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The Special Counsel

December 10, 2024

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-20-000743

Dear Mr. President:

I am forwarding to you a report transmitted to the Office of Special Counsel (OSC) in response to the Special Counsel's referral of disclosures of wrongdoing at the Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response, Washington, D.C. I have reviewed the disclosure, the agency report, and whistleblower comments and, in accordance with 5 U.S.C. §1213(e), I have determined the report contains the information required by statute and the findings appear reasonable. The HHS Office of Inspector General (OIG) investigated the allegations. As summarized below, the agency partially substantiated the allegations, including that the distribution of donated hydroxychloroquine to distributors and retail pharmacies during the pandemic posed a substantial and specific danger to public health and safety by expanding the supply of the drugs available for off-label prescribing for COVID-19, which FDA assessed as too risky for outpatients.

The whistleblower, former Biomedical Advanced Research and Development Authority (BARDA) Director [redacted], who consented to the release of his name, disclosed improprieties related to HHS's response to the COVID-19 pandemic and agency contracts. Specifically, [redacted] reported five allegations that OSC referred to HHS for investigation. First, [redacted] alleged that HHS officials dismissed BARDA's requests for necessary resources to begin vaccine, drug, and diagnostic development in response to the COVID-19 pandemic. Second, he alleged that HHS leadership failed to acknowledge and respond to nationwide scarcities of critical supplies necessary to respond to the COVID-19 pandemic.

With respect to the first two allegations, although the agency found that there were delays in the procurement of medical countermeasures and supplies in the initial stages of the pandemic, the investigation did not find that the delays were due to employee misconduct or that concerns were dismissed. The agency determined that HHS officials took many actions to

obtain both financial and nonfinancial resources needed to begin development of medical countermeasures, including submission of requests for emergency funding from Congress in March 2020, procurement of virus sequencing and samples for medical countermeasure development, and creation of the Medical Countermeasures Task Force, which was responsible for exploring potential therapeutics and candidates for vaccine development.[1]

Additionally, the agency concluded that HHS officials began taking steps to address supply shortages as early as January 2020, including N95 masks, needles and syringes, and testing swabs. However, the report noted that until the supplemental funding became available in mid-March 2020, the agency's ability to immediately procure needed supplies was limited. Moreover, the investigation found that HHS addressed the shortages even prior to receipt of the supplemental funding.

The third allegation raised by [redacted] was that senior HHS officials pressured BARDA to promote the use of chloroquine and hydroxychloroquine as therapeutic treatments 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. The agency partially substantiated this allegation. Specifically, the report detailed that between March 10 and 28, 2020, HHS career and non-career officials were internally reviewing the use of chloroquine and hydroxychloroquine as therapeutic treatments for COVID-19 because a chloroquine manufacturer offered to donate the drug to HHS to include in its Strategic National Stockpile (SNS). The agency substantiated that the donated chloroquine was produced in factories in India and Pakistan that were not inspected by FDA but found that FDA officials tested samples of the donated chloroquine and determined that the drug met established U.S. Pharmacopeia standards and authorized its importation. Thus, the report concluded that there were no safety risks associated with the manufacture of the drugs.

Additionally, the report noted that when HHS officials urged [redacted] to apply for an expanded access investigational new drug (IND) status with the FDA for the donated chloroquine, [redacted] disagreed with this approach due to safety concerns and the lack of clinic testing. Instead, [redacted] suggested that BARDA and FDA officials transition from the use of an IND to an Emergency Use Authorization (EUA). The report explained that with the EUA (issued on March 28, 2020) attached to the use of chloroquine and hydroxychloroquine, the FDA could implement several conditions 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 reactions. Following the issuance of the EUAs, HHS officials authorized the distribution of the drugs from the SNS to distributors and retail pharmacies beginning on April 5, 2020.

[1] The report noted that before supplemental emergency response funding became available in mid-March 2020, HHS career officials explained that BARDA was only able to take limited steps toward medical countermeasure procurement and development, such as securing donations and amending a few existing contracts, to help expedite future medical countermeasure development.

However, the FDA ultimately revoked the EUAs for chloroquine and hydroxychloroquine on June 15, 2020, and stopped distribution of the drugs for purposes of treating COVID-19.

Notwithstanding these events, the report substantiated that the distribution of donated hydroxychloroquine from the SNS to distributors and retail pharmacies posed a risk to public health and safety. The report found that by distributing donated hydroxychloroquine to retail pharmacies, HHS expanded the supply of the drugs available for off-label prescribing for COVID-19, which FDA assessed as too risky for outpatients. However, the agency found that HHS officials also reported that the donated hydroxychloroquine was being distributed for FDA-approved uses, such as for the purpose of addressing shortages of the drug for rheumatoid arthritis. Thus, the investigation could not conclude that the distribution of donated hydroxychloroquine constituted wrongdoing. Nevertheless, the report recommends that the agency examine its policies to ensure added overview of public health and safety concerns in association with future EUAs. The report also recommends that the agency 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.

Fourth, [redacted] asserted that Assistant Secretary for Preparedness and Response (ASPR) [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 well before the emergence of COVID-19. These irregularities specifically refer to contracts associated with Aeolus Pharmaceuticals (Aeolus), Alvogen, Inc. (Alvogen), Partner Therapeutics, Emory University, and Ridgeback Biotherapeutics LP. Relatedly, in his fifth allegation, [redacted] alleged that [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. As to both allegations, the investigation did not find any evidence of contracting improprieties, concluding that technical and scientific review processes were properly followed, and that decisions for contracting proposals also considered administrative, business, and strategic factors prior to award.

In his comments, [redacted] disputed the report's findings, specifically in the decision-making processes of the prior Administration and non-career HHS officials. Overall, [redacted] maintains that HHS officials overruling career scientists' analyses throughout the early stages of the pandemic led to a deficient response and a breach in trust of public health institutions.

I commend [redacted] for bringing forward these important allegations. I credit his reporting of these concerns at a time of significant public scrutiny concerning our nation's response to the COVID-19 pandemic. As required by 5 U.S.C. § 1213(e)(3), I have sent a copy of this letter, the report, and the whistleblower's comments to the Chair and Ranking Members of the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on

Energy and Commerce. I have also filed redacted copies of these documents and the redacted referral letter in our public file, which is available at www.osc.gov.

Respectfully,

Hampton Dellinger

Hampton Dellinger
Special Counsel

Enclosures