Document # 8

Report of Victor Patnella, R. Ph.
09/07/06

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

CARMEN BRITT and LULA BAITY,

Plaintiffs,

vs.

BUFFALO MUNICIPAL HOUSING AUTHORITY, et. al.,

Defendants.

AFFIDAVIT OF EXPERT WITNESS

06-CV-0057

STATE OF NEW YORK)
COUNTY OF ERIE) :ss
CITY OF BUFFALO)

VICTOR PATNELLA, R. PH., being duly sworn, deposes and says:

1.) I am a registered pharmacist duly licensed to practice my profession in the State of New York.

2.) Based upon a plenary study of Ms. Baity's medical records, as well as thorough review of a copy of Grace Manor Health Care Facility's December 19, 2003 application to the Social Security Administration to obtain "representative payee" status for Ms. Baity's social security benefits, I have been requested by Plaintiffs' counsel to render a professional opinion on the issue of the long-term prescription and administration to Ms. Baity by Drs. Nelda Lawler and Teresa Chau at Grace Manor of the medicine, Risperdone, trade name **Risperdal**.

3.) Without addressing the separate and distinct issue of the validity and/or reliability of the assessment and diagnosis of Ms. Baity's alleged "**Dementia Alzheimer's**

Type (**DAT**)" and/or "**advanced dementia**" rendered by Grace Manor Health Care providers, Drs. Lawler and Chau, respectively, I duly note that the medication, **Risperdal**, was prescribed and administered to Ms. Baity on a daily basis for the entirety of her 92 day confinement at Grace Manor.

4.) In this regard, ECMC's medical records, which documentation was included in the medical records provided to Plaintiffs' counsel by Grace Manor, indicate that Ms. Baity's original admission (**prior** to Grace Manor) was a medical one, as opposed to psychiatric, for hypertension and atrial fibrillation.

5.) Given, then, the daily administration to Ms. Baity of **Risperdal** at Grace Manor by Drs. Lawler and Chau, it is to be further noted that **Risperdal's** only current accepted pharmaceutical uses for an individual of her (Ms. Baity's) advanced age group are for indications of treatment of psychotic disorders such as acute *psychosis*, *schizophrenia* or psychotic depression, including maintenance treatment of schizophrenia, for severe behavioral disturbances, such as agitation, aggression and psychosis due to organic brain syndromes, for treatment of bipolar disorder with mania or mixed episodes with or without psychotic features, tics associated with Tourette's syndrome or severe behavior disorders associated with Tourette's or attention-deficit hyperactivity disorder.

6.) Based thereon, I, respectfully, state that I could locate **no** objective data and/or other basis present in Ms. Baity's Grace Manor records, via medical testing, psychiatric evaluations and/or assessments, to establish that any of the above afore-mentioned conditions existed **prior** to her October 10, 2003 admission at Grace Manor Health Care Facility and/or otherwise manifested themselves during her lengthy stay there.

7.) Critically, there is a pharmaceutical "**black box warning**" included in all dispensing information concerning **Risperdal**. (see attached **Exhibit "A"**)

8.) In the United States, a "**black box warning**" (also sometimes called a "**black warning label**") is a type of warning that appears on certain prescription drugs as to serious adverse medicinal effects. A "**black box warning**" means that medical studies indicate that said particular drug carries a *significant risk of serious or even life threatening adverse effects.*

9.) The U.S. Food and Drug Administration (FDA) can require a pharmaceutical company to place a "**black box warning**" on the labeling of a prescription drug or in literature describing it. It is the strongest warning that the FDA requires and, of necessity, is judiciously employed because of its seriousness.

10.) Additionally, the most recent **Contraindications/Precaution** warnings for Risperdone (**Risperdal**) advise that: "[a] significantly increased incidence of cerebrovascular events (stroke, transient ischemia attack) have been reported in the elderly (aged 73 to 97 years) with dementia-related psychosis taking Risperdone. Some events have been fatal; use Risperdone with **extreme** caution in **elderly** patients..." (see attached **Exhibit "B", at page 2**)

11.) Risperdone (**Risperdal**), it must be noted, is grouped in a class of drugs known as atypical antipsychotics. Atypical antipsychotics are **not** approved for control of behavioral disorders in elderly patients with **dementia**. The FDA has mandated that all manufacturers of atypical antipsychotics include a "**black box warning**" to the labeling noting that increased death rates have been noted in these patient populations receiving

atypical antipsychotics. Death typically has occurred due to heart failure, sudden death and/or infections (primarily, pneumonia).

12.) To further ascertain as to whether there existed any viable basis in this matter for the attendant daily long-term prescribing of **Risperdal** by Drs. Lawler and Chau to Ms. Baity, I, personally, consulted with the professional division of Jannsen Pharmaceuticals, the developer and manufacturer of **Risperdal**.

13.) The above mentioned personnel at Jannsen Pharmaceuticals represent a definitive source of the most current studies available regarding **Risperdal**, including any off-label uses (off-label meaning possible new or previously not accepted indications for use of their drug). I, thereupon, was so advised and alerted by appropriate Jannsen Pharmaceuticals personnel that there are **no** current investigational trials that, in any manner, would negate the present "**black box warning**" for **Risperdal**.

14.) Based thereon, I state that it is my professional opinion, under the facts and circumstances present in Ms. Baity's particular situation, that there exists **no** supportable pharmaceutical basis for the daily long-term administration by Drs. Nelda Lawler and Teresa Chau, respectively, of **Risperdal** to the elderly Ms. Baity at Grace Manor Health Care Facility, such pharmaceutical caregiving being specifically contra-indicated and, further, conducted at *very high risk* for Ms. Baity's specific age group with the possible result of death from its use in her particular situation.

15.) In conclusion, therefore, I hereby state to a reasonable degree of pharmaceutical certainty that, individually and collectively, the conduct of Drs. Lawler and Chau in so prescribing and administering **Risperdal** on a daily long-term basis to the elderly Ms. Baity

was a gross deviation from good and acceptable pharmaceutical standards of care in the community and, as such, constituted malpractice.

16.) I have been retained by Plaintiffs in the above-captioned action as an expert witness. The total compensation to be remitted for my study and testimony in this case is $2,500.00, to be paid as follows: $500.00 for initial affidavit and $2,000.00 for trial preparation and testimony.

17.) I have had no prior acquaintance with either Plaintiffs Ms. Baity or Ms Britt and/or their legal representative, Glenn E. Murray, Esq..

18.) My Curriculum Vitae is attached to this affidavit as **Exhibit "C"**.

VICTOR PATNELLA, R. PH.

Duly sworn to before me this
7th day of September, 2006

NOTARY PUBLIC

ROGERS HICKS
COMMISSIONER OF DEEDS
In and for Buffalo, Erie County, NY
Commission Expires December 31, 2006

Exhibit "A"

Janssen L.P.

RISPERDAL®
(RISPERIDONE)
TABLETS/ORAL SOLUTION

RISPERDAL® M-TAB®
(RISPERIDONE)
ORALLY DISINTEGRATING TABLETS

7503230

WARNINGS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning).

Neuroleptic Malignant Syndrome (NMS)

Increased Mortality in Elderly Patients with Dementia –Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. RISPERDAL® (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

Exhibit "B"

Risperidone

Print

Contraindications/Precautions

Risperidone has the potential to impair cognitive and motor skills. The sedative effects of risperidone may be most evident in the initial days of treatment. Patients should be advised to use caution when driving or operating machinery, or performing other tasks that require mental alertness, until they know how this drug affects their cognition. Ethanol intoxication should be avoided. Because risperidone may cause CNS depression, it is not recommended for use in patients who exhibit severe CNS depression. Patients with head trauma may be more susceptible to the CNS effects of this drug.

As with all schizophrenic patients, suicidal ideation may occur. Close supervision and control of medication is advisable. Prescribe risperidone in the smallest quantity consistent with good management in order to reduce the risk of overdose.

Abrupt discontinuation of risperidone is not recommended, unless required by the patient's medical condition. Otherwise discontinuation should usually occur via a gradual 1—2 week reduction in dosage. Patients should be carefully observed for the recurrence of psychotic symptoms during drug discontinuation.

Risperidone may induce a variety of CNS effects and should be used cautiously in those with preexisting forms of neurological disease. Patients or their guardians should be informed of the risk of antipsychotic-induced neurological effects. Antipsychotics may induce extrapyramidal symptoms, including tardive dyskinesia, dystonias, and other movement disorders. Tardive dyskinesia may be irreversible. A rare but potentially fatal syndrome, neuroleptic malignant syndrome (NMS), may occur and requires immediate drug discontinuation. Periodic clinical observation for the presence of movement disorders is recommended (e.g., AIMS assessments).

Secondary to alpha-blockade, risperidone can inhibit vasoconstriction and can produce vasodilation. The resultant drop in blood pressure through decreased peripheral resistance can precipitate orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope. This effect may especially occur during the initial dose-titration period. Limiting the initial dose and titration of the dosage according to recommended schedules might minimize the risk of orthostatic hypotension and syncope. Monitoring of orthostatic vital signs should be considered in patients for whom hypotension is of concern. Patients should be counseled on measures to prevent orthostatic hypotension, such as sitting on the edge of the bed for several minutes prior to standing in the morning, or rising slowly from a seated position. Consider dose reduction if hypotension occurs. Use with particular caution in patients with known cardiac disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, or with conditions that would predispose patients to hypotension (e.g., dehydration and hypovolemia). Patients should avoid sodium depletion, alcohol intake (ethanol intoxication) or high ambient temperatures. Antipsychotics also affect various neurotransmitters that are responsible for temperature regulation in the hypothalamus. Patients receiving risperidone should avoid exposure to extremes of cold (to prevent hypothermia) or heat (ambient temperature increase) to prevent heat stroke. Clinically significant hypotension has been observed with concomitant use of risperidone and antihypertensive medications (see Drug Interactions).

Risperidone and/or 9-hydroxyrisperidone appears to produce QT prolongation in some patients, although there is no average increase in treated patients with no known underlying heart disease, even at 12—16 mg/day, well above the recommended dose. Other drugs that prolong the QT interval have been associated with the occurrence of *torsade de pointes*, a life-threatening arrhythmia. Existent *QT*

prolongation increases the risk of this arrhythmia. Certain conditions may also increase the risk of drug-induced QT prolongation such as bradycardia, electrolyte imbalance (e.g., hypokalemia, hypomagnesemia), or the concomitant use with other drugs that prolong QTc interval (see Drug Interactions). Use risperidone cautiously in patients with known cardiac conduction defects (e.g., AV block, bundle-branch block, and cardiac arrhythmias); congenital heart disease (i.e., congenital long QT syndrome); uncompensated heart failure, or a recent acute myocardial infarction.

Risperidone should be used with caution in patients with Parkinson's disease because of possible development of extrapyramidal symptoms. However, atypical antipsychotics like risperidone are less likely to interfere with treatments for Parkinson's disease than traditional antipsychotic agents are. In general, avoid risperidone use during therapy for Parkinson's disease unless the benefit of the drug outweighs the risk of decreased therapeutic response to levodopa or other treatments.

In clinical trials, risperidone was associated with seizures in a small number of patients (0.3%), two in association with hyponatremia. For this reason, patients with a seizure disorder or uncorrected hyponatremia be treated cautiously with risperidone. Since becoming available on the US market, the manufacturer reports rare instances of seizures during risperidone therapy.

Risperidone has an antiemetic effect in animals; this effect may also occur in humans, and may mask signs and symptoms of overdosage with certain drugs or may mask symptoms of conditions such as GI obstruction (e.g., ileus), Reye's syndrome, or brain tumor.

Lower initial doses of risperidone are recommended for those patients with severe hepatic disease or renal impairment, including renal failure (see Dosage). The drug is metabolized by the liver to an active metabolite; increased free-fractions of the drug in the plasma are seen with severe hepatic disease. The kidney excretes both risperidone and its metabolite; increased plasma concentrations of risperidone occur in those patients with a creatinine clearance < 30 ml/min.

Lower initial doses of risperidone are recommended in elderly patients (see Dosage) due to decreased medication clearance in this population and a greater frequency of hepatic, renal and cardiac dysfunction, concomitant chronic disease, and other drug therapy. To decrease the incidence of orthostatic hypotension in the elderly, careful titration of dosage is recommended. A significantly increased incidence of cerebrovascular events (stroke, transient ischemia attack) have been reported in the elderly (aged 73—97 years; mean 85 years) with **dementia**-related psychosis taking risperidone vs. placebo (n=1230). Some events have been fatal; use risperidone with extreme caution in elderly patients with cerebrovascular disease.[4651] In addition, patients with dysphagia or who are at risk for aspiration should be closely monitored while receiving risperidone. Risperidone has been associated with esophageal dysmotility and aspiration of gastric contents, which may increase the incidence of aspiration pneumonia in certain patient populations, such as elderly patients with advanced Alzheimer's dementia. Atypical antipsychotics are not approved for control of behavioral disorders in elderly patients with dementia. In April 2005 the FDA mandated that all manufacturers of atypical antipsychotics include a black box warning to the labeling noting that increased death rates (1.6—1.7 times that of placebo) have been noted in these patient populations receiving atypical antipsychotics. Death typically occurred due to heart failure, sudden death, or infections (primarily pneumonia). Of 17 placebo controlled trials (n=5106) performed with olanzapine, aripiprazole, risperidone, or quetiapine in elderly demented patients with behavioral disorders, 15 showed numerical increases in mortality in the active compared to the placebo-treated patients.

Hyperglycemia, in some cases associated with diabetic ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics (see Adverse Reactions). Epidemiological studies suggest an increased risk of 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. Additionally, an increased risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in general complicates this concern. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia (polydipsia, polyuria, polyphagia, weakness). Patients with established diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history) should undergo fasting blood glucose testing at the beginning of treatment. Patients who develop symptoms of hyperglycemia during treatment should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the antipsychotic was discontinued; however, some patients required continuation of anti-diabetics despite discontinuation of the suspect drug.[5144]

Similar to other antipsychotics, risperidone can cause hyperprolactinemia, likely due to central D_2 antagonism. Elevations in prolactin may induce infertility in either men or women, or may induce other endocrine abnormalities (see Adverse Reactions). Some human breast cancers may be prolactin-dependent and therefore most antipsychotics should be used cautiously in those who have a history of breast cancer.

Risperidone is classified as FDA pregnancy category C. At this time, evidence is insufficient to establish the safe use of risperidone in humans during pregnancy. Risperidone is known to cross the placenta in animals. Animal studies have not shown evidence of teratogenicity or mutagenicity, but they have shown an increase in deaths during the immediate post-natal period. There is one human case report of agenesis of the corpus callosum occurring *in utero* as well as reversible extrapyramidal symptoms. The drug is recommended for use during pregnancy only when the benefits outweigh the risks.

Risperidone and its metabolite are excreted in human breast milk. According to the manufacturer, risperidone should not be used during lactation and *breast-feeding* should be discontinued. Four case reports document the excretion of risperidone and 9-hydroxyrisperidone into breast milk. The milk/plasma ratio for all 4 women was less than 0.5 for both compounds. The calculated relative doses the infants received were 2.3, 2.8, 4.3 and 4.7% of the maternal doses (weight adjusted). When the infant plasma samples were assayed, risperidone and 9-hydroxyrisperidone were not detectable. The infants were thriving and no reported adverse effects were attributable to risperidone. According to the authors, maternal use of risperidone is unlikely to be a significant risk for breast-fed infants in the short-term, but the potential risks/benefits should be evaluated.[4561] [4562]

Risperidone should not be used in children under the age of 15 years. Safe and effective use has not been established.

Photosensitivity can occur during risperidone therapy, and patients should be warned either to keep out of the sun or to use effective sunscreens (SPF 15+) on exposed areas of the body. Patients should avoid undue sunlight (UV) exposure and the use of tanning beds.

[Last revised: 8/14/2006 7:53:00 PM]

References

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milk: case report and estimated infant exposure during breast-feeding (letter). *J Clin Psychopharmacol* 2000; 20:2285--6.

4651. British Medicines and Healthcare Products Regulatory Agency (MHRA), Committee on the Safety of Medications (CSM). Risperidone Clinical Trial Data. March 9, 2004. Internet version, retrieved March 18, 2004. Available on the World Wide Web at: http://www.mca.gov.uk/ourwork/monitorsafequalmed/safetymessages/risperidoneclinicaltrialdata_final.p

5144. Risperdal® (risperidone) package insert. Titusville, NJ: Janssen Pharmaceutica Products, L.P.; 2003 Dec.

Home

Exhibit "C"

Curriculum Vitae

Victor Patnella

Education: B.A. Biochemistry from Canisius College 1975
B.S. Pharmacy: Brooklyn College of Pharmacy 1978

Employment: Brooks Drugs 1978 to 1988
Fays Drugs 1989 to 1990
Buffalo Psychiatric Center 1990 to 1992
Vix Drugs, Pharmacy Supervisor 1992 to 1996
Walgreens, Pharmacy Supervisor 1996 to current
WKBW-TV pharmacy consultant to news department, AM-Buffalo and PM-Buffalo 1993 to current

Professional Associations: PAWNY (Pharmaceutical Association of Western New York) and PSSNY (Pharmaceutical Society of the State of New York)