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By Electronic and First-Class Mail
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RE: [redacted], OSC File No. DI-20-000743

Dear [redacted]

On January 31, 2024, you shared with me three reports (the "Reports") you received from the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") regarding a whistleblower disclosure my client, [redacted], former Director of the Biomedical Advanced Research and Development Authority ("BARDA"), made to the Office of Special Counsel ("OSC") in May 2020. As you know, [redacted] is an internationally recognized expert in the fields of immunology, therapeutic intervention, vaccine, and diagnostic development. He is also one of the nation's leading experts in pandemic preparedness and response and in the design of diagnostic tools required to track pandemics, such as COVID-19. In May 2020, [redacted] reported to OSC that employees at the Office of Assistant Secretary for Preparedness and Response ("ASPR") were engaged in conduct that constituted violations of law, rules, or regulations; gross mismanagement; a gross waste of funds; abuses of authority; a substantial and specific danger to public health and safety; and censorship related to scientific research. Specifically, the Reports evaluated the following 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. 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

U.S. Food and Drug Administration ("FDA") and despite a lack of scientific data to support the use of these drugs as therapeutics.

4. Assistant Secretary for 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 both before and during the COVID-19 pandemic.

5. [redacted] and ASPR 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 Reports largely failed to substantiate [redacted] allegations.

In your letter of January 31, you invited [redacted] to comment on the Reports. This letter represents those comments. In sum, the conclusions set forth in the Reports are contradicted by substantial evidence from whistleblower accounts, government audits, media investigations, and expert analyses. This evidence demonstrates that during the critical months leading up to and following the outbreak of the COVID-19 pandemic in the United States, HHS was beset by cronyism and political appointees overruling scientific experts, resulting in a failure to gather and maintain necessary supplies and a decision to recklessly promote unproven COVID-19 treatments that likely contributed to American deaths. By dismissing [redacted] allegations, the OIG has neglected its core duty to safeguard against corruption and ethical lapses. These comments will not endeavor to address or correct every misstatement included in the Reports. Instead, these comments will provide additional context regarding three egregious failures identified by [redacted] in 2020: (1) failures in HHS's early response to COVID-19; (2) HHS's decision to promote the use of hydroxychloroquine to treat COVID-19; and (3) political interference in HHS and the resultant erosion of scientific integrity within the Agency.

I. Failures in the Trump Administration's Initial Response to COVID-19

The Reports misrepresent the facts surrounding the Trump Administration's delayed and mishandled response to the COVID-19 pandemic in early 2020. As set forth below and in [redacted] initial OSC disclosure, the evidence shows that senior HHS political leadership, particularly Assistant Secretary for Preparedness and Response [redacted], repeatedly dismissed urgent warnings from career officials like [redacted] about the grave threats posed by the novel coronavirus. The failure to heed these warnings and take decisive action led to severe shortages of critical medical supplies, a hampered testing and surveillance program, delays in vaccine and therapeutic development, and ultimately, hundreds of thousands of preventable American deaths.

[redacted] recognized the potential for a devastating pandemic from the very first days of the outbreak. *See* Addendum to [redacted] May 12, 2020 OSC Disclosure (hereinafter,

"Addendum") at 15–20. However, [redacted] disregarded his pleas, stating he was "not sure if [they were] a time sensitive urgency." *See* Exhibit 3.[1] Throughout January, as the virus spread abroad, [redacted] persistently raised alarms about vulnerabilities in the nation's personal protective equipment ("PPE") supply chain, including the N95 respirator supply. He warned of the "imminent risk" from overreliance on Chinese manufacturing and lobbied for ramping up domestic production. *See* Exhibits 6, 7, 9, 11, 12. Yet HHS officials ignored these warnings, allowing cronyism and lobbying from industry consultants to distort procurement decisions instead of heeding career experts' warnings.

When the pandemic hit U.S. shores, this inaction left the nation perilously dependent on uncertain foreign imports of substandard masks. (N.Y. Times 2020).[2] A Boston Medical Center Infectious Diseases study found that many of the imported N95-style respirators healthcare workers relied upon filtered as little as 35% of particles. (Plana et al., 2021). The same unpreparedness plagued efforts to ramp up COVID-19 testing capacity in the opening months of the pandemic. (Wash. Post 2020). Despite [redacted] repeated urgings about looming shortages of testing supplies, HHS leadership remained inert and dismissive. *See* Exhibits 30, 32–35, 39–41.

Critically, the Reports' premise—that HHS could not act without supplemental funding from Congress—is contradicted by the evidence. [redacted] informed HHS officials that the agency already had funding mechanisms and authorities enabling an aggressive early pandemic response without new appropriations, including reallocation of existing funds, modifications on current agreements, rapid use of Secretarial Transfer funds, and leveraging smaller seed awards. *See generally* Addendum at 15–20 (describing [redacted] push for action in January 2020). He also worked directly with [redacted] in the White House Trade Office to draft memos directed to the White House Task Force (including HHS Secretary Alex Azar), White House Chief of Staff, and the National Security Agency to suggest actions that could be taken immediately, some prior to supplemental funding, that would have a significant impact on getting in front of the pandemic and saving more lives. *See* Exhibits 21–22, 26–28.

Instead, HHS leadership and other Trump appointees opted to stall and obfuscate, while misinforming the American public of the true nature of the emerging threat. Numerous studies confirmed their sluggish response had cataclysmic consequences. As a University of California San Francisco Institute for Global Health report concluded, the country missed its initial chance for early intervention, for which [redacted] was forcefully advocating. The report authors concluded that "the United States failed to act early and decisively in combating the virus. Critical delays and poorly executed basic public health interventions, compounded by chronic underinvestment in public health, were key contributors to the staggering number of cases and

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[1] References to exhibits refer to the exhibits attached to [redacted] May 12, 2020 OSC Disclosure.

[2] Full references to academic or media publications are located in the enclosed bibliography.

deaths in the U.S." (Feachem et al., 2021). Analyses in medical journals concluded robust early action could have prevented 70% or more of the deaths in the pandemic's first year. (Pei, 2020; Sachs et al., 2022). Decisive action on testing and PPE, even two weeks sooner, would have saved many more lives. In sum, hundreds of thousands of American lives were lost due to the Trump HHS's complacency in the face of [redacted] alarms.

No *post hoc* excuses about funding or bureaucracy can absolve HHS's profound failure in this crisis. Rebuffing [redacted] warnings and the ensuing delays represented a reckless betrayal of public servants' duties. The OIG's decision to whitewash these failures disserves those who needlessly suffered and abdicates its responsibility to educate the Agency regarding its mistakes so that it is better prepared for the next pandemic.

II. The Reckless Authorization and Distribution of Hydroxychloroquine

The Reports' dismissal of grave public health risks from a White House-directed premature authorization and rampant misuse of hydroxychloroquine ("HCQ") and chloroquine for COVID-19 treatment represents a disregard of core duties. Evidence from clinical studies, expert analyses, and accounts shows that federal health authorities, facing intense political pressure from the Trump administration, recklessly endangered lives by enabling and, indeed, encouraging the widespread and hazardous use of unproven drugs. In addition to the immediate health consequences for those who ingested dangerous drugs and forewent more effective treatments, this deference to political pressure over medical evidence will have long-term consequences of undermining public trust in institutions meant to safeguard health.

Despite former President Trump and his allies insisting HCQ was a "game-changer" COVID-19 therapeutic, robust clinical data demonstrated the drugs' inefficacy for treatment. The United Kingdom's RECOVERY trial of over 4,000 patients found no benefit and higher mortality in HCQ recipients versus placebo. (Horby et al., 2020). The World Health Organization's 30-country SOLIDARITY trial and U.S. COALITION studies, involving over 6,000 participants, echoed these results. (WHO Solidarity, 2021; Cavalcanti, 2020). These trials and many others collectively demonstrated that HCQ, with or without azithromycin, did not provide a significant benefit in treating COVID-19 patients and, in some cases, may have been associated with increased adverse events, more severe illness, and even death. Based on this evidence, major medical societies and health authorities worldwide—including the FDA eventually revoking its Emergency Use Authorization ("EUA") in June 2020—strongly recommended against using HCQ for COVID-19.

Yet in an extraordinary malfeasance, HHS leaders bowed to President Trump's unfounded HCQ insistence over career experts' vigorous objections. The OIG confirmed that the FDA issued its hasty HCQ EUA ostensibly based on sketchy data from small, flawed studies, due to "tremendous" political pressure. *See* C. Grimm, Off. of Special Counsel, Sept. 26, 2023

Report ("Sept. 2023 Report") at 9.[3] Worse, HHS compounded this error by distributing millions of HCQ doses from unregulated plants in Pakistan and India previously cited for shocking quality lapses. (Eban, 2020).

Most concerning, the OIG confirmed that HHS leaders ignored FDA warnings about outpatient use risks, giving directives to flood pharmacies nationwide with tens of millions of HCQ tablets to be used for treating people with COVID-19, while disregarding the EUA's conditions restricting use only for closely monitored and hospitalized patients. In fact, even after the EUA was in place to restrict the use to hospitalized patients under close physician monitoring, HHS Secretary Azar announced that HCQ and chloroquine "are like any other approved drug in the United States. They may be used in hospital, they may be used in out-patient, they may be used at home, all subject to a doctor's prescription." Dr. Paul Offit, a member of the FDA Vaccine Advisory Committee and international authority on COVID-19, opined in his recent book that for all practical purposes, Secretary Azar's comments gave consent from the country's top public health department that doctors were free to prescribe a drug for COVID-19 when, in fact, that drug not only did not work to treat or prevent COVID-19, it posed a serious health risk to patients. (Offit, 2024).

President Trump relentlessly promoted unproven COVID-19 treatments, particularly HCQ and chloroquine, from March 1 to April 30, 2020. He mentioned these therapies 65 times in White House briefings and made 11 tweets about them. President Trump's endorsements had a direct, measurable impact on public interest and behavior. His tweets had an impression reach—300% higher than that of his average tweet. Google searches for these therapies spiked after his HCQ and chloroquine-focused press conference on March 19 and related tweets on March 21. Conservative media, including Fox News, amplified his message, dedicating at least two percent of their airtime to these unproven treatments. Purchases of HCQ and its substitutes on Amazon skyrocketed by 200%. (Niburski, 2020; Shaub, 2024). Thus, the President's aggressive promotion of unproven treatments, despite limited scientific evidence, influenced public opinion and led to potentially risky changes in consumer behavior.

The OIG concluded that these actions "posed a substantial and specific danger to public health and safety," fueling improper outpatient prescribing of HCQ despite FDA assessing the drug as "too risky . . . due to known and potential [HCQ] health risks." Sept. 2023 Report at 10–11. Analyses suggest HCQ distribution resulted in nearly 12,000 American deaths from cardiac complications and other severe side effects in the first months of the pandemic alone. (Pradelle et al., 2023). Despite this, because the OIG was unable to conclude that they "were made *solely* for an unapproved purpose . . . OIG could not conclude that the distributions of [HCQ] from the [Strategic National Stockpile] to retail pharmacies" violated federal law. Sept. 2023 Report at 12 (emphasis added).

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[3] The OIG issued two reports in September 2023. References to the "Sept. 2023 Report" refer to the 12-page report that "addresses OIG's review of Allegation 3 regarding chloroquine and hydroxychloroquine." Sept. 2023 Report at 2.

The OIG's attempt to downplay this disastrous series of decisions abdicates its oversight responsibilities. The purpose of the HCQ donations to the Strategic National Stockpile was clear, as evidenced in company press releases. The purpose of the HCQ distribution was similarly clear: HHS officials openly defied the FDA's own stringent patient safety regulations to advance the Trump administration's agenda. The OIG's decision to shrug its shoulders at this blatant misconduct is a dereliction of its duty. Indeed, by failing to forcefully condemn the regulatory distortion enabling willful public health jeopardy for narrow political interests, the Reports signal a lack of consequences for even egregious abuses, undermining the clinical testing and impartial review system protecting Americans. If unaddressed, it invites future transgressions by administrations prioritizing expediency and politics over scientific integrity standards and the health and safety of Americans.

The HCQ debacle illustrated how precipitously leadership lapses endanger public trust in institutions meant to safeguard health resilience. It underscored the urgent need to insulate regulatory processes and drug safety protocols from intense political pressures. Restoring trust and reinforcing America's world-leading medical institutional integrity must begin with fully reckoning with and explicitly rejecting the missteps that damaged the pandemic response. Rather than papering over affronts to medical ethics, the OIG should leverage investigative authorities to substantiate this interference pattern, ensuring such travesty never reoccurs.

III. Political Interference and Systemic Erosion of Scientific Integrity

The Reports demonstrate a gross indifference to unethical and unlawful conduct by failing to substantiate credible allegations of widespread political interference in the medical countermeasure contracting process for COVID-19. The OIG appears to have willfully ignored corroborating evidence in dismissing well-documented descriptions of HHS officials overruling career scientists' analyses to cater to private allies' interests. This evidence paints a shameful portrait: cronyism and backroom dealing took precedence over impartial, evidence-based decision-making during a crisis demanding the utmost integrity and care.[4]

[redacted] disclosure contained a litany of specific examples and insider testimony. It outlined how the BARDA technical evaluation processes were routinely pressured and at times circumvented under politically appointed HHS leaders like [redacted]. Time and again, career

[4] This misdirection of critical funding was no aberration. In an HHS OIG report issued just this month following a three-year-long audit, the OIG found that "ASPR may not have used BARDA FY 2018 and FY 2019 appropriations for their intended purpose in accordance with Federal requirements. . . . ASPR may have violated the Purpose Statute if the allocated [joint funding arrangement] expenses and the employees' salary expenses served to augment other ASPR offices' funding. Therefore, ASPR potentially violated the Antideficiency Act." Further, ASPR was dismissive in the case of the OIG's recommendations to resolve the issues it identified: "While ASPR identified actions it has taken to address the recommendations, we do not believe the actions are sufficient to ensure that BARDA appropriations are used for their intended purpose in accordance with Federal requirements." (HHS OIG 2024).

scientists' rigorous recommendations from impartial reviews were brushed aside in order to facilitate awards of lucrative contracts to companies and institutions with ties to pharmaceutical consultants enjoying undue HHS leadership influence. *See* Addendum at 4–15, 33–39. From close colleagues securing grants for dubious "miracle cure" drugs like famotidine, to the hollow basis for funneling funds toward obscure anti-viral projects tied to [redacted] own consultants, the disclosure provided a detailed window into systemic scientific integrity breakdowns driven by cronyism and regulatory capture. *Id.*

Yet the OIG report minimizes these concerning accounts while failing to substantively address the broader pattern of misconduct alleged by [redacted] and others. Furthermore, OIG investigators admittedly faced self-imposed limitations preventing timely interviews with a fuller range of government employees who might have corroborated additional undue political interference examples. For example, the OIG made no mention of anonymity, whistleblower protections, or other safeguards to potential witnesses to address the deep-seated and legitimate retaliation fears pervading agencies under Trump, as an audit by the non-partisan Government Accountability Office ("GAO") suggested had historically frustrated an open dialogue with career civil servants. (Dodaro, 2022). This failure represents a troubling lapse by the OIG and hampered its ability to corroborate the serious wrongdoing described by [redacted].

Indeed, independent investigators paint a far more troubling picture—a picture which contradicts the OIG's milquetoast conclusions. A 2020 Associated Press exposé provided on-record interviews with government health officials raising concerns about patient safety and scientific integrity over the Trump HHS's unconscionable $21-plus million grant for an outlandish plan to inject high doses of Pepcid into people to treat COVID-19. (Assoc. Press, 2020). These interviews closely corroborate the improper political interference in funding [redacted] warned of internally. Yet the OIG made no attempt to reconcile its rosy assessment with this whistleblower evidence from impartial career officials.

Further, in stark contrast to the OIG's findings, GAO audits also identified systemic scientific integrity deficiencies at HHS, which substantiated the ethical breaches described by [redacted] Specifically, a 2022 GAO audit found HHS lacked any centralized system for adjudicating political interference claims, offered no integrity violation reporting training, and, most shockingly, had a complete lack of formal policies and procedures. (GAO, 2022). These lapses created an environment ripe for abuse. The probe faulted HHS for neglecting COVID-19 contracting scrutiny despite the auditors' prior instructions, opening the door to the insider dealing and graft [redacted] alleged over BARDA procurements. (GAO, 2022).

The consequences of this wanton cronyism usurping the scientific process are self-evident and represent a significant breach of public trust. Taxpayer resources intended for rigorous, proven countermeasures were squandered on dubious academic vanity projects greenlighted through political access, not merit. Trust in public health institutions eroded as impartial, evidence-driven reviews were supplanted by shadowy private interest campaigns. American lives were jeopardized through the reckless promotion and uncontrolled outpatient

distribution of potentially harmful treatments like HCQ, championed solely to satisfy a deluded political agenda over career medical professionals' explicit safety objections. *See* Sept. 2023 Report at 10–11. Each action represents a galling dereliction of HHS's public health and security mandate.

Instead of whitewashing this vulnerability to malfeasance, the OIG should have fulfilled its mandate by sounding an alarm and advocating for reform. At minimum, HHS must heed long-delayed GAO recommendations to implement comprehensive scientific integrity protocols, including centralized violation reporting and adjudication without retaliation, mandatory staff training, and explicit firewalls insulating procurement and research decisions from improper private influence and political interference. (GAO, 2022).

Beyond simple ethics reform, accountability is paramount. Considering GAO's alarms about questionable pandemic procurement practices, together with [redacted] credible allegations and evidence of outright contracting improprieties, the GAO should conduct an independent audit of every suspect COVID-19 award. Any illegal conduct, abuse of authority, or instance of gross mismanagement must face appropriate disciplinary action, or, at the very least, a public accounting. The American people should be able to expect zero tolerance for self-dealing or corruption in the disbursement of taxpayer health security funds, especially during a once-in-a-century crisis.

Finally, to prevent similar scientific integrity breaches, decisive actions must insulate critical drug approval, procurement, and research funding processes from improper political, private consultant, or industry influence. The Trump-era commingling of these spheres with ideologically or profit-driven private interests created a public health vulnerability by exposing infrastructure to potential subversion. To regain confidence and biological threat resiliency, guardrails preserving America's world-leading medical and scientific institutional impartiality and independence are urgently needed.

The OIG's puzzling deference to HHS leadership, while ignoring substantiated evidence of impropriety, represents an injustice for Americans. Nearly 1.2 million Americans have died of COVID-19. A large percentage of those deaths were preventable. Thousands more died as a result of HHS's reckless decision to widely distribute HCQ in contravention of the medical evidence. Only comprehensive, zero-tolerance reform coupled with rigorous accountability can begin to restore integrity to this fractured system. The Reports reflect the OIG's neglect of its obligation and mandate to robustly police misconduct within the bureaucracy. The integrity and resilience of America's public health infrastructure necessitate a higher standard.

IV. Conclusion

The evidence presented in this rebuttal, drawn from official audits, whistleblower accounts, media reports, and expert analyses, directly contradicts the HHS OIG's conclusions absolving the Trump Administration of wrongdoing in its COVID-19 response. The factual

record demonstrates a dereliction of duty, with political interests prioritized over evidence-based policymaking designed to safeguard public health. From dismissed pandemic warnings to deadly medical misinformation to cronyism in vaccine and treatment procurement, the COVID-19 response represented a profound moral failing and breach of public trust. The OIG's findings downplay this litany of lapses that cost American lives. Implementing strong accountability mechanisms and shielding scientific decisions from political influence are essential measures to avoid the repeat of past failures that jeopardized public welfare during the COVID-19 pandemic. The OIG can contribute to the rehabilitation of trust in public health agencies by validating [redacted] claims and formally recognizing the grave improprieties that took place within the Department of Health and Human Services in 2020.

Sincerely,

Debra S. Katz
Attorney for [redacted]

cc: [redacted]

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