



U.S. OFFICE OF SPECIAL COUNSEL

1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

The Special Counsel

December 9, 2014

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

Re: OSC File No. DI-13-2584

Dear Mr. President:

Pursuant to my duties as Special Counsel, enclosed please find the Department of Veterans' Affairs (VA) investigative reports based on disclosures of wrongdoing at the G.V. (Sonny) Montgomery VA Medical Center (Jackson VAMC), Jackson, Mississippi, made to the Office of Special Counsel (OSC). 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, who wishes to remain anonymous, disclosed that Jackson VAMC management permitted the use of non-compliant laminar airflow workstations resulting in the unsafe preparation and dissemination of pharmaceuticals, and allowed unlicensed employees to provide drug counseling to patients.

The VA substantiated the whistleblower's allegation that two of the Jackson VAMC pharmacy's laminar airflow workstations, used for drug compounding, continued to be used after they were found by an independent laboratory to be noncompliant. However, the agency was unable to conclude that the improper use of the hoods posed a danger to the health and safety of patients or staff. Despite this finding, the facility undertook a number of corrective actions to ensure that similar actions do not occur in the future. While I cannot conclude that the hoods never posed a danger, the agency's investigation did not find any actual harm from the non-compliant hoods, and the agency has since taken corrective action. I have reviewed the agency's report and the whistleblower's comments and determined that the agency's reports contain all the information required by statute and that the findings appear to be reasonable.

The whistleblower's allegations were initially referred to then-Secretary Eric K. Shinseki to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d).¹ The matter

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

The President
December 9, 2014
Page 2 of 9

was then referred to the Under Secretary for Health, who tasked the Office of the Medical Inspector (OMI) to conduct the investigation. The Secretary delegated the authority to review and sign the agency's report to Chief of Staff Jose Riojas. The agency submitted its report on the whistleblower's allegations to this office on August 26, 2013. The OMI submitted a supplemental report on June 11, 2014. Pursuant to 5 U.S.C. § 1213(e)(1), the whistleblower provided comments on the agency's reports. As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the reports and the whistleblower's comments to you.

I. Laminar Air Flow Workstations Were Non-Compliant

A. The Allegation

The whistleblower alleged that two of Jackson VAMC pharmacy's laminar air flow workstations, or hoods, were not in compliance with required standards. The whistleblower explained that the Jackson VAMC Inpatient Pharmacy is a compounding pharmacy that supplies the facility with various pharmaceuticals, including chemotherapy drugs for use in treating cancers. These drugs are considered Compounded Sterile Preparations (CSPs) and can be hazardous to the pharmacists who handle them if exposure occurs.² In order to avoid such exposure, CSPs must be compounded under sterile circumstances. Thus, *Veterans Health Administration (VHA) Handbook 1108.06*, para. 10.a. requires all CSPs to be correctly purified, sterilized, labeled, stored, dispensed, and distributed in a manner consistent with U.S. Pharmacopeia (USP) Chapter <797>, *Pharmaceutical Compounding – Sterile Preparations* (2012).

The USP establishes standards for regulatory agencies and manufacturers of pharmaceuticals to ensure their products are correctly identified and have the proper consistency, purity, strength and quality. The USP explains that compounding facilities must be designed and environmentally controlled to minimize airborne contamination from contacting "critical sites" such as beakers, opened ampuls, and needle hubs,³ because direct or physical contact of critical sites of CSPs with contaminants "poses the

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).

² Carol Smith, *Ailing Pharmacist Recalls Lax Chemo Precautions*, The Seattle Times (July 10, 2010), available at http://seattletimes.com/html/localnews/2012327353_chemopatient11.html (last visited May 9, 2013); Carol Smith, *Lifesaving Drugs May Be Killing Health Workers*, The Seattle Times (July 10, 2010), available at http://seattletimes.com/html/localnews/2012327665_chemo11.html (last visited May 9, 2013).

³ *Id.* at 35.

The President
December 9, 2014
Page 3 of 9

greatest probability of risk to patients.”⁴ Thus, the USP states that “[c]ompounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO [International Organization for Standardization] Class 5 areas.”⁵ ISO Class 5 areas are considered to have particle counts of approximately 100 particles per cubic foot.⁶

In order to maintain a USP-compliant environment within the required areas of a compounding pharmacy, the USP prescribes the use of Primary Engineering Controls, which are devices or rooms that provide an ISO Class 5 environment when compounding CSPs.⁷ Primary Engineering Controls can include hoods, biological safety cabinets, or other approved equipment.⁸ Further, secondary engineering controls, such as ante-areas, generally serve as a core for the location of the Primary Engineering Control, and must maintain an ISO Class 7 environment.⁹ The USP states that it is “imperative” that Primary Engineering Controls and secondary engineering controls perform as designed and that the resulting levels of contamination be within acceptable limits.¹⁰ Certification procedures must be performed no less than every six months by qualified operators.¹¹

The Jackson VAMC Inpatient Pharmacy is located in an enclosed area with no windows on the basement level of the facility. It contains an intravenous (IV) room, where intravenous drugs, including CSPs, are compounded. Within the IV room are two clean rooms, one for compounding chemotherapy drugs, the other for non-chemotherapy drugs. Each of the clean rooms has its own ante area. The chemotherapy clean room contains two laminar airflow workstation hoods, manufactured by Baker Company, which are designed to maintain an ISO Class 5 area.

The whistleblower disclosed that on March 29, 2013, technicians from Allometrics, Inc., a private company, conducted a certification review on the Jackson VAMC’s two Baker hoods. The technicians found the hoods to be non-compliant, and placed notices on both hoods warning that they were not recommended for use. The whistleblower noted that James Whelan, acting chief of pharmacy service, was responsible for notifying employees of the certification test. However, according to the whistleblower, employees never received a notice from management prohibiting them from using the hoods.

⁴ *Id.* at 1.

⁵ *Id.* at 1.

⁶ *Id.*

⁷ *Id.* at 3.

⁸ *Id.*

⁹ *Id.* at 35. ISO Class 7 constitutes approximately 1000 particles per ft³.

¹⁰ *Id.* at 13.

¹¹ *Id.*

The President
December 9, 2014
Page 4 of 9

B. The Agency's Findings

The agency substantiated the allegation that Jackson VAMC's pharmacy's two hoods were found to be non-compliant in March 2013. The investigation determined that the pharmacy contains two hoods, but that only one was vented and connected for use. However, during the March 2013 certification, both hoods were tested and failed certification in the areas of air velocity and air flow smoke pattern testing. As a result, Allometrics placed a sticker on each hood noting that they were non-compliant and recommending that they not be used. On the same day, Mr. Whelan advised the chief engineer, the facilities manager, the inpatient pharmacy supervisor, and the IV room supervisor of the compliance failure and submitted work orders for the repair of the hoods. However, it took almost a month to complete the repairs. The hoods were re-tested and certified by Allometrics on April 24, 2013.

II. Non-Compliant Hoods Remained In Use

A. The Allegation

The whistleblower alleged that, despite the fact that the hoods failed certification and, thus, were not in compliance with USP <797>, Jackson VAMC employees continued to use the hoods to compound chemotherapy drugs until the hoods were repaired approximately one month later. According to the whistleblower, at least ten oncology patients received chemotherapy drugs that were compounded on April 9, 2013, using the non-compliant hoods. A number of these patients received more than one compounded chemotherapy drug on the same day.

The whistleblower indicated that the Jackson VAMC overlooked options that would have allowed employees to avoid using the faulty hoods, including short-term rental of compliant, certified hoods from Allometrics, Inc. or a similar company, or the temporary outsourcing of compounding services to another local compounding pharmacy. However, according to the whistleblower, management instead allowed employees to continue using the non-compliant hoods.

B. The Agency's Findings

The agency substantiated the allegation that pharmacists continued to use the hoods to compound sterile chemotherapy drugs until the end of April 2013, despite the finding of noncompliance. According to the report, on the day the hoods failed compliance testing, Mr. Whelan made the decision to allow continued use of the active hood. He relayed this decision to the inpatient pharmacy supervisor, who then informally shared it with the other inpatient pharmacists the following Monday. Mr. Whelan reported to investigators that he believed the hood would continue to ensure sterility of the IV admixtures with minimal risk to the pharmacists preparing the drugs. The agency found that the option to obtain the intravenous preparations from local health care

The President
December 9, 2014
Page 5 of 9

facilities was not considered, although the facility had existing arrangements for emergency pharmaceutical support with local hospitals.

The report notes that some pharmacists said that they had seen the Allometrics warning stickers advising against continued use, while others reported confusion over the consequences of the failed certifications. The pharmacists who were interviewed did not recall receiving a formal notification from pharmacy leadership on the failed certification of the hoods or a warning against their continued use. However, informal discussions were held between some pharmacists and management, during which the pharmacists were advised that they could elect not to prepare mixtures requiring the hoods until recertification was achieved. Some of the pharmacists reported that they continued to work with the non-compliant hood; one pharmacist opted out. OMI confirmed that no other personnel working in the pharmacy, other than the pharmacists, prepare IV admixtures and chemotherapy agents in the hoods.

III. Use of Non-Compliant Hoods Posed a Health and Safety Threat

A. The Allegation

The whistleblower alleged that management's decision to continue using the noncompliant hoods placed pharmacy service employees at risk for exposure to proven carcinogens. Furthermore, the whistleblower noted that the sterility of chemotherapy drugs compounded using the hoods was questionable, as there could be no guarantee that an ISO Class 5 environment was maintained during the compounding process. Thus, the whistleblower alleged that patient health and safety was also placed at risk during this period.

B. The Agency's Findings

The agency could not substantiate the allegation that the use of the noncompliant hoods posed a threat to the health and safety of the pharmacists who compounded the drugs or the patients who received them. The agency found that there were no reports by pharmacy staff of exposure to hazardous chemicals during fiscal year 2013, up to the date of the OMI site visit. There was also no data to suggest that any bloodstream infections occurred in patients receiving chemotherapy during fiscal year 2013, to the date of the OMI site visit.

OMI also reviewed Medical Center Policy L-119-06, which provides guidance on how to monitor employees working with hazardous drugs. OMI confirmed that surveillance, including an annual physical and laboratory evaluation, is offered to all pharmacists that work with hazardous drugs. According to the report, all the pharmacists but one confirmed their participation in the surveillance program. No pharmacist who was interviewed reported any signs or symptoms of ill health. The agency also reviewed

The President
December 9, 2014
Page 6 of 9

the records for pharmacy-related exposures and found no reported cases of exposures from the hoods from 2011 through the date of the OMI's site visit. In order to investigate concerns that using the noncompliant hoods posed a threat to patients, the agency also reviewed infection control data, which include all positive blood cultures for inpatients and outpatients. The agency found that no bloodstream infections were identified for chemotherapy patients in fiscal year 2013.

IV. Unsupervised Pharmacy Technicians Improperly Provided Drug Counseling

A. The Allegation

The whistleblower also alleged that pharmacy technicians are improperly permitted to provide drug advice to patients over the telephone. The whistleblower explained that the Jackson VAMC nursing service operates a telephone advice hotline for patients who have medication-related questions. Pharmacy Service employees, specifically pharmacy technicians, staff this hotline along with nursing service employees. The whistleblower explained that under most state licensing regulations, pharmacy technicians are not certified to provide counseling to patients regarding medications. For example, Mississippi Board of Pharmacy Regulations, Article XL, para. 4.B. specifically prohibits pharmacy technicians from orally communicating any drug information or counseling a patient on medications.

The whistleblower alleged that pharmacy technicians at the Jackson VAMC work the hotline without the supervision of a licensed and registered pharmacist, as required. One of the pharmacy technicians, Patricia Quick, answers the advice hotline for at least the first 30 minutes of her shift without staff from either the Pharmacy Service or the Nursing Service to assist her. The whistleblower noted that there is a licensed pharmacist who works under the supervision of the nursing service and is assigned to the advice hotline, but is not responsible for supervising pharmacy technicians. The whistleblower alleged that this is a potential violation of state licensing policy, and also poses a possible danger to the health and safety of patients who may receive faulty advice from unlicensed pharmacy technicians.

B. The Agency's Findings

The agency did not substantiate the allegation that unsupervised pharmacy technicians are improperly permitted to provide telephone drug counseling to patients. The report explained that the facility runs a call center for veterans to speak with a pharmacy technician about medication questions, a nurse about clinical concerns, or a medical administration clerk for administrative concerns. A clinical pharmacist is assigned to the call center to support the call center nurses, while a lead pharmacy technician supervises the pharmacy technicians and keeps a call log for each of the pharmacy-related calls handled by the pharmacy technicians. One pharmacy technician works full-time in the call center and the remaining technicians rotate through.

The President
December 9, 2014
Page 7 of 9

The agency reviewed the pharmacy technician employee folders and determined that they all included the appropriate education and required ongoing training. The report notes that pharmacy technicians are employed at a GS-5 level, and are therefore not required to obtain certification or licensure while working at VA, nor do they fall under oversight by the Mississippi licensing bodies.

During the investigation the pharmacy technicians described the circumstances under which they refer calls to an inpatient pharmacist. They did report occasional delays in initially reaching a pharmacist, but indicated that there were no gaps in follow-up with veterans. Return call were made to veterans, when necessary, within a few hours. However, pharmacy technicians did state that they were often unable to access or refer calls to the call center clinical pharmacist. The agency also reviewed the pharmacy technician call log for appropriateness of advice content and referral to pharmacy experts, and found no evidence to support the allegation that pharmacy technicians offered advice beyond their scope of practice.

V. Lack of Cleanliness in Pharmacy Break Room

A. The Allegation

The whistleblower reported a cleanliness issue in the pharmacy and specifically disclosed that the inpatient pharmacy and break room contain dirty carpeting covered with crushed medications and shelves covered in dust. The whistleblower alleges that a live reptile was found in the nonchemotherapy clean room during 2011.

B. The Agency's Findings

During the OMI's site visit, investigators found no evidence of stained carpeting, crushed medication, or dusty shelves in the inpatient pharmacy, IV room, or unit-dose areas. Investigators did observe stained carpeting in the break room, which also serves as a clean supply area. The break room contains a refrigerator, table, and chairs for employee use but no sink. OMI observed no reptiles while on the tour, and no one reported seeing a live reptile during 2011; however, one pharmacist recalled that someone had found a small lizard in the area about 10 years ago.

VI. The Agency's Recommendations

In its report, the agency made seven recommendations for the facility. OSC received a supplemental report addressing the status of the facility's response to those recommendations. First, the facility reviewed Mr. Whelan's decision to continue use of the active hoods despite the non-compliance finding. Mr. Whelan was counseled and returned to his previously held position. In order to ensure compliance with the facility's policy on employee safety, Medical Center Policy L-119-06 was distributed via email to

The President
December 9, 2014
Page 8 of 9

pharmacy staff. All pharmacy employees acknowledged their review of the policy and had the opportunity to ask questions.

The facility entered into a memorandum of understanding with the local university hospital to obtain emergent intravenous admixture and chemotherapy services, should the need arise. Additionally, per local policy, pharmacy staff members continue to be monitored via a surveillance program designed to gauge potential exposure to hazardous substances encountered in the workplace. The facility also continues to monitor any and all exposures reported by pharmacy staff.

With regard to the call center, effective October 25, 2013, pharmacy technicians were relocated to the Pharmacy Service where they are under the direct supervision of a pharmacist. In reference to the break room, the flooring was replaced in the existing break area and carpet was removed and replaced with standard flooring. In addition, a purchase request for necessary furniture to relocate the break room to the other side of the pharmacy and away from clean supplies was submitted on March 10, 2014.

VII. The Whistleblower's Comments

The whistleblower provided extensive comments on the agency's report and supplemental report. In response to the agency's report about the health and safety of pharmacists and patients, the whistleblower provided background information on the untoward effects of cumulative exposures to chemotherapeutic drugs, which can take a long time to be seen. The whistleblower also believes that patients may have attributed negative effects to the cancer treatment process rather than to the chemotherapeutic agents prepared in the non-compliant hoods. Also, the whistleblower contends that most VAMC pharmacists do not report minor cuts and needle sticks that occur when preparing chemotherapy; that some of the pharmacy staff either do not wear protective gowns or inappropriately wear them outside of the clean room; and, some pharmacists were never offered an annual physical and laboratory evaluation as part of the facility's surveillance program. The whistleblower was unaware of the alleged surveillance program prior to the agency report.

The whistleblower contends that facility administrators made sure the carpeted areas, flooring, and shelves were clean in anticipation of the scheduled OMI site visit. The whistleblower noted that live reptiles were not found during the OMI tour because the appearance of reptiles is not an everyday occurrence. Furthermore, the whistleblower believes that the pharmacy's plan to remove carpet and flooring is an effective admission of uncleanliness.

With respect to unsupervised pharmacy technicians, the whistleblower notes that all pharmacy technicians who were rotating through or permanently assigned to the call center have since been removed from the call center. The whistleblower contends that

The President
December 9, 2014
Page 9 of 9

such an act is an admission of guilt. Finally, the whistleblower argues that providing counseling to Mr. Whelan was insufficient because it permits him to continue “business as usual.”

VIII. The Special Counsel’s Findings and Conclusions

The agency’s assertion that the non-compliant hoods did not pose a danger is facially illogical. The hoods were tagged as non-compliant because they posed a danger to employees and patients. That said, the agency has conducted substantial monitoring to ensure no actual harm resulted, and taken corrective actions to prevent a recurrence. In addition, the agency confirmed that patients are receiving appropriate information via the facility’s call center, and took steps to ensure that the pharmacy break room is appropriately appointed and maintained. Therefore, having reviewed the agency’s reports and the whistleblower’s comments, I have determined that the agency’s report contains all of the information required by statute and its findings appear to be reasonable.

As required by 5 U.S.C. § 1213(e)(3), I have sent unredacted copies of the agency’s reports and the whistleblower’s comments to the Chairs and Ranking Members of the Senate and House Committees on Veterans’ Affairs. I have also filed copies of the redacted reports and the whistleblower’s comments in our public file, which is now available online at www.osc.gov.¹² This matter is now closed.

Respectfully,



Carolyn N. Lerner

Enclosures

¹² The VA provided OSC with a report containing employee names (enclosed), and a redacted report in which employees’ names were removed. The VA did not provide a legal basis for its redactions. However, OSC objects to the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as a basis for redactions to a report produced in response to 5 U.S.C. § 1213, 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). OSC also objects to redactions made pursuant to the Privacy Act of 1974 (Privacy Act) (5 U.S.C. § 552a) on the basis that the application of the Privacy Act in this manner is overly broad. However, OSC has agreed to post the redacted version of the agency’s report as an accommodation.