Congress of the United States
Washington, DC 20515

June 22, 2021

Dr. Pascal Soriot
Executive Director and Chief Executive Officer
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

Dear Dr. Soriot:

The Committee on Oversight and Reform and the Select Subcommittee on the Coronavirus Crisis are investigating Emergent BioSolutions, Inc.'s receipt of multimillion-dollar contracts from the Trump Administration to manufacture coronavirus vaccines and therapeutics despite a history of quality control issues. Our investigation has revealed that Emergent was warned multiple times that serious manufacturing problems and deficient controls at its Bayview facility in Baltimore, Maryland, could lead to the contamination of vaccines manufactured at the facility. Despite these warnings, Emergent failed to promptly and fully remediate the problems at the facility, and millions of doses of desperately needed coronavirus vaccines were contaminated, including doses of the coronavirus vaccine developed by AstraZeneca. We write to request documents and information to understand what went wrong and what corrective steps are necessary to ensure these mistakes are mitigated and not repeated.

On May 24, 2020, the Trump Administration awarded Emergent a $628 million contract to expand the capacity of the company's facilities in Bayview, Camden, and Rockville, Maryland, in order to support the manufacturing of coronavirus vaccines.[1] Emergent also signed agreements with Johnson & Johnson and AstraZeneca to manufacture their respective coronavirus vaccines at Emergent's facilities. On April 23, 2020, Emergent signed an initial agreement with Johnson & Johnson to support the manufacturing of its coronavirus vaccine at the Bayview facility.[2] Emergent signed a similar agreement with AstraZeneca on June 11, 2020.[3] Both agreements were expanded in July 2020 when Emergent signed multi-year contracts

[1] Contract No. HHSO100201200004I, Order No. 75A50120F33007 between ASPR-BARDA and Emergent Manufacturing Operations Baltimore LLC (May 24, 2020) (EBSI_HCOR_0001860 – 70). Prior to the award of this contract, the Trump Administration gave Emergent an Authorization to Proceed on May 12, 2020, which allowed the company to immediately begin performance and incur costs under this initiative. *See* Department of Health and Human Services, *Authorization to Proceed, to Sean Kirk, Executive Vice President, Manufacturing & Technical Operations, Emergent BioSolutions* (May 12, 2020) (EBSI_HCOR_0001838 – 47).

[2] Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Agreement to Be U.S. Manufacturing Partner for Johnson & Johnson's Lead Vaccine Candidate for COVID-19* (Apr. 23, 2020) (online at https://investors.emergentbiosolutions.com/node/19376/pdf).

[3] Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Agreement to Be U.S.*

for large-scale development and manufacturing services with each company.[4] Combined with its federal contracts, Emergent's coronavirus vaccine manufacturing deals with Johnson & Johnson and AstraZeneca are reportedly worth up to $1.5 billion.[5]

Evidence recently released by the Committees shows that Emergent was warned multiple times that serious manufacturing problems and deficient controls at the Bayview facility could lead to contamination but that Emergent failed to act. These warnings came in internal inspections as well as inspections and audits by the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority, Operation Warp Speed, Johnson & Johnson, and AstraZeneca. These inspections and audits found that Emergent's Bayview facility had persistent problems with mold, poor disinfection of plant equipment, and inadequate training of employees.[6]

For example, Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, conducted an audit of Emergent's Bayview facility from June 9 through June 18, 2020. On July 24, 2020, Janssen sent Emergent a report with its audit findings, which concluded that Emergent's "quality systems may have weaknesses or gaps that require CAPA [Corrective and Preventive Actions]." The audit report included numerous findings related to deficient virus contamination practices, noting, "There is not a formal Bayview contamination control strategy for the site."[7]

As a result of these unaddressed manufacturing errors and contamination, in fall 2020 and winter 2021, Emergent discarded millions of coronavirus vaccine doses manufactured at the Bayview facility:

- In October 2020, Emergent destroyed two to three million doses of AstraZeneca's vaccine due to suspected contamination;

Manufacturing Partner for AstraZeneca's COVID-19 Vaccine Candidate (June 11, 2020) (online at https://investors.emergentbiosolutions.com/node/19631/pdf).

[4] Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Five-Year Agreement for Large-Scale Drug Substance Manufacturing for Johnson & Johnson's Lead COVID-19 Vaccine Candidate* (July 6, 2020) (online at https://investors.emergentbiosolutions.com/node/19676/pdf); Emergent BioSolutions, *Press Release: Emergent BioSolutions Signs Agreement with AstraZeneca to Expand Manufacturing for COVID-19 Vaccine Candidate* (July 27, 2020) (online at https://investors.emergentbiosolutions.com/node/19716/pdf).

[5] *Shake-Up at Covid Vaccine Manufacturer That Tossed Millions of Doses*, New York Times (Apr. 29, 2021) (online at www.nytimes.com/2021/04/29/us/emergent-biosolutions-covid-vaccine-manufacturing.html).

[6] *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); *see also U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

[7] Letter from Stephen Green, Senior Manager External Supply Integration – Quality, Johnson & Johnson, to Judith Adair McCorry, Director of Quality Assurance, Emergent BioSolutions (July 24, 2020) (EBSI_HCOR_0014442 – 54 at EBSI_HCOR_0014448).

- In November 2020, Emergent discarded a batch of Johnson & Johnson vaccine after workers "hooked up" the wrong gas line and accidentally "suffocated" the cells where the virus for the vaccine is grown;

- In December 2020, Emergent destroyed another 8 to 12 million doses of AstraZeneca's vaccine due to bacterial contamination of equipment; and

- In February 2021, Emergent contaminated millions of doses of Johnson & Johnson's coronavirus vaccine with ingredients from AstraZeneca's vaccine and was forced to destroy up to 15 million tainted doses of Johnson & Johnson's vaccine immediately, and 60 million more after additional testing.[8]

At a May 19, 2021, Select Subcommittee hearing, Emergent's President and Chief Executive Officer, Robert Kramer, portrayed the series of contamination events in the fall of 2020 as routine. He testified, "There were a number of contaminations while we were starting up the AstraZeneca manufacturing process, which you would normally find." He also blamed AstraZeneca for manufacturing problems at the Bayview plant and the need to discard millions of vaccine doses, stating:

> I think what has not been reported accurately is the fact the package of IP that we received from AstraZeneca, under normal circumstances that would be well defined, you would bring that into your manufacturing facility and be able to quickly replicate that. That was not the case with the AstraZeneca product. And, in fact, we ended up making 80 different process changes alone in the first 60 to 90 days of trying to stand that manufacturing process up. So it was very difficult, very complicated, and it did result in a number of lost production runs.[9]

Following the discovery of the cross-contamination, the Biden Administration took several steps to address the systemic manufacturing problems at the Bayview facility. On April 3, 2021, the Biden Administration put Johnson & Johnson in charge of the Bayview facility and asked Emergent to stop manufacturing the AstraZeneca vaccine to reduce the risk of cross-contamination.[10] On April 12, 2021, FDA commenced a wide-ranging inspection of Emergent's Bayview facility.[11] Four days later, the agency asked the company to stop

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[8] *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html); *The F.D.A. Tells Johnson & Johnson to Throw Out About 60 Million Doses Made at Troubled Plant*, New York Times (June 11, 2021) (online at www.nytimes.com/2021/06/11/us/politics/johnson-covid-vaccine-emergent.html).

[9] 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).

[10] *J&J Takes Over Plant Where Contractor Ruined 15 Million Vaccine Doses*, New York Magazine (Apr. 6, 2021) (online at https://nymag.com/intelligencer/2021/04/j-and-j-takes-over-vaccine-plant-where-15m-doses-were-ruined.html).

[11] Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore*,

manufacturing any new vaccine material at the facility and to quarantine all existing vaccine substance.[12] On April 20, 2021, FDA issued a scathing inspection report of the Bayview facility.[13] In its initial response to this report, Emergent referred to FDA's instruction to stop manufacturing new material as a "voluntary shutdown period."[14] As of June 21, 2021, manufacturing at the Bayview facility remains on hold. On June 11, 2021, FDA ordered an additional 60 million doses of Johnson & Johnson vaccine that were manufactured at the Bayview facility to be destroyed because they were not suitable for use due to possible contamination.[15] According to *Politico*, approximately 60 million doses of AstraZeneca's vaccine manufactured at Bayview are still being tested to determine whether they are safe.[16]

With more than 85 million total doses destroyed and tens of millions more held back for testing,[17] Emergent's mistakes have reduced the number of vaccines available for global vaccination efforts.[18] We are troubled by the impact Emergent's manufacturing errors have had on the availability of coronavirus vaccine doses, as well as the potential effect on public perceptions regarding the safety and efficacy of these vaccines. We are also concerned about the circumstances that led AstraZeneca and Johnson & Johnson to sign contracts with Emergent to produce their respective coronavirus vaccines.

* * *

LLC (Apr. 20, 2021) (online at www.fda.gov/media/147762/download).

[12] *Johnson & Johnson Suffers Another Setback as FDA Tells Md. Vaccine Maker to Suspend Production*, Washington Post (Apr. 19, 2021) (online at www.washingtonpost.com/business/2021/04/19/johnson-johnson-covid-vaccine-emergent/).

[13] Food and Drug Administration, *Inspection Report of Emergent Manufacturing Operations Baltimore, LLC* (Apr. 20, 2021) (online at www.fda.gov/media/147762/download); *FDA Issues Withering Report on Problems at Emergent BioSolutions Factory That Ruined Millions of J&J Vaccines*, USA Today (Apr. 21, 2021) (online at www.usatoday.com/story/news/nation/2021/04/21/covid-19-fda-issues-withering-report-us-factory-making-j-jvaccine/7319674002/).

[14] Letter from Dino Muzzin, Senior Vice President, Manufacturing and Interim General Manager, Emergent Manufacturing Operations Baltimore, LLC, to Lisa Harlan, Acting Staff Director, Investigations Branch, Office of Biological Products Operations, Office of Regulatory Affairs, Food and Drug Administration, at 31 (Apr. 30, 2021).

[15] *The F.D.A. Tells Johnson & Johnson to Throw Out About 60 Million Doses Made at Troubled Plant*, New York Times (June 11, 2021) (online at www.nytimes.com/2021/06/11/us/politics/johnson-covid-vaccine-emergent.html); Food and Drug Administration, *FDA Takes Steps to Increase Availability of COVID-19 Vaccine* (June 11, 2021) (online at https://www.fda.gov/news-events/press-announcements/fda-takes-steps-increase-availability-covid-19-vaccine).

[16] *FDA Tells J&J to Scrap 60 Million Vaccine Doses Made at Troubled Plant*, Politico (June 11, 2021) (online at www.politico.com/news/2021/06/11/fda-10-million-jj-vaccine-493434).

[17] *The F.D.A. Tells Johnson & Johnson to Throw Out About 60 Million Doses Made at Troubled Plant*, New York Times (June 11, 2021) (online at www.nytimes.com/2021/06/11/us/politics/johnson-covid-vaccine-emergent.html); *U.S. Bet Big on COVID Vaccine Manufacturer Even as Problems Mounted*, New York Times (Apr. 6, 2021) (online at www.nytimes.com/2021/04/06/us/covid-vaccines-emergent-biosolutions.html).

[18] *Baltimore Vaccine Plant's Troubles Ripple Across 3 Continents*, New York Times (May 6, 2021) (online at www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html).

For these reasons, please produce the following information and documents by July 6, 2021:

1. All contracts between AstraZeneca or any of its subsidiaries or affiliates and Emergent BioSolutions or any of its subsidiaries or affiliates between January 1, 2020, and the present;

2. All documents and communications related to the decision to contract with Emergent BioSolutions or use Emergent BioSolutions' facilities to manufacture coronavirus vaccines, including but not limited to communications with federal government officials, employees, or agents regarding AstraZeneca's decision to enter into a contract with Emergent BioSolutions or to use Emergent facilities for coronavirus vaccine manufacturing;

3. All inspection, audit, or risk assessment reports and related communications with Emergent BioSolutions concerning manufacturing, quality, or compliance at Emergent BioSolutions' facilities from January 1, 2020, through the present, including with respect to disinfection and contamination protocols, staff training and competence, the ability of Emergent BioSolutions to comply with contract terms, or other issues;

4. All communications, as well as a detailed written description, related to any steps taken by AstraZeneca to supervise manufacturing, quality, or compliance at Emergent BioSolutions' Bayview facility with respect to AstraZeneca's coronavirus vaccines, including but not limited to stationing staff on-site to oversee operations, implementing or approving process changes, or performing quality testing, as well as Emergent BioSolutions' compliance with or objections to any of AstraZeneca's requests or recommendations;

5. For all AstraZeneca coronavirus vaccines manufactured at Emergent BioSolutions' Bayview facility:

    a. the total number of vaccine doses that have been discarded or destroyed, as well as the reasons for discarding or destroying the vaccines, the date the doses were discarded or destroyed, and the location within Bayview where the vaccines were manufactured;

    b. the total number of vaccine doses that have been shipped, as well as the current status of those vaccines (including the total number of doses held for further testing by FDA or foreign authorities to determine they are safe, the anticipated timeline for completing such testing, and any results of such testing received by the company to date); and

    c. the total number of vaccine doses that have been manufactured but not shipped, as well as the current status of those vaccines;

6. A detailed description of the causes of the suspected contamination of any AstraZeneca coronavirus vaccines manufactured at Emergent BioSolutions' Bayview facility, the status of any investigation into this contamination, and any findings, outcomes, or recommendations resulting from that investigation, including all documents related to such investigation; and

7. A detailed description of all costs or cost analyses resulting from delay of the production of AstraZeneca's coronavirus vaccine at Emergent BioSolutions' Bayview facility, waste or spoilage of vaccine components (including the cost of materials, replacement vaccines, testing of potentially contaminated doses, and other related items), or failure of Emergent BioSolutions to fulfill any obligation under the contract(s) to manufacture AstraZeneca's coronavirus vaccine or any component thereof.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. The House of Representatives authorized the Select Subcommittee on the Coronavirus Crisis "to conduct a full and complete investigation" of "issues related to the coronavirus crisis," including the "preparedness for and response to the coronavirus crisis, including the development of vaccines and treatments."[19]

An attachment to this letter provides additional instructions for responding to this request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051. Thank you for your prompt attention to this request.

Sincerely,

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

James E. Clyburn
Chairman
Select Subcommittee on the Coronavirus Crisis

Enclosure

cc: The Honorable James Comer, Ranking Member
Committee on Oversight and Reform

The Honorable Steve Scalise, Ranking Member
Select Subcommittee on the Coronavirus Crisis

[19] H.Res. 8, sec. 4(f), 117th Cong. (2021); H.Res. 935, 116th Cong. (2020).

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.