



THE CORONAVIRUS VACCINE MANUFACTURING FAILURES OF EMERGENT BIOSOLUTIONS

STAFF REPORT
MAY 2022

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EXECUTIVE SUMMARY

This staff report was prepared for Rep. Carolyn B. Maloney, Chairwoman of the Committee on Oversight and Reform, and Rep. James E. Clyburn, Chairman of the Select Subcommittee on the Coronavirus Crisis, following an investigation into the Trump Administration's award of a multimillion-dollar contract to Emergent BioSolutions, Inc. (Emergent) to manufacture coronavirus vaccines despite a history of serious deficiencies. The report includes the following key findings:

- **Nearly 400 million doses of coronavirus vaccines have been destroyed as a result of Emergent's failure to meet or maintain quality standards.**¹ The Committees' investigation revealed that due to poor quality control approximately 240 million vaccine doses had to be destroyed in late 2020 and early 2021—significantly more than revealed previously. Following the discovery that Emergent had cross-contaminated vaccine doses in March 2021, the Biden Administration halted Emergent's manufacturing from April to July 2021. The Food and Drug Administration (FDA) ultimately released more than 180 million doses manufactured before the pause, while an additional 60 million doses will have to be destroyed because they expired while in quarantine. After Emergent was permitted to resume manufacturing in July 2021, an additional 90 million newly manufactured coronavirus vaccine doses had to be destroyed for quality control reasons, and 135 million remain sequestered pending further testing.
- **Emergent hid evidence of contamination from government inspectors.** Documents reveal that immediately before an FDA site visit in February 2021, Emergent employees removed quality-assurance "hold tags" from Johnson & Johnson vaccine batches—which indicated that the containers had a potential quality issue. In an email obtained by the Committees, an outside consultant stated that the tags were removed "to avoid drawing attention" from FDA inspectors. Documents also show that Emergent personnel expressed concern that the Department of Health and Human Services (HHS) was "getting too involved" following the company's cross-contamination of the Johnson & Johnson and AstraZeneca vaccines in March 2021, and company executives strategized regarding how to evade questions from HHS.
- **Emergent executives promoted the company's manufacturing capabilities despite being warned of severe deficiencies.** Documents obtained by the Committees reveal that before Emergent finalized manufacturing agreements with Johnson & Johnson and AstraZeneca, Emergent's then-Executive Vice President of Manufacturing and Technical Operations privately acknowledged that he had warned Emergent senior executives "for a few years" about the company's deficient quality systems, including that "room to improve is a huge understatement." Despite these internal warnings, Emergent entered into contracts with Johnson & Johnson and AstraZeneca to manufacture coronavirus vaccines for \$482 million and \$174 million, respectively. After manufacturing started, internal Emergent communications reveal that the Senior Director of Quality at the Bayview manufacturing facility stated, "Our risk is high!" and, "we lack commercial GMP [good manufacturing practices] compliance maturity."

- FDA, Johnson & Johnson, and AstraZeneca identified multiple deficiencies at Bayview, which Emergent failed to remediate despite urgent warnings.** Documents reveal that the Trump Administration was aware, prior to awarding the contract in May 2020, of serious deficiencies at Emergent’s Bayview facility that could impact manufacturing. In July 2020, AstraZeneca personnel raised concerns to Emergent about the need to remediate these deficiencies before starting manufacturing, noting that they were “concerned that the FDA observation was that Emergent isn’t prepared for commercial manufacturing as things stand currently, and yet we will start commercial manufacture [sic] there very soon.” Internal Johnson & Johnson communications from October 2020 show that Emergent had struggled to maintain quality standards and that it was “unclear” if the site was ready for commercial manufacturing and to “effectively manage all the remediation efforts.” An outside consultant to Emergent provided a stark warning in November 2020 with regards to manufacturing: “I am stating very loudly that this work is NON-CGMP compliant. And a direct regulatory risk.”
- Inexperienced staff and high staff turnover contributed to vaccine contamination.** The investigation revealed that Emergent acknowledged in July and August 2020 that their staff were insufficiently trained, noting that “most temporary employees [have] little or no pharmaceutical experience.” In November and December 2020, following persistent issues with contamination, AstraZeneca sent teams to Bayview because Emergent “lacked the appropriate level of knowledge or expertise.” Ultimately, AstraZeneca concluded that “poor cleaning was part of the root cause.” Internally, one Emergent executive posed questions on the state of the Bayview facility, asking, “When will all these trash going to be out of here? Trash are piling up.” During a staff briefing, FDA acknowledged, “Clearly, in retrospect, they hired a lot of individuals not as familiar with vaccine manufacturing, that did not have adequate training to do so.”
- HHS terminated its contract with Emergent because the company failed to follow federal manufacturing standards.** After Emergent notified HHS in March 2021 that it had contaminated millions of doses of coronavirus vaccines, the Biden Administration permanently halted production of AstraZeneca’s vaccine at Bayview and stopped payment on Emergent’s contract. Although Emergent continued to seek payment, HHS concluded that the government should not pay any additional money since Emergent had not met its contract requirements to follow current good manufacturing practices. According to HHS, Emergent received \$330 million in taxpayer dollars before the Biden Administration terminated the company’s contract in November 2021. This action saved taxpayers \$320 million and came after the Committees launched an investigation and released preliminary findings about Emergent’s troubling conduct. The federal government did not seek reimbursement for payments made before the cross-contamination event in March 2021 because some vaccines manufactured at the facility were cleared and released by FDA.

I. BACKGROUND

On May 24, 2020, the Trump Administration awarded Emergent a \$628 million contract to support the manufacturing of Johnson & Johnson and AstraZeneca coronavirus vaccines.² The contract required Emergent to maintain the cleanliness and readiness of its facilities, equipment, and personnel, and provided that Emergent “shall maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities.”³ The Committees launched a joint investigation into Emergent in April 2021 after public reporting revealed a series of quality control and staffing issues at the company’s Bayview facility in Baltimore, Maryland.⁴

On May 19, 2021, the Committees released preliminary findings detailing how Emergent failed to promptly and fully remediate serious deficiencies in its performance on this taxpayer-funded contract, resulting in the destruction of millions of desperately needed vaccine doses. The Committees found that even though Emergent executives privately admitted to serious manufacturing problems, senior company executives were awarded millions of dollars in raises and bonuses as vaccines were destroyed.⁵

At a hearing on May 19, 2021, held by the Select Subcommittee on the Coronavirus Crisis, Emergent’s Chairman and Chief Executive Officer apologized and acknowledged some of the company’s failures but continued to minimize the seriousness of vaccine contamination at the company’s Bayview facility.⁶

The Committees expanded the investigation on June 22, 2021, in order to fully understand the manufacturing problems plaguing Emergent’s Bayview facility and the impact they had on the availability of Johnson & Johnson and AstraZeneca vaccines.⁷ In the course of this investigation, Committee staff conducted bipartisan briefings with Johnson & Johnson and AstraZeneca representatives and conducted a site visit to Emergent’s Bayview facility.

II. EMERGENT EXECUTIVES PROMOTED THE COMPANY’S MANUFACTURING CAPABILITIES DESPITE QUALITY CONCERNS

The investigation has revealed evidence that prior to awarding the contract to Emergent, HHS identified serious deficiencies at Emergent’s Bayview facility that could impact manufacturing. According to a quality risk analysis obtained by the Committees, on April 1, 2020, the Biomedical Advanced Research and Development Authority (BARDA) found “substantial evidence of site cGMP non-compliance,” including “inadequate quality unit oversight” and “failure of quality systems” at Bayview.⁸ FDA also conducted an inspection of the Bayview facility in April 2020 and identified multiple deficiencies, including that “employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices” and that “separate or defined areas to prevent contamination or mix-ups are deficient.”⁹

The Committees’ investigation also revealed that even after these concerns were raised, the Trump Administration recommended that AstraZeneca and Johnson & Johnson, through its subsidiary Janssen Pharmaceuticals, work with Emergent to manufacture coronavirus vaccines.¹⁰ New evidence reveals that Emergent executives privately expressed serious concerns about the company’s manufacturing shortcomings at the same time they promoted the capabilities of the

Bayview facility and solicited and negotiated contracts with AstraZeneca and Johnson & Johnson.

For example, on May 31, 2020, one week after the Trump Administration awarded Emergent's contract, Syed Husain, an Emergent senior executive, emailed AstraZeneca representatives about a forthcoming press release, stating that Emergent was "ready and focused on ensuring the AZ [AstraZeneca] project is a success."¹¹

Audits performed by both AstraZeneca and Johnson & Johnson between June 9 and June 18, 2020, identified further issues at the Bayview facility. AstraZeneca identified "documentation control issues; contamination control deficiencies; an inadequate quality management system; inadequate computerized systems; and certain other faulty manufacturing and cleaning practices."¹² Johnson & Johnson's audit also found that "the disinfectant program used in the facility," "the Quality Management Review process," and "the site virus contamination control strategy" were all deficient.¹³

Both AstraZeneca and Johnson & Johnson identified corrective actions that Emergent needed to implement for the Bayview facility to be ready for manufacturing. Both companies accepted Emergent's plans to address the observations with the understanding that they would work closely with Emergent to mitigate and address ongoing issues.¹⁴

On June 10, 2020, Emergent entered into an interim Master Services Agreement with AstraZeneca to manufacture the company's coronavirus vaccine, which required Emergent to comply with current good manufacturing practices.¹⁵ One day later, on June 11, 2020, FDA told Emergent that the company's responses to the April 2020 inspection of Bayview were deficient, the agency did not consider Emergent "ready to support commercial operations," and remaining deficiencies "should be addressed."¹⁶

Following this admonition from FDA, Sean Kirk, Emergent's then-Executive Vice President of Manufacturing and Technical Operations, emailed the company's Senior Vice President of Global Quality, John Ducote, that the situation was "deeply concerning" and demanded: "Fix this."¹⁷

From: Kirk, Sean <[REDACTED]@ebsi.com>
Sent: Wednesday, June 24, 2020 9:25 AM
To: Ducote, John <[REDACTED]@ebsi.com>; Muzzin, Dino <[REDACTED]@ebsi.com>
Cc: Havey, Adam <[REDACTED]@ebsi.com>; [REDACTED] <[REDACTED]@ebsi.com>
Subject: RE: [External] Please Review: Post Application Action Letter, FEI 3015448605
Sensitivity: Confidential

John,
After all the assurances from you that we were putting our best foot forward on this response, this is deeply concerning. That concern is exponentially amplified as we ramp up to produce hundreds of millions of doses of covid vaccine.

Fix this
sk

Sean Kirk
Executive Vice President
Manufacturing and Technical Operations

Karen Smith, Emergent's Executive Vice President and Chief Medical Officer, replied to Mr. Kirk expressing further concern about Emergent's deficient response to the April 2020 FDA audit:

It concerns me that John [Ducote] says "The level of expectation from the FDA is at a new level for us, and we'll need to adjust accordingly." My view is that we should always have been operating at a level that would pass an FDA audit! In addition, it is one thing to incur audit findings, but then we shouldn't also 'fail' the subsequent clean up plan.¹⁸

Mr. Kirk replied that he "had the same response" and was "very frustrated." Mr. Kirk added, "The one thing about OWS [Operation Warp Speed] effort that keeps me up at night is this. The perception of quality systems at bayview [sic]."¹⁹ Ms. Smith asked, "I get the impression you think our Quality group has room to improve?"²⁰ Mr. Kirk responded, "Yes, Room to improve is a huge understatement." He noted that he previously warned Emergent's senior executives about the company's deficient quality systems:²¹

From: [REDACTED]@ebsi.com
To: Smith, Karen
Sent: 5/24/2020 11:22:19 AM
Subject: Re: [External] Please Review: Post Application Action Letter, FEI 3015448605

Yes, Room to improve is a huge understatement. I've been on this soapbox for a few years with Adam, John, and Bob. As our complexity as an org has increased our quality systems and associated harmonization have not kept pace in my opinion

Thx
Sk

Sean Kirk
EVP, Manufacturing and Technical Operations
[REDACTED] (m)

Sent from my iPhone

Mr. Kirk forwarded FDA’s letter to Robert Kramer, Emergent’s President and Chief Executive Officer, on June 24, 2020, noting that although Emergent was able to “navigate” audits of the Bayview facility performed by AstraZeneca and Johnson & Johnson, the overall state of quality systems at the facility “keeps me up at night.”²²

From: Kirk, Sean <[REDACTED]@ebsi.com>
Sent: Wednesday, June 24, 2020 10:34 AM
To: Kramer, Robert (CEO) <[REDACTED]@ebsi.com>
Subject: Fwd: [External] Please Review: Post Application Action Letter, FEI 3015448605

Bob
To our parking lot discussion at bayview last Friday, see below.

Of all the things we have to deliver on OWS, the thing that keeps me up at night is overall perception of state of quality systems at bayview. As we discussed, Thankfully, we navigated the AZ and JNJ audits although they designated our systems as not ready for commercial. Barda will audit bayview I Friday

Despite Emergent’s executives’ private acknowledgement that its quality systems were deficient, the company finalized agreements with Johnson & Johnson and AstraZeneca to manufacture coronavirus vaccines for \$482 million and \$174 million, respectively in July 2020.

Johnson & Johnson’s Manufacturing Services Agreement required Emergent to maintain, at its own expense, “the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of cGMP (if applicable) and Applicable Law.”²³ The contract included the following terms:

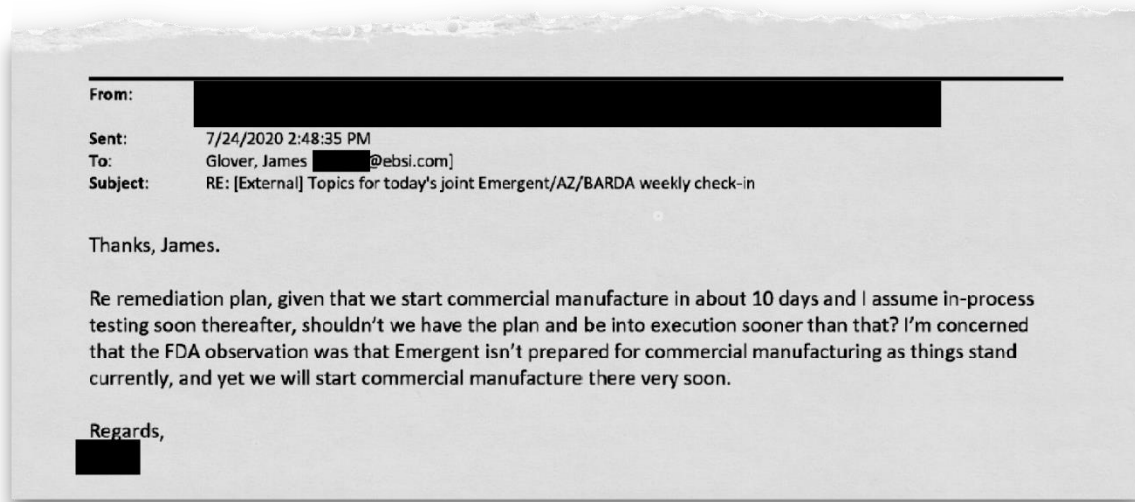
Emergent and Johnson & Johnson’s July 1, 2020, Manufacturing Agreement²⁴		
Years 1 to 2	160 batches	Year 1: \$2.5 million per batch Year 2: \$3.5 million per batch
Years 3 to 5	Option to manufacture additional batches at \$3.5 million per batch	

Emergent continued to negotiate the details of its manufacturing agreement with AstraZeneca during this period. On July 8, 2020, AstraZeneca and Emergent entered into a Master Quality Assurance Agreement that required Emergent to ensure its facilities complied with current good manufacturing practices.²⁵ On July 22, 2020, Mr. Kirk assured an AstraZeneca senior vice president that Emergent was “confident Bayview has the appropriate fundamental quality systems and the capable workforce to successfully execute this acceleration”²⁶—despite having privately conveyed his serious concerns about Bayview’s quality systems to other Emergent executives just one month earlier.²⁷

On July 24, 2020, AstraZeneca entered into a more detailed Master Services Agreement with Emergent, which included the following terms:²⁸

Emergent and AstraZeneca's July 24, 2020, Manufacturing Agreement ²⁹		
July 2020 to November 2020	15 batches	\$28.4 million
September 2020 to April 2021	80 batches	\$145.8 million
May 2021 to June 2021	Option to manufacture additional batches for \$63 million	

On the same day, an AstraZeneca representative emailed Emergent personnel and raised concerns regarding the need to remediate deficiencies before starting vaccine manufacturing. They wrote, "I'm concerned that the FDA observation was that Emergent isn't prepared for commercial manufacturing as things stand currently, and yet we will start commercial manufacture [sic] there very soon."³⁰



BARDA conducted another audit of the Bayview facility from June to July 2020, which resulted in numerous observations, including three "critical" observations on Emergent's quality-control unit, its control of microbiological contamination, and data integrity issues with its audit trails and electronic records. BARDA also confirmed that Emergent had not fully addressed FDA's finding from April 2020 that Bayview was "not ready for commercial operations."³¹

Despite these findings, the Trump Administration added \$30 million to Emergent's contract on July 23, 2020, to reserve additional manufacturing capabilities at Bayview.³² Emergent began manufacturing the first commercial batches of AstraZeneca's vaccine in late July 2020 before all deficiencies were remediated.³³

III. EMERGENT'S PERSISTENT COMPLIANCE FAILURES RESULTED IN THE CONTAMINATION OF VACCINES, REQUIRING THE DESTRUCTION OF MILLIONS OF DOSES

During the late summer and fall of 2020, Emergent executives continued to internally acknowledge compliance shortcomings and the lack of commercial manufacturing experience at the Bayview facility. On September 3, 2020, Bayview's Senior Director of Quality emailed Adam Havey, Emergent's Executive Vice President of Business Operations, in advance of an FDA site visit and attached a document titled "FDA Prep Meeting 02Sep2020." Mr. Havey also shared this document with Mr. Kirk, then-Executive Vice President of Manufacturing and

Technological Operations. The document stated, “Our risk is high!” and warned of other problems:³⁴

Excerpts from “FDA Prep Meeting 02Sep2020”

"We have been operating a clinical phase GMP Quality System (phase appropriate with a lot of flexibility) until the pandemic hit – we lack commercial GMP compliance maturity. We have little to no FDA (Regulatory) inspection experience."

"Make sure short term, mid-term continuous improvement provisions are in place – we are not in full compliance yet-BUT- we are making batches NOW."

"What do I mean when I say "manage" the inspection/visit? AND THIS IS IMPORTANT... We have a limited window to give FDA confidence in our ability to achieve commercial GMP compliance at an accelerated pace – how do we do it?"

"Only SUPER SMEs (already known to FDA if possible) will be allowed to interact (for the most part) – this way we can consistently manage the message of continuous improvement and build confidence with FDA (when you are head of Q at a mature commercial site with a great GMP record, you can sit back and parade SMEs in and out all day – we are not there)."

FDA subsequently conducted a site visit at Bayview in September 2020. Dr. Peter Marks, the Director of FDA’s Center for Biologics and Evaluation Research, informed the Committees in a staff briefing that Emergent’s manufacturing practices were not compliant at the time of FDA’s visit and that FDA gave Emergent a set of recommendations to bring the facility into compliance.³⁵

Following a readiness review conducted by Johnson & Johnson in October 2020, Johnson & Johnson personnel raised concerns that Bayview was still not ready for commercial manufacturing and stated that it was “unclear” whether Emergent “can effectively manage all the remediation efforts,” given that the company had been “challenged” to “maintain focus on basic GMP standards.”³⁶ A Johnson & Johnson representative emailed Bayview’s Site Head of Quality, Tammy Lucik, listing six issues identified during the site visit related to the facility’s readiness to follow current good manufacturing practices. The issues included “mold remediation,” “floor damage,” “overcrowding of equipment,” and “retrospective deviation review,” meaning the review of unexpected events that occur from the normal manufacturing process. The Johnson & Johnson employee expressed concern about the start of manufacturing, stating, “I had hoped for a more detailed list but wanted to get you a start ASAP. Basically the concern from Janssen related to GMP readiness (being less than 2 weeks away).”³⁷

On November 16, 2020, an outside consultant to Emergent provided another stark warning to the company:

Ultimately Emergent will have to decide what level of risk they are willing to accept, but this is one of those where you really better listen to me and do exactly what I tell you to. ... I am stating very loudly that this work is NON-CGMP compliant. And a direct regulatory risk.³⁸

It is unclear whether Emergent took any immediate steps to address the consultant’s concerns.

Internal Johnson & Johnson communications reveal that senior executives agreed to “move forward” with manufacturing at Bayview on November 19, 2020, despite the company’s Director of Pharmaceutical Regulatory Compliance identifying concerns with Emergent’s “limited experience” and readiness: “This is not without known risks as have been previously communicated.” In this same email, Johnson & Johnson identified basic issues the company needed to continue monitoring, such as general housekeeping, mold problems, and deviation review.³⁹

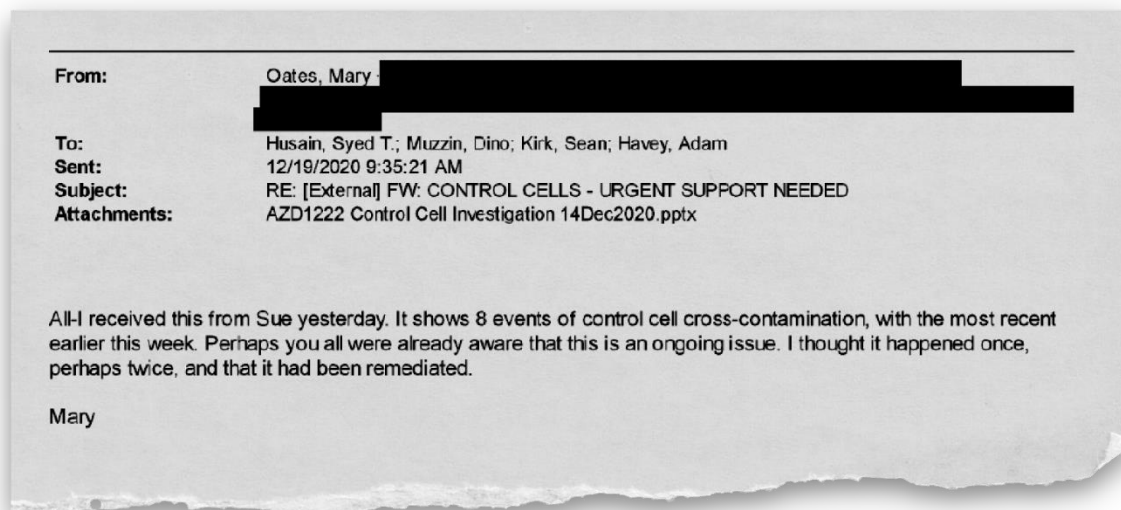
Despite numerous concerns about Bayview’s quality failures raised within Emergent, as well as by AstraZeneca, Johnson & Johnson, and FDA, Emergent did not remediate the issues, and problems persisted at the facility for months. The investigation has revealed that the impact of these issues is larger than previously known—with more incidents of contamination and millions more vaccines destroyed than previously revealed by Emergent.

Documents obtained during the investigation show that between October and November 2020, Emergent aborted or rejected seven batches of AstraZeneca’s vaccine due to microbial contamination.⁴⁰ AstraZeneca representatives told Committee staff that they sent teams to the Bayview facility in November 2020 to help Emergent identify and control the microbial contamination after Emergent “acknowledged that its team lacked the appropriate level of knowledge or expertise to address the contamination event.” The AstraZeneca team concluded that “poor cleaning was part of the root cause of the persistent microbial contamination,” and resulted in “the proliferation of undesirable microorganisms growing in the facility.” While on-site, the AstraZeneca team “identified potential issues related to lack of oversight and general GMP expectations that were likely directly related to the microbial contamination.”⁴¹

On November 10, 2020, Dino Muzzin, Emergent’s Senior Vice President of Manufacturing, wrote in an internal email that “[AstraZeneca] said lack of GMP fundamentals (gowning, clean room behavior, etc) contributing to bioburden issue.” Mr. Muzzin commented on one particular observation related to trash in the hall outside the manufacturing suites, asking, “When will all these trash going to be out of here? Trash are piling up.”⁴² The observations and concerns noted privately by Emergent executives were echoed during a briefing that AstraZeneca provided to Committee staff, during which one AstraZeneca representative stated, “The biggest things were making sure the facility was clean, personnel were trained, and that procedures were followed.”⁴³ AstraZeneca continued to send teams to Bayview through December 2020 to help Emergent identify and remediate the ongoing contamination.⁴⁴

In December 2020, microbial contamination and equipment failure necessitated the termination of roughly 30 million Johnson & Johnson vaccine doses. A Johnson & Johnson representative acknowledged at a staff briefing that “the reject rate at Emergent is typically higher than what we normally see.”⁴⁵

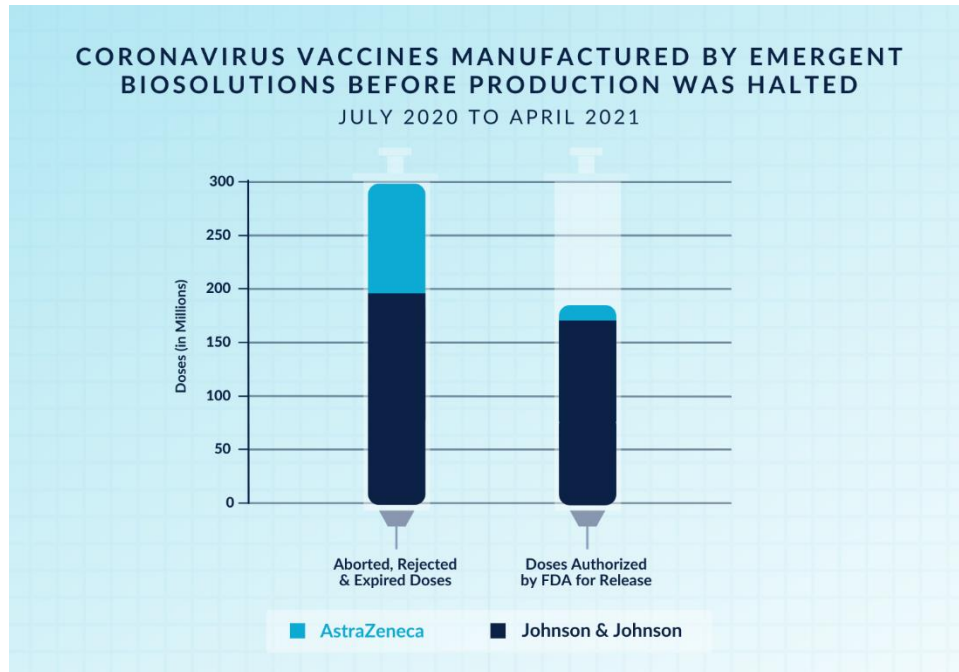
On December 19, 2020, Mary Oates, Emergent’s Senior Vice President of Global Quality, expressed surprise in an internal email to other Emergent executives at the extent of control cell cross-contamination and the company’s failure to remediate the problem:⁴⁶



The Committees' investigation revealed that in the months that followed, Emergent failed to remedy these issues, producing millions of doses of contaminated vaccines while receiving millions of dollars from Johnson & Johnson, AstraZeneca, and the federal government.

Six additional AstraZeneca batches were aborted or rejected between December 2020 and April 2021. According to AstraZeneca, one-third of the commercial AstraZeneca batches manufactured at Bayview between July 2020 and April 2021 were either rejected or aborted due to Emergent's deficiencies.⁴⁷ Two batches of Johnson & Johnson's vaccine drug substance—roughly 30 million doses—were also terminated and discarded due to microbial contamination in March and April 2021.⁴⁸

The Committees' investigation found that in late 2020 and early 2021, Emergent's failure to follow current good manufacturing practices at Bayview led to the destruction of more than 240 million vaccine doses, including approximately 45.6 million AstraZeneca doses⁴⁹ and 195 million Johnson & Johnson doses⁵⁰—significantly more than revealed previously. FDA ultimately authorized the release of approximately 165 million Johnson & Johnson doses and 15 million AstraZeneca doses manufactured during this period, after testing determined that they were safe. However, an additional 60 million doses of AstraZeneca's vaccine will be destroyed—at significant taxpayer expense—because the drug substance has passed its expiration date. Under AstraZeneca's funding agreement, the federal government would reimburse the company \$176,000 to destroy the expired doses.⁵¹



During a bipartisan briefing with staff, Dr. Marks acknowledged that, under the Trump Administration, FDA failed to provide sufficient oversight of Emergent’s manufacturing, stating:

Shame on us for thinking that their experience in manufacturing would mean they would be able to move ahead and make the vaccines in a high-quality manner that we would expect for an experienced vaccine manufacturer.

Dr. Marks acknowledged that, for FDA, “this has been a clear learning experience not to make assumptions.”⁵²

IV. EMERGENT’S INEXPERIENCED STAFF AND HIGH TURNOVER CONTRIBUTED TO VACCINE CONTAMINATION

The Committees’ investigation revealed that inexperienced staff and high employee turnover at the Bayview facility impaired Emergent’s quality systems and ability to manufacture vaccines in compliance with good manufacturing practices. Documents obtained by the Committees show that Emergent’s President and Chief Executive Officer Robert Kramer was aware of these issues. On June 24, 2020, Mr. Kramer emailed Mr. Kirk and acknowledged the need to discuss “bringing in outside resources to get in front of this, while we recruit permanent resources to lead.”⁵³ In reports submitted to HHS in July and August 2020, Emergent noted its staff were mostly “temporary employees [with] little or no pharmaceutical experience” and that it needed “in the short term to increase the rate of experienced, full time hires.”⁵⁴

Following the microbial contamination of AstraZeneca’s vaccine substance in October and November 2020, AstraZeneca’s Chief Microbiologist visited Bayview and reported multiple concerning observations of Bayview’s workforce that could contribute to contamination, including an “individual without a hair net – not acceptable” and a “person sitting on the floor – not acceptable.” An AstraZeneca representative told Committee staff, “If I had seen some of

those instances, my first comment would be, ‘do these people know what is happening in the manufacturing area?’”⁵⁵

On November 6, 2020, Syed Husain of Emergent emailed AstraZeneca executives, acknowledging the need for improvements in Emergent’s workforce. He wrote:

QC [quality control] we fully understand is a critical topic for Emergent to improve on, we see major improvements on timelines with our dedicated PM [project manager] managing the daily review board. We have a new Sr Director starting Monday that will be fully focuses [sic] on processes and people.⁵⁶

As Emergent undertook coronavirus vaccine manufacturing, it experienced high turnover in its quality-oversight function. For example, the company’s Senior Vice President of Global Quality changed twice between November 2020 and October 2021.⁵⁷ The Senior Director of Quality at Bayview also changed twice between August 2020 and April 2021.⁵⁸

During briefings with Committee staff, representatives from AstraZeneca, Johnson & Johnson, and FDA acknowledged the negative impact of this high turnover in the quality-oversight function at Bayview. A Johnson & Johnson representative explained, “From my perspective it was difficult to establish a relation [sic] with Site Quality Head as it was changing over time.”⁵⁹ AstraZeneca representatives specifically noted that high turnover was a “disruption” and uncommon at other contract manufacturing organizations they work with. One AstraZeneca representative said: “The quality organization was not running like a clock. There were definitely gaps and issues in the quality organization.”⁶⁰

On March 5, 2021, Johnson & Johnson detected an “out of specification” result for one batch of vaccine drug substance manufactured in February 2021, which testing later revealed was due to cross-contamination with AstraZeneca’s vaccine. One Johnson & Johnson representative explained at a staff briefing that the cause of the contamination was that “Emergent personnel were not decontaminating properly and disposing of waste properly.”⁶¹

Following the discovery of the cross-contamination in March 2021, internal communications show that senior Johnson & Johnson executives worried about the future of manufacturing their vaccine at Bayview. In preparation for a call on April 3, 2021, one Johnson & Johnson executive wrote to Mr. Kramer:

Bob, unfortunately since we spoke just two days ago, we have continued to get signals—sometimes more than signals—that FDA is very unhappy. As I shared, they were very strong in the meeting last week. And since we spoke on Thursday, they have expressed specific concerns about us continuing even at risk to fill your [drug substance] into vials.⁶²

Despite these findings, internal documents show that deficiencies in the manufacturing and cleaning processes and the lack of supervision of personnel continued at Bayview. On April 11, 2021, Johnson & Johnson’s Quality Lead on Vaccines emailed Ms. Lucik and described repeated quality failures observed at Bayview by Johnson & Johnson’s on-site personnel. The email stated:

On April 6th one of our QA [quality assurance] persons-in-plant observed two instances of associates entering the material airlock from the warehouse and crossing over the line of demarcation. The issue was escalated so that cleaning and disinfection could take place. According to our person-in-plant, once the cleaning was performed inappropriate crossing of the line of demarcation occurred again.

Additionally, our QPIP [quality persons-in-plant] indicated that EMOB [Emergent BioSolutions] associates were not sure what bins could travel to which locations, how to clean and disinfect items, and the absence of cleaning materials (sporklenz, wipes and IPA) in the area. The QPIP also indicated a lack of supervision on the floor.⁶³

AstraZeneca and FDA representatives later acknowledged the challenges with Emergent's inexperienced workforce. During a staff briefing on July 20, 2021, one AstraZeneca representative stated:

The facility was built for this and with appropriate controls, it could be used for that. It is unfortunate the issues that arose did come up. The lack of following GMPs and appropriate controls, and proper training, contributed to the issues that occurred.⁶⁴

Dr. Marks also told Committee staff, "Clearly, in retrospect, they hired a lot of individuals not as familiar with vaccine manufacturing, that did not have adequate training to do so."⁶⁵

V. EMERGENT OBSTRUCTED OVERSIGHT BY FDA, HHS, AND THIRD PARTIES WHILE QUALITY FAILURES PERSISTED

The investigation revealed that Emergent took repeated steps to conceal its quality failures from the federal government and other third parties by limiting access to Bayview, tampering with drug-substance labels to impede FDA oversight, and strategizing to withhold information from HHS following the cross-contamination event in March 2021.

Internal documents obtained by the Committees show that in early February 2021, Emergent rebuffed multiple requests from Johnson & Johnson's quality staff to access Bayview in advance of an upcoming FDA site visit.⁶⁶ After repeated requests on February 3 and 4, 2021, Ms. Lucik told Johnson & Johnson personnel, "I appreciate your want to be onsite and tour, but I would prefer that we not add additional folks at this time. We are walking through daily as a leadership team."⁶⁷

The following week, FDA conducted its second site visit of the Bayview facility to assess whether Emergent had remediated the deficiencies previously identified during its September 2020 site visit. According to an email from an outside consultant hired by Emergent, on February 11, 2021—the final day of FDA's site visit—Emergent employees removed "yellow and conspicuous" quality-assurance "hold tags" from two containers of Johnson & Johnson's vaccine drug substance approximately one hour before FDA inspectors began their tour. The yellow hold tags designated that a portion of the batch had a potential quality issue. The containers were re-tagged after the inspection and "before the end of the evening."⁶⁸

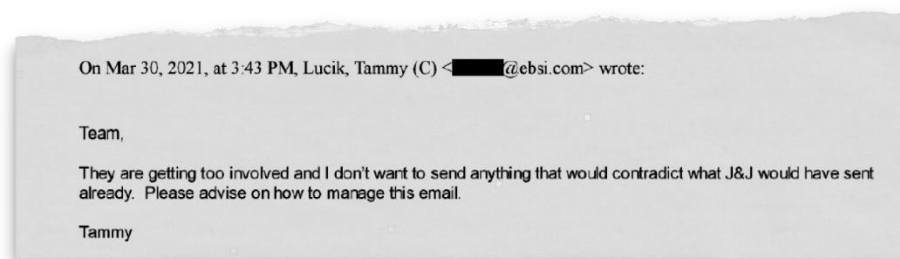
Four days later, the Emergent consultant expressed concern that the quality assurance hold tags were removed “to avoid drawing attention” from FDA to the potential quality issue, stating in an email:

Since the tags were deemed necessary before and after the FDA’s visit, it is my understanding, based on the entirety of what I observed and was told, that the purpose of removing the QA [quality assurance] hold tags was to avoid drawing attention to the two subject containers during the tour by the FDA inspectors.

Internal communications reveal that multiple senior leaders at Emergent were aware of the removal of the tags, including the Vice President of Manufacturing Operations, the Quality Assurance Manager, the Senior Manager in Quality Systems, and the Senior Director of Quality.⁶⁹

Despite this apparent attempt to impede oversight, FDA still identified serious concerns during its February 2021 site visit. During a briefing with Committee staff, Dr. Marks stated that while FDA granted Emergent some leniency, the agency found that the company was “operating in a manner still not in compliance with good manufacturing practices and still needed to make changes.” Dr. Marks further explained, “To be very blunt about it and very concrete, having many cross-contamination events – regardless of GMP – is not acceptable.” Asked whether Emergent was aware they were being given leniency in regards to current good manufacturing practices compliance, Dr. Marks stated, “I am pretty certain with conversations with the firm, subsequent to the site visits, that they were aware of that.”⁷⁰

The Committees’ investigation revealed that on March 26, 2021—three weeks after Johnson & Johnson identified the presence of another viral vector in a batch of vaccine drug substance, indicating cross-contamination between different types of vaccine substances—Emergent informed AstraZeneca and HHS of the cross-contamination.⁷¹ On March 30, 2021, BARDA contacted Ms. Lucik, posing questions and requesting information regarding the possible causes of the cross-contamination event.⁷² Ms. Lucik forwarded the email internally to several senior Emergent employees:⁷³



On Mar 30, 2021, at 3:43 PM, Lucik, Tammy (C) <[REDACTED]@ebsi.com> wrote:

Team,

They are getting too involved and I don't want to send anything that would contradict what J&J would have sent already. Please advise on how to manage this email.

Tammy

An hour later, Mr. Husain suggested that Ms. Lucik provide a response that avoided answering BARDA’s questions. He wrote:

Pls respond along the following lines – Appreciate the questions, we are actively working on the investigation with Janssen, we will share the details via Janssen as we conclude the investigation.⁷⁴

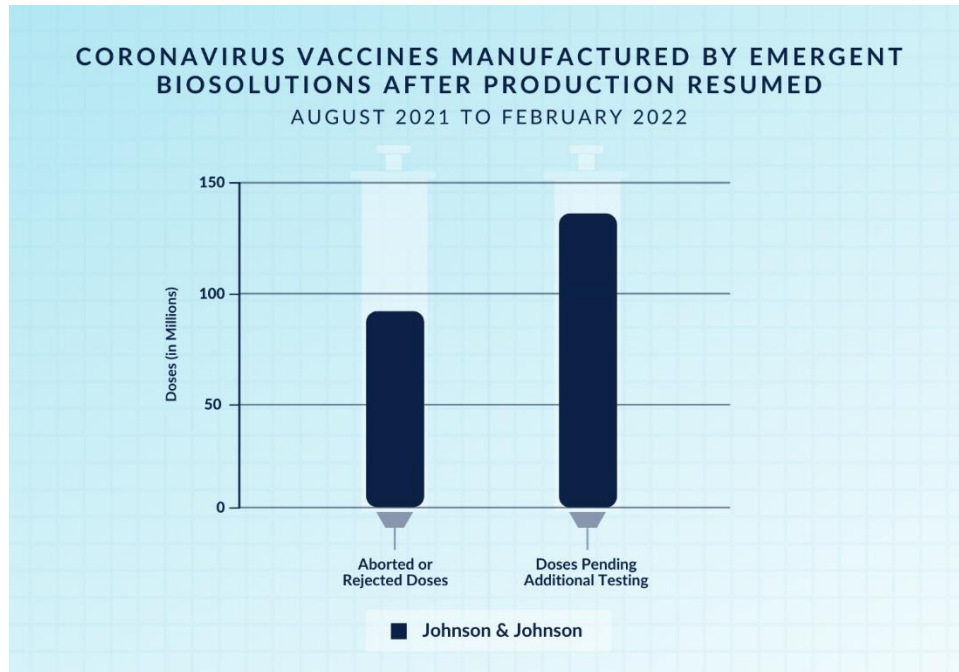
VI. AFTER PRODUCTION RESUMED FOLLOWING A PAUSE FOR REMEDIATION, CONTINUED PROBLEMS REQUIRED THE DESTRUCTION OF MILLIONS OF NEW DOSES

After Emergent notified HHS in March 2021 that it had contaminated millions of coronavirus vaccines, the Biden Administration permanently halted production of AstraZeneca's vaccine at Bayview on April 11, 2021. Five days later, HHS paused manufacturing of Johnson & Johnson's vaccine and began withholding payments to Emergent.⁷⁵

In June and July 2021, FDA conducted two investigations at Bayview to assess Emergent's remediation efforts. In June, FDA found that Emergent had not made needed corrective actions and outlined ten concerns, including that "[r]esponsibilities applicable to the quality unit [are] not fully followed," "[e]mployee Training [is] not adequately documented," and "[p]rocedures for transporting materials and waste are not followed."⁷⁶ FDA returned to the facility in July, but its investigation was limited because manufacturing had not yet resumed. FDA shared five concerns, including issues related to equipment, employee training, and decontamination protocols. Despite these concerns, FDA told Emergent it did not object to the resumption of manufacturing Johnson & Johnson's vaccine at Bayview on July 28, 2021.⁷⁷ According to FDA, the importance of complying with current good manufacturing practices to ensure the safety, efficacy, and quality of vaccines was communicated to Emergent during both the June and July investigations.⁷⁸

Emergent resumed manufacturing for Johnson & Johnson on August 11, 2021. FDA had planned to conduct a comprehensive inspection of the Bayview facility in October 2021—after Emergent had completed several manufacturing lots—to determine compliance with current good manufacturing practices and evaluate the effectiveness of Emergent's remediation efforts. However, FDA postponed this inspection due to manufacturing delays at the facility and planned inspections by foreign regulatory authorities.⁷⁹ FDA has not returned to Bayview for an on-site inspection since July 2021.⁸⁰

Between August 2021 and February 2022, Emergent manufactured 15 new batches of Johnson & Johnson's vaccine drug substance. Six of these batches—approximately 90 million newly manufactured doses—were either aborted or rejected by Johnson & Johnson. The remaining batches, equal to roughly 135 million doses, are either undergoing final manufacturing or final testing with ultimate release contingent on Emergent and Johnson & Johnson and regulatory approval.⁸¹ FDA regulators have not cleared any Johnson & Johnson batches manufactured since the Bayview facility resumed manufacturing in August 2021 for distribution or administration.⁸²



Emergent representatives told staff that Bayview stopped manufacturing on February 7, 2022, and entered a “maintenance shutdown period” to clean and modify its manufacturing suites while Johnson & Johnson performed an evaluation of its global supply chain to assess the demand for its coronavirus vaccine. The shutdown activities are ongoing and Emergent plans to restart manufacturing by August 2022. As of May 8, 2022, FDA has been unwilling to share when its next inspection will occur.⁸³

VII. THE BIDEN ADMINISTRATION CANCELED EMERGENT’S CONTRACT BECAUSE THE COMPANY FAILED TO MEET QUALITY STANDARDS

After the discovery of the cross-contamination in March 2021, the Biden Administration stopped payment on Emergent’s contract. Emergent continued to seek monthly payments provided under the Trump Administration’s contract despite manufacturing being paused. However, HHS concluded that the government should not have to pay these additional funds since Emergent had not met its contract requirements to follow current good manufacturing practices.⁸⁴

On November 1, 2021, HHS terminated Emergent’s multimillion-dollar contract to manufacture coronavirus vaccines.⁸⁵ During a briefing with staff on November 23, 2021, BARDA Director Dr. Gary Disbrow explained that HHS did not seek reimbursement for payments made before the cross-contamination event because some vaccines manufactured at the facility were cleared and released by FDA to support international donations.⁸⁶

Dr. Disbrow further explained that HHS could have pursued a contract termination for default or cause, but instead terminated the contract for the government’s convenience—pursuant to an agreement with Emergent and to avoid a lengthy and costly legal battle. In total, Emergent received \$330 million in taxpayer dollars under the contract awarded by the Trump Administration, as well as millions from its private contracts with AstraZeneca and Johnson &

Johnson.⁸⁷ The Biden Administration’s decision to terminate the contract saved taxpayers more than \$320 million remaining on the contract.

Emergent’s failure to reliably manufacture vaccines also cost AstraZeneca and Johnson & Johnson tens of millions of dollars. Johnson & Johnson estimates that it incurred more than \$11 million in costs to respond to and remediate “deficiencies that led to the cross-contamination” at the Bayview facility. Johnson & Johnson’s expenses included costs for additional quality personnel, technical support, and equipment and materials.⁸⁸ AstraZeneca also reported that it paid Emergent more than \$21 million for 18 batches of vaccines that were aborted or rejected.⁸⁹ Internal AstraZeneca communications dated January 25, 2021, acknowledged that some rejected vaccine batches were “very clearly GMP deficiency related.”⁹⁰ Johnson & Johnson and AstraZeneca representatives told the staff that both companies continue to incur substantial costs in connection with the issues at Bayview.⁹¹

VIII. CONCLUSION

Emergent’s failures wasted hundreds of millions of taxpayer dollars and impacted our country’s ability to meet the urgent, global need for coronavirus vaccines. Emergent’s inability to meet or maintain quality standards at its Bayview facility, both before and after the Trump Administration awarded a multimillion-dollar contract, raises questions about whether additional contracting controls could have prevented the destruction of nearly 400 million doses of coronavirus vaccine and the loss of taxpayer funds. Given Emergent’s significant lapse in performance on this contract, HHS and other federal agencies that contract with Emergent should ensure they are adequately monitoring Emergent’s compliance with manufacturing practices and ensuring Emergent is meeting all the requirements in its remaining government contracts. In the future, the vetting of any prospective federal contracts with Emergent should include a careful consideration of Emergent’s failure to perform under this contract and the actions by Emergent’s executives to keep the extent of its manufacturing problems from its federal and private partners.

¹ “Destroyed” includes batches that were either aborted or rejected. An “aborted” batch is one for which manufacturing stopped for any reason prior to the completion of processing. For example, a batch may be aborted because of its failure to meet a critical in-process parameter, which in turn renders the batch not viable for final release. A “rejected” batch is one that was rejected after completion of processing and before quality-assurance release, usually because that batch failed to meet quality-release criteria. The number of doses of vaccine derived from a particular batch varies due to several factors during the manufacturing process (e.g., protocol deviations, contamination, other errors) as well as cell-viable culture growth. See Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021).

² See Memorandum from Majority Staff to Members of the Select Subcommittee on the Coronavirus Crisis and Members of the Committee on Oversight and Reform, *Preliminary Findings from Investigation into Emergent BioSolutions, Inc.* (May 19, 2021) (online at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Staff%20Memo%20re%20Emergent%20-%20FINAL.pdf>).

³ *Id.* cGMP regulations contain minimum standards throughout the manufacturing process to ensure that a product is safe for use and that it has the ingredients and strength it claims to have. FDA is responsible for enforcing compliance with these standards. See Food and Drug Administration, *Current Good Manufacturing Practice*

(CGMP) Regulations (online at www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations) (accessed May 7, 2022).

⁴ 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>).

⁵ See Memorandum from Majority Staff to Members of the Select Subcommittee on the Coronavirus Crisis and Members of the Committee on Oversight and Reform, *Preliminary Findings from Investigation into Emergent BioSolutions, Inc.* (May 19, 2021) (online at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Staff%20Memo%20re%20Emergent%20-%20FINAL.pdf>).

⁶ Select Subcommittee on the Coronavirus Crisis, *Hybrid Hearing on Examining Emergent BioSolutions' Failure to Protect Public Health and Public Funds* (May 19, 2021) (online at <https://coronavirus.house.gov/subcommittee-activity/hearings/hybrid-hearing-examining-emergent-biosolutions-failure-protect-public>).

⁷ Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Pascal Soriot, Executive Director and Chief Executive Officer, AstraZeneca Pharmaceuticals LP (June 22, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-06-22.CBM%20JEC%20to%20Soriot-AstraZeneca%20re%20Emergent.pdf>); Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Alex Gorsky, Chief Executive Officer, Johnson & Johnson (June 22, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-06-22.CBM%20JEC%20to%20Gorsky-Johnson%20%26%20Johnson%20re%20Emergent.pdf>).

⁸ Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, *CGMP Quality Risk Analysis, Emergent BioSolutions Bayview Facility, BARDA Quality Branch Evaluation* (Apr. 1, 2020) (online at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/04.01.20%20-%20BARDA%20Emergent%20Quality%20Issues.pdf>).

⁹ Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 20, 2020) (online at www.fda.gov/media/147884/download).

¹⁰ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021); Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021).

¹¹ Email from Syed Husain, Senior Vice President, CDMO Business Unit, Emergent BioSolutions, to Head of Biologics External Supply and Enabling Functions, AstraZeneca Pharmaceuticals LP (June 1, 2020) (AZ_COR_001330–001334) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.01.20%20-%20AZ_COR%20_001330-001334.pdf).

¹² Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 3, 2021); see also AstraZeneca, Global Quality Audit, Operations Quality, Audit #464481 (June 9–17, 2020) (AZ_COR_000248–000254) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.09.20%20-%20AZ_COR_000248-000254.pdf).

¹³ Johnson & Johnson, June 2020 Audit of Emergent BioSolutions Bayview Facility (July 24, 2020) (JNJ_HOUSE_COR00000178–00000190) (online at

https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.09.20%20-%20JNJ_HOUSE_COR00000178%20-%20190.pdf).

¹⁴ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021); Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021).

¹⁵ Master Services Agreement between AstraZeneca Pharmaceuticals LP and Emergent Manufacturing Operations Baltimore, LLC (effective June 10, 2020) (AZ_COR_000049–000067) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.10.20%20-%20AZ_COR%20_000049%20-%200000067.pdf). The June 10, 2020, Master Services Agreement was superseded by a second Master Services Agreement signed on July 24, 2020. See Contract No. US 167916159 Master Services Agreement between AstraZeneca Pharmaceuticals LP and Emergent Manufacturing Operations Baltimore, LLC (July 24, 2020) (AZ_COR_000166–000215) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.24.20%20-%20AZ_COR%20_000166-000215.pdf).

¹⁶ Email from Food and Drug Administration to Emergent BioSolutions (June 11, 2020) (EBSI_HCOR_0033072–0033073) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.11.20%20-%20EBSI_HCOR_0033072-0033073.pdf).

¹⁷ Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to John Ducote, Senior Vice President, Global Quality, Emergent BioSolutions, and Dino Muzzin, Senior Vice President, Manufacturing Operations, Emergent BioSolutions (June 24, 2020) (EBSI_HCOR_0033061–0033062) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf).

¹⁸ Email from Karen Smith, Executive Vice President, Chief Medical Officer, Emergent BioSolutions, to Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions (June 24, 2020) (EBSI_HCOR_0033060–0033061) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf).

¹⁹ Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to Karen Smith, Executive Vice President, Chief Medical Officer, Emergent BioSolutions (June 24, 2020) (EBSI_HCOR_0033060–0033061) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf).

²⁰ Email from Karen Smith, Executive Vice President, Chief Medical Officer, Emergent BioSolutions, to Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions (June 24, 2020) (EBSI_HCOR_0033060–0033061) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf).

²¹ Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to Karen Smith, Executive Vice President, Chief Medical Officer, Emergent BioSolutions (June 24, 2020) (EBSI_HCOR_0033060–0033061) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf). Mr. Kirk is likely referring to Adam Havey, John Ducote, and Robert Kramer.

²² Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to Robert Kramer, President and Chief Executive Officer, Emergent BioSolutions (June 24, 2020) (ESBI_HCOR_0035634–0035636) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20ESBI_HCOR_0035634-0035636.pdf).

²³ Manufacturing Services Agreement between Janssen Pharmaceuticals, Inc., and Emergent Manufacturing Operations Baltimore, LLC (effective July 1, 2020) (JNJ_HOUSE_COR00000134-00000176) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.02.20%20-%20JNJ_HOUSE_COR00000134%20-%20000000176.pdf).

²⁴ In addition, Johnson & Johnson agreed to pay Emergent a non-refundable, multimillion-dollar capacity commitment fee to reserve capacity in Areas 1 and 2 of the Bayview facility to manufacture a total of up to 80 commercial batches during the first year. Emergent charged lower fees per batch in the first contract year than in subsequent years in exchange for the payment in full of this capacity-commitment fee. See Second Amendment to Technology Transfer Letter Agreement (effective Jan. 27, 2021) (JNJ_HOUSE_COR00000081-00000093) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/01.27.21%20-%20JNJ_HOUSE_COR00000081-00000093.pdf).

²⁵ Master Quality Assurance Agreement between AstraZeneca Pharmaceuticals LP and Emergent Manufacturing Operations Baltimore, LLC (effective July 8, 2020) (AZ_COR_000255-000318) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.08.20%20-%20AZ_COR%20_000255-000318.pdf).

²⁶ Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to AstraZeneca Pharmaceuticals LP (July 22, 2020) (AZ_COR_001347-001349) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.22.20%20-%20AZ_COR_001347-001349.pdf).

²⁷ Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to Robert Kramer, President and Chief Executive Officer, Emergent BioSolutions (June 24, 2020) (ESBI_HCOR_0035634) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20ESBI_HCOR_0035634-0035636.pdf); Email from Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, to Karen Smith, Executive Vice President, Chief Medical Officer, Emergent BioSolutions (June 24, 2021) (EBSI_HCOR_0033060-0033062) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20EBSI_HCOR_0033060-0033062.pdf).

²⁸ Contract No. US 168059200 between AstraZeneca Pharmaceuticals LP and Emergent Manufacturing Operations Baltimore, LLC, Manufacturing Product Schedule #5997-02—Large Scale Manufacturing of Covid-19 Vaccine Drug Substance (July 24, 2020) (AZ_COR_000145-000149) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.24.20%20-%20AZ_COR%20_000145-000149.pdf); Contract No. US 167916159 Master Services Agreement between AstraZeneca Pharmaceuticals LP and Emergent Manufacturing Operations Baltimore, LLC (July 24, 2020) (AZ_COR_000166-000215) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.24.20%20-%20AZ_COR%20_000166-000215.pdf).

²⁹ The Master Services Agreement and Manufacturing Product Schedule also gave AstraZeneca the option to purchase an additional 25 “extended” batches, which Emergent would manufacture in Area 3 at the Bayview facility from May 2021 through June 2021 for \$63 million. See *id.*

³⁰ Email from AstraZeneca Pharmaceuticals LP to James Glover, Camden Vice President, Manufacturing and Site Head/COVID-19 Program Lead, Emergent BioSolutions (July 24, 2020) (AZ_COR_001809-001810) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.24.20%20-%20AZ_COR_001809-001810.pdf).

³¹ A critical observation indicates “a significant compliance risk that would adversely impact patient safety, product quality and/or result in significant regulatory action if not corrected immediately.” See Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, *Emergent—Bayview (CIADM) Audit Report* (July 10, 2020) (EBSI_HCOR_0020156-0020221) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/08.10.20%20-%20EBSI_HCOR_0020156%20-%200020221.pdf).

³² See Memorandum from Majority Staff to Members of the Select Subcommittee on the Coronavirus Crisis and Members of the Committee on Oversight and Reform, *Preliminary Findings from Investigation into Emergent BioSolutions, Inc.* (May 19, 2021) (online at <https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/Staff%20Memo%20re%20Emergent%20-%20FINAL.pdf>).

³³ Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 3, 2021). “Commercial” batches refer to all batches except those allocated as engineering batches. Unlike commercial batches, which may be released for public consumption, an engineering batch is a trial run or practice batch used to test the manufacturing process. See Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021).

³⁴ Email from Adam Havey, Executive Vice President, Business Operations, Emergent BioSolutions, to Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions (Sept. 3, 2020) (EBSI_HCOR_0032963–0032966) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/09.03.20%20-%20EBSI_HCOR_0032963%20-%200032966.pdf); Email from Adam Havey, Executive Vice President, Business Operations, Emergent BioSolutions, to Senior Director of Quality at Bayview, Emergent BioSolutions (Sept. 9, 2020) (EBSI_HCOR_0032967–0032970) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/09.09.20%20-%20EBSI_HCOR_0032967%20-%200032970.pdf).

³⁵ Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

³⁶ Email from Director, Pharmaceutical Regulatory Compliance, Johnson & Johnson, to Vice President, Pharmaceutical Regulatory Compliance, Johnson & Johnson, et al. (Oct. 22, 2020) (JNJ_HOUSE_COR00000926–00000929) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/10.22.20%20-%20JNJ_HOUSE_COR00000926%20-%2000000929.pdf); Email from Johnson & Johnson to Emergent BioSolutions (Oct. 23, 2020) (JNJ_HOUSE_COR00000722) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/10.23.20%20-%20JNJ_HOUSE_COR00000722.pdf).

³⁷ Email from Johnson & Johnson to Emergent BioSolutions (Oct. 23, 2020) (JNJ_HOUSE_COR00000434–00000435) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/10.23.20%20-%20JNJ_HOUSE_COR00000434-00000435.pdf); Email from Johnson & Johnson to Emergent BioSolutions (Oct. 27, 2020) (JNJ_HOUSE_COR00000436–00000439) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/10.27.20%20-%20JNJ_HOUSE_COR00000436%20-%2000000439.pdf).

³⁸ Email from Pharmaceutical Consultant to Emergent BioSolutions (Nov. 17, 2021) (EBSI_HCOR_0026591–0026592) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/11.17.20%20-%20ESBI_HCOR_0026591-0026592.pdf).

³⁹ Email from Director, Pharmaceutical Regulatory Compliance, Johnson & Johnson, to Vice President, Pharmaceutical Regulatory Compliance, Johnson & Johnson, et al. (Nov. 18, 2020) (JNJ_HOUSE_COR00000990–00000994) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/11.18.20%20-%20JNJ_HOUSE_COR00000990-00000994.pdf).

⁴⁰ One batch of AstraZeneca vaccine drug substance was also aborted in September 2020 due to a start-up issue (i.e., poor cell growth). Four additional AstraZeneca batches were “aborted due to business decision: needed to create gap in schedule to allow EBSI [Emergent] time to implement manufacturing changes in Area 3” in November 2020. See Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney,

Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021).

⁴¹ Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 3, 2021).

⁴² Email from Dino Muzzin, Senior Vice President, Manufacturing Operations, Emergent BioSolutions, to Vice President, GM Maryland Sites, Emergent BioSolutions (Nov. 10, 2020) (EBSI_HCOR_0029954–0029955) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/11.10.20%20-%20EBSI_HCOR_0029954-0029955.pdf).

⁴³ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021).

⁴⁴ Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 3, 2021).

⁴⁵ Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021); *see also* Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Aug. 13, 2021).

⁴⁶ Email from Mary Oates, Senior Vice President of Global Quality, Emergent BioSolutions, to Syed Husain, Senior Vice President, CDMO Business Unit, Emergent BioSolutions, Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions, Dino Muzzin, Senior Vice President, Manufacturing Operations, Emergent BioSolutions, and Adam Havey, Executive Vice President of Business Operations, Emergent BioSolutions (Dec. 19, 2020) (EBSI_HCOR_0030446–0030448) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/12.19.20%20-%20EBSI_HCOR_0030446%20-%200030448.pdf).

⁴⁷ Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021); *see also* Email from Senior Director, External Manufacturing Procurement, AstraZeneca Pharmaceuticals LP, to AstraZeneca Pharmaceuticals LP employees (Jan. 25, 2021) (AZ_COR_001794–001795) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/01.25.21%20-%20AZ_COR%20_001794-001795.pdf); Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021).

⁴⁸ Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021).

⁴⁹ Between July 2020 and April 2021, Emergent initiated manufacturing for 59 batches of vaccine drug substance for AstraZeneca. The average number of doses per batch of AstraZeneca drug substance is approximately 2.4 million. AstraZeneca paid Emergent more than \$21 million for 18 batches that were aborted or rejected, and more than \$11 million for 13 batches canceled in April 2021 by the federal government following the cross-contamination event. Approximately 64 million finished doses of AstraZeneca’s vaccine had been produced from batches manufactured at Emergent’s Bayview facility as of November 5, 2021. Between March 2021 and February 2022, FDA permitted the export of 15.8 million doses to Mexico, Canada, and Brazil. However, the Biden Administration approved AstraZeneca’s request to destroy approximately 59.6 million doses of its vaccine manufactured at Bayview because the vaccine product had passed its expiration date, as of March 14, 2022. These expired doses came from batches that FDA eventually permitted AstraZeneca to export; doses that completed the fill-finish manufacturing process, but which were comprised of a rejected drug substance batch; and all 15 batches that had been pending FDA review. AstraZeneca expects to pay approximately \$232,000 to destroy these expired doses, \$176,000 of which will be reimbursed by the federal government. There are no remaining AstraZeneca batches under FDA review. *See* Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 14, 2022); Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney,

Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021).

⁵⁰ Between November 2020 and April 2021, Emergent manufactured 24 batches of vaccine drug substance for Johnson & Johnson. Each batch is roughly equivalent to 15 million finished doses. As of March 3, 2022, Johnson & Johnson had aborted or rejected 13 batches, including one batch cross-contaminated with AstraZeneca's viral vector. FDA has authorized 11 batches for release after concluding the vaccines were safe and not contaminated. After Bayview reopened in late July 2021, Emergent manufactured 15 batches, six of which were aborted or rejected by Johnson & Johnson. As of March 3, 2022, the remaining nine batches are either undergoing additional release testing or fill-finish manufacturing, with ultimate release contingent on testing results and regulatory approvals. See Letter from Johnson & Johnson, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 3, 2022); Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 1, 2021).

⁵¹ Letter from AstraZeneca Pharmaceuticals LP, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 14, 2022).

⁵² Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

⁵³ Email from Robert Kramer, President and Chief Executive Officer, Emergent BioSolutions, to Sean Kirk, Executive Vice President, Manufacturing and Technical Operations, Emergent BioSolutions (June 24, 2020) (ESBI_HCOR_0035634-0035636) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.24.20%20-%20ESBI_HCOR_0035634-0035636.pdf).

⁵⁴ Emergent BioSolutions, Monthly Report: July 2020 (EmerCly_0005554-0005564) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/07.31.20%20-%20EmerCly_0005554%20-%200005564.pdf); Emergent BioSolutions, Monthly Report: August 2020 (EmerCly_0005565-0005574) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/08.31.20%20-%20EmerCly_0005565%20-%200005574.pdf).

⁵⁵ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021).

⁵⁶ Email from Syed Husain, Senior Vice President, CDMO Business Unit, Emergent BioSolutions, to AstraZeneca Pharmaceuticals LP (Nov. 6, 2020) (AZ_COR_001664-001665) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/11.06.20%20-%20AZ_COR%20_001664-001665.pdf).

⁵⁷ Briefing by Emergent BioSolutions to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 14, 2021); see also *Federal Government Cuts Ties with Troubled Vaccine Maker*, New York Times (Nov. 4, 2021) (online at www.nytimes.com/2021/11/04/us/emergent-biosolutions-covid-vaccine.html).

⁵⁸ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021); Briefing by Emergent BioSolutions to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 14, 2021).

⁵⁹ Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021).

⁶⁰ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021).

⁶¹ Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021).

⁶² Talking Points (Apr. 3, 2021) (JNJ_HOUSE_COR00004290–00004291) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/18_JNJ_HOUSE_COR00004290_TR.pdf).

⁶³ Email from Johnson & Johnson to Emergent BioSolutions (Apr. 11, 2021) (JNJ_HOUSE_COR00001551–00001552) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/04.12.21%20-%20JNJ_HOUSE_COR00001551%20-%2000001552.pdf).

⁶⁴ Briefing by AstraZeneca Pharmaceuticals LP to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 20, 2021).

⁶⁵ Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

⁶⁶ Email from Johnson & Johnson to Emergent BioSolutions (Feb. 3, 2021) (JNJ_HOUSE_COR00001063) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/02.03.21-%20JNJ_HOUSE_COR00001062-00001063.pdf); Email from Emergent BioSolutions to Johnson & Johnson (Feb. 3, 2021) (JNJ_HOUSE_COR00001062) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/02.03.21-%20JNJ_HOUSE_COR00001062-00001063.pdf).

⁶⁷ Email from Emergent BioSolutions to Johnson & Johnson (Feb. 5, 2021) (JNJ_HOUSE_COR00001062–00001063) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/02.03.21-%20JNJ_HOUSE_COR00001062-00001063.pdf).

⁶⁸ Email from Lachman Consultants to Lachman Consultants (Feb. 15, 2021) (EBSI_HCOR_0046940–0046942) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/02.15.21%20-%20EBSI_HCOR_0046940-0046942.pdf).

⁶⁹ *Id.*

⁷⁰ Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

⁷¹ Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Sept. 3, 2021).

⁷² Email from Biomedical Advanced Research and Development Authority to Emergent BioSolutions (Mar. 30, 2021) (EBSI_HCOR_0023029–0023030) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/03.31.21%20-%20EBSI_HCOR_0023029%20-%2000023030.pdf).

⁷³ Email from Tammy Lucik, Bayview’s Site Head of Quality, Emergent BioSolutions, to Syed Husain, Senior Vice President, CDMO Business Unit, Emergent BioSolutions, et al. (Mar. 30, 2021) (EBSI_HCOR_0023029) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/03.31.21%20-%20EBSI_HCOR_0023029%20-%2000023030.pdf).

⁷⁴ Email from Syed Husain, Senior Vice President, CDMO Business Unit, Emergent BioSolutions, to Tammy Lucik, Bayview’s Site Head of Quality, Emergent BioSolutions (Mar. 3, 2021) (EBSI_HCOR_0023029) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/03.31.21%20-%20EBSI_HCOR_0023029%20-%2000023030.pdf).

⁷⁵ Briefing by Johnson & Johnson to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (July 21, 2021); Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

⁷⁶ Food and Drug Administration, *Investigation of Emergent Manufacturing Operations Baltimore LLC*; Investigation Dates: 2–10 June 2021 (July 9, 2021) (EmerCly_0005644–0005733) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/06.14.21%20-%20EmerCly_0005644%20-%200005733%20-%20excerpt.pdf).

⁷⁷ Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021); Food and Drug Administration, *Investigation of Emergent Manufacturing Operations Baltimore LLC*; Investigation Dates: 26–27 July 2021 (Aug. 5, 2021) (EmerCly_0005627–0005643).

⁷⁸ Briefing by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, and Dr. Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, Food and Drug Administration, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Sept. 2, 2021).

⁷⁹ Food and Drug Administration, Written Responses to Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis, to Secretary Xavier Becerra, Department of Health and Human Services, Acting Commissioner Janet Woodcock, Food and Drug Administration, and Dawn O’Connell, Assistant Secretary for Preparedness and Response, Department of Health and Human Services (Nov. 21, 2021).

⁸⁰ Call with Chris Frech, Senior Vice President, Global Government Affairs, Emergent BioSolutions, and Staff, Select Subcommittee on the Coronavirus Crisis (Apr. 20, 2022).

⁸¹ Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 3, 2022).

⁸² *J.&J. Pauses Production of Its Covid Vaccine Despite Persistent Need*, New York Times (Feb. 8, 2022) (online at www.nytimes.com/2022/02/08/business/johnson-johnson-covid-vaccine.html).

⁸³ Call with Chris Frech, Senior Vice President, Global Government Affairs, Emergent BioSolutions, and Staff, Select Subcommittee on the Coronavirus Crisis (Apr. 20, 2022); Email from Staff, Office of the Assistant Secretary for Legislation, Department of Health and Human Services, to Staff, Select Subcommittee on the Coronavirus Crisis (Mar. 10, 2022).

⁸⁴ Briefing by Dr. Gary Disbrow, Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Nov. 23, 2021).

⁸⁵ Emergent BioSolutions, *Press Release: Emergent BioSolutions Reports Financial Results for Third Quarter 2021* (Nov. 4, 2021) (online at <https://investors.emergentbiosolutions.com/static-files/f971a759-e8e3-4276-9d33-a0e248432e54>); *Emergent BioSolutions, Operator of Troubled Baltimore Facility, Ends Contract with Federal Government to Produce COVID Vaccines, Respond to Pandemic*, Baltimore Sun (Nov. 4, 2021) (online at www.baltimoresun.com/coronavirus/bs-md-ob-cv-emergent-biosolutions-statement-earnings-call-ciadm-20211104-nr5rhudnwnfqpeo7m3mqprqoly-story.html). See also Amendment/Modification No. P00032, Contract No. HHSO100201200004I, between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/11.01.21%20-%20ModP00031_HHSO100201200004I_TforC.pdf). This also terminated the public-private partnership established in 2012 between Emergent and HHS for pandemic preparedness.

⁸⁶ Briefing by Dr. Gary Disbrow, Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Nov. 23, 2021).

⁸⁷ Briefing by Dr. Gary Disbrow, Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, to Majority and Minority Staffs, Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (Nov. 23, 2021).

⁸⁸ Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 1, 2021); Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 3, 2022).

⁸⁹ Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Nov. 5, 2021).

⁹⁰ Email from Senior Director, External Manufacturing Procurement, AstraZeneca Pharmaceuticals LP, to Head of Biologics External Supply and Enabling Functions, AstraZeneca Pharmaceuticals LP, et al. (Jan. 25, 2021) (AZ_COR_001794–001795) (online at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/01.25.21%20-%20AZ_COR%20_001794-001795.pdf).

⁹¹ Letter from Johnson & Johnson to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 3, 2022); Letter from AstraZeneca Pharmaceuticals LP to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Chairman James E. Clyburn, Select Subcommittee on the Coronavirus Crisis (Mar. 14, 2022).