

Congress of the United States
House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

Phone (202) 225-4400
<https://coronavirus.house.gov>

MEMORANDUM

May 14, 2021

To: Members of the Select Subcommittee on the Coronavirus Crisis

Fr: Committee Staff

Re: Hybrid Hearing on “Examining Emergent BioSolutions’ Failure to Protect Public Health and Public Funds”

On **Wednesday, May 19, 2021, at 10:30 a.m. ET**, the Select Subcommittee on the Coronavirus Crisis will host a hybrid in-person/remote hearing on “Examining Emergent BioSolutions’ Failure to Protect Public Health and Public Funds.”

This hearing will convene in person in 2154 Rayburn House Office Building and remotely using Zoom, which has been approved by the House, at the discretion of the Chairman, the witnesses, and other Members.

Strict adherence to the Attending Physician’s Guidelines—as updated on May 13, 2021, and any further updates that may be issued prior to the hearing—is required for all participants attending in person.

Members attending remotely are asked to connect by 10:00 a.m. to ensure their participation and troubleshoot any connectivity issues. The hearing will be recorded and livestreamed for the public.

I. SCOPE AND PURPOSE OF HEARING

The hearing will examine Emergent BioSolutions, Inc.’s (Emergent) role in and impact on the response to the coronavirus pandemic, including its manufacturing of coronavirus vaccines developed by other companies. Contamination at Emergent’s Bayview plant in Baltimore, Maryland caused up to 15 million doses of Johnson & Johnson vaccines to be destroyed and required millions of others to be segregated for testing to ensure they are safe for use.

II. BACKGROUND ON EMERGENT BIOSOLUTIONS

Emergent is a publicly traded life sciences company headquartered in Gaithersburg, Maryland that develops, manufactures, and sells vaccines and therapeutics, with a specialty in

biodefense products. Fuad El-Hibri served as Emergent's CEO from the founding of the company in 1998 until 2012, when he became Executive Chairman of the Board of Directors. Robert Kramer has held various positions at Emergent since 1999, becoming President in March 2018 and CEO in April 2019.¹

Although the company's commercial division has grown in recent years, the U.S. government has historically been and remains Emergent's biggest customer—accounting for \$988.5 million in revenue, 63 percent of Emergent's total revenues in 2020.² Emergent has received dozens of federal contracts since its founding, including awards totaling \$4.8 billion since fiscal year 2008.³ BioThrax, the only anthrax vaccine licensed by the Food and Drug Administration (FDA), was the company's main product for more than a decade, with most of its sales going to the Department of Health and Human Services (HHS) and the Department of Defense.⁴ Although anthrax vaccines still account for over a third of the company's net sales, Emergent currently sells a variety of other products, including vaccines for smallpox, cholera, and typhoid, treatments for anthrax and botulism, as well as NARCAN Nasal Spray, a treatment for suspected opioid overdoses.⁵

Emergent entered into a number of contracts with the federal government in response to the coronavirus pandemic, primarily to manufacture coronavirus vaccines at its facilities. These contracts include:

- Up to \$23 million on April 2, 2020, for Emergent to develop an antibody-based therapeutic for coronavirus patients;
- \$628 million on May 24, 2020, to reserve and expand the manufacturing capacities and capabilities of Emergent's Bayview, Camden, and Rockville facilities to produce coronavirus vaccines; and
- \$30 million on July 23, 2020, to reserve additional manufacturing capacities at Emergent's Bayview facility. This was reduced to \$20 million on November 17.⁶

¹ Emergent BioSolutions, Inc., *Management Team* (online at https://investors.emergentbiosolutions.com/corporate-governance/management_team) (accessed on May 7, 2021).

² Emergent BioSolutions, *Annual Report for the Fiscal Year Ended December 31, 2020* (Feb. 21, 2021) (online at <https://investors.emergentbiosolutions.com/node/20191/html>).

³ USASpending.gov, *Recipient Profile Emergent BioSolutions Inc., All Fiscal Years* (online at www.usaspending.gov/recipient/e7312c38-3d35-5dea-d7f1-62e8924b5f39-P/all) (accessed on May 5, 2021).

⁴ Emergent BioSolutions, *Prospectus Summary* (Nov. 14, 2006) (online at <https://investors.emergentbiosolutions.com/node/10281/html>).

⁵ Emergent BioSolutions, *Annual Report for the Fiscal Year Ended December 31, 2020* (Feb. 21, 2021) (online at <https://investors.emergentbiosolutions.com/node/20191/html>).

⁶ USASpending.com, *Delivery Order PIID 75A50120F33006* (online at www.usaspending.gov/award/CONT_AWD_75A50120F33006_7505_HHSO100201200004I_7505) (accessed May 9, 2021); USASpending.com, *Delivery Order PIID 75A50120F33007* (online at www.usaspending.gov/award/CONT_AWD_75A50120F33007_7505_HHSO100201200004I_7505) (accessed May 9, 2021); USASpending.com, *Delivery Order PIID 75A50120F33008* (online at www.usaspending.gov/award/CONT_AWD_75A50120F33008_7505_HHSO100201200004I_7505) (accessed May 9, 2021).

Between April and July 2020, Emergent signed additional agreements with Johnson & Johnson and AstraZeneca to manufacture their respective coronavirus vaccines.⁷

III. CONTAMINATION OF CORONAVIRUS VACCINES AT EMERGENT'S BALTIMORE PLANT

In late February 2021, Emergent employees contaminated millions of doses of Johnson & Johnson's coronavirus vaccine by mixing them with ingredients from AstraZeneca's vaccine. Emergent was forced to destroy up to 15 million tainted doses of Johnson & Johnson's vaccine as a result. Approximately 62 million additional Johnson & Johnson doses and 70 million AstraZeneca doses are in jeopardy until tests reveal whether they are safe for use.⁸

This incident followed several other incidents in which vaccine doses were destroyed due to errors:

- In October 2020, Emergent destroyed two to three million doses of AstraZeneca's vaccine due to suspected contamination;
- In November 2020, Emergent discarded a batch of Johnson & Johnson vaccine after workers "hooked up" the wrong gas line and accidentally "suffocated" the cells where the virus for the vaccine is grown; and
- In December 2020, Emergent destroyed another eight to 12 million doses of AstraZeneca's vaccine due to bacterial contamination of equipment.⁹

Although investigation of the February 2021 contamination of the Johnson & Johnson doses is still ongoing, one likely cause is the failure of some employees to shower and change clothes as required when they moved between the factory zones dedicated to production of the AstraZeneca and Johnson & Johnson vaccines.¹⁰ Inspections of the Bayview facility conducted in 2020 flagged problems with mold, poor disinfection of plant equipment, and inadequate training of employees.¹¹

⁷ Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Five-Year Agreement for Large-Scale Drug Substance Manufacturing for Johnson & Johnson's Lead COVID-19 Vaccine Candidate* (July 6, 2020) (online at <https://investors.emergentbiosolutions.com/node/19676/pdf>); Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Agreement with AstraZeneca to Expand Manufacturing for COVID-19 Vaccine Candidate* (July 27, 2020) (online at <https://investors.emergentbiosolutions.com/node/19716/pdf>).

⁸ *Johnson & Johnson's Vaccine Is Delayed by a U.S. Factory Mixup*, New York Times (Mar. 31, 2021) (online at www.nytimes.com/2021/03/31/world/johnson-and-johnson-vaccine-mixup.html); *Johnson & Johnson Confirm Vaccine Production Problems at Emergent Plant in Baltimore*, Washington Post (Apr. 1, 2021) (online at www.washingtonpost.com/business/2021/03/31/vaccine-johnson-johnson-emergent/); *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

⁹ *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

¹⁰ *Baltimore Vaccine Plant's Troubles Ripple Across 3 Continents*, New York Times (May 6, 2021) (online at www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html).

¹¹ *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6,

On April 3, 2021, Johnson & Johnson was placed in charge of Emergent's Bayview facility and Emergent was ordered to stop making the AstraZeneca vaccine to reduce the risk of cross-contamination.¹²

On April 12, 2021, FDA commenced a wide-ranging inspection of Emergent's Bayview facility.¹³ Four days later, the agency asked the company to stop manufacturing any new material, and to quarantine all existing vaccine substance.¹⁴ Emergent announced on April 19 that it had agreed with FDA to shut down new manufacturing "pending completion of the inspection and remediation of any resulting findings."¹⁵ On April 21, FDA issued an inspection report, which found that:

- Emergent failed to properly investigate the incident that led to the contamination of Johnson & Johnson's vaccine, noting that "there is no assurance that other batches have not been subject to cross-contamination."
- Emergent's facility is "not maintained in a clean and sanitary condition," noting that unsealed bags of medical waste came into contact with raw manufacturing materials, and that paint flecks and black and brown residue covered the walls and floors.
- Emergent "failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross contamination of bulk drug substances."¹⁶

Emergent's serious errors have not impacted the safety or efficacy of coronavirus vaccines available to Americans. Because FDA has not certified the Bayview plant, no vaccines manufactured at the facility have been distributed to the American public, including the contaminated doses.¹⁷ FDA is continuing to evaluate the situation and may decide that none of

2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

¹² *J&J Takes over Plant Where Contractor Ruined 15 Million Vaccine Doses*, New York Magazine (Apr. 6, 2021) (online at <https://nymag.com/intelligencer/2021/04/j-and-j-takes-over-vaccine-plant-where-15m-doses-were-ruined.html>).

¹³ *FDA Inspection Finds Numerous Problems at Facility Intended to Make J&J Vaccine*, National Public Radio (Apr. 21, 2021) (online at www.npr.org/sections/coronavirus-live-updates/2021/04/21/989549809/fda-inspection-finds-numerous-problems-at-facility-intended-to-make-j-j-vaccine).

¹⁴ *Johnson & Johnson Suffers Another Setback as FDA Tells Md. Vaccine Maker to Suspend Production*, Washington Post (Apr. 19, 2021) (online at www.washingtonpost.com/business/2021/04/19/johnson-johnson-covid-vaccine-emergent/).

¹⁵ Emergent BioSolutions, *Form 8-K* (Apr. 19, 2021) (online at <https://investors.emergentbiosolutions.com/node/20371/html>).

¹⁶ Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 21, 2021) (online at www.fda.gov/media/147762/download); *FDA Issues Withering Report on Problems at Emergent BioSolutions Factory that Ruined Millions of J&J Vaccines*, USA Today (Apr. 21, 2021) (online at www.usatoday.com/story/news/nation/2021/04/21/covid-19-fda-issues-withering-report-us-factory-making-j-j-vaccine/7319674002/).

¹⁷ *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

the doses from the plant can be released in the United States.¹⁸ Acting FDA Commissioner Janet Woodcock stated: “We will not allow the release of any product until we feel confident that it meets our expectations for quality.”¹⁹ However, some vaccines manufactured at the facility have been distributed abroad. Foreign regulators have said that they are testing vaccine doses for safety before distribution, which is delaying urgent vaccination efforts.²⁰

IV. WITNESSES

Robert G. Kramer

President and Chief Executive Officer
Emergent BioSolutions, Inc.

Fuad El-Hibri

Executive Chairman of the Board of Directors
Emergent BioSolutions, Inc.

¹⁸ *Baltimore Vaccine Plant’s Troubles Ripple Across 3 Continents*, New York Times (May 6, 2021) (online at www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html).

¹⁹ Food and Drug Administration, *Press Release: Statement from Acting Commissioner of Food and Drugs – Food and Drug Administrator Janet Woodcock M.D.* (Apr. 21, 2021) (online at www.fda.gov/news-events/press-announcements/fda-continues-important-steps-ensure-quality-safety-and-effectiveness-authorized-covid-19-vaccines).

²⁰ *Baltimore Vaccine Plant’s Troubles Ripple Across 3 Continents*, New York Times (May 6, 2021) (online at www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html).