Responses by Fuad El-Hibri,
Executive Chairman of the Board of Directors, Emergent BioSolutions Inc., to
Questions for the Record of the
Select Subcommittee on the Coronavirus Crisis

Chairwoman Carolyn Maloney

Please provide the date when Mr. El-Hibri 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.**

As Executive Chairman of the Board of Directors, from time to time Mr. El-Hibri is made aware of inspections and audits of Emergent's facilities, including the Bayview facility, through discussions with company executives. Mr. El-Hibri would not in the ordinary course of business be apprised of the many audits and inspections that take place or the specific details of such audits and inspections and has no recollection of being specifically apprised of the results of any of the audits and inspections that took place in 2020. Mr. El-Hibri was generally aware of the fact that Janssen, AstraZeneca, and BARDA had audited Bayview and that FDA and the European Medicines Agency had visited the facility as well. Mr. El-Hibri was also made aware of Janssen's assessment conducted after Emergent notified FDA of the incident involving cross-contamination of a batch of bulk drug material for the Johnson & Johnson/Janssen COVID-19 vaccine. Mr. El-Hibri was informed in April 2021 of the FDA inspection that took place at Bayview that month.

Please provide the date when Mr. El-Hibri 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. El-Hibri was not aware of any "event requiring the destruction of AstraZeneca vaccines at the Bayview facility." All parties involved, including Mr. El-Hibri, understood that starting the manufacturing of the bulk drug substance while the manufacturing processes were still being refined and scaled up from 500 to 2,000 liters, as was the case for the AstraZeneca vaccine bulk drug substance, carried a significant risk of some batches of the bulk drug substance not meeting all specifications and therefore not being suitable for use in vaccines.

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

Mr. El-Hibri was not aware of any "event requiring the destruction of Johnson & Johnson vaccines at the Bayview Facility." On March 31, 2021, Mr. El-Hibri was made aware of the cross-contamination of a batch of bulk drug substance for the Johnson & Johnson/Janssen COVID-19 vaccine candidate.

Regarding any public disclosures of information concerning the manufacturing of COVID-19 bulk drug material, Emergent discloses information to the public as required by federal securities laws. Emergent's public disclosures are available in its filings with the Securities and Exchange Commission.

In the late 1990s, Emergent charged the U.S. government approximately $3 per dose for its anthrax vaccine. Today, Emergent charges the U.S. government over $30 per dose. Mr. El- Hibri testified he would provide further information regarding Emergent's anthrax vaccines.

1. **Please provide the following information for Emergent's anthrax vaccines, BioThrax and NuThrax:**
   a. **the company's cost to produce a dose; and**
   b. **the company's profit margin per dose.**
2. **Why has Emergent raised the price it is charging the U.S. government for its anthrax vaccines more than 800% since 1998?**

Over the period of 2019 and 2020, the U.S. government procured doses of anthrax vaccine (BioThrax and AV7909, formerly referred to as NuThrax) for a weighted average price of $24.75. On a per dose basis, the weighted average cost for these doses was $6.78. The gross margin for anthrax vaccines sold to the U.S. government during this period was approximately 72.6%, but that figure relates only to manufacturing costs and does not include R&D that supports the products, administrative costs attributable to the products, taxes, or financing costs, all of which must be considered in the overall management of the business. Emergent on the whole reported a net profit margin of 13.5% across this period.

The current price of BioThrax and AV7909 is derived from a number of factors and resulted from negotiations with sophisticated, career government contracting officials, who determined price reasonableness based on the federal acquisition regulations. Emergent's anthrax vaccines remain one of the lowest priced vaccines that the government procures across all relevant vaccine programs. Notably, the State of Michigan was unable to maintain the facility at a price of $3 per dose, demonstrating that such a price was not reasonable or sustainable to continue manufacturing of the product. When HHS first started contracting for BioThrax with Emergent over 15 years ago, the Government conducted a cost and price audit and determined $24.50 was a fair and reasonable price, which is comparable to the current per dose price. Additionally, raw material costs have increased over time, and Emergent has made significant at-risk infrastructure investments to produce the quantity of vaccines needed to fulfill requirements. The price agreed upon by Emergent and the U.S. government also takes into account the cost of sustaining manufacturing capability, as the commercial market for the product is small and Emergent has been required to undertake substantial cGMP quality systems enhancements to

meet regulatory expectations. The quality and value of the vaccine has improved, including dose reduction and increased shelf-life, and its approval for another indication, post-exposure prophylaxis alongside antibiotics.

Rep. Nydia Velázquez

Following Dr. Robert Kadlec's appointment as Assistant Secretary for Preparedness and Response, Mr. El-Hibri testified that he spoke to Dr. Kadlec "four to five times in that two-to-three-year period." What were the dates and subject matter of these conversations?

At the May 19 hearing, Mr. El-Hibri testified that he recalled meeting with Dr. Kadlec "maybe four or five times during a two-to-three year period" after his confirmation. Mr. El-Hibri does recall a social meeting with Dr. Kadlec in December 2019, which he recalls was the last time he met with Dr. Kadlec. Mr. El Hibri does not recall the specific dates of other interactions with Dr. Kadlec after his confirmation, but he does recall seeing Dr. Kadlec on three other occasions, one of which was principally social and two of which were principally business. At the two business meetings, Mr. El-Hibri recalls discussing policy issues with regard to medical countermeasures, as well as the role Emergent plays in supporting BARDA's mission. Mr. El-Hibri also believes he may have interacted with Dr. Kadlec via telephone on one or two occasions during this period, but he does not recall the specific dates of such calls.

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

Mr. El-Hibri recalls seeing Dr. Kadlec socially on two occasions after his confirmation. One of the social meetings was in December 2019, and Mr. El-Hibri does not recall the specific date of the other social meeting.

Rep. Bill Foster

Mr. El-Hibri testified that due to a historical lack of work orders, the Bayview facility was unable to achieve manufacturing readiness. Since the inception of the CIADM program in 2012, how much of an investment would have been needed to reach and maintain "capacity readiness"?

Since 2012, Emergent has invested more than $200 million of its own funds in capital expenditures and operating costs at Bayview. Despite these substantial investments and those of the U.S. government, the facility, prior to commencing COVID-19 vaccine manufacturing, was operating only at the base minimal requirements outlined in the 2012 contract with BARDA with no commercial production. The facility was not fully staffed or operating anywhere near capacity. During this time, Bayview operated at a substantial annual loss. Mr. El-Hibri is not aware of a specific dollar figure for funding that would have been sufficient to achieve full readiness for Bayview, but it is likely to be in the tens of millions of dollars on an annual basis. In Mr. El-Hibri's opinion, in order to achieve and maintain the status of readiness to produce commercial products or products under an Emergency Use Authorization at a large scale with only months of response time, any CIADM facility would have to be tested for technology transfer, scale up, and commercial manufacturing and produce at least one product candidate per year.