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The Special Counsel

April 24, 2015

The President
The White House
Washington, D.C. 20510

Re: OSC File No. DI-14-2755

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veterans Affairs (VA) report based on disclosures of wrongdoing at the William Hefner VA Hospital (Hefner VA Hospital), Salisbury, North Carolina. The Office of Special Counsel (OSC) has reviewed the report and, in accordance with 5 U.S.C. §1213(e), provides the following summary of the allegations and our findings.

The whistleblower, Donald Miller, who consented to the release of his name, alleged that employees at the Hefner VA Hospital engaged in conduct that may constitute a violation of law, rule, or regulation; gross mismanagement; an abuse of authority; and a substantial and specific danger to public health and safety. Specifically, Mr. Miller alleged that employees in the nuclear medicine department mishandled radioactive materials, failed to keep records, and failed to post required signage in material treatment areas. Further, he asserted that hospital staff failed to appropriately monitor patients during cardiac stress tests and the physical arrangement of hospital office space resulted in repeated breaches of patient confidentiality. Mr. Miller also had allegations concerning pending patient waitlists.

The agency did not substantiate Mr. Miller's allegations. The report explained that there was no mishandling of radioactive materials, improper record keeping, or lack of proper signage for radioactive material treatment areas. The report did not substantiate the allegation that hospital staff failed to appropriately monitor patients during cardiac stress tests. The report also did not substantiate the allegation that the physical arrangement of the hospital office space breached patient confidentiality. With respect to Mr. Miller's allegations concerning patient wait lists, this matter is the subject of an ongoing review, and will be addressed in a supplemental report. As the allegations investigated in the present matter were not substantiated, no corrective actions were recommended. Based on my review, I have determined that the report meets all statutory requirements and that the findings appear to be reasonable. However, I am closing this matter conditionally, pending receipt of the agency's supplemental report.

Mr. Miller's allegations were referred to then-Acting Secretary Sloan D. Gibson, to conduct an investigation pursuant to 5 U.S.C. §1213 (c) and (d). Acting Secretary Gibson asked the Interim Under Secretary for Health to refer Mr. Miller's allegations to the Office of

the Medical Inspector (OMI) and the National Health Physics Program (NHPP) for investigation. Chief of Staff Jose D. Riojas was delegated with the authority to review and sign the report. On January 30. 2015, Mr. Riojas submitted the agency's report to OSC. Mr. Miller did not provide comments to the agency report. As required by 5 U.S.C. §1213(e)(3), I am now transmitting the report to you.[1]

I. Mr. Miller's Allegations

Mishandling of Nuclear Materials

Mr. Miller stated that during the week of March 17, 2014, he found discarded radioactive biohazard waste products and containers lying on a counter in the hospital's radiopharmaceutical hot lab. This is an aseptic room free from contamination where radioactive materials are stored and radiopharmaceuticals are arranged prior to dosing patients. Mr. Miller observed six empty food containers, including Styrofoam boxes and cups containing uneaten food, which were in non-labeled bags on the aseptic counter of the lab where medications are prepared. Mr. Miller explained he knew the uneaten food contained radioactive materials because the containers were the type used by the department. According to Mr. Miller, not only were these containers and their contents a biohazard which could contaminate injectable radioactive tracers prepared in the lab, they also constituted low-level radioactive waste that must be disposed of in accordance with relevant regulations and procedures.

Improper Signage and Record Keeping

Mr. Miller alleged that a room used for injecting patients with radiopharmaceuticals and the hospital's scanning room lacked federally required signage alerting individuals to the fact that radioactive materials were present and used in the area. *See* 10 CFR § 20.1902. Mr. Miller also disclosed that the department did not maintain a radioactive decay-in-storage log, which is used to track radioactive materials for later disposal, in violation of NRC regulations. *See* 10 CFR § 35 Subpart L.

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[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, she is required to advise the appropriate agency head of her 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). 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).

Failure to Monitor Patients During Cardiac Stress Tests

Mr. Miller disclosed that on February 24, 2014, he discovered a nuclear cardiac stress test patient who had been left unattended for over 30 minutes. Mr. Miller asserted that the nuclear medicine technologist responsible for administering the test, Kevin Gaynor, had left the patient unattended while he was in an office completing paperwork.

Mr. Miller stated that at this particular stage of the test, the patient was hooked up to an EKG, which was linked to a scanning camera. Mr. Miller looked at the EKG readouts and determined the patient's EKG had been reporting abnormal results for more than 30 minutes, which automatically prevented the camera from beginning to scan. In this instance, Mr. Gaynor set up the test, initiated the protocol, and then exited the scanning room before the test actually began.

In addition to this instance of alleged patient neglect, Mr. Miller observed that the patient had been sent to the scanning room unattended from the Cardiology Department two floors above after undergoing a drug-stimulated stress test for a scan of his heart. Mr. Miller explained that sending patients who have just completed stress tests without escort or assistance is an unsafe but routine practice at Hefner VA Hospital. He noted that he personally observed this practice on a daily basis. Allowing drug-stimulated and exercise stress test patients to walk unattended from one floor of the hospital to another violates good clinical practices, Veterans Health Administration (VHA) care standards, and agency national patient safety objectives. *See* VHA Directive 2006-041 and VHA Handbook 1101.10.

Breaches of Patient Confidentiality

Mr. Miller asserted that due to a lack of space at Hefner VA Hospital, his assigned duty station was a room that doubled as a location for patient procedures and as administrative office space. He alleged that frequently non-essential staff would enter into the room while patients were in procedure, and would often perform routine office work and hold conversations. According to Mr. Miller, this represented a serious breach of VA policy and an inappropriate intrusion into patient privacy. Under VHA policy, access to examination rooms must be restricted to ensure the privacy of patients. *See* VHA Handbook 1101.10 § 9

II. The Agency Report

The VHA NHPP investigated Mr. Miller's allegations concerning mismanagement of nuclear materials, signage, and record keeping. NHPP did not substantiate the allegations regarding the improper disposal of food materials in the hot laboratory. This conclusion was based on the observation of work areas, interviews with three nuclear medicine technologists assigned to work in the food preparation area, and a review of relevant decay-in-storage information. NHPP did not substantiate or identify any mishandling or loss of control of radioactive materials associated with related procedures during the times identified by Mr. Miller, and noted that the description of the food items was not consistent with materials used for testing at the facility.

NHPP reviewed all radioactive material use rooms in the nuclear medicine department and two cardiac stress labs and determined that all rooms requiring signage were properly designated. The report determined that the rooms at issue were exempt from signage posting requirements articulated in 10 C.F.R. § 20.1903, because radioactive materials are not present in the room for more than eight hours, and as such there were no associated violations.

NHPP did not substantiate Mr. Miller's allegation concerning the decay-in-storage log. The report noted that during the inspection a nuclear medicine technologist readily retrieved three years of decay-in-storage records, which were maintained electronically on a computer system in the nuclear medicine hot laboratory. The report found that the records contained the minimum information specified in 10 C.F.R. § 35.2092.

In addition to the specific review of these allegations, NHPP performed a core inspection of nuclear medicine activities at the center. This inspection identified two unrelated, previously identified violations, which were self-corrected by the facility. The first concerned a failure to notify NHPP that the cardiology stress lab was moved from the second floor to the fifth floor of Building 2. The facility remedied this situation by providing written notification of the move to NHPP in June 2014. The second was associated with a self-identified failure to properly document the monitoring of external surfaces of labeled packages of radioactive materials. No harm was attributed to this oversight and the employee responsible for this omission was removed from this duty and the problem has not recurred.

With respect to Mr. Miller's allegations concerning failure to monitor cardiac stress test patients, investigators from OMI could find no corroboration of the events described above. The report noted that patient electronic health records for cardiac stress test patients on the day identified by Mr. Miller revealed no evidence of complications during or after the test. The investigative team interviewed employees who explained that patients were not left unattended during nuclear imaging performed before and after cardiac stress tests.

In addition, the report did not substantiate the allegation that hospital staff allowed patients to walk unattended from the cardiology clinic to scanning rooms in the Nuclear Medicine Department. A review of electronic health records indicated that patients were monitored by cardiologists during stress tests and only released from monitoring after physicians determined that they were stable. Patients cleared to go to the Nuclear Medicine Department were clinically ready to go home if no post-test scanning was required.

The report also determined that the arrangement of the hospital office space did not result in breaches of patient confidentiality. The investigation determined that every member of the Nuclear Medicine Department was able to describe appropriate procedures implemented to maintain patient privacy on occasions when rooms were used for both administrative and patient care purposes. The report explained that the room at issue in Mr. Miller's allegations was designated for patient care twice in the time he was working at the facility and proper protections were in place both times when it was used in this capacity.

Because Mr. Miller's allegations were not substantiated, no corrective actions were required. With respect to the violations identified by NHPP, the report noted that all appropriate actions to resolve those issues had already been.

III. The Special Counsel's Findings

I have reviewed the original disclosure and the agency report. I am satisfied that the report meets all statutory requirements and the findings of the agency head appear reasonable. However, as noted above, I am closing this matter on a conditional basis, pending the outcome of the agency's review of Mr. Miller's scheduling allegations. As required by 5 U.S.C. §1213(e)(3), I have sent copies of the agency report to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed copies of the redacted agency report and whistleblower comments in our public file, which is available at www.osc.gov.[2] OSC has now closed this file.

Respectfully,

Carolyn N. Lerner

Enclosures

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[2] The VA provided OSC with reports containing employee names (enclosed), and redacted reports in which employees' names were removed. The VA has cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the reports produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the reports in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version of the reports as an accommodation.