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The Special Counsel

November 2, 2018

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

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

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), I am forwarding to you reports from the Department of Veterans Affairs (VA) based on disclosures of wrongdoing within the VA San Diego Healthcare System (VASDHS), San Diego, California. Dr. [redacted] and Dr. [redacted] who 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. Dr. [redacted] and Dr. [redacted] submitted comments on the VA's report on February 25 and February 27, 2018. I have reviewed the agency reports and whistleblowers' comments and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the reports and my findings.[1]

I. Executive Summary

The whistleblowers disclosed that Dr [redacted] is performing transjugular biopsies on seriously ill patients as part of a research protocol, 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 protocol.[2] The VA did not substantiate the whistleblowers' allegations but 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 serious nature of the whistleblowers' allegations and the VA's unsatisfactory support for its investigative findings, I have determined that the VA's report appears unreasonable.

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[1]The whistleblower's allegations were referred to former VA Secretary Robert J. Shulkin for investigation pursuant to 5 U.S.C. § 1213(c) and (d). Former Secretary Shulkin delegated the responsibility to review and sign the reports to former Chief of Staff Vivieca Wright Simpson.

[2] The whistleblowers noted that the legal definition of standard of care is the level at which the average, prudent provider in a given community would practice.

II. Allegations of Unapproved Human Research

a. The Allegations

Dr. [redacted] the [redacted], disclosed that the VASDHS Institutional Review Board (IRB) approved Dr. [redacted] proposal to perform transjugular biopsies on patients diagnosed with alcoholic hepatitis for a research study involving alcohol-related liver injuries and the presence of biomarkers. Dr. [redacted] objected because it was his belief, and the belief of other experts, that transjugular biopsies are not the standard of care for patients suffering from alcoholic hepatitis, nor are they necessary for diagnosis. The procedure also creates a serious risk of excessive bleeding and possible death.[3] Dr. [redacted] disclosed that the IRB's approval was limited to the use of archival biopsies—biopsies already in existence—but, because biopsies are not the standard of care for this population, none were available.

Dr. [redacted] further disclosed that Dr. [redacted] is not informing patients of the serious risks associated with the biopsies as required by most human research protocols and is not informing patients that their biopsy will be included in a research project. Patients are instead led to believe that biopsies are taken for diagnostic purposes only and are a necessary part of their care plans.

b. The VA's Findings

The VA did not substantiate that Dr. [redacted] is performing unapproved human research without informed consent. The agency noted, however, that the members of the IRB who approved Dr. [redacted] research were not qualified to determine whether transjugular biopsies were the appropriate standard of care for the relevant patient group. Further, the IRB did not consult independent clinical providers with experience treating patients with alcoholic hepatitis until April 2014, a full year after the research was approved.

While the approved research protocol was limited to archival biopsies, the VA argued those biopsies could be obtained prospectively for clinical purposes. At the time of the agency's report, nine patients (of a total of thirty-eight, including those in the control group) had undergone transjugular biopsies, which were shared with the research study. The VA determined that all nine patients received appropriate care given their clinical conditions.

The VA also acknowledged that VASDHS management failed to appropriately follow up on Dr. [redacted] ethical concerns about the research study. The investigation found that Dr. [redacted] management of the research team was lacking. For example, Dr. [redacted] delegated many of his research oversight responsibilities to his study coordinators, who

[3] Dr. [redacted] noted that the American Association for the Study of Liver Diseases does not recommend biopsies due to the risks associated with the procedure.

lacked appropriate training and, in one case, obtained informed consent from a patient before the IRB approved the coordinator to participate in the study. In addition, Dr. [redacted] research records were incomplete and communication between Dr. [redacted] and the study coordinators was poor.

Additionally, the underlying master protocol for Dr. [redacted] research did not include a control group of patients without liver disease. In April 2014, Dr. [redacted] submitted an amendment to the IRB to add a control group to his study. The requested amendment did not detail the goal of adding the control group, nor did it describe how the data from the control group would be analyzed. Nevertheless, the IRB approved the requested amendment.

The VA found that while patients with alcoholic hepatitis did receive consent statements that appropriately explained the parameters of the study, patients in the control group did not. Control group patients were not informed that their samples would be sent to a co-investigator's laboratory. Samples from control group patients included personally identifiable information restricted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and included a dietary questionnaire that was not fully described in the IRB-approved protocol. Despite these shortcomings, the VA determined that the research protocol's provisions for ensuring that patients were capable of providing informed consent were appropriate.

OSC requested a supplemental report clarifying the VA's findings. OSC specifically asked the VA to support its contention that transjugular biopsies were the standard of care for the relevant patient cohort, given that (1) VASDHS had performed no transjugular biopsies until *after* the approval of the research protocol and (2) experts in the facility, including Dr. [redacted] asserted at the time that transjugular biopsies were not the standard of care. The VA explained that the introduction of the research study opened the facility up to a clinical option—transjugular biopsy—it had not previously explored and that this was why they only began performing the biopsies after IRB approval. The VA also stated that in April 2014, after the IRB approved the research, it consulted the acting Chief of Liver Transplants at the University of California, San Diego (UCSD), who asserted that transjugular biopsies were the standard of care for the research patient cohort.

OSC also requested further explanation of the VA's determination that archival biopsies included biopsies obtained prospectively for clinical purposes. The VA explained that, while the whistleblowers had reviewed an initial version of the protocol that referenced archival biopsies, "IRB minutes and correspondence between the IRB and the investigator reflect IRB approval of a revised version of the protocol in which surplus tissue obtained prospectively for clinical purposes may be used for the research."

c. The Whistleblowers' Comments

Dr. [redacted] emphasized her concerns with the VA's standard of care determination. She noted that neither VASDHS nor UCSD, both part of the San Diego community, performed transjugular biopsies on patients with alcoholic hepatitis until after the initiation of the research study. The lack of transjugular biopsies prior to the study is a strong indication that transjugular biopsies are not, in fact, the standard of care for these patients. In addition, she noted that scientific literature does not support the VA's standard of care finding and that the biopsied samples do not contain sufficient histological markers to make a firm diagnosis.

Dr. [redacted] also stated that the VA's Human Research Training explicitly defines archival samples as "samples already obtained ("on the shelf") prior to the approval and initiation of any research." Thus, the prospective acquisition of samples, as described in the agency's report, would not meet the VA's definition of archival in its initial report.

Dr. [redacted] also highlighted the shortcomings with consent and the management of the research project, expressing skepticism that consent statements could be valid when collected by an unapproved study coordinator or when in violation of HIPAA privacy rules. Further, although the VA found that the research protocol included sufficient provisions to assess patients' decisional capacity, Dr. [redacted] asserted that Dr. [redacted] found no cognitive evaluations in any of the relevant patients' charts. Dr. [redacted] noted that this was unsurprising, given the lack of training and oversight of study coordinators described by the agency, but still troubling in light of the agency's conclusions.

III. **The Whistleblowers' Additional Allegations**

The whistleblowers made additional allegations regarding Dr. [redacted] actions that the VA reviewed in its investigation and report. For example, the agency found that Dr. [redacted] had, on several occasions, directed the gastroenterology (GI) nurse practitioner to submit liver transplant paperwork for patients who clearly did not meet the transplant criteria. The agency was unable, however, to determine whether Dr. [redacted] directed a former GI nurse practitioner to stop tumor imaging requests in 2014; minimize the need for transplants when talking with patients and their families; or complete transplant requests in a manner resulting in rejection.

Dr. [redacted] did halt endoscopies for patients with liver cirrhosis and hepatitis, stating that they did not require follow up in the Liver Clinic. The GI nurse practitioner believed this direction differed from clinical guidelines and voiced her concerns to her supervisor, who directed her to continue ordering endoscopies for her patients. The agency found that the clinical guidance does recommend follow-up surveillance for patients with cirrhosis. The VA recommended that the facility use peer reviews to resolve internal differences of

opinion on standards of care and develop internal practice guidelines on acceptable standards of care at VASDHS.

The VA further determined that, although Dr. [redacted] appropriately directed administrative staff to close GI consults, he permitted staff to use his login information to access electronic health records for about six months. Dr. [redacted] also admitted to logging into multiple computers at the same time to permit staff to enter patient information. The agency advised Dr. [redacted] that these actions violated agency policy and recommended appropriate administrative action in response. The agency's supplemental report indicated that no action was taken against Dr. [redacted] but that local leadership implemented technological updates to resolve the issue.

Dr. [redacted] specifically focused on these allegations in his written comments. He noted that, according to the VA's report, Dr. [redacted] admitted to referring ineligible patients for liver transplant. Dr. [redacted] highlighted that these referrals are not only a drain on resources, but they also expose patients to potentially unrealistic expectations and require them to unnecessarily undergo potentially risky invasive procedures. Similarly, Dr. [redacted] noted that the VA's findings indicate that Dr. [redacted] advised against surveillance of certain patients in contradiction to accepted guidance. Thus, Dr. [redacted] asserted that, despite the language in the VA's report, the agency did, in fact substantiate the allegation that Dr. [redacted] was not properly advising patients of their treatment options.

IV. The Special Counsel's Findings

I have reviewed the original disclosure, the agency reports, and whistleblowers' comments. Based upon my review, I have concluded that the agency's findings are unreasonable. A brief discussion of the basis for this determination follows.

The VA's findings with respect to Dr. [redacted] research protocol rely on the assertions that (1) transjugular biopsies are the standard of care for this patient cohort, and (2) that biopsies obtained prospectively for clinical purposes can subsequently be considered archival. The VA's determinations are questionable, at best, given the information the VA itself provided and in light of the whistleblowers' comments. The VA asserted that the reason neither VASDHS nor UCSD performed transjugular biopsies prior to the research protocol was that the research protocol opened the facility up to a new clinical option. If, as the VA states, transjugular biopsies are the standard of care, this leaves open the important question of how the standard of care was met prior to the initiation of the research project. It is also notable that the IRB approved the research protocol without consulting appropriate experts.

Moreover, the VA's report failed to acknowledge a serious potential conflict of interest on the part of the clinical expert consulted by the IRB. As reported by the

whistleblowers, the clinical expert the IRB consulted after approval was a physician at UCSD who trained under Dr. [redacted] and has co-authored with Dr. [redacted] research papers based on material gleaned from the research. Arguably, this individual has a conflict of interest, which should have necessitated an additional independent opinion to answer the questions of standard of care.

The agency's assertions regarding archival tissue are questionable and inconsistent. In its initial report, the VA stated that, in fact, tissue samples obtained prospectively for clinical purposes could be considered archival. In its supplemental report, the VA revised its approach, asserting that a previously unmentioned alteration to the research protocol permitted the use of prospective tissue samples. Thus, it is not clear whether the agency considers prospectively obtained tissue to be archival, or whether the protocol was altered to remove the archival requirement. Regardless, Dr. [redacted] reference to the VA's own definition of archival as obtained "prior to the approval and initiation of any research" is compelling, as is the agency's own recitation of the IRB Protocol Application, which specifically references the use of archival liver biopsy tissue.

The VA's failure to clearly and comprehensively address these two basic foundations of the whistleblowers' allegations, as well as other demonstrated inconsistencies in the VA's findings regarding the quality of Dr. [redacted] care, compel me to find the VA's reports unreasonable, despite its substantiation of other, less serious allegations. I remain deeply concerned about the quality of care provided to veterans at VASDHS, especially those participating in the research protocol, and I continue to question whether the IRB's review and approval of the protocol was sufficient, unbiased, and correct. I strongly urge the VA to revisit its findings in this matter and take a truly critical look at the research being conducted and care provided to liver patients at VASDHS.

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 Chairmen 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