STATE OF NORTH CAROLINA)
) ss.
New Hanover COUNTY)

To: Mr. Jim Gottstein, Esq.
Law Project for Psychiatric Rights
406 G. Street – Suite 206
Anchorage, AK 99501

From: Grace E. Jackson, MD
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Date: 20 May 2008

Re: William Bigley
Case # 3AN-08-00493 P/R
API Petition for Court Ordered Administration of Medication

I. Introduction

Educational and Professional Background

I am a Board Certified psychiatrist residing in North Carolina where I specialize as a clinical psychiatrist, an independent researcher in the areas of neuropharmacology and neurotoxicology, and a writer and lecturer.

I hold a B.A. in political science, a B.S. in Biology, and a Master's degree in Public Administration. I received my medical degree from the University of Colorado School of Medicine in May of 1996. Following medical school, I was commissioned in the U.S. 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 to Bethesda Naval Hospital, where I supervised the work of 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 private consultant, and have worked as a clinician within the North Carolina Department of Corrections and the Veterans Administration health care system.

II. Testimony as an Expert in Psychopharmacology

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 antipsychotic drugs. Special emphasis was placed upon the FDA's analysis and approval of olanzapine (Zyprexa) as a primary example of the newer therapies. Interestingly, on March 1, 2004, the FDA announced its requirement for warnings about health risks associated with olanzapine and similar chemicals. This FDA alert was consistent with many of the concerns which I had expressed in my affidavit. In considering my testimony in the Myers case, the Alaska Superior Court, and the former Director of Schizophrenia Research at NIMH (National Institute of Mental Health) qualified me as an expert in the area of psychopharmacology. Subsequent forensic experience and independent research have been preparatory for peer reviewed journal articles and book chapters explaining the mechanisms through which psychiatric medications often prevent or delay recovery. For the past six years, I have lectured locally, nationally, and internationally on the subject of psychiatric drug toxicity. My first book (*Rethinking Psychiatric Drugs: A Guide for Informed Consent*) has been adopted by several professors nationwide as a required text for students in sociology, psychology, psychotherapy, and social work. Most recently, I have accepted an invitation from Florida International University to join a panel of independent experts in preparing a website-based "Critical Skills Curriculum on Psychiatric Medications for Mental Health Professionals."

III. Sources of Information

In preparing this report, I have relied upon the following materials:

1) Motion for Less Intrusive Alternative, dated 10 March 2008

2) Submission for Representation Hearing, dated 06 March 2008
pages 1-13, 23-28, 32-34

3) Selected Medical Records
API admission note of 4/18/80 by Annie Bowen, MSW
API discharge note of 4/30/08 by Robert Alberts, MD
API discharge summary from 5/4/81 by Robert Marshall, MD
API admission note of 2/22/07 by William Worrall, MD
API discharge summary of 3/14/07 by William A. Worrall, MD
API report contact of 3/19/07 re: Depakote, by L. Silberschimidt, LCSW

4) Affidavit of Ronald Bassman, PhD, dated 04 SEP 2007

5) Affidavit of Paul A. Cornils, dated 12 SEP 2007

6) Affidavit of Robert Whitaker, undated (? SEP 2007)

7) log notes from Superior Court at Anchorage, AK dated 12 May 2008

8) Exhibit E: my affidavit prepared for hearing of 14 May 2008

9) product labels for Risperidone tablet, Risperidone liquid, Risperidone Consta

10) findings and Order of Superior Court in Anchorage, AK, dated 19 May 2008

11) consultation with pertinent articles in peer reviewed literature (etc)

IV. Purpose of This Affidavit

This affidavit is written for the express purpose of responding to the Findings and Order of the Superior Court of Anchorage, AK (Judge Sharon L. Gleason) as rendered on 19 May 2008 in the aforementioned case. Specifically, this affidavit presents the reasons why a failure to grant a stay of the Superior Court's order will most likely result in irreparable and (ultimately) lethal harm.

V. Limitations of Current Report

The content of the current report is limited by the following factors:

1) lack of face-to-face or telephonic interview with the patient

2) lack of access to *all* medical records, including:

   all admission and discharge summaries from hospitalizations
   all outpatient provider notes (from birth to present)
   all pharmacy records

3) lack of access to collateral sources of information (e.g., interviews with immediate and extended family, friends of patient, etc.).

4) apparent failure of past and present providers to obtain up-to-date diagnostic tests, including but not limited to: EKG, MRI of brain, EEG, heavy metal toxicity screens, tests of renal/thyroid/liver/heme/pancreatic function, tests of metabolic and dietary abnormalities (e.g., vitamins, electrolytes, lipids, glucose), tests for infectious disease, consultations with pertinent specialists

These limitations are mentioned, not as a disqualification of the remarks which follow, but as a reminder of the crucial pre-requisites for the rendering of appropriate diagnoses and treatments.

VI. Failure to Grant Stay of Order Will Result in Irreparable Harm

The failure of the Higher Court(s) to grant a Stay of Order will result in irreparable harm. Commensurate with the *Myers vs. API* decision of 2003 ("best interest" standard), there are three reasons why the proposed intervention of the Alaska Psychiatric Institute should now be rejected: a) misdiagnosis; b) failure to perform essential baseline assessments; and c) failure to act in the patient's best interests.

Misdiagnosis

Beginning with the respondent's very first API hospitalization at the age of 27 (4/15/80 through 4/30/80), Mr. Bigley was subjected to a dose of Haldol (10 mg po bid) which was 4 times higher than today's therapeutic dose ["therapeutic" as defined by those physicians who believe that antipsychotic effects arise from the blockade of 60-80% of the D2 receptors in the striatum]. Mr. Bigley's initial dose of Haldol guaranteed the induction of Parkinsonian symptoms by day #3 of treatment (4/17/80). Furthermore, the continued administration of Haldol -- a chemical which replicates the mitochondrial effects of rat poison and insecticide -- guaranteed the rapid deterioration of his condition. By killing brain cells, Haldol converted a possibly transient and reversible episode of psychosis or psychotic depression into a case of tardive dysmentia.

For example, the discharge summary from hospitalization #3 (2/27/81 through 5/4/81) reveals continuing problems with paranoia and disorganized speech; frontal lobe damage (several frontal release reflexes were noted on physical exam); and possible signs of tardive dystonia ("sitting in stiff fashion with head and neck markedly extended as he gazes at the ceiling"). Unfortunately, Mr. Bigley was not only continued on Haldol at that time, but the dose was raised to 20 mg po tid (60 mg per day). This was a dose which was 12 times higher than recommended, according to the theory of D2 receptor blockade.

Although the time constraints of this case have, thus far, limited my ability to review all pertinent records, the materials which I have reviewed (see Section III, #3 above) demonstrate a persistent and continuing failure of API clinicians to consider the most likely diagnosis in the case at hand. In all probability, Mr. Bigley now suffers from a chemical brain injury (CBI). This development should preclude the attachment of any and all psychiatric labels at this time. It should also trigger the legal and medical systems to prioritize the delivery of interventions which promote neuro-rehabilitation, rather than neurodegeneration.

Failure to Perform Essential Baseline Assessments

Prior to administering risperidone (or any other neuroleptic), the current recommendations of the drug manufacturers and professional organizations (such as the American Psychiatric Association) call for the performance of certain "baseline" evaluations of physical health. These assessments are crucial, in order to prevent sudden death arising from adverse cardiac events (e.g., tachycardia, QT prolongation, torsades, or other arrhythmia), endocrine disease (e.g., diabetic ketoacidosis or non-ketotic hyperosmolar coma), and/or other potential emergencies (e.g., infection due to low white blood cell count; liver failure; or neuroleptic malignant syndrome).

Especially before initiating risperidone, it is essential for providers at API to establish the presence or absence of pre-existing dysfunctions as described above (see Section V, #4). Moreover, given Mr. Bigley's 28-year history of exposure to various neurotoxicants, the differential diagnosis must now include several varieties of dementia (such as Lewy Body dementia and Alzheimer's disease), *for which the use of risperidone is specifically not advised.*

To put it simply, even if the Higher Court(s) were to agree with the Order of the Superior Court, the form of that order as presently written contradicts the recommendations of the medical profession, the Food and Drug Administration, and the manufacturers of the antipsychotic drugs.

Failure to Act in the Patient's Best Interests

Alaska Psychiatric Institute has proposed the immediate use of injectable risperidone (Consta) up to the maximal dose of 50 mg (IM) every two weeks. There are four chief problems with this treatment plan.

1) the manufacturer of risperidone specifically recommends a trial period of the short-acting preparation of the drug, prior to initiating Consta, in order to rule out a hypersensitivity reaction which might be fatal

[i.e., one does not begin with the injectable form of the drug and hope for the best]

2) the injectable form of risperidone (Consta) takes three weeks to take effect

From the available records, it does not appear that API has requested a court order for additional medication (such as oral risperidone) to cover the initial three week interval. To the extent that API would consider a three-week period of psychosocial supports to be adequate treatment during this interval, one must seriously question API's objections to the even more rigorous plan which has been outlined as the "less intrusive alternative" to pharmacotherapy.

3) the injectable form of risperidone (Consta) persists in the bloodstream for a period of seven weeks (and persists in the brain for at least one week longer)

It is because of the enduring effects of injectable forms of neuroleptics, such as Consta, that many concerned physicians oppose their use. Should Mr. Bigley develop neuroleptic malignant syndrome, cardiac defects, constipation and bowel obstruction, and/or a variety of tardive phenomena (such as respiratory dyskinesia), it will not be possible to eliminate the source of these events for up to two months.

4) risperidone (Consta or oral forms) will potentially kill Mr. Bigley while offering no significant prospect of improvement, and zero probability of recovery

Risperidone is an inhibitor of mitochondrial function and an inducer of oxidative stress. Through these cellular effects, risperidone then disrupts the structure and function of the cardiac, endocrine, hepatic, and neurological systems. It possesses some features which make it particularly undesirable, even among drug enthusiasts.

First, risperidone is unique among the newer "antipsychotic" drugs in terms of its potential to elevate prolactin. In some studies, hyperprolactinemia has occurred in as many as 90% of the risperidone patients. This is more than a trifling occurrence, due to the fact that hyperprolactinemia has been repeatedly linked to cardiac disease (e.g., via platelet aggregation, cardiomegaly, and heart failure).

Second, even at typical or "ordinary" doses (D2 blockade of 60-80%), risperidone induces Parkinsonian side effects at a rate which equals or surpasses the so-called traditional or conventional neuroleptics (e.g., in 30-50% of the patients).

Third, the real-world risk of tardive dyskinesia due to risperidone is significant and far more prominent than API's spokesmen have presumably opined. In Jose de Leon's recent study of patients who began treatment with the newer therapies (65% receiving risperidone), more than 60% of the subjects with treatment histories similar to Mr. Bigley's developed tardive dyskinesia despite the use of these "safer" drugs.

Fourth, given Mr. Bigley's advancing age (55 considered "elderly" in at least one published study); the early onset of Parkinsonian side effects (EPS at age 27); and a pre-existing organic brain syndrome (i.e., chemical brain injury), he is at high risk for tardive dyskinesia. In light of the fact that tardive dyskinesia (TD) reflects extensive damage to the brain – including impairments of judgment and insight, as much as impairment of movement – it is essential to avoid the use of any chemical intervention which might accelerate the emergence of this condition.

Fifth, commensurate with the affidavits, exhibits, and testimony on behalf of the respondent, it is extremely improbable that risperidone will do anything but aggravate the effects of the dysmentia (chemical brain injury) from which Mr. Bigley continues to suffer. To the contrary, risperidone will compound that condition with real and substantial risks of sudden death from stroke, heart attack, pulmonary embolism, diabetes, falls, accidents, pneumonia, NMS, and – ultimately – dementia.

For the aforementioned reasons, a Failure to Grant a Stay of the Superior Court's Order will result in irreparable harm.

DATED this 20th day of May, 2008, in WILMINGTON, North Carolina.

Grace E. Jackson MD

Grace E. Jackson, MD

SUBSCRIBED AND SWORN TO before me this 20 day of May, 2008.

"OFFICIAL SEAL"
NOTARY PUBLIC, NORTH CAROLINA
COUNTY OF WAKE
ERIN JENKINS
My Commission Expires:3-23-2009

Notary Public in and for North Carolina
My Commission Expires: 3/23/09