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The Special Counsel

June 5, 2014

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

Re: OSC File No. DI-12-4217

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find agency reports based on disclosures made by a whistleblower at the Department of Veterans Affairs (VA), Manila Outpatient Clinic (Clinic), Pasay, Philippines. The whistleblower, Robert Crawford, chief logistics and facilities manager at the Clinic, alleged that employees engaged in conduct that constituted a violation of law, rule, or regulation, gross mismanagement, a gross waste of funds, and a substantial and specific danger to public health and safety by purchasing and dispensing controlled substances that were not approved by the U.S. Food and Drug Administration (FDA). He further alleged that there was a lack of VA operational directives to address the unique characteristics of the Clinic, which is the only VA healthcare facility located in a foreign country.

The agency's investigation substantiated Mr. Crawford's allegation that the Manila Outpatient Clinic was purchasing and dispensing controlled substances that were not FDA-approved in violation of VA regulations and policy. The investigation also confirmed that there is a lack of specific VA directives addressing the Clinic's unique operations in a foreign country. Nevertheless, local and regional VA leadership have extrapolated from VA Handbooks and directives to develop local policies and procedures for the Clinic when necessary. In response to the findings, the agency took several corrective actions. These included instituting a process for purchasing FDA-approved controlled substances for the Clinic that not only complies with VA regulations and policy, but also results in cost savings. In addition, the agency developed a policy that describes the circumstances and process for obtaining non-FDA approved drugs for use in foreign countries. I have determined that the VA's investigative report meets all of the statutory requirements, and that the finding of a violation of VA regulations and policy appears to be reasonable. Based on the evidence presented in the reports, however, I do not find reasonable the agency's conclusions that there was no gross mismanagement, a gross waste of funds, or a substantial and specific danger to public health or safety.

On October 3, 2012, the Office of Special Counsel (OSC) referred Mr. Crawford's allegations to then-Secretary of Veterans Affairs Eric K. Shinseki to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). Secretary Shinseki asked the Under Secretary for Health to investigate the matter, who tasked the Veterans Integrated Service Network (VISN) 21 with the investigation. On March 21, 2013, Secretary Shinseki submitted the agency's report to OSC. In response to OSC's request, the agency provided a supplemental report on June 3, 2013. Pursuant to 5 U.S.C. § 1213(e)(1), Mr. Crawford submitted comments on the agency report and supplemental report on April 15, 2013, and June 17, 2013. As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the agency reports and whistleblower's comments to you.[1]

I. Mr. Crawford's Disclosures

The Manila Outpatient Clinic provides outpatient healthcare services to U.S. veterans in the Philippines. The Clinic is part of the VA Health Administration's (VHA) Sierra Pacific Network. Mr. Crawford discovered the controlled drug issue while he was serving as the acting clinic manager from December 2011 to July 2012.

According to the VA's Foreign Medical Program Policy Manual, drugs not approved by the FDA are not covered or paid for by the VA. *See* Foreign Medical Program Policy Manual, Ch. 2, Sec. 4, "Pharmacy Services, Supplies, and Over-the-Counter Items," December 28, 2009. Mr. Crawford explained that the purpose of this requirement is to ensure that drugs prescribed to veterans and paid for by the VA meet the quality and safety standards established by the FDA, the sole agency responsible for ensuring that drugs are safe and effective for their intended purpose. Further, Mr. Crawford stated that there is no condition or policy under which the Clinic can waive the requirement that drugs be FDA-approved, regardless of the fact that the Clinic is the only foreign VA healthcare facility.

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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) 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).

Mr. Crawford alleged that the Clinic was unable to obtain FDA-approved controlled substances[2] since its previous source, Clark Air Force Base in the Philippines, closed in 1991. Since then, the Clinic had been prescribing and paying for veterans' controlled substance medications, such as oxycodone, morphine, and fentanyl obtained from local Philippine prescription drug suppliers. According to Mr. Crawford, these controlled substances were not FDA-approved and cost significantly more than the corresponding FDA-approved drugs. Specifically, the 2013 fiscal year pharmacy budget estimated that the Clinic could save approximately $490,000 annually if it received FDA-approved controlled drug shipments from the VA's Pharmaceutical Prime Vendor (PPV), McKesson Corporation (McKesson).

Mr. Crawford contended that the VA ignored the requirement to use FDA-approved controlled substances, jeopardizing the health and safety of its veteran patients. He explained that he obtained the necessary Drug Enforcement Agency (DEA) license for the Clinic in 2011, but the ordering process was delayed on numerous occasions. By at least March 2012, several VA officials were aware of his concerns; however, progress to resolve the problem was so slow that it was meaningless. Mr. Crawford further asserted that there was a lack of specific VA directives to address the operations of this clinic.

II. The Agency's Report

The agency investigation substantiated that the Manila Outpatient Clinic was in violation of 38 CFR § 17.38, prohibiting non-FDA-approved drugs, biologics, and medical devices from inclusion in medical benefits packages available to eligible veterans. The Clinic was also in violation of VA policy interpreting this provision. The report noted that problems arose in the mid-1990s, when the VA initiated its PPV contract with McKesson. Most non-controlled drugs were purchased through McKesson; however, because the Clinic was not registered with DEA at that time, McKesson was unable to ship controlled substances directly to the Clinic. Due to the inability to receive these controlled substances from the PPV, the Clinic began to procure these drugs locally. Initially, the Clinic procured small quantities of controlled substances from Clark Air Force Base and Subic Naval Base hospitals, as well as the U.S. Embassy Clinic. As demand for medications grew, the Clinic began obtaining drugs from other local sources, such as pharmacies and pharmaceutical distributers. During this time, the Clinic unsuccessfully pursued a variety of options to acquire FDA-approved controlled substances. Unable to obtain medications from sources that distributed FDA-approved controlled substances, the Clinic continued to purchase these drugs from local pharmaceutical vendors.

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[2] Controlled substances are drugs that have a legitimate medical purpose, but also have the potential for significant abuse and can create psychological and physiological dependence issues. *See* 21 U.S.C. § 811.

The report further explained that in February 2011, the Clinic relocated to space within the U.S. Embassy grounds. When Mr. Crawford was hired by the Clinic in April 2011, he began to pursue a DEA license for the Clinic with VISN staff and regional counsel. Through Mr. Crawford's coordination, the Clinic obtained a DEA license in September 2011. The report confirmed, however, that it was not until March 2013, after the referral of Mr. Crawford's disclosure to the VA Secretary, that the Clinic finally resolved the issues relating to shipping controlled substances via the U.S. Postal System with the State Department and DEA. The Clinic began to receive shipments of FDA-approved controlled substances from McKesson in March 2013.

The report recommended that VISN 21 leadership continue to move forward with implementing a permanent process for procuring, shipping, and receiving controlled substances from the PPV. In addition, the report recommended that the VA develop a policy that describes the circumstances and processes for obtaining non-FDA-approved drugs for use in foreign countries. This may be necessary in emergency situations and where inpatient and non-VA community care is provided through fee-for-service arrangements with local medical facilities and health care providers that may administer non-FDA-approved drugs. In addition, certain vaccines, such as the Southern Hemisphere flu vaccine, are only available from non-FDA-approved sources.

The report also confirmed that there is a lack of specific VA and VHA directives that address the Manila Outpatient Clinic. VA and VHA handbooks and directives are written to guide VA facilities located within the United States and generally do not take into account the differences of operating a VA clinic in a foreign country. The report stated that VHA, VISN 21, and Clinic leadership have interpreted the handbooks and directives as they apply to the unique conditions in Manila, and have developed local policies and procedures since the inception of the Clinic. The report recommended that VISN 21 collaborate with VHA program offices to interpret VHA directives, handbooks, and information letters to apply the requirements as appropriate for the distinct circumstances of the Clinic. It also recommended that the Foreign Medical Program process for reimbursement for non-FDA-approved drugs according to 38 C.F.R. § 17.38(c)(3) be clarified.

As noted, in response to OSC's request for additional information and an update on the corrective actions taken, the agency provided a supplemental report on June 3, 2013. The Office of the Medical Inspector, upon the request of the Under Secretary for Health, conducted an investigation into the outstanding issues raised by OSC. This investigation included interviewing Mr. Crawford who, contrary to OSC policy, had never been contacted or interviewed by VISN 21 investigators. Further, the supplemental report explained that the Clinic was still implementing the process for acquiring FDA-approved controlled substances from the PPV and that the delays in full implementation noted by Mr. Crawford were the consequence of the location and unique circumstances of the Clinic. The supplemental report confirmed that the PPV purchasing process is now fully implemented. It also confirmed that a process is in place for coordination between

the Clinic and VHA program offices when issues of compliance with VA and VHA handbooks and directives arise.

The supplemental report also explained the agency's conclusion that, despite substantiating Mr. Crawford's allegations of a violation of agency regulations and policy, there was no gross mismanagement, gross waste of funds, or a substantial and specific danger to public health and safety. The supplemental report acknowledged that the Manila Outpatient Clinic was able to realize cost savings by implementing the PPV process. Based on a comparison of actual and projected costs using the PPV, the report noted that the Clinic would have saved $655,648 in fiscal year 2012 had controlled substances been purchased through the PPV. The PPV purchase process now enables the Clinic to realize those cost savings. However, the agency justified the Clinic's spending greater amounts on controlled substances purchased from local vendors prior to implementing the PPV purchase program, stating that such expenditure allowed the Clinic to continue to provide care for veterans while resolving the issues associated with procuring controlled substances through the PPV. The supplemental report stated that, without local purchasing of controlled substances, the Clinic would have been unable to provide adequate care to veterans.

In regard to allegations that the Clinic's purchase of non-FDA-approved controlled substances created a substantial and specific danger to public health and safety, the agency reviewed the Clinic's Adverse Drug Events Reporting System and found no reported instances of adverse drug events for the Clinic. While no evidence of a danger to veterans' health or safety was found, the finding of no reported adverse events for any medications at the Clinic raised questions regarding the Clinic's reporting practices and the validity of the data. Therefore, the supplemental report recommended that the Clinic review its Adverse Drug Event policy and procedures, train staff on the use of the reporting system, and monitor compliance. Mr. Crawford confirmed that the Clinic has provided such training to staff and that new procedures for reporting adverse drug events have been implemented.

III. The Whistleblower's Comments

Mr. Crawford provided comments on the report and supplemental report pursuant to § 1213(e)(1). He confirmed that the Manila Outpatient Clinic is now purchasing and dispensing FDA-approved controlled drugs to patients through the PPV purchasing process. In addition, he agreed with the need to coordinate and develop policies specifically suited to the Clinic. Mr. Crawford noted that he was never contacted by VISN 21 investigators during the primary investigation. As noted, OSC alerted the agency to this issue, and investigators interviewed Mr. Crawford during the supplemental investigation.

Mr. Crawford disagreed with the agency's conclusions that no gross mismanagement, gross waste of funds, or substantial and specific danger to public health

and safety occurred. Specifically, he noted that during the 22-year period when the Clinic was not in compliance with VA regulations, controlled substances were purchased from local vendors who likely obtained their supplies from non-FDA-approved pharmaceutical manufacturing facilities, which could present significant safety risks. He noted that the VA failed to present any evidence that the drugs purchased from these local vendors did not pose a substantial and specific danger to the health and safety to the 25,000 veterans seen at the Clinic during that time frame. He believes that, pursuant to VA's procedures for disclosure of adverse events to patients, the VA should be required to notify all Clinic patients regarding the Clinic's prior, longstanding practice of dispensing non-FDA-approved drugs. He questioned the validity of the lack of adverse drug events and suggested that this finding resulted from deficiencies in the Clinic's record keeping processes rather than an actual absence of problems.

In addition, Mr. Crawford took issue with the agency's conclusion that despite the significant cost savings realized after corrective action was taken, a gross waste of funds was not found. Mr. Crawford pointed out the length of time that the Clinic purchased non-FDA-approved drugs at a higher cost from local vendors. Based on the VA's admission that the Clinic would have saved $655,000 in fiscal year 2012 had it purchased controlled substances through the PPV process, he estimated that the Clinic could have saved roughly $6 million during the eight years that McKesson held the PPV contract with the VA. He believes that officials within the VA's National Acquisition Center are responsible for this waste of funds by failing to require McKesson to perform the terms of its PPV contract. He asserted that, contrary to the VA's claims, the problems related to purchasing controlled substances through the PPV were not difficult to solve; he believes that VA officials simply ignored the problems.

IV. The Special Counsel's Findings

I have reviewed the original disclosure, the agency reports, and the whistleblower's comments. Based on that review, I have determined that the reports contain all of the information required by statute. I have also found reasonable the agency's conclusion that the Clinic's practice violated agency policy and regulations, but based on the record, I am unable to determine that the practice did not pose a substantial and specific danger to public health or safety. It is troubling that the VA was unable to resolve the issues associated with procuring FDA-approved controlled substances for the Manila Outpatient Clinic for two decades. By its own admission, the VA is now realizing cost savings of more than $600,000 per year by finally implementing a process to purchase these drugs through the VA's PPV. Given the length of time taken to resolve this problem, and the significant costs incurred by failing to do so sooner, I have determined that the VA's findings that there was no gross mismanagement or a gross waste of funds are not reasonable. Nevertheless, I am pleased that the problem is finally resolved, with a process in place that not only ensures that our veterans receive FDA-approved medications, but also results in a cost-savings for the VA.

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

Respectfully,

Carolyn N. Lerner

Enclosures

[3] 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.