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**The Special Counsel**

July 8, 2021

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

Re: OSC File Nos. DI-20-0069

Dear Mr. President:

I am forwarding to you a report from the Department of Health and Human Services (HHS) provided to the Office of Special Counsel (OSC) in response to disclosures of wrongdoing at the National Institutes of Health (NIH), National, Heart, Lung, and Blood Institute (NHLBI) in Bethesda, Maryland. I have reviewed the agency report and whistleblower comments and, in accordance with 5 U.S.C. §1213(e), provide the following summary of the report, whistleblower comments, and my findings.<sup>1</sup> As summarized below, I have determined that the findings of the agency are unreasonable.

The whistleblower, [REDACTED], who consented to the release of his name, is a former lead Other Transaction (OT) officer, and alleged that NHLBI violated federal appropriation and funding laws and failed to exercise sufficient oversight in its use and administration of OTs.<sup>2</sup> Specifically, the whistleblower alleged NHLBI: (1) inappropriately used OTs and did not properly document its rationale and justification for using OTs; (2) did not properly monitor, manage, and oversee OTs; (3) failed to ensure that the costs it pays through the use of OTs are reasonable; and (4) violated federal appropriation and funding laws through its use of OTs.

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<sup>1</sup> OSC referred the allegations to former HHS Secretary Alex M. Azar II for investigation pursuant to 5 U.S.C. §1213(c) and (d). HHS's Office of Inspector General (OIG) conducted the investigation, which was done in the form of an audit. HHS's report, signed by HHS Secretary Xavier Becerra, is comprised of the findings from OIG and a memorandum from NIH addressing those findings.

<sup>2</sup> OTs are transactions other than contracts, grants, or cooperative agreements that give NIH flexibility when entering into agreements for "demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders." 42 U.S.C. § 284n(b). Unlike traditional instruments, OT agreements may be exempt from the Federal Acquisition Regulation and government cost accounting standards. Yet, these agreements must be awarded and administered in a way that ensures proper stewardship of federal funds.

The HHS OIG investigation found that NHLBI did not fully comply with federal requirements for OTs.<sup>3</sup> The investigation found that NHLBI did not consistently and adequately document: (1) its justification for using OTs rather than traditional award instruments; (2) that awards were fair and reasonable and incurred costs were allowable; or (3) that it complied with federal requirements for obligating annual appropriations. Thus, OIG found NHLBI lacked effective internal controls to ensure the proper stewardship of the federal funds at issue.

In response to the investigation's findings, the OIG recommended that NHLBI strengthen its internal controls for OTs by updating its policies and procedures, as follows: (1) require that OT justification memos be properly documented and explain why a traditional award instrument could not be used; (2) require that justifications for the continued use of OT authority be documented throughout the life of OT agreements at a defined frequency; and (3) specify requirements for determining and documenting: (a) the fairness and reasonableness of OT award amounts or cost estimates, (b) the allowability of related OT costs, and (c) its compliance with federal funding requirements, including the proper establishment of bona fide needs through specific work requirements before obligating funds. HHS directed that NHLBI implement the recommendations. NIH has agreed to update its policies and procedures by November 15, 2021.

Despite accepting the OIG's recommendations, HHS concluded that [REDACTED] allegations were all unsubstantiated, as conveyed in the NIH memorandum that was submitted as part of the agency report. The agency's conclusions do not appear to match the OIG's findings with respect to three out of four of the referred allegations, as follows:

(1) NHLBI has inappropriately used OTs and does not properly document its rationale and justification for using OTs. While the OIG report found that NHLBI's stated justification for using OTs is recognized by policy,<sup>4</sup> it found NHLBI did *not* always comply with policy by: (a) documenting its analysis and justification for using OTs, as opposed to conventional funding instruments, prior to issuing OT awards, and (b) tracking whether continued OT use was appropriate throughout the life of the OT agreement.<sup>5</sup>

(2) NHLBI does not properly monitor, manage, and oversee OTs. Proper management and oversight include acting in accordance with agency policy and taking the actions needed to be able to demonstrate that the agency is complying with relevant laws, rules, and regulations. The OIG found NHLBI did not fully comply with requirements and that its internal controls were ineffective.

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<sup>3</sup> OIG determined the allegations would best be answered with an audit covering the period from October 1, 2016, to September 30, 2019, during which time NHLBI awarded or co-funded \$84.3 million in federal funds for 29 OTs. The audit covered a sample of 12 NHLBI OTs totaling \$71.9 million executed during the audit period.

<sup>4</sup> Under 42 U.S.C. § 285b-3(b)(3), NHLBI may enter into OTs, as necessary, under policies established by the Director of NIH. NIH "Other Transactions" Policy Guide (May 2017) establishes the policies on OTs and NHLBI Standard Operating Procedure provides further guidance for OT authority.

<sup>5</sup> The agency's initial and continued evaluation of appropriate OT use is important because OTs are considered to be higher risk than traditional awards given that they are generally not subject to federal laws and regulations. As such, OTs should only be used when the objectives of a federally funded project cannot otherwise be accomplished.

(3) NHLBI has failed to ensure that the costs it pays through the use of OTs are reasonable. NIH policy requires that internal documentation address the reasonableness of anticipated costs of OTs, as well as the fairness and reasonableness of OT cost estimates. The OIG found NHLBI did not comply with this requirement. It also found that NHLBI had ineffective internal controls for determining fair and reasonable award amounts and allowable costs. Specifically, the OIG found NHLBI lacked policies and procedures for documenting its determinations on the reasonableness and allowability of costs. As such, the OIG concluded NHLBI could not ensure that it always maintained proper stewardship of federal funds awarded under its OT agreements.

With respect to the fourth allegation—that NHLBI violated federal appropriation and funding laws through its use of OTs—the OIG found NHLBI failed to document its compliance with federal funding requirements or to adopt comprehensive guidance with regard to the proper obligation of federal funds, compliance with the *bona fide* needs rule, or compliance with other related federal funding requirements, including the Recording Statute and the Antideficiency Act. While the OIG found that NHLBI *may* have violated the *bona fide* needs rule and, consequently, the Antideficiency Act, it could not confirm that a violation occurred because there are no legal criteria that outline how fiscal laws apply to OTs and no HHS or NHLBI policies or procedures that outline how HHS should apply fiscal law to OTs. The OIG has represented to OSC that it has asked the Government Accountability Office to clarify how the *bona fide* needs rule applies to OTs to better inform OIG’s future oversight efforts.

In his comments, the whistleblower described the OIG’s report as accurate and found that it confirmed his allegations. However, he found the agency’s conclusions were problematic due to their effort to absolve NHLBI of any wrongdoing by downplaying OIG’s findings and attributing the agency’s deficiencies to “administrative documentation issues.”

I have reviewed the original disclosure, agency report, and whistleblower comments. The results of the OIG’s audit clearly support a determination that three of the four referred allegations were, at a minimum, partially substantiated. Based on the incongruence between the OIG audit’s conclusions and HHS’s determination that those allegations were unsubstantiated, OSC requested further clarification from HHS of its position. HHS reiterated its belief that the OIG’s findings and recommendations are appropriate and supported by the record but did not change its position that the allegations were unsubstantiated. HHS’s refusal to acknowledge that three of the four allegations were, at a minimum, partially substantiated, evidences illogical conclusions and also indicates that HHS has failed to take full responsibility for the wrongdoing that has been uncovered. While OSC recognizes and applauds HHS’s willingness to update its policies and procedures to strengthen NHLBI’s internal controls for OTs, taking full responsibility for the wrongdoing is an important part of ensuring transparency and accountability in government. Accordingly, I cannot determine that the agency’s findings are reasonable. I thank the whistleblower for bringing these serious concerns about the proper stewardship of federal funds to our attention.

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As required by 5 U.S.C. §1213(e)(3), I have sent copies of this letter, the agency report, and the whistleblower's comments to the Chairs 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 §1213(c) referral letter in our public file, which is available online at [www.osc.gov](http://www.osc.gov). This matter is now closed.

Respectfully,

A handwritten signature in black ink, appearing to read "Henry J. Kerner". The signature is fluid and cursive, with a prominent initial "H" and "J".

Henry J. Kerner  
*Special Counsel*

Enclosures