**Response of Robert Kramer,**
**President and Chief Executive Officer, Emergent BioSolutions Inc.,**
**to Questions for the Record of the**
**Select Subcommittee on the Coronavirus Crisis**

**Chairman James Clyburn**

**Mr. Kramer testified that the "viral contamination incident" at the Bayview facility was limited to one batch of the Johnson & Johnson vaccine, which he stated was roughly equivalent to "about 15 million doses." Mr. Kramer acknowledged that doses of the AstraZeneca vaccine were also discarded due to contamination at the Bayview facility, but was unable to provide the total number, and agreed to provide these figures at a later date.**

1. **Please provide the following information for the AstraZeneca and Johnson & Johnson coronavirus vaccines manufactured at the Bayview facility:**
   a. **total number of vaccine doses that have been discarded or destroyed, as well as the reason(s) for discarding or destroying the vaccines, the date the doses were discarded, and the location within Bayview where they were manufactured;**
   b. **total number of vaccine doses that have been shipped, as well as the current status of those vaccines (including the total number of doses held for further testing, such as by the Food and Drug Administration or foreign authorities to determine they are safe, the anticipated timeline for completing such testing, and any results of such testing received by the company to date); and**
   c. **total number of vaccine doses that have been manufactured but not shipped, as well as the current status of those vaccines.**

Emergent does not manufacture finished doses of COVID-19 vaccine. Emergent produces bulk drug substance used in the Johnson & Johnson COVID-19 vaccine, and Johnson & Johnson manufactures the actual doses. The same was true for the AstraZeneca COVID-19 vaccine. Our understanding, however, is that each batch of Johnson & Johnson COVID-19 vaccine bulk drug substance Emergent provides can yield approximately 10 to 15 million doses of Johnson & Johnson COVID-19 vaccine and that each batch of AstraZeneca COVID-19 vaccine bulk drug substance can yield approximately 2.5 to 3 million doses of AstraZeneca COVID-19 vaccine. These ranges are only estimates, as each batch differs. Furthermore, Emergent is not directly aware of the outcome of each subsequent manufacturing step and status of the vaccine substance after a batch leaves Bayview, including in the drug product fill and finish process, during which some loss of bulk drug substance is normal.

**Chairwoman Carolyn Maloney**

**Please provide the dates when Mr. Kramer became aware of the results of each of the inspections, audits, or risk assessments of the Bayview facility relating to manufacturing, quality, or compliance that were completed in 2020 and 2021, including but not limited to inspections, audits, or risk assessments conducted by:**

1. **the Food and Drug Administration;**
2. **Janssen Pharmaceuticals;**
3. **AstraZeneca;**
4. **the Biomedical Advanced Research and Development Agency;**
5. **Operation Warp Speed; or**
6. **any inspector or auditor hired by Emergent, or any subsidiary or affiliate thereof.**

Mr. Kramer was not routinely apprised of the specific details of the many audits, inspections, and risk assessments that took place. Reports of inspections, audits, and risk assessments are a constant in Emergent's industry, and information contained in those reports is provided to senior management where appropriate. Emergent, like other companies involved in the manufacturing of regulated products, regularly conducts audits and risk assessments with respect to its own processes, procedures, and facilities. In addition, Emergent's customers and regulators, including the FDA, inspect and audit Emergent's facilities from time to time. Such internal and external inputs are a necessary and welcomed source of feedback that assists the manufacturer in making its processes and end products safe and compliant with applicable laws and regulations.

On a routine basis, the observations and findings from audits, inspections, and risk assessments are reviewed and discussed both internally and with those who issued the relevant reports. Emergent assesses the observations contained in such reports to ensure that issues are addressed appropriately, including via process and facility improvements. The identification of areas for improvement is a critically important output of the process of conducting inspections and audits. It also is a routine occurrence and is designed to strengthen the integrity of the company's quality systems. Such findings are recorded in the company's systems to make sure that they are monitored and responded to appropriately and in a timely manner. Bayview, like each of the company's other eight facilities, has a head of quality and a head of manufacturing. Typically, those individuals, in conjunction with their managers and other relevant personnel, address the findings from audits or inspections.

Mr. Kramer was aware that vendors, such as Janssen and AstraZeneca, conducted audits from time to time and that the FDA and other regulators conducted inspections as well. Similarly, he was aware that the company carried out risk assessments of Bayview and other facilities when needed. As a general matter, Mr. Kramer did not normally receive copies of the reports from such audits, inspections, or risk assessments. Similarly, he was not routinely advised of any findings made in such reports. Rather, issues raised during these normal course activities were elevated to Mr. Kramer when deemed appropriate, taking into account the development-stage status of the Bayview facility prior to the pandemic. Mr. Kramer does not recall the exact dates on which he became aware of any particular inspection, audit, or risk assessment.

**Please provide the date when Mr. Kramer became aware of each event requiring the destruction of AstraZeneca vaccines at the Bayview facility, and the date when this information disclosed to the public by Emergent.**

Mr. Kramer was not aware of any "event requiring the destruction of AstraZeneca vaccines at the Bayview facility."

Beginning in June 2020, Emergent worked with AstraZeneca to develop the processes for manufacturing bulk drug substance for use in a potential AstraZeneca vaccine. Normally, it takes many months, if not years, to develop consistent manufacturing processes in a facility for manufacturing a biologics product like the AstraZeneca vaccine, including when those processes are well-developed elsewhere. Even after manufacturing processes are well-developed and mature, it is common to reject or terminate batches for many reasons, including human error, equipment failure, out-of-specification tests, and in the case of a low-bioburden facility like Bayview, excess microbial growth. With respect to AstraZeneca, the manufacturing process for the bulk drug substance began as AstraZeneca was still refining the manufacturing process, including with inputs from lessons learned at Emergent and other manufacturing facilities. It was understood by all parties involved that starting the manufacturing of the bulk drug substance while the manufacturing processes were still being refined would likely result in batches of the drug bulk substance not meeting all specifications and therefore not being suitable for use in vaccines. Indeed, this approach was taken at the direction of AstraZeneca and Operation Warp Speed. The judgment was made that the likelihood of having to dispose of batches of bulk drug substance produced under these circumstances was acceptable in light of the dual benefits of expediting the refinement of production processes and the possibility of producing at least some batches that would meet rigorous quality standards. During the relevant time period, AstraZeneca, BARDA, and other government agencies were advised on a routine basis of the status of individual batches, including those determined to be out of specification.

**Please provide the date when Mr. Kramer become aware of each event requiring the destruction of Johnson & Johnson vaccines at the Bayview facility, and the date when this information was disclosed to the public by Emergent.**

Mr. Kramer was not aware of any "event requiring the destruction of Johnson & Johnson vaccines at the Bayview facility."

As with AstraZeneca, Emergent entered into a contract to manufacture bulk drug substance for Johnson & Johnson for use in a COVID-19 vaccine. In early March 2021, a sample from a batch of bulk drug substance manufactured for Johnson & Johnson was, as a result of routine quality control testing, suspected to be out-of-specification. Investigative steps were then taken, which included subjecting the batch of bulk drug substance to additional analysis. On March 24, 2021, investigational testing by Emergent identified the presence in the batch of a viral vector consistent with the AstraZeneca viral vector, which meant that the batch could not be used. Mr. Kramer recalls being informed of that development on either March 24 or March 25, 2021, and also recalls being informed earlier that a sample from a batch had failed an out-of-specification test. Out-of-specification tests happen from time to time and he does not recall the date on which he learned of that. The manufacturing investigation, in accordance with Emergent's normal procedures, commenced on March 17, 2021 and the Investigation and Impact Assessment report containing the initial findings from the investigation was submitted by Janssen to the FDA on April 5, 2021. The New York Times reported the cross-contamination

event on March 31, 2021, which necessitated Emergent to comment publicly before the manufacturing investigation had been completed and, accordingly, on April 1, 2021, the company issued a press release regarding the need to dispose of the batch. Again, during the relevant time period, AstraZeneca, BARDA, and other government agencies were advised on a routine basis of the status of individual batches, including those determined to be out of specification.

**What steps did Emergent take following the destruction of AstraZeneca vaccines at the Bayview facility in late 2020, such as, but not limited to, notification to Emergent management, AstraZeneca, or the Food and Drug Administration, or implementation of new quality control processes, training, or manufacturing standards?**

As noted above, based on a collaborative decision made by all stakeholders in light of the pandemic, production for AstraZeneca commenced while AstraZeneca was still developing the manufacturing processes for the bulk drug substance. At the time the process was transferred to Bayview, it was not even clear what manufacturing scale would be used. After manufacturing began, there were dozens of changes to the manufacturing process in a 60-day period. By contrast, under usual, non-pandemic circumstances, the processes would have been fully validated prior to beginning commercial-scale manufacturing activity, and there normally would have been no process changes during production. This approach to manufacturing was a departure from what would normally occur, but all stakeholders supported this approach given the urgent need to quickly ramp up the manufacturing of the vaccine. The approach did not jeopardize patient safety, as all parties focused on the need to maintain quality and safety steps, but the accelerated development and production plan did increase the likelihood that issues would arise with respect to production batches of drug bulk substance and that some would need to be discarded. The lessons learned from runs of drug bulk substance for the AstraZeneca vaccine that were rejected or terminated fed into process development and modification and were shared with the other facilities across the world manufacturing drug bulk substance for the AstraZeneca COVID-19 vaccine. The overall manufacturing success rate increased significantly based upon what was learned from early runs. Again, during the relevant time period, AstraZeneca, BARDA, and other government agencies were advised on a routine basis of the status of individual batches, including those determined to be out-of-specification.

**<u>Rep. Nydia Velázquez</u>**

**Mr. Kramer testified that he did not have any conversations with Dr. Kadlec about contracts awarded to Emergent. Did Mr. Kramer have any conversations, on any subject, with Dr. Kadlec following his appointment? If so, what were the dates and subject matter of these conversations?**

During the hearing, Mr. Kramer was asked whether he had spoken with Dr. Kadlec about two agreements "while these contracts were being issued." Specifically, Rep. Velázquez referenced an ASPR award of a new 10-year, $2 billion contract for smallpox vaccines and a $261 million option exercise for anthrax vaccines under an existing contract. The government exercised an option under the $261 million anthrax contract on July 30, 2019. As he testified, Mr. Kramer did not recall having spoken with Dr. Kadlec about the agreements while they were being issued.

In November 2019, months after the $261 million option exercise under an existing anthrax contract had been signed, Mr. Kramer spoke with Dr. Kadlec about the government's strategy

for utilization of BioThrax, the FDA-approved vaccine manufactured by the company, and AV7909, the second-generation vaccine candidate under development that the Strategic National Stockpile had begun procuring. In addition, Mr. Kramer recalls interacting briefly with Dr. Kadlec at an event in May 2019, when they met in passing. Mr. Kramer recalls that he and Dr. Kadlec exchanged pleasantries but does not recall there having been any substantive discussions.

**Did Mr. Kramer socialize with Dr. Kadlec after his appointment? Please provide specific dates and descriptions of these interactions.**

As noted above, Mr. Kramer recalls meeting him in passing at an event.

**Rep. Bill Foster**

**Mr. Kramer testified that he did not have the "exact numbers" on how much Emergent spends on lobbying and government relations. For the past five years, how much has Emergent spent on an annual basis on: (a) lobbying and government relations; and (b) quality control processes and training?**

Emergent has reviewed its Lobbying Disclosure Act reports, which indicate Emergent and its subsidiaries spent approximately $17 million on federal lobbying activity from 2016 through 2020. During that same period, Emergent spent more than $229 million on Quality Department costs. While Emergent does not separately track training expenses on a comprehensive basis, the company has invested significantly in a training system that tracks and monitors employee review of policies, procedures, and other training programs.

**Rep. Jamie Raskin**

**Please describe how bonuses were distributed across all levels of Emergent's workforce in 2020 and 2021, including to employees who worked on the manufacturing floor, in cleaning and sanitation, and in other non-executive positions.**

All Emergent employees are eligible for bonuses. The proportion of an employee's total compensation package made up by a target bonus increases based on seniority, as does the impact of corporate results on the amount of a bonus.

Emergent also generally makes annual equity grants to employees at the senior manager (or equivalent) level or above. In addition to these regular grants, in June 2020, Emergent made a special equity grant in the value of $7,500 to all full-time employees below the senior vice president level. Part-time employees received a pro-rated award based on their normal part-time work schedule. This equity grant program was extended through the end of 2020 for certain new hires. Additionally, Emergent currently provides $7,500 equity grants to newly hired employees at the Bayview, Camden, and Maryland Central Warehouse facilities who are not otherwise equity eligible.

Emergent has also instituted a number of additional cash and equity incentives, particularly for employees in Bayview and the central warehouse. For example, exempt employees who are working more than 55 hours per week are earning a 20% pay premium.

**Mr. Kramer testified that the $27 million per month reservation fee set forth in Emergent's May 24, 2020, agreement with the Trump Administration was based on the "market rate" of "production suite time." Please provide specific detail on how this "market rate" was determined.**

The reservation fee was priced based on the comparable fees that actual commercial customers had been willing to pay Emergent for production of COVID-19 vaccine drug substance. The price was reviewed and approved by experienced government contracting officers with transparency as to how the fee was calculated and an understanding of the costs, risks, and benefits. In particular, BARDA understood and clearly specified they wanted to pay to reserve the space so they could direct what programs were being manufactured in that space and understood that they would be paying the fee even if they did not use the facility.

**In both documents and in their testimony, Emergent's leadership has acknowledged FDA's finding that Emergent employees were not adequately trained. Mr. Kramer testified that Emergent is using the current pause in new manufacturing to provide "comprehensive training" to its Bayview personnel.**

**1. What does this "comprehensive training" consist of? Please provide a detailed description of all training that has been or will be provided, as well as a timeline for the completion of this training.**

**2. Prior to the current pause in new manufacturing, what training was conducted at the Bayview facility relating to quality control and contamination prevention?**

Emergent does not believe its employees were inadequately trained. The cross-contamination incident involving a batch of Johnson & Johnson vaccine bulk drug substance was, however, unacceptable, and the company has taken a number of steps, including enhancing employee training at Bayview, in response.

Our strengthened training program includes instructor-led and on-the-job training to instill best practices and address prior inspectional observations. While deployment of the enhanced training program is ongoing, we have, since the manufacturing pause, completed instructor-led training sessions on a number of topics, including gowning practices and proper cleanroom behavior, waste handling and material and waste flow, the Bayview facility's strengthened cleaning program, and Good Manufacturing Practice principles, microbial contamination prevention, and viral containment.

Before the manufacturing pause, Bayview employees received industry standard training, including on every standard operating procedure required to perform their specific roles. Rapidly ramping up operations at Bayview and hiring a hundreds of new skilled workers there, to facilitate production of COVID-19 vaccine bulk drug substance at an unprecedented pace, did present training challenges, and we have redoubled our efforts to continually train new and existing personnel at Bayview.