THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

December 8, 2023

Karen Gorman
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW
Washington, DC, 20036-4505

Dear Karen Gorman:

I have enclosed a report prepared by the Department of Health and Human Services' Office of Inspector General concerning a whistleblower disclosure referred to me by you in correspondence dated May 12, 2020.

I hope this information is helpful.

Sincerely,

Xavier Becerra

Enclosures

Department of Health and Human Services

Office of Inspector General

Office of Evaluation and Inspections

Report of Findings

To the Secretary of Health and Human Services

In response to:

Office of Special Counsel

File DI-20-000743

Christi A. Grimm

Inspector General

Department of Health and Human Services

Office of Inspector General

Washington, DC

September 2023

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EXECUTIVE SUMMARY

Background. On May 12, 2020, the Office of Special Counsel (OSC), under its authority in 5 U.S.C. § 1213, referred a whistleblower disclosure filed by [redacted] former Director of the Biomedical Advanced Research and Development Authority (BARDA), to the then-Secretary of Health and Human Services (HHS), Alex M. Azar II (OSC File No. DI-20-000743). The referral directed HHS to investigate and produce a report regarding the allegations described in the whistleblower disclosure. On June 1, 2020, Secretary Azar delegated investigation of the allegations to the Office of Inspector General (OIG).

In the 63-page disclosure to OSC, [redacted] who consented to the release of [redacted] name, alleged several improprieties related to the HHS response to the COVID-19 pandemic and contract award and administration by HHS. The OSC referral grouped the alleged improprieties into five allegations:

1. Senior HHS officials dismissed BARDA's requests for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic.
2. HHS leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles. [redacted] stated that supply chain deficiencies continued for the production of syringes and needles, and that these shortages would impede the administration of any vaccine, once developed and proven safe and effective, to the American public.
3. Office of the Assistant Secretary for Preparedness and Response (ASPR) and other senior HHS officials pressured BARDA to promote the use of chloroquine and hydroxychloroquine as a therapeutic treatment for COVID-19, even though those drugs were produced in factories located in India and Pakistan that were not inspected by the Food and Drug Administration (FDA) and despite a lack of scientific data to support the use of these drugs as therapeutics.
4. [redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels both before and during the COVID-19 pandemic. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals; Alvogen, Inc.; Partner Therapeutics; Emory University; Ridgeback Biotherapeutics LP; Northwell Health; Novavax; and Alchem Laboratories.[1]
5. [redacted] and the ASPR Next staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

This report addresses OIG's review of Allegation 1 about medical countermeasures (i.e., vaccine, drug, and diagnostic development) and Allegation 2 about supplies needed for the response to

[1] [redacted] Secretary for Preparedness and Response during the period of our review, [redacted] the position in [redacted].

the COVID-19 pandemic, and consistent with 5 U.S.C. § 1213, assesses whether the allegations made by [redacted] constitute a violation of any law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety.

Assessment Summary. For the time period that we examined, January–March 2020, OIG did not substantiate that HHS noncareer officials dismissed requests from BARDA for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic; OIG did not find that associated conduct by HHS employees appeared to be a violation of any law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

For the time period that we examined, January–March 2020, OIG did not substantiate that HHS noncareer leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles; OIG did not find that associated conduct by HHS employees appeared to be a violation of any law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG found that ASPR worked with HHS and the Assistant Secretary for Financial Resources (ASFR) during January and February 2020 to request supplemental funding needed for both developing medical countermeasures and addressing supply scarcities. However, it was mid-March 2020 before ASPR had available emergency supplemental funds, and in the meantime, HHS career and noncareer staff reported to OIG that some significant response efforts regarding medical countermeasures and supplies were delayed. These delays were consistent with several points included in [redacted] disclosure; however, OIG did not find that the delays were caused by employee misconduct.

Methodology. To review the allegations in the OSC referral, from July 2020 through May 2021, OIG staff conducted telephone interviews with 28 HHS career and noncareer officials who were either directly involved or knowledgeable about conduct related to the allegations. These individuals included [redacted] (the whistleblower), officials in the Centers for Disease Control and Prevention (CDC), and the Office of the Secretary (including ASPR and ASFR). For each interview, OIG developed a series of interview questions tailored to the interviewee and their position within the Department during the period of the review. We sought to gain information about activities with which the interviewees were personally familiar, as well as their perspectives, based on their experience, expertise, and positions, related to the allegations.

We examined documents that interviewees provided to us about their activities and communication with others related to their interview responses. These documents included reports, meeting notes, emails, and supporting documentation for certain activities. We also reviewed selected document that we requested from HHS agencies, including ASPR. These documents included reports and analyses. We also examined relevant laws, regulations, and guidance documents.

Review Period. Our review focused on HHS employee conduct during January–March 2020. Position titles mentioned in this report refer to HHS officials who held that position during this period of our review.

Limitations. Our interviews with HHS officials occurred several months after the review period. Officials often referenced notes and other available records for their responses. However, interviewees reported that they were sometimes unable to recall full details from our review period. When possible, we corroborated information that interviewees provided with documentation, but it was not always possible to verify the accuracy of the events and statements described by HHS officials during our interviews.

The testimonial evidence that we considered is limited to the HHS officials whom we interviewed and their knowledge about the activities discussed. Those interviewees included key HHS officials referenced in the whistleblower disclosure and HHS officials to whom we were directed for more information. Nonetheless, it was not feasible to interview every HHS official involved with or knowledgeable about the allegations.

The findings in this report are relevant to the allegations that OIG reviewed and do not represent a comprehensive assessment of the HHS response to COVID-19 during the period of our review. See OIG's COVID-19 Portal for more information about OIG's Oversight of COVID-19 Response and Recovery, including multiple public reports previously issued, investigations, and numerous ongoing audits and evaluations.

Standards. We conducted this review in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

ASSESSMENT

1. **[redacted] alleged that HHS noncareer officials dismissed requests from BARDA for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic.**

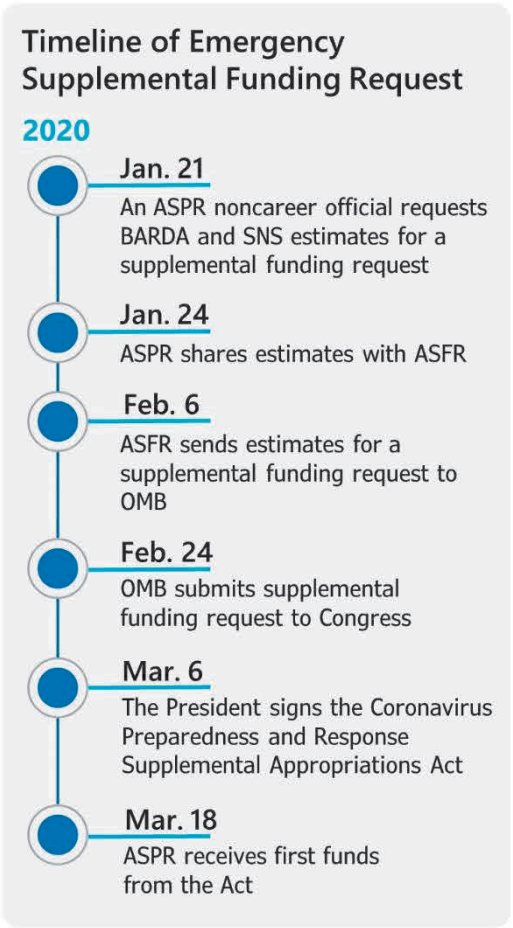
[redacted] reported to OIG that, beginning in January 2020, [redacted] urged HHS and ASPR noncareer officials to take action to begin the development of medical countermeasures for COVID-19. [redacted] reported telling HHS and ASPR noncareer officials that supplemental funds were urgently needed. [redacted] also reported pressing for emergency funding during an HHS leadership meeting on January 23, 2020. [redacted] reported urging HHS noncareer officials to move quickly to obtain virus sequencing and samples to support developing medical countermeasures. [redacted] reported to OIG that HHS and ASPR noncareer officials responded to [redacted] messages with indifference.

OIG did not substantiate that HHS noncareer officials dismissed requests from BARDA for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic; OIG did not find that associated conduct by HHS employees appeared to be a violation of any law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG found that ASPR took actions to address both financial and nonfinancial resources needed to begin development of medical countermeasures. These actions include the following activities:

Requesting Emergency Supplemental Funding from Congress. OIG found that ASPR career and noncareer officials worked on a supplemental funding request during January and February 2020. ASPR career and noncareer officials were aware that when the COVID-19 outbreak started in January 2020, additional funds would be immediately needed to begin development of medical countermeasures and to replenish supplies in the Strategic National Stockpile (SNS). As documented in emails, ASPR career and noncareer officials began preparing an initial emergency supplemental funding request for a response to COVID-19 in January 2020. However, the length of time from ASPR's initial planning until receipt of supplemental funds for medical countermeasures and supplies was about 2 months (until mid-March 2020). Some HHS officials reported that the 2-month period until supplemental funds became available to ASPR significantly delayed its COVID-19 response activities for the development of medical countermeasures and procurement of needed medical supplies.

As shown in the exhibit timeline, by January 21, 2020, an ASPR noncareer official requested BARDA and SNS career officials to provide cost estimates for the emergency supplemental funding request. On February 24, 2020, the Office of Management and Budget (OMB) submitted the request to Congress. Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which was signed into law on March 6, 2020. The Act made $3.4 billion available to the Public Health and Social Services Emergency Fund (ASPR's funding source) for the pandemic response. ASPR received its initial funds from the Act on March 18, 2020. According to a ASFR career official, this 2-month process was fast compared to supplemental funding requests for past emergencies.



Obtaining Virus Sequencing and Samples for Medical Countermeasure Development. OIG found that the genetic sequence of the virus (i.e., the genetic code of the virus) quickly became available when, on January 12, 2020, Chinese researchers shared on the internet the genetic sequence of the virus that would be called SARS-CoV-2 and caused what came to be known as COVID-19. Although this was not an action by ASPR itself, the release of the sequence happened a couple of days after the whistleblower began urging HHS officials to obtain the sequence.

The Assistant Secretary for Preparedness and Response reported to OIG that attempts were made to obtain samples of the virus from China through U.S. contacts at the National Academies of Sciences, Engineering, and Medicine in mid-January 2020. The Assistant Secretary for Preparedness and Response also reported that, in exchanges with the Minister

of Health in China in January 2020, the HHS Secretary made direct requests for virus samples.[2] In addition, the Assistant Secretary for Preparedness and Response and an HHS career official also reported that CDC tried to coordinate with the Chinese Center for Disease Control and Prevention to obtain virus samples from China. Ultimately, the U.S. Government obtained virus samples from confirmed cases of COVID-19 in the United States.

Establishing the Medical Countermeasures Task Force. On January 25, 2020, the Assistant Secretary for Preparedness and Response created the COVID-19 Medical Countermeasures (MCM) Task Force that included career officials from BARDA. The MCM Task Force immediately began identifying potentially promising medical countermeasures, including potential therapeutics and candidates for vaccine development.[3]

Before supplemental emergency response funding became available in mid-March 2020, ASPR career officials reported that BARDA was only able to take limited steps toward medical countermeasure procurement and development, such as securing donations and amending some existing contracts to lay the groundwork for future medical countermeasure development, including contracts that later became part of Operation Warp Speed.[4]

2. [redacted] alleged that HHS noncareer leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles.

[redacted] reported to OIG that [redacted] repeatedly pushed HHS noncareer officials to secure and increase supplies, including N95 masks, needles and syringes, and testing swabs and, as mentioned, to obtain the emergency funding to support such procurements. [redacted] alleged that HHS noncareer officials failed to take urgent action to mitigate known supply shortages.

OIG did not substantiate that HHS noncareer leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles; OIG did not find that conduct by HHS employees appeared to be a violation of any law, rule, or regulation; gross

[2] The whistleblower disclosure mentioned a January 27, 2020, call between the Secretary and the Minister of Health of China about obtaining virus samples. The whistleblower reported disbelief that the Secretary did not request virus samples during the call [redacted]

[3] For example, OIG found that ASPR officials identified remdesivir, an antiviral medication, as a potential therapeutic and were working with the drug's manufacturer, Gilead Sciences, Inc., to secure a donation. The Assistant Secretary for Preparedness and Response told OIG that Gilead did not want to donate the product until the beginning of May 2020, in part because of the amount of time it would take to complete a clinical trial and get an Emergency Use Authorization (EUA) in place. HHS eventually acquired remdesivir from Gilead once FDA granted an EUA for the drug on May 1, 2020.

[4] On May 15, 2020, the U.S. Government announced Operation Warp Speed, a partnership between HHS and the Department of Defense aimed to help accelerate the development of a COVID-19 vaccine. (Government Accountability Office, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts To Address Manufacturing Challenges*, February 2021. Available at https://www.gao.gov/assets/720/712410.pdf. Accessed on February 17, 2023.)

mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG found that ASPR career and noncareer officials began taking steps to address supply shortages as early as January 2020, including the types of supplies referenced in [redacted] disclosure (e.g., N95 masks, needles and syringes, and testing swabs). However, they reported to OIG that, until the supplemental funding became available in mid-March 2020, ASPR's ability to immediately procure needed supplies was limited. Once the supplemental funds became available to ASPR in mid-March 2020, ASPR career and noncareer officials reported taking steps to procure supplies, yet they also reported that existing supply chains for many of the needed supplies were either heavily strained or exhausted.

Prior to ASPR receiving supplemental funding, OIG found that ASPR undertook the following actions toward addressing medical supply needs:

Establishing Supply Chain Task Force. In late January, the Assistant Secretary for Preparedness and Response created the COVID-19 Supply Chain Task Force. The co-lead of the Supply Chain Task Force reported that they began identifying specific supply shortages, estimating quantities needed, and reaching out to locate potential sources within the supply chain. By mid-March 2020, the task force transitioned to the Federal Emergency Management Agency (FEMA).[5]

Preparing To Obtain N95 Masks, Needles, and Syringes. ASPR career and noncareer officials reported to OIG that they took steps beginning in January 2020 to secure N95 masks for the SNS. As an initial step, the Assistant Secretary for Preparedness and Response reported that, in January 2020, he met with a major manufacturer of PPE to discuss availability of N95s. One executive lead of ASPR's Supply Chain Task Force reported that the task force met during the early weeks of the COVID-19 pandemic to discuss domestic supply and manufacturing capabilities for N95 masks. An HHS career official also reported meeting with the same mask manufacturer that the whistleblower referenced in the disclosure.

However, ASPR's efforts were mostly limited to identifying potential supply sources that could be tapped once supplemental funding for the SNS became available. Both the Assistant Secretary for Preparedness and Response and the co-lead of the Supply Chain Task Force confirmed that ASPR did not have the ability to procure N95 masks or other supplies until supplemental funding became available through the Coronavirus Preparedness and Response Supplemental Appropriations Act in mid-March 2020. Once funds became available in March, the Assistant Secretary for Preparedness and Response reported that ASPR ordered 500 million N95 masks.

OIG found that, like other critical supply needs, ASPR did not have sufficient funds to make procurements of needles and syringes for COVID-19 vaccines until mid-March 2020 when supplemental funding became available. An ASPR career official explained to OIG that, as early as January 2020, officials began having conversations about needles and syringes with three manufacturers with whom it had contracts in place prior to the COVID-19 pandemic.

[5] On March 19, 2020, FEMA assumed leadership of the Federal response to COVID-19 and the task forces that HHS stood up were transferred to FEMA. (FEMA, Initial Assessment Report, pp. 4, 7, and 24.)

OIG found that, historically and prior to the COVID-19 pandemic, the SNS had not stockpiled testing swabs. An ASPR career official explained to OIG that testing swabs had not been considered as a specific medical supply need for stockpiling.

CONCLUSION

This report addresses two allegations from the whistleblower disclosure filed by [redacted] former Director of BARDA, regarding medical countermeasures and supplies needed for the response to the COVID-19 pandemic. OIG did not substantiate the allegations and did not find that conduct by HHS employees appeared to be a violation of any law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

TO: Xavier Becerra
Secretary

THROUGH: Elizabeth J. Gramling
Executive Secretary

FROM: Christi A. Grimm
Inspector General

CHRISTI GRIMM

Digitally signed by CHRISTI GRIMM
Date: 2023.09.26 15:50:43 -04'00'

SUBJECT: OSC File No. DI-20-000743

By letter dated June 1, 2020, the Department of Health and Human Services (HHS) delegated to the Office of Inspector General (OIG) a referral for investigation regarding a disclosure from [redacted] former Director of the Biomedical Advanced Research and Development Authority (BARDA). Attached is our completed OIG Report of Findings addressing a subset of the allegations included in the disclosure. OIG has addressed the remaining allegations in separate reports.

The OIG Report of Findings addresses the allegation that the Office of the Assistant Secretary for Preparedness and Response and other senior HHS officials pressured BARDA to promote the use of chloroquine and hydroxychloroquine as a therapeutic treatment for COVID-19, even though those drugs were produced in factories that were not inspected by the Food and Drug Administration and despite a lack of scientific data to support the use of these drugs as therapeutics.

If you have any questions about this report, please do not hesitate to contact me, or one of your staff may contact [redacted] at (202) [redacted] or [redacted]@oig.hhs.gov.
To facilitate identification, please refer to report number OEI-09-20-00571 in all correspondence.

Attachment

Department of Health and Human Services

Office of Inspector General

Office of Evaluation and Inspections

Report of Findings

To the Secretary of Health and Human Services

In response to:

Office of Special Counsel

File No. DI-20-000743

Christi A. Grimm

Inspector General

Department of Health and Human Services

Office of Inspector General

Washington, DC

September 2023

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EXECUTIVE SUMMARY

Background. On May 12, 2020, the Office of Special Counsel (OSC), under its authority in 5 U.S.C. § 1213, referred a whistleblower disclosure filed by [redacted] former Director of the Biomedical Advanced Research and Development Authority (BARDA), to the then-Secretary of Health and Human Services (HHS), Alex M. Azar II (OSC File No. DI-20-000743). The referral directed HHS to investigate and produce a report regarding the allegations described in the whistleblower disclosure. On June 1, 2020, Secretary Azar delegated investigation of the allegations to the Office of Inspector General (OIG).

In the 63-page disclosure to OSC, [redacted] who consented to the release of [redacted] name, alleged several improprieties related to the HHS response to the COVID-19 pandemic and contract awarding and administration by HHS. The OSC referral grouped the alleged improprieties into five allegations:

1. Senior HHS officials dismissed BARDA's requests for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic.
2. HHS leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles. [redacted] stated that supply chain deficiencies continued for the production of syringes and needles, and that these shortages would impede the administration of any vaccine, once developed and proven safe and effective, to the American public.
3. Office of the Assistant Secretary for Preparedness and Response (ASPR) and other senior HHS officials pressured BARDA to promote the use of chloroquine and hydroxychloroquine as a therapeutic treatment for COVID-19, even though those drugs were produced in factories located in India and Pakistan that were not inspected by the Food and Drug Administration (FDA) and despite a lack of scientific data to support the use of these drugs as therapeutics.
4. [redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels both before and during the COVID-19 pandemic. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals; Alvogen, Inc.; Partner Therapeutics; Emory University; Ridgeback Biotherapeutics LP; Northwell Health; Novavax; and Alchem Laboratories.[1]
5. [redacted] and the ASPR Next staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

[1] [redacted] Secretary for Preparedness and Response during the period of our review, [redacted] the position in [redacted].

This report addresses OIG's review of Allegation 3 regarding chloroquine and hydroxychloroquine,[2] and consistent with 5 U.S.C. § 1213, assesses whether the allegations made by [redacted] constitute a violation of any law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety. [redacted] allegations, according to [redacted] written disclosure and as summarized by OSC's referral letter to Secretary Azar, are as follows:

1. [redacted] alleged that HHS noncareer officials exerted pressure on career staff to promote the use of chloroquine and hydroxychloroquine as therapeutics for COVID-19.[3]
2. [redacted] alleged that HHS accepted donations of chloroquine produced in factories in India and Pakistan, which posed a safety risk because the factories had not been inspected by FDA.
3. [redacted] alleged that HHS distributed donated hydroxychloroquine from the Strategic National Stockpile (SNS) to retail pharmacies, which posed a substantial and specific danger to public health and safety because of a lack of scientific data to support their use as therapeutics for COVID-19, and that these distributions violated the Emergency Use Authorization (EUA).

Assessment Summary. OIG substantiated that HHS noncareer officials exerted pressure on HHS career officials leading up to the issuance of the EUA; however, OIG did not find that this pressure led to a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

Although OIG substantiated that the donated chloroquine accepted by HHS was produced in factories in India and Pakistan that were not registered or inspected by FDA, OIG did not find that the acceptance of those donations led to a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG substantiated that HHS distributed donated hydroxychloroquine from the SNS to retail pharmacies and found that these distributions posed a substantial and specific danger to public health and safety. By distributing donated hydroxychloroquine to retail pharmacies, HHS expanded the supply of the drugs that were available for off-label prescribing for COVID-19 outside of hospitals, which FDA assessed as too risky for outpatients due to the known and potential health risks of hydroxychloroquine.

OIG could not conclude that the distributions of donated hydroxychloroquine led to a violation of law, rule, or regulation. Although the HHS officials who directed the SNS to distribute hydroxychloroquine from the SNS to retail pharmacies acknowledged to OIG that some of the supplies would likely be used off-label for COVID-19, they also reported the hydroxychloroquine was being distributed for FDA-approved purposes (i.e., to treat or prevent malaria, lupus, and rheumatoid arthritis), in part because FDA had identified ongoing supply shortages of the drug

[2] The other four allegations are being addressed by OIG in other reports.

[3] Therapeutics, such as drugs and medical devices, are used in the prevention or treatment of an illness.

in the commercial market.[4] As a result, the facts did not demonstrate that the distributions were made solely for an unapproved purpose, therefore, OIG could not conclude that the distributions of hydroxychloroquine from the SNS to retail pharmacies violated the provision of the Food, Drug, and Cosmetic Act (FDCA) that prohibits the distribution of drugs for unapproved purposes.

[redacted]

Methodology. To review the allegations in the OSC referral, from July 2020 through May 2021, OIG staff conducted telephone interviews with 28 HHS career and noncareer officials who were either directly involved or knowledgeable about conduct related to the allegations. These individuals included [redacted] (the whistleblower) and officials in FDA and the Office of the Secretary (including ASPR and the Office of the Assistant Secretary for Health). For each interview, OIG developed a series of interview questions tailored to the interviewee and their position within the Department during the period of the review. OIG also obtained written responses to questions from the HHS General Counsel.[5] We sought to gain information about activities with which interviewees were personally familiar, as well as their perspectives, based on their experience, expertise, and positions, related to the allegations.

We examined documents that interviewees provided to us about their activities and communication with others related to their interview responses. These documents included reports, meeting notes, emails, and supporting documentation for certain activities. We also reviewed selected documents that we requested from HHS agencies, including ASPR and FDA. These documents generally included reports and analyses. We also examined relevant laws, regulations, and guidance documents.

Review Period. Our review focused on HHS employee conduct in March and April 2020. Position titles mentioned in this report refer to HHS officials who held that position during this period of our review.

Limitations. Our interviews with HHS officials occurred several months after the review period. Officials often referenced notes and other available records for their responses. However, interviewees reported that they were sometimes unable to recall full details from our review period. When possible, we corroborated information that interviewees provided with documentation, but it was not always possible to verify the accuracy of the events and statements described by HHS officials during our interviews.

The testimonial evidence that we considered is limited to the HHS officials whom we interviewed and their knowledge about the activities discussed. Those interviewees included key HHS career

[4] When health care providers prescribe a drug for its FDA-approved use, it is called "on-label" use. Health care providers may also prescribe FDA-approved drugs for unapproved uses, known as "off-label" use. FDA, "Understanding Unapproved Use of Approved Drugs 'Off Label.'" Accessed at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label on July 5, 2023.

[5] [redacted] an HHS noncareer official who served as HHS General Counsel during the period of our review, left the position in January 2021.

and noncareer officials referenced in the whistleblower disclosure and HHS officials to whom we were directed for more information. It was not feasible to interview every HHS official involved with or knowledgeable about the allegations.

The findings in this report are relevant to the allegations that OIG reviewed and do not represent a comprehensive assessment of the HHS response to COVID-19 during the period of our review. See OIG's COVID-19 Portal for more information about OIG's Oversight of COVID-19 Response and Recovery, including multiple public reports previously issued, investigations, and numerous ongoing audits and evaluations.

Standards. We conducted this review in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

CHRONOLOGY OF EVENTS

This section provides a chronology of relevant information about the allegation, collected by OIG through interviews and document review.

On **March 10** and **March 17, 2020**, via emails, an HHS noncareer official asked a BARDA career official about chloroquine as a potential therapeutic for COVID-19. (Chloroquine is an FDA-approved drug to treat or prevent malaria.) A member of the Medical Countermeasures (MCM) Task Force reported to OIG that during this time chloroquine and other drugs were being monitored as a potential therapeutic for COVID-19.[6]

On **March 17, 2020**, via email, a senior advisor to the Assistant Secretary for Preparedness and Response told HHS career and noncareer officials that a drug manufacturer had approached HHS with an offer to donate chloroquine.

On **March 17, 2020**, a senior advisor to the Assistant Secretary for Preparedness and Response, who was coordinating a chloroquine donation from a drug manufacturer, emailed the MCM Task Force lead and other BARDA career officials with a request to review data on chloroquine that had been provided by the manufacturer offering to donate the drug. The MCM Task Force lead asked two BARDA career officials to review the material, one who co-led the Therapeutics Working Group and the other who co-led the Clinical Trials Working Group.

The MCM Task Force lead reported to OIG that on **March 18, 2020**, he received a consensus statement from the Clinical Trials Working Group about potential use of chloroquine and hydroxychloroquine for COVID-19. (Hydroxychloroquine, which is chemically similar to chloroquine, is an FDA-approved drug to treat or prevent malaria, lupus, and rheumatoid arthritis.) According to the consensus statement provided to OIG, the group noted that the safety and efficacy of either drug for prevention or treatment of COVID-19 were not supported by the existing data. The co-lead of the Clinical Trials Working Group reported to OIG that the

[6] The MCM Task Force was created by the Assistant Secretary for Preparedness and Response and included interagency subject matter experts who responded to inquiries from senior leadership and conducted analyses in their focus areas. The MCM Task Force was composed of four working groups: (1) Therapeutics Working Group, (2) Clinical Trials Working Group, (3) Vaccines Working Group, and (4) Diagnostic Working Group. MCM Task Force membership included representatives from ASPR and HHS Operating Divisions, including FDA, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense.

group's position was that there were "significant safety concerns" associated with both drugs. The MCM Task Force lead reported to OIG that, during this time, the Therapeutics Working Group was assessing data about many different drugs as potential therapeutics for COVID-19. The MCM Task Force lead also reported to OIG that consensus statements were reviewed by the MCM Task Force leadership in an iterative process and represented a type of Governmentwide position on a particular matter.

On **March 19, 2020**, at a Coronavirus Task Force briefing, the President and the FDA Commissioner discussed chloroquine and hydroxychloroquine. The President stated: "[W]e're going to be able to make that drug available almost immediately. And that's where the FDA has been so great. [T]hey've gone through the approval process, it's been approved. And they did it—they took it down from many, many months to immediate." An HHS career official told OIG that they interpreted these statements as the President implying that FDA had already authorized the use of the drugs as therapeutics for COVID-19. During the same Coronavirus Task Force briefing, the FDA Commissioner stated that the drugs were FDA-approved "for the treatment of malaria as well as an arthritis condition." He further stated that "the President has directed us to take a closer look" at the drugs to see whether they have clinical benefit as therapeutics for COVID-19.

On **March 21, 2020**, via email, a senior advisor to the Assistant Secretary for Preparedness and Response told HHS officials that a drug manufacturer had offered a donation of hydroxychloroquine.

On **March 21, 2020**, the President tweeted: "[Hydroxychloroquine and azithromycin], taken together, have a real chance to be one of the biggest game changers in the history of medicine."

On **March 23, 2020**, at a Coronavirus Task Force briefing, the President stated that the State of New York would begin distributing hydroxychloroquine "tomorrow morning [March 24, 2020] to a lot of people in New York City and New York."

[redacted] reported to OIG that [redacted] received a directive from the HHS General Counsel on **March 23, 2020**, to submit an application to FDA for an expanded access investigational new drug (IND) for the donated chloroquine. An expanded access IND is an FDA mechanism that would have authorized the widespread use of the donated drug as a therapeutic for COVID-19.[7]

On **March 24, 2020**, according to [redacted] there was agreement between BARDA and FDA that the lack of supporting scientific data and known safety risks associated with chloroquine and hydroxychloroquine did not support an expanded access IND. FDA career officials reported to OIG that they did not support the use of an expanded access IND for use of the drugs for COVID-19. An FDA career official reported to OIG concerns about a lack of any data from randomized controlled clinical trials indicating that these drugs might provide any medical

[7] FDA is authorized to issue an expanded access IND for widespread treatment use when the drug is either being investigated under a controlled clinical trial under an IND designed to support a marketing application or all clinical trials of the drug have been completed; the sponsor is actively pursuing marketing approval for the drug for the expanded access use with due diligence; and either: (1) the use is for a serious disease or condition and there is sufficient clinical evidence of safety and effectiveness to support the expanded access use, or (2) the use is for an immediately life-threatening disease or condition and the available scientific evidence, taken as a whole, provide a reasonable basis to conclude that the investigational drug may be effective for the expanded access use and would not expose patients to an unreasonable and significant risk of illness or injury. 21 CFR § 312.320.

benefit for treating or preventing COVID-19. Additionally, these FDA career officials reported that hydroxychloroquine and chloroquine had long histories of known patient safety risk and were previously shown to be ineffective as antivirals when examined as possible treatments for other viruses. BARDA and FDA career officials further reported that the most serious known safety risk involved heart rhythm problems.

To address these known and potential patient safety risks associated with chloroquine and hydroxychloroquine, BARDA and FDA career officials transitioned to an EUA, rather than pursue an expanded access IND. The FDCA gives FDA the authority to issue an EUA to allow the distribution and use of an unapproved drug or approved drug for an unapproved purpose during declared public health emergencies prior to distribution for that purpose.[8] This authority also allows FDA to set conditions for distribution and use of a drug under an EUA, such as limiting use to certain types of patients and in certain clinical settings.[9]

On **March 26, 2020**, HHS and a hydroxychloroquine manufacturer finalized a formal donation agreement for 130 million hydroxychloroquine 200 mg tablets.

On **March 27, 2020**, FDA determined that the imported donated chloroquine from manufacturing sites in India and Pakistan met established U.S. Pharmacopeia standards, on the basis of FDA's analysis of sample tablets of the drug. Although chloroquine is FDA-approved to treat or prevent malaria, HHS career officials were concerned about the quality of the donated chloroquine from the manufacturing facilities in India and Pakistan.

On **March 28, 2020**, BARDA submitted to FDA an EUA request for the emergency use of chloroquine and hydroxychloroquine donated to the SNS for the treatment of certain hospitalized patients with COVID-19.

On **March 28, 2020**, FDA issued an EUA authorizing use of chloroquine and hydroxychloroquine distributed from the SNS to public health authorities (e.g., State and local health departments)[10] for response to the COVID-19 pandemic.[11] FDA specified several conditions for use of the drugs under the EUA, including:

- The drugs must be administered by a health care provider pursuant to a valid prescription of a licensed practitioner.
- The drugs may only be used to treat adult and adolescent patients who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.

[8] Section 564 of the FDCA (21 U.S.C. § 360bbb-3).
[9] Section 564(e) of the FDCA (21 U.S.C. § 360bbb-3(e)).
[10] As defined in the EUA, a "public health authority" means the public agency or its delegate that has legal responsibility and authority for responding to a public health emergency, based on political or geographical (e.g., city, county, Tribal, State, or Federal) or functional (e.g., law enforcement or public health range) or sphere of authority to prescribe, administer, deliver, distribute, or dispense oral chloroquine phosphate and hydroxychloroquine sulfate products during public health emergencies.
[11] EUA for chloroquine and hydroxychloroquine issued by FDA on Mar. 28, 2020. Accessed at https://www.fda.gov/media/136534/download on June 21, 2023.

- FDA also set conditions for labeling of the drugs (which varied somewhat for the two drugs), including that they should be accompanied by Fact Sheets that FDA developed for health care providers and patients pertaining to use under the EUA.

The EUA mandated that health care systems and providers track adverse events and report to FDA in accordance with the Fact Sheets.

FDA career officials reported to OIG that the conditions were established to help ensure that hospitalized patients who received the donated drugs under the EUA would be monitored by hospital staff who could address any adverse events that arose. In addition, the data reporting was to mitigate the risks and to assess whether the drugs had any beneficial effect for treating COVID-19.

On **March 29, 2020**, HHS issued a news release stating that HHS had accepted donations of chloroquine and hydroxychloroquine to the SNS from two manufacturers and that FDA had issued an EUA to allow the drugs "to be distributed and prescribed by doctors to hospitalized teen and adult patients with COVID-19, as appropriate, when a clinical trial is not available or feasible."[12] The news release indicated that the SNS would work with the Federal Emergency Management Agency to ship donated doses to States. The news release also stated: "Use of the donated medications is expected to help ease supply pressures for the drug, and the FDA is also working with manufacturers of chloroquine and hydroxychloroquine to increase production to ensure these drugs also remain available for patients dependent on them for treatment of malaria, lupus, and rheumatoid arthritis."[13]

On **March 30, 2020**, HHS and a chloroquine manufacturer finalized a formal donation for approximately 3 million chloroquine 250 mg tablets.

On **March 31, 2020**, Hydroxychloroquine was added to FDA's drug shortage list, indicating a scarcity of supplies available for FDA-approved on-label uses.

On **April 4, 2020**, via an email to other HHS officials, the Assistant Secretary for Health directed the SNS to release or ship the donated hydroxychloroquine to wholesale distributors for further distribution to retail pharmacies and hospitals.[14] The Assistant Secretary for Health reported to OIG that the order to ship the drug to pharmacies was given over the telephone by a senior advisor to the President and was understood to be a directive from the President. The Assistant Secretary for Preparedness and Response, who oversees the SNS, and the FDA Commissioner agreed with the order to distribute hydroxychloroquine to retail pharmacies and hospitals.[15]

On **April 5, 2020**, at the Coronavirus Task Force briefing, the President confirmed that shipments of hydroxychloroquine had begun: "We've given it to drug stores. We're sending it all over."

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[12] HHS, press release, "HHS accepts donation of medicine to the SNS as possible treatments for COVID-19 patients." Issued on Mar. 29, 2020.

[13] Ibid.

[14] [redacted], an HHS noncareer official who served as Assistant Secretary for Health during the period of our review, left the position in January 2021.

[15] [redacted], an HHS noncareer official who served as the FDA Commissioner during the period of our review, left the position in January 2021.

Between **April 6** and **April 9, 2020**, of the nearly 29 million tablets of donated hydroxychloroquine immediately available in the SNS, the SNS released almost 77percent (approximately 22 million tablets) to wholesale distributors. (No donated chloroquine was distributed from the SNS.) Initial distributions of hydroxychloroquine from the SNS to wholesale distributors were for further distribution to retail pharmacies. The SNS also shipped about 6.6 million tablets to public health authorities and hospitals, distributions that were authorized under the EUA.

On **April 7, 2020**, HHS and a hydroxychloroquine manufacturer finalized a formal donation for 10 million hydroxychloroquine 200 mg tablets.

On **June 15, 2020**, FDA revoked the EUA for chloroquine and hydroxychloroquine. FDA concluded that chloroquine and hydroxychloroquine were unlikely to be effective in treating COVID-19 based on the analysis of emerging clinical trial data and information. Further, in light of reports related to serious cardiac adverse events, FDA concluded that the known and potential benefits of the drugs did not outweigh the known and potential risks associated with their use as a therapeutic for COVID-19.[16]

ASSESSMENT

1. [redacted] alleged that HHS noncareer officials exerted pressure on career staff to promote the use of chloroquine and hydroxychloroquine as therapeutics for COVID-19.

Although OIG substantiated that HHS noncareer officials exerted pressure on HHS career officials leading up to the issuance of the EUA, OIG did not find that this pressure led to a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety. HHS career officials reported feeling pressured to quickly authorize chloroquine and hydroxychloroquine as therapeutics for COVID-19, despite their assessment that the clinical data on efficacy were not strong and that there were safety concerns related to use of the drugs for COVID-19. However, career officials also reported that they found a way to make the donated drugs available for treating COVID-19 in a manner that addressed known patient safety risks associated with the drugs.

HHS career officials reported experiencing intense pressure during the period between March 23 and March 28, 2020, beginning when [redacted] reported receiving a directive from the HHS General Counsel for BARDA to submit an application to FDA for a nationwide expanded access IND. HHS career officials reported to OIG that the HHS General Counsel told them [redacted] drafted an informed consent document to be used for the expanded access IND being sought. FDA

[16] Letter issued by FDA revoking the EUA for chloroquine and hydroxychloroquine, June 15, 2020. Accessed at https://www.fda.gov/media/138945/download?%202020 on June 21, 2023.

[17] Informed consent documents are intended to ensure that individuals (or their representatives) who participate in clinical research projects and trials are provided "sufficient opportunity to consider whether or not to participate and [to] minimize the possibility of coercion or undue influence." The information must be presented "in language understandable to the subject or the representative." 21 CFR § 50.20.

career and noncareer officials reported to OIG that they perceived the HHS General Counsel's involvement as "highly unusual" and "surprising" because informed consent documents are typically written by scientists involved in the research.[18] Another HHS career official expressed the view that decisions about these drugs required medical and scientific expertise and that the HHS General Counsel's involvement seemed "very strange" and signaled that political considerations were involved.

An FDA career official reported receiving many inquiries from HHS noncareer officials about the progress of their review, which the official perceived as "a tremendous amount of pressure."[19] The FDA career official reported to OIG feeling somewhat "backed into a corner" to quickly authorize the drugs for COVID-19. The FDA career official characterized one source of the pressure as "the President of the country had already accepted these drugs into the stockpile and was touting that they would be gamechangers and they were going to be available."

FDA career officials reported to OIG that pressure from HHS noncareer officials did not prevent FDA from following due diligence in its review and ensuring that the drugs met the appropriate standards. BARDA and FDA officials ultimately did not request or issue the expanded access IND sought by HHS noncareer officials, and instead issued an EUA for the donated drugs, which established conditions for distribution and use under the EUA.

According to [redacted] on March 24, 2020, there was agreement between FDA and BARDA that the lack of supporting scientific data and known safety risks associated with the drugs did not support FDA issuing an expanded access IND to make the drugs widely available as therapeutics for COVID-19. FDA career officials reported to OIG that FDA did not support the use of an expanded access IND because hydroxychloroquine and chloroquine had a long history of known patient safety risk, and the drugs were previously shown to be ineffective as antivirals when examined as possible treatments for other viruses. HHS career officials reported to OIG that the most serious safety risk involved heart rhythm problems.

An FDA career official reported to OIG that they recommended that BARDA submit a request to FDA for an EUA instead of an expanded access IND. As previously mentioned, the FDCA provides FDA with the authority, during declared public health emergencies, to issue an EUA to allow the use of an unapproved drug or an approved drug for an unapproved purpose, including the authority for FDA to establish conditions on the distribution and use of the drugs under the EUA.[20] BARDA agreed with FDA on this approach and submitted a request for an EUA on March 28, 2020.

On March 28, 2020, FDA completed its review and issued an EUA for donated chloroquine and hydroxychloroquine. FDA career officials reported that the EUA included conditions for use, including treating only certain hospitalized patients with COVID-19, that were intended to help ensure that any patients who received the donated drugs under the EUA would be monitored by

[18] Ultimately, an informed consent document was not needed because BARDA did not request an expanded access IND from FDA.

[19] As part of FDA, the Center for Drug Evaluation and Research is responsible for ensuring that safe and effective drugs are available by regulating over-the-counter and prescription drugs, including biological therapeutics and generic drugs. Accessed at https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder on June 26, 2023.

[20] Section 564 of the FDCA (21 U.S.C. § 360bbb-3).

hospital staff who could address any adverse events that arose. Further, the EUA mandated that hospitals report data on adverse events and clinical outcomes associated with treating COVID-19 patients with the drugs. The data reporting was to mitigate the risks and to assess whether the drugs had any beneficial effect for treating COVID-19.

2. [redacted] **alleged that HHS accepted donations of chloroquine produced in factories in India and Pakistan, which posed a safety risk because the factories had not been inspected by FDA.**

OIG substantiated that the donated chloroquine accepted by HHS was produced in factories in India and Pakistan that were not inspected by FDA; however, OIG did not find that the acceptance of these donations led to a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety. Although the FDCA generally prohibits the importation of unapproved drugs manufactured outside of the United States for commercial use, FDA tested samples of the donated chloroquine and determined that the drug met established U.S. Pharmacopeia standards and authorized its importation.[21] Therefore, the safety risk based on where the drugs were manufactured was not substantiated.

3. [redacted] **alleged that HHS distributed donated hydroxychloroquine from the SNS to retail pharmacies, which posed a substantial and specific danger to public health and safety because of a lack of scientific data to support their use as therapeutics for COVID-19 and that these distributions violated the EUA.**

OIG substantiated that HHS distributed donated hydroxychloroquine from the SNS to retail pharmacies and found that these distributions posed a substantial and specific danger to public health and safety. OIG did not find that the distributions led to gross mismanagement; gross waste of funds; or abuse of authority. OIG could not conclude that the distributions of donated hydroxychloroquine violated any Federal law, rule, or regulation.

To protect patient safety, FDA career officials told OIG that they did not support the proposed expanded access IND that would have allowed for the widespread availability of these drugs. Rather, FDA issued the EUA authorizing distribution of the drugs from the SNS for use as therapeutics for COVID-19 for certain hospitalized patients with COVID-19. FDA career officials reported to OIG that the conditions in the EUA were added to ensure the higher level of patient monitoring offered in a hospital setting, given the known and potential risks associated with hydroxychloroquine, such as heart rhythm problems.

However, by distributing donated hydroxychloroquine to retail pharmacies, HHS expanded the supply of the drugs that was available for off-label prescribing for COVID-19, which FDA assessed as too risky for outpatients. Making the donated drug widely available outside of hospitals exposed individuals who received off-label prescriptions for COVID-19 to the known and potential health risks of hydroxychloroquine. An FDA career official told OIG that FDA's judgment was that the donated drugs should not be made broadly available because of the known risks of the drugs based on the available scientific information at the time. Accordingly,

[21] Section 801 of the FDCA (21 U.S.C. § 381).

distributing donated hydroxychloroquine to retail pharmacies posed a substantial and specific danger to public health and safety.

As mentioned, OIG could not conclude that the distributions of donated hydroxychloroquine violated any Federal law, rule, regulation. Our review gathered information related to two Federal laws—the Public Health Service Act (PHSA) and the FDCA—with relevance regarding the distributions from the SNS.

In response to inquiries from OIG about the permissibility to distribute the donated hydroxychloroquine to retail pharmacies, the [redacted][22] As previously mentioned, hydroxychloroquine had been added to FDA's drug shortage list on March 31, 2020.

The Assistant Secretary for Health and the Assistant Secretary for Preparedness and Response reported to OIG their understanding that distributions of the donated hydroxychloroquine to retail pharmacies were permissible. Each noted that the drug was FDA-approved for treating illnesses other than COVID-19 and could be prescribed for on- or off-label use, including to treat COVID-19. Further, each reported their belief that the distributions would help to alleviate shortages of hydroxychloroquine at retail pharmacies for individuals who required the drug for one of its FDA-approved indications (e.g., malaria, lupus, or rheumatoid arthritis).

The FDA Commissioner reported to OIG his view that relieving drug shortages for FDA-approved uses was a "primary motivator" for HHS accepting donations of hydroxychloroquine into the SNS. The FDA Commissioner also reported that the HHS General Counsel had told him that distributions of the donated hydroxychloroquine to retail pharmacies were permissible. The FDA Commissioner reported that he was deferring to the HHS General Counsel's advice when he concurred with the decision to release hydroxychloroquine from the SNS on April 4, 2020.

OIG's review also considered whether the distributions of hydroxychloroquine to retail pharmacies potentially violated the FDCA. As mentioned, the FDCA gives FDA the authority to issue an EUA and allows FDA to set conditions for distribution and use of a drug under an EUA, such as limiting use to certain types of patients and in certain clinical settings. FDA authorized use of chloroquine and hydroxychloroquine distributed from the SNS to public health authorities to be used for certain hospitalized patients who were already diagnosed with COVID-19.

OIG examined whether distributing hydroxychloroquine to retail pharmacies potentially violated the provision of the FDCA that prohibits the distribution of approved drugs for unapproved purposes.[23] Before a drug is distributed or used, the FDCA requires that the drug be approved by FDA for a specific use, have an EUA, or have an IND.[24] Although hydroxychloroquine is an

[22] Section 319F-2(a)(1) of the PHSA (42 U.S.C. 247d-6d).
[23] Section 301(d) of the FDCA (21 U.S.C. § 331(d)).
[24] Sections 505 and 561 of the FDCA (21 U.S.C. §§ 355, 360bbb-3); 21 CFR 201.128.

FDA-approved drug, it was never FDA-approved as a therapeutic for COVID-19. If the distributions of hydroxychloroquine from the SNS were made for the purpose of addressing shortages of the drug for FDA-approved uses (e.g., rheumatoid arthritis) it would likely not violate the FDCA. However, if the distributions were not for an FDA-approved use, but rather intended for an unapproved use, such as for COVID-19, it could constitute a violation of the FDCA.

The circumstances surrounding the distribution of the donated hydroxychloroquine from the SNS and the statements of HHS noncareer officials who ordered the distributions, could suggest that the drugs were intended to be used, at least in part, as a therapeutic for COVID-19 outside of hospitals—an unapproved purpose. The Assistant Secretary for Preparedness and Response reported to OIG that he believed the distributions to retail pharmacies would, in part, be used off-label for COVID-19 for nonhospitalized patients, as well as for on-label uses. The Assistant Secretary for Health stated to OIG during interviews that the distributions from the SNS to retail pharmacies were to fill off-label prescriptions by physicians for individuals for COVID-19, as well as for on-label uses.

Although the HHS officials who directed the SNS to distribute hydroxychloroquine from the SNS to retail pharmacies acknowledged that some of the supplies would likely be used off-label for COVID-19, they each also reported that the hydroxychloroquine was being distributed for FDA-approved uses. As a result, the facts did not demonstrate that the distributions were made solely for an unapproved purpose, and therefore, OIG could not conclude that the distributions of hydroxychloroquine from the SNS to retail pharmacies violated the provision of the FDCA that prohibits the distribution of drugs for unapproved purposes.

[redacted]

During the review, OIG learned about a distribution of 5,000 courses of hydroxychloroquine by HHS officials to the White House. (This matter was not an allegation in [redacted] whistleblower disclosure.) [redacted].

CONCLUSION

OIG substantiated that HHS noncareer officials exerted pressure on HHS career officials leading up to the issuance of the EUA; however, OIG did not find that it led to a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG substantiated that the donated chloroquine accepted by HHS was produced in factories in India and Pakistan that were not registered or inspected by FDA; however, OIG did not find that accepting the donation led to a violation of law, rule, or regulation; gross mismanagement;

gross waste of funds; abuse of authority; or a substantial and specific danger to public health and safety.

OIG substantiated that HHS distributed donated hydroxychloroquine from the SNS to retail pharmacies and found that these distributions posed a substantial and specific danger to public health and safety. In considering corrective actions, HHS may want to determine whether action is needed to ensure public health and safety in association with future EUAs.

OIG did not find that the distributions led to gross mismanagement; gross waste of funds; or abuse of authority.

OIG could not conclude that the distributions of donated hydroxychloroquine led to a violation of law, rule, or regulation. OIG found that the facts did not demonstrate that the distributions were made solely for an unapproved purpose; therefore, OIG could not conclude whether the distributions of hydroxychloroquine from the SNS to retail pharmacies violated the provision of the FDCA that prohibits the distribution of drugs for unapproved purposes. In considering corrective actions, HHS may want to determine whether there is a need for additional clarification or legal guidance to ensure compliance with all laws should similar circumstances arise in the future.

CORRECTIVE ACTIONS

This report addresses allegations from the whistleblower disclosure filed by [redacted] former Director of BARDA, regarding chloroquine and hydroxychloroquine as potential therapeutics for COVID-19. OIG is providing this report to the Department for its use in determining any corrective actions.

Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

May 30, 2023

CONFIDENTIAL

TO: Xavier Becerra
Secretary

THROUGH: Elizabeth Gramling
Executive Secretary

FROM: Christi A. Grimm
Inspector General

SUBJECT: Investigation into the Assistant Secretary for Preparedness and Response for Inappropriate Contract Actions
H-20-0-0620-8

On May 12, 2020, the Office of Special Counsel (OSC), under its whistleblower disclosure authority found in 5 U.S.C. § 1213(c), referred the above-subject complaint to the Secretary of the Department of Health and Human Services (HHS). On June 1, 2020, then-Secretary Alex M. Azar II delegated investigation of the complaint to the Office of Inspector General (OIG). Accordingly, the Office of Investigations (OI), Special Investigations Branch (SIB), was assigned to conduct the investigation.

The OSC complaint referral, OSC File No. DI-20-000743, consisted of five allegations reported from [redacted] former director of the Biomedical Advanced Research and Development Authority (BARDA), who consented to the release of [redacted]name. SIB investigated two of the five allegations; the remaining allegations in the referral were separately reviewed by the OIG Office of Evaluation and Inspections. SIB investigated the following allegations referred from OSC, whether:

1. [redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels both before and during the COVID-19 pandemic. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals, Alvogen, Inc., Partner

Therapeutics (PTx), Emory University, Ridgeback Biotherapeutics LP, Northwell Health, Novavax, and Alchem Laboratories; and

2. [redacted] and the ASPR Next[1] staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

In June 2020, SIB initiated an investigation into these allegations. SIB requested investigative assistance from the OIG Office of Audit Services in July 2020. At the conclusion of the investigation and investigative assistance, OIG determined that the allegations were unsupported by the evidence obtained.

This report is submitted for your consideration and appropriate action, based on the information, facts, and evidence provided. This report contains highly sensitive investigative information and should only be disseminated when required by 5 U.S.C. § 1219, and as necessary to determine and initiate appropriate administrative activity. Please be particularly sensitive to individual identities and identifying information provided in this report.

Should you have any questions or need any additional clarification, please do not hesitate to contact me, or, alternatively, one of your staff may contact [redacted], Assistant Inspector General for Investigations, at [redacted]@oig.hhs.gov or (202) [redacted].

[1] Program developed within ASPR to "spur innovation in the development of new technologies and products that can be used to provide lifesaving care in austere circumstances." *See* https://www.phe.gov/ASPRNext?Pages/default.aspx. Accessed on March 7, 2023.

Department of Health and Human Services
Office of Inspector General
Office of Investigations
Special Investigations Branch

Report of Investigation
Regarding the Assistant Secretary for Preparedness and Response
and Staff Members

Office of Investigations Case # H-20-0-0620-8
Office of Special Counsel File # DI-20-000743
Office of Audit Services Investigative Assist # A-03-20-05004

Notice

THIS REPORT CONTAINS SENSITIVE INFORMATION

This report summarizes an Office of Inspector General investigation initiated by an Office of Special Counsel referral to the Secretary of the U.S. Department of Health and Human Services. It contains highly sensitive investigative information and should only be disseminated as necessary, with particular care given to protecting individual identities and identifying information. This report cannot be released without specific approval by the Deputy Inspector General for Investigations except as required by 5 U.S.C. § 1219 or any other applicable bodies of law.

INVESTIGATIVE FINDINGS

The Investigative findings are based on the facts set forth in this report, as supported by the accompanying attachments. The report is submitted for management consideration and appropriate action, based on the information, facts, and evidence provided.

I. SUMMARY OF ALLEGATIONS

On May 12, 2020, the Office of Special Counsel (OSC), under its whistleblower disclosure authority in 5 U.S.C. § 1213, referred a whistleblower complaint (complaint) filed by [redacted] formerly the Biomedical Advanced Research and Development Authority (BARDA) Director, to the then-Secretary of Health and Human Services (HHS), Alex M. Azar II.[2]

On June 1, 2020, Secretary Azar delegated investigation of the complaint to the Office of Inspector General (OIG).[3]

In the 63-page complaint narrative to OSC, [redacted] alleged several improprieties related to contract award and administration by HHS, and its response to the COVID-19 pandemic. The OSC referral letter to Secretary Azar grouped the alleged improprieties into five allegations to be investigated:

1. Senior HHS officials dismissed BARDA's requests for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic;

2. HHS leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic, including N95 masks, testing swabs, syringes, and needles. [redacted] stated that supply chain deficiencies continued for the production of syringes and needles, and that these shortages would impede the administration of any vaccine, once developed and proven safe and effective, to the American public;

3. ASPR and other senior HHS officials pressured BARDA to promote the use of chloroquine and hydroxychloroquine as a therapeutic treatment for COVID-19, even though those drugs were produced in factories that were not inspected by the Food and Drug Administration (FDA) and despite a lack of scientific data to support the use of these drugs as therapeutics;

4. [redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels both before and during the COVID-19 pandemic. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals, Alvogen, Inc., Partner Therapeutics (PTx), Emory University, Ridgeback Biotherapeutics LP, Northwell Health, Novavax, and Alchem Laboratories; and

[2] Under 5 U.S.C. § 1213, when OSC refers a matter for investigation, the receiving agency is required to investigate the matter and produce a report of its findings on the specific allegations and any other related matters. The findings should address whether there was a violation of any law, rule, or regulation; or, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

[3] *See* Attachment 1, OSC Referral Letter Package.

5. [redacted] and the ASPR Next[4] staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

The Office of Investigations (OI), Special Investigations Branch (SIB), was assigned to conduct an investigation and produce this report that examines the fourth and fifth allegations.[5] More specifically, there are five instances where [redacted] alleges that [redacted] engaged in contracting improprieties involving procurements both before and during the COVID-19 pandemic. According to [redacted], and summarized by OSC's referral letter to Secretary Azar, the specific alleged contract improprieties are as follows:

1. In 2017, [redacted] and ASPR staff improperly worked with [redacted] an industry consultant and friend of [redacted] to exert undue pressure on [redacted] to extend an existing contract with Aeolus in contravention of the Procurement Integrity Act (PIA)[6] as implemented by the Federal Acquisition Regulation (FAR).[7] [redacted] alleged that the PIA "expressly bars consultants and lobbyists from participating in discussions regarding contract awards."[8]

2. In 2018, [redacted] ignored the scientific review process and recommendations to procure a competing influenza drug for the Strategic National Stockpile (SNS), instead choosing to use BARDA funds to award a contract to Alvogen under a narrowly tailored request for proposal (RFP) that encouraged selection of Alvogen's oseltamivir (generic) drug.

3. In 2018, [redacted] overruled subject matter experts to award a $55 million sole-source contract to PTx for radiation exposure treatment drugs for the SNS instead of awarding it to another contractor that produced a competing product.

4. In 2019, ASPR compromised the independent scientific integrity[9] of the review and contract award process by improperly pressuring [redacted] to award a contract to Emory University for its antiviral drug, EIDD 2801, which was presented as a "miracle cure" for influenza, Ebola, and other viruses.

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[4] Program developed within ASPR to "spur innovation in the development of new technologies and products that can be used to provide lifesaving care in austere circumstances." *See* https://www.phe.gov/ASPRNext?Pages/default.aspx. Accessed on March 7, 2023.

[5] Allegations one through three are being addressed in reporting by the OIG Office of Evaluation and Inspections (OEI), which will issue its findings separately. HHS OIG's reports do not address [redacted] retaliation allegations, as those would be handled exclusively by OSC.

[6] 41 U.S.C. §§ 2101–2107.

[7] FAR 3.104.

[8] Attachment 1 at 17; Aeolus was a client of [redacted]

[9] SIB's investigation was limited to a review of the alleged contracting improprieties and whether there were violations under Federal procurement laws, regulations, or policies. SIB does not opine as to the "scientific integrity" or validity of [redacted] assertions regarding the safety of any products discussed during its investigation.

5. In 2020, [redacted] and ASPR Next Staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts with Ridgeback and Northwell without appropriate scientific review.[10]

In this report, OIG endeavored to clearly and succinctly synthesize and present all of the information contained in [redacted] complaint and all of the information gathered through interviews with [redacted] and numerous other witnesses over the course of a 2-year investigation. The groupings and headings that follow are our own.[11]

II. BACKGROUND

1. The Administration for Strategic Preparedness and Response

The Administration for Strategic Preparedness and Response (ASPR) was established by Congress with the passage of the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006.[12] ASPR "leads the Nation's medical and public health preparedness for, response to, and recovery from disasters and other public health emergencies."[13] ASPR "is responsible for securing our Nation from chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza and emerging infectious diseases and natural disasters."[14] Furthermore, ASPR "supports the transition of medical countermeasures such as vaccines, drugs, diagnostics, and medical devices from research through advanced development towards consideration for approval by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile (SNS)," while also supporting "health care systems in developing resilience to 21st-century threats through leadership, public/private partnerships, and technical and medical support to State, local, Territorial, and Tribal partners."[15]

In support of these missions, "ASPR collaborates with hospitals, health care coalitions, biotech firms, community members, State, local, Tribal, and Territorial governments, and other partners across the country to improve readiness and response capabilities."[16]

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[10] Attachment 1 at 5-7.

[11] As mentioned, OSC referred the complaint to HHS and HHS delegated it to OIG to investigate five, specific allegations arising from [redacted] complaint. [redacted] complaint contained headings and multiple subheadings; OSC subsequently summarized the complaint into five allegations. In its referral letter to HHS, OSC provided the summarized allegations and then grouped the first three allegations under the heading, "[redacted] Allegations Concerning the HHS Response to the COVID-19 Pandemic" and included additional subheadings. OSC grouped the last two allegations, handled by this report, under the heading, "[redacted] Allegations Concerning Improper Contracting Practices."

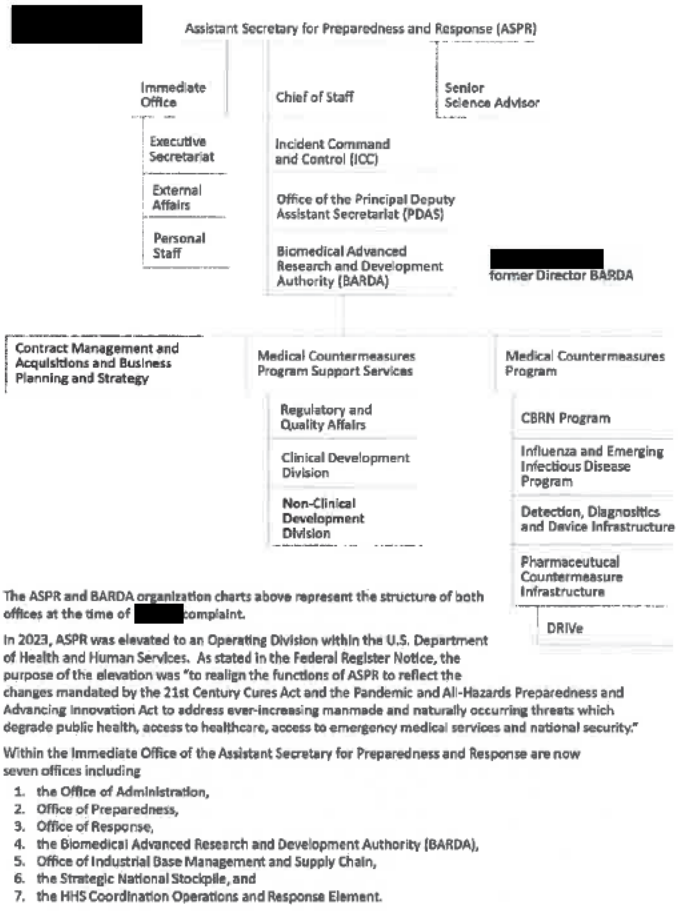
[12] 42 U.S.C. § 300hh-10. Within ASPR lies the following program offices: Office of Administration, Office of Preparedness, Office of Response, the Biomedical Advanced Research and Development Authority (BARDA), the Office of Industrial Base Management and Supply Chain, Strategic National Stockpile, and the HHS Coordination Operations and Response Element.

[13] Available at https://aspr.hhs.gov/AboutASPR/ProgramOffices/Pages/ProgramOffice.aspx. Accessed on Feb. 17, 2023.

[14] ASPR Next Broad Agency Announcement (BAA), BAA-19-ASPRNext-SOL-75A50119R00044; Available at https://sam.gov/opp/826a435bbae7570b1f9f66ab3fcb54bf/view#history. Accessed on Feb. 27, 2023.

[15] *Id.*

[16] Available at https://aspr.hhs.gov/AboutASPR/ProgramOffices/Pages/ProgramOffice.aspx. Accessed on Feb. 17, 2023.



The ASPR and BARDA organization charts above represent the structure of both offices at the time of [redacted] complaint.

In 2023, ASPR was elevated to an Operating Division within the U.S. Department of Health and Human Services. As stated in the Federal Register Notice, the purpose of the elevation was "to realign the functions of ASPR to reflect the changes mandated by the 21st Century Cures Act and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act to address ever-increasing manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and national security."

Within the Immediate Office of the Assistant Secretary for Preparedness and Response are now seven offices including

1. the Office of Administration,
2. Office of Preparedness,
3. Office of Response,
4. the Biomedical Advanced Research and Development Authority (BARDA),
5. Office of Industrial Base Management and Supply Chain,
6. the Strategic National Stockpile, and
7. the HHS Coordination Operations and Response Element.

2. The Biomedical Advanced Research and Development Authority

BARDA was also established by Congress with the passage of the PAHPA in 2006 and is a program office within ASPR. Its mission is to improve preparedness and response through public-private partnerships that promote innovations that reduce the time and cost of advanced research and development, manufacturing, and procurement of medical countermeasures and other pandemic and endemic products. These products are directed toward protecting against health security threats such as CBRN incidents, pandemic influenza, COVID-19, and other emerging infectious diseases. BARDA, "together with its industry partners," promotes the advanced development of countermeasures to protect and respond to 21st-century health threats.[17]

[17] *See* https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx. Accessed on Mar. 1, 2023.

3. Pandemic and All-Hazards Preparedness Act of 2006

As evidenced by the PAHPA, both ASPR and BARDA are specifically responsible for coordinating, collaborating, and communicating with relevant private industries and Federal agencies to strengthen the United States' preparedness for public health emergencies.

For example, the PAHPA tasks the ASPR with overseeing advanced research, development, and procurement of qualified countermeasures and epidemic products.[18] The ASPR must also coordinate with Federal partners "and other public and private entities" to provide logistical support for medical and public health aspects of Federal responses to public health emergencies. Such support includes working with other relevant public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster. This includes entities capable of assisting with, responding to, and mitigating the effect of a public health emergency.[19] Regarding BARDA, the PAHPA tasks the HHS Secretary with coordinating the acceleration of countermeasures and product advanced research and development by facilitating collaboration between HHS and other Federal agencies, relevant industries, and academia regarding advanced research and development.[20]

4. [redacted]

In 2010, [redacted] oined HHS as a program lead of BARDA's Influenza Division International Program. In 2014, [redacted] became the director of BARDA's Influenza and Emerging Diseases Division. In 2016, he was appointed the Deputy Assistant Secretary for Preparedness and Response and Director of BARDA.[21] [redacted] held this position until April 20, 2020, when he was reassigned to the National Institutes of Health (NIH).[22]

5. [redacted]

[redacted] at HHS during the timeframe of [redacted] allegations. [redacted] on matters related to public health emergencies. [redacted] from [redacted] until [redacted]

6. BARDA Contracting

Per [redacted] complaint, at issue are two methods by which BARDA solicits proposals for contract awards: RFPs and broad agency announcements (BAAs). Each are described below to provide context.

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[18] 42 U.S.C. § 300hh–10(b)(3).
[19] 42 U.S.C. § 300hh–10(b)(5).
[20] 42 U.S.C. § 247d-7(e)(c)(2)(A).
[21] Attachment 1 at 10.
[22] *Id.* at 57.

a. RFP Process

Under the RFP process,[23] BARDA communicates its specific requirements for a particular acquisition and solicits proposals from prospective contractors. RFPs are issued individually and publicized on the Governmentwide point of entry (GPE).[24] Submitted proposals are reviewed consistent with instructions and evaluation criteria announced in the solicitation, with the proposal that best meets the publicized criteria for awards receiving a contract. The RFP process is commonly used with the procurement of commercial items where goods or services are identifiable and can be readily acquired or manufactured in the marketplace. BARDA uses the RFP process for the procurement of medical countermeasures associated with its Project Bioshield responsibilities.[25]

b. BAA Process

The BAA process[26] is utilized to support research and development efforts not related to the development of a specific system or hardware procurement.[27] BAAs identify an agency's general areas of research interest, with offerors independently identifying and submitting proposed solutions to potential issues of concern within those areas of interest (AOIs) that the Government has identified. BAAs allow agencies to fulfill their requirements for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding and are issued as standing notices to industry and prospective partners through the GPE. Notably, BAA proposals are evaluated throughout the life of the BAA on a rolling basis and are not evaluated in comparison to other proposals that may be received under the BAA.

These standing notices must:

(1) describe the agency's research interest, either for an individual program requirement or for broadly defined areas of interest covering the full range of the agency's requirements;

(2) describe the criteria for selecting the proposals, their relative importance, and the method of evaluation;

(3) specify the period during which proposals submitted in response to the BAA will be accepted; and

(4) contain instructions for the preparation and submission of proposals.

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[23] FAR 15.203.
[24] https://SAM.gov.
[25] Project Bioshield was established through the enactment of the Project Bioshield Act of 2004. The objective of Project Bioshield is to accelerate the research, development, procurement, and availability of effective medical countermeasures against CBRN agents. Available at https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield. Accessed on March 8, 2023.
[26] FAR 35.016.
[27] FAR 6.102(d)(2).

BARDA's current standing notice for CBRN and pandemic influenza advanced research and development activities is available on www.SAM.gov and was originally published in its current format on November 6, 2017.[28] This standing notice sets forth BARDA's advanced research and development AOIs and solicits proposals focusing on these areas to protect the United States against public health emergency threats. The current notice contains 9 separate (active) AOI categories divided into 42 specific (active) product areas and has been amended several times since its initial publication.[29] These amendments include several extensions to the closing date, a temporary narrowing of the AOIs to focus on COVID-related countermeasures during the COVID-19 pandemic, and additions and other suspensions to the specific product areas and AOIs.[30]

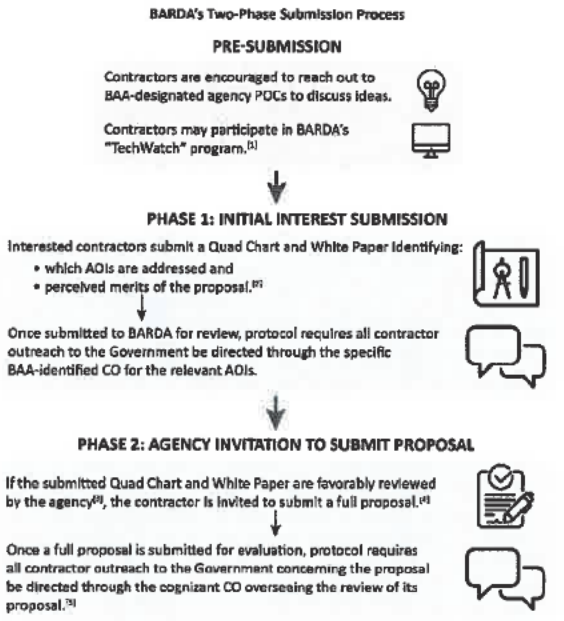
Proposals received in response to the BAA are evaluated under a peer or scientific review process in accordance with the publicized evaluation criteria within the BAA. As mentioned, proposals are evaluated throughout the life of the BAA on a rolling basis and are not evaluated in direct comparison to other proposals that may be received under the BAA. Proposals are instead evaluated on their own merits against the agency's announced AOIs. The primary bases for selecting proposals for acceptance are technical merit, importance to agency programs, and fund availability.[31]

BARDA utilizes a two-phased submission process.

1. **Phase One: Initial Interest Submission**. Phase one requires interested contractors to submit a quad chart and a white paper identifying which AOIs are addressed and the perceived merits of the proposal.[32] Prior to phase one, interested contractors are encouraged to reach out to the agency points of contact (POCs) designated in the BAA to discuss ideas and may participate in BARDA's "TechWatch" program.[33] Once a quad chart and white paper are submitted to BARDA for review, protocol requires that all outreach to the Government must be directed to the specific contracting officer (CO) for the relevant AOIs, as identified in the BAA.

[28] BAA-18-100-SOL-00003. Available at www.sam.gov. Accessed on February 24, 2023. BARDA has a second standing BAA (BAA-18-100-00018) for its Division of Research, Innovation, and Ventures (DRIVE), which is not relevant for purposes of this ROI.
[29] BAA-18-100-SOL-00003. Available at https://sam.gov/opp/822bf022eae2484293cddb4d2cecefbb/view. Accessed on February 24, 2023.
[30] BAA-18-100-SOL-00003, Amendment 37, January 13, 2023.
[31] BAA-18-100-SOL-00003, at Part VII.B.
[32] BAA-18-100-SOL-00003, at Part VII.A.
[33] BAA-18-100-SOL-00003, at 11; Participation in the TechWatch program affords Offerors an opportunity to present their capabilities to BARDA scientific subject matter experts and program managers, as well as Contracts Management and Acquisition (CMA) acquisition professionals. These personnel can evaluate products and technologies, suggest techniques and strategies for meeting technical and regulatory challenges, provide insight on how a product or technology may address BARDA's objectives, and provide general information about BARDA's mission and programs.

2. **Phase Two: Agency Invitation to Submit Proposal**. If an interested contractor's quad chart and white paper submissions are favorably reviewed by the agency,[34] the contractor is invited to participate in the second phase of the process by submitting a full proposal.[35] Once a full proposal is submitted for evaluation, protocol requires the contractor to limit any communications with the Government directly concerning the proposal to the cognizant CO overseeing the review of its proposal.[36]



A technical evaluation panel, consisting of various Government scientific experts and procurement specialists, is established to conduct the evaluations of the quad charts, white papers, and full proposals once submitted. Although a CO is assigned to each AOI and is ultimately responsible for awarding and administering a contract—if a contract award is made—the award decision itself rests with the source selection authority (SSA) that is separate and distinct from the CO.[37] Accordingly, the technical evaluation panel and CO evaluate a contractor's full proposal against the criteria established in the BAA,[38] and rate them as either Acceptable or Unacceptable. However, a finding of Acceptable does not guarantee contract

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[34] BAA-18-100-SOL-00003, Part VII.A. (Program Relevance, Overall Scientific and Technical Merits of the Proposal, and Offeror's Capabilities and Related Experience, Including the Qualifications, Capabilities, and Experiences of the Proposed Key Personnel).

[35] *Id.* at 9.

[36] *Id.* at 11.

[37] The FAR provides that the CO may also be the SSA; however, in these procurements, a different individual served as the SSA. [redacted] often had this responsibility during the scope of this investigation. In accordance with FAR § 15.303, the SSA appoints boards, teams, and so forth; considers their recommendations; and ultimately selects the awardee.

[38] BAA-18-100-SOL-00003, Part VII.B. (Program Relevance, Overall Scientific and Technical Merits of the Proposal, and Offeror's Capabilities and Related Experience, including the Qualifications, Capabilities, and Experiences of the Proposed Key Personnel, and to a lesser extent, cost/price, past performance, subcontracting program evaluation, and requested proof of concepts studies, if applicable).

award. Instead, program priorities, negotiations, and availability of funds are taken into consideration.[39] This provides a great level of discretion to the agency as proposals are not guaranteed a contract award even where they are determined to meet or exceed any one (or combination of bases) for selection.[40] Furthermore, the FAR confers ultimate decision-making authority on whether to make a contract award to the SSA, in accordance with the solicitation's published instructions and evaluation criteria.[41]

If the Government decides to potentially award a contract, the contractor will then be invited to conduct negotiations with the agency. If negotiations are successful, a contract award is issued. Proposals that are selected for award are considered to have been awarded as a result of full and open competition and are in full compliance with the competition requirements of 41 U.S.C. § 3301.

III. SUMMARY OF INVESTIGATIVE ACTIVITIES

OIG requested records and sought interviews with [redacted] and 17 other witnesses. OIG also requested assistance from the OIG Office of Audit Services (OAS) in determining whether ASPR properly awarded the contracts at issue. This investigation covered the period from June 2020 through August 2022.

IV. SUMMARY OF EVIDENCE OBTAINED

OIG received and reviewed contract-related documentation and emails for the following companies:

- Aeolus Pharmaceuticals,
- Alvogen,
- Amgen, Inc.,
- Alchem Laboratories,
- Emory University,
- Northwell Health,
- Novavax,
- PTx, and
- Ridgeback Biotherapeutics LP.

OIG also received the following documents and information: (1) emails and other supporting documents from relevant officials; (2) Procurement Integrity Act investigation documents related to PTx and (3) policies and procedures related to the BARDA and ASPR contract award process, including policies and procedures related to the ASPR Next program.

[39] *See* BAA-18-100-SOL-00003, Part VII.C.
[40] BAA-18-100-SOL-00003, at VII.D.; *see also* FAR 15.303 Source Selection Responsibilities.
[41] *Id.*

V. SUMMARY OF OFFICE OF AUDIT SERVICES INVESTIGATIVE ASSIST

SIB requested investigative assistance from OAS regarding this investigation. OAS initiated its investigative assistance on July 17, 2020.[42]

Specifically, SIB requested OAS assistance in determining whether alleged improprieties which concerned ASPR and BARDA contract award and administration were substantiated. OAS analyzed 11 contracts identified by SIB and mentioned in the allegations referenced in the OSC referral. Of the 11 contracts, 2 were awarded as sole-source contracts; the remaining 9 contracts were negotiated competitively using either an RFP or a BAA. OAS analyzed the pre-award process for these 11 contracts.

Based on OAS's analysis of the 11 contracts, OAS concluded that ASPR/BARDA complied with pre-award provisions of the FAR for 2 sole-source contracts and 8 competitively negotiated contracts and complied with FAR novation procedures for 1 contract.[43]

VI. INVESTIGATIVE FINDINGS

As mentioned, SIB was tasked with investigating the fourth and fifth allegations in [redacted] complaint:

- [redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels both before and during the COVID-19 pandemic. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals, Alvogen, Partner Therapeutics (PTx), Emory University, Ridgeback Biotherapeutics LP, Northwell Health, Novavax, and Alchem Laboratories; and

- [redacted]nd the ASPR Next staff circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

At the conclusion of the investigation and investigative assistance, OIG determined that the fourth and fifth allegations were unsupported by the evidence obtained.

We note that the individuals interviewed during this investigation held diverse positions with distinct scientific, medical, and other professional backgrounds, experiences, and responsibilities. Not all individuals held formal roles in the procurement and decision-making process. Those that were involved in procurement and decision making held varying roles with differing levels

[42] An OAS Investigative Assist is not an audit. OAS did not follow the audit requirements set forth in generally accepted Government auditing standards created by the Comptroller General and the Government Accountability Office. As such, the investigative assist product is not an audit report.
[43] Attachment 2, OAS Investigative Assist.

of responsibility and corresponding levels of access to information. Decision-making officials in the procurement process were also required to consider varying concerns beyond what was recommended to them by subject matter experts (SMEs) and technical evaluation panels, to include not only scientific, but also administrative, business, strategic, and other concerns. These combined differences and responsibilities contributed to a sometimes incomplete understanding of how or why certain decisions were made, and whether appropriate processes were followed.

We also note that the onset of the COVID-19 pandemic and its immediate aftermath presented novel challenges for HHS. Because ASPR and BARDA lead the Federal public health and medical response during public health emergencies, circumstances demanded, and the Nation called for, their quick action to treat and mitigate the further spread of COVID-19. At the time, there were no therapeutics, limited diagnostics, and no vaccines.[44] [redacted] perspective was that "anything that looked promising, uh, as far as an antiviral drug, um, I listened to"[45] and that "...any potential product that could have be- -- benefit for, you know, dealing with this COVID problem, I was listening. I was happy to listen to but then deferred it for – technical evaluation by BARDA,"[46] as [redacted] as not willing to accept at face value a contractor's assurances.[47]

OIG acknowledges that both ASPR and BARDA officials were operating during a unique time and under extraordinary pressure. OIG found no instances of contracting impropriety. Because the facts and circumstances within the fourth and fifth allegations are interconnected, it would be inefficient to discuss each allegation on its own. Therefore, the discussion below addresses both of those allegations in a combined examination.

a. [redacted] nd other senior HHS leaders did not engage in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels.

i. Aeolus Pharmaceuticals, Inc. (2017).

During spring 2017, BARDA conducted an in-process review (IPR) of an existing research and development contract with Aeolus.[48] As a result, the IPR panel recommended that BARDA allow the contract to expire instead of exercising an available option to extend contract performance. The SSA for the contract, [redacted] Deputy Assistant Secretary and BARDA Director of Medical Countermeasures Programs, accepted and approved the recommendation.[49] [redacted] was subsequently briefed on the decision and informed that Aeolus

[4] [redacted] interview at 120.
[45] *Id.* at 89. Specifically referencing EIDD-2801 and famotidine clinical trials.
[46] *Id.* at 90.
[47] *Id.* at 93.
[48] Contract No. HHS0100201100007C, awarded pursuant to BAA-BARDA-09-34.
[49] As mentioned previously, although a CO is assigned to each AOI and is ultimately responsible for awarding and administering a contract—if a contract award is made—the award decision itself is SSA's alone. Within the context of the contracts examined in this report, [redacted] did not serve as the SSA or serve as part of the BARDA contracting team. Accordingly, he may not have been privy to all procurement-related meetings or considerations taken into account during the acquisition and decision-making processes.

was "unhappy about the process."[50] [redacted] stated that he "greatly valued the integrity of the BARDA process and sought to ensure that process was fair to all involved" and "directed the team to allow Aeolus to present all relevant data that the company felt was missing in the IPR."[51] At the conclusion of this process, Aeolus was again informed that the contract would be allowed to expire, at which point Aeolus responded through the media.

After [redacted] that summer, [redacted] alleged that [redacted] a pharmaceutical industry consultant and friend of [redacted] began making calls and sending emails to [redacted] and [redacted] staff on Aeolus's behalf. While noting that discussions between BARDA and its industry partners and representatives are "not uncommon once a contract is in place," [redacted] stated that he received "internal pressure" from HHS leadership to act on behalf of Aeolus, which was "both unusual and improper."[52]

On August 29, 2017, [redacted] accepted [redacted] coffee invitation. During their meeting, [redacted] claimed that [redacted] suggested that the BARDA review process was unfair; that Aeolus [redacted] and [redacted] who was scheduled to meet with [redacted] the next day, was a "wildcard," that he was friends with [redacted][53] has "Hollywood connection[s]," and "is the kind of person who would write stories about you for the newspapers."[54] [redacted] suggested that [redacted] promoted the merits of a particular pharmaceutical during their conversation that he suspected was related to the Aeolus research and development contract—something he claimed to have later confirmed after the meeting. According to [redacted], he "became uncomfortable with the direction of [redacted] comments and ended the meeting."[55]

On August 30, 2017, [redacted] met with [redacted] who expressed [redacted] concerns about BARDA's contract decision and advocated for BARDA to reconsider its decision or consider using the remaining contract funds for another purpose. [redacted] invited [redacted] to speak to [redacted] concerning BARDA's decision due to [redacted] superior knowledge as the SSA for the procurement. According to [redacted], instead of speaking to [redacted] reached out directly to [redacted]

On September 27, 2017, [redacted] contacted [redacted] and requested another meeting concerning the Aeolus contract. That same day, [redacted] stated that ASPR [redacted] called [redacted] to discuss Aeolus and informed [redacted] that [redacted] discussing his displeasure concerning the contract. [redacted] asked [redacted] to prepare to discuss the contract with [redacted] [redacted] stated that [redacted] also advocated the merits behind Aeolus's contract despite neither having a technical or scientific background, which led [redacted] to believe that [redacted] had been in contact with [redacted] and/or [redacted] staff due to their similar talking points. [redacted] was also alleged to have, on multiple occasions, urged [redacted] to reconsider BARDA's decision or to find an alternative use for the drug that Aeolus was producing.

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[50] Attachment 1 at 16.
[51] *Id.*
[52] *Id.* at 16-17.
[53] [redacted]
[54] Attachment 1 at 8.
[55] *Id.*

On September 29, 2017, [redacted] met with [redacted] an ASPR contractor-consultant to discuss the Aeolus contract. Three days later, [redacted] was forwarded an email by [redacted] from [redacted] thanking [redacted] for the meeting and "reiterating the options they had discussed for a path forward with the existing or a new BARDA contract."[56] [redacted] then asked [redacted] for a "timeline to provide feedback on a proposed path forward."[57] [redacted] informed [redacted] that [redacted] would have to submit [redacted] information through the contracting office for "proper proposal submission."[58]

a) ASPR senior staff did not inappropriately communicate with [redacted] and Aeolus.

Regarding the allegation that [redacted] and ASPR staff inappropriately communicated with Aeolus and exerted inappropriate pressure on [redacted] to extend an existing contract with Aeolus through the use of a contract option period, OIG did not identify conduct that violated Federal procurement laws, regulations, or policies, or that were otherwise inappropriate. Furthermore, OIG did not uncover independent documentation that would otherwise support such a finding.

The PIA, as implemented by the FAR, does not prohibit meetings between an agency official and a contract offeror (or potential offeror) prior to, or after contract award, provided that the meeting does not result in the unauthorized disclosure of a competitor's proposal, or source selection information.[59] OIG determined during its investigation that although [redacted] maintained frequent access to both ASPR and BARDA staff, including [redacted] and [redacted], OIG did not find that this access was inappropriate or resulted in improper or illegal influence over the BARDA procurement process.

As an industry-facing office with statutory requirements to communicate with industry, ASPR and BARDA further promote Government-industry relations, advanced research and development efforts, and the procurement of qualified countermeasures through their active engagement and collaboration with industry.[60] Regardless of these statutory requirements, witnesses indicated during their interviews that it is generally not unusual for industry representatives to contact and lobby high-ranking Government officials (with or without prior relationship), and do so where such representatives ignore or are unaware of proper agency communications protocols to advocate for their clients or products.[61] It is not improper for ASPR and BARDA to entertain such outreaches.

Both [redacted] and [redacted] discussed the issue of access in depth during their interviews, with both holding the practical and strategic view that meeting with industry partners, such as Aeolus

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[56] *Id.* at 18.
[57] *Id.*
[58] *Id.*
[59] 41 U.S.C. § 2102, as implemented by FAR 3.104-4(e)(3).
[60] 42 U.S.C. § 247d-7e(c)(2)(A) (Facilitating collaboration between HHS, other Federal agencies, relevant industries, academia, and other persons with respect to qualified countermeasures advanced research and development); 42 U.S.C. § 300hh-10(b)(3) (Subject to the authority of the Secretary, ASPR oversees advanced research and development, and procurement of qualified countermeasures and qualified pandemic or epidemic products).
[61] [redacted] interview at 28, 50; [redacted] transcript at 21, 22.

and [redacted] were necessary for various reasons, and that a failure to do so could result in unacceptable risk.[62]

[redacted] was familiar with the concept of holding strategy meetings with industry partners. [redacted] indicated in [redacted] complaint and interviews that [redacted] also often took meetings with industry representatives such as [redacted] and his clients and that [redacted] would direct them to the appropriate POCs within BARDA for further communication.[63] [redacted] complaint also details [redacted] own efforts to bring attention to potential N95 mask shortages and describes [redacted] multiple conversations with [redacted] mask manufacturer, Prestige Ameritech). [redacted] details numerous emails [redacted] sent to HHS executives to continue "to put pressure on HHS leadership to take action," regarding information obtained from [redacted] concerning the U.S. mask supply. [redacted] also sent emails to BARDA colleagues "about considering providing financial support to Prestige Ameritech to reopen its defunct factories."[64] [redacted] understood that [redacted] offered a means of production from the country's largest mask manufacturer and [redacted] thanked [redacted] for his offer.[65]

Moreover, [redacted] described his ASPR role with industry in a similar fashion.[66] If a company approached [redacted] and offered a briefing on their product [redacted] would take the briefing, learn more about the product, and then refer the company to BARDA for consideration. [redacted] believed that one his "implicit obligations" [redacted] was to meet with industry representatives "on a regular basis to maintain contacts to hear their issues" and refer them to BARDA, as appropriate.[67] Further, [redacted] stated in [redacted] interview that if a company did not, "fight for, you know, the product that they're developing, that would give me pause, meaning that well, they don't really believe in [their product]."[68]

Access does not necessarily equate to influence, especially with Federal agencies such as ASPR and BARDA that are tasked by statute to engage with industry stakeholders.[69] For example, practical concerns could play a role in such meetings, with [redacted] describing meetings with [redacted] as a type of "prevent defense,"[70] because a decision not to do so might result in [redacted] (who [redacted] described as "unscrupulous in their tactics and methods") raising and framing the matter with the media or with Congress.[71] Ultimately, [redacted] perception of [redacted] role in the procurement process, was that [redacted] did not "involve" [redacted] with contracts as [redacted] believed, as a [redacted] that there was "no reason" why [redacted] should be involved in contracting

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[62] *See* [redacted] interview transcript at 104; and [redacted] interview transcript at 25, 26 (both discussing the risks that a disappointed industry partner would air their frustrations to the media or with Congress if they failed to meet with industry partners; something that senior officials would need to be ready to address).

[63] Attachment 1 at 27-28. Per [redacted], [redacted] accepted a coffee meeting with [redacted] where [redacted] brought up the subject of the BARDA contracting process.

[64] *Id.* at 28.

[65] *Id.* at 26.

[66] [redacted] interview transcript at 126.

[67] *Id.*

[68] [redacted] interview at 23.

[69] 42 U.S.C. § 300hh–10(b)(5); 42 U.S.C. § 247d-7(e)(c)(2)(A).

[70] [redacted] interview at 104.

[71] *Id.* at 176 (discussing [redacted] in the context of the matter with PTx).

decisions.[72] The extent of his efforts was to "listen" and "nurture a public-private partnership" but defer to BARDA for evaluation.[73]

Indeed, [redacted] demonstrated [redacted] own propensity to engage personally with industry representatives in his complaint and interviews when he described meeting or communicating with both [redacted] and [redacted] on multiple occasions to discuss Aeolus's contract concerns without changing his own opinion supporting the SSA's decision to allow Aeolus's contract to expire.

Absent any evidence of inappropriate or unlawful conduct, such as disclosing a competitor's proposal, or Government source selection information, entertaining communications with [redacted] and [redacted] concerning BARDA's decision not to exercise the option year on Aeolus's existing contract was not presumptively improper. Accordingly, OIG found that the allegation that ASPR staff inappropriately communicated with [redacted] and Aeolus was unsupported by the evidence.

b) [redacted] and ASPR senior staff did not inappropriately pressure [redacted] and BARDA to extend an existing contract with Aeolus.

The complaint alleges that [redacted] and ASPR senior staff inappropriately pressured [redacted] and BARDA to extend an existing contract with Aeolus. OIG did not identify any conduct that amounted to inappropriate pressure to extend Aeolus's existing contract with BARDA.

Inquiring about, following up on earlier discussions, or expressing differences of opinion with staff in general or as a result of communications from a contractor raising issues with its own contract or contract performance, is not in and of itself prohibited activity. Internal agency discussions routinely occur in the normal operation of business for a variety of practical reasons. In [redacted] interview, [redacted] discussed the need and value of keeping leadership apprised of major decisions and engaging in subsequent and "robust" discourse.[74] [redacted] also discussed the consistent risk that a disappointed company would air its frustrations in the media, "and those things will come back, and senior officials are gonna have to answer those media questions. So, we always try to give that, you know, um, heads up."[75] Similarly, [redacted] ASPR Director of the Division of Acquisitions and Assistance Policy and Program Oversight and ASPR Head of Contracting Activity (HCA), discussed [redacted] efforts to consider all viewpoints in the decision-making process.[76]

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[72] *Id.*

[73] [redacted] interview transcript at 90, 126.

[74] [redacted] interview transcript at 25, 26, 59, and 60 (stating that it was important to keep leadership informed on contract decisions; that such updates would generate questions and robust discussions; and that such questions were not challenges to decisions and were important in potentially answering external inquiries; something that senior officials would have to address).

[75] *Id.* at 25, 26.

[76] [redacted] interview transcript at 8 (referencing [redacted] character; "[redacted] wants everybody to bring what they have to the table. So, if I'm a business guy and I'm in the room, then I should be bringing what I know to the table. Um, if you're the policy person, you need to tell me what's going on. Um, [redacted] looks at us like a squad, like a team, and like everybody is pulling is what they're supposed to pull, and bring that to the table. Um, I've never been boxed out if I was invited in. So, in other words, if I'm in the room and I say something, they look; they listen.").

Neither [redacted][77] nor [redacted][78] considered this discourse to be inappropriate or described witnessing or feeling pressured by [redacted] or ASPR staff to inappropriately change their procurement-related decisions. To this point, [redacted] acknowledges in [redacted] complaint that Aeolus's contract, despite the level of interest displayed by ASPR, was allowed to expire, without extension. [redacted] ASPR [redacted] Science Advisor, stated that [redacted] would often seek out [redacted] advice and either agree or disagree with it, but that [redacted] did not "see that as any kind of failing."[79] Meanwhile, [redacted] perception of [redacted] role in the procurement process, to the extent that [redacted] maintained any, was to "listen" and "nurture a public-private partnership," but defer to BARDA for evaluation.[80] Ultimately, the decision to exercise the Aeolus option or not remained with BARDA's SSA [redacted] and the contract was allowed to expire at the end of its period of performance, despite Aeolus's desired extension.

Accordingly, OIG found that the allegation that ASPR staff exerted inappropriate pressure on [redacted] to extend an existing contract with Aeolus was unsupported by the evidence.

c) The Procurement Integrity Act was not violated by [redacted] communications with BARDA and ASPR staff.

The complaint alleges that the PIA[81] was violated by [redacted] communications with BARDA and ASPR staff about the continuance of Aeolus's existing contract. OIG did not identify any conduct that violated the PIA.

The PIA prohibits the release of source selection and contractor bid or proposal information *before* the award of an agency procurement contract to which the information relates.[82] This prohibition applies to both current and former agency officials who are "acting or have acted for or on the behalf of, or who is advising or has advised the United States with respect to, a Federal agency procurement; and by virtue of that office, employment, or relationship, has or had access to contractor bid or proposal information or source selection information."[83] Here, Aeolus had already been awarded the contract and had been performing under its terms for some time.

Although contractor bid or proposal information and source selection information must be protected from unauthorized disclosure in accordance with the FAR, applicable law, and agency regulations,[84] a contractor is not prohibited from disclosing or discussing its own proposal information or a recipient from receiving that information directly from the contractor.[85] Furthermore, meetings between an agency official and a contract offeror (or potential contract

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[77] [redacted] interview transcript at 25, 26 (describing never feeling pressure to approve a proposal or having a decision overturned).
[78] [redacted] interview transcript at 29 (stating that [redacted] never saw any indication that [redacted] made decisions to benefit friends or acquaintances).
[79] [redacted] interview transcript at 17, 18.
[80] [redacted] interview transcript at 90, 126.
[81] 41 U.S.C. §§ 2101–2107.
[82] 41 U.S.C. §§ 2101–2107; codified at 48 C.F.R. § 3.104; implemented by FAR §3.104; and supplemented by HHS at HHSAR § 303.104-7.
[83] 48 C.F.R. § 3.104-3(a)(2); FAR § 3.104-3(a)(2).
[84] FAR § 3.104-4(b), citing FAR § 14.401 and § 15.207.
[85] FAR § 3.104-4(e)(1)-(4).

offeror) are not prohibited under the PIA, provided that the meeting does not result in the unauthorized disclosure of a competitor's bid, proposal, or source selection information.[86]

In other words, the PIA does not prohibit a contractor from discussing its own existing contract with the Government or Government personnel.[87] Here, interviews indicate that Aeolus was unhappy with the results of BARDA's decision not to exercise the option on its *existing* contract, and that Aeolus used both [redacted] and [redacted] to further discuss and argue for the merits of its contracted work with BARDA and ASPR. This conduct, in and of itself, is not prohibited by the PIA. Accordingly, OIG found that the allegation that the PIA was violated was unsupported by the evidence.

ii. Alvogen (2018):

In late 2018, [redacted] stated that [redacted] and [redacted] met with [redacted] to direct BARDA to transfer $40 million to the SNS for the purchase of an influenza antiviral drug, specifically, generic oseltamivir (Tamiflu). [redacted] suggested that ASPR consider an alternative influenza antiviral drug that had recently been approved by the FDA, baloxavir (Xofluza). [redacted] further stated that subject matter experts had determined that "it was critical to diversifying the SNS holdings, which would better prepare the SNS to save lives in a pandemic because viruses can become resistant to certain drugs." After the meeting, [redacted] directed the interagency Flu Risk Management Meeting (FRMM) group to meet to discuss recommendations for the SNS concerning influenza drug purchases.

On November 29, 2018, the FRMM issued a report calling on the SNS to prioritize the purchase of baloxavir and to maintain oseltamivir at then current levels, which was subsequently briefed to [redacted] and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) executive team. The SNS did not accept the interagency recommendation and instead began its own process to procure influenza drugs, which [redacted] claimed was unusual, although within the SNS's authority. [redacted] subsequently learned that the SNS was planning to procure generic oseltamivir from Alvogen, and that [redacted] was representing Alvogen and had been speaking to [redacted] ASPR [redacted] and [redacted] ASPR [redacted][88]

During an offsite pandemic preparedness exercise[89] at George Mason University on [redacted], 2019, [redacted] stated that [redacted] and [redacted] were having a hallway conversation when [redacted] who was also in attendance, interrupted to advise [redacted] that Alvogen was preparing to submit a

[86] *Id.*
[87] *Id.*
[88] The position of ASPR [redacted] and [redacted] at different times during the period of investigation.
[89] Offsite pandemic preparedness exercises are usually a "multistate, whole-of-government effort" measuring the Nation's ability to respond to a large-scale outbreak, such as a novel influenza strain. For example, ASPR's Crimson Contagion 2019 Functional Exercise included 19 Federal Departments or Agencies, 12 States, 74 local health departments and coalition regions, 15 Tribal Nations and pueblos, 87 hospitals, more than 100 health care and public health private sector partners, and the White House Security Council. *See* Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Crimson Contagion 2019 Functional Exercise After-Action Report*, January 2020. Consequently, it was not unorthodox that private industry partners attend these exercises.

proposal to the SNS to provide generic oseltamivir and that [redacted] was confident that [redacted] had Alvogen 'locked down' for the purchase, i.e., that Alvogen was in line to get the award," to which [redacted] 'laughed uncomfortably and said something to the effect of, 'That sounds good to me. I'm not sure I need to know all that right now.'"

ASPR and the SNS subsequently issued an RFP to procure influenza antiviral medication. [redacted] alleged that the language of the RFP was "narrowly tailored" to limit the types of drugs that could be considered for purchase and to advantage oseltamivir and Alvogen. [redacted] also claimed that ASPR and the SNS did not consult the influenza experts on the FRMM and kept the procurement "closely held within a small group." Ultimately, on September 30, 2019, ASPR awarded a $40 million contract to Alvogen for generic oseltamivir for the SNS, transferring funds from BARDA. [redacted] objected, but [redacted] concerns were dismissed by [redacted][90]

a) [redacted] and ASPR senior staff did not ignore the scientific review process in awarding a contract to Alvogen for oseltamivir.

The complaint alleges that [redacted] and ASPR senior staff ignored the scientific review process in awarding a contract to Alvogen for generic oseltamivir. OIG did not identify any conduct that supported this allegation.

As [redacted] described in the complaint, recommendations for the SNS to procure baloxavir as opposed to oseltamivir were issued both internally and through the FRMM, which is advisory in nature, to [redacted] OIG did not uncover any evidence that these recommendations were not considered by the decision-making officials. Absent any guidance to the contrary, recommendations are not, by definition, mandates. As previously discussed, decision-making officials are not obligated to enact recommendations in making their solicitation, evaluation, and contract award decisions.[91] OIG did not identify a requirement that recommendations from BARDA or the FRMM be accepted and implemented. Indeed, [redacted] acknowledged in [redacted] OIG interview that the recommendations to procure baloxavir could be dismissed, although to do so would be "unusual." Although it may have been unusual, a decision against implementing a recommendation in this instance was not legally improper.

Importantly, this decision does not, in and of itself, indicate that the scientific review process was ignored. Every procurement involves recommendations to the contracting officer (CO) and/or SSA. Every procurement requiring a technical evaluation panel utilizes subject matter experts to review the proposals. Notably, the FRMM did not serve as the technical evaluation panel on this procurement. Although the SSA must consider the recommendations that are proposed to him/her, the SSA's decision is commonly impacted by other considerations, such as available budget, logistical considerations, and strategic concerns. In this case, for example, the SSA would determine how best to stock and manage the SNS to adequately meet its statutorily required mission.[92]

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[90] This investigation did not address the substantive conclusions of what drugs should, or should not, have been added to the SNS. For OIG work on this topic, *see* https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000464.asp.

[91] SSA makes the independent decision and may disregard recommendations.

[92] 42 U.S.C. § 300hh-10(c)(4)(c) (Discussing ASPR responsibilities regarding the SNS).

In [redacted] interview, [redacted] described the cost of baloxavir as impacting his decision to pursue generic oseltamivir, due to the higher costs per dose and substantially fewer number of treatments that could be procured and subsequently made available and administered during an emergency. While acknowledging [redacted] concerns of a 10- to 14-percent potential global resistance to oseltamivir, baloxavir was roughly 10 times as expensive at the time, which meant that the SNS could "only buy a small amount that would be practically irrelevant in the light of a pandemic of influenza."[93] Subsequently, the manufacturer of baloxavir offered to cut their prices significantly, at which point [redacted] referred them to the SNS to evaluate whether a procurement could be made.[94]

Furthermore, at the time during which this award decision occurred, the SNS fell under the responsibility of SNS management, not BARDA.[95] Management of the SNS, including what drugs were ultimately procured and in what quantities, was consequently outside the responsibility of BARDA and its contracting office. Therefore, OIG determined that it would not be unusual to keep procurement specifics and processes within the confines of the responsible contracting office.

b) The Request for Proposal (RFP) for influenza antivirals was not narrowly tailored to direct an award to Alvogen for procurement of oseltamivir.

The complaint alleges that the RFP for influenza antivirals was narrowly tailored to direct an award to Alvogen for procurement of oseltamivir, and that this was unlawful. OIG did not identify conduct that violated Federal procurement laws, regulations, or policies, or that were otherwise inappropriate.

The RFP for influenza antivirals was issued in January 2019. A review of the RFP revealed that the SNS was seeking proposals for either oseltamivir or zanamivir and that the Government would rely on the contractor's own pharmaceutical supply chain during influenza emergencies for rapid distribution of the antiviral procured.[96] The RFP also included language that allowed prospective contractors to propose "alternate solutions that ultimately meet the Government objective."[97] Moreover, although the initial RFP specifically identified oseltamivir or zanamivir as acceptable antivirals, the RFP was subsequently amended in May 2019 to delete reference to both oseltamivir and zanamivir, and substitute language allowing for "oral antiviral drugs that are FDA-approved or in process of obtaining FDA-approval for influenza treatment."[98]

An RFP is not narrowly tailored (otherwise known as being unduly restrictive of competition) if the procuring agency can demonstrate that the requirement (and how to accommodate them) is

[93] [redacted] interview transcript at 127, 128.
[94] *Id.* at 129.
[95] Effective October 1, 2018, HHS transferred responsibility for the SNS from CDC to ASPR. 42 U.S.C. § 300hh-10(c)(4)(b)(1); *see also* Disbrow interview transcript, at 28-30.
[96] Solicitation No. 19-100-SOL-00008, available at https://sam.gov/opp/7e23dfd2449eb8045849439e1568dc65/view. Accessed on February 24, 2023.
[97] Solicitation No. 19-100-SOL-00008, at C.3. Technical Requirements.
[98] BAA-19-100-SOL-00008, Amendment 4, available at https://sam.gov/opp/a074fb6c05c6089784a2f5d42e4b2bed/view. Accessed on February 24, 2023.

reasonably necessary to meet the agency's needs.[99] Here, the RFP did not contain language that restricts, or had the effect of restricting, an award to Alvogen, which produced a generic form of oseltamivir. To the contrary, the initial inclusion of "alternate solutions," and ultimately the deletion of initial references to oseltamivir and zanamivir in their entirety, as well as inclusion of language accepting any FDA-approved antiviral (or antiviral in the approval process) was a strong indication that the RFP requirement could be met by a wider range of drugs and drug providers and was not narrowly tailored or unduly restrictive of competition. Furthermore, the award was not guaranteed to Alvogen even if oseltamivir was the desired product for procurement, as Alvogen was one of three producers of generic oseltamivir.

Accordingly, OIG found that the allegation that the RFP for influenza antivirals was narrowly tailored to direct an award to Alvogen for procurement of oseltamivir was unsupported by the evidence.

iii. Partner Therapeutics (2018):

Prior to 2018, BARDA had contracts with both Partner Therapeutics (PTx) and Amgen, Inc., for radiation exposure treatment drugs. In June 2018, both companies were invited to submit proposals for the procurement of additional radiation treatment drugs for the SNS. A technical evaluation panel recommended that additional drugs be procured from Amgen. PTx challenged the subsequent award decision and protested the award to the Government Accountability Office (GAO), [redacted] asserted that during the protest, [redacted] was in "regular communication" with [redacted] and [redacted] advocating for PTx, and that they approached [redacted] to advocate for the purchase of the PTx drug, which they indicated was "critical" due to financial difficulties that PTx was going through, which could result in bankruptcy. In both December 2018 and January 2019, [redacted] further asserted that [redacted] contacted [redacted], using the same "talking points" as [redacted] and [redacted] "suggesting [to [redacted] that they had been talking and coordinating their efforts."[100]

In late 2018, ASPR initiated a PIA investigation into the PTx proposal. ASPR had learned that a former senior BARDA employee had transitioned to PTx as a consultant. BARDA staff had also observed that the PTx proposal was "suspiciously aligned" with BARDA's internal considerations, suggesting that they were aware of BARDA's internal processes. Based on the investigation,[101] which determined that a former BARDA employee had provided protected information to PTx, PTx entered into a settlement agreement with HHS, limiting its general ability to contract with the Federal Government for a period of 1 year; however, pursuant to the settlement agreement, HHS agreed to procure a certain quantity of the PTx radiation exposure drug before the end of fiscal year 2019; allowed PTx to continue to compete for research and development contracts; and permitted HHS to procure additional supplies of the PTx drug within the one year period of exclusion, subject to ASPR approval.[102]

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[99] *Remote Diagnostic Techs., LLC*, B-413375.4, B-41375.5, Feb. 28, 2017, 2017 CPD ¶ 80 at 3-4, B-412794, June 2, 2016, 2016 CPD ¶ 158 at 2.
[100] Attachment 1 at 21.
[101] *See* "HCA's FAR Part 3 and Subpart 9.5 Procurement Integrity Act and Organizational Conflict of Interest Report and Request for Concurrence," dated January 2019, concurrence dated, February 6, 2019.
[102] *See* PTx Signed Settlement Agreement 8-20-2019.

After completion of ASPR's investigation, [redacted] subsequently learned that as a result of this settlement agreement, a sole-source contract award of $55 million[103] had been made to PTx in September 2019 based on industrial mobilization concerns.[104] [redacted] asserted that the award essentially overruled the TEP's recommendation to procure additional radiation treatment drugs from Amgen and instead of PTx under its prior contract.

a) [redacted] and ASPR senior staff did not act improperly in awarding PTx a sole-source contract for radiation exposure treatment drugs for the SNS.

The complaint alleged that [redacted] and ASPR staff acted improperly in awarding PTx a sole-source contract for radiation exposure treatment drugs for the SNS. OIG did not identify conduct that violated Federal procurement laws, regulations, or policies, or that were otherwise inappropriate.

While [redacted] alleges that [redacted] and ASPR staff acted improperly by ignoring BARDA and the FRMMs recommendations in awarding PTx a $55 million sole-source contract for its radiation exposure treatment drug, [redacted] acknowledges in [redacted] complaint that although [redacted] and [redacted] Division, objected to the award decision, all believed that this was a permissible course of action taken by ASPR.[105]

[redacted] provided additional information and context concerning this allegation during [redacted] interview.[106] According to [redacted] the procurement was handled by the SNS, which used its own technical evaluation panel during the review process,[107] and the drugs produced by PTx and Amgen each had their own scientific benefits which were supported by BARDA research.[108] [redacted] indicated that although [redacted] did not participate in the TEP, [redacted] was asked during the PTx discussions for [redacted] input as to whether the drug was "scientifically sound," the "potential benefits," the risks, and whether it was "true that the company could go out of business."[109] Moreover, [redacted] stated that [redacted] was unaware of any instances where a technical evaluation panel was overridden.[110]

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[103] Contract No. 75A50119C00062; *See also,* Final J&A Cytokine–DSNS Redacted.pdf, and further clarified by Leukine ASPR 2019 00406 J&A Clarification, dated September 29, 2019.

[104] FAR 6.302-3(a)(2)(i) (To maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a national emergency or to achieve industrial mobilization).

[105] Attachment 1 at 22.

[106] [redacted] also stated to investigators that [redacted] did not take personal notes of any allegedly improper actions [redacted] brought to [redacted] attention and was not able to recall specifics of any conversations where [redacted] complained about improper actions. While [redacted] recalled conversations where [redacted] was venting about certain issues, [redacted] told investigators that [redacted] did not always agree with [redacted] during these conversations.

[107] [redacted] interview transcript at 28, 30.

[108] *Id.* at 47 (stating that the Amgen drug could be administered within the first 24 hours of exposure while the PTx drug could be administered within the first 48 hours of exposure).

[109] *Id.* at 36.

[110] *Id.* at 13, 14 (stating that no decision to override the technical evaluation panel's recommendation to [redacted] knowledge occurred with the past two years of [redacted] interview date).

Upon review of the evidence, the PTx award decision involved complicated business considerations. During the PIA investigation, PTx provided ASPR with information indicating that it was in dire financial straits and that absent an award for its drug or other investment, it would be required to seek bankruptcy. PTx also mentioned that the licensed factory where it produced its drug would be forced to close, and that the drug would be unavailable from any source if needed in the future by the SNS.

[redacted] discussed in [redacted] interview the importance of keeping "the [SNS] portfolio diversified," and if PTx had not been supported under the industrial mobilization exception, that the only other product that would have been available was produced by Amgen, making that product the only one of its kind in the SNS, which in turn would necessitate future sole-source awards to stock the SNS.[111]

An HHS Office of General Counsel (OGC) Senior Attorney provided additional context into the decision-making process involving the award to PTx despite its settlement agreement with the agency for violating the PIA. During [redacted] interview, [redacted] detailed how OGC provided legal support on both the PIA investigation and subsequent procurement work associated with the sole-source award. Regarding the latter, the senior OGC attorney outlined the extent to which OGC researched and provided available legal options to ASPR senior leaders following the determination that a PIA violation occurred, to include sole-source award under the FAR's industrial mobilization exception to full and open competition.[112]

[redacted] ASPR [redacted] ASPR [redacted] also stated in [redacted] interview that, "they [PTx] provided enough evidence that they were getting ready to tank" and "to watch them go bankrupt and lose everything that was invested [previously by the Federal Government] was not a good business decision on behalf of the Government."[113] [redacted] further indicated that, as the [redacted] it was ultimately [redacted] ecision, not [redacted] to approve a sole-source contract through the industrial mobilization exception.[114]

Notably, [redacted] in [redacted] interview expressed [redacted] personal aversion to awarding a contract to PTx due to their "coercive" negotiation tactics,[115] and that it "was clearly an effort by someone [redacted] uh, who I know is unscrupulous in their tactics and methods, I was not going to bend to that—to that end state."[116] Moreover [redacted] stated in [redacted] interview that at the time of [redacted] interview [redacted] did not believe that PTx had received any award because of the OGC-supported PIA investigation.[117] However, there is some discrepancy as to this decision as the senior OGC attorney in [redacted] interview indicated that [redacted] briefed [redacted] on the three options legally available

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[111] [redacted] transcript at 45.
[112] OI-3 Report of Interview–Senior Attorney, Office of General Counsel (OGC) at 3.
[113] [redacted] interview transcript at 25–26.
[114] *Id.* at 25.
[115] [redacted] interview transcript at 130, 137 (stating [redacted] initial belief that [redacted] and PTx's negotiation position that they would go bankrupt without a Government award).
[116] *Id.* at 176.
[117] *Id.*

to [redacted][118] while [redacted] indicated that the determination of industrial mobilization, was done "outside of [redacted]."[119]

The senior OGC attorney noted in [redacted] interview that [redacted] was unaware of any case where [redacted] was excluded from a meeting and that [redacted] was not in any meetings that [redacted] was not also attending. The senior OGC attorney also stated that OGC additionally went back and talked to [redacted] even when [redacted] was not in attendance (but [redacted] or BARDA staff were) to ensure that [redacted] was aware of the information presented and decisions made. The senior OGC attorney noted this was done because it was important to disseminate all the information uncovered, especially since a PIA violation can exist, but there can be a business decision to award a contract nonetheless.

Regardless of who ultimately decided to proceed with the sole-source award option, to use the industrial mobilization exception to award a sole-source contract, HHS had to complete a justification and approval (J&A) document that outlined the rationale for using the industrial mobilization exception. They had to meet the requirements to utilize a J&A, adequately support its determination, and staff the request from the program office through the contracting office to send to [redacted] for approval as the HCA.[120]

[redacted] was the only individual with the authority to approve the J&A, as it is an exception to the usual acquisition process of seeking out competition in the solicitation and issuance of contract awards. Accordingly, even if [redacted] and ASPR staff wished to demonstrate favoritism toward PTx,[121] the award process, which required additional justification and approvals in this circumstance, would make it unlikely that they would be able to easily do so. Moreover, [redacted] stated in [redacted] interview that neither [redacted] gave any indication that they made decisions to benefit their friends or connections.[122]

Consequently, OIG did not find evidence that ASPR violated any laws, regulations, or policies in awarding a sole-source contract to PTx under the industrial mobilization exception to full and open competition.

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[118] OI-3 at 3.

[119] [redacted] interview transcript at 25, 26.

[120] FAR 6.302-3(a)(2)(i).

[121] [redacted] also alleged that ASPR leadership engaged in inappropriate communications with PTx and its consultant, [redacted] during this time period. During [redacted] interview, [redacted] asserted that a senior OGC attorney had specifically confirmed that inappropriate communications did exist, including a meeting at Starbucks between [redacted] PTx, and [redacted] When questioned about this assertion in an interview, the senior OGC attorney did not recall the particular meeting at which this allegedly occurred but did acknowledge that during the performance of the investigation, conduct implicating FAR Part 3 (conflicts of interest) and Subpart 9.5 came to the attention of the investigative team. The senior attorney also noted that legal guidance was provided to [redacted] concerning the options available to [redacted] pursuant to the FAR, including notification requirements if a violation was determined. The senior attorney indicated that a different OGC attorney spoke to [redacted] and [redacted] about concerns regarding the possible "appearance" of a conflict of interest pursuant to FAR Part 3 if meeting or communicating with PTx and its consultant. The senior attorney further indicated that [redacted] was not a participant to these conversations but was under the impression that there was a determination that no violation occurred and that no statutory or regulatory decision (e.g., notification of potential PIA violation to the senior procurement executive) was required pursuant to the FAR, as no further communications were uncovered by the investigation team, and no further actions were taken by [redacted] as a result of the legal guidance provided to [redacted]

[122] [redacted] interview transcript at 29.

iv. Emory Institute for Drug Development (2019):

On November 1, 2019, [redacted] held a meeting with [redacted] and [redacted] ASPR [redacted] to discuss a new drug, EIDD 2801, which was being promoted by [redacted] and [redacted] Emory Institute for Drug Development and the [redacted] Emory. EIDD 2801 was presented as a "cure-all" for influenza, Ebola, and other viruses, for which BARDA was encouraged to invest millions of dollars. [redacted] however, raised concerns with the safety of EIDD 2801 based on reproductive toxicity in animals and offspring from treated animals that had arisen with similar experimental drugs of the same class. [redacted] inquired about whether any clinical trials had been conducted and whether Emory had conducted a reproductive study for toxicity. Although the response was negative, [redacted] and [redacted] informed the group that they had received DoD and NIH funding to conduct trials.

[redacted] continued to insist at the meeting that BARDA needed evidence that EIDD 2801 was safe before it could consider funding manufacture of the drug. On the other hand, [redacted] and [redacted] advocated for immediate BARDA funding. Following the meeting, [redacted] claimed that [redacted] repeatedly called [redacted] and [redacted] to ask whether BARDA was going to fund EIDD 2801, and that [redacted] brought up the subject of EIDD 2801 in various staff meetings, asking [redacted] whether BARDA had taken any steps to move forward with EIDD 2801.

In late February 2020, [redacted] and [redacted] BARDA's Division of Influenza and Emerging Infectious Diseases, informed [redacted] that [redacted] and [redacted] were seeking funding for EIDD 2801 as a COVID-19 treatment. They informed [redacted] that [redacted] and [redacted] had contacted the ASPR Strategic Innovation and Emerging Technology [redacted] ASPR [redacted] instead of submitting proposals through the interagency Medical Countermeasures Task Force (MCM-TF), which consisted of interagency Government subject matter experts reviewing COVID-specific science requests for funding on an expedited and collaborative basis. [redacted] asserted that [redacted] was concerned about this for several reasons: (1) that EIDD 2801 had still not undergone clinical trials; (2) that [redacted] and [redacted] had circumvented the streamlined MCM-TF submissions process for COVID-specific funding requests; and (3) that ASPR Next was an inappropriate venue for seeking funding as it "was designed to fund products, equipment, and technology and did not have the resources or technical expertise to fund drug development."

While looking into Emory's efforts with ASPR Next, [redacted] alleged that BARDA's [redacted] advised [redacted] that some companies were attempting to circumvent the rigorous scientific and contractual processes set in place by the MCM-TF by submitting short proposals to ASPR Next for funding, and that ASPR Next did not appear to limit its consideration to proposals for products, equipment, and technology.

[redacted] asserted that "it was becoming increasingly clear to [redacted] and others that [redacted] and [redacted] were using ASPR Next to circumvent the BARDA review process and to fund their 'pet' projects, regardless of scientific merit," and that [redacted] efforts "were doing little more than escalating tensions with [redacted] and members of his leadership team."

[redacted] also asserted that [redacted] had informed [redacted] that [redacted] "frequently took phone calls directly from industry partners and agreed to fund their proposals without following the requisite review processes," and that [redacted] had discussed the issue with ASPR [redacted] "who was 'angry' about ASPR Next's deviation from the requisite contracting protocol."

a) ASPR did not compromise the independent scientific integrity of the review and contract award process and did not inappropriately pressure BARDA to award a contract to Emory for the antiviral drug, EIDD 2801.

The complaint alleges that [redacted] compromised the independent scientific integrity of the review and contract award process by pressuring [redacted] to award a contract to Emory for the antiviral drug EIDD 2801.[123] OIG did not identify conduct that violated Federal procurement laws, regulations, or policies, or that were otherwise inappropriate.

Inquiring about, following up on earlier discussions, or expressing differences of opinion internally with staff regarding a contract or contractor, is not in and of itself prohibited activity. Also, as discussed previously, internal agency discussions with contractors routinely occur in the normal course of business for a variety of practical and strategic reasons, such as fostering relations between Government and industry, learning what industry has to offer, and attempting to deter disappointed contractors from unnecessarily raising issues through the media or with Congress. The conduct alleged appears to involve simple differences in professional opinion as to the safety and potential efficacy of EIDD 2801 and the proper sequence of steps necessary to ensure safe proceedings.[124] During [redacted] interview, [redacted] expressed [redacted] belief that ASPR did not attempt to award contracts by circumventing BARDA through their conduct and "expect[ed] nothing less than to have a robust discussion with ASPR leadership" on contract decisions.[125]

Moreover, at this time in late 2019, Emory had not yet submitted a white paper, draft budget, or formal proposal to initiate the contract review process by BARDA. As such, Emory (through [redacted] and [redacted] was not necessarily limited to whom in ASPR or BARDA it could speak with about the potential of its product, and Government personnel were not necessarily prohibited from entertaining such communications by the PIA or agency policies, as the procurement and evaluation process had not yet formally begun.

Furthermore, [redacted] follow-up inquiries do not support a finding that BARDA's independent scientific integrity review process was compromised as again, no white paper, draft budget, or formal proposal had been submitted as of late 2019 for contract review, much less scientific review. To the extent that the idea of funding EIDD 2801 was being discussed, any consideration by BARDA for contract award would presumably then be subject to proper

[123] OIG does not opine as to the scientific integrity or validity of [redacted] assertions regarding the safety of EIDD 2801. This finding is solely limited to a review of the contracting process for EIDD 2801 and whether there were violations under Federal procurement laws, regulations, or policies.

[124] In [redacted] interview, [redacted] stated that "at that time, anything that looked promising, uh, as far as an antiviral drug, um, I listened to...." *See* [redacted] interview transcript at 89.

[125] [redacted] interview transcript at 59, 60.

scientific review by the agency once a white paper and projected budget or proposal was submitted, which as discussed in the following section regarding Ridgeback's efforts on behalf of EIDD 2801, subsequently occurred.

Despite the allegations of undue pressure to award Emory a contract for EIDD 2801 in late 2019, neither ASPR nor BARDA awarded such a contract. Ultimately, EIDD 2801 was eventually marketed as molnupiravir by Merck and Ridgeback Biotherapeutics. On June 7, 2021, Merck was awarded Contract No. W911QY21C0031 by the Department of Defense (DoD), Army Contracting Command, Natick, Massachusetts, and received additional funding support from ASPR and BARDA at that time, almost 2 years after the allegations were made concerning undue pressure on BARDA to award a contract for EIDD 2801.[126]

Accordingly, OIG found that the allegation that [redacted] compromised the independent scientific integrity of the review and contract award process and inappropriately pressured [redacted] to award a contract to Emory in late 2019 for the antiviral drug EIDD 2801, was unsupported by the evidence.

v. Ridgeback Biotherapeutics (2020):

After its initial attempts to promote EIDD 2801, Emory subsequently partnered with Ridgeback on the further promotion and development of EIDD 2801. The complaint alleges [redacted] and ASPR staff directed BARDA to award a contract to Ridgeback for EIDD 2801 within 24 hours, on or about April 8, 2020. It also describes how on April 7, 2020, [redacted] Ridgeback [redacted] contacted [redacted] BARDA S[redacted] to inquire about "the funding proposal [redacted] had submitted to ASPR Next for a clinical trial that was scheduled to begin the following day." [redacted] states that [redacted] informed [redacted] that [redacted] ASPR [redacted] "had directed [redacted] to work with [redacted] to secure approximately $100 million in pre-award funding because ASPR Next contracting staff were overwhelmed" and that "[redacted] had called [redacted] the previous evening to ask [redacted] to 'accelerate [the clinical trials] as fast as possible.'"

According to [redacted] then directed [redacted] to fund the Ridgeback proposal as quickly as possible, and preferably within 24 hours. This directive concerned [redacted] for several reasons: (a) an in-depth analysis for an award of this magnitude would take 10–20 days, (b) an award would require the submission of a BAA white paper or full proposal, and (c) BARDA did not have the personnel resources to manage a time-sensitive award in conjunction with their COVID-19 responsibilities.

[126] *See* https://www.hhs.gov/sites/default/files/merck-mab-therapeutic-production-contract.pdf. *Also see* https://www.merck.com/news/merck-announces-supply-agreement-with-u-s-government-for-molnupiravir-an-investigational-oral-antiviral-candidate-for-treatment-of-mild-to-moderate-covid-19/.

a) ASPR did not compromise the contract award process and did not inappropriately pressure BARDA to award Ridgeback a contract within 24-hours.

Upon review of the evidence, ultimately, no contract award was issued or approved by BARDA or ASPR to Ridgeback at this time. Accordingly, OIG found that the allegation that [redacted] and ASPR staff had directed BARDA to award a contract to Ridgeback for EIDD 2801 within 24 hours, on or about April 8, 2020, was unsupported by the evidence.

OIG determined that potential confusion in the complaint surrounding the Ridgeback allegation existed. Specifically, OIG identified three separate areas of confusion: the request for a precontract award (1) *spend plan agreement* versus a (2) *contract award*, and (3) whether there was a 24-hour directive for contract award. It is plausible that the concerns over the alleged directive to award a contract to Ridgeback within 24 hours involved Ridgeback's request for a precontract award spend plan agreement, as this request aligns with the timeline associated with the alleged 24-hour award directive.[127] Such a request for authorization would be much simpler than a request to review and award a contract.

Generally, Government contractors may only recover costs incurred *after* a contract is awarded. However, precontract costs are exempt from this rule if they are incurred in anticipation of a specific contract award, are necessary to meet the proposed contract delivery schedule, would have been allowable if incurred after the date of the contract, and meet the circumstances prescribed by the cost principle.[128]

The cost principle advises (but does not require) that contracting officers and contractors seek an advance agreement, also known as a precontract award spend plan agreement, to avoid disputes over the reasonableness, allocability, and allowability of precontract costs.[129] Nevertheless, many agency-specific FAR supplements require the agency to obtain an advance agreement for precontract costs to be allowable. The HHS Acquisition Regulation (HHSAR) does not reference precontract costs or advance agreements, which means that HHS does not require advance agreements, but that would not prevent a company from seeking one to avoid assuming too much risk prior to an actual contract award. In the absence of such an agreement on costs, the contractor would need to subsequently negotiate or litigate with the Government to recover any precontract costs.

On April 3, 2020, Ridgeback submitted its request for a pre-contract award spend plan agreement by email, to the ASPR Next inbox, where it had previously submitted a copy of its proposal, requesting expeditious approval to support a planned independent clinical trial for EIDD 2801 the following week. In this email, [redacted] explained that Ridgeback had been directed to submit its proposal to the ASPR Next inbox and the "ASPR Next funding Mechanism by ASPR (and

[127] FAR 31.205-32 Precontract Costs (addressing costs incurred prior to the award of a contract being eligible for reimbursement under a subsequent contract award under certain conditions); and FAR 31.109 Advance Agreements (addressing the negotiation of written agreements identifying allowable, allocable, and reasonable costs prior to a subsequent contract award).
[128] FAR 31.205-32.
[129] FAR 31.109.

with BARDA's direction to Emory in November 2019 that it could not fund EIDD 2801 prior to entering the clinic)." However, during [redacted] interview, [redacted] clarified that Ridgeback had submitted its proposal (and subsequent documentation) to the ASPR Next inbox because it was unclear where its EIDD 2801 proposal should go, but since the CARES Act (signed into law on March 27, 2020) appropriated COVID-related funds to ASPR, it would submit its proposal to the ASPR Next inbox.[130] [redacted] indicated that [redacted] did not recall whether [redacted] or ASPR leadership otherwise directed Ridgeback to do so.[131]

[redacted] subsequently sent a follow-up email to the ASPR Next inbox on April 6, 2020, addressed "To whom it may concern," and requesting an update on [redacted] precontract spend plan agreement proposal as Ridgeback's clinical trial was expected to start on April 8.[132] On April 7, 2020, [redacted] emailed [redacted] directly to request action on the precontract spend plan authorization, as further discussed in the next section, below.[133] [redacted] did not make a request for contract award itself, acknowledging that any costs incurred by its independent clinical trial, pursuant to an approved precontract spend plan authorization would be unrecoverable by Ridgeback if its EIDD 2801 contract proposal was subsequently unsuccessful.[134] Accordingly, [redacted] communications did not request the immediate award of a contract, but rather, expeditious approval of a precontract spend plan agreement by ASPR, so that it could begin incurring potentially recoverable costs on its already planned and upcoming independent clinical trial.

Furthermore, OIG could not independently confirm that a 24-hour directive was issued to BARDA to award a contract to Ridgeback.[135] In response to OIG requests, [redacted] was able to provide emails that explained [redacted] logistical concerns with being asked to award a contract within a condensed timeframe. However, those emails indicate that after raising [redacted] initial concerns, [redacted] was subsequently questioned by [redacted] BARDA [redacted] about the 24-hour contracting directive. [redacted] could not provide written documentation of such a directive, instead informing [redacted] that the directive was provided orally by [redacted] at a meeting with the ASPR [redacted] BARDA [redacted] and [redacted] did, however, upon direction by [redacted] and [redacted], document the alleged oral directive in an email for record, along with his logistical concerns toward awarding a contract within a 24-hour timeframe, and agreed to email his concerns to [redacted] and other members of ASPR and BARDA leadership.

Notably, [redacted] in summarizing the discussion in which BARDA was allegedly directed to award a contract to Ridgeback within 24-hours by [redacted] and the HCA, did not indicate that such

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[130] [redacted] interview transcript at 4, 6.

[131] *Id.* at 6.

[132] [redacted] email to ASPR Next mailbox, subject: FW: Request for a Pre-Contract Spend Agreement, dated April 6, 2020.

[133] [redacted] email to [redacted] subject: Request for a Pre-Contract Spend Agreement, dated April 7, 2020.

[134] [redacted] email to ASPR Next mailbox, subject: Request for a Pre-Contract Spend Agreement, dated April 3, 2020; [redacted] email to ASPR Next mailbox, subject: FW: Request for a Pre-Contract Spend Agreement, dated April 6, 2020; *Id.*

[135] [redacted] provided emails where [redacted] discussed receiving a verbal directive to award a contract to Ridgeback within a 24-hour timeframe during a meeting with [redacted] ASPR [redacted] and BARDA [redacted]

a timeline was actually given. Instead, according to [redacted] the BARDA Director of Contracting asked whether BARDA was being tasked to conduct a Ridgeback procurement, to which the answer was "yes."[136]

Regardless of whether a 24-hour directive to award a contract was issued or not, it does not appear that such a directive in this instance would in and of itself be inappropriate. Here, there is no indication in the record that such an award timeline was further pursued by [redacted] or ASPR staff once BARDA and ASPR contracting staff input was provided, or that any directions were given to disregard any standing policies or procedures.[137] Instead, BARDA, in coordination with ASPR contracting staff, initially set up a plan for ASPR contracting to establish a technical evaluation panel to review Ridgeback's proposal the following week (week of April 13) as ASPR personnel were not available until then.[138] Meanwhile, [redacted] proposed that BARDA would review Ridgeback's precontract spend plan authorization request.[139] However, it appears that before a course of action was implemented, [redacted] had reached out to the National Institute of Allergy and Infectious Diseases (NIAID), which,

> has made available their contract with Emory to support the phase 1 SAD study. They have offered to change the wording of the clinical protocol from influenza to COVID-19 since a phase 1 SAD is in healthy adults. They have also offered to allow any changes to the protocol. The group at NIAID is willing to support the phase I SAD, the clinical site is open and they can accommodate. At this point, it is the decision of Emory and Ridgeback. However, NIAID has done everything to accommodate the two groups. They also stated that they submitted their proposal to ASPR Next and NOT BARDA. Stating several times that ASPR Next is within the ASPR Office and different from BARDA. Which NIAID fully understands. The ball is in the court of Emory and Ridgeback.[140]

Ultimately, no contract award or precontract spend plan agreement were issued or approved by BARDA or ASPR. Accordingly, OIG found that the allegation that [redacted] and ASPR staff had directed BARDA to award a contract to Ridgeback for EIDD 2801 within 24 hours, on or about April 8, 2020, was unsupported by the evidence.

OIG also could not confirm the existence of the request for, and direction to secure $100 million in pre-award funding. Prior to contacting [redacted] sent two emails to the ASPR Next

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[136] [redacted] email to [redacted] subject: RE: Follow up RE ASPR Next Requirement Concerns, dated April 13, 2020 (recapping meetings that occurred on April 7, 2020, and April 8, 2020).

[137] *See* for example, email from [redacted] to [redacted] and [redacted] cc'ing [redacted] RE: Status update re oral antiviral, dated April 9, 2020, at 9:16 a.m. (in response to BARDA and ASPR contracting efforts to establish a technical evaluation panel and approve the precontract spend agreement, stating: "Anyway, just want to make sure a technical evaluation panel is queued up and if deemed appropriate proceeds with haste. Appreciate all of your guys' work on this and the many fast-moving items—do it fast, right, coordinated, and legal.").

[138] [redacted] email to [redacted] subject: RE: Follow up Re ASPR Next Requirement Concerns, dated April 13, 2020.

[139] *Id.*

[140] [redacted] email to [redacted] and cc'ing [redacted] subject: NIAID assistance with clinical study, dated, April 9, 2020 (SAD is short for Single Ascending Dose).

general mailbox, with the subject line "Request for a Pre-Contract Spend Agreement."[141] In her email, dated April 3, 2020, [redacted] states that Ridgeback desperately needed guidance on whether to submit its pre-contract proposal to ASPR Next or BARDA to ensure that it was submitted to the correct office. The email included as an attachment, a draft precontract spend plan agreement request in the amount of $15,005,150.

[redacted] states that a member of [redacted] team had spoken to [redacted] that morning and had said that ASPR contracting staff were "underwater," and that [redacted] planned on reaching out to [redacted].[142] OIG did not identify any evidence indicating [redacted] actually reached out to [redacted] or instructed [redacted] or [redacted] to do so directly themselves, despite [redacted] allegation. [redacted] also mentions in [redacted] email that "Ridgeback must receive approval from ASPR as soon as possible to incur pre-award costs to launch this trial. We completely understand that these costs are at our own risk and, if there is no contract that results from our proposal, the [United States Government] will not be responsible for these costs."[143]

[redacted] stated during [redacted] interview that Ridgeback submitted the pre-contract spend plan in March 2020 related to commercial manufacturing to ASPR Next through ASPR Next's general mailbox, but not to BARDA directly. [redacted] confirmed that [redacted] was familiar with the BARDA process, but not with the ASPR Next process.[144] [redacted] also stated during [redacted] interview that [redacted] had never met, spoken to, or received any emails from [redacted] despite [redacted] allegations.[145] [redacted] also did not recall speaking to [redacted] directly, but [redacted] did remember [redacted] contacting members of [redacted] team to communicate a sense of urgency about the project.[146] [redacted] had spoken to [redacted] and [redacted] about Ridgeback's proposal. [redacted] and Ridgeback had previously executed an Advance Agreement for precontract costs with BARDA for their Ebola work and were seeking to follow that same procedure with EIDD 2801.[147]

During [redacted] interview, [redacted] confirmed that [redacted] had called [redacted] regarding Ridgeback's ASPR Next submission via email. [redacted] told [redacted] was not aware of the proposal.[148] and [redacted] followed up the conversation with an email to [redacted] thanking [redacted] for [redacted] willingness to help guide Ridgeback.[149]

[redacted] also confirmed during [redacted] interview that [redacted] was aware of the Ridgeback proposal for EIDD 2801. However [redacted] was unaware whether any discussions with [redacted] and [redacted] regarding the Ridgeback proposal occurred, but that [redacted] was referenced in an email from

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[141] [redacted] email to ASPR Next mailbox, subject: Request for a Pre-Contract Spend Agreement, dated April 3, 2020; and [redacted] email to ASPR Next mailbox, subject: Request for a Pre-Contract Spend Agreement, dated April 6, 2020.

[142] [redacted] email to [redacted] subject: FW: Request for a Pre-Contract Spend Agreement, dated April 7, 2020.

[143] *Id.*

[144] [redacted] interview transcript at 12.

[145] *Id.* at 9, 10.

[146] *Id.* at 13. [redacted] that [redacted] mentions in [redacted] complaint does not state that [redacted] spoke to [redacted] directly, but instead states that [redacted] "called us," which according to [redacted] interview, meant that [redacted] had reached out to members of [redacted] team.

[147] [redacted] email to ASPR Next mailbox, subject: Request for a Pre-Contract Spend Agreement, dated April 3, 2020.

[148] [redacted] interview transcript at 11.

[149] [redacted] email to [redacted] subject: FW: Request for a Pre-Contract Spend Agreement, dated April 7, 2020.

[redacted][150] [redacted] also could not recall whether Ridgeback received any funding for the proposal, and [redacted] confirmed that neither [redacted] nor his office within BARDA had ever awarded a contract to Ridgeback under ASPR Next.[151] [redacted] was directly asked whether [redacted] and [redacted] staff circumvented [redacted] and BARDA in order to direct funding to contracts without scientific merit. [redacted] stated that [redacted] could not recall any such instances and that [redacted] had not personally experienced such actions.[152]

[redacted] confirmed that [redacted] concerns with the Ridgeback proposal were communicated to [redacted] and [redacted] via email. Although [redacted] was "uncomfortable" with BARDA awarding Ridgeback the contract, those concerns were focused on resources regarding personnel and procurement lead times.[153] [redacted] did not express concerns regarding the proposal's content or alleged pressure from [redacted] also told investigators that [redacted] did not recall hearing anything about interference from senior officials or any similar issues related to contracts in general.[154]

However, as stated above, Ridgeback was not seeking immediate contract award via these communications in early April; rather, they were seeking authorization for precontract costs. Ridgeback was seeking to obtain authorization for precontract costs which was the same process they undertook with Ebola. Ultimately, Ridgeback was not awarded a contract with either ASPR Next or BARDA.

Accordingly, OIG found that the allegation that [redacted] increasingly circumvented [redacted] and BARDA to direct money without regard to scientific merit to Ridgeback was unsupported by the evidence.

vi. Northwell Health, Inc., and Alchem Laboratories (2020):

Northwell Health (Northwell) was working with Alchem Laboratories (Alchem) on a COVID-19 treatment using hydroxychloroquine in combination with famotidine, the active compound in the heartburn drug, Pepcid AC. [redacted] wrote to the Executive Vice President of Research at Northwell, [redacted] on March 20, 2020, to request that Northwell expedite its review of its clinical trial and invited Northwell to submit a proposal to ASPR Next and instructed it to "work with COVID clinical expert, [redacted] in the preparation of this white paper and draft budget."

[redacted] who was hired to advise HHS about the Government's COVID-19 response and was not a Government employee. [redacted] asserted that even as a [redacted] was "prohibited from disclosing information about a contractor bid or proposal, or source selection information, before the award of a Federal agency procurement contract," in accordance with the Procurement Integrity Act (PIA), 41 U.S.C. § 2102(a)(3)(A). By directing [redacted] to assist Northwell, [redacted] argued that [redacted] was

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[150] [redacted] interview transcript at 12.
[151] *Id.*
[152] *Id.* at 10.
[153] [redacted] email to [redacted] dated April 13, 2020, sent at 1:41 p.m.
[154] [redacted] interview transcript at 9, 10.

"directing a member of [redacted] staff to work as an agent of both the company and the Government regarding the proposal" and was in violation of Government procurement law.

On March 31, 2020, [redacted] emailed a proposal and budget to [redacted] confirming tha[redacted]ad worked with [redacted] to prepare the submission to BARDA. According to [redacted] complaint, [redacted] had discussed this with [redacted] but not [redacted] [redacted] asserted in [redacted] complaint that [redacted] and [redacted] who oversaw BARDA's clinical team, discussed the matter of [redacted] participation and believed it to be a conflict of interest. [redacted] continued to exclude [redacted] from subsequent emails to [redacted] and [redacted] concerning the submission, instructing them to make "sure we support this trial." Ultimately, on April 14, 2020, BARDA awarded Alchem a $20.7 million contract for work to be performed by Northwell .

a) ASPR staff did not violate 41 U.S.C. § 2102(a)(3)(A) by assisting Northwell in the preparation of its white paper and draft budget.

The complaint alleges that ASPR staff violated 41 U.S.C. § 2102(a)(3)(A) by assisting Northwell in the preparation of its white paper and draft budget, however OIG did not identify conduct that violated 41 U.S.C. § 2102(a)(3)(A).

Section 2102(a)(3)(A) prohibits the disclosure of contractor bid, proposal, or source selection information before a contract award by current or former officials of the Federal Government; or persons advising or acting for or on the behalf of the Federal Government.

[redacted] was asked by [redacted] to assist Northwell with the preparation of their white paper and draft budget submissions. At this time, no proposal had been submitted. According to BARDA's standing BAA, few communications limitations existed prior to the submission of a white paper, draft budget, or full proposal.

As [redacted] provided pre-submission assistance to Northwell on behalf of the Government, this conduct did not fall within the prohibitions outlined by 41 U.S.C. § 2102(a)(3)(A). Furthermore, OIG's investigation did not reveal any indication that [redacted] was privy to or improperly revealed competing contractor bid, proposal, or source selection information while assisting Northwell.

After submission of a contractor's white paper, draft budget, or full proposal, however, prospective contractors are limited in their ability to communicate about their submissions to HHS personnel. Specifically, prospective contractors are required to communicate solely with the relevant CO when the subject of those communications involved the specifics of their submissions and the Government's evaluation thereof. OIG did not identify any evidence that any violations involving post submission restrictions occurred under this allegation or that [redacted] participated in the evaluation and award process in his capacity as a Government consultant, which would have been improper.[155]

[155] [redacted] interview transcript at 121.

Accordingly, OIG found that the allegation that ASPR staff violated 41 U.S.C. § 2102(a)(3)(A) by assisting Northwell in the preparation of its white paper and draft budget was unsupported by the evidence.

b) [redacted] and ASPR staff did not improperly exclude [redacted] from the contracting process involving Northwell/Alchem.

The complaint alleges that [redacted] and ASPR staff improperly excluded [redacted] from the Northwell/Alchem contracting process. OIG did not identify conduct that violated Federal procurement laws, regulations, or policies, or that were otherwise inappropriate.

[redacted] alleged that [redacted] and ASPR staff improperly excluded him from the contracting process in favor of continued communications with [redacted] and [redacted]. At the time, [redacted] BARDA [redacted] while [redacted] BARDA's [redacted] These two individuals were central players in the contract award process as [redacted] was responsible for the award decision and [redacted] would have been involved in the development and performance of the contract given [redacted] for BARDA's clinical teams (including the teams involved in the Northwell and Alchem clinical studies). Although OIG takes no position on the propriety of any intentional or unintentional exclusion of [redacted] from the contracting process in this matter, it does not appear that any exclusion of [redacted] would have been legally improper as [redacted] was not a contracting official and was not required to be involved in the technical aspects of the contract award process.

Accordingly, OIG found that the allegation that [redacted] and ASPR staff improperly excluded [redacted] from the Northwell/Alchem contracting process was unsupported by the evidence.

vii. Novavax (2020):

On April 10, 2020, Novavax CEO [redacted] called [redacted] office requesting to speak directly to [redacted] on its proposal for a COVID-19 vaccine.[156] Because Novavax had already submitted a BAA white paper, [redacted] instructed [redacted] assistant to inform [redacted] that BARDA could not discuss [redacted] submission. Three days later, Novavax [redacted] sent an email directly to [redacted] promoting the virtues of its vaccine and requested the opportunity to speak directly to [redacted]. Soon after learning of this email, [redacted] emailed [redacted][157] [redacted] BARDA, and [redacted] informing them that BARDA could not discuss Novavax's submission with them and that "all submissions would be reviewed by the [MCM-TE] for prioritization."[158] Additionally, [redacted] encouraged [redacted] to coordinate with [redacted] ASPR [redacted] "to determine the best way to handle this call with ASPR" as [redacted] had responded to the email on April 13, 2020, from [redacted] that [redacted] was "looking forward to" speaking with [redacted].[159] [redacted] was reassigned 4 days later and did not know whether [redacted] had ultimately spoken with representatives from Novavax about their BAA submission.

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[156] Attachment 1 at 38.
[157] BARDA [redacted]
[158] Attachment 1 at 38.
[159] *Id.* at 39.

a) [redacted] did not violate the PIA regarding the Novavax COVID-19 BAA submission.

The complaint alleges that [redacted] may have violated the PIA by responding to an email from Novavax concerning its vaccine candidate submission. With respect to this allegation, OIG did not identify conduct that violated the PIA.

As discussed earlier, the PIA is intended to prohibit the disclosure or receipt of contractor bid, proposal, or source selection information before contract award to/by unauthorized sources by both current and former Government employees with access to the information. Although the PIA establishes certain categories of prohibited conduct, notably, it does not prohibit individual meetings between an agency official and an offeror or potential offeror for, or a recipient of, a contract or subcontract under an agency procurement, provided that unauthorized disclosure or receipt of contractor bid or proposal information or source selection information does not occur.[160] In other words, a contractor and a Government official are allowed to meet and discuss matters pertaining to their company, if source selection information (such as Government procurement plans, review of submitted proposals, or competing contractor information) are not discussed.

Here, there is no indication from multiple witnesses, including [redacted] that [redacted] did in fact ultimately follow up on his email to speak to [redacted] much less any indication that prohibited source selection information was communicated. During [redacted] interview, [redacted] indicated that [redacted] reached out to the BARDA contracting office, as required by the solicitation once a proposal had been submitted, to ascertain the then-current status of the Novavax application. Ultimately, no award was issued by BARDA as Novavax was informed that Operation Warp Speed had been created by HHS and was interested in talking to Novavax about a contract, which Novavax ended up pursuing.

During the interviews multiple witnesses mentioned that it was not unusual for industry to fail to adhere to protocol when reaching out to discuss proposed submissions or submitted proposals. According to these witnesses, this appeared to occur frequently. It was incumbent on the Government official communicating with industry, however, to direct industry to the correct POC within the appropriate organization when this occurred. Interviews did not indicate that [redacted] communicated any further with [redacted] or Novavax.

Accordingly, OIG found that the allegation that [redacted] may have violated the PIA by responding to an email from Novavax concerning its vaccine candidate submission was unsupported by the evidence.

VII. ATTACHMENTS

- Attachment 1: OSC Referral Package
- Attachment 2: OAS Investigative Assist

[160] FAR 3.103-4(e)(1)-(4).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

By Email

DATE: March 17, 2023

TO: [redacted]
Special Agent in Charge
Office of Investigations, Special Investigations Branch

FROM: [redacted] [redacted] Digitally signed by [redacted] Date: 2023.03.17 12:21:15 -04'00'
Regional Inspector General for Audit Services

SUBJECT: Investigative Assist: *Contracts for the Administration for Strategic Preparedness and Response*, OAS A-03-20-05004

This memorandum conveys the results of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services (OAS) investigative assist work requested by the OIG Office of Investigations (OI), Special Investigations Branch (SIB).[1] Our work relates to SIB's investigation into allegations that the Administration for Strategic Preparedness and Response (ASPR) awarded some contracts inappropriately.[2] Specifically, this memorandum summarizes the results of the work we performed that your office requested for 11 specific contracts negotiated by ASPR's Biomedical Advanced Research and Development Authority (BARDA).

The SIB is investigating the role that pharmaceutical industry executives, consultants, and other lobbyists have in the Federal procurement process and the approval of drugs at ASPR. This matter was referred to the SIB for investigation via a complaint originally sent directly to the HHS Office of the Secretary on May 12, 2020, by the Office of Special Counsel (OSC) under its whistleblower disclosure authority in 5 U.S.C. section 1213(c). The request cited concerns brought forth by [redacted] the BARDA Director at the time, who consented to the release of [redacted] name when [redacted] disclosed alleged improprieties related to contracts and to HHS's response to the COVID-19 pandemic. Specifically, the allegations stated that [redacted]

[1] This product is the result of an investigative assist, not an audit. We did not follow the audit requirements set forth in generally accepted government auditing standards created by the Comptroller General and the Government Accountability Office. As such, this product is not an audit report.

[2] In 2022, the Office of the Assistant Secretary for Preparedness and Response became an HHS Operating Division and was renamed the Administration for Strategic Preparedness and Response.

[redacted] and other senior HHS leaders engaged in contracting improprieties when awarding contracts to private corporations against the recommendation of BARDA's technical evaluation panels and circumvented [redacted] and BARDA to direct Federal funds to drug development contracts without appropriate scientific review.

Having received this request, SIB in turn requested investigative assistance from OAS. We initiated our investigative assist in July 2020. Specifically, SIB requested that we perform work related to the pre-award procedures for 11 contracts to determine whether ASPR/BARDA complied with Federal requirements.

Based on our analysis of the 11 contracts, we concluded that ASPR/BARDA complied with Federal requirements when performing pre-award procedures for the specific contracts identified by SIB.

If you require additional assistance, you may contact me, or your staff may contact [redacted] Assistant Regional Inspector General, at [redacted]@oig.hhs.gov.

Attachment

INTRODUCTION

BACKGROUND

Administration for Strategic Preparedness and Response

The mission of the Administration for Strategic Preparedness and Response (ASPR) is to protect Americans from 21st century health security threats.[3] ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals; health care coalitions; biotech firms; community members; State, local, Tribal, and territorial Governments; and other partners across the country to improve readiness and response capabilities. In 2022, ASPR was elevated to an Operating Division within the Department of Health and Human Services (HHS), enabling it to mobilize a coordinated national response more efficiently and effectively during future disasters and emergencies. The mission of ASPR, to protect Americans from 21st century health security threats, remains.

Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) was established to aid in securing our nation from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases. BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the Food and Drug Administration and inclusion into the Strategic National Stockpile. A portion of the annual appropriations ASPR receives are designated for use specifically by BARDA for expenses necessary to support advanced research and development.

ASPR and BARDA both award contracts to accomplish their mission.

Office of Investigations and Office of Audit Services Involvement

The HHS Office of Inspector General (OIG), Office of Investigations (OI), Special Investigations Branch (SIB), is investigating several alleged improprieties related to contract award and administration by HHS. The Office of Special Counsel (OSC) referral grouped the alleged improprieties into five allegations to be investigated: (1) the dismissal of BARDA's requests for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic; (2) the failure to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic; (3) pressure on BARDA to promote the use of chloroquine and hydroxychloroquine as a therapeutic treatment for COVID-19; (4) contracting improprieties when awarding contracts to private corporations against the recommendation of the technical evaluation panel and (5) staff circumventing BARDA to direct federal funds to drug development contracts without appropriate scientific review both before and after the emergence of COVID-19.

[3] During the period relevant to our investigative assist, ASPR was the Office of the Assistant Secretary for Preparedness and Response.

SIB requested the OIG Office of Audit Services' assistance in identifying whether specific contracts complied with Federal pre-award procedures. Specifically, SIB requested our assistance in determining whether alleged improprieties, which concerned contract award and administration, were substantiated (see allegations four and five above). We initiated our investigative assist in July 2020.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether ASPR/BARDA complied with Federal requirements when performing pre-award procedures for specific contracts identified by SIB.

Investigative Assist Scope

To respond to the SIB investigative assist request, we analyzed 11 contracts identified by SIB and addressed in specific allegations mentioned in the OSC referral. Of the 11 contracts, 2 were awarded as sole-source contracts. The remaining nine contracts were negotiated competitively using either a Request for Proposal (RFP) or a Broad Agency Announcement (BAA).[4] We analyzed the pre-award process for these 11 contracts. See Figure 1 on the next page.

[4] BAAs are competitive solicitation procedures used to obtain proposals for basic and applied research and the part of development not related to the development of a specific system or hardware procurement.

Figure 1: Contracts for BARDA SIB Investigative Assist

Contractor	Award Method*	Contract Services Procured	Contract Value
Aeolus Pharmaceuticals	C	Develop Drug	$21,866,469
Alchem Laboratories Corp.	C	Controlled trial	20,747,018
Alvogen, Inc.	C	Purchase Drug	429,628,066
Amgen	C	Manufacture Drug	154,395,969
Emory University, #1	C	Develop Drug	15,891,151
Emory University, #2	C	Develop Drug	699,376
Emergent Biodefense	C	Manufacture drug	910,710,699
Novavax, Inc.	C	-	‡
Partner Therapeutics	S	Manufacture/Store drug	54,999,800
Partner Therapeutics (novation)†	C	Manufacture/Store drug	2,128,609
Ridgeback Therapeutics	S	Manufacture Drug	14,000,000
Totals			**$1,625,067,157**

* C = Competitive award, S = Sole-source award
† Through novation procedures, ASPR transferred to Partner Therapeutics two task orders for one contract that was originally awarded competitively.
‡ ASPR/BARDA did not award a contract to Novavax because Novavax chose to instead pursue an award through Operation Warp Speed.[5] ASPR/BARDA, however, still completed the pre-award procedures.

Investigative Assist Methodology

To accomplish our objective, we:

- obtained contract files from SIB for 11 contracts for which assistance was requested;
- determined the type of award for each contract;
- identified and reviewed the relevant Federal Acquisition Regulation (FAR) criteria for each contract;
- reviewed the following contract documentation, if applicable for each contract:
    - Request for Proposal (RFP),
    - Broad Agency Announcement (BAA),
    - contract award,

[5] Operation Warp Speed, officially announced on May 15, 2020, was a public–private partnership initiated by the U.S. Government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

- Technical Evaluation Panel (TEP),
- market research,
- posting to Government point of entry,
- sole-source justification for other than full and open competition, and
- novation agreement[6] documentation; and

- concluded whether pre-award procedures were performed in accordance with the FAR.

We performed this investigative assist for SIB between July 2020 through February 2023.

RESULTS OF INVESTIGATIVE ASSIST

Federal Requirements

The FAR is the primary regulation that all Federal Executive agencies must follow when acquiring goods and services with appropriated funds. The FAR provides policies and establishes responsibilities for recording and maintaining contract information. Personnel responsible for contracting, contract administration, and payment must establish files that contain a record of all contractual actions, and these files must be readily accessible to principal users (FAR 1.101, 4.801, 4.802).

Contracting officers, appointed by the agency head, are the only individuals authorized to enter, administer, or terminate contracts. Among other things, contracting officers must publicize contract actions to increase competition (post to a Government point of entry) and conduct market research to arrive at the most suitable approach to acquiring, distributing, and supporting supplies and services. Market research appropriate to the circumstances should be completed prior to solicitation (FAR 1.602, 5.002, and 10).

The FAR also specifies requirements for both competitive and sole-source awards. It states that contracting officers must promote and provide for full and open competition in soliciting offers and awarding Government contracts and provides seven circumstances permitting the award of a contract using noncompetitive procedures (FAR 6.101).

Awarding contracts using noncompetitive procedures (sole source) is permissible provided the contracting officer justifies the use of such actions in writing. Specifically, sole-source contracts may only be awarded if there is: (1) only one responsible source, (2) an unusual and compelling urgency, (3) an industrial mobilization requirement, (4) an international agreement, (5) a statute

[6] A novation agreement is a legal contract that transfers the contractual obligations of one party to a third party or replaces a contractual obligation with another one. All parties involved—generally a transferee, transferor, and counterparty—must agree to these changes.

authorization or requirement, (6) a national security requirement or (7) public interest for other than full and open award. Justifications must contain sufficient facts and rationale to justify the use of the specific authority cited (FAR 6.301, 6.302 and 6.303).

Any contract awarded using other than sealed bidding procedures is considered a negotiated contract. The FAR further describes some of the acquisition processes and techniques in designing competitive acquisitions in addition to selecting a contract type appropriate to the circumstances of the acquisition (FAR 6.1, 15, and 16).

For competitively awarded contracts, the Government must request proposals from potential contractors. Two methods for requesting proposals are RFPs and BAAs. RFPs are used in negotiated acquisitions to communicate Government requirements to prospective contractors and to solicit proposals. BAAs are competitive solicitation procedures used to obtain proposals for basic and applied research and the part of development not related to the development of a specific system or hardware procurement (FAR 6.102, 15.203, and 35.016).

Agency heads are responsible for source selection. The contracting officer is designated as the source selection authority, unless the agency head appoints another individual for a particular acquisition or group of acquisitions. According to the FAR, the source selection authority must: (1) establish a TEP, (2) approve the source selection strategy or acquisition plan, (3) ensure consistency among the solicitation requirements, (4) ensure that proposals are evaluated based solely on the factors and subfactors contained in the solicitation, (5) consider the recommendations of advisory boards or panels (if any), and (6) select the source or sources whose proposal is the best value to the Government (FAR 15.303).

The contracting officer, designated as the source selection authority, should consider numerous factors when awarding a contract. All factors and significant subfactors that will affect contract award and their relative importance should be stated clearly in the solicitation. Those factors should represent the key areas of importance and emphasis to be considered in the source selection decision and support meaningful comparison and discrimination between and among competing proposals. Factors to consider may include price or cost analysis, type and complexity of the requirement, urgency, the contractor's technical capability, financial responsibility, and acquisition history. Documentation relevant to each contract award will differ based on the type of award (FAR 16).

If a contractor wishes the Government to recognize a successor in interest to its contracts, the contractor must submit a written request to the responsible contracting officer. This novation process is the consensual replacement of a contract, when a new party takes over the rights and obligations of the original party, thus releasing the latter from that obligation (FAR 42).

ASPR/BARDA COMPLIED WITH PRE-AWARD REQUIREMENTS

Based on our analysis of the 11 contracts provided to us by SIB, we conclude that ASPR/BARDA complied with Federal requirements when performing pre-award procedures. Specifically, ASPR complied with pre-award provisions of the FAR for two sole-source

contracts and eight competitively negotiated contracts and complied with FAR novation procedures for one contract. Due to the variable factors when awarding a contract, the documentation we reviewed was based on the particular contract being negotiated, and not all of the same FAR sections were applicable to all of the contracts we reviewed. See Figure 2 for the FAR requirements we analyzed for each contract.

Figure 2: Work Performed for SIB-Identified Contracts

Contractor	FAR Section						
	6, 35	16	15	10	5	6.3	42
Sole Source							
Partner Therapeutics		√		√	√	√	
Ridgeback Therapeutics		√		√	√	√	
Competitive							
Aeolus Pharmaceuticals	√	√	√	√	√		
Alchem	√	√	√	√	√		
Alvogen, Inc.	√	√	√	√	√		
Amgen	√	√	√	√	√		
Emergent Biodefense	√	√	√	√	√		
Emory University, #1	√	√	√	√	√		
Emory University, #2	√	√	√	√	√		
Novavax, Inc.	√		√	√	√		
Novation							
Partner Therapeutics (novation)		√			√		√

Note: Shaded areas indicate FAR sections that were not required for the particular contract and do not indicate missing documentation.

FAR Section	LEGEND
Part 6, 35	Proper RFP/BAA
Part 16	Proper or complete contract awarding documents
Part 15	Proper Technical Evaluation Panel
Part 10	Appropriate market research documentation
Part 5	Appropriately posted to Government point of entry
Part 6.3	Proper sole-source documentation
Part 42	Appropriate novation agreement documentation

In conclusion, ASPR and BARDA complied with relevant Federal requirements for the 11 contracts when they:

- awarded 9 contracts,
- completed pre-award procedures for 1 contract, and
- performed novation procedures for 1 contract.