

Congress of the United States
Washington, DC 20515

MEMORANDUM

May 19, 2021

**To: Members of the Select Subcommittee on the Coronavirus Crisis
Members of the Committee on Oversight and Reform**

Fr: Majority Staff

Re: Preliminary Findings from Investigation into Emergent BioSolutions, Inc.

This memorandum describes evidence recently obtained by the Select Subcommittee on the Coronavirus Crisis and the Committee on Oversight and Reform (the Committees) in their ongoing investigation into Emergent BioSolutions, Inc. (Emergent).¹ The Committees' investigation raises troubling new questions about the lucrative contract Emergent received under the Trump Administration, the company's failure to address manufacturing problems that led to the destruction of millions of desperately needed coronavirus vaccine doses, and large bonuses paid to top executives despite these failures. New documents reveal:

- **Under the contract awarded by the prior Administration, Emergent has been paid millions despite destroying millions of vaccine doses.** Under the May 2020 contract issued by the Trump Administration, Emergent has charged the federal government \$27 million per month in reservation fees to maintain its "readiness" to manufacture vaccines pursuant to "current good manufacturing practices." Despite known flaws in Emergent's manufacturing operations, the Trump Administration agreed to these fees under a contract that provided, "capacity shall lapse and the unused batch production capacity cannot be allocated to a future period" even if no manufacturing activity occurred. As a result of these contract terms, taxpayers have already paid Emergent more than \$271 million. Emergent executives have acknowledged that the reservation fees were among the "primary drivers" of the company's high profit margins last year. After the Department of Health and Human Services (HHS) was notified about the contamination of vaccine doses at Emergent's facility, HHS partially stopped payment.
- **Emergent's systemic failure to address serious deficiencies at its facility led to the destruction of millions of vaccine doses.** New documents from two separate inspections performed in June 2020 show that Emergent was warned that it needed

¹ Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Robert G. Kramer, President and Chief Executive Officer, Emergent BioSolutions, and Fuad El-Hibri, Executive Chairman, Emergent BioSolutions (Apr. 19, 2021) (online at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021-04-19.CBM%20JEC%20to%20Emergent%20Biosolutions%20re%20Investigation%20.pdf>).

“extensive training of personnel” and “strengthening of the quality function,” and that it had a “deficient” virus contamination control strategy. Despite the serious nature of these findings and similar concerns raised during four other inspections in 2020, Emergent failed to promptly and fully remediate the problems at the facility.

- **Emergent has privately admitted to serious manufacturing problems.** In its response to an April 2021 Food and Drug Administration (FDA) inspection report, Emergent admitted that the “sudden scale-up to full-scale manufacturing activities for two different Covid-19 vaccine drug substances” contributed to “a dramatic increase in storage and staging demands” and “strained the capacity” of Emergent’s equipment as the facility “operated at full capacity for the first time.” This report provides new detail on the failures that led to the contamination of up to 15 million Johnson & Johnson vaccines at its facility in January and February 2021, as well as the events leading up to the discovery and investigation of the contamination.
- **Key official who awarded contracts had previously been paid by Emergent.** Dr. Robert Kadlec—a former consultant to Emergent who later became a senior Trump Administration official—received at least \$360,000 in consulting fees from Emergent prior to joining HHS and awarding Emergent billions of dollars in contracts.
- **Company executives reaped a windfall as vaccines were destroyed.** In February 2021, Emergent awarded millions in raises and bonuses to its senior executives, praising them for their “exceptional leadership” and “exemplary” performance in 2020—despite the dysfunction at the Bayview plant. Emergent even awarded the executive vice president responsible for manufacturing a “special bonus award” of \$100,000 for “significant CDMO [Contract Development and Manufacturing] expansion related to COVID-19” and in recognition of “his exceptional performance in 2020.”²

I. TRUMP ADMINISTRATION AGREED TO PAY EMERGENT TO USE ITS FACILITIES DESPITE FLAWS IN MANUFACTURING OPERATIONS

Documents obtained by the Committees provide new detail on the multi-million dollar coronavirus contract awarded by the Trump Administration to Emergent.³ On May 24, 2020,

² Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415); Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001365).

³ Ex. 3, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (May 24, 2020) (EBSI_HCOR_0001860 – 70); Ex. 4, Amendment/Modification No. P00002, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Sept. 18, 2020) (EBSI_HCOR_0001833 – 37); Ex. 5, Amendment/Modification No. P00003, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Oct. 7, 2020) (EBSI_HCOR_0001858 – 59); Ex. 6, Amendment/Modification No. P00004, Contract No. HHSO100201200004I,

HHS awarded Emergent a \$628 million contract to expand the manufacturing capacities and capabilities at Emergent facilities in Maryland from May 13, 2020, through December 31, 2021.⁴ On July 23, 2020, HHS awarded Emergent another \$30 million contract to reserve two additional manufacturing suites at the Bayview facility between October 1 and December 31, 2020.⁵ On November 17, 2020, HHS reduced the amount of the award to reserve manufacturing capacity to \$20 million.⁶

Due to various modifications, the total fixed price of Emergent’s contract is now worth over \$650 million, divided into the following tasks:

May 24, 2020, Contract to Reserve and Expand Emergent Capacities and Capabilities⁷		
Task 1	Capacity Reservation	\$542,480,000
Task 2	Pharmaceutical Manufacturing Capacity Expansion	\$85,500,000
Task 3	Janssen Equipment	\$22,815,445
Total fixed price of May 24, 2020, contract		\$650,795,445

Multiple inspections and audits conducted in 2020 warned of serious quality control issues at Emergent’s Bayview facility. However, documents show that Dr. Kadlec, then-Assistant Secretary for Preparedness and Response, requested in August 2020 that Emergent’s contract receive a “priority rating.”⁸ Dr. Kadlec’s office “had determined that [Emergent]

Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Jan. 22, 2021) (EBSI_HCOR_0001851); Ex. 7, Amendment/Modification No. P00005, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Feb. 22, 2021) (EBSI_HCOR_0001848 – 50). In addition to these vaccine manufacturing contracts, the Trump Administration also awarded Emergent a \$14.5 million contract on April 2, 2020, to develop a plasma-based therapeutic treatment for coronavirus infection, which can provide up to \$22 million for additional development activities. Ex. 8, Contract No. HHSO100201200004I, Order No. 75A50120F33006 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Apr. 2, 2020) (EBSI_HCOR_0001788 – 804); Ex. 9, Amendment/Modification No. P00001, Contract No. HHSO100201200004I, Order No. 75A50120F33006 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Apr. 12, 2021) (EBSI_HCOR_0001805 – 06); Biomedical Advanced Research and Development Authority, *Press Release: BARDA Leverages CIADM Partner for Development of Plasma-based Therapeutic Treatment for COVID-19* (online at www.medicalcountermeasures.gov/newsroom/2020/emergent-plasma/) (accessed on May 14, 2021).

⁴ Ex. 3, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (May 24, 2020) (EBSI_HCOR_0001860 – 70). Prior to the award of this contract, the Trump Administration gave Emergent an Authorization to Proceed on May 12, 2020, which allowed the company to immediately begin performance and incur costs under this initiative. See Ex. 10, Department of Health and Human Services, *Authorization to Proceed, to Sean Kirk, Executive Vice President, Manufacturing & Technical Operations, Emergent BioSolutions* (May 12, 2020) (EBSI_HCOR_0001838 – 47).

⁵ Ex. 11, Contract No. HHSO100201200004I, Order No. 75A50120F33008 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (July 23, 2020) (EBSI_HCOR_0001936 – 50).

⁶ Ex. 12, Amendment/Modification No. P00002, Contract No. HHSO100201200004I, Order No. 75A50120F33008 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Nov. 17, 2020) (EBSI_HCOR_0001933 – 35).

⁷ Ex. 13, Amendment/Modification No. P00006, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Mar. 23, 2021) (EBSI_HCOR_0001852 – 57).

⁸ Ex. 14, Amendment/Modification No. P00001, Contract No. HHSO100201200004I, Order No.

possesses the required experience and available capacity to be ready to manufacture... vaccine components at a commercial scale and within the [Operation Warp Speed] required timeline.”⁹ This conclusion raises questions regarding whether Dr. Kadlec’s office performed sufficient diligence before awarding the contract to Emergent.

A. Emergent Failed to Maintain Readiness of Facility and to Deliver Under Contract, But Still Collected Hundreds of Millions of Dollars in Fees

Under the terms of the May 2020 contract, Emergent was required to maintain the cleanliness and readiness of its facilities, equipment, and personnel, so that the company would be ready to safely and reliably manufacture vaccines. The contract provides: “[Emergent] shall maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities ... for the entirety of the period of performance.”¹⁰ The serious deficiencies identified during numerous inspections and audits raise questions as to whether Emergent met the contract requirement.

Despite its failed performance, Emergent has collected over \$271 million in reservation fees from the federal government. Over the term of the contract, 83 percent—or \$542 million—of the Trump Administration’s May 2020 award to Emergent was to reserve the company’s facilities and equipment for coronavirus vaccine manufacturing in Bayview, Camden, and Rockville.¹¹ Emergent planned to use its Bayview facility to produce coronavirus vaccine doses while the company’s Camden and Rockville facilities would package it for distribution.

The federal government paid Emergent over \$27 million per month to reserve its space and manufacturing capacity. The contract specifically requires, “The Contractor shall reserve drug substance and drug product manufacturing capacity at the contract’s Bayview CIADM [Centers for Innovation in Advanced Development and Manufacturing], Camden, MD, and Rockville, MD.” If the capacity reserved at Emergent’s facilities is utilized for manufacturing vaccines on behalf of the federal government, then the reservation fee is credited towards the manufacturing costs—with the federal government responsible for paying any cost difference between the applied reservation fee and the actual cost of performing the manufacturing of the batch. Emergent set the reservation fee amount by estimating the number of batches it could produce and the price of each batch. The reservation fees do not include technology transfer,

75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Aug. 24, 2020) (EBSI_HCOR_0001826 – 32); Ex. 15, Amendment/Modification No. P00001, Contract No. HHSO100201200004I, Order No. 75A50120F33008 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (Aug. 24, 2020) (EBSI_HCOR_0001926 – 32).

⁹ *Id.*

¹⁰ Ex. 3, Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (May 24, 2020) (EBSI_HCOR_0001860 – 70 at EBSI_HCOR_0001865).

¹¹ *Id.* at EBSI_HCOR_0001862.

process and analytical development, process development, raw materials, and lot release testing of a batch.¹² The process to determine the reasonableness of the fees is unknown at this time.

The contract stipulates that Emergent is paid even if no manufacturing activity occurs. The contract makes clear that if Emergent is not tasked with producing batches in a given month, then that the “capacity shall lapse and the unused batch production capacity cannot be allocated to a future period.”¹³ Thus, the federal government was obligated to continue to pay Emergent to reserve manufacturing capacity at the Bayview facility even after FDA ordered all manufacturing halted on April 16, 2021. As of May 12, 2021, the federal government had paid Emergent over \$271 million for capacity reservation under this contract.¹⁴ After HHS was notified about the contamination of vaccine doses at the Bayview facility, HHS held payment of the portion of the monthly fee that covers two manufacturing areas, which equates to \$18.5 million of the \$27 million reservation fee.

During a July 30, 2020, earnings call, Richard Lindahl, Emergent’s Chief Financial Officer, admitted that the reservation fees were primarily profit for the company. He explained:

[T]here is minimal costs [sic] associated with the reservation piece itself, the cost really come [sic] through as manufacturing candidates comes [sic] through the plant. So that certainly is a positive factor, as it relates to the margin.

He also acknowledged that the reservation fees were one of the “primary drivers” of the increase in the company’s gross profit margins in 2020.¹⁵

II. EMERGENT’S SYSTEMIC FAILURE LED TO THE DESTRUCTION OF MILLIONS OF VACCINE DOSES

In 2020, Emergent was warned multiple times that serious manufacturing problems and deficient controls at the Bayview facility could lead to contamination. These warnings came in internal inspections as well as inspections and audits by FDA, Johnson & Johnson, and AstraZeneca. The inspections found that Emergent’s Bayview facility had persistent problems with mold, poor disinfection of plant equipment, and inadequate training of employees.¹⁶

¹² *Id.* at EBSI_HCOR_0001864 – 65.

¹³ *Id.* at EBSI_HCOR_0001864.

¹⁴ Ex. 16, Department of Health and Human Services, *Description of Payments Made to Emergent Pursuant to PHID 75A50120F33007* (May 12, 2021).

¹⁵ *Emergent BioSolutions, Inc. (EBS) CEO Bob Kramer on Q2 2020 Results - Earnings Call Transcript*, Seeking Alpha (July 30, 2020) (online at <https://seekingalpha.com/article/4362714-emergent-biosolutions-inc-ecs-ceo-bob-kramer-on-q2-2020-results-earnings-call-transcript>).

¹⁶ *See, e.g.*, Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 20, 2020) (www.fda.gov/media/147884/download); *Top Official Warned that COVID Vaccine Plant Had to Be ‘Monitored Closely’*, New York Times (Apr. 7, 2021) (online at www.nytimes.com/2021/04/07/us/emergent-biosolutions-coronavirus-vaccine.html); *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).

New evidence obtained by the Committees shows that Emergent was aware of the problems and failed to take sufficient action. Ultimately, this led to the contamination of millions of vaccine doses in separate incidents in October 2020, December 2020, and February 2021.¹⁷ Emergent’s response to FDA’s April 20, 2021, inspection report, a previously undisclosed document, shows that the company admitted to some of the failures and committed to remediation.¹⁸ However, the company’s troubling history raises questions regarding whether Emergent will ever be able to comply fully with FDA standards and produce safe and effective vaccines.

A. New Documents Show that Emergent Failed to Address Deficiencies

Evidence recently obtained by the Committees shows that Emergent was aware of serious control issues at its Bayview facility but failed to act. In June 2020, an advisor to Operation Warp Speed identified “risks” in relying on Emergent to handle the production of two coronavirus vaccines.¹⁹ During a separate audit, Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, found that the Bayview facility had a “deficient” contamination control strategy.²⁰

On June 17, 2020, Carlo de Notaristefani, the lead manufacturing advisor for Operation Warp Speed, issued a private report on Emergent. The report identified multiple “risks” at the Bayview facility, including concerns about facility readiness, personnel, and compliance. The report stated:

- **“Most of the large scale existing equipment is not suitable for the new processes, and will be either removed or mothballed....** The supporting infrastructure is very limited, and will need substantial remediation and expansion to allow manufacturing to proceed at the planned rate”;²¹
- **“Personnel risk – significant: The staffing plans presented seem inadequate to the level of current activities required for full scale production of 3 programs.** In

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).

¹⁸ Ex. 17, Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 20, 2021).

¹⁹ Ex. 18, Memorandum from Carlo de Notaristefani, Operation Warp Speed Advisor, Manufacturing & Supply Chain, *Emergent BioSolutions Site Visit Report* (June 17, 2020) (EmerCly_0000001 – 7 at EmerCly_0000001).

²⁰ Ex. 19, Letter from Stephen Green, Senior Manager External Supply Integration - Quality, Johnson & Johnson, to Judith Adair McCorry, Director of Quality Assurance, Emergent BioSolutions (July 24, 2020) (EBSI_HCOR_0014442 – 54 at EBSI_HCOR_0014454).

²¹ Ex. 18, Memorandum from Carlo de Notaristefani, Operation Warp Speed Advisor, Manufacturing & Supply Chain, *Emergent BioSolutions Site Visit Report* (June 17, 2020) (EmerCly_0000001 – 7 at EmerCly_0000001) (emphasis added).

addition, recent FDA and customer audits has [sic] highlighted the need for extensive training of personnel, and strengthening of the quality function”,²² and

- **“Compliance risk – significant:** Emergent Bayview has been focused on R&D [research and development] activities for the last 8+ years, and **will have to strengthen the change control process, systems audit trails, and quality oversight to address audit observations and ensure products licensure. This will require significant resources and commitment.**”²³

On June 9 through June 18, 2020, Janssen Pharmaceuticals conducted a virtual audit of Emergent’s Bayview facility. On July 24, 2020, Janssen sent Emergent a report with its audit findings, which concluded that Emergent’s “quality systems may have weaknesses or gaps that require CAPA [Corrective and Preventive Actions].”²⁴

The audit report identified numerous concerns related to deficient virus contamination practices at the Bayview facility. For example, the report stated:

- **“The site virus contamination control strategy is deficient,”** noting that **“There is not a formal Bayview contamination control strategy for the site”;**²⁵
- **“The disinfectant program used in the facility is deficient,”** and Emergent failed to follow basic industry standards for disinfecting the plant;²⁶
- There were **“mold issues** associated with the facility shutdown / startup” and **“inadequate gowning / wipe down procedures** for materials coming from the warehouse to weigh and dispense”;²⁷ and
- There is **“no process” for the hand-over of cell banks and viral seed banks** from the warehouse to manufacturing.²⁸

²² *Id.* (emphases added).

²³ *Id.* (emphases added).

²⁴ Ex. 19, Letter from Stephen Green, Senior Manager External Supply Integration - Quality, Johnson & Johnson, to Judith Adair McCorry, Director of Quality Assurance, Emergent BioSolutions (July 24, 2020) (EBSI_HCOR_0014442 – 54 at EBSI_HCOR_0014448).

²⁵ *Id.* at EBSI_HCOR_0014454 (emphases added).

²⁶ *Id.* at EBSI_HCOR_0014452 (emphasis added).

²⁷ *Id.* at EBSI_HCOR_0014449 (emphases added).

²⁸ *Id.* at EBSI_HCOR_0014453 (emphasis added).

B. Emergent’s Response to FDA’s April 2021 Inspection Detailed Extensive Contamination Issues

On April 20, 2021, FDA issued a report—known as a Form 483—on findings from FDA’s inspection of Emergent’s Bayview facility.²⁹ The Committees received a copy of Emergent’s April 30, 2021, response to FDA.³⁰ This response provides new insight regarding the events that led up to the discovery and investigation of vaccine contamination in January and February 2021. The response also outlines steps that Emergent is taking to address the persistent manufacturing problems that have plagued the facility since at least April 2020.

Emergent admits to several failures at the Bayview plant:

- Emergent admitted that the “sudden scale-up to full-scale manufacturing activities for two different Covid-19 vaccine drug substances” contributed to “a dramatic increase in storage and staging demands” and “strained the capacity” of Emergent’s equipment as the facility “operated at full capacity for the first time”;³¹
- Emergent acknowledged FDA’s finding that Emergent employees were not adequately trained. Emergent stated that it is “using the pause in new manufacturing to provide comprehensive training to facility personnel, to ensure that, upon resumption of operation, site personnel will be prepared to execute their roles in a consistently GMP-compliant manner”;³² and
- Emergent committed that all new batches of Johnson & Johnson vaccine manufactured at the Bayview facility will be tested—by both an independent third party and Johnson & Johnson—to ensure that the doses are safe, until Emergent is able to fully remediate the problems at its Bayview facility.³³

Emergent’s response to FDA provides detail on the discovery of the most recent contamination, when stakeholders were notified, and Emergent’s investigation:

- **March 5, 2021: Johnson & Johnson discovers possible contamination of vaccine doses during quality control testing.** This batch was manufactured by Emergent between January 19 and February 21, 2021, and then sent to Johnson & Johnson for

²⁹ Ex. 17, Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 20, 2021).

³⁰ Ex. 20, Letter from Dino Muzzin, Senior Vice President, Manufacturing and Interim General Manager, Emergent Manufacturing Operations Baltimore, LLC, to Lisa Harlan, Acting Staff Director, Investigations Branch, Office of Biological Products Operations, Office of Regulatory Affairs, Food and Drug Administration (Apr. 30, 2021).

³¹ *Id.* at 44, 26.

³² *Id.* at 42; *see also id.* at 8.

³³ *Id.* at 15.

quality control testing.³⁴

- **March 11 and 15, 2021: Additional testing confirms the presence of a viral vector not used in the manufacturing of Johnson & Johnson’s vaccine**, indicating possible cross-contamination with the AstraZeneca vaccine.³⁵ Manufacturing both AstraZeneca and Johnson & Johnson in the same facility raised the risk of cross-contamination.
- **March 16, 2021: Johnson & Johnson alerts Emergent.** Johnson & Johnson notifies Emergent of the batch’s test results and preliminary identification of the contaminant.³⁶
- **March 17, 2021: Emergent initiates a manufacturing investigation.** According to Emergent, the affected batch was not sent for further processing.³⁷
- **March 24, 2021: Emergent and Johnson & Johnson approve the investigation plan.** Emergent’s testing of the batch indicated the presence of a viral vector similar to the AstraZeneca vector.³⁸
- **March 25, 2021: Emergent notified Johnson & Johnson of the investigation results.**³⁹
- **March 31, 2021: Public reporting reveals for the first time that up to 15 million doses of Johnson & Johnson’s vaccine have been contaminated at Emergent’s Bayview facility.**⁴⁰
- **April 3, 2021: The Biden Administration places Johnson & Johnson in charge of Bayview facility.**⁴¹ According to Emergent’s response to FDA, Johnson & Johnson will now provide “24/7 oversight of all production areas in addition to the suites in which their vaccine is manufactured.” Johnson & Johnson will also provide “full oversight of change controls, qualifications, and process items, including final

³⁴ *Id.* at 2.

³⁵ *Id.*

³⁶ *Id.* at 3.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Factory Mix-Up Ruins Up to 15 Million Vaccine Doses from Johnson & Johnson*, New York Times (Mar. 31, 2021) (online at www.nytimes.com/2021/03/31/us/politics/johnson-johnson-coronavirus-vaccine.html).

⁴¹ *U.S. Taps Johnson & Johnson to Run Troubled Vaccine Plant*, New York Times (Apr. 3, 2021) (online at www.nytimes.com/2021/04/03/us/politics/emergent-vaccine-plant-johnson-johnson.html).

approval.”⁴²

- **April 5, 2021: Emergent provides investigation report to FDA regarding the contamination of the Johnson & Johnson vaccines.** The analysis determined that the most probable cause for the contamination of the batch was contact with waste moving out of the area where the AstraZeneca vaccine was manufactured.⁴³
- **April 11, 2021: The Biden Administration asks Emergent to stop manufacturing AstraZeneca vaccine.** Emergent permanently stopped manufacturing of the AstraZeneca vaccine.⁴⁴
- **April 12 to April 20, 2021: FDA conducts inspection of Bayview facility.** On April 16, 2021, FDA asks Emergent to stop manufacturing any new material at the facility, and to quarantine all existing vaccine substance.⁴⁵ In its initial response to the Form 483, Emergent refers to this as a “voluntary shutdown period.”⁴⁶ On April 20, 2021, FDA issued a scathing inspection report of the Bayview facility.⁴⁷
- **May 18, 2021: Manufacturing at Bayview facility remains on hold.**

III. HHS OFFICIAL WHO AWARDED EMERGENT BILLIONS IN CONTRACTS WAS PREVIOUSLY PAID BY COMPANY

Documents obtained by the Committees reveal new details regarding Dr. Kadlec’s extensive professional ties to Emergent in the years before his appointment to serve as Assistant Secretary for Preparedness and Response. During the previous Administration, Dr. Kadlec awarded billions of dollars in contracts to Emergent.⁴⁸ The awards included a \$261 million order

⁴² Ex. 20, Letter from Dino Muzzin, Senior Vice President, Manufacturing and Interim General Manager, Emergent Manufacturing Operations Baltimore, LLC, to Lisa Harlan, Acting Staff Director, Investigations Branch, Office of Biological Products Operations, Office of Regulatory Affairs, Food and Drug Administration, at 9 (Apr. 30, 2021).

⁴³ *Id.* at 3.

⁴⁴ *Id.* at 7.

⁴⁵ *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/).

⁴⁶ Ex. 20, Letter from Dino Muzzin, Senior Vice President, Manufacturing and Interim General Manager, Emergent Manufacturing Operations Baltimore, LLC, to Lisa Harlan, Acting Staff Director, Investigations Branch, Office of Biological Products Operations, Office of Regulatory Affairs, Food and Drug Administration, at 31 (Apr. 30, 2021).

⁴⁷ Ex. 17, Food and Drug Administration, Inspection Report of Emergent Manufacturing Operations Baltimore, LLC (Apr. 20, 2021); *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/).

⁴⁸ *Before Pandemic, Trump’s Stockpile Chief Put Focus on Biodefense. An Old Client Benefited*, Washington Post (May 4, 2020) (online at www.washingtonpost.com/investigations/before-pandemic-trumps-

for anthrax vaccines in 2019; a ten-year, \$2 billion contract for smallpox vaccines in 2019; and the \$650 million coronavirus vaccine manufacturing agreements from 2020, which Dr. Kadlec later acknowledged were a risky decision.⁴⁹

New documents show that Emergent retained Dr. Kadlec to serve as a consultant from 2012 through 2015, agreeing to pay him \$120,000 annually over the three-year period.⁵⁰ In return, Dr. Kadlec agreed to provide advice on “international biosecurity and biodefense related issues to Emergent BioSolutions,” including outreach to senior government officials in Saudi Arabia and other countries.⁵¹

These documents raise further questions about Dr. Kadlec’s role awarding significant contracts to Emergent during the Trump Administration.

IV. EMERGENT GAVE MILLIONS IN RAISES AND BONUSES TO TOP EXECUTIVES AS PERFORMANCE PROBLEMS MOUNTED

New documents obtained by the Committees reveal that Emergent executives were praised for their management of the company in 2020 and rewarded with millions of dollars in bonuses and raises, despite serious manufacturing failures and the destruction of millions of doses of coronavirus vaccines.

On February 9, 2021, the Compensation Committee of Emergent’s Board of Directors met to rate and award bonuses for executive performance in 2020 and set executive compensation rates for 2021. At the meeting, Emergent’s executives were praised for “exceptional leadership” and “exemplary” performance and rewarded with large bonuses. None

stockpile-chief-put-focus-on-biodefense-an-old-client-benefited/2020/05/04/d3c2b010-84dd-11ea-878a-86477a724bdb_story.html); *Robert Kadlec, the Trump Administration’s Top Official for Addressing Biological Threats, Awarded a \$2 Billion Contract to a Company He Used to Advise*, Business Insider (May 5, 2020) (online at www.businessinsider.com/trump-official-awarded-2-billion-contract-to-a-former-employer-2020-5); *Trump Health Official’s Approach to Contracts Faces Scrutiny*, Roll Call (June 10, 2020) (online at www.rollcall.com/2020/06/10/trump-health-officials-approach-to-contracts-faces-scrutiny/).

⁴⁹ Emergent BioSolutions, *Press Release: Emergent BioSolutions Announces Exercise by BARDA of the First Contract Option, Valued at \$261 Million, to Procure Doses of AV7909 Anthrax Vaccine Candidate for the Strategic National Stockpile* (July 30, 2019) (online at <https://investors.emergentbiosolutions.com/node/18786/pdf>); Emergent BioSolutions, *Press Release: Emergent BioSolutions Awarded 10-Year HHS Contract to Deliver ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) into the Strategic National Stockpile* (Sept. 3, 2019) (online at <https://investors.emergentbiosolutions.com/node/18856/pdf>); *Congress Is Investigating the Company Whose Factory Ruined Vaccine Doses and Received a \$628 Million Contract*, New York Times (Apr. 20, 2021) (online at www.nytimes.com/live/2021/04/20/world/covid-vaccine-coronavirus-cases/congress-is-investigating-the-company-whose-factory-ruined-vaccine-doses-and-received-a-628-million-contract).

⁵⁰ Ex. 21, Consulting Agreement Between Emergent BioSolutions Inc. and RPK Consulting Group, Inc. (Feb. 1, 2012) (EBSI_HCOR_0007020 – 28); Ex. 22, Work Order No. 1 Between Emergent BioSolutions Inc. and RPK Consulting Group, Inc. (Feb. 1, 2012) (EBSI_HCOR_0007029 – 30); Ex. 23, Work Order No. 2 Between Emergent BioSolutions Inc. and RPK Consulting Group, Inc. (Feb. 1, 2013) (EBSI_HCOR_0007031 – 32); Ex. 24, Work Order No. 3 Between Emergent BioSolutions Inc. and RPK Consulting Group, Inc. (Feb. 1, 2014) (EBSI_HCOR_0007033 – 34).

⁵¹ Ex. 25, Dr. Bob Kadlec Scope of Work (EBSI_HCOR_0007019).

of the performance evaluations made any reference to the manufacturing problems at the Bayview facility. The executive in charge of manufacturing operations and ensuring operational excellence was even awarded a “special bonus” of \$100,000—on top of a regular bonus of \$320,000—in recognition for his “exceptional performance” over the year “related to COVID-19.”⁵²

A. **Robert Kramer – President and CEO**

Emergent found that CEO Robert Kramer “**Significantly Exceed[ed]**” expectations in his 2020 performance—the highest rating available in the company’s annual performance reviews.⁵³ The company also found that he “Led Executive Management Team **to deliver exemplary overall 2020 corporate performance.**”⁵⁴ Mr. El-Hibri praised Mr. Kramer’s performance:

Mr. El-Hibri discussed his assessment of Mr. Kramer’s **exceptional leadership** throughout the year with **stellar performance for the Corporation**, despite facing extraordinary obstacles during the COVID-19 pandemic and **steering the company on a successful path despite such challenges.**⁵⁵

The Compensation Committee awarded Mr. Kramer a cash bonus of \$1,225,020 in recognition of his performance in 2020—on top of a base salary of \$875,014 and \$4.1 million in stock awards and options issued earlier in the year.⁵⁶ The Committee also approved a 2021 compensation package for Mr. Kramer of \$7.8 million. This included a salary of \$1 million

⁵² Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001414 – 21); Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001346 – 73).

⁵³ Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415); Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001353) (emphasis added); Ex. 26, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Dec. 22, 2021) (EBSI_HCOR_0001252 – 339 at EBSI_HCOR_0001278).

⁵⁴ Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001353) (emphasis added).

⁵⁵ Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415) (emphases added).

⁵⁶ *Id.* at EBSI_HCOR_0001415 – 16; Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001353).

(a 14 percent raise from 2019), a target bonus of 120 percent his base salary, and \$5.6 million in stock awards and options to be issued in February 2021.⁵⁷

B. Fuad El-Hibri – Executive Chairman

Emergent found that Mr. El-Hibri “exceed[ed]” expectations and lauded his **“contributions to the Corporation’s exemplary success in 2020, including leveraging his critical relationships with key customers, Congress, and other stakeholders.”**⁵⁸ The company noted that Mr. El-Hibri provided: “Executive team support, including mentorship and guidance to CEO on strategic, business development, management and culture.”⁵⁹ The Compensation Committee granted Mr. El-Hibri a 2021 compensation package worth more than \$3.7 million, including a salary of \$1,135,000 (a 4.5 percent raise from 2019) and stock awards and options totaling \$2.6 million.⁶⁰

C. Other Executives

Emergent praised the other members of the executive management team for delivering “exemplary overall 2020 corporate performance including significantly outperforming revenue and earnings targets.”⁶¹ Sean Kirk, the executive responsible for overseeing development and manufacturing operations at all of Emergent’s manufacturing sites, including Bayview, was praised for his **“exceptional role in executing on key manufacturing strategy throughout the year”** and **“exceptional performance and contribution to the Corporation’s stellar financial performance.”**⁶² Despite Emergent’s failure to address shortcomings at Bayview, the Compensation Committee awarded Mr. Kirk a cash bonus of \$320,611 and a “special bonus

⁵⁷ Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001354); Emergent BioSolutions, *Form 8-K* (Feb. 16, 2021) (online at www.sec.gov/ix?doc=/Archives/edgar/data/0001367644/000136764421000020/ebs-20210209.htm).

⁵⁸ Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415) (emphasis added).

⁵⁹ Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001351).

⁶⁰ *Id.* at EBSI_HCOR_0001352; Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415); Emergent BioSolutions, *Form 8-K* (Feb. 16, 2021) (online at www.sec.gov/ix?doc=/Archives/edgar/data/0001367644/000136764421000020/ebs-20210209.htm).

⁶¹ Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001365).

⁶² Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415) (emphases added).

award” of \$100,000 for “**significant CDMO expansion related to COVID-19**” and in recognition of “**his exceptional performance in 2020.**”⁶³

The Compensation Committee awarded each executive the following performance ratings, bonuses for 2020, and compensation packages for 2021:

Name	2020 Performance Rating⁶⁴	2020 Bonus⁶⁵	2021 Base Salary⁶⁶	2021 Target Bonus⁶⁷	2021 Stock Awards and Options⁶⁸
Sean Kirk – EVP, Manufacturing and Technical Operations	“Significantly Exceeds”	\$320,611 + \$100,000 “Special Bonus Award”	\$510,000	60% of Base Salary	\$1.2 million
Richard Lindahl – EVP, Chief Financial Officer, and Treasurer	“Exceeds”	\$462,012	\$575,000	60% of Base Salary	1.5 million
Adam Havey – EVP, Business Operations	“Exceeds”	\$445,204	\$555,000	60% of Base Salary	1.4 million
Atul Saran – EVP, Corporate Development and General Counsel	“Exceeds”	\$445,204	\$555,000	60% of Base Salary	1.4 million

⁶³ *Id.* at EBSI_HCOR_0001415 (emphasis added); Ex. 2, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Jan. 20, 2021) (EBSI_HCOR_0001340 – 411 at EBSI_HCOR_0001365) (emphasis added).

⁶⁴ Ex. 1, Memorandum from Daniel Woubishet, Associate General Counsel and Assistant Secretary, Emergent BioSolutions, to the Compensation Committee of the Board of Directors, Emergent BioSolutions (Feb. 19, 2021) (EBSI_HCOR_0001412 – 502 at EBSI_HCOR_0001415 – 16).

⁶⁵ *Id.* at EBSI_HCOR_0001416.

⁶⁶ *Id.* at EBSI_HCOR_0001417.

⁶⁷ *Id.*

⁶⁸ *Id.* at EBSI_HCOR_0001431 – 33.