

**OSC FILE NUMBER MA-15-4557**

**FROM:** Francis L. Castagna CT (ASCP) SCT<sup>CM</sup>

**TO:** Disclosure Unit  
U.S. Office of Special Counsel  
1730 M. Street NW, Ste 218  
Washington DC 20036

**RE: OSC FILE NUMBER MA-15-4557  
WRITTEN COMMENTS RESPONSE TO AGENCY REPORT**

February 29, 2016

I would like to make the following written comments in response to the evidence, findings, and conclusions presented in the agency report.

I believe I can no longer remain anonymous, and am rescinding my request to the Office of Special Counsel (OSC) to keep my identity confidential.

This is necessary because of adverse actions against me taken in recent months by my immediate superiors in the Pathology and Laboratory Medicines Services (P&LMS), as well as by the Medical Center leadership in the Chief of Staff's (COS) office and the Human Resources (HR) department. These actions lead me to believe they are aware I filed the complaint with OSC.

The specific adverse actions include detailing me out of my assigned position as a Cytotechnologist, a position I have held for 18 years, and assigning me to the Office of Care Coordination, as a Care Coordination Assistant. They have also replaced me in my position as a Cytotechnologist with a recent new hire.

The Medical Center's COS explained I was removed from my assigned position for my safety, health and wellbeing, as well as for potential agency legal liabilities. While others are also at risk, no other P&LMS employee has been removed, including for reasons of safety.

I believe the aforementioned reasons are a pretext. I believe my removal is actually the result of disclosures to OSC regarding the Electron Microscopy (EM) department; disclosures to my superiors, Medical Center Leadership and the Occupational Health and Safety Administration (OSHA) regarding safety violations; and for filing an Office of Workers Compensation (OWCP) claim.

My superiors have also modified my Position Description (PD) by changing direct supervisory controls and chain of command reporting, which have remained unchanged during my past 18 years of service. In the past, I have reported directly to the Director of Anatomic Pathology (AP) for all technical and scientific diagnostic cytopathology work performed. Under the modified PD, I now report to the Supervisor of AP, who has also been designated as the Technical Supervisor of the Cytopathology Department. The Supervisor of AP lacks the education and technical qualifications to be a Technical Supervisor, which are clearly stipulated in VHA Directive 1106.1 and the Clinical Laboratory Improvement Act (CLIA 88 / CFR 493).

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After earning two bachelor undergraduate degrees, I received a Post-Baccalaureate certificate in Cytotechnology from Thomas Jefferson University College of Allied Health Sciences, an accredited Cytotechnology program. As part of the program, I completed four clinical rotations that included large reference laboratories and suburban hospital settings. My initial work experience included practicing both Gynecological (GYN) and Non-gynecological (NON-GYN) cytology at a large suburban medical center and a small independent reference laboratory. I am an American Society for Clinical Pathology-Board of Registry (ASCP-BOR) certified Cytotechnologist and am also certified by the ASCP-BOR as a Specialist in Cytotechnology.

As a VISN 4 Cytotechnologist with twenty two years overall experience and over eighteen (18+) years of experience with the Department of Veteran Affairs Medical Center (VAMC) located in Philadelphia, PA, I provide specialized diagnostic services for patients admitted to the VA Medical Centers in Philadelphia, PA, Lebanon, Wilkes Barre, PA, as well as Wilmington, Del. As the only Specialist in Cytotechnology for VISN 4, I am responsible for the day to day oversight of Cytology, including operations, personnel, and reporting of results.

I provide onsite telephone or electronic consultation to resolve technical problems in accordance with policy and procedures of the department. I maintain compliance with all accreditation standards in cytology to ensure the department conforms to the strict requirements of the VA Region II Commissioner's Office, VA Pathology and Laboratory Medicine National Enforcement Program, as well as various accreditation agencies such as College of American Pathologists (CAP), and the Joint Commission (JC).

I am considered a technical expert who is responsible for all Cytopathology program services. I am also the liaison for the Woman's Health Initiative (WHI) and the Cytopathology Department compliance officer.

For over 18 years I have served as a qualified laboratory accreditation inspector for both CAP and VA inspection teams. I also participate in the Pathology and Laboratory Medicine Service (P&LMS) Doctoral meetings, and the P&LMS Quality Management (QM) meetings, where I report and present all Cytopathology Quality Improvement (QI), Quality Control (QC), and Quality Assessment (QA) clinical indicator monitors.

For 16 of the last 18 years, the department of P&LMS has operated without an Anatomic Pathology (AP) supervisor, manager, administrator, or Cytopathology supervisor in place. As a result, I have been assigned and have performed all essential duties and responsibilities required of these positions. They include providing expert program direction, technical/scientific advice, and oversight for the Cytology subsection within P&LMS. Supervisory responsibilities include overall planning, administration, evaluation, and coordination of Anatomic Pathology services.

**Allegation 1:**

OMI states that in 1999 renal biopsies were discontinued in Philadelphia, PA, with the EM program no longer conducting studies for diagnostic purposes. EM diagnostic studies are employed for a diverse group of specimen types from AP, such as bladder, lung, and brain, and also for clinical virology and microbiology samples.

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Therefore it is not reasonable nor does it make sense for the agency to assert the diagnostic program ended **only because renal biopsies were discontinued**.

I find it convenient Dr. Einhorn became EM Director in 1999, the same year that the Electron Microscope (EM) diagnostic program ceased, and since that time 2,021 EM case reports were not finalized. The EM program appears to have accommodated Dr. Einhorn's lack of board certification, which is required to issue any final diagnostic patient medical reports.

I am troubled by the agency's conclusion that the requirement for the Director of EM to be board-certified is moot and has no bearing on nearly 2000 patient cases supposedly used for quality assurance, education and research.

Agency OMI findings confirm that a non-board certified pathologist "must always be reviewed by a board certified pathologist prior to any report being issued". OMI spoke with four other pathologists who all confirmed that one of them signs off on all of Dr. Einhorn's cases.

There is no mention a board certified pathologist reviewed, closed out, and or verified final interpretations of the quality assurance, education, and research cases. Rather, the non-board certified Director of EM issued-- in his medical, scientific opinion--finalized interpretations that in essence found nothing relevant to patient care. This is suspect considering the number of cases, and as previously mentioned the lack of review by a board certified pathologist required for the rest of Dr. Einhorn's work.

Testimonials reported by OMI from coworkers and colleagues such as pathologists and surgeons are self-serving, and provide insufficient evidence Dr. Einhorn is an expert in the area of EM and qualified to examine quality assurance, education and research cases.

I believe our veterans deserve the same high qualifying certification standards as those applied to diagnostic services when it comes to quality assurance, education, and research.

While the recommendations appear to be reasonable fixes to this problem, I have serious concerns as to whether the P&LMS and Medical Center leadership, as well as the leadership of the National EM Program, will effectively implement them based on the chronic insufficient oversight and monitoring for the past 18 years.

**Allegation 2:**

OMI states that within the VA, EM is currently used mainly for diagnosis of renal biopsy specimens, and that the cost benefit analysis conducted warranted sending out all renal specimens.

As I stated earlier in ALLEGATION 1:

EM diagnostic studies are employed for a diverse group of specimen types from AP, such as bladder, lung, and brain, also for clinical virology and microbiology samples.

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Therefore it is not reasonable nor does it make sense for the agency to assert the diagnostic program ended **only because renal biopsies were discontinued**.

It is contradictory that the EM program under Dr. Einhorn has somehow demonstrated, through submissions to the Central EM Program, the ability to maintain the proficiency levels of a clinical EM program. It is not a reasonable conclusion the EM program maintained the required proficiency level under Dr. Einhorn, when OMI clearly states he does not meet the qualifying board certified competency standards, and has not performed any diagnostic clinical work in his entire tenure as EM Director.

Of serious concern is the entire EM program over a 15 year period has only 23 of 2,021 accessioned EM specimens that went to final diagnosis, and these were only for quality assurance, education and research purposes.

These 23 cases were finalized through the VISTA system to make it appear to the EM Central Oversight offices that the required standards for continuation of the program in Philadelphia were being maintained.

I question the 54 research cases that were not electronically verified in the same manner as the 23 quality certification specimens. Research sample cases require selection, informed consent by veteran patients, and interpretative expertise by a qualified pathologist to be valid for research purposes.

The agency report cites an audit of the EM Vista computer files that revealed 1,998 pending cases, yet again citing that electronic closing out of these records is not required, and that paper records show completion of the process within the proper time frames. However, there is no mention the paper records contain any sort of interpretation i.e., "non-contributory," "unsatisfactory," or "correlates with original surgical/cytology specimen."

I find it contradictory and not reasonable that electronic accessioning is required in cases where no electronic (diagnostic) interpretative comment (regarding quality assurance, education and research) is needed. The diagnostic path to interpretative accuracy surely must be severely compromised by this.

I agree with the agency conclusion that this lack of electronic closure of cases is problematic.

I disagree that it creates a misconception of unfinished diagnostic work. I believe it confirms the perception of unfinished diagnostic work, and that patient medical records were left incomplete by such deliberate exclusions.

Agency Recommendations to "close out the open EM reports in VISTA, using the existing paper records to obtain the actual date of completion" appears to be an attempt to "back date" computer completion dates.

Verifying the accuracy of paper records after more than 15 years corrupts the integrity of the entire EM program. At this point these records could be made to say anything by anyone.

**Allegation 3:**

As I am highly experienced with the turnaround time (TAT) requirements for AP, the statement that "referring physicians reported that they obtained their pathology diagnoses usually within 2-3 days", needs clarification here.

This does not mean physicians received an EM report in this time frame. This time frame refers to the mandatory Surgical Pathology turnaround time frame of 24 hours.

The reference to "residual tissue that are not needed for the patient's anatomic pathology diagnosis" for EM specimens, also needs some clarification.

EM submissions require that a specimen, if it is to be submitted to EM for processing, be unfixed- that is no cytology preservatives or Formalin/Formaldehyde be used. The specimen must be submitted fresh, without any additives as previously mentioned, or immediately fixed in Glutaraldehyde, in order for the testing to be as accurate as possible. Therefore the standard collection protocol requires splitting the original sample for the various testing formats. Since delaying this submission to EM degrades the sample, making it less viable for successful EM testing, these split samples are used, not residual ("leftover") samples. This calls to question the use of primary samples, not residual samples, for research purposes.

In Findings, OMI states "in none of the specimens reviewed were clinical requests made for EM testing". It does not seem reasonable that not one clinician requested EM testing in all the years reviewed, yet 2,021 specimens were referred for EM testing by someone in either the EM or AP department.

OSC should be demanding an accounting of this practice. This suggests workload manipulation, with the intent to justify and validate salaries and positions that appear to have produced absolutely no benefits to either our specific veteran patients or to the government in general. I am petitioning the OSC to require further VA supplemental investigations of the EM issues brought up through their OMI.

As referenced by OMI on page 4, V BACKGROUND, VHA Handbook 1106.01 Subparagraph 10j, 10j (5), 10k, it appears that the Philadelphia EM program does not meet any of these guidelines that are the criteria for an EM program justification.

I believe that OMI does not offer any evidence that the Philadelphia EM program was used for any of the following purposes:

- Quality assurance – this is defined as EM used to confirm a diagnosis made by other tests
- Education – this is defined as EM used to train Medical students and residents in AP
- Research – this is defined as EM used for collection and analysis leading to publication

OSC should demand an accounting of any and all EM cases tested. It is inconceivable that the EM program does not have an official accounting of results produced by their testing.

The EM Director should account for all categories' he has interpreted. They should at the least be detailed as Satisfactory/Unsatisfactory/Negative/Abnormal (Malignant), and these findings should be

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correlated with the original clinical/surgical/cytology specimens they originated from, with any discrepancies and agreements fully explained.

To support the previously mentioned concerns, I would like to point out the following occurrences under the current P&LMS leadership of Darshana Jhala, M.D., Chief, P&LMS, Director of AP, Eugene Einhorn, M.D., Director, EM, Director, Quality Control, Supervisor, Cytolopathology, Ronald Macomber, MT, Supervisor, AP, as follows:

1 – June 2016 EM department shut down for violating Medical Center policy and procedures pertaining to Formaldehyde and Chemical Safety protocols. These violations have been ongoing since 1993 and substantiated by an investigation by the Medical Centers Health and Safety Office.

2 – Dr. Einhorn has confiscated all of the EM departments patient medical reports/photos/SF515's, refusing to return them to the EM technologist, who has been the responsible employee for approximately the last 30 years.

Respectfully Submitted,



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