February 5, 2015

John U. Young
Attorney, Disclosure Unit
U.S. Office of Special Counsel
1730 M Street, NW, Suite 218
Washington, DC 20036-4505

Re: OSC File No. DI-14-3389

Dear Mr. Young:

Please allow this letter to serve as my comments on the Report of Investigation provided to me on January 15, 2015. I note that the investigation made no effort to review practices in the pharmacy here beyond what was brought in the specific allegations. There was, for example, no assessment of whether other drugs or classes of drugs had been changed due strictly to cost concerns. There was no review of other drugs on the controlled list and, as can be seen in the attached recent e-mail, the Chief of Pharmacy is apparently unable to identify the drugs on the restricted list or why they are on it.

**Allegation 1:**

**Substituting for Aripiprizole and Ziprasidone**

As described in the report, the first of my allegations was that the agency was denying provider prescription orders for Aripirazole or Ziprasidone and substituting older, riskier medications in an effort to save money. While the agency finds this allegation to be substantiated, it misstates the facts in order to downplay the significance and culpability of the officials involved.

First, the suggestion in the report and executive summary that providers were simply "encouraged" to avoid prescribing the newer and more expensive medications is untrue and not supported by the investigation. The switch in medications was carried out by the pharmacy without an option being offered to the providers. The providers were overruled. The claim by the Chief of Staff on page five of the investigation that this was merely presented to providers for consideration is untrue and inconsistent with the other evidence referenced.

The pharmacy did, in fact, overrule the prescribing providers and the providers felt any appeal to the Chief of Staff was pointless. These changes were not a considered change by the providers but were done exclusively at the insistence of the pharmacy relying on the instructions of the P &T committee. The changes were made exclusively based on cost considerations for the pharmacy and were contrary to the best interest of the patients.

**Alprazolam**

Similarly, the agency has imposed nonsensical limits on the prescribing and dispensing of Alprazolam. This allegation was found to not be substantiated but the justification is internal inconsistent and leads to the conclusion that either the limits are unjustified (and therefore an unnecessary limitation on patient care) or are under applied (and therefore put patients at risk). The limitation here is based on the idea that Alprazolam is particularly dangerous. There is no support for this however and the cited references were not intended to measure the VA's patient population prescribed the drug or the unique risk of this drug to that population. While there is a risk of abuse for this entire class of drugs, it makes no sense to impose limits on a population of patients where that risk has not been shown to exist.

If there were some reason to distinguish Alprazolam from other benzodiazepines, then the agency's approach here still makes no sense. If it is a particular risk then why is there no review being conducted of the 422 patients already with active orders for Alprazolam? Why would 422 patients at risk be grandfathered in without review if a review is important? In addition, I know from asking the pharmacist conducting the review that there are no criteria for what the review will consist of or how the drug will or will not be found to be appropriate during this review. Again, what is the value of reviewing only new prescriptions with no criteria or guidance for what the review is looking for or accomplishing?

**Prescription Quantities**

There is no support for the conclusion that this limitation was based on safety and not cost considerations.

First, there is no explanation for why a supply of these drugs for a longer period poses any particular risk. There is no reference to any harm to any patient from being able to obtain a larger supply at one time without more refills. These drugs have little potential for misuse and it is no coincidence that they are also drugs on the cost list. Other than an effort to save money for the agency, there is no medical reason to restrict refills that have been properly prescribed.

More importantly, there is no analysis of the obvious harm and burden placed on patients in having to obtain a refill every 30 days. A refill through the VA is not an

immediate or burden-free event. The patient has to plan for the delay in ordering and shipping to the point that a patient with a 30-day supply of a drug that they are expected to take for much longer would have to begin the process of re-ordering almost immediately upon receiving their current 30-day supply with an obvious risk that they would not do so and experience an interruption in their medication schedule. The conclusion that providers "did not identify any patient who had their medication interrupted" is asinine given there is no process in place to monitor this and it would be dependent on the patient reporting.

**Allegation 2:**

This allegation concerns actions by a pharmacist acting as a provider to override the prescription of the patient's provider.

It should be noted that while the VA has approved some pharmacists to act in this role, it is still arguably not legal and it is not good practice. The pharmacist is being allowed to prescribe without oversight in spite of never having been to medical school or trained in any interaction with patients.

In this particular instance, the pharmacist overrode a prescription for a safe and effective drug, Gabapentin, for no apparent reason other than cost. In its place, the patient was given Lamotrigine. This use of Lamotrigine was off label and the medical research makes clear that there is no support for concluding it is effective for pain relief.

It is not appropriate for a pharmacist to substitute a cheaper drug that is not shown to be useful for pain management in the place of another drug prescribed that is actually shown to be effective.

Thank you for your attention to this matter.

Sincerely,

[redacted]