INTRODUCTION

In its motion to order the involuntary injection of antipsychotic drugs, the government has failed to meet its burden of showing that this is one of the "rare" instances where involuntary medication is appropriate. *See Sell v. United States*, 539 U.S. 166, 180 (2003).

DISCUSSION

While the government correctly identifies the Sell analysis as the appropriate legal standard, it has failed in its motion to meet the Sell factors warranting forced medication. As the Ninth Circuit has explained, "It is well-established that involuntary medical treatment raises questions of clear constitutional importance." *United States v. Rivera-Guerrero*, 377 F.3d 1064, 1070 (9th Cir. 2004). Forced medication of Mr. CLIENT NAME based on the government's current (insufficient) showing would violate the defendant's constitutional rights, and should not be ordered.

I. The Government Has Not Shown that Important Federal Interests Are at Stake

The first *Sell* factor is whether "important governmental interests are at stake." *Sell*, 539 U.S. at 180. The government's imprecise discussion of the facts underlying this factor undermine its showing.[1]

For example, the government repeatedly asserts that the defendant was Afound with" a loaded revolver and a box of ammunition. Gov't Mot. at 2:7-10, 6:11-14. The implication is that

[1] It bears emphasis that in this case, as in *Sell*, the government has explicitly disclaimed reliance on a "dangerousness" theory in its motion for involuntary medication. *See* Gov't Opp. at 5 & n.3. In light of this concession, the defense does not address that basis for involuntary medication.

CLIENT NAME was in actual possession of a loaded weapon when arrested.

This is not the case. According to the incident report, the weapon was found inside of a gun carrying case, inside of a backpack, inside of a trunk of a car. *See* Exhibit A, SFPD Incident Report 031125879 pg. 7/16. The officers had never seen Mr. CLIENT NAME open or access the trunk. *Id*. There is no forensic evidence B such as fingerprint or trace DNA analysis B to suggest that Mr. CLIENT NAME ever handled this weapon.

As the Supreme Court cautioned, "Courts . . . must consider the *facts of the individual* case in evaluating the Government's interest in prosecution." *Id.* In the case now before the Court, there was no allegation that Mr. CLIENT NAME was engaged in any unlawful or dangerous activity before he was arrested. To the contrary (as is noted in the defense suppression motion) Mr. CLIENT NAME was allegedly stopped late at night because he parked briefly in a bus loading zone. *See* Exhibit A, SFPD Incident Report 031125879 pg. 7/16. It would be hard to imagine behavior less likely to support a forced medication order than parking in a bus zone.[2] Moreover, the government gives short shrift to the "special circumstances" that may "lessen the importance of that interest." *Sell*, 539 U.S. at 180. As explained by the Supreme Court:

> The defendant's failure to take drugs voluntarily, for example, may mean lengthy confinement in an institution for the mentally ill B and that would diminish the risks that ordinarily attach to freeing without punishment one who as committed a serious crime.

Id.

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[2] In relying on a speech by former Attorney General Ashcroft, the government appears to view the "government interest" prong of *Sell* as categorical analysis. *Sell*, however, suggests that this is in fact a case-specific inquiry based on the particular facts of the offense. *Sell*, 539 U.S. at 180 ("Courts, however, must consider the facts of the individual case in evaluating the Government's interest in prosecution." It remains for this Court to determine—apparently for the first time in this Circuit—which approach is correct.

In its discussion of the "special circumstances," the government in its Motion relies heavily on the Second Circuit's opinion in *Gomes*, but fails to report that decision's finding that lengthy civil commitment in an institution for the mentally ill would prove no bar to subsequent prosecution under the indictment. *United States v. Gomes*, __ F.3d __, 2004 WL 2377601, *3 (2d Cir. Oct. 15, 2003) ("We then consider whether the potential for civil commitment abates the Government's interest in prosecuting *Gomes*. After oral argument, we requested supplemental briefing from the parties on whether the Government would lose the ability to pursue the present indictment if *Gomes* were civilly committed or if at some point, by some means, he achieves sufficient competence to assist in his defense. The parties agree that in either case, the Government could still proceed against *Gomes* on the present indictment.")

If the government is convinced that Mr. CLIENT NAME will not recuperate without forced medication, he will certainly be subjected to a lengthy involuntary civil commitment in a mental health institution. Mr. CLIENT NAME accordingly fits precisely into that "special circumstance" contemplated in *Sell* that cuts against forced medication. *See Sell*, 539 U.S. at 180.

The government's that "there is some question as to whether the defendant would be committed civilly should this motion be denied" is unpersuasive. Gov't Opp. at 8:9-10. It is the government's burden to establish that this is the "rare" *Sell* case that merits forced medication. The government has not shown that this mentally-ill, hallucinating inmate would not be civilly committed—and, again, it is the government's burden to rebut this special circumstance.

Section 4246 of Title 18 specifically anticipates the civil commitment of an inmate who is "presently suffering from a mental disease or defect as a result of which his release would create a substantial risk of injury to another person or serious damage to property of another." 18 USC § 4246(a). That

evaluation can be undertaken sua sponte by the director of the facility in which the person is hospitalized. *Id*. To accomplish this commitment, the court need only find the above-described disease or defect by "clear and convincing evidence." *Id*. at § 4246(d). The government has not explained why the Bureau of Prisons did not undertake this evaluation as part of the *Sell* analysis, or why the government has failed to meet its burden of showing that the "special circumstance" of civil commitment is not likely. The defense would specifically request that the likelihood of Mr. CLIENT NAME's civil commitment (should he not be forcibly medicated) be taken up at an evidentiary hearing.

Finally, the government's concern that "memories may fade and evidence may be lost" is not well taken. *See* Gov't Opp. at 8:17. Mr. CLIENT NAME's original arrest took place on September 24, 2003. *See* Exhibit A, Incident Report, pg. 2. The only percipient witnesses to the alleged offense were law enforcement officers, who are trained witnesses and who have committed their observations to paper in incident reports. *See id.* This is not the case where elusive citizen witnesses will have disappeared or forgotten events by the time the case proceeds to trial; the SFPD police officers will be perfectly able to refresh their recollections with their incident reports when it is time for them to testify.

The government has not shown that the specific facts of this case rise to the level of an important governmental interest, particularly when the likelihood of lengthy civil commitment is considered. Forced medication is therefore inappropriate.

II. The Government Has Not Shown that Involuntary Medication is Substantially Likely to Render Mr. CLIENT NAME Competent to Stand Trial, and That Administration of the Drugs is Substantially Unlikely to Have Side Effects that Will Interfere

Significantly with the Defendant's Ability to Assist Counsel in Conducting a Trial Defense

The government has failed to make its required showing that involuntary medication is "substantially likely Mr. CLIENT NAME competent to stand trial," and to make the simultaneous showing that "administration of the drugs is substantially unlikely to have side effects that will interfere significantly with the defendant's ability to assist counsel in conducting a trial defense." *Sell*, 539 U.S. at 181.

The government's reliance on a profoundly inadequate report from the Bureau of Prisons undermines its showing on this, the second *Sell* prong. The Bureau of Prisons (and, accordingly, the government) fail to specify which drug it intends to forcibly administer. This shortcoming makes an evaluation of the likelihood of return to competency, and the dangers of side effects that would impact trial performance, impossible.

Notably, the Supreme Court in *Sell* repeatedly emphasized that the district court's analysis must focus upon the *particular drug* to be administered:

> Has the Government, in light of the efficacy, the side effects, the possible alternatives, and the medical appropriateness of *a particular course of antipsychotic drug treatment*, shown a need for that treatment sufficiently important to overcome the individual's protected interest in refusing it?

539 U.S. at 183 (emphasis added); *see also id.* at 185 ("Whether a *particular drug* will tend to sedate a defendant, interfere with communication with counsel, prevent rapid reaction to trial developments, or diminish the ability to express emotions are matters important in determining the permissibility of medication to restore competence.") (emphasis added).

The BOP report B and the government's motion B are silent as to the particular course of treatment anticipated for Mr. CLIENT NAME. See, e.g., Gov't Opp. at 9. Instead, the government attempts

to reassure the Court in platitudes that do not rise to the rigorous showing required in *Sell*. See id. at 9:21-22 (AThe risks and benefits of the particular medication are considered prior to initiating treatment, and if serious side effects emerge they are managed in a clinically appropriate manner.")

There are very good reasons to be concerned about the specific drug contemplated, and the specific dosage anticipated. To provide insights into the potential dangers of antipsychotic drugs, the defense has retained expert Dr. Pablo Stewart. *See* Exhibit B, Curriculum Vitae of Dr. Pablo Stewart. Dr. Stewart has reviewed the BOP report regarding Mr. CLIENT NAME. *See* Exhibit C, Declaration of Dr. Pablo Stewart. Dr. Stewart, a licensed psychiatrist, has experience with BOP antipsychotic treatment procedures, and has in fact qualified as a *Sell* expert in another federal case. *See id.*

In his experience with BOP treatment protocols, he has seen the Bureau prescribe dosage regimes that far exceed the FDA recommended dosages. *Id*.

Notably B and consistent with the suggestions in *Sell* B in Dr. Stewart's experience, an inmate would not be forcibly medicated in the California state courts unless the antipsychotic drug was specified and the dosage regime was described. *Id*.

In Dr. Stewart's opinion, it is medically inappropriate to predict the likelihood that a drug treatment would be likely to restore an inmate to competency to face trial without i) specifying the drug and dosages involved, and ii) first reviewing the medical and clinical history of the inmate. *Id*. As described above, the BOP report and the government's motion is entirely silent as to the specific drug and dosage contemplated. Moreover, the BOP did not consider Mr. CLIENT NAME's medical and mental health history—even though this history was provided to the Bureau before the evaluation was distributed.

BOP Warden Beeler wrote to this Court on October 12 with the CLIENT NAME report. *See* Exhibit D, Letter of Warden Beeler to Hon. Fern M. Smith and Forensic Report, Oct. 12, 2004. In this report, the evaluators state A[w]e do not have past medical records . . . ." See Exhibit D, Forensic Report pg 7 of 11. The evaluators conclude, "Therefore, there is no available established historical pattern of treatment response upon which to base the probability of his current response to medication." *Id*. at pg. 8 of 11.

Undersigned counsel, however, had sent CLIENT NAME's medical and mental health records to the BOP before this report was prepared. In fact, these records were received by the Bureau of Prisons on October 1, 2004 B nearly two weeks before Warden Beeler wrote to the Court. *See* Exhibit E, Letter of Kalar and FedEx delivery receipt.

As Dr. Stewart explains in his declaration, a patient's past experience and reactions to treatments with antipsychotic medication is one of the best indicators as to the likelihood for success for future treatment. *See* Exhibit C, Decl. Pablo Stewart. Therefore, it is a generally accepted medical practice to first review a patient's clinical and medical history, and to incorporate those histories into a patient's evaluation, before prescribing an antipsychotic drug treatment regimen. *Id.*

The Bureau's failure to secure, review, and analyze CLIENT NAME's clinical and medical records before seeking forced involuntary medication undermines the reliability of its diagnoses and recommendations.

A. The Government Has Not Shown a Substantial Likelihood that CLIENT NAME Will Be Restored to Trial Competency Through Forced Medication

A review of Mr. CLIENT NAME's clinical and medical history reveals that he may not in fact respond to forced medication of antipsychotic drugs. For example, in 2003—while incarcerated

B the defendant was hospitalized in at the ValleyCare Medical Center in Pleasanton, California.[3] *See* Exhibit F, Clinical and Medical Records at Bates 003. Mr. CLIENT NAME was receiving 100 mg of the drug seroquel.[4] Exhibit F, Bates 019. The defendant received medication for eight days, with increasing doses. *Id.*; *see also* Bates 018 (reflecting 200 mg dosage beginning 12/5/03). Although treating physician Dr. Ruiz said that CLIENT NAME was "calmer" "with violent outbursts," *id*. at Bates 026, later documents reported that the defendant was not responsive to medication. Specifically, on December 17, 2003, the treating physician noted that the defendant was still hostile at times—despite the medication. Id. at Bates 034.

After reviewing these records, defense expert Dr. Stewart has explained that the drug seroquel works fairly quickly; if the medication was indeed going to work, one could anticipate seeing results beginning in eight days. *See* Exhibit C, Declaration Pablo Stewart. Dr. Stewart has opined that the 2003 ValleyCare Medical treatment history suggests that Mr. CLIENT NAME may not respond as typically expected to medication with antipsychotic drugs. *Id.*

Dr. Stewart is also concerned with the conclusions the BOP draws from the observation that Mr. CLIENT NAME's psychotic symptoms are Achronic and persistent." *See id; see also* Exhibit D, Forensic Report pg. 9 of 11. From that observation, the BOP concludes, "It is our opinion that Mr. CLIENT NAME is unlikely to improve in the foreseeable future without treatment with

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[3] This hospitalization occurred while Mr. CLIENT NAME was in federal custody, at Santa Rita jail. The government offers no explanation why the BOP did not retrieve these custodial records before completing its evaluation. In any event, as explained above, these records were provided to the BOP by undersigned counsel nearly two weeks before the report was completed

[4] Seroquel is a psychotropic medication shown to be effective in the treatment of symptoms of schizophrenia, as well as mania associated with bipolar disorder. *See* http://www.seroquel.com/ (as visited Nov. 13, 2004)

antipsychotic medication . . . ." Exhibit D, Forensic Report pg. 9 of 11. In Dr. Stewart's opinion, however, "chronic and persistent" psychotic symptoms may also indicate intractability—of a mental illness so severe that it is nonresponsive to medication. *See* Exhibit C, Declaration Pablo Stewart. The "chronic and persistent" nature of Mr. CLIENT NAME's symptoms do not increase the likelihood that he will respond well to forced medication, or become competent to face trial if forcibly medicated. *Id.*

B. Antipsychotic Drugs Can Have Dramatic Side Effects That Can Impair a Defendant's Ability to Assist at Trial

In its motion, the government glosses over the serious side-effects that can arise from antipsychotic medications. The BOP report itself concedes, "A few of the side effects of the antipsychotic medications are serious . . . ." Exhibit D, Forensic Report at pg. 9 of 11. That is a rather profound understatement. Drugs used to treat psychotic illnesses can have profound side-effects that will dramatically impair Mr. CLIENT NAME's ability to evaluate the case and any settlement offers, assist counsel to prepare for the trial, and to convey appropriate emotions during his testimony. By failing to identify the anticipated drug treatment and dosage regimen, and by failing to reveal these various side-effects, the government has not met its burden justifying forced involuntary medication.

A review of the current status and dangers of antipsychotic drugs reveal the importance of specificity regarding the type of drug, and the dosage. Drugs used to treat psychotic illnesses in general C and schizophrenia in particular—are classified into two categories, "typical" antipsychotics and "atypical" antipsychotics. The typical antipsychotics are the older drugs, the first of which was approved for use by the FDA in the early 1950's.

Two of the more serious side effects associated with the typical antipsychotics are tardive dyskinesia and neuroleptic malignant syndrom (NMS). Tardive dyskinesia is a potentially irreversible syndrome consisting of involuntary, dyskinetic movements which may develop in patients treated with antipsychotic drugs. *See* Exhibit G, Typical Antipsychotics, Warning Label Inserts, Haldol, Navane, and Thorazine. As described by the National Institute of Neurological Disorders and Stroke, tardive dyskinesia is a physically conspicuous syndrome:

> Tardive dyskinesia is a neurological syndrome caused by the long-term use of neuroleptic drugs. Neuroleptic drugs are generally prescribed for psychiatric disorders, as well as for some gastrointestinal and neurological disorders. Tardive dyskinesia is characterized by repetitive, involuntary, purposeless movements. Features of the disorder may include grimacing, tongue protrusion, lip smacking, puckering and pursing, and rapid eye blinking. Rapid movements of the arms, legs, and trunk may also occur. Involuntary movements of the fingers may appear as though the patient is playing an invisible guitar or piano.

See http://www.ninds.nih.gov/health_and_medical/disorders/tardive_doc.htm (as visited Nov. 13, 2004).

Needless to say, grimacing, tongue protusion, lip smacking, puckering and pursing, rapid eye blinking, and rapid arm, leg, and trunk movement will have a dramatic (and perhaps irreversible) impact on Mr. CLIENT NAME's ability to present an effective defense and assist counsel at trial.

The side effect of neuroleptic malignant syndrome is equally troubling:

> Neuroleptic malignant syndrome is a life-threatening, neurological disorder most often caused by an adverse reaction to neuroleptic or antipsychotic drugs. Symptoms include high fever, sweating, unstable blood pressure, stupor, muscular rigidity, and autonomic dysfunction. In most cases, the disorder develops within the first 2 weeks of treatment with the drug; however, the disorder may develop any time during the therapy period. The syndrome can also occur in people taking anti-Parkinsonism drugs known as dopaminergics if those drugs are discontinued abruptly.

See http://www.ninds.nih.gov/health_and_medical/disorders/neuroleptic_syndrome.htm (as visited

Nov. 13, 2004).

The newer atypical medications are now considered the first line of treatment for schizophrenia and bipolar disorders.[5] Even these newer drugs, however, have serious side effects that would impair Mr. CLIENT NAME's ability to assist in his defense. For example, olanzapine (brand name "Zyprexa") has a commonly reported adverse event of somnolence, occurring in over 25% of all patients taking the drug. *See* http://pi.lilly.com/us/zyprexa-pi.pdf (Eli Lilly Drug Warnings) (as visited Nov. 13, 2004) ("olanzapine has the potential to impair judgment, thinking, or motor skills."); *see also* Exhibit H (Atypical Warning Label Inserts, Zyprexa, Seroquel, Risperdal).

To weigh the likelihood and severity of side effects of any psychotropic medication this Court must know i) the specific medication at issue, ii) the anticipated dosage levels, and iii) the defendant's previous history with this or similar medications. The government has provided none of this information, and has accordingly failed to meet its burden to show this is the "rare" case meriting involuntary medication.

III. Involuntary Medication is Not Necessary to Further the Government's Interests

To authorize involuntary medication, this Court "must conclude that involuntary medication is necessary to further [important governmental interests.] The court must find that any alternative, less intrusive treatments are unlikely to achieve substantially the same results . . . And the court must consider less intrusive means for administering the drugs, e.g., a court order to the defendant backed

[5] The BOP report and the government's motion are silent as to whether the forced medication will involve typical, or atypical, antipsychotic medication.

by the contempt power, before considering more intrusive methods." *Sell*, 539 U.S. at 181. The government has failed to meet its burden to show that involuntary injections of psychotropic drugs are necessary, and that other less intrusive means of administering the drugs are not feasible.

As an initial matter, it is unclear whether the Bureau of Prisons has actually attempted voluntary medication of antipsychotic drugs. On the one hand, the Bureau states, AIt is our opinion that Mr. CLIENT NAME is unlikely to improve in the foreseeable future without treatment with antipsychotic medication, which he is now refusing on a voluntary basis." *See id.* at pg. 9 of 11. The report also states, "Mr. CLIENT NAME was not treated with psychotropic medication; he refused to be treated." *Id*. at 8 of 11.

The report also states, however, that "It is likely that the antipsychotic medication would have to be administered involuntarily as Mr. CLIENT NAME is currently actively psychotic, does not communicate with the staff in [a] realistic and meaningful manner, does not appear to have the capacity to give voluntary consent, and refuses treatment with medication." *See* Exhibit D, Forensic Report at pg. 8 of 11. This suggests that Mr. CLIENT NAME has not yet been presented with the option of voluntary medication with antipsychotic drugs. Similarly, Chief Psychiatrist Jean Zula apparently told AUSA Crudo that "prior to forcibly medicating the defendant, the Butner would request that he voluntarily take the medications; in their experience, informing a patient that a court has ordered the medication is sometimes sufficient to cause him or her to comply." *See* Gov't Mot., Decl. Tim Crudo at 2:11-14.

Before this Court can order involuntary medication, it must have before it a declaration or affidavit describing when, and how many times, voluntary medication with antipsychotic drugs have been attempted, which drugs were offered, and the defendant's reaction to these attempts.

This prong of the *Sell* analysis deserves special attention by this Court, because Mr. CLIENT NAME has a history of voluntarily complying with psychotropic drug regimens. For example, during his hospitalization in the ValleyCare Medical Center in 2003 it appears that he was voluntarily taking the antipsychotic drug seroquel. *See* Exhibit F, Clinical and Medical Records at Bates 007 ("[Patient] says he will take meds if offered even though he's not feeling paranoid at this time.") Moreover, when the defendant was returned to the Alameda County jail (Santa Rita) after hospitalization, he asked that he be kept on the same medication Bdemonstrating voluntary compliance. *Id*. at Bates 036.

Similarly, Mr. CLIENT NAME was on Thioridazine (brand name "Mellaril") while committed in Atascedero in 1994. *See* Exhibit F, Clinical and Medical Records at Bates 02. During that commitment, he was prescribed 600 mg of the drug. *Id.* Because Mellaril can only be taken orally, this was likely voluntary medication as well. *See* Exhibit C, Declaration of Dr. Pablo Stewart.

The government's motion is also notably silent on other "less intrusive means for administering the drugs, e.g., a court order to the defendant backed by the contempt power . . . ." *Sell*, 539 U.S. at 181. According to the Chief Psychiatrist at the Federal Medical Center, Dr. Jean Zula, Ainforming a patient that a court has ordered the medication is sometimes sufficient to cause him or her to comply." *See* Gov't Opp., Decl. AUSA Crudo. Before ordering the extraordinarily intrusive measure of involuntary medication, this Court must first consider an order that Mr. CLIENT NAME simply take the drugs orally and voluntarily—an order that BOP psychiatrist Dr. Zula herself speculates may be effective. The Court can only revisit the need for forced, involuntary medication after such an order has been tried, and failed.

Finally, the defense respectfully declines the government's invitation to litigate the

defendant's suppression motion before deciding the issue of involuntary medication. *See* Gov't Opp. at 11:8-10. Mr. CLIENT NAME is currently incompetent and is 3,000 miles from this Court. The defense does not consent to proceeding on substantive matters in the defendant's mental and physical absence.

IV. The Involuntary Injection of Antipsychotic Drugs is Not Medically Appropriate, i.e., in Mr. CLIENT NAME's Best Medical Interest in Light of His Medical Condition

Certainly the most troubling of the *Sell* prongs in relation to Mr. CLIENT NAME is the fourth; whether "administration of the drugs is *medically appropriate*, i.e., in the patient's best medical interest in light of his medical condition." *Sell*, 539 U.S. at 181 (emphasis in original). The involuntary injection of psychotropic drugs in Mr. CLIENT NAME's case are decidedly *not* in his best medical interest, in light of his medical condition.

The Bureau of Prisons Forensic report reveals that Mr. CLIENT NAME suffers from a number of medical conditions that are given short shrift in the recommended treatment regimen. The report states, "Medical history was positive for sarcoidosis,[6] diabetes mellitus,[7] asthma, and anemia."

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[6] "Sarcoidosis is a disease that causes inflammation of the body's tissues. Inflammation is a basic response of the body to injury and usually causes reddened skin, warmth, swelling, and pain. Inflammation from sarcoidosis is different. In sarcoidosis, the inflammation produces small lumps (also called nodules or granulomas) in the tissues. The inflammation of sarcoidosis can occur in almost any organ and always affects more than one. Most often, the inflammation starts in either the lungs or the lymph nodes (small bean-shaped organs of the immune system). Once in a while, the inflammation occurs suddenly and symptoms appear quickly, but usually it develops gradually and only later produces symptoms. *See* http://www.nhlbi.nih.gov/health/public/lung/other/sarcoidosis/sarcoid.pdf (as visited Nov. 13, 2004) (web page of the Department of Health and Human Services, National Heart, Lung, and Blood Institute).

[7] "Diabetes mellitus is a group of metabolic disorders with one common manifestation: hyperglycemia. Chronic hyperglycemia causes damage to the eyes, kidneys, nerves, heart and

Exhibit D, Forensic Report at pg. 4 of 11. Mr. CLIENT NAME himself complained of having diabetes to Bureau physicians. *Id.* at pg. 3 of 11. Although the report states that Aserial check of blood sugar by Accu Check were within the normal range," *id*. at 5, the report does not provide the defendant's blood sugar readings.

The report also concedes that the "blood chemistries were within normal limits with the exception of several indices which showed [] mild abnormalities and were not considered clinically significant." *Id.*

These vague medical results are troubling, because Mr. CLIENT NAME was recently hospitalized at the ValleyCare Medical Center in Pleasanton and was much more specifically diagnosed with several diseases. *See* Exhibit F, Clinical and Medical Records at Bates 024. Specifically, Mr. CLIENT NAME was diagnosed with chronic viral hepititus B,[8] and with adult onset diabetes (type II).[9] *Id.*

Defense expert Dr. Pablo Stewart opines that, before prescribing any antipsychotic drug, he would insist on more complete data from blood sugar and blood chemistry tests than that reflected in the BOP forensic report. *See* Exhibit C, Declaration of Dr. Pablo Stewart. This would be

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blood vessels. The etiology and pathophysiology leading to the hyperglycemia, however, are markedly different among patients with diabetes mellitus, dictating different prevention strategies, diagnostic screening methods and treatments." *See* http://www.aafp.org/afp/981015ap/mayfield.html (as visited Nov. 13, 2004) (American Academy of Family Physicians web page).

[8] "Hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus (HBV), can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death." *See* http://www.cdc.gov/ncidod/diseases/hepatitis/b/ (as visited Nov. 13, 2004) (CDC web page).

[9] *See* footnote 6, *supra*.

particularly true when the patient presented with recent diagnoses for liver disease and diabetes. *Id.* Dr. Stewart's concern is based on the fact that antipsychotic drugs can have side-effects that can pose a serious health risk to diabetics, and to those who suffer from liver disease. *Id.*

For example, in its report the Bureau of Prisons refers to a "newer antipsychotic medication" that is now available Ain an injectable form and can be administered on an involuntary basis." *See* Exhibit D, Forensic Report at pg 10 of 11. Dr. Stewart suspects that the BOP is here referring to risperidone (brand name "Risperdal.")[10] *See* Exhibit C, Declaration of Pablo Stewart.

As reported in the FDABrequired warning labels for this drug, the medication presents very real risks for diabetics—risks that have not yet been quantified:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL7. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

http://www.risperdal.com/active/janus/en_US/assets/ris/risperdal.pdf (as visited Nov. 13, 2004); *see also* Exhibit H (Atypical Antipsychotic Drugs, Warning Label Inserts, Zyprexa, Seroquel, Risperdal).

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[10] "RISPERDAL® (risperidone) is a prescription medication that has been approved by the Food and Drug Administration (FDA) for treatment of bipolar I disorder or to treat acute to manic or mixed episodes associated with bipolar I disorder. It is approved for use as therapy alone or in combination with drugs called mood stabilizers, such as lithium or valproate." *See* http://www.risperdal.com/html/ris/consumer/pd_risperidone.xml;jsessionid=HP0DXYO5JMKOICQPCCFTC0YKB2IIQNSC?article=index_risperidone.jspf (as visited Nov. 13, 2004).

Similarly, another medication frequently prescribed (off-label) as a mood stabilizer can have a serious side-effects for those who suffer from liver disease. Valproic acid (brand name, "Depakene") is extremely harsh on the liver. The Physician's Desk Reference warns flatly, "You should not take this drug if you have liver disease or your liver is not functioning properly . . ." *See* http://www.pdrhealth.com/ drug_info/rxdrugprofiles/drugs/dep1124.shtml (as visited Nov. 13, 2004). The FDA warning label states:

> Liver disease impairs the capacity to eliminate valproate. In one study, the clearance of free valproate was decreased by 50% in 7 patients with cirrhosis and by 16% in 4 patients with acute hepatitis, compared with 6 healthy subjects. In that study, the half-life of valproate was increased from 12 to 18 hours. Liver disease is also associated with decreased albumin concentrations and larger unbound fractions (2 to 2.6 fold increase) of valproate. Accordingly, monitoring of total concentrations may be misleading since free concentrations may be substantially elevated in patients with hepatic disease whereas total concentrations may appear to be normal.

http://www.fda.gov/medwatch/SAFETY/2002/Depakote_PI.pdf (as visited Nov. 13, 2004) (emphasis added).

The government's treatment "plan," such as it is, does not acknowledge Mr. CLIENT NAME's medical limitations; specifically, his adult-onset diabetes and his liver disease. This is of particular concern because many psychotropic drugs are specifically contraindicated for these diseases. Because of the defendant's previously-diagnosed medical conditions, and because the government failed to address the interactions of these conditions and forced medication, the government has not met its burden under this last *Sell* factor. Involuntary injection of psychotropic medication cannot, therefore, be ordered.

V. This Court Should Either Deny the Government's Motion, or Schedule the Matter for an Evidentiary Hearing Before Ordering Involuntary Injection of Psychotropic Drugs

The government has moved this Court to order the forced injection of antipsychotic drugs that can cause permanent, irreversible damage to Mr. CLIENT NAME's health. It has not made a showing commiserate with such a weighty request. The prudent course for this issue of constitutional dimensions would be to deny the government's motion.

In the alternative, this Court should order an evidentiary hearing with testimony from the Bureau of Prison evaluators, and from defense expert Dr. Pablo Stewart. At this hearing, the government should be prepared to describe the precise type and dosage of the drug regimen anticipated.

CONCLUSION

For the foregoing reasons, the defense asks that the Court deny the government's motion or, in the alternative, schedule this matter for an evidentiary hearing.