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The Special Counsel

April 7, 2016

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

Re: OSC File No. DI-15-0563

Dear Mr. President:

Pursuant to my duties as Special Counsel, I am enclosing an unredacted Department of Veterans Affairs' (VA) report based on disclosures of wrongdoing at the Washington, D.C. VA Medical Center (DC VAMC), Washington, D.C., made to the Office of Special Counsel (OSC). John Leahy, a staff registered nurse at the DC VAMC, alleged that the facility's failure to leak test flexible endoscopes in the DC VAMC Ear, Nose, and Throat (ENT) Clinic potentially placed thousands of patients at risk of exposure to infection. Mr. Leahy further alleged that, even after learning of the potential exposure, the facility failed to notify affected patients. I have reviewed the VA's report and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the agency investigation and whistleblower comments.[1]

I referred Mr. Leahy's allegations to Secretary Robert A. McDonald for investigation pursuant to 5 U.S.C. § 1213(c) and (d). Secretary McDonald asked the Interim Under Secretary for Health to refer the allegations to the Office of the Medical Inspector (OMI) to conduct the investigation. Secretary McDonald delegated responsibility to submit the agency's report to then-Chief of Staff Robert L. Nabors, II, who submitted the report to OSC on July 8, 2015. Under Secretary for Health David J. Shulkin, M.D., submitted the agency's supplemental report on December 11, 2015, and

[1]The Office of Special Counsel (OSC) is authorized by law to receive disclosure of information from federal employees alleging violation 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 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).

second supplemental report on February 24, 2016. Mr. Leahy provided comments on the initial report and supplemental report pursuant to 5 U.S.C. § 1213(e)(1). He declined to comment on the agency's second supplemental report.

I. The Agency Report

The agency did not substantiate Mr. Leahy's allegation that the DC VAMC's handling of flexible endoscopes in the ENT Clinic placed patients at risk of infection. The agency acknowledged that the facility did not conduct leak testing on the endoscopes until 2008, but asserted that the endoscopes were otherwise properly cleaned and disinfected in accordance with established guidelines and the manufacturers' recommendations. The investigation determined that it was "most likely" providers could identify leaks because of poor image quality or other malfunctions and that regardless of a visual inspection, the disinfectant used to clean the endoscopes would follow the path of the leak, thereby inactivating biohazardous materials. The agency further determined that the facility was not required to provide notice to patients because there is no evidence that an adverse event occurred as a result of reprocessed endoscopes. Based upon its findings, the OMI recommended that the DC VAMC request guidance from the National Program Office for Sterile Processing (NOSP) on consolidating sterile processing operations. The report also recommended that VHA convene a Clinical Review Board to assess the risk of possible exposure to patients prior to 2008, and if necessary, to recommend a large-scale disclosure.

In its first supplemental report, the agency repeated its determination that, despite the failure to conduct leak tests, the endoscopes were cleaned according to the manufacturers' guidelines. The agency also reiterated its finding that visual leak inspections were a reliable alternative to leak testing, stating, "With a thorough visual inspection of the endoscope, observed abnormalities (which may include a hole or damage), can be detected and scopes removed from service."

In its second supplemental report, the agency stated that, in response to the recommendation that the facility seek assistance with consolidating sterile processing operations, NOSP conducted a site assistance visit at the DC VAMC in April 2015 and a follow-up visit on September 22, 2015. The facility created plans to consolidate sterile processing, and NOSP is tracking all process changes, staff training compliance, and process outcomes.

The agency also reported that the Clinical Episode Response Team (CERT) met on August 31, 2015, to assess the risk posed to patients by the failure to leak test and the possible need for large-scale disclosure. The CERT determined that based upon the facts presented, the risk to patients was "negligible" and warranted neither a large-scale disclosure nor a review by the Clinical Review Board. The assistant deputy under secretary for health for clinical operations concurred with these findings in October 2015.

II. Mr. Leahy's Comments

In his comments on the agency's reports, Mr. Leahy asserted that leaks are not always visible to the naked eye and that a visual inspection is not sufficient to determine whether an endoscope leaks. Mr. Leahy pointed out that when he arrived at the ENT Clinic in 2008, he obtained a leak tester and discovered that at least four of the Clinic's endoscopes were leaking. Prior to the purchase of the leak tester, providers only visually inspected the endoscopes and did not identify these leaks, which directly contradicts the agency's assertion that the visual inspections were sufficient. Mr. Leahy also noted that although the agency's supplemental report refers to leak testing as a "preventative measure" to avoid damage and costly repairs, the manufacturer's guidelines for the endoscopes universally consider leak testing a crucial and required step for effective disinfection. Mr. Leahy provided sample instructions for an Olympus endoscope, which notes that cross-contamination due to improper cleaning, disinfection, or sterilization can occur, and the instructions include leak testing as one of the necessary steps for effective reprocessing.

Mr. Leahy further explained that damage to the fiberoptics of the endoscope from small amounts of fluid may take a long time to develop, during which time the endoscope may be used on a large number of patients. Mr. Leahy also explained that some leaks are positional, and not constant, due to the rubbery nature of the endoscopes, and that this may prevent disinfectant from reaching the same areas as the leak. Further, Mr. Leahy provided the manufacturer's instructions for the use of CIDEX OPA, which is the disinfectant used to clean the endoscopes. The instructions state that the presence of residual material in the endoscopes can decrease the efficacy of the germicide. Mr. Leahy asserted that an undetected leak can result in deposits of organic matter inside the endoscopes, reducing the ability of the disinfectant to properly clean the endoscope. He argued that regardless of the disinfectant quality, the disinfectant and the endoscopes must be used and cleaned in accordance with the manufacturer's instructions in order to be effective.

Mr. Leahy provided further evidence that despite the agency's assertion that no adverse events were reported as a result of the endoscopes, the danger to public health remains. Mr. Leahy provided a publication by The Hospital Infection Society on bronchoscopy-related cross-contamination. The publication offers an example of nine patients who were cross-contaminated with tuberculosis after being exposed to a single flexible endoscope that was not properly leak tested. All nine patients were infected over a two-and-a-half week period. Mr. Leahy asserted that prior to regular leak testing in the DC VAMC ENT Clinic, the leaking endoscopes had been used on potentially 52,000 patients and that infection on some level is therefore a near certainty.

III. The Special Counsel's Findings and Conclusions

I have reviewed the original disclosures, the agency reports, and Mr. Leahy's comments. Because of unresolved issues, and the contradictory evidence provided by the whistleblower and the VA, OSC does not have sufficient information to determine that the agency's findings and corrective actions are supported and reasonable. Mr. Leahy's comments are compelling and highlight significant gaps in the agency's reasoning. For example, the VA's determination that visual inspection of endoscopes is sufficient is directly contradicted by Mr. Leahy's discovery of leaking endoscopes in 2008. Those leaks went undetected for an indeterminate period of time and were not discovered until they were leak tested, despite reported regular visual inspection. Further, the specific example of cross-contamination at another VA facility that Mr. Leahy provided refutes the agency's assertion that the repeated use of leaking endoscopes did not place any patients in danger.

The agency's report contains unsupported findings. For example, the report contains inconsistent assertions, such as the finding that the ENT Clinic was reprocessing endoscopes prior to 2008 in accordance with manufacturer guidelines, despite the Clinic's lack of a required leak tester. As noted above, manufacturer guidelines specifically include leak testing as part of the proper reprocessing of endoscopes. The agency also failed to substantively respond to several questions that OSC posed in its initial request for a supplemental report, which OSC submitted in an attempt to understand and clarify the agency's determinations. For example, based upon information provided by Mr. Leahy, OSC requested an explanation of the efficacy of Cidex disinfectant on positional leaks and in the presence of biomaterial. In response to this specific question, the agency stated only, "Cidex has been on the market for more than 25 years, and Cidex OPA for 12. These products are still considered to be the best available for High Level Disinfection." The response addressed neither positional leaks nor biomaterial.

The VA chose not convene a Clinical Review Board as recommended by the report. The VA did not provide OSC with specifics on what information was provided to the CERT. But, according to the agency's second supplemental report, it appears that the CERT's review was limited to the information and determinations contained in the agency's initial report. As noted, the whistleblower pointed out inconsistencies in the agency report. Further, the CERT's determination that the risk to patients was "negligible" appears to disregard not only examples of cross-contamination due to a failure to leak test ENT endoscopes, but also the VA's own past experiences with the risks associated with improperly cleaned endoscopes. In 2009, the VA Office of the Inspector General (OIG) issued a report titled *Use and Reprocessing of Flexible*

Fiberoptic Endoscopes at VA Medical Facilities.[2] This report details the systemic failure of VA facilities to properly reprocess endoscopes, which includes leak testing. That report concludes that the failure to ensure compliance with endoscope reprocessing resulted in "a risk of infectious disease to veterans."[3] In response to this conclusion, the VA conducted a large-scale disclosure to over 10,000 patients. While such a disclosure may not be warranted in this instance, the information contained in the agency's reports to OSC are insufficient for the CERT to make that determination.

Based upon the foregoing, I cannot determine whether the agency's findings are reasonable. OSC does not have the specific expertise to make medical safety determinations. Rather, when OSC is presented with contradictory information and assessments between an agency and a whistleblower, OSC looks for findings and conclusions that are well-supported by the information provided in the agency's report. In this matter, OSC is not asserting that the VA has made an incorrect determination about the risk to patients and to forego notification. However, based on the record, I have concluded that the VA has not provided sufficient information for OSC to determine whether its findings are reasonable and supported by the facts.

As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the unredacted agency reports and Mr. Leahy's comments to you and 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 Mr. Leahy's comments in OSC's public file, which is available online at www.osc.gov.[4] This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosures

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[2]Report No. 09-01784-146 (June 16, 2009) *available at* http://www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf (last accessed February 24, 2016).

[3] *Id.* at i.

[4]The VA provided OSC with a report containing employee names (enclosed), and a redacted report in which employees' names were removed. The VA 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 report produced in response to 5 U.S.C. § 1213, and requests that OSC post the redacted version of the report 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 as an accommodation.