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The Special Counsel

December 14, 2012

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

Re: OSC File No. DI-11-0967

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), please find enclosed reports received from the Honorable Eric K. Shinseki, Secretary of Veterans Affairs, in response to disclosures made by William D. Thorne, a Registered Respiratory Therapist, alleging that employees at the Department of Veterans Affairs (VA), Overton Brooks VA Medical Center (Medical Center), Respiratory Department, Shreveport, Louisiana, engaged in conduct that constituted a violation of law, rule, or regulation, gross mismanagement and a substantial and specific danger to public health and safety. Specifically, Mr. Thorne, a former employee of the Medical Center who consented to the release of his name, alleged that staff of the Respiratory Therapy Department re-issued medical equipment for inpatient use without conducting the safety and maintenance checks required by the VA.

The allegations were referred to Secretary Shinseki on February 28, 2011. Upon completion of the investigation by the Office of the Medical Inspector (OMI), Secretary Shinseki transmitted the agency's initial report to OSC on June 24, 2011. In response to questions from OSC, and due to an additional concern identified by the OMI, the VA provided a supplemental report on November 15, 2011. Mr. Thorne declined to comment on the reports.

The investigation substantiated the allegation that Continuous Positive Air Pressure (CPAP) machines[1] were put into service in the Medical Center without maintenance and safety inspections despite a policy that required all medical equipment to be inspected prior to use. In its initial report, the OMI concluded that the equipment was not inspected prior to use by Medical Center inpatients, but did not find that a violation of law, rule, or regulation occurred. The initial investigation also found that it was likely that biologic filters were not used in the home-use CPAP machines, thus creating a potential risk in converting home-use CPAP machines to inpatient use. The supplemental report of November 15, 2011, clarifies the agency's findings and states that the Medical Center's handling and management of the CPAP machines violated Veterans Health Administration

[1]The report notes that the term CPAP as used herein also includes Bi-Level Positive Air Pressure (BiPAP) machines.

(VHA) Directives 2009-004 and 2009-031 requiring medical facilities to develop and follow standard operating procedures for the proper maintenance of reusable medical equipment. After further review, the OMI also concluded that the failure to conduct the biomedical safety and maintenance checks did not result in a substantial and specific danger to public health and safety to patients. Finally, after review and consideration of the investigative findings, the Medical Center removed from service all CPAP machines initially distributed for home use and discontinued the program.

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) 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).

Background

The initial report submitted to OSC on June 24, 2011, omitted the names of VA employees interviewed and referred to employees by title only. The agency did not provide a legal basis for the omission of the employee names as is customary under OSC's accommodation policy when agencies redact the names of their employees. Under OSC's accommodation policy, instituted in April 2011, OSC allows the agency to redact employee names from the report available in OSC's public file, but notes its objection to the redaction on the basis that the public has an interest in knowing the names of those federal employees involved. The agency provides an unredacted report for transmittal to you, Chairmen and Ranking Members of the Senate Committee on Veterans' Affairs and the House Committee on Veterans' Affairs, and the whistleblower.

In July 2011 and continuing through 2012, the VA declined to follow the accommodation policy and objected to the inclusion of employee names in its reports. As a result, in many cases the VA provided a report containing only employee titles. In an attempt to address the agency's concerns and OSC's objections, OSC staff met with VA Office of General Counsel staff on April 13, 2012. No agreement was reached at that meeting, but the agency indicated that that OSC would be notified of the VA's final determination on the matter by June 11, 2012. The agency was aware that, while awaiting the VA's response, OSC was delaying the transmission of reports

to you and Congress. When the VA failed to respond by June 11, 2012, discussions among OSC, VA General Counsel staff, and the White House Counsel's Office ensued. On August 30, 2012, OSC reached an agreement with the VA, wherein, for all future matters, the VA will provide OSC with an unredacted report containing employee names and titles for you, Congress, and the whistleblower, and a redacted report, containing employee titles only, for OSC's public file. For pending matters, such as this one, the VA provided a revised report containing employee names and titles. OSC received the revised report in this case on November 9, 2012. The whistleblower was given the opportunity to comment on the revised report but declined.

The Whistleblower's Allegations

Mr. Thorne disclosed that Donna Brown, Technical Director of Respiratory Therapy, acquired 10 to 15 used CPAP and (BiPAP) breathing devices from the Outpatient Department of the Medical Center for the treatment of inpatients with sleep apnea and other conditions where the patient does not receive sufficient oxygen from a traditional face mask. Mr. Thorne reported that the machines were used in outpatients' homes for approximately one to two years before being returned to the Medical Center. He explained that after the machines were returned, they were used by Medical Center inpatients for approximately one and a half years.

Mr. Thorne disclosed that the Biomedical Engineering Department did not perform the maintenance and safety checks on the CPAP and BiPAP machines, as required by VA Directive 2009-004, prior to placing them in service for inpatients receiving treatment from the Respiratory Therapy Department. In December 2010, Mr. Thorne notified Ms. Brown and Dr. John Areno, Chief of Pulmonary Medicine, that maintenance and safety checks had not been completed on the machines in use by Medical Center inpatients. Mr. Thorne believed that the safety and maintenance checks remained outstanding at the time of OSC's referral in February 2011.

The Reports of the Department of Veterans Affairs

The OMI Investigation

The OMI investigative team included the Deputy Medical Inspector for National Assessments, a physician, a clinical program manager, and a nurse practitioner. The OMI team conducted a site visit on March 8-9, 2011, met with the Medical Center leadership and toured the CPAP, Respiratory Therapy, and Biomedical Engineering Departments as well as the utility area where the machines are cleaned. The investigation included interviews with Mr. Thorne and 15 other employees, and a review of work orders, medical records, and VA policies and directives listed in Attachment A to the report.

The investigation substantiated the allegation that the CPAP machines[2] were put into service in the Medical Center without the maintenance and safety checks required by the Medical

[2]The report notes that the term CPAP as used herein also includes BiPAP machines.

Center policy set forth in "Management of the Environment of Care." The report states that work orders for the maintenance and safety checks on home-use machines converted to inpatient machines were not issued by the Respiratory Therapy Department to the Biomedical Engineering Department. The OMI found that, as a result, the equipment was not inspected prior to use by Medical Center inpatients.

The report explains that the Medical Center converted 22 CPAP machines from home use to inpatient use from 2004 to 2010. The Medical Center did not have standard operating procedures or guidelines describing the criteria used to accept the CPAP machines from veterans and convert them to multiple patient, in-hospital use equipment. After the machines were returned by outpatients, they were placed in a soiled utility room where a registered respiratory therapist discarded the tubing and masks and cleaned the exterior of the machine with disinfectant. The registered respiratory therapist then brought the machine to the Respiratory Therapy Department where it was placed in service for multiple patient, in-hospital use.

The Respiratory Department began submitting the work orders for the safety and maintenance reviews of the home-use CPAP machines in June 2010, due to concerns raised by Mr. Thorne and other employees. Of the 22 machines, 10 were no longer in service. Maintenance and safety checks were completed on the remaining 12 by September 20, 2010. Thus, the OMI concluded that as of January 2011, the CPAP machines in use had undergone the requisite Biomedical Engineering maintenance and safety checks and did not substantiate the allegations that the use of uninspected machines continued through January 2011.

On March 8, 2011, in response to the investigative findings regarding the lack of standard operating procedures, the Medical Center issued written guidance on receiving donated CPAP and BiPAP machines. The policy, entitled, "Respiratory Therapy Policy and Procedure 2.6, Donated CPAPs and BiPAPs," establishes the requirements for accepting machines previously dedicated to single patient use and documents the procedures for maintenance and safety checks and entering the machines into the Medical Center system for multiple patient, in-hospital use.

In the initial report, the OMI concluded that no law, rule, or regulation was violated, but noted that the Medical Center had a policy that required all medical equipment to be inspected prior to use and failed to follow it. OSC requested clarification from the VA on this finding, in particular, whether the investigation had determined that the failure to properly inspect the machines prior to using them as multiple patient devices was a substantial and specific danger to public health and safety. The initial investigation also found that it was likely that biologic filters were not used in the home-use CPAP machines, thus creating a potential risk in converting home-use CPAP machines to inpatient use.

The OMI's supplemental report of November 15, 2011, stated that the Medical Center's handling and management of the CPAP machines violated Veterans Health Administration (VHA) Directives 2009-004 and 2009-031 requiring medical facilities to develop and follow standard operating procedures for the proper maintenance of reusable medical equipment. While

the Medical Center had developed a policy and procedures entitled, "Management of the Environment of Care" the OMI found that the Medical Center violated its policy by failing to follow those procedures with respect to the safety and maintenance checks required for CPAP machines.

The OMI also concluded that the failure to conduct the biomedical safety and maintenance checks did not result in a substantial and specific danger to public health and safety to patients. The supplemental report explains that the purpose of the safety and maintenance checks is two-fold: 1) to verify the equipment is operating correctly, and 2) to enroll the equipment in the facility's maintenance program to ensure the proper scheduling of future maintenance. In the case of the CPAP machines at issue in this case, the routine maintenance check, e.g., turning on the machine to verify it functions and performing the maintenance tasks included in the user manual for the machine, were conducted by respiratory therapy technicians. The report notes that the respiratory therapy technicians did not enter the machines into the medical equipment database for future maintenance. However, because the maintenance tasks were completed, the failure to enter the machines into the database did not result in a substantial and specific danger to public health and safety.

With respect to the issue of potential risk posed by the absence of biologic filters on the home-use CPAP machines, the OMI concluded that converting a machine from single patient use, which does not require the use of a biologic filter, to multiple patient use, which requires the use of biologic filter, carries a potential risk of biologic contamination, the extent of which was not known. However, the OMI found that there was insufficient evidence to conclude that the risk constituted a substantial and specific danger to public health or safety.

The OMI's Recommendations

In response to the investigative findings, the OMI recommended that the Medical Center remove the 23 CPAP machines[3] from inpatient use until: 1) a risk assessment could be completed, and 2) the risk to each veteran who used a home-use CPAP machine was assessed. The OMI also recommended that the Medical Center consider abandoning the program of placing single patient home-use CPAP machines into multiple patient use in the hospital. In the alternative, if the program continues, the OMI recommended that the Medical Center develop a policy for the use of single patient home-use CPAP machines in the hospital that complies with the manufacturer's recommendations for multiple patient use.

The OMI also recommended that the VHA determine the extent of conversion of home-use CPAP machines to multiple patient, hospital use machines across the VHA. Finally, the OMI recommended that the VHA take appropriate action based on a comprehensive risk assessment.

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[3]The Medical Center added one additional CPAP machine following the OMI's initial investigation bringing the total number of machines to 23.

The VA's Response to the OMI Recommendations

The Medical Center leadership consulted with the Veterans Integrated Service Network 16 Chief Medical Officer, the Acting Chief Medical Officer over Supply, Processing, and Distribution (SPD) in the VA Central Office, the VA National Infectious Disease Program Director, and the VA SPD Field Advisory Group regarding the risk to patients who used CPAP machines converted from single-patient use. This review group concluded the potential risk of contamination was very low because of the manner in which the machine works. The report stated that exhaled, potentially contaminated, air is expelled through valves in the mask and does not pass through the tubing of the machine. Thus, even if a biologic filter is not used there was minimal risk to the hospital inpatients who used the machines originally designated for single-patient use. Based on the low risk of contamination this review group did not recommend that patients who used the CPAP machines undergo medical evaluation. Finally, the Medical Center has removed from service all CPAP machines initially distributed for home use and discontinued the program.

The Special Counsel's Findings and Conclusion

I have reviewed the original disclosure and the agency reports. Based on that review, I have determined that the reports contain all of the information required by statute and the findings appear to be reasonable. As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the agency reports to the Chairmen and Ranking Members of the Senate Committee on Veterans' Affairs and the House Committee on Veterans' Affairs. I have also filed a redacted copy of the agency report,[4] OSC's file in this matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosure

[4]The VA provided OSC with a report containing employee names (enclosed), and a redacted report which removes employees' names. The VA cited the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the report produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version 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).