U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

February 28, 2018

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

VIA ELECTRONIC MAIL

Re: OSC File No. DI-16-3664

Dear Mr. President:

Pursuant to my duties as Special Counsel, I am forwarding to you a report provided to OSC in response to disclosures received from an employee of the Department of Veterans Affairs (VA), Miami VA Medical Center (Miami VAMC), Pathology and Laboratory Medicine Service (PLMS), Miami, Florida. The whistleblower, Roman A. Miguel, who consented to the release of his name, is a Chemistry Department supervisor in the Miami VAMC PLMS. Mr. Miguel alleged improprieties with Human Immunodeficiency Virus (HIV) testing at the Miami VAMC. I have reviewed the report and Mr. Miguel's comments and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the agency investigation, the whistleblower's comments, as well as my findings.[1]

Mr. Miguel's allegations were referred to former VA Secretary Robert A. McDonald on September 26, 2016, pursuant to 5 U.S.C. §1213(c). He delegated to then-Acting Chief of Staff Gina Farrisee the authority to sign the investigative report and take any actions deemed necessary as a result of the investigation. The VA's Office of the Medical Inspector (OMI) was charged with investigating Mr. Miguel's allegations. Ms. Farrisee forwarded the report on January 25, 2017. Mr. Miguel provided comments on

[1] The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, he is required to advise the appropriate agency head of his determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c) and (g). Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

March 23, 2017. The VA submitted a revised report on August 24, 2017, and Mr. Miguel provided comments on October 17, 2017.

I. The Whistleblower's Allegations

Mr. Miguel alleged that the Miami VAMC failed to comply with procedures for HIV testing set forth in a May 5, 2015, VA directive. VA Directive 1113 (Directive 1113) adopted the Centers for Disease Control and Prevention's (CDC) updated HIV testing guidelines which, according to Mr. Miguel, required implementation of "fourth generation HIV testing" within one year of its publication. Mr. Miguel also alleged that patients who were tested for HIV at the Miami VAMC during a period of time beginning in October 2015, may have received inaccurate diagnoses because of the continued use of outdated HIV testing. Finally, he alleged that Miami VAMC management officials ignored his repeated concerns regarding the facility's noncompliance with Directive 1113 and continued using outdated HIV testing past the deadline for implementation of the new testing.

II. The Agency Investigation

A. The Miami VAMC's HIV testing procedures

The VA investigation did not substantiate Mr. Miguel's allegation that the Miami VAMC failed to comply with procedures for conducting HIV testing set forth in Directive 1113 by the required deadline. The VA arrived at this conclusion by interpreting the deadline set forth in Directive 1113 (one year from the date of its issuance) to apply to preparation of the local guidelines rather than implementation of the updated testing program. Adopting this interpretation, the report concluded that the Miami VAMC met the mandate of Directive 1113 because it published Healthcare System Policy Memorandum (HSPM) 111-03-15, *Screening for Human Immunodeficiency Virus Infection*, on October 20, 2015, more than six months before the one-year deadline set forth in the directive. The report concluded that there was "no required date for implementation of the new CDC algorithm."

As the PLMS chief, Dr. [redacted] was responsible for "[e]nsuring availability of HIV testing assays that meet current CDC recommendations."[2] However, she testified that she was unaware of the CDC changes to the recommended screening algorithm. According to the report, Dr. [redacted] stated that the chief medical technologist (CMT) was responsible for coordinating activities between the Chemistry Section, which conducts the initial screening, and the Special Immunology Section (SIS), which conducts confirmatory testing. The report indicated that the CMT position was vacant during this timeframe.

---

[2] See, attached report at page 5, citing Healthcare System Policy Memorandum (HSPM) 111-03-15, *Screening for Human Immunodeficiency Virus Infection.*

During this same time-period, Mr. Miguel, who was aware of the CDC changes to the recommended screening algorithm, identified a piece of Miami VAMC equipment that could be repurposed to comply with the new screening protocol. As a result, the Chemistry Section initiated fourth generation screening on October 8, 2015. The SIS continued to perform confirmatory testing using the Western Blot supplemented by the ADVANCE HIV-1/2 ORAQUICK test to capture HIV-2 infections missed by the Western Blot.[3]

The report concluded that Miami VAMC officials initiated a "reevaluation" of its HIV screening and testing protocols in July 2016 following inquiries from the VA Office of Inspector General and the White House.[4] The Miami VAMC decided to adopt the CDC's recommendations and obtain the fourth generation equipment for SIS. However, delays occurred in obtaining the necessary fourth generation equipment, because the VA employee responsible for executing the procurement was on extended leave.

In September 2016, the Miami VAMC began sending all samples requiring confirmatory testing to Quest Diagnostics, a contract laboratory outside the VA. Outside confirmatory testing was necessary, because the equipment needed to perform the fourth generation confirmatory testing recommended by the CDC had not yet been ordered.[5] The fourth generation testing equipment was ordered on October 11, 2016, with a requested delivery date of November 1, 2016. Installation of the new system was completed on December 13, 2016.

Even though Mr. Miguel's allegation that the Miami VAMC failed to comply with Directive 1113 was not substantiated, the report recommended the following corrective actions:

1) Provide enough staff training to ensure consistent availability of personnel in the procurement process in each section;
2) Provide appropriate administrative and human resource support to PLMS to address vacancies and other staff issues;
3) Develop a policy to provide periodic updates to all PLMS staff regarding new

[3] According to the report, Dr. [redacted] asserted that she received assurances from the chief of the Infectious Disease (ID) Section and Facility HIV lead clinician (chief, ID & HIV), the "subject matter expert and the approval level for facility HIV testing policies," that this "alternative testing sequence" used by SIS for confirmatory testing was acceptable. On June 20, 2016, the Miami VAMC developed SIS PLMS Policy #SI-002-16, formalizing an alternative testing sequence.

[4] These inquiries were the result of Mr. Miguel's disclosures to both the VA Office of Inspector General and the White House.

[5] A review of the timeline suggests that the decisions to forward samples to Quest Diagnostics and renew efforts to purchase the equipment necessary to conduct fourth generation confirmatory testing were precipitated by OSC's communication to VA management on September 8 and 9, 2016 regarding the serious health and safety concerns brought to our attention by Mr. Miguel.

internal and external guidelines/procedures/recommendations/equipment, staying attuned to possible conflicts and/or redundancies between sections; and

4) Improve internal coordination and communication with PLMS, especially related to specimen testing that crosses sequentially between sections.

B. Patient test results for HIV at the Miami VAMC since October 2015

The VA report did not substantiate the allegation that patients received inaccurate diagnoses. The investigation identified eight instances of discordant results[6] during the timeframe between October 2015, when the Chemistry Section transitioned to fourth generation HIV screening, and October 2016, when the Miami VAMC began sending samples to Quest Diagnostics for confirmatory testing.[7] In one of the eight cases, the patient was deemed by his provider to be "high-risk," and his sample was subjected to more precise testing. Ultimately, it was determined that he was HIV infected and he commenced treatment. In another case, the Miami VAMC repeatedly attempted to contact a veteran with discordant results. Eventually, the veteran returned for repeat testing, tested positive for HIV, and commenced treatment. The remaining six veterans with discordant results returned to the Miami VAMC for retesting and tested negative. The investigation further determined that the Miami VAMC has a policy outlining reporting and referral requirements for newly-diagnosed HIV patients, as well as a policy on notification in the case of positive or inconsistent results.

C. Miami VAMC management officials' response to Mr. Miguel's concerns regarding noncompliance with Directive 1113

The VA report did not substantiate the allegation that Miami VAMC management officials ignored Mr. Miguel's repeated concerns regarding noncompliance with Directive 1113. According to the report, the investigative team reviewed the minutes from the PLMS Chemistry Section monthly meetings from September 3, 2015, through June 2016. The review found no discussion about changes to the HIV screening process or concerns about confirmatory testing. According to the report, in response to questions regarding when she became aware of Mr. Miguel's concerns about HIV testing, Dr. [redacted] stated that the issue was discussed at a November 5, 2015 meeting. It was at this meeting that the chief, ID & HIV, the facility's subject matter expert, approved the use of the alternative testing sequence. There is no indication that Dr. [redacted] took any action because of this discussion.

The chief of staff testified that he became aware of concerns about the HIV confirmatory testing following inquiries from the OIG and White House. The chief of

---

[6] Discordant results occur when initial test results differ from subsequent confirmatory test results.
[7] A review of the timeline suggests that the decision to forward samples to Quest Diagnostics for confirmatory testing was precipitated by OSC's communication to VA management regarding the serious health and safety concerns brought to our attention by Mr. Miguel.

staff indicated that he notified the facility director of the HIV testing concerns on or about June 14, 2016. However, there is no indication that anyone took action regarding these concerns until Mr. Miguel hand-delivered documents related to this issue to the director on June 30, 2016. According to the report, that same day, the director instructed the chief of staff to ask the medical director, Infection Control, to investigate the confirmatory HIV testing issue.

III. The Whistleblower's Comments

Mr. Miguel asserted that he has been retaliated against because of his disclosures regarding HIV testing at the Miami VAMC. Mr. Miguel stated that he met with Dr. [redacted] on November 20, 2015 at what was described as a "Behavior Evaluation" and directed "to mind [his] own business." According to Mr. Miguel, at the same meeting, Dr. [redacted] refused to discuss the fact that Directive 1113 mandated that in her capacity as the chief of PLMS, she was responsible for implementing the new recommended testing procedures. Mr. Miguel explained that he persisted in reporting this problem knowing he would be retaliated against, and "escalated" the matter outside the Miami VAMC in the hope that the issues would eventually be addressed. According to Mr. Miguel, Miami VAMC management took no action in response to his repeated complaints until after they became aware that he took his disclosures outside the VA.

With respect to the first allegation, Mr. Miguel objected to the agency's interpretation of Directive 1113 as mandating that local policies rather than revised testing procedures be implemented within one year of issuance of the directive. Mr. Miguel asserted that there was "no coordination, guidance, or plan for implementation by the chief of PLMS" prior to his disclosures outside the Miami VAMC. Mr. Miguel deemed it "remarkable" that Dr. [redacted] defended herself by claiming ignorance of her responsibilities under Directive 1113, and denying knowledge of the CDC recommendations. Further, Mr. Miguel was incredulous about Dr. [redacted]'s attempts to deflect responsibility by suggesting that Mr. Miguel was remiss in not bring the mandates of the directive to her attention.

With respect to the report's contention that the SIS used ORAQUICK tests to capture HIV-2 infections missed by the Western Blot on patients with discordant results, Mr. Miguel indicated that the agency report was the first time he was informed about the use of ORAQUICK. Describing the agency's assertion as "dubious," Mr. Miguel indicated that he never saw a log recording ORAQUICK results or any reference to ORAQUICK tests in any patients' records. In addition, Mr. Miguel asserted that, over a period of months, he and the SIS supervisor exchanged emails regarding HIV testing and the new CDC recommendations, and the SIS supervisor never mentioned the use of ORAQUICK testing. Finally, Mr. Miguel noted that the Food and Drug Administration has not approved the ORAQUICK test as an HIV supplemental test. Its use by SIS, therefore, even if verifiable, would not have met CDC's recommendations.

Mr. Miguel deemed the report's finding that Miami VAMC management ignored his repeated concerns regarding the facility's noncompliance with Directive 1113 was not substantiated as "demonstrably false." Mr. Miguel indicated that he explicitly stated this to Dr. [redacted] and her CMT "on multiple occasions in October and November 2015." His persistence in bringing this matter to Dr. [redacted]'s attention culminated in her directing him "to mind [his] own business" during a November 20, 2015 meeting. Mr. Miguel characterized the VA's finding that he did not repeatedly express concerns about the noncompliance with Directive 1113 as "absurd." In conclusion, Mr. Miguel reiterated that the Miami VAMC finally modified their policies and procedures only after he disclosed the issue outside the facility in May 2016.

IV. Special Counsel's Findings and Conclusions

I have reviewed the original disclosure, the agency report, and Mr. Miguel's comments and have determined that the agency's report contains the information required by statute. However, the report's findings do not appear reasonable. The available information establishes that Miami VAMC officials failed to respond to Mr. Miguel's concerns until after Mr. Miguel filed his disclosure with OSC in May 2016 and hand-delivered his disclosure to Miami VAMC Director [redacted] on June 30, 2016. I am incredulous that compliance with Directive 1113 and implementation of fourth generation HIV testing occurred only after Mr. Miguel's disclosures and OSC's intercession.

Although the HIV testing issues affected a small percentage of those tested at the Miami VAMC and OSC has not been made aware of similar problems at other VA facilities, I strongly encourage the VA to take immediate action to ensure that every facility throughout the VA-network is in compliance with Directive 1113. To this end, I have asked Secretary Shulkin to query VA facilities nationwide regarding this extremely important patient and public health and safety concern and report back to me regarding the results within 30-days. I thank Mr. Miguel for bringing this matter to OSC's attention and commend him for his dedication to the health and well-being of our veterans.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of this letter, the agency report, and Mr. Miguel's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans Affairs. I have also filed a copy of this letter, the redacted agency report, and Mr. Miguel's comments in our public file, which is available online at www.osc.gov, and closed the matter.

Respectfully,

Henry J. Kerner
Special Counsel

Enclosures