Testimony of Fuad El-Hibri
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Before the Select Subcommittee on the Coronavirus Crisis
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Chairman Clyburn, Chairwoman Maloney, Ranking Member Scalise, and Members of the Subcommittee, my name is Fuad El-Hibri and I am the Executive Chairman of Emergent BioSolutions Inc. I have been asked to address questions regarding Emergent's role in the COVID-19 pandemic response, including the federal contracts awarded to Emergent.

Emergent started as a small company that in 1998 acquired the rights to a Michigan vaccine laboratory and manufacturing facility. The site's primary function was to produce anthrax vaccine for the Department of Defense, but the manufacturing capacity at the time was only a fraction of the tens of millions of doses the U.S. Armed Forces required per year. At the time we acquired it, the facility was subject to an FDA notice of intent to revoke its license. Manufacturing medical countermeasures for public health threats like anthrax has always been a challenge because maintaining quality manufacturing infrastructure for complex biological products is an intricate and expensive undertaking. Indeed, significant investment of our capital and funding from the Department of Defense were required to make the Michigan facility viable. This work took on heightened importance after the anthrax attacks on Congress that immediately followed the events of September 11, 2001.

I served as the President and Chief Executive Officer of Emergent from its inception until 2012. By the time I stepped down, the company had stabilized the manufacturing of anthrax vaccine at a high quality, a larger scale, and a regular cadence, which allowed for vaccinating American troops and supplying the Strategic National Stockpile to protect the American public. The investments made during that time enabled the establishment and long-term maintenance of this critical capability. Since that time, I have been Executive Chairman of the Emergent Board of Directors, which means I am responsible for Board leadership, governance-related external outreach, and advising the management team on strategic decisions, rather than day-to-day management.

Emergent handles some of the most challenging biological materials in its manufacturing processes, including anthrax bacteria and live virus strains. Accordingly, since its founding, we have strived to manufacture at the highest quality in all of our facilities. The Board takes that responsibility very seriously. On behalf of the Board, I would like to assure the Subcommittee, and the American people, that we understand the importance of the work Emergent has undertaken. In this pandemic, the company has been working with a number of biopharmaceutical companies on COVID-19 vaccine and therapeutic candidates, most notably Johnson & Johnson and AstraZeneca, as well as its own internal R&D programs. Many of these programs have been funded, directly or indirectly, by the U.S. Government.

Emergent's Board has long believed in rigorous standards of governance. We have continued to externally benchmark our approach to governance as we have grown over the last two decades.

We recognize the challenges presented by the COVID-19 pandemic and have been supportive of Emergent's role in responding to the pandemic.

As you are aware, we recently had a cross-contamination event with one lot of vaccine bulk substance at our Bayview facility in Baltimore, Maryland. Manufacturing drug substance for two viral products in one facility on a massive scale, while incorporating new manufacturing technology into the facility, is a challenge at any time, even more so in the midst of a public health emergency. Regardless, the contamination was unacceptable. Mr. Kramer will testify regarding the specific actions that the company is taking to remedy the situation. Given this incident, at the Board level, we have expanded our oversight. In the last six weeks, in addition to our regular meetings, the Board has met six times to oversee management's progress. At our last meeting, the Board authorized the creation of a Special Committee charged with manufacturing and quality oversight.

In addition, in consultation with the Board, Mr. Kramer has recently changed the reporting structure for the quality organization, so that it now reports directly to him, and changed the management oversight for the Bayview facility. I want to assure the Subcommittee that Emergent is committed to addressing all quality and manufacturing issues at the Bayview facility with diligence, thoroughness and urgency, so that Johnson & Johnson can deliver safe and effective vaccines to the American people and the world in response to the continuing global health crisis.

I would also like to address the suggestion that has been made that my personal relationship with Dr. Robert Kadlec influenced the award of government contracts to Emergent. This is simply not true. Dr. Kadlec had a distinguished career in the United States Air Force for more than 20 years as an officer and physician. He served in many senior positions in government dealing with biodefense issues. During his time outside of government, he was a valued consultant to our company and others, and years later re-entered the federal government as HHS Assistant Secretary for Preparedness and Response. Emergent's relationship with Dr. Kadlec was appropriate. And Emergent's contracts with the U.S. Government, including those associated with the COVID-19 response, have all been subject to standard government contracting procedures, overseen by independent career government contracting officers.

To conclude, I would like to emphasize that Emergent takes very seriously its role as a reliable supplier of medical countermeasures, vaccines, and therapeutics for public health threats to the U.S. Government and to patients and customers. This is important work, which is why I have dedicated so much of my professional life to this cause. We remain very focused on addressing the manufacturing challenges at the Bayview facility, and the Board's top priority is to ensure that management takes all corrective actions required to resume production.

Thank you for the opportunity to appear today. I look forward to answering your questions.