Dear Mr. Kramer and Mr. El-Hibri:

The Oversight Committee and the Select Subcommittee on the Coronavirus Crisis are investigating whether Emergent BioSolutions, Inc. (Emergent) leveraged its relationship with a key Trump Administration official to secure and profit from federal contracts, despite a track record of increasing prices without justification and failing to meet contract requirements, and whether these actions impeded our nation’s response to the coronavirus crisis.

Specifically, we are investigating reports that Emergent received multi-million-dollar contracts to manufacture coronavirus vaccines despite a long, documented history of inadequately trained staff and quality control issues. Emergent received $628 million in June 2020 to establish the primary U.S. facility for manufacturing vaccines developed by Johnson & Johnson and AstraZeneca.\(^1\) Dr. Robert Kadlec, who served as Assistant Secretary for Preparedness and Response under President Trump and previously worked as a consultant for Emergent, appears to have pushed for this award despite indications that Emergent did not have the ability to reliably fulfill the contract.

A series of issues came to light last month after public reporting revealed quality control issues at Emergent’s Baltimore plant. During the manufacturing process, your company contaminated millions of doses of Johnson & Johnson’s one-shot coronavirus vaccine with ingredients from the AstraZeneca vaccine.\(^2\) Emergent was forced to destroy up to 15 million tainted doses of the Johnson & Johnson vaccine, with another 62 million doses in jeopardy until it can be determined that they were not affected. The plant also had to destroy millions of doses of AstraZeneca’s coronavirus vaccine between October 2020 and January 2021 due to suspected contamination.\(^3\) The Food and Drug Administration (FDA) is currently reviewing Emergent’s manufacturing problems, and Emergent announced on April 19, 2021, that it has agreed with

---


FDA to halt the manufacturing of new material at its Baltimore plant “pending completion of the inspection and remediation of any resulting findings.”

Thankfully, these serious errors have not impacted the safety or efficacy of coronavirus vaccines available to Americans. The Johnson & Johnson coronavirus vaccine doses that have been delivered and used nationwide were produced at a different Johnson & Johnson facility. Because FDA has not certified the Baltimore plant, vaccines manufactured at the facility have not been distributed to the public. As a result, the contaminated doses from Emergent’s Baltimore plant have not been delivered to the American public. We commend the Biden Administration for moving swiftly to address the manufacturing problems by directing Johnson & Johnson to assume full responsibility for vaccine manufacturing at your company’s plant. Nevertheless, we remain concerned about the circumstances that led to the award of this contract under the prior Administration and whether Emergent’s manufacturing errors could hinder vaccination efforts that are critical to saving lives and ending the coronavirus crisis.

We are also investigating Emergent’s actions to unduly influence the assets currently stockpiled in the Strategic National Stockpile (SNS), which is critical to providing for the emergency health security of the United States in the event of a public health emergency or bioterrorist attack. Emergent is the sole supplier of the SNS’s stockpile of anthrax vaccine. Emergent has raised the government purchasing price of the anthrax vaccine by 800% since acquiring the drug in 1998. As a result, through most of the last decade, nearly half of the SNS’s budget has been spent purchasing Emergent’s anthrax vaccine. These spiraling costs contributed to shortages of critical supplies, including ventilators, reusable respirator masks, and other personal protective equipment, which severely impacted the government’s ability to respond to the coronavirus crisis.

**Emergent Received Lucrative Contracts Despite a Track Record of Failures**

In June 2012, the Department of Health and Human Services (HHS) awarded a $163 million contract to Emergent to retrofit and expand its Baltimore manufacturing plant. Through this public-private partnership, the federal government hoped to increase its ability to rapidly manufacture vaccines in the event of an infectious disease outbreak or biological attack.

---


The contract required Emergent to demonstrate that it could produce 50 million doses of a pandemic influenza vaccine within four months, and partner with a company developing a flu vaccine candidate to gain manufacturing approval from FDA by June 2020.9

In 2017, Dr. Kadlec was nominated by President Trump and confirmed by the Senate to lead the Office of the Assistant Secretary for Preparedness and Response (ASPR). Until 2015, Dr. Kadlec provided consulting services to Emergent through his company, RPK Consulting.10 Following Dr. Kadlec’s confirmation, Emergent received millions of dollars in federal contracts from ASPR, including contracts for the SNS that were awarded without competitive bidding.11 Emergent encouraged oversight of the SNS to be transferred from the Centers for Disease Control and Prevention (CDC) to ASPR, under Dr. Kadlec’s control.12

In 2019, ASPR commissioned a review of the company’s progress under the 2012 contract, which determined that Emergent’s ability to deliver in a pandemic remained largely unproven.13 Emergent ultimately failed to meet the contract’s June 2020 deadline. An FDA inspection of the Baltimore plant in April 2020 revealed that Emergent did not have the necessary personnel to produce a coronavirus vaccine.14 A separate inspection in June 2020 found that Emergent’s plan for manufacturing urgently needed coronavirus vaccines was inadequate due to poorly trained staff and quality control problems.15

Even in light of these failures, the Trump Administration awarded an additional $628 million to Emergent in June 2020 to manufacture coronavirus vaccines.16 Dr. Kadlec has


13 Id.


16 Department of Health and Human Services, Press Release: HHS Adds $628 Million to Contract with Emergent BioSolutions to Secure CDMO Manufacturing Capacity for Operation Warp Speed (June 1, 2020) (online at www.hhs.gov/about/news/2020/06/01/hhs-adds-628-million-contract-emergent-biosolutions-secure-
reportedly said he knew this was a risky decision.\textsuperscript{17} Emergent’s coronavirus manufacturing deals are worth up to $1.5 billion.\textsuperscript{18} Emergent also has separate agreements with Johnson & Johnson and AstraZeneca worth another $875 million.\textsuperscript{19}

FDA continues to investigate Emergent’s manufacturing problems. We are concerned by the costs to taxpayers and the potential impact on our nation’s vaccination efforts caused by Emergent’s failed attempts to manufacture these vaccines.

**Undue Influence and Unjustified Pricing Led to Critical Supply Shortages**

We are also concerned that Emergent may have used its political connections to acquire lucrative manufacturing contracts and significantly increase its profits, while failing to deliver on these contracts. In 1998, Emergent, which was previously organized under the name BioPort, purchased the license to the anthrax vaccine from the State of Michigan for $25 million.\textsuperscript{20} The anthrax vaccine, BioThrax, is the only FDA-licensed vaccine for the prevention of anthrax infection. BioThrax received initial approval in 1970 and the price of this vaccine has increased substantially over the years.\textsuperscript{21} When the company acquired the license to BioThrax in 1998, the price of a dose of the vaccine averaged about $3.35. By 2010, according to data from Emergent, the company had increased the price it charges to the government to about $28 per dose. It is now over $30 per dose.\textsuperscript{22} Average wholesale prices for BioThrax are even higher, reaching $90 per dose.\textsuperscript{23}

Over the last 12 years, the federal government has implemented changes to storage and dosing for the anthrax vaccine that should have reduced both the number of doses needed to respond to an emergency and the cost of supplying BioThrax to the government. In 2009, FDA changed its guidelines to extend the shelf life of BioThrax from three years to four years.\textsuperscript{24} In manufacturing-capacity-operation-warp-speed.html).


\textsuperscript{18} *Id.*

\textsuperscript{19} *Id.*


2019, CDC put forward recommendations of the Advisory Committee on Immunization Practices to space out anthrax vaccine booster shots from one year to three years.²⁵

Emergent used these changes to justify an increase in the price of vaccines sold to the government. The Washington Business Journal reported that the “shelf life extension also allows Emergent to charge more for future doses of the vaccine delivered to the government’s stockpile.”²⁶ According to an Emergent press release, the change in shelf life not only enabled the company to receive an additional payment of approximately $30 million for doses previously delivered to the SNS, but also resulted in an immediate price increase for the future delivery of anthrax doses under both the then-current contract and the follow-on multi-year contract.²⁷

Although anthrax infection is still a danger, the last time it appeared in the intelligence community’s annual Worldwide Threat Assessment was in 2012. At that time, then-Director of National Intelligence James R. Clapper stated, “we assess the anthrax threat to the United States by lone actors is low.”²⁸

In 2020, Emergent continued development of a new anthrax vaccine called NuThrax.²⁹ Even though Emergent’s new anthrax vaccine was unlicensed and had not yet been approved, Dr. Kadlec’s office awarded your company roughly $3 billion in long-term contracts for anthrax and other bioterrorism threats in the months before the coronavirus pandemic.³⁰ We are concerned that Emergent’s demands and financial interests—rather than legitimate threat-based assessments—drove the type and amount of assets maintained in the SNS under the prior Administration.

During the Trump Administration and Dr. Kadlec’s tenure with ASPR, Emergent’s anthrax vaccine contracts put an enormous strain on the budget for the SNS, contributing to


critical supply shortages that impacted the nation’s ability to respond to other threats. In 2020, the government spent more than $370 million on Emergent’s anthrax vaccine. Dr. Kadlec admitted that spending on your company’s anthrax vaccines limited the federal government’s ability to prepare for other disasters, saying: “If I could spend less on anthrax replenishment, I could buy more N95s. I could buy more ventilators. I could buy more of other things that quite frankly I didn’t have the money to buy.”31 It appears that the SNS shortages of basic medical supplies during the coronavirus pandemic last year are directly related to Emergent’s outsized influence over the price and procurement of its anthrax vaccines.

**Increased Profits and Executive Compensation**

Emergent’s profits rose significantly during the Trump Administration and Dr. Kadlec’s tenure with ASPR. In 2020, Emergent’s profits soared while the United States was in the depths of a global pandemic. By the fourth quarter of 2020, Emergent’s total revenues were $583 million, an increase of 62% over the same period in 2019. Product sales for anthrax vaccines more than doubled from $173 million to $374 million over the same time period.32 Emergent’s President and Chief Executive Officer Robert G. Kramer boasted to investors last month that profitability for 2020 was “off-the-chart successful.”33

Corporate compensation at Emergent has also soared. According to the New York Times, in 2020, “Emergent’s stock performed so well that its founder and chairman cashed in shares and options worth over $42 million, more than he had redeemed in the previous five years combined, corporate filings show.”34 In addition to this windfall for Emergent’s Executive Chairman, Fuad El-Hibri, Mr. Kramer’s annual compensation increased by 51% between 2019 and 2020. Emergent’s most recent annual proxy disclosure shows that in 2020 Mr. Kramer received $893,000 in salary, a $1.2 million bonus, $2.1 million in stock awards, and $1.4 million in stock options. At $5.7 million, his total annual compensation for 2020 is more than 43 times the total compensation for the median employee at Emergent.35

* * *

For these reasons, please produce the following information and documents by May 3, 2021:

31 *Id.*


1. All contracts between Emergent BioSolutions or any of its subsidiaries or affiliates, and the Department of Health and Human Services between 2015 and the present;

2. All inspection, audit, or risk assessment reports related to manufacturing, quality, or compliance at Emergent BioSolutions’ Baltimore plant from 2017 through the present, including with respect to disinfection and contamination protocols, staff training and competence, and ability to comply with contract terms;

3. All documents and communications related to the suspected contamination of coronavirus vaccines at Emergent BioSolutions’ Baltimore plant, including but not limited to the discovery of the suspected contamination, any testing or investigation related thereto, and any determination related to destroying vaccine doses;

4. A detailed description of the causes of the suspected contamination of coronavirus vaccines at Emergent BioSolutions’ Baltimore plant, the status of any investigation into the suspected contamination of coronavirus vaccines at Emergent BioSolutions’ Baltimore plant, and any findings, outcomes, or recommendations resulting from that investigation;

5. All documents and communications related to any financial or reputational consequences resulting from delay of the production of any coronavirus vaccine, waste or spoilage of vaccine components, or failure to fulfill any obligation under any contract to manufacture any coronavirus vaccine or component thereof;

6. All documents and communications with Robert Kadlec between November 9, 2016, and January 20, 2021;

7. All agreements between Emergent BioSolutions, or any of its subsidiaries or affiliates, and Robert Kadlec, RPK Consulting, or any agent or affiliate thereof, and a summary of all payments under those contracts;

8. All documents and communications related to the calculation of compensation for each of the following executives for each of the past five years, including but not limited to any determination of whether the executive has satisfied requirements for incentive-based compensation; any description of the reasons for the year-to-year changes in compensation; and any related communications and approval documentation regarding the compensation:

   a. Fuad El-Hibri, Executive Chairman of the Board of Directors; and

   b. Robert Kramer, President and Chief Executive Officer;

9. All documents reflecting Emergent BioSolution’s policies, procedures, and practices related to executive compensation;
10. The dates, times, locations, and attendees of any meetings between representatives of Emergent BioSolutions or any of its subsidiaries or affiliates, and officials from the Department of Health and Human Services or Operation Warp Speed, between 2017 and the present;

11. For each calendar year from 2015 through the present, provide the following for the anthrax vaccine:
   a. total gross sales;
   b. number of units sold;
   c. cost of goods sold; and
   d. total sales net of any rebates, discounts, and all other price concessions, including the type, amount, and recipient of each discount or concession;

12. An organizational chart for Emergent BioSolutions, and a list of each Emergent business unit, component, or division involved in the pricing of the anthrax vaccine and organizational charts for those entities;

13. A list of all third-party entities that have been contracted to provide services related to the marketing, manufacturing, pricing, or lobbying of the anthrax vaccine, and a description of the services provided by the third-party entity;

14. All internal and external presentations, analyses, or other documents prepared for or provided to Emergent BioSolutions’ Board of Directors, any subcommittee of the Board of Directors, or any corporate officers, discussing:
   a. pricing strategies, pricing changes, or methods, approaches, or strategies to lobby or solicit for increased or continued purchases of the anthrax vaccine or agreements to manufacture coronavirus vaccines by the federal government;
   b. manufacturing, quality, and compliance risks related to the operation of Emergent BioSolution’s Baltimore plant or the company’s production of coronavirus vaccines, including with respect to disinfection and contamination protocols, staff training and competence, and ability to comply with contract terms;

15. All documents related to changes or improvements in the production, manufacturing, or development of the anthrax vaccine;

16. A searchable, sortable, downloadable spreadsheet that contains the following information for each contract between Emergent BioSolutions, or any of its subsidiaries or affiliates, and the federal government related to the anthrax vaccine or any coronavirus vaccine from 2015 to present:
a. contract number;
b. date of contract;
c. contracting entity;
d. manufacturing cost per unit or dose;
e. contract price per dose; and
f. total contract value.

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 established 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” and “executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus crisis.”36

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

36 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,
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.