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The Special Counsel

February 9, 2021

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

Re: OSC File Nos. DI-16-1945 and DI-17-1294

Dear Mr. President:

I am forwarding to you a report transmitted to the Office of Special Counsel (OSC) by the Department of Veterans Affairs (VA) in response to disclosures of wrongdoing within the VA San Diego Healthcare System (VASDHS), San Diego, California. Dr. [redacted] and Dr. [redacted] consented to the release of their names, disclosed that Dr. [redacted] chief of the Gastroenterology Section at VASDHS, placed patients at risk by performing unapproved human research. We previously closed these matters on November 2, 2018. At that time, I determined that the agency's findings did not appear reasonable and expressed my deep concern about the quality of care provided to veterans at VASDHS. The VA subsequently provided two supplemental reports updating OSC on the status of its ongoing actions related to these disclosures. I have reviewed the VA's second and third supplemental reports and the whistleblowers' comments and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the report and my findings.[1]

I. Summary of Prior Actions

The whistleblowers disclosed that Dr. [redacted] performed transjugular biopsies on seriously ill patients as part of a VASDHS research study, placing patients at serious risk. The whistleblowers asserted that transjugular biopsies do not represent the standard of care for the relevant patient population and that the biopsy samples obtained were not considered "archival" for the purposes of the approved research study protocol. The VA did not substantiate the whistleblowers' allegations and provided inconsistent explanations for its findings. For example, the VA asserted that transjugular biopsies are the standard of care for these patients, but failed to adequately reconcile this finding with the fact that, prior to the research protocol, no transjugular biopsies were performed at VASDHS. In light of the

[1]The whistleblowers' allegations were initially referred to former VA Secretary Robert J. Shulkin for investigation pursuant to 5 U.S.C. § 1213(c) and (d). VA Secretary Robert Wilkie reviewed and signed the VA's second and third supplemental reports.

serious nature of the whistleblowers' allegations, and the VA's unsatisfactory support for its investigative findings, I determined that the VA's report did not appear reasonable.

II. **VA's Second Supplemental Report**

In April 2018, the whistleblowers alleged to facility leadership that portions of liver biopsy samples intended solely for clinical diagnostic use were taken for research purposes from study participants. VASDHS leadership convened an Institutional Review Board (IRB) and initiated an internal investigation that did not substantiate these allegations. However, the IRB did determine that extra biopsy samples were taken from nine participants specifically for research purposes, in serious violation of the research protocol, which permitted only the use of excess diagnostic tissue. The IRB further determined that research staff did not obtain informed consent for these second biopsies, which could be associated with an increased risk of bleeding or other complications.

In response to OSC's continuing concerns and the VASDHS IRB's findings, the VA conducted a de novo review (2019 review) of the research protocol, which confirmed the IRB's findings. According to the second supplemental report, the relevant research and medical record documentation were significantly incomplete and inconsistent, hampering investigators' ability to identify the full universe of participants who underwent biopsies as part of the research study. Nevertheless, the VA confirmed the IRB's finding that Dr. [redacted] and other research staff collected non-archival liver tissue from study participants, above and beyond what was needed for diagnosis.

The 2019 review also confirmed the IRB's finding that research staff failed to obtain informed consent from participants for non-diagnostic biopsies. In addition, the VA found that obtaining additional tissue in this manner was associated with increased risk of bleeding and pain for participants, who were not properly notified of these risks. According to the report, these failures violated then-existing federal regulations and agency policy.[2] The report also notes that in one case researchers performed a biopsy on a participant, before obtaining informed consent.

The VA reiterated its finding that transjugular biopsies can represent the standard of care for the relevant patient population. The report noted, however, that investigators identified seven cases in which Dr. [redacted] overruled colleagues who did not recommend transjugular biopsies, and stated that those cases were sent out for external peer review. The VA further reaffirmed its determination that archival tissue did not have to be obtained prior to approval of the research protocol. The report stated that local staff used the term "archival" colloquially to refer to excess tissue no longer needed for clinical purposes, and that this meaning was in line with the language in the research protocol.

[2] 38 CFR 16.116(a); VHA Handbook 1200.05, *Elements of Informed Consent Required by the Common Rule* (May 2, 2012).

In response to these findings, the VA recommended that VASDHS establish uniform expectations and processes for clinical service lines to verify that procedures performed for research purposes receive appropriate prior approvals, with non-compliance addressed through education, training, or disciplinary action. The VA also recommended that VASDHS consult with the VA National Center for Ethics in Healthcare concerning the research use of tissue samples obtained without consent and that the IRB and research investigators ensure the use of any forms proposed in a protocol.

III. **VA's Third Supplemental Report**

In response to OSC's request for additional information, the VA provided a third supplemental report summarizing a peer review of the seven cases in which a transjugular biopsy was performed over the objection of Dr. [redacted] colleagues. The peer review found that six of the seven cases met the standard of care. The seventh case required additional review due to documentation inconsistencies. The VA later determined that the documentation in the seventh case was appropriate and that the case did meet the standard of care.

The report explained that investigators could not determine if the inconsistent dates recorded in the research records for one patient were intentional, or if they resulted from record-keeping deficiencies identified by investigators during their review. In response to this finding, facility leadership convened a workgroup, composed of individuals from clinical services commonly involved in research. The workgroup agreed on a process and communication strategy for clinical service lines to verify that research-specific procedures have received appropriate approvals prior to performing the procedures. The facility broadcast an email reminder to staff regarding existing policies for collecting and processing laboratory specimens and set the reminder as an alert on the home page of the research protocol submission system. The facility also updated its human protocol template to include questions about diagnostic specimens.

IV. **Whistleblower Comments**

In his comments, Dr. [redacted] reasserted his contention that transjugular biopsies are not the standard of care for the relevant patient population. He also highlighted specific, detailed instances of substandard care resulting from participation in the research protocol, including one example in which a patient was prevented from receiving his prescribed medication so that he could qualify for inclusion in the protocol. Dr. [redacted] again emphasized that transjugular biopsies were not regularly performed on these patients at VASDHS prior to initiation of the protocol, and also noted that they had not been performed at the VASDHS in any of more than 20 patients with decompensated Acute Alcoholic Hepatitis since the protocol funding expired in 2018.

Dr. [redacted] also described the specific complications experienced by patients who underwent unnecessary extra biopsies, including bleeding from the neck and liver, necessitating blood transfusion, and clinically deteriorating that led to a life-threatening

medical emergency. Dr. [redacted] estimated that the harvesting of extra tissue samples contributed to the death of 60 percent of the patients who underwent the procedure. Dr. [redacted] also outlined a series of statements and actions by the research principals that he characterized as deceitful.

Dr. [redacted] stated that he provided this information to the Office of Medical Inspector (OMI), along with evidence of other concerns regarding the sufficiency and authenticity of participant consent—particularly with respect to cognitively-impaired patients—and the structure of the research protocol, but OMI did not address them. Dr. [redacted] also questioned the status of the previously obtained tissue samples, stating that they should not be used in any academic or funding pursuits given the egregious flaws in the research protocol, and that all published work based on the protocol should be retracted.

In her comments, Dr. [redacted] questioned the quality, depth, and objectivity of OMI's investigation and the appropriateness of the agency's response, highlighting as a significant issue OMI's inability to determine the total number of patients enrolled as subjects in the study. Dr. [redacted] also noted that no disciplinary action was recommended or taken against the individuals responsible for the substantiated research shortcomings, including VASDHS leadership. Dr. [redacted] also offered strong support, including IRB notes, for the whistleblowers' contention that biopsies are not the standard of care for the research patient population. Dr. [redacted] further reiterated the whistleblowers' contention that the samples taken were not archival within the commonly accepted definition of the word. Dr. [redacted] cited required training for all VA staff doing human research, which defines archival as "as those samples previously obtained and on the shelf prior to the start of the study in question."

Dr. [redacted] offered a comprehensive summary of the questionable assertions contained in—and numerous violations of—the underlying research grant. She also summarized the alleged conflicts of interest that occurred at the introduction of the research protocol, including the failure to ensure IRB approval from VASDHS-affiliate University of California, San Diego, of which one of the principal investigators is also Vice Chancellor of the School of Medicine.

V. **The Special Counsel's Findings**

We appreciate the VA's willingness to provide additional reports in these matters, confirming that non-archival tissue was collected from patients without informed consent. However, we continue to have grave misgivings about the agency's broader findings regarding the research that occurred at VASDHS. The whistleblowers continue to provide consistent, clear support for their contention that transjugular biopsies are not the standard of care for the patient population included in the study. The agency's determination that the standard of care was met, in light of the whistleblowers' evidence, remains unconvincing, as do the agency's continued assertions regarding the meaning of "archival tissue." The overall picture of alleged malfeasance painted by the whistleblowers is compelling and is not sufficiently refuted by the assertions contained in the agency reports. For example, the

whistleblowers outlined several egregious flaws in the initial research protocol that raise serious questions about the integrity of the review that led to its approval. The whistleblowers also provided extensive information to support their assertion that patients were, in fact, harmed by their participation in this study.

Based upon the foregoing, I am again compelled to conclude that the findings in the VA's reports do not appear reasonable. I continue to be concerned about the quality of care provided to veterans at VASDHS, especially those who participated in the research protocol, and still question whether the IRB's review and approval of the protocol was conducted in a forthright and objective manner. I encourage the VA to consider additional critical review of the actions of the principal investigators during the lifecycle of the study and to reconsider its stance on the appropriate standard of care for the patients involved and future VASDHS patients.

As required by 5 U.S.C. § 1213(e)(3), I have sent a copy of this letter, the agency's reports, and the whistleblowers' comments to the Chairs and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed redacted copies of these documents and the redacted § 1213(c) referral letter in our public file, which is available at www.osc.gov. This matter is now closed.

Respectfully,

Henry J. Kerner
Special Counsel

Enclosure