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**Analysis of Disclosures, Agency Investigation and Reports, Whistleblower Comments, and  
Comments of the Special Counsel**

**OSC File Nos. DI-04-0685 and DI-04-0765**

**Summary**

The disclosures in this matter were made by Drs. Dennis Beshara and Jane Holtzclaw, psychiatrists. Dr. Beshara began practicing psychiatry in 1985, and Dr. Holtzclaw, in 1981. Both whistleblowers have worked for the Department of Veterans Affairs (VA) since 1995. Dr. Beshara is board-certified in general psychiatry and board-eligible in child psychiatry, and Dr. Holtzclaw is board-certified in child psychiatry, adult psychiatry, and geriatric psychiatry.

Drs. Beshara and Holtzclaw disclosed to the Office of Special Counsel (OSC) that their colleague, Dr. Anup Sidhu, psychiatrist, intentionally misdiagnoses numerous VA mental health patients and over-prescribes certain medications, thereby creating a substantial and specific danger to public health.

The VA Office of Inspector General (OIG), with the assistance of the Veterans Health Administration (VHA), investigated Drs. Beshara and Holtzclaw's allegations and found them to be unsubstantiated. The agency report states that "[t]here is no evidence that Dr. Sidhu is prescribing deviantly or endangering patients." However, the investigators did find significant interpersonal conflicts among the psychiatric staff. OSC reviewed the agency report and informed the OIG that the report contained several deficiencies. In response, the OIG submitted a supplemental report. Having reviewed the supplemental report, OSC finds that the supplemental report is also deficient, and several of the agency's findings are unreasonable.

**The Whistleblowers' Disclosures**

Drs. Beshara and Holtzclaw alleged that Dr. Sidhu diagnoses a disproportionate number of patients with bipolar disorder or with the related diagnosis of mood disorder not otherwise specified ("not otherwise specified" is hereafter abbreviated as "NOS"). Bipolar disorder, also known as "manic depressive disorder," is a serious mental illness characterized by extreme mood fluctuations, wherein the individual cycles between episodes of mania and depression.<sup>1</sup> Bipolar disorder is classified as a psychotic mental illness because a person with this disorder may

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<sup>1</sup> During a manic episode, a bipolar individual usually experiences feelings of intense elation, excitability and hyperactivity. A depressive episode, on the other hand, is characterized by feelings of extreme sadness and hopelessness.

experience a break from reality when in the throes of a manic episode.<sup>2</sup> The related condition mood disorder NOS is similarly classified as a psychotic mental illness. Mood disorder NOS is intended to be a default, catch-all diagnosis to describe those individuals who are suffering from psychosis, but who do not appear to meet the criteria for one of the more specific psychotic illnesses. It is rarely invoked by most psychiatrists.

Recent statistics published by the National Institutes of Health show that approximately 1.2 percent of the general population in this country suffers from bipolar disorder. In order to ascertain the prevalence of bipolar disorder among patients served by the VA health care system, OSC contacted the VA Center for Practice Management and Outcomes Research, Serious Mental Illness Treatment Research and Evaluation Center (SMITREC), Ann Arbor, Michigan. According to SMITREC, the VA health care system treated a total of 4,152,377 patients in the year 2002. Of this total, 746,291 patients were treated by mental health professionals, and 70,345 of these patients were diagnosed with bipolar disorder. Thus, in 2002, bipolar patients comprised approximately 1.7 percent of all patients treated by the VA health care system, and approximately 9.4 percent of VA mental health patients. In regard to their own caseloads, Drs. Beshara and Holtzclaw advised that approximately 15 percent of their own patients at the VAMC have been diagnosed with bipolar disorder. They stated that they rarely diagnose patients with mood disorder NOS, and have each done so perhaps only two or three times since they began working for the VA in 1995. In contrast, they alleged that Dr. Sidhu diagnoses approximately 60 to 70 percent of his VAMC patients with either bipolar disorder or mood disorder NOS.

In support of their allegations, the whistleblowers provided OSC with data pertaining to all 29 individuals Dr. Sidhu treated on an outpatient basis during the month of December 2003. The data show that Dr. Sidhu diagnosed 13 of the patients with bipolar disorder and 6 with mood disorder NOS. Hence, he diagnosed a total of 19 out of 29 patients -- or approximately 66 percent -- with one of these two psychotic mental illnesses. The whistleblowers stated that Dr. Sidhu's diagnostic pattern during the month of December 2003 is representative of his pattern over the past several years.

According to Drs. Beshara and Holtzclaw, a bipolar diagnosis can have serious, far-reaching ramifications in a patient's life. In addition to any social stigma or emotional distress that an individual may endure as a result of being labeled bipolar, he or she may also experience difficulty obtaining employment. For instance, Drs. Beshara and Holtzclaw advised that individuals diagnosed with bipolar disorder are generally unable to obtain licenses to operate certain types of equipment and are routinely denied government security clearances because of their illness. Furthermore, an individual diagnosed as bipolar who is not already insured or who has to change insurance companies will have difficulty obtaining health insurance. If they succeed in obtaining coverage, they will usually be required to pay exorbitant health insurance premiums because of the diagnosis. Thus, Drs. Beshara and Holtzclaw contended that a

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<sup>2</sup> Mental illnesses are generally divided into two broad categories -- neurotic disorders and psychotic disorders. Neurotic disorders -- e.g., depression, anxiety, and phobias -- are more common and less debilitating than psychotic disorders -- e.g., schizophrenia and bipolar disorder. The primary distinction between the two types of mental illness is that a psychotic disorder entails a diminished ability to distinguish between reality and unreality.

misdiagnosis of bipolar disorder can unnecessarily inflict severe emotional, social and financial harm on the misdiagnosed patient and his or her family.

Drs. Beshara and Holtzclaw also alleged that, for the majority of patients Dr. Sidhu diagnoses with bipolar disorder or mood disorder NOS, he generally prescribes the drug Seroquel® (generic name "quetiapine fumarate"), usually in combination with either Neurontin® (generic name "gabapentin") or Trileptal® (generic name "oxcarbazepine"). Seroquel, manufactured by the pharmaceutical company Astra Zeneca, is an antipsychotic medication indicated for the treatment of schizophrenia. In January 2004, the U.S. Food and Drug Administration (FDA) also approved Seroquel for the short-term treatment of acute manic episodes associated with bipolar disorder. Neurontin, manufactured by Pfizer, and Trileptal, manufactured by Novartis, are anticonvulsant medications that have been approved by the FDA for the treatment of epileptic seizures. The whistleblowers stated that, in addition to prescribing the foregoing medications, Dr. Sidhu usually discontinues any antidepressant medications previously prescribed to the patient by another psychiatrist.

Drs. Beshara and Holtzclaw provided medication profiles for the 29 outpatients Dr. Sidhu treated in December 2003. The profiles list all medications Dr. Sidhu prescribed to these patients in December, as well as all medications prescribed to them during the previous 120 days. The data reveal that Dr. Sidhu prescribed the antipsychotic drug Seroquel to 25 of the 29 patients. He also prescribed Neurontin to 12 of the 29 patients, and Trileptal to another 12 patients. For eight patients, Dr. Sidhu discontinued the antidepressant medications that had been prescribed to them by other psychiatrists.

Drs. Beshara and Holtzclaw asserted that Dr. Sidhu's treatment patterns deviate significantly from accepted norms and are extremely dangerous. First, the whistleblowers objected to Dr. Sidhu's practice of routinely discontinuing patients' antidepressant medications. They maintained that many of Dr. Sidhu's patients suffer from clinical depression, rather than bipolar disorder, and, consequently, they depend on antidepressants to mitigate their depressive symptoms. Without antidepressants, these patients are likely to experience a relapse of their depression. Drs. Beshara and Holtzclaw further contended that the manner in which Dr. Sidhu discontinues the patients' antidepressant medication only compounds the danger. They stated that he generally takes his patients off of antidepressants in an abrupt fashion, rather than gradually decreasing their dosage over the span of several weeks. The whistleblowers explained that Dr. Sidhu's "cold turkey" approach significantly increases the possibility that a patient will regress into a deeper depression or possibly even attempt suicide.

Next, Drs. Beshara and Holtzclaw alleged that the frequency with which Dr. Sidhu prescribes Seroquel to his patients is of great concern. They advised that antipsychotic medications such as Seroquel pose several grave health risks. According to the whistleblowers, patients on antipsychotic medication are at a heightened risk of developing several debilitating health conditions, including (1) tardive dyskinesia – a syndrome marked by repetitive, involuntary, purposeless movements; (2) neuroleptic malignant syndrome -- a life-threatening condition characterized by fever, muscular rigidity, altered mental status and autonomic dysfunction; and (3) diabetes mellitus. Neurontin and Trileptal also pose significant health risks

and side effects, although these tend to be less severe than those associated with Seroquel. The most common side effects that patients experience from taking these medications include dizziness, somnolence, and nausea. There is also evidence suggesting that Neurontin may increase a patient's risk of developing cancer, and Trileptal may cause some patients to suffer from severe headaches and/or hyponatremia.<sup>3</sup> Although individuals who are genuinely suffering from a psychotic illness may find that the benefits they derive from these medications outweigh any health risks, this would not be true for any individuals who are not suffering from psychosis -- as the whistleblowers contended is the case for most of the patients to whom Dr. Sidhu has prescribed these medications.

Finally, Drs. Beshara and Holtzclaw advised that Dr. Sidhu has a long-standing financial relationship with Astra Zeneca, the manufacturer of Seroquel. Dr. Sidhu has informed his VA colleagues that he is conducting several research studies for Astra Zeneca on the efficacy of Seroquel in the treatment of bipolar disorder. In addition, Drs. Beshara and Holtzclaw stated that Dr. Sidhu meets with Mary Hansen, an Astra Zeneca representative, in his VAMC office approximately once per month. According to Drs. Beshara and Holtzclaw, Dr. Sidhu maintains that his research studies do not include any data obtained from his VAMC patients; rather, he asserts the studies rely exclusively upon data he obtained from patients in his private practice. Notwithstanding this claim, Drs. Beshara and Holtzclaw expressed concern that Dr. Sidhu's financial relationship with Astra Zeneca may unduly influence the decisions he makes in the course of diagnosing and treating his VAMC patients.

#### **Department of Veterans Affairs Investigation and Reports**

According to the agency report, the agency divided the whistleblowers' allegations into two main categories: (1) those concerning patient care and (2) those involving a possible improper financial relationship between Dr. Sidhu and the pharmaceutical company Astra Zeneca. The VHA referred the patient care allegations to the Network Director, VA Rocky Mountain Network Office, Glendale Colorado, whose jurisdiction includes the Sheridan VAMC. The Network Director tasked two psychiatrists from the Denver VAMC with conducting the investigation: Dr. Lawrence Adler, Chief of Mental Health Services, and Dr. Herbert T. Nagamoto, Director of Outpatient Mental Health Services. The allegations concerning Dr. Sidhu's relationship with the pharmaceutical company were investigated by the OIG.

Drs. Adler and Nagamoto conducted an on-site investigation at the Sheridan VAMC May 12th and 13th, 2004. They interviewed Maureen Humphreys, Hospital Director; Dr. Trehan, Chief of Staff; Dr. Schultz, Chief of Psychiatry; Dr. Olsen, Psychiatrist; Dr. Sidhu; members of the nursing staff; several psychiatric patients and the whistleblowers. They also reviewed 8 of the 29 patient records that Drs. Beshara and Holtzclaw provided OSC in support of their allegations.

According to the agency report, the investigation did not substantiate the whistleblowers' allegations of patient abuse, but did find "significant interpersonal issues among the parties." The agency report states that "[t]here is no evidence that Dr. Sidhu is prescribing deviantly or

<sup>3</sup> Hyponatremia is a condition characterized by abnormally low levels of sodium in the blood.

endangering patients.” Rather, Drs. Adler and Nagamoto attributed the whistleblowers’ concerns to the fact that they espouse a “differing viewpoint within psychiatry” from that espoused by Dr. Sidhu. The report explains that “Dr. Sidhu believes the data support diagnosing more patients in the bipolar spectrum and treating them accordingly.” Drs. Adler and Nagamoto did not express a preference for either position, noting that there is objective evidence in the research literature to support both viewpoints. The report also states that most of Dr. Sidhu’s patients related that he did not spend enough time with them, as he usually only spends approximately five minutes at a time with each patient.

In the course of investigating the whistleblowers’ allegations, Drs. Adler and Nagamoto found that the psychiatric unit at the Sheridan VAMC was beset by interpersonal problems among the staff psychiatrists. They noted that the staff psychiatrists had difficulty cooperating and learning from each other. In addition, the report states that, during his interview with the investigators, Dr. Beshara made accusations against Dr. Sidhu “that were presumptive, had no data for them, and appeared to be delusional.” Notwithstanding the foregoing observations, Drs. Adler and Nagamoto ultimately concluded that these conflicts did not appear to adversely affect patient care.

The agency report also states that the whistleblowers’ allegation that Dr. Sidhu maintains an improper relationship with Astra Zeneca was not substantiated. To address this allegation, OIG criminal investigators issued a subpoena to Astra Zeneca. Upon reviewing the documents provided by the pharmaceutical company, the OIG did not find any evidence of a violation of law, nor did it find any evidence of a research relationship involving the VA.

Finally, the agency report includes a list of recommended corrective actions. Specifically, Drs. Adler and Nagamoto recommended that (1) Dr. Sidhu be allowed to return to work, (2) Dr. Beshara should undergo a clinical evaluation, (3) the psychiatrists’ time should be restructured to enable them to spend a half-hour per week with each inpatient in addition to the usual round time.

On October 14, 2004, OSC notified the OIG that we found the report to be deficient under § 1213(d). Among other points, we explained that § 1213(d) requires agencies to provide a description of any action taken or planned as a result of the investigation. The report provided by the OIG instead merely lists recommendations -- it does not indicate whether these recommendations actually have been, or will be, implemented. We also informed them that the agency report is not responsive to some of the allegations that we referred for investigation. For example, Drs. Adler and Nagamoto did not perform a thorough review of the medical records we provided, as they only reviewed 8 of the 29 records. Also, the report fails to address the statistical evidence OSC provided to the agency that clearly demonstrates that Dr. Sidhu’s diagnostic and treatment patterns deviate dramatically from the norm. Instead, the report summarily dismisses Dr. Sidhu’s aberrant practices by simply attributing them to a difference of opinion within psychiatry. The report also neglects to address the potentially harmful nature of many of the drugs heavily prescribed by Dr. Sidhu.

On November 22, 2004, the OIG submitted a supplemental report. In response to OSC's request for further information about corrective actions actually taken or planned, the report indicates that (1) Dr. Sidhu returned to work on May 14, 2004, (2) the agency is in the process of arranging for Dr. Beshara to receive a clinical evaluation, and (3) Dr. Schultz instructed the psychiatrists that they were to see each of their inpatients for a minimum of 30 minutes per week.

The supplemental report also states that Drs. Adler and Nagamoto reviewed 12 additional outpatient charts, for a total of 20 charts reviewed out of the 29 charts OSC provided to the agency. Based on the information contained in these charts, the report states that Drs. Adler and Nagamoto identified several patterns in Dr. Sidhu's diagnosis and treatment of patients. First, they noted that, when Dr. Sidhu diagnoses a patient with bipolar disorder, he does cite specific symptoms that are consistent with depressive and manic traits. Next, they observed that the follow-up notes Dr. Sidhu records on patients frequently stress the same symptoms of difficulty sleeping, racing thoughts, and vivid dreams and that he frequently notes that the patient's "prognosis [is] poor," without providing a clear discussion to support this prognosis. The report also states that Dr. Sidhu prescribes Neurontin as a primary mood stabilizer "more than would be considered mainstream practice at this time, especially given the current evidence in the literature on this issue." In addition, Drs. Adler and Nagamoto found that Dr. Sidhu should be devoting more attention to some of his patients' substance abuse problems. The report ultimately concludes that, in spite of the shortcomings in Dr. Sidhu's performance, "there is no evidence of willful misdiagnosing or mistreatment of patients and no evidence of a substantial or specific danger to public health."

The supplemental report also lists recommendations for corrective action. Chiefly, Drs. Adler and Nagamoto recommended that the Sheridan VAMC take steps to implement and facilitate a system for the psychiatrists to engage in effective peer review. As with the recommendations contained in the initial report, the supplemental report does not indicate whether the agency has actually taken, or plans to take, corrective action in response to the report's recommendations.

### **The Whistleblower's Comments**

Drs. Beshara and Holtzclaw submitted joint comments on the agency reports. They expressed their opinion that the agency's investigation was inadequate. First, Drs. Beshara and Holtzclaw pointed out that the Denver psychiatrists who conducted the investigation lack investigative training and experience. Next, the whistleblowers stated that they do not believe that the Denver psychiatrists were able to examine the situation from an unbiased perspective, as the Denver VAMC is part of the same Veterans Integrated Service Network as the Sheridan VAMC. Thus, the whistleblowers asserted, the Denver psychiatrists were placed in the uncomfortable position of having to investigate a colleague.

In addition, Drs. Beshara and Holtzclaw contended that they were allotted only one hour to speak with the investigators; they stated that they requested, but were denied, additional time. They related that, as a result, they did not have a sufficient opportunity to present their concerns. They also stated that they were not provided advance notice of their meeting with the Denver

psychiatrists, and, therefore, they did not have the opportunity to prepare or present supporting documentation.

### Conclusion

Based on the representations made in the agency reports, I am unable to conclude that the agency's findings are reasonable. First, it does not appear that the agency conducted a thorough investigation. According to Drs. Beshara and Holtzclaw, the agency did not provide them with advance notice of their interview, and the investigators did not allow them sufficient time to present their allegations or provide them with the opportunity to provide supporting documentation. In addition, the investigators did not review all of the patient charts that OSC provided to the agency in support of the whistleblowers' allegations. I would not have forwarded this supporting information to the agency if I did not believe it to be significant to the investigation.

Next, the agency failed to adequately address key issues that OSC referred for investigation. For example, Drs. Beshara and Holtzclaw alleged that Dr. Sidhu abruptly discontinues patients' antidepressant medications on a routine basis, a practice which they claim jeopardizes patients' mental health and places them at greater risk of suicide. The patient charts OSC forwarded to the agency in support of the allegations include several instances where Dr. Sidhu engaged in this practice. However, the agency reports do not discuss this issue. When OSC raised this problem with the OIG, the OIG responded that the initial report addresses the issue in Finding No. 1, which states that "[t]here is no evidence that Dr. Sidhu is prescribing deviantly or endangering patients. By objective outcome criteria, especially suicides and length of stay, he has the best results." However, this statement is too general to adequately resolve this allegation. In the absence of specific information explaining the rationale behind the agency's conclusion, I am unable to determine that the agency's findings on this issue are reasonable.

The whistleblowers also presented evidence that Dr. Sidhu diagnoses approximately 60 to 70 percent of his VAMC patients with either bipolar disorder or mood disorder NOS, which stands in sharp contrast to the percentage of bipolar patients among the general population of VA mental health patients, which is approximately 10 percent. The report simplistically attributes this dramatic departure from the norm to a mere difference of opinion within psychiatry, without questioning whether the practice is detrimental to the well-being of Dr. Sidhu's patients. As the whistleblowers explained, a bipolar diagnosis can have serious emotional, financial and social consequences for a patient, and, consequently, should not be bestowed lightly or indiscriminately, as Dr. Sidhu appears to do. Not only does Dr. Sidhu appear to bestow this diagnosis on far too many patients, but his methods for arriving at this diagnosis appear suspect. As mentioned in the agency reports, Dr. Sidhu repeatedly cites similar presenting symptoms for most patients he diagnoses as bipolar, and he often arrives at this diagnosis after meeting with them for a mere five minutes. In light of the foregoing, I find the agency's dismissive treatment of this issue to be unreasonable.

The agency reports also do not adequately explain the reasoning behind the agency's conclusion that Dr. Sidhu's diagnosis and treatment patterns do not pose a substantial and

specific danger to public health. In the supplemental report, Drs. Adler and Nagamoto found that Dr. Sidhu prescribes Neurontin as a primary mood stabilizer "more than would be considered mainstream practice at this time, especially given the current evidence in the literature on this issue." In their disclosures to OSC, the whistleblowers enumerated the serious side effects caused by Neurontin and the other drugs over-prescribed by Dr. Sidhu -- Seroquel and Trileptal. The agency report does not address these concerns at all. Even though the investigators did find that Dr. Sidhu over-prescribes Neurontin, the report does not indicate that the agency has taken or plans to take action to correct this problem. Based on the foregoing, I find the agency's conclusion that Dr. Sidhu's actions do not pose a substantial and specific danger to public health to be unreasonable.

While the agency failed to adequately investigate and address the whistleblowers' allegations concerning Dr. Sidhu, the investigation and report unnecessarily focused a great deal of attention on Dr. Beshara. This preoccupation with Dr. Beshara and his supposed shortcomings is an obvious red herring, intended to divert attention away from the actual allegations OSC referred for investigation.

### **Recommendations**

Because I find that the VA's investigation was inadequate and several of its findings appear unreasonable, I recommend that the President and Congress follow up with the agency to insure that a more comprehensive investigation is conducted. I also recommend that the agency consider taking corrective and/or disciplinary action in response to the investigation's finding that Dr. Sidhu over-prescribed the medication Neurontin to VA patients. Any follow-up investigation should address whether he also over-prescribed the medications Seroquel and Trileptal.