Testimony of Robert Kramer
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Chairman Clyburn, Chairwoman Maloney, Ranking Member Scalise, and Members of the Subcommittee, my name is Bob Kramer. I am the President, Chief Executive Officer, and a Board Member of Emergent BioSolutions Inc. Thank you for the opportunity to appear today to discuss Emergent's role in the COVID-19 pandemic response, as well as the recent suspension of manufacturing of new COVID-19 bulk vaccine substance at our Bayview facility in Baltimore, following the identification of viral contamination in a single batch of vaccine material through existing quality control procedures for this program.

Emergent has performed many vital missions for the United States Government since its founding in 1998, and especially since the nation focused on the critical importance of biodefense after the September 11th terrorist attack and subsequent anthrax attacks. We recognize that our role in helping the nation respond to, and hopefully end, the COVID-19 pandemic is a profound and unique responsibility, unlike any we have confronted before. We have worked around the clock, at every level of our company, since we were called upon to be a critical manufacturer for the COVID-19 vaccine supply chain. And I can assure you, no one is more disappointed than we are that we had to suspend our 24/7 manufacturing of new vaccine, after all the heroic efforts that our employees have made during this pandemic. As CEO, I take full responsibility for that. And I take full responsibility for executing the corrective actions that are needed to enable resumed manufacturing of up to a billion doses annually of COVID-19 vaccine, in close collaboration with Johnson & Johnson.

Background and History of Emergent

Emergent is a global life sciences company headquartered in Gaithersburg, Maryland. For more than two decades, we have provided civilian and military populations with products that help ensure they are protected from and prepared to respond to public health threats, ranging from bioterrorism and bioweapons to emerging infectious diseases. The company currently has more than 1,800 employees and operates seven manufacturing and development facilities in the United States, which are located in Maryland, Massachusetts, Michigan, California, and Mississippi. We conduct research and development on our own highly specialized products, manufacture most of those products ourselves, and provide contract development and manufacturing services to third-party customers in the pharmaceutical industry, particularly for complex biologic products. Since our founding, we have focused on public health threats that could pose an

extraordinary danger to the nation, such as bioterror weapons. Addressing these threats requires a unique set of capabilities for which there is little demand in the normal commercial market, which has made the U.S. Government our largest customer.

Since 2003, we have spent more than $854 million on research and development, which is 10% of our revenue over that period of time. This is in addition to the significant amount of research and development funding we have received from the U.S. Government. We have also invested more than $900 million dollars in capital expenditures for our facilities and technology. Currently, we have a portfolio comprised of 12 products and procured product candidates, including vaccines, therapies, devices, and drug-device combinations. These include vaccines for anthrax, a disease with a fatality rate as high as 80 percent, which can be weaponized by terrorists or state actors. Our BioThrax product is the only vaccine licensed by the Food and Drug Administration ("FDA") for general use prophylaxis and post-exposure prophylaxis of anthrax disease. We are also developing AV7909, our next-generation anthrax vaccine candidate, which the U.S. Government has started procuring for the Strategic National Stockpile ("SNS").

Our product ACAM2000 provides the U.S. Government with the only single-dose smallpox vaccine licensed by FDA for active immunization against smallpox disease. Routine vaccination of the American public for smallpox ended in 1972, and the disease was eradicated worldwide in 1980. A large proportion of the population has no immunity, and fatality rates could be higher than 25% if smallpox were to be released as a bioterror weapon. We also offer vaccines for typhoid fever and cholera, as well as drugs to treat anthrax, botulism, and complications from smallpox vaccination. Our RSDL Kit, Trobigard Auto-Injector, and several auto-injector product candidates under development are procured by, and under development with, certain U.S. and foreign government agencies as medical countermeasures for chemical nerve agent attacks. We are also part of the fight against the opioid crisis that has claimed so many lives, with our Narcan® Nasal Spray product, and we work closely with state and local governments to ensure that this overdose countermeasure is made widely available throughout the United States.

From the beginning, Emergent has taken on challenges that other companies were not prepared to undertake in order to fill critical needs for the U.S. Government and the American people. When the State of Michigan decided to discontinue its role operating the sole U.S. facility that made anthrax vaccine for the military, Emergent, called BioPort at the time, purchased the facility and spent several years restoring it and rebuilding its capacity to provide a safe and reliable supply of anthrax vaccine for the Department of Defense, including investing $91 million of our funds to expand the manufacturing capability. Since then, through five administrations, both Democratic and Republican, the U.S. Government has repeatedly turned to Emergent to produce critically needed vaccines and therapies for biodefense. For example, in 2016, under the Obama-Biden Administration, we received a $1.5 billion contract to develop and

produce our AV7909 anthrax vaccine candidate for the U.S. Government. In March 2017, in the early weeks of the Trump-Pence Administration, we were awarded an additional $100 million contract for BioThrax and our AV7909 contract was modified to increase the number of doses from two million to three million.

Given the lack of private sector customers for any of these products, the company's financial viability is heavily dependent on the shifting priorities of its federal agency customers. As noted by the Congressional Research Service, "[t]he relatively small market for most bioterrorism countermeasures provides little incentive for companies to invest in developing a countermeasure when compared with the larger potential market of other products of the same industry, such as anti-cholesterol drugs."[1] But Emergent has invested when others would not, with vital support from our U.S. Government customers. We are proud that we play this unique role for the country, notwithstanding the business risks, and we have a proven record of delivering on our commitments. We have worked hard to ensure that both political leaders and career government officials understand the importance of preparedness and the investment required not only to manufacture product, but also to ensure that the capability can be sustainably maintained.

Because of our deep expertise in, and commitment to, preparedness against public health threats, we have vigorously advocated for increased government funding to respond to the full range of threats, including both bioterror weapons and emerging infectious diseases. We have engaged extensively with policymakers in Congress and the executive branch, again through Democratic and Republican administrations, to advocate for federal funding and programs commensurate with the threats we face as a nation.

The CIADM Program

After the 2009 H1N1 influenza pandemic, the Biomedical Advanced Research and Development Authority ("BARDA") recognized that the United States lacked sufficient domestic manufacturing capacity and capability to manufacture influenza vaccine in quantities necessary to vaccinate the American public in a short period of time. The problem was not trivial—the capability to manufacture complex biologic products, whether for influenza or other infectious disease threats, can often take years to develop and must be maintained constantly in order to be at the ready. This concern prompted BARDA to fund three Centers for Innovation in Advanced Development and Manufacturing ("CIADM") facilities, in order to establish and maintain a domestic capability to meet the demands of a potential influenza pandemic or other pandemic emergency. As originally conceived, the program was intended not only to identify and build

[1] Frank Gottron & Dana Shea, Cong. Rsch. Serv., RL 41123, Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress 14 (2011), *available at* https://crsreports.congress.gov/product/pdf/R/R41123/6.

out facilities that could produce medical countermeasures on a large scale, but also to invest in training and maintaining a work force for those facilities. The aim was to invest in ongoing manufacturing operations and work force development, so that in time the facilities could be ready for action on short notice.

In 2009, Emergent purchased the Bayview manufacturing facility in Baltimore, Maryland. In 2012, under the Obama-Biden Administration, Bayview was selected by BARDA as one of the three CIADM facilities. We invested more than $200 million of our funds in operating and building out the facility, expanding its number of manufacturing suites, and bringing the facility up to industry standards over a period of years, in conjunction with funding provided by the U.S. Government. The facility buildout was aimed at being able to produce 50 million doses of influenza vaccine within a four-month period. The expectation was that Emergent would manufacture a wide variety of products both under task orders from the U.S. Government and under commercial contracts with our own customers. From 2012 to 2016, the site progressed largely as planned. We were successfully ramping up the manufacture of a development-stage influenza vaccine and worked on manufacturing other clinical-stage product candidates for our own account and for the U.S. Government under task orders, notably when Zika and Ebola outbreaks occurred.

However, the influenza vaccine sponsor withdrew their product because it was not progressing clinically, and by the time the Bayview buildout was completed in early 2017, the pipeline of task orders from the U.S. Government to utilize the facility, and therefore to hire and train personnel, persistently fell short of what we and the government recognized was needed for the facility to reach its full operating potential. As a result, by the end of 2019, just before the onset of the COVID-19 pandemic, Bayview only had about 100 employees on site and was still at least a year away from licensure to produce its first FDA-approved product.

Throughout this period, Emergent cooperated closely with the U.S. Government on the operation of the facility, and it was the subject of site visits and audits. Meanwhile, the other two CIADM facilities owned by other companies had changed hands several times and were not yet prepared to undertake large-scale, short-notice operations for the U.S. Government. Bayview was the closest of the three CIADM facilities established by BARDA to realizing the CIADM program's original goals.

When the COVID-19 pandemic emerged and rapidly spread around the globe, Emergent, the U.S. Government, and our other partners recognized that, while Bayview was not yet FDA-licensed to produce any product and not yet fully staffed or operating at scale, the facility's unique attributes could be used to support the unprecedented challenge of mass-producing life-saving vaccine for hundreds of millions of Americans. Bayview was constructed to facilitate the use of disposable manufacturing equipment at a very large scale, accommodating bulk drug

substance batch sizes up to 2,000 liters. The facility was also designed and constructed to enable the rapid transfer of new technologies, production of multiple products in the same facility, and to permit biologic product manufacturing dependent on live virus vectors, which requires additional controls, capabilities, and expertise. Bayview's combination of available capacity, use of disposable manufacturing equipment at a large scale, and ability to manufacture live virus vaccines makes it very rare among biologic manufacturers in the United States. So when the U.S. Government and our other partners asked us to undertake a rapid ramp-up of the Bayview facility, with the unprecedented goal of producing hundreds of millions of dose equivalents of COVID-19 vaccine in a one-year period, we immediately agreed and began working around the clock.

Emergent's Role in Combating the COVID-19 Pandemic

In April 2020, Emergent executed an initial agreement to manufacture drug substance for the Johnson & Johnson COVID-19 vaccine candidate at Bayview. Then, in late May 2020, the Government issued a task order under the CIADM contract requiring us to reserve manufacturing capacity at Bayview that was not being allocated to Johnson & Johnson. We were then directed by the U.S. Government to release that capacity to AstraZeneca for large-scale drug substance manufacturing of its COVID-19 vaccine candidate, alongside production of the Johnson & Johnson vaccine.

Ramping up production of two novel vaccines on a very large scale in the same facility on a highly expedited schedule is unprecedented. But the Government decided that, given the critical need for COVID-19 vaccine and the mounting death toll, Emergent should manufacture both drug substances simultaneously at full-scale immediately. We moved with extraordinary dispatch to bring in the new equipment and technology required for the two vaccines' manufacturing processes, dramatically expand the workforce at the facility from approximately 100 to more than 400 workers, train those new employees, and launch manufacturing operations. Emergent accomplished this with complete transparency and in close consultation with Johnson & Johnson, AstraZeneca, and the U.S. Government, all of whom had visited the Bayview facility, audited it and were regularly on-site. All of the parties involved understood the advantages of utilizing this particular facility, as well as the enormous challenges posed by proceeding directly to large-scale manufacturing of both vaccines at the same time. Indeed, both the Johnson & Johnson and AstraZeneca manufacturing supply chains, including Emergent's supporting activities, were issued "rated" orders by the U.S. Government under the Defense Production Act, in order to ensure that the work could be done as expeditiously as possible.

It is important to understand that when Emergent was first asked to manufacture COVID-19 vaccine candidates, over 100 such candidate programs had been initiated against the novel coronavirus and no one knew which of those would demonstrate safety and efficacy to FDA's satisfaction. The mRNA vaccine candidates then being developed by Pfizer and Moderna relied on a novel, untested technology. It was more than conceivable that everything would come to

depend on the Johnson & Johnson and/or AstraZeneca vaccine candidates, both of which are based on proven technology used in existing vaccines. Delaying the start-up of the Bayview facility and large-scale production would have risked inadequate vaccine supplies, particularly if the Pfizer and Moderna vaccine candidates had failed.

The Out-of-Specification Test Result and Initial Laboratory Investigation

Emergent began manufacturing of the AstraZeneca bulk drug substance in August 2020 and did the same for Johnson & Johnson in November. By the end of February 2021, we had established a regular manufacturing cadence, anticipating over one billion dose equivalents of bulk drug substance in 2021. However, in March 2021, a single batch of Johnson & Johnson's COVID-19 vaccine candidate failed routine quality control testing. The batch had been manufactured at Bayview and sent to Johnson & Johnson's laboratory in Leiden, The Netherlands, for testing, consistent with existing quality control requirements. This was one of several rounds of testing that are conducted at various points in the process before vaccine is ever shipped for use in humans.

Biologic product manufacturing is inherently challenging, given the nature of the biological processes being harnessed to generate the vaccine drug substance, and failed batches do occur, and had previously occurred, during the manufacturing process. However, further testing suggested a possible contamination with another adenoviral substance, which is a serious issue. At the time, drug substance manufacturing for the Johnson & Johnson vaccine was underway in Bayview's manufacturing Areas 1 and 2 while AstraZeneca drug substance manufacturing was operating in Area 3. Although the areas are independent and separated from each other, the manufacturing of drug substances of both vaccine candidates in the same facility raised the possibility that the contaminant was the AstraZeneca adenovirus substance.

We immediately initiated a manufacturing investigation in accordance with our standard quality control procedures and quickly agreed upon an investigation plan with Johnson & Johnson. An investigation report was provided to FDA on April 5, 2021. The analysis determined that bioreactor media used for the Johnson & Johnson program was in the vicinity of material being disposed from the AstraZeneca suite, and it is believed that was the point of contamination for this one batch. Detailed testing was also conducted on other batches that were in process, which did not detect the presence of the AstraZeneca virus. While there was no indication that the AstraZeneca manufacturing would have been subject to contamination, out of concern for the Johnson & Johnson program, the U.S. Government decided to immediately terminate all further manufacturing of the AstraZeneca product candidate at Bayview.

Following the contamination of this batch, FDA initiated a for-cause inspection of the Bayview facility. Emergent was instructed to suspend manufacturing of new vaccine and to put a hold on any lots already produced, pending FDA's further review.

Corrective Actions

The contamination incident that led to the shutdown of new vaccine production at Bayview was very serious and completely unacceptable. While it was caught through our standard quality control process and isolated to a single batch, everyone at Emergent is acutely aware of the high stakes involved in fighting the pandemic. The nation is counting on us to meet the highest standards of excellence. We are taking aggressive corrective action to assure FDA, the U.S. Government as a whole, and the American people that we are able to resume operations and to help meet the demand for COVID-19 vaccine across the country and around the world.

Let me describe the corrective steps we are taking. Critically, we have removed the AstraZeneca vaccine candidate from the Bayview facility. Bayview is now solely dedicated to manufacturing drug substance for Johnson & Johnson's COVID-19 vaccine. Not having the adenoviral material from two separate vaccines within the same facility will remove the possibility of cross-contamination.

As we have told FDA, we are implementing significant improvements at the Bayview facility before initiating any new manufacturing. Specifically, in collaboration with Johnson & Johnson, we are implementing a Quality Enhancement Plan ("QEP"). The QEP—developed following a comprehensive assessment of manufacturing operations at the facility by Emergent and Johnson & Johnson—includes immediate actions and interim controls that will assure the safety and quality of drug substance manufactured at the Bayview facility while longer term improvements are implemented. Emergent's interim control strategy includes engaging an independent, outside quality assurance firm to provide continuous oversight of critical activities and to perform independent batch certification for each and every COVID-19 vaccine drug substance batch manufactured at the Bayview facility.

The enhancements detailed in the QEP also address potential routes of contamination. These include:

- Performing additional cleaning, disinfection, and repairs throughout the facility;
- Ensuring enhanced segregation of personnel, material and waste flows;
- Enhancing material handling practices;
- Extensively improving waste handling practices and procedures;
- Expanding training and skill development for site personnel; and
- Strengthening oversight by Emergent Quality Assurance professionals, Johnson & Johnson, and an independent outside quality assurance firm.

Johnson & Johnson has been on-site with us throughout the pandemic, and they are now providing 24/7 oversight of all production areas, in addition to the suites in which their vaccine is manufactured. Further, they are now providing full oversight of change controls, qualifications, and process items, including final approval.

Emergent recognizes the need for effective and timely implementation of these improvements, and we are working expeditiously and collaboratively to execute the remediation process. Individual work streams are being jointly led by subject matter experts in the Emergent and Johnson & Johnson organizations. Program leaders from Emergent and Johnson & Johnson are meeting twice daily to review remediation activities and escalate issues, as necessary. A Steering Committee, comprised of both companies' quality and operations leadership, meets daily with program leads for further accountability and oversight.

Consistent with Emergent's commitment to continuous improvement, the QEP also includes a Sustainable Compliance Plan, detailing ongoing actions to maintain a robust culture of quality at the Bayview facility. We understand that sustainable compliance is achieved through consistent evaluation and improvement of quality activities. Emergent expects nothing less than the consistent adoption of industry best practices in the company's manufacturing and quality operations.

To that end, in November 2020, Dr. Mary Oates joined Emergent as Senior Vice President of Global Quality. Dr. Oates brings over 30 years of biopharmaceutical experience in Quality, Manufacturing Operations and Regulatory Affairs, including as head of Global Quality Operations for Pfizer. Dr. Oates now reports directly to me, and she is firmly in charge of quality operations at the Bayview facility. Under Dr. Oates's leadership, Emergent has significantly strengthened the Bayview facility quality leadership with external hires in recent months, including:

- Edward Elmore, Senior Director of Quality. Mr. Elmore has over 30 years of experience in pharmaceutical manufacturing and quality, including as Executive Director of Quality Assurance at Elanco and Senior Director of Quality Assurance at Eli Lilly and Company. Mr. Elmore joined Emergent in April 2021.

- James Kirk, Director of Quality Assurance. Mr. Kirk has over 25 years of quality leadership experience and joined Emergent from Johnson & Johnson in March 2021.

- William Hatcher, Director of Quality Control. Mr. Hatcher has more than 15 years of experience in Quality Control focusing on drug product and drug substance from clinical to commercial manufacturing. Mr. Hatcher joined Emergent in March 2021 after serving as Director of Quality Control for Catalent Pharma Solutions.

Emergent's new corporate and Bayview quality leadership are fully engaged in the enhancement efforts underway at Bayview and will provide direct oversight of quality operations at the facility.

In addition to the QEP, our Board of Directors has established a Special Committee responsible for oversight of manufacturing and quality operations across the company. This Special Committee of the Board will provide an additional level of oversight.

Conclusion

I understand that we are here today to answer for, and to explain the circumstances that led to, the cross-contamination incident. I apologize for the failure in our controls that led to the contamination, and I give you my personal assurance that I and my leadership team will take every step that is needed to resume production safely.

At the same time, I do want to take this opportunity to let the Subcommittee know that there are many hundreds of Emergent employees, from line workers to engineers and managers, who have been working around the clock, sacrificing much else in their lives, sometimes at considerable personal risk amid the pandemic, as they have sought to ensure that all of us have access to COVID-19 vaccine. They have been true heroes, and I am deeply moved by their dedication, hard work, and sacrifice.

Healthcare workers and first responders have received much public praise, as well they should. We are all grateful to them. I am grateful as well to the scientists, engineers, and manufacturing workers, not only at Emergent but across the country, who are devoting every ounce of their being to expanding the supply of COVID-19 vaccine for the entire world. I want to take this moment to praise especially my colleagues at Emergent, and their families, in gratitude for everything they have accomplished, under the most trying of circumstances, during this global health crisis.

Thank you again for the opportunity to share these points with the Subcommittee, and I look forward to answering your questions.