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February 14, 2013

Ms. Johanna L. Oliver
Attorney, Disclosure Unit
U.S. Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

Re: OSC File No. DI-12-1098

Dear Ms. Oliver:

As you know this office represents Carolyn Bogal (the "whistleblower") in regard to the above-referenced matter. Ms. Bogal is in receipt of your letter of January 3, 2013 which included a copy of a Supplemental Report dated December 18, 2012 received by OSC from the Department of Veterans Affairs along with copy of a Consent to Public Release form.

Kindly consider this correspondence to constitute Carolyn Bogal's response to that Supplemental Report.[1] In addition, Ms. Bogal encloses herein the signed Consent to Public Release form authorizing OSC to include these written comments in its public file.

The VA's December 18, 2012 Supplemental Report addresses the question of whether or not disciplinary action was taken against the PI. In its response the VA writes that "Since the PI's actions were not adjudged to constitute research misconduct, counseling was decided to be an appropriate response to a first offense." It is beyond comprehension to the whistleblower as to how the VA could reach a determination that the PI's actions did not constitute research misconduct in light of ORO's specific findings that the PI did not fulfill all responsibilities required of investigators in violation of VHA Handbook 1200.05 § 9(e) and 9(h). Specifically, ORO found the PI to have failed to sufficiently oversee research staff to ensure that CSP Protocol #562 was implemented in accordance with the approved protocol.

Specific failures on the part of the PI as found by ORO included:

1. Having acknowledged Research Progress Notes indicating that the Un-Blinded Adverse Event (AE) Assessor had conducted full body skin examinations for research

[1] OSC granted Ms. Bogal an extension until February 15, 2013 to provide this response.

purposes, the PI did not identify this practice as a protocol deviation and did not intervene to ensure protocol compliance by study staff.

2. The PI did not ensure that the FBSE was documented prior to enrollment of at least one subject.

3. The PI did not ensure adherence to the protocol's "un-blinding" procedures.

4. The PI did not ensure that the study drug was prescribed only by an authorized provider.

When pressed by OSC, the VA conceded on October 3, 2012 that violation of VHA policies found in VHA Handbook 1200.05 rose to the level of a violation of "law, rule or regulation." Despite specific and numerous findings of that a law, rule or regulation had been violated, the VA determined that counseling for the PI was appropriate. No discipline issued.

The VA's treatment of the PI lies in stark contrast to its treatment of the whistleblower. As conveyed to OSC in her November 14, 2012 submission, subsequent to the whistleblower's contacting the national coordinator of the study to report her concerns about protocol violations with respect to the initial skin exams, both the PI and Chief of Medicine questioned her clinical competence. This included allegations that the whistleblower had failed to properly identify the presence of skin cancers during skin exams performed in her clinical practice (i.e. outside the study). The whistleblower received a series of communications from the VA in late 2011 into early 2012 alleging clinical incompetence and threatened of the potential reporting of the matter to the state licensing board.[2] The whistleblower believes this sudden questioning of her clinical competence in late 2011 to be retaliatory in light of her earlier complaints to the national coordinator, especially when one considers that the alleged events at issue dated back to 2010 and early 2011 and the whistleblower had not even worked for the VA since going out on disability in the spring of 2011.

Despite raising concerns as to the whistleblower's clinical competence in late 2011, and despite the VA last communicating with the whistleblower about them in early February, 2012, it was not until October 2, 2012 that the VA took action to report the matter to the Massachusetts Board of Registration in Nursing.[3] The retaliatory nature of the VA's actions is again inferred as a review of the record in this matter shows that it was on April 4, 2012 that OSC contacted the

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[2] In her November 14, 2012 response to the Agency's Report of Investigation and Supplement Report the whistleblower incorrectly stated that the last such communication was dated December 7, 2011, to which the whistleblower responded on January 13, 2012. In fact, the last such communication was dated February 8, 2012, to which she responded on February 24, 2012. The remainder of that November 14, 2012 submission was accurate in stating that as of that date, November 14, 2012, the whistleblower had received no similar communications since that time and had no knowledge that a report to the state licensing board was ever actually made.

[3] The whistleblower was not aware of this reporting until early February 2013 when she received notice of it from the Healthcare Investigator assigned to the matter. The mater is currently under initial investigation and no determination has been made as to whether any action on the VA's complaint will be taken.

VA regarding this matter, that the VA, through its ORO, spent the better part of the summer conducting an investigation into the whistleblower's complaint expending an enormous amount of time and effort, and that it was only after OSC questioned ORO's findings and requested further information on September 12, 2012, which ultimately forced the VA to concede that violation of laws, rules and regulations had occurred, that the VA initiated its complaint against the whistleblower with the state licensing board. The whistleblower finds no irony in the fact that the VA's complaint to the Board of Registration in Nursing is dated October 2, 2012, one day prior to its October 3, 2012 Supplement Report to OSC conceding a violation of law, rules or regulations.

Very truly yours,

Marc J. Levy

MJL/mjl
Enc.