneca CEO Pascal Soriot why the pharmaceutical giant did not act on several FDA warnings about Emergent's facilities.

The lawmakers asked each company to provide contract details, correspondence with Emergent and government officials about the manufacturing issues and information about the costs and damages of doses lost.

"With more than 85 million total doses destroyed and tens of millions more held back for testing, Emergent's mistakes have reduced the number of vaccines available for global vaccination efforts," Maloney and Clyburn wrote.

Background: Evidence from the probe suggests that Emergent discarded millions of AstraZeneca and J&J doses last fall and winter because of manufacturing issues.

Emergent CEO Robert Kramer defended his company in testimony at a hearing of the coronavirus crisis panel last month, saying that AstraZeneca shared flawed manufacturing processes that required Emergent to make 80 different process changes.

"It was very difficult, very complicated, and it did result in the number of lost production lines," Kramer said.

What's next: The committee leaders instructed AstraZeneca and J&J to respond by July 6.

Meanwhile, with no clear timeline for when FDA could clear AstraZeneca doses made at the Emergent plant, the Biden administration has tabled plans to send AstraZeneca doses abroad.

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YOUR ACCOUNT MANAGEMENT TEAM

Thomas Zhang

Senior Account
Manager

tzhang@politico.com

(703) 236-7925