# Etta Bavilla vs. State of Alaska, Department of Corrections

# I. Introduction

# Educational and Professional Background

I am a Board Certified psychiatrist residing in North Carolina. The scope of my current practice includes clinical duties as a contract psychiatrist, independent research in the areas of neuropharmacology and epidemiology, and educational lectures for medical professionals and the public.

Academically, my background includes baccalaureate degrees from California Lutheran University (BA in political science, BS in Biology - completing both programs summa cum laude), as well as a Master's in Public Administration. My professional education in medicine was completed at the University of Colorado School of Medicine in May 1996. Following medical school, I was commissioned in the US Navy with orders for post-graduate training in psychiatry: internship at San Diego Naval Medical Center (Balboa Hospital - graduating in 1997); residency in Washington, D.C. in the National Capital consortium (a tri-service training program performed at Walter Reed Army Hospital, Bethesda Naval Hospital, and Malcolm Grow Hospital at Andrews Air Force Base).

Subsequent to the successful completion of my residency in June 2000, I was assigned as a staff psychiatrist at Bethesda Naval Hospital where I supervised the work of other trainees, and provided care to active duty personnel, their dependents, and retirees. Since transitioning out of the military in spring 2002, I have pursued work as a Locum Tenens provider and independent consultant.

# II. Forensic Experience

In spring of 2003, I participated as an expert witness in the case of Myers vs. Alaska Psychiatric Institute (API). The case was important because of its consideration of my testimony about the efficacy and safety of neuroleptics. Special emphasis was placed upon the FDA's analysis and approval of olanzapine (Zyprexa) as a primary example of the "newer" antipsychotic therapies. Interestingly, it was not until March 22, 2004, that the FDA announced to physicians its requirement for new warnings about health risks associated with olanzapine and other atypical neuroleptics [1]. This FDA alert has finally reflected some of the concerns which I have expressed in my writings over the past year [2, 3]. In considering my testimony in the Myers case, the Alaska Superior Court, and the former Director of Schizophrenia Research at NIMH (National Insitutes of Mental Health) both qualified me as an expert in the area of psychopharmacology. This expertise continues to expand, particularly through my personal research which has been preparatory for the publication of a book explaining the mechanisms through which psychiatric medications often prevent or delay recovery. My most recent work with patients involved a Locum Tenens assignment in the North Carolina Department of Corrections. In that position, which I held between August 2003 and March 2004, I was directly responsible for the medication management, multidisciplinary treatment plans, and initial psychiatric assessments of patients at three different facilities: 1) an in-processing misdemeanor camp; 2) a minimum custody prison camp; and 3) a medium- and close-custody camp, housing inmates with chronic medical and mental illnesses. My experience as the lead psychiatrist at the latter facility is especially pertinent to the current case, for it sensitized me to the complexities associated with the care of chronically ill prisoners, and the stressors associated with extended confinement. It also heightened my concern about the provision of humane and competent treatment for mentally ill prisoners with co-morbid physical disease and substantial histories of substance abuse, for whom the prisons of our nation have become the primary forums of health care.

# III. Impact of Former Testimony and Relevance to Present Case

In the 2003 case of Myers vs. API, my testimony addressed many of the flaws associated with the development and approval of psychiatric drugs, and with the dissemination of information explaining the risks associated with chemical therapies. As many physicians and legal professionals seem unaware of the scope of these problems, a brief review may be helpful in the current deliberations:

- ghost writing: this refers to the process by which payments are given by pharmaceutical companies to physicians who lend their names to drug-company generated research reports. This perpetuates the illusion of independent research and objective findings, when in fact the listed authors have never participated in the production or review of the data for which they assume authorship [4]
- 2) file drawer effect & publication bias: this refers to the process by which journals, professional organizations, and the media "file" negative studies in the waste can or other "file" drawer, delaying or refusing to publish them. Negative studies are far less likely to be reported in medical journals, due to pressures upon editors from advertisers and other sources [5]
- 3) non-disclosure agreements: this refers to the process by which drug companies and other funders of research force their employees to sign contracts prohibiting uncensored release of investigations and findings. These agreements can prevent or delay public access to vital information for many years, often with tragic results [6,7]

4) biased trial designs: this refers to the numerous methods used by drug companies and other agencies to produce and interpret data favorable to new products, relative to placebo or older therapies. Specific examples of the biases employed include the use of non-comparative dosing strategies; placebo washout; penetration of blinding procedures; the use of concomitant medications; rater-scored rather than patient-scored assessment scales; post-hoc determinations of efficacy; and the manipulation of intention to treat data to favor LOCF vs. OC results [8,9]

Influenced in part by a consideration of these problems, the Superior Court of Alaska found in the Myers case that:

"it is troubling that the statutory scheme apparently does not provide a mechanism for presenting scientific evidence challenging the proposed treatment plan [10]."

Furthermore, the ruling Judge held that:

"a valid debate does exist among qualified experts regarding the use of psychotropic medications for schizophrenia [11]."

As the debate about the use of medications remains equally viable today, it is to the presentation of the most relevant scientific evidence that this report now turns.

IV. Materials Reviewed

I have been asked to review the matter of Etta Bavilla vs. State of Alaska, Department of Corections, in order to provide my perspective on treatment(s) that would be in the best medical interest of the patient.

In preparing this report, I have reviewed the following materials:

- Opposition to Motion for Temporary Restraining Order filed by Assistant Attorney General, John K. Bodick dated 04/02/04
- Deposition of Laura Brooks, MS, LPA Director of Mental Health Services for Alaska DOC dated 04/02/04
- Involuntary Psychotropic Medication Policy Alaska DOC Signed by Margaret M. Pugh, Commissioner, Dept. of Corrections dated 07/09/95

- 4) Form #807.16C Basis for Decision (of Involuntary Medication) Revised 6/95
- 5) Deposition of Dr. Dwight Stallman Chief Psychiatrist, Alaska DOC dated 04/02/04
- Findings of Fact, Conclusions of Law and Order on Application for Post-Conviction Relief filed by the Honorable Fred Torrisi, Judge dated 01/20/04
- 7) Telephone conversations with Mr. Jim Gottstein, Esq. 04/02/04 04/04/04
- V. Limitations of Current Report

Due to a variety of restrictions (temoral, geographic, and procedural), this report has been prepared in the context of the following limitations:

- 1) lack of access to complete medical records and evaluations, past and present
- 2) lack of an opportunity to perform a direct face-to-face interview with the patient for the purpose of assessing mental state, neurocognitive functions, and judgment; and for the purpose of performing a thorough review of this patient's social and development background (including history of physical, emotional, and /or sexual abuse) past symptoms, and subjective response to treatments
- 3) lack of an opportunity to perform interviews with collateral sources of information, [such as family members, friends, former employers, teachers]

- 4) lack of an opportunity to perform an independent, comprehensive medical evaluation with referrals to pertinent specialists for immediate consultations:
  - a) lab tests such as CBC, liver function tests, comprehensive metabolic panel, heavy metal screen, hepatitis screen, RPR and FTA-ABs (to rule out latent or neurosyphilis), prolactin and cortisol levels, ESR and ANA (to rule out lupus), HIV, urine drug screen (to rule out on-going use of cannabis or other substances), thyroid function tests (to include TSH and free T4), B12 and folate levels, urinalysis, urine or serum HCG to rule out pregnancy
  - b) thorough neurological exam to include review and assessment of all cranial nerves, sensory, and motor abilities, coordination, verbal fluency, gross cognitive limitations
  - c) neuroimaging as current standard of care for psychosis includes CT, MRI, or both to rule out intracranial lesions or other anatomic pathology
  - d) EEG assessment: (especially while patient is off all medications) to rule out epilepsy
  - e) referrals to OB/GYN and urology for pelvic exam, vaginal and cervical cultures, and assessments of urinary sphincter tone and/or urinary incontinence

These limitations are duly acknowledged not as a disclaimer for the remarks which follow, but as a reminder of the essential need for comprehensive and up-to-date assessments in the care of mental health patients.

# VI. Diagnosis

Re: Schizophrenia, Paranoid Type - Chronic

The available information suggests that Ms. Bavilla experienced the onset of psychotic symptoms at age seventeen. Reference is also made to a diagnosis of "cannabis abuse," but no details appear relative to age of first use; amounts consumed; frequency of use; or recent pattern of ingestion. The medical literature on cannabis-induced psychosis is robust. Without obtaining or documenting a thorough history of cannabis (and other drug) use, it is premature to render the diagnosis of schizophrenia. The most accurate diagnosis at this time would therefore be Psychotic Disorder, Not Otherwise Specified, permitting the consideration of the broadest spectrum of etiologies:

--the contributions of remote or ongoing drug use

- --the possible existence of undetected medical disease (such as epilepsy, brain tumors, or neurosyphilis)
- -- the impact of previous medications (e.g., tardive psychosis)
- -- the psychological effects of previous traumas or abuse (e.g., sexual abuse, which occurs in as many as 35% or more of those diagnosed with schizophrenia) [12]

# Re: Cannabis Abuse

The available documents include the diagnosis of "cannabis abuse," but they do not reveal whether this is an old or continuing problem. If the former is true, it remains critical to establish the potential contributions of cannabis intoxication or cannabis withdrawal to the crime for which the patient is serving time, for the following reason. An unfortunate misconception continues to be the attribution of violence to the condition of schizophrenia itself, rather than to the acute or long-lasting effects of the street drugs or alcohol frequently abused by individuals with psychosis [13]. Without an accurate substance abuse history, it is difficult to know the extent to which Ms. Bavilla's past actions were determined by exogenous chemicals. It is also difficult to provide an accurate projection of future risks, if past actions were influenced by cannabis but the patient has now attained a period of extended sobriety.

Re: Characterization of Current Symptoms - "Decompensated Schizophrenia"

Pertinent to the issue of involuntary medication in this case is the State's contention that Ms. Bavilla's "hostility and delusions" are the result of an underlying schizophrenic condition. This is the same condition to which the State's medical providers attribute the patient's crime and past suicide attempts. Missing from the depositions is a consideration of unstable or undetected medical conditions; recent drug abuse; cultural belief systems; psychosocial stressors; and/or physiological changes related to the use and interruption of previous psychiatric drugs. Each of these factors must be considered and appreciated, if the State is to intervene meaningfully in the provision of appropriate medical care.

Re: psychosocial stressors

The tendency of the State to reduce Ms. Bavilla's agitation and delusions to the presence of an organic brain disease, best remedied by neuroleptics, is consistent with a cultural Zeitgeist that has been shaped largely by the irregularities identified above (Section II). The philosophy which regards psychosis as biologically determined, rather than biologically mediated, is opposed by many highly respected health care professionals in this country: Dr. Loren Mosher, Dr. Bertram Karon, Dr. Garry Prouty, Dr. Clancy Mckenzie, Dr. Ann-Louise Silver among them [14]. In fact, an active and expanding organization of clinicians (ISPS) opposes the limited perspective exemplified by the State of Alaska in this case [15]. What one might hope for at this point is a compelling review of the stressors which Ms. Bavilla has previously survived, and which she continues to confront. Among the items to be explored:

-- the possible contributions of real or perceived sexual mistreatment (particularly relevant here, given the State's allegations that the patient has been obsessed with a non-existent Sexually Transmitted Disease; given the patient's concerns about continuing genitourinary problems; and given the fact that a history of sexual trauma is commonly ignored but is present in 30% or more of individuals diagnosed with schizophrenia)

-- the continuing anguish arising from memories of the crime itself (in this regard, Ms. Bavilla's agitation might be more reflective of a PTSD constellation of symptoms, rather than a deteriorating psychosis)

-- the presence of specific triggers in the prison setting (sexual pressures from other inmates; conflicts with authorities that may be re-enactments of past relationships; cultural misunderstandings and racial tensions; and justifiable fears or animosity with regards to the loss of autonomy associated with incarceration and the involuntary administration of mind-altering drugs).

Re: neuroleptic withdrawal

Given the fact that Ms. Bavilla most recently consumed neuroleptics between August 18, 2003 and February 27, 2004, it is essential for the State to entertain the possibility that her present condition is consistent with a neuroleptic discontinuation syndrome, rather than a relapse of schizophrenia. The distinction is crucial, as so many physicians have failed to receive instruction about the homeostatic changes that occur in the brain following the cessation of dopamine blockade. In this regard, the work of Tranter and Healy [16] is fundamental, for it reviews the historic evidence corroborating the induction or exacerbation of psychotic symptoms in many individuals during the first weeks or months after a neuroleptic (or other dopamine blocking agent) has been reduced or stopped. [That this problem is attributable to the cessation of previous therapy, rather than an underlying psychosis, is corroborated in their research.]

# VII. Facts of the Case Relative to Involuntary Medication

#### Current Condition:

The Assistant Attorney General's report asserts that the plaintiff has exhibited "increased delusional thinking" since she stopped taking medication on February 27, 2004. Mr. Bodick describes Ms. Bavilla as increasingly "hostile" toward staff. He refers to the prisoner making "nonsensical statements," and states that she has been seen gesturing or talking to "spirits" in her cell. He refers to journal entries in which the patient has stated that "she cannot think of her son or she will 'give in to the destroyer' and die."

The deposition of the Director of Mental Health Services summarizes the history of the patient's mental health care: mental illness (not specified) beginning at age 17; antipsychotic medications prior to her arrest in July 1998. Reference is made to a history of paranoid delusions, a belief in special powers, and a past history of suicide attempts. Not mentioned is the context in which each of these symptoms occurred (depression ? drug abuse? alcohol? physical abuse ? pregnancy? poverty? ). A chronology of three hospitalizations at API is presented: 7/17/97-7/28/97; 7/24-7/28/98; and an extended admission between 2/23/99 and 5/01/00, which involved 14 months of involuntary medication administered to restore competency. The deposition mentions several episodes of compliance with pharmacotherapy, followed by refusal and the resumption of proceedings for involuntary treatment. The most recent order for involuntary medication was initiated in August 2003, apparently in the context of the State's concerns about delusions and poor insight.

The deposition of the chief psychiatrist (Dr. Stallman) makes reference to two evaluations performed by him in March 2004, one additional evaluation ("several months ago"), and a review of the available medical and mental health records. One sentence in his testimony refers to a history of auditory hallucinations, but no suggestion is made that the prisoner has continued to experience such dysperceptions. More crucially, there is no mention of command hallucinations in the past or present. According to Dr. Stallman's report, the patient believes that she suffers from a variety of physical problems which she attributes to an inadequately treated STD. Presumably, this was a real event for which the patient sought medical care many years ago. The precise details of the prisoner's somatic delusions, relative to age of onset; chronicity and variability; and biopsychosocial context are never identified. Curiously, the available materials make no reference to imminent dangerousness. Despite the interruption of neuroleptic therapy in late February 2004, there have been no episodes of physical violence or aggression; no instances of property damage; no episodes of self-injury or self-mutilation; and no evidence of suicidal or homicidal thoughts with clear plan or intent for self-harm. There has been no report of failing hygiene or deteriorating activities of daily living. There has been no evidence of grossly disorganized behavior or speech.

# VIII. State Requirements for Administration of Involuntary Psychotropic Medication

According to the State of Alaska Department of Corrections policy on Involuntary Psychotropic Medication, a psychiatric order for the involuntary administration of a psychotropic drug may only be given if it is demonstrated that a prisoner suffers from a mental disorder, and as a result of that disorder, constitutes a likelihood of serious harm to self or others; a likelihood of property destruction; or is gravely disabled.

Based upon the aforementioned facts and statement of condition, there remain valid questions about the most accurate diagnoses in this case (cannabis induced psychosis?) undiagnosed neurological condition? infectious disease? tardive psychosis?). Notwithstanding these concerns, however, the prisoner does not appear to meet the requirement for being gravely disabled. Indeed, it is the concern of the Assistant Attorney General Bodick that the patient presents as a "bright, intelligent woman who may appear to be well to the untrained observer." Clearly, these words suggest anything but grave disability, implying that most observers would not find any evidence of mental disorder. One would not expect the detection of grave disability to require special powers or methods of detection.

In the absence of a psychiatric emergency, a prisoner has the right to refuse to comply with a psychiatric order for medication unless a Mental Health Review Committee (at the end of a due process hearing) has determined that the prisoner suffers from a mental disorder; is gravely disabled or poses a likelihood of serious harm to self, others, or the property of others; and has determined that the medication is in the best interest of the prisoner, for medical reasons.

While the State worries about "the likelihood of serious harm," Ms. Bavilla has failed to display a single episode of physical aggression since February 27, 2004. In fact, there is no mention of any harmful behavior since July 1998. The facts of the case underscore the ability of the prisoner to remain non-dangerous for more than five years, even in the context of intermittently administered, unwanted medication.

#### IX. Best Interest of The Prisoner, For Medical Reasons

Although the patient has continued to demonstrate delusions and poor insight, it remains unlikely that the resumption of pharmacotherapy – particularly, unwanted medication -- would be in the best interest of this prisoner for medical reasons.

According to the Assistant Attorney General and the depositions of the State's health care providers, an order for involuntary medication should now be granted on the basis of the following assertions:

1) the patient has benefited from antipsychotic treatment in the past

It should be recognized that a viable debate exists, relative to the concept of "benefit." From the patient's perspective, the use of antipsychotic medication has apparently been sufficiently distressing that she has chosen to stop taking it on many occasions. From the State's perspective, medications administered in the past have prevented dangerousness. Yet, on at least two occasions (June through August 2003, February through April 2004) the termination of neuroleptic therapy has not resulted in a return of violent behaviors. This is all the more remarkable, when one considers the possibility that neuroleptic medication may have been halted abruptly, as this is precisely the kind of situation that enhances the risk of severe psychosis through the mechanisms of neuroleptic withdrawal.

Whatever else this case demonstrates, the overall pattern of care thus far suggests that past treatment plans have clearly failed to effect a "cure." They have failed to prevent at least three hospitalizations, one murder, and multiple suicide attempts. If Ms. Bavilla's experience has echoed that of many, if not most psychotic patients, it is more likely to be the case that antipsychotic treatments given in the past have never eradicated delusions, as these cognitive ideas are particularly resistant to medication.

2) the patient had taken neuroleptics between 2/99 and 6/03, at which time she refused all medication. Resulting symptoms were interpreted by staff as reflective of a "noticeable decline in mental functioning." An involuntary medication order (olanzapine) was initiated on 8/18/03. When the patient again refused neuroleptics on 2/27/04, the staff became worried about delusions, hostility, and journal entries which they interpreted as communicating suicidal thoughts.

The State now emphasizes a pattern of poor medication compliance leading to violence, but the facts suggest that no aggression has occurred since 1998. The possibility that mind-altering substances contributed to past violence has not been mentioned, yet this consideration is particularly germane to estimates of present dangerousness.

The possibility that the patient's criminal behavior was iatrogenically induced or enhanced has not been mentioned. Several elements of the patient's history make this a distinct possibility. Her previous record of neuroleptic treatment since age 17; and more recent treatment with Navane, Thorazine, and Zyprexa may have contributed to the development of a tardive or supersensitivity psychosis. Such a psychosis is thought to be mediated by adaptive changes in the dopamine receptors of the mesolimbic and mesocortical systems of the brain, arising from the chronic administration of dopamine-blocking agents. With the protracted administration of antipsychotic therapy, a patient's brain becomes more sensitive to dopamine, and the patient becomes more susceptible to relapsing or progressive symptoms. [17]

A second manifestation of supersensitivity psychosis involves the onset of new or worsening symptoms, in the immediate aftermath of neuroleptic reduction or cessation. In this case, the causative physiology is thought to involve the up-regulation of dopamine receptors and enhanced dopamine transmission. These physiological changes can produce symptoms which are mistakenly identified as a primary or relapsing psychosis, rather than a drug "rebound" or withdrawal syndrome. Although treatment of such symptoms may be managed by the reinstatement of low dose neuroleptic therapy, there is no requirement to do so. In fact, because of the likelihood that chronic dopamine blockade may promote permanent psychosis through the aforementioned mechanisms, many professionals prefer non-medication interventions, or non-neuroleptic strategies, to surmount the challenges of supersensitivity psychosis.

3) Dr. Stallman proposes that the use of Zyprexa and Thorazine are necessary to prevent Ms. Bavilla from imminent harm to self or others

Again, it must be emphasized that the prisoner has not demonstrated harm to self, others, or property since 1998. She has communicated no threats of imminent danger, and has demonstrated no intent or plan for self-harm.

Even if the current situation were to demonstrate a finding of imminent dangerousness, it is unlikely that neuroleptics would be the only way, or the optimal way, of intervening. One possibility, already pursued by the State, involves the containment of the prisoner within a more structured or restrictive environment. This appears to have been effective in the past. Another possibility, apparently not considered, involves the aggressive provision of psychosocial interventions. Ideally, this would involve regular psychotherapy until sufficient progress has been achieved. At the very least, this would involve a course of action limiting the prisoner's exposure to precipitating stressors; and limiting her access to instruments which could be used to harm self or others. What the State has failed to appreciate in its calculation of dangerousness is the likelihood that psychotropic therapy itself – particularly, involuntarily administered medication -- can create side effects which increase the risk of violence. An extensive literature exists, corroborating the link between akathisia, suicide, and aggression [18, 19]. As neuroleptics are the most likely medications to induce akathisia, due to dopamine blockade, their use increases rather than diminishes the risk of violence and self-harm in many patients.

4) Dr. Stallman asserts that side effects of Zyprexa are fewer in number and are more tolerable than Thorazine and Navane.

Dr. Stallman appears to be unaware of the FDA's September 2003 announcement, which required the manufacturers of atypical neuroleptics to provide new warnings about the risks of hyperglycemia and diabetes. Not until March 1, 2004 did Eli Lilly – the manufacturer of Zyprexa – send out its "Dear Doctor" notifications, informing physicians of the new warnings that would appear on their product label.

Indeed, the risks associated with the newer antipsychotic medications have concerned a great number of providers for many years, although the FDA has been slow to acknowledge them. As clarified in my previous writings, the risk of potentially significant weight gain was identified in 29% of the subjects who participated in the initial clinical trials which led to the approval of olanzapine in 1996. While diabetes and lipid abnormalities are now being attributed by the drug companies to obesity or the underlying "condition of schizophrenia," their comments contradict the research of many investigators who have witnessed the development of diabetes and high lipids in many patients who did not develop obesity, and even in subjects who received the atypical neuroleptics for conditions other than schizophrenia. Thus, the available evidence suggests that the newer antipsychotic medications may be directly toxic to the liver and pancreas of many subjects, even though those mechanisms have not yet been fully revealed.

While Dr. Stallman is correct about the conjecture that current research suggests a lower likelihood of certain risks – such as tardive dyskinesia and neuroleptic malignant syndrome – with the newer medications, his statement is not accurate when he suggests that "overall side effects are less" or "better tolerated." As is commonly seen in the history of psychiatry, each new generation of chemical therapies is briefly heralded as the "new and improved" alternative to the antecedents. However, as case reports accumulate, litigation mounts, and physicians themselves accumulate an anecdotal history, the initial claims are invariably modified once the risks become more fully accepted over time.

5) Mr. Bodnick holds that "agitation" is indicative of psychotic decompensation

While agitation may be a symptom associated with psychosis, it may also be a character trait; a manifestation of an underlying neurological disease; a reaction to increased or new stressors; a symptom of anxiety, depression, or mania; a by-product of ongoing drug abuse; or the product of a neuroleptic discontinuation syndrome. Agitation must always be distinguished from akathisia, particularly in individuals whose dopamine systems have been modulated by many years of neuroleptic therapy. As the possibility always exists that "agitation" has been caused or exacerbated by medications, the first steps in its amelioration include the identification of etiology, and the containment of the patient in a secure environment which provides safety. Neither one of these steps demands the use of a neuroleptic.

6) Dr. Stallman holds that any delay in the resumption of neuroleptic therapy will result in further decompensation, and claims that repeated episodes of decompensation tend to make each subsequent episode more severe

There is nothing in the psychiatric literature, or in Dr. Stallman's deposition, to substantiate the claim that "each episode of decompensation makes each subsequent episode more severe." In fact, the literature on untreated psychosis [20] suggests the absence of neurophysiological change due to delays in administering medication. The catamnestic research in psychosis suggests that many individuals experience a natural diminution of their symptoms over time. This fact might imply that the premature resumption of neuroleptic therapy may impede what would otherwise be a gradual march towards recovery. Furthermore, the naturalistic outcomes research in epilepsy suggests that certain unmedicated brain conditions appear to remit spontaneously as the problematic pathways might "burn themselves out." These adaptive mechanisms might be compromised by the introduction of external agents such as psychotropic drugs.

#### X. Neuroleptic Dangers Commonly Dismissed or Denied

In arguing its case to support the involuntary administration of neuroleptics, the State of Alaska has advanced several critical assertions. Among these is the chief psychiatrist's claim that the most serious potential side effects involve neuroleptic malignant syndrome and tardive dyskinesia. It is reassuring to see the State identify these risks, but the descriptions given stop significantly short of providing a fully informed review of the potential risks.

# Tardive phenomena

Tardive (delayed onset) conditions, in addition to the movement abnormalities subsumed under the label of "dyskinesias," include a variety of cognitive and affective deficits. These changes have been named "tardive dysmentia," for they mimic or exacerbate many of the negative deficits associated with dementia. Furthermore, the chronic blockade of mesolimbic receptors has been associated by some researchers with tardive or supersensitivity psychosis. This model suggests that some patients who receive neuroleptics chronically become susceptible to a delayed progression of their symptoms, as their brains undergo changes associated with disrupted neurotransmission.

# Hyperprolactinemia

One of the side effects of all conventional neuroleptics, and many of the newer drugs (especially Risperdal) is their induction of hyperprolactinemia. Prolactin, along with cortisol and growth hormone, is one of the body's major hormones secreted in response to stress. The immediate effects of abnormally elevated prolactin levels include sexual dysfunction, amenorrhea, galactorrhea (lacatation), infertility, and (in males) gynecomastia (enlarged breast tissue). The long term effects include a depletion of bone mineral density. For females, this leads to a two- to three-fold higher risk of osteoporosis and associated bone fractures.

Although the potential impact of hyperprolactinemia remains debated in the field of oncology, many researchers have speculated that prolonged elevations of this hormone expose patients to an increased risk of breast cancer [21].

Yet another potential side effect of elevated prolactin involves the promotion of cardiovascular disease. Research has demonstrated that prolactin fragments inhibit endothelial cells and impede angiogenesis, suggesting two possible mechanisms through which hyperprolactinemia be damaging to blood vessels of the heart and brain [22].

#### Suppression of REM Sleep

An inevitable feature of brain-altering medications is their impact upon sleep architecture. Experts in the field of sleep medicine have advanced the theory that one of the major functions of REM (rapid eye movement) sleep is the consolidation of memory. In studies of non-primates and humans with lesions of the hippocampus (the brain region which regulates REM sleep), it has been found that learning and memory are significantly impaired. A leading theory of dementia suggests that many of the cognitive deficits associated with that disorder are mediated by hippocampal deterioration, marked by the deterioration of REM. Each of these discoveries should give physicians pause when they administer medications which suppress REM sleep. As all neuroleptics have been linked to significant disruptions in REM frequency or duration, it is perhaps not surprising that many patients administered these drugs eventually develop signs of neurocognitive slowing and deterioration.

#### Learned Helplessness

The phenomenon of learned helplessness, or learned passivity, refers to the process by which humans (or animals) subjected to chronic or inescapable stress develop an inability to overcome feelings of hopelessness and helplessness. The neurological pathways associated with the conditioning of these responses have been well studied in animal models, where – not surpisingly – chemical changes in the hippocampus mediate the phenomenon. What is significant about the use of neuroleptics in young animals is the fact that their administration appears to stimulate, rather than diminish, the later manifestation of learned helplessness in response to unavoidable stress [23]. This suggests that neuroleptic therapies, when given to humans, may be similarly detrimental by creating chemical or physiological changes that reduce adaptations to stress. As learned helplessness is a model of depression, this suggests another mechanism through which neuroleptics may contribute to increased risks of suicide and self-harm.

From a psychological perspective, the psychiatric community has generally dismissed the prognostic significance of patients' attitudes about the treatments which they receive [24]. While some individuals may tolerate the relative toxicities of neuroleptics, and may count themselves among the happy population of pill-poppers, other individuals experience the use of medications as demoralizing. In the case at hand, Ms. Bavilla has clearly conveyed to her attorney that she feels discouraged by the very thought of receiving neuroleptics. In her words, she states that the use of such drugs makes her feel like giving up, even to the point of refusing food and preferring to die. Clearly, Ms. Bavilla exemplifies the perspective of many subjects for whom neuroleptics would be more likely to induce feelings of despair than empowerment, with the associated risks of suicide and self-harm.

# Morbidity and Mortality

In the publicity and hype which typically surround the announcements of each new medical therapy, the broader forest is frequently unaddressed. In the case of neuroleptics, most references and professionals speak only about the short-term effects. While current time constraints prevent a comprehensive review in this report of the inflated estimation of neuroleptic efficacy, more than a few observers have suggested that the newer drugs are no less successful in ameliorating or eliminating psychotic symptoms than their predecessors [25, 26] whose advantages have been dubious [27, 28].

Given the fact that neuroleptics have a poor record of even short-term benefit, the rejection of their chronic administration is enhanced by epidemiological evidence which suggests that these drugs appear to hasten early death. While acknowledging the estimate that psychotic patients have a 10% lifetime risk of suicide, it appears that far more schizophrenics succumb to early cardiac or lung disease than to suicide. While the textbooks and journals do not mention it, the overall mortality for schizophrenics worldwide is higher than non-schizophrenic mental health patients and healthy controls. Researchers who have studied the association between cumulative neuroleptic exposure believe there is a viable relationship between the medications and early death. A developing body of evidence suggests that the chronic use of neuroleptics not only diminishes the quality of life for many patients (via such side effects as tardive dyskinesia, diabetes, and obesity) but also diminishes the quantity of life (long term longevity) as well.

#### IX. Conclusions

#### **Diagnostic Concerns**

Legitimate questions remain about the major determinants of the patient's current symptoms. While the diagnosis of paranoid schizophrenia has been consistently rendered, no mention has been made about the role of substance abuse in the manifestation of initial or recurrent symptoms. Furthermore, no suggestion has been made about revising the current diagnosis to Psychotic Disorder, Not Otherwise Specified, which would permit the broadest acknowledgement of symptoms with undefined or multifactorial causation. As any treatment plan is doomed to fail if it focuses upon the wrong condition, diagnostic clarification must always assume the first priority in any medical treatment plan.

Inadequate consideration may have been paid to the influence of psychological and environmental stressors upon this patient's delusions and agitation. It is especially critical in this case to identify a possible history of sexual trauma, given the patient's concerns about Sexually Transmitted Disease, and given the sexual tensions and predation which typically pervade correctional settings. While the point may be argued by some that these historical considerations are moot, the reality is that this patient (like all delusional patients) will more than likely fail to surrender her delusional belief system, even when medicated, until she has been guided by a therapist who strives to understand the real world precipitants of these beliefs; and who then works patiently with the inmate long enough to discover and deliver the pertinent reflections as Ms. Bavilla becomes ready to receive them.

Regrettably, it appears that no consideration has been given to the possibility that Ms. Bavilla's most recent behaviors or thoughts have been iatrogenically induced. The phenomenon of a neuroleptic rebound syndrome (or supersensitivity psychosis) refers to the effects which arise from homeostatic changes in the brain (increases in receptor density and affinity) when a dopamine antagonist is first withdrawn. As this condition is most likely to occur at any point during the first six months after the cessation of dopamine blockade, Ms. Bavilla's condition at this time is highly suggestive of such a drug discontinuation syndrome, rather than a schizophrenia relapse. This should have a significant bearing upon the quality and duration of treatments.

# Treatment Concerns

Several conjectures have been advanced by the State of Alaska, without corroborating evidence to support them. It appears, from all the materials reviewed, that the plaintiff fails to meet the State's requirements for being gravely disabled. The State may have overestimated the alleged benefits associated with previous administration of neuroleptic therapy, just as it has underestimated the inherent capacity of the prisoner to remain "safe" during two occasions of interrupted neuroleptic therapy. Clearly, the State's agents do not appear to be familiar with the broad body of evidence – both epidemiological and neurophysiological – documenting the supremacy of psychosocial interventions in psychosis, and clarifying the inferiority of drug treatment.

Previous episodes of symptom exacerbation may have been wrongly attributed to an underlying brain disorder, instead of the existence of a neuroleptic discontinuation syndrome. An unsubstantiable claim has been advanced, asserting that symptoms of agitation or hostility are definite and exclusive signs of psychotic decompensation, which will inevitably deteriorate as long as neuroleptic therapy is withheld. The number and severity of possible risks associated with neuroleptic therapy have not been clearly conveyed to the patient, nor fully appreciated by agents of the State. The deleterious effects of neuroleptic therapy upon dangerousness, including tardive psychosis and akathisia, appear to have been minimized or overlooked. The negative, long term effects of neuroleptic medication, relative to overall mortality and morbidity, appear to have been ignored. Finally, the impact of the patient's own feelings of helplessness and demoralization if subjected to involuntary psychotropic medication, does not appear to have entered into the State's overall calculation of appropriate medical care.

#### Recommendations

In Dante's Cure, Dr. Dan Dorman describes the journey of a former patient with whom he worked psychotherapeutically for seven years. The case involved the completely drug-free treatment of a woman who struggled with psychosis, beginning in her teenage years. Today, she is fully recovered; employed as a mental health nurse; and engaged in political and social activism, focusing upon the rights of the mentally ill. When asked many years after her recovery about the aspects of care that she found essential, this was Catherine's response:

"The last thing a person needs is to have a doctor go along or initiate a false solution....If I had received drugs, I might have gotten temporarily out of my catatonic state, but I'd have been back there sooner or later. I've seen patients leave the hospital, then go off their tranquilizers. The decrease in anxiety wasn't initiated by the patient, so when he goes off his tranquilizer or antidepressant, his pain comes back and he still doesn't know how to cope, except by going back on the drug. I think that is demeaning.

"When medications are given, I think the doctor is looking for relief from his own anxieties. He sees mental problems as something to fear, something to get rid of. By using tranquilizers, the doctor is just making his patient's problems more inaccessible. When the doctor gives drugs, he is really saying the drugs will do it for the person. He is stunting his patient's growth. It tells the patient that he is hopeless, and puts him into a role as a chronically sick person.

"The time and effort need to be taken to get down to the crux of the matter, even though it takes a long time, because in the long run a lot of time is wasted if the proper thing isn't done [29]."

Ms. Bavilla is a patient without grave disability, and without harmful actions since 1998. She appears to be asking now for a chance to receive the quality of care that promotes recovery. She appeals to the State to avoid the provision of treatment that would, in all likelihood, impede recovery.

As Dr. Dorman's former patient has explained: time and effort were needed for her to reach the crux of her problems, but the benefits have been enormous and sustained. Ms. Bavilla is clearly a patient who has plenty of time. The real issue is whether or not the State of Alaska can provide the effort necessary to deliver the most appropriate form of treatment, instead of reflexively defaulting to interventions which are not in the best interests of the prisoner for medical reasons.

Signed:

<u>/s/</u>

\_\_\_\_\_

Grace E. Jackson, MD April 4, 2004

#### References

1 FDA MedWatch 2004 Safety Alert: Zyprexa. March 1, 2004. Available at : <u>http://www.fda.gov/medwatch/SAFETY/2004/zyprexa.html</u>

2 Jackson, Grace E. Affidavit in case of Faith Myers vs. API. Prepared March 3, 2003. Available at http: psychrights.org

3 Jackson, Grace E. "Olanzapine and the FDA: Clinical Trials and Tribulations." Under consideration by Psychothearpy and Psychomatics.

4 Bodenheimer, T. Uneasy Alliance. NEJM. May 18, 2000; 243 (20): 1539-44.

5 Editorial. The file drawer phenomenon: suppressing the clinical evidence. eCMAJ. 2004; 170: 437.

6 Angell, M. Is Academic Medicine for Sale? NEJM. May 18, 2000; 342 (20): 1516-18.

7 Antonuccio, D.; Danton, WG, McClanahan TM. Psychology in the Prescription Era: Building a Firewall Between Marketing and Science. American Psychologist. December 2003; 58 (12): 1028-1043.

8 Ibid.

9 Safer, D. Design and Reporting Modifications in Industry Sponsored Comparative psychopharmacology. Journal of Nervous and Mental Disease. September 2002; 190 (9): 583-92.

10 Superior Court, State of Alaska, 3<sup>rd</sup> Judicial District. Order of Superior Ct. Judge Morgan Christen, 3/24/03.

11 Ibid.

12 Read, J. and Ross, C. Psychological Trauma and Psychosis: Diagnosed Schizophrenics Must Be Offered Psychological Therapies. JAAPDP. Spring 2003; 31 (1): 247-268.

13 Shaw, J.; Amos, T; Hunt, I; Flynn, S; Turnbull, P; et. al. Mental Illness in people who kill strangers: longitudinal study and national clinical survey. BMJ 2004; 328: 734-7.

14 Silver, Ann-L. ISPS Debate: "I oppose educating patients that their brains are broken." Delivered at ISPS International Convention in Melbourne, Australia. Sept. 2003. Available at: <u>www.isps-us.org</u>.

15 ISPS-US Mission Statement: Available at <u>www.isps-us.org</u>

16 Tranter, R. and Healy, D. Neuroleptic Discontinuation Syndromes. Journal of Psychopharmacology. 1998; 12 (4): 401-6.

17 Kirkpatrick, B; Alphis, L; Buchanan, R. The concept of supersensitivity psychosis. Journal of Nervous and Mental Disease. 1992; 180 (4): 265-70.

18 Galynker, I; Nazarian, D. Akathisia as violence. J Clin Psychiatry. January 1997; 58 (1): 31-2.

19 Healy, D. SSRIs and deliberate self-harm. British Journal of Psychiatry. June 2002; 180: 547-8.

20 Beng-Choon, H.; Alicata, D; Ward, J.; Moser, DJ; O'Leary, DS, et. al. Untreated Initial Psychosis: Relation to Cognitive Deficits and Brain Morphology in First Episode Schizophrenia. American Journal of Psychiatry. January 2003; 160 (1): 142-8.

21 Maus, MV; Reilly, SC; Clevenger, CV. Prolactin as chemoattractant for human breast carcinoma. Endocrinology. Nov 1999; 140 (11): 5447-50.

22 Freeman, ME, Kanyicska, B. Lerant, A.; Nagy, G. Prolactin: Structure, Function, and Regulation of Secretion. Physiological Reviews. 2000; 80: 1523-1631.

23 King, JA; Edwards, E. Early stress and genetic influences upon hypothalamicpituitary-adrenal axis functioning in adulthood. Horm Behavior. Oct 1999; 36 (2): 79-85.

24 Day, JC; Bentall, RP; Warner, S. Schizophrenic patients' experiences of neuroleptic medications: a Q-methodological investigation. Acta Psychiatrica Scandinavica. May 1996; 93 (5): 397-402.

25 Geddes, J; Freemantle, N; Harrison, P. Bebbington, P. Atypical Neuroleptics in the treatment of schizophrenia: systematic overview and meta-regression analysis. BMJ 2000; 321:1371-6.

26 Stip, E. Happy Birthday neuroleptics! 50 years later: la folie du doute. European Psychiatry. May 2002; 17 (3): 115-9.

27 Cohen, D. "A critique of the use of neuroleptic drugs in psychiatry." In Fisher and Greenberg: From Placebo to Panacea. New York: John Wiley & Sons, 1997.

28 Whitaker, B. Mad in America. Cambridge, MA: Perseus. 2002.

29 Dorman, D. Dante's Cure. New York: Other Press. 2003.