CANADA
Province of Alberta

Report to the Minister of Justice and Attorney General
Public Fatality Inquiry

Fatality Inquiries Act

WHEREAS a Public Inquiry was held at the Law Courts

in the City (City, Town or Village) of Edmonton (City, Town, Village), in the Province of Alberta,

on the 5th day of March, 2012 (year), (and by adjournment

on the 6th, 7th and 12th day of March, 2012 (year)),

before The Honourable Elizabeth A. Johnson, a Provincial Court Judge,

into the death of Carol Pifko (Name in Full) 61 (Age)

of Capital Care Norwood Long Term Facility (Residence) and the following findings were made:

Date and Time of Death: May 1, 2009 at approximately 12:12 a.m.

Place: Royal Alexandra Hospital

Medical Cause of Death:
("cause of death" means the medical cause of death according to the International Statistical Classification of Diseases, Injuries and Causes of Death as last revised by the International Conference assembled for that purpose and published by the World Health Organization – The Fatality Inquiries Act, Section 1(d)).

Neuroleptic Malignant Syndrome due to adverse reaction to Olanzapine

Manner of Death:
("manner of death" means the mode or method of death whether natural, homicidal, suicidal, accidental, unclassifiable or undeterminable – The Fatality Inquiries Act, Section 1(h)).

Accidental

I. INTRODUCTION AND SUMMARY

Carol Pifko died at the Royal Alexandra Hospital ("RAH") on May 1, 2009 as a result of Neuroleptic Malignant Syndrome ("NMS"). NMS is a rare and potentially life-threatening neurological disorder caused by an adverse reaction to an anti-psychotic medication. Ms. Pifko had been prescribed an anti-psychotic medication, Zyprexa (generic name Olanzapine), on April 24, 2009. Prior to that time, on March 15, 2009 she had been prescribed Seroquel (generic name Quetiapine), also an anti-psychotic.

At the time of her death Ms. Pifko was a resident of Capital Care Norwood where she was waiting for a placement in long term care.

II. THE INQUIRY AND ITS MANDATE

The Fatality Review Board recommended that a public fatality inquiry be held in this matter pursuant to s. 33(2) of the *Fatality Inquiries Act* (the "*Act*") in order to determine if a similar death can be prevented with respect to the drug Olanzapine (Zyprexa) in dementia patients.

The inquiry convened on March 5, 2012 and heard evidence on March 5, 6, 7, and 12. Evidence was led through inquiry counsel.

Pursuant to s. 49(2) of the Act Jodi Pifko, next-of-kin of Carol Pifko, has standing to participate in the Inquiry. At a pre-Inquiry meeting, Alberta Health Services and certain independent physicians were granted interested person status pursuant to s. 49(d) of the Act. Jodi Pifko and the interested parties appeared and participated in the inquiry through counsel.

The inquiry heard from the following witnesses:

Dr. Bernard Bannach, Assistant Chief Medical Officer,
Graham Jones, Chief Toxicologist,
Jodi Pifko, daughter of Carol Pifko,
Penny Reynolds RN, Administrator at Capital Care Norwood,
Jan Barton RN, provided psychiatric consulting services to Norwood,
Susan Haggarty, pharmacist, then with Capital Care Norwood,
Marilyn Woolley RN, (then) acting manager, 3rd floor, Norwood,
Helen Wellsbury RN, team leader, evening shift, third floor, Norwood,
Brian Sereda MD, treated Ms. Pifko at Norwood,
Douglas Faulder MD, treated Ms. Pifko at Norwood,
Asad Brahim MD, geriatric psychiatry - consulted with Jan Barton,
John McDermott MD, neurologist, RAH,
Luke Savage MD, family medicine resident, RAH,
Rith Chea MD, general and internal medicine, RAH.

The Act calls upon the judge conducting the Inquiry to make a report to the Minister containing findings as to: the identity of the deceased; the date, time and place of death; the circumstances under which the death occurred; the cause of death; the manner of death (s. 53(1)).

The judge may make recommendations as to the prevention of similar deaths (s. 53(2)).

The findings of the judge may not include any findings of legal responsibility or any conclusion of law (s. 53(3)).

III. CIRCUMSTANCES UNDER WHICH DEATH OCCURRED:

A. Background

Ms. Pifko had been diagnosed with Alzheimer's in 2006 when she was living in Ontario. In August 2007 Ms. Pifko moved to Alberta where her daughter Jodi was living. (I will refer to Jodi Pifko in this report as "Jodi" to differentiate her from Carol Pifko to whom I will refer as "Ms. Pifko").

When Ms. Pifko arrived in Alberta she was assessed at the Glenrose Hospital where, after testing, her condition was diagnosed as a form of dementia called corticosalbasal degeneration (with Parkinsonian symptoms). Ms. Pifko was discharged from the Glenrose in January 2008 and moved into Capital Care Norwood, pending placement into long term care.

In order to be placed in long term care or on a waiting list, Ms. Pifko had to meet a one year Alberta residency requirement. She was lodged on the third floor transitional unit at Norwood until August 2008 at which time she met the residency requirement.

In August 2008, Ms. Pifko was moved to the second floor at Norwood and was placed on a waiting list for a placement at Touchmark by Wedgewood.

Dr. Faulder, medical director of Capital Care, was one of the physicians who dealt with Ms. Pifko while she was on the transition unit. He described her as being stable between January and August 2008.

Dr. Faulder took over the care of Ms. Pifko again in March 2009. At that time, he reviewed her chart and spoke to the nurses and received information that she had been experiencing some problems relating to her dementia, including symptoms and signs of fear and possibly hallucinations and some manifestations of paranoia.

Jodi indicated that her mother had difficulties during her stay on the second floor. Some of those were addressed as staffing issues. She described her mother as becoming paranoid about staff taking her things.

B. Introduction of Seroquel and Zyprexa

On March 11, 2009 Dr. Faulder ordered a 3-day behavioural observation of Ms. Pifko, to establish a behavioural baseline. He directed that she be started on a prescription for the anti-psychotic Seroquel. His note said:

> "Recently increased suspiciousness, accusatory and paranoia, mood normal. Will try Seroquel first at low dose and observe for effect, positive or negative"

Dr. Faulder said he would not necessarily treat every hallucination or delusion in a patient with dementia, but he would where those things were distressful to the patient as Dr. Faulder felt they were for Ms. Pifko.

Dr. Faulder did not contact Jodi or Ms. Pifko about prescribing Seroquel. Jodi indicated that the nursing staff told her that her mother had been prescribed Seroquel.

Ms. Pifko's mood and behaviour did not improve. Jodi identified an incident on April 19 when her mother was very upset about something which Jodi determined could not really have happened. Ms. Pifko mentioned to Jodi that she was thinking about throwing herself out the window. These incidents were brought to the attention of staff and ultimately to Dr. Faulder.

Dr. Faulder requested a consultation with the Long Term Psychiatric care team. Jan Barton RN, who is employed to provide psychiatric consulting services within Continuing Care, assessed Ms. Pifko on April 23, 2009. She testified that she was concerned with Ms. Pifko's level of thought disorder.

Jan Barton contacted Asad Brahim, a physician with an interest and considerable experience in geriatric psychiatry. He provides consulting services to, among other places, Capital Care Norwood.

Jan Barton conveyed her concerns about Ms. Pifko to Dr. Brahim. They agreed that it would be appropriate to recommend that Ms. Pifko be transferred to the Glenrose.

Ms. Barton and Dr. Brahim also discussed Ms. Pifko's medications and decided it would be appropriate to try something different to settle her down. Dr. Brahim's recommendation was that the Seroquel be reduced to 12.5 mg. He felt it would be appropriate to try Zyprexa. Dr. Brahim testified that the normal dose of Zyprexa is 5 mg three times a day. He recommended what he described as a very small dose of 2.5 mg

twice a day. Other changes were recommended.

Jan Barton passed along the recommendations to Dr. Faulder over the telephone and in writing. The medication changes were effected by order of Dr. Faulder on April 24, 2009.

Dr. Faulder also directed that Ms. Pifko be transferred to the third floor transition unit, in anticipation of her transfer elsewhere. No beds were then available at the Glenrose. Jodi felt that her mother should be transferred back to the third floor where she had done well.

No one discussed the addition of Zyprexa to her mother's medications with Jodi.

C. Double Dose of Zyprexa

An error was made dispensing the Zyprexa to Ms. Pifko. Medications prescribed for Norwood patients come from the pharmacy dispensary at Capital Care Dickensfield. Medications come already packaged based on the time the drugs are to be taken.

The Zyprexa for Ms. Pifko came in a plastic baggie inside which are individually wrapped tablets. The baggie said 2.5 mg (the dose prescribed by Dr. Faulder), but the actual tablet wrapper said 5 mg.

The result was that Ms. Pifko received a double dose of Zyprexa 5 times - once on April 24, twice on April 25, twice on April 26.

The error was discovered by one of the pharmacists, Susan Haggarty. She said that pharmacists do not generally review packaged medications to ensure that the dosage is correct, however, the Dickensfield pharmacy was closed on April 26 so Ms. Haggarty went to Ms. Pifko's unit on April 27 to make sure she had enough medication to last until the next shipment. At that time she noted that the dosage on the outside of the bag did not match the dosage inside the medicine bag.

Ms. Haggarty notified the nurse (Helen) so that she could monitor Ms. Pifko and told her what side effects to look for. She noted the medication error on the Physician/Team Communication Record. She created an Incident Report which would have been sent to the pharmacy department.

The Physician/Team Communication Record is a conduit for communication between physicians and nursing staff. Its use is to inform the physician about something, or ask a question relating to clinical care. On the third floor at Norwood the Physician/Team Communication Record is kept at the nursing station in a separate binder with orange coloured sheets. The staff nurse and the physician going through the charts each day would look at the binder first. The orange notes do not become a part of the patient's file until the patient is discharged.

Helen Wellsbury was the nurse on duty and the nurse to whom Susan Haggarty spoke. Ms. Wellsbury completed a Behavioural Observation Record for Ms. Pifko for her shift (evening). She noted that Ms. Pifko was crying, afraid and agitated between 1500 and 1700 hours, after that Ms. Wellsbury's notes indicate "settled no odd behaviour".

The Medication Administration Record shows administration of Zyprexa on April 24 (1 dose), April 25 (2 doses), April 26 (2 doses), April 27 (1 dose - no dose is charted for 0800 on April 27), and one dose for April 28.

Helen Wellsbury was asked about the apparently missed dose on April 27 but she had no knowledge of it and did not know whether an incident report was prepared in respect of it.

Ms. Pifko's family learned about the double dose after her death.

D. April 28 and the Transfer to the Royal Alexandra Hospital

Dr. Sereda examined Ms. Pifko on April 27 and found nothing unusual.

On April 28 Ms. Pifko's behaviour changed. Staff came to Marilyn Woolley, Acting Manager on the third

floor, early in the morning of April 28 saying that Ms. Pifko was acting in an unusual manner. Ms. Woolley observed that Ms. Pifko was trembling, shaking, her arms were rigid and she was grabbing onto things. She was having hallucinations.

Ms. Woolley called for Dr. Sereda and left a message for Dr. Faulder.

Dr. Sereda directed that Ms. Pifko's psychotropic medications be discontinued including Seroquel and Zyprexa. He noted in the "Physicians Order and Progress Record" Neuroleptic Malignant Syndrome (NMS) as a part of his differential diagnosis. He directed that Ms. Pifko be taken to the RAH emergency.

When it became apparent that Ms. Pifko was to be sent to the RAH, Ms. Woolley began to get the chart documents ready to go with Ms. Pifko. She thought the unit clerk helped out with this task. Ms. Woolley said they send the patient medication administration record ("MAR"), the "patient registry" with Ms. Pifko's list of her diagnoses, contact numbers for the family and for Norwood, the recent nurses' notes, the physician's orders. The RAH patient care records, entered as an exhibit in the Inquiry, include a number of pages which Ms. Woolley identified came from Norwood. Ms. Woolley said the documents are generally handed to the paramedics. She said she had no doubt that the documents went with Ms. Pifko.

The Physician/Team Communication Record which was completed by Ms. Haggarty on which the double dose was recorded was not a part of Ms. Pifko's chart at the time she was transferred to RAH and accordingly did not accompany her when she was sent to the RAH on April 28. The physicians who dealt with Ms. Pifko at the RAH were not aware of the double dose.

Ms. Woolley called Jodi to tell her about her mother's condition. Jodi arrived at Norwood at about the same time as EMS which was around 11:00 a.m. on April 28. Jodi said that as she followed the ambulance attendants out of Norwood she picked up a piece of paper which appeared to be a list of medications which had her mother's name on it. She gave it to the ambulance attendant.

Dr. Sereda said he called the RAH emergency to let them know that Ms. Pifko was coming. His notes indicate that he spoke to Dr. Mohler. Dr. Sereda said he would have told Dr. Mohler about his suspicions relative to Neuroleptic Malignant Syndrome.

When Ms. Pifko arrived at the RAH she was seen at approximately 8:00 p.m. by Luke Savage, who was then a first year resident. His task was to do a history, a physical and come up with a plan. He testified that in preparing the history he would have reviewed the written material available to him and spoken to anyone who could provide him with information. He was not able to say which documents he reviewed.

The history he prepared reflected the medication changes made on April 24 (adding Zyprexa and reducing Seroquel). Dr. Savage did not recall seeing a document in which Dr. Sereda discontinued the medications including Zyprexa. He was not able to say with certainty the specific documents which were the source of the information he included in his history.

Dr. Savage wrote orders under which Ms. Pifko was to be admitted to the RAH. He directed that all psychiatric medications be held. He continued her heart medication, Tylenol for fever and the Zyprexa for her agitation and delirium. Dr. Savage arranged for a lumbar puncture to be done.

Dr. Savage was not able to say whether he discussed the medications with Jodi.

Dr. Chea became the attending physician for Ms. Pifko on April 29 after she was admitted to the RAH. He had not had the opportunity to review any documents from Norwood when he took over her care. At that time, the admission history had been completed, blood work done with some results done and cultures pending.

Dr. Chea was primarily concerned with Ms. Pifko's agitation and felt the Zyprexa would address that. He examined Ms. Pifko who was not in a condition to be able to provide him with any information. He spoke to Jodi and obtained collateral information. His differential diagnosis included poly pharmacy and meningitis. His notes indicate that he included NMS in the differential diagnosis.

On April 30, Dr. Chea was paged to Ms. Pifko's unit. Jodi was there and very upset about her mother's

condition. Dr. Chea had reviewed the culture reports and blood work which suggested that infection was an unlikely diagnosis. He felt that the more likely diagnosis was NMS.

Jodi had done her own reading and she thought her mother had NMS. She discussed her conclusion with Dr. Chea.

The medication administration record from the RAH indicates that Ms. Pifko was given doses of Zyprexa (2.5 mg) at the RAH on 7 occasions - on April 29 at 4:45, 8:00, 10:30, 14:30, 19:05, 20:00, and on April 30 at 2:50, and 6:40. Dr. Chea gave a verbal order that the Zyprexa dose for 10:00 be "held". He wrote an order to discontinue it after his discussion with Jodi on April 30. He substituted Lorazepam for the agitation. He said he did not initially prescribe that drug for agitation because it can make elderly patients more confused.

Dr. Chea discussed possible treatment of NMS with Jodi. Dr. Chea indicated that he had to consult with a neurologist as he did not have much experience with NMS which he said is a rare condition.

On April 30, Dr. Chea requested a consultation with Dr. McDermott. Dr. McDermott examined Ms. Pifko for about 10 minutes. Because of her decreased level of consciousness, he was not able to obtain information from her and had to rely on collateral information.

He recorded his impression of her clinical status as encephalophy (meaning one's brain is not working properly, associated with decreased consciousness and confusion).

Dr. McDermott testified that with individuals having an underlying dementive disorder, a spot diagnosis is difficult and so he does a differential diagnosis. He described that process as one of identifying those things which could provide an explanation to unify the patient's symptoms, and then eliminating those that can be eliminated. For Ms. Pifko, he considered infection, which is often associated with fever and the presence of white blood cells in the urinalysis, although the count was low. He indicated that meningitis had been eliminated by the results of the lumbar puncture which had already been done. He identified NMS as being relatively high on the differential. He considered Serotonin Syndrome (which is associated with anti-depressants) but felt that NMS was the more likely diagnosis. In this respect he took into account the fact that Zyprexa had been introduced on April 24.

Dr. McDermott indicated that there is some controversy about the treatment of NMS. It is a rare condition and there have not been randomized clinical data to direct how physicians should proceed. He indicated that the offending agent (Zyprexa) should be discontinued, and that this had already been done. He recommended that Dantrolene be started with the possibility Bromocriptine be added later on.

Dr. Chea ordered that Dantrolene be commenced as soon as possible. He also requested that Ms. Pifko be moved to a "high intensity unit" where she could be more closely monitored and managed. He increased the frequency of monitoring her vital signs to once an hour.

Jodi was very involved with her mother's care throughout.

Jodi described her experience of events after her mother was sent to the hospital. Jodi said she responded to a call from Norwood on the morning of April 28 and arrived to find her mother delirious with a high fever and rigid. She went to the RAH with her mother in the ambulance. She spoke to nurses and doctors who dealt with Ms. Pifko at the RAH emergency. She was asked by doctors what medications her mother was on and she told them about the medications she was aware of, including Seroquel. She was not aware of the Zyprexa. She was told by one of the doctors that they were checking for infection, meningitis or a medication related reason for her mother's current condition. She consented to the spinal tap which was done later that evening. She was told her mother's medications were being stopped.

Jodi returned to the RAH on April 29 after going to Norwood to pick up some of her mother's things. Ms. Pifko had been moved to the 5th floor. She spoke to Dr. Chea who told her that the cultures were microscopically clear but needed to sit for 48 hours.

Upset, Jodi went home in the afternoon and sent a message to an online corticobasal support group she belonged to, describing her mother's symptoms. One of the responses she received was that the

symptoms she described sounded like NMS caused by an anti-psychotic. She returned to the hospital that evening, asked about what medications her mother was on and was told Ms. Pifko was receiving Zyprexa and Trazodone. She called Norwood and was told what medications her mother was on. She looked up Zyprexa and learned that it is an anti-psychotic.

Jodi called the RAH, spoke to a nurse, explained about Zyprexa and asked to speak to her mother's doctor. She asked to have her mother taken off Zyprexa and was told that that decision had to made by the doctor.

Jodi returned to the hospital on the morning of April 30. She wanted to make sure her mother was not given another dose of Zyprexa. She was not able to speak to Dr. Chea until around 12:00 or 1:00 pm. She told him about her research on NMS and Zyprexa. He told her the Zyprexa would be discontinued and they discussed further medication. Later, the neurologist came to see Ms. Pifko. Jodi said he spoke about Lewy body dementia and NMS.

Jodi was told that they were starting Dantrolene and would consider Bromocriptine later if Ms. Pifko could take it orally.

Jodi remained with her mother until about 8:00 p.m., and left when she was sleeping peacefully. Jodi's husband called at 11:00 p.m. and was told that Ms. Pifko's blood pressure had gone up, but they had given her something for that and she was fine.

At 12:38 on May 1, 2011, Jodi received a call from Dr. Chea to tell her that her mother had died.

E. Norwood Policies and Policy Review

The inquiry heard evidence about some of the Capital Care policies in place at Norwood. Penny Reynolds described those policies.

Capital Care Edmonton has a medication administration policy applicable to RNs and LPNs when administration of medication falls within their scope of practice.

Capital Care has a policy respecting anti-psychotic medication use which was amended in 2009. Both policies required a baseline observation of 72 hours, included appropriate and inappropriate indications for the use of such medications and required monitoring for side effects. The amended policy included a definition of chemical restraint, and required physician tracking on a monthly basis.

Capital Care has a written Patient Transportation policy. Penny Reynolds said she had not seen the written policy but indicated that the practice in the area of patient transportation has been the same for many years. She said that information is sent with the patient which would assist the referring hospital, generally including recent physician orders, medication profile, any interdisciplinary notes, recent lab reports, and advanced directives if they are on the chart.

After the death of Ms. Pifko, Penny Reynolds was contacted by Alberta Health Services to obtain some information from Ms. Pifko's chart which had been requested by Jodi. She received and reviewed Ms. Pifko's chart, which by that time included the orange sheet (the Physician/Team Communication Record) identifying the double dose of Zyprexa. She spoke to Susan Haggarty.

Ms. Reynolds began an investigation into the medication error. She arranged for a meeting with the family to advise them. That meeting was held on May 8, 2009 and the family (including Jodi) were advised of the medication error.

Very shortly after discovering the error, Ms. Reynolds together with the manager of pharmacy changed the incident reporting procedure so that any incident report would be copied immediately and a copy sent to the care manager on the unit as well as to the pharmacy.

Ms. Reynolds indicated that it was her understanding that the pharmacy manager reviewed the processes in the pharmacy area following this incident.

As well, in-services were provided to the LPNs to ensure that all steps required in the administration of medication are followed.

F. Health Canada Advisories, Black Box Warnings, NMS

A document generated by Health Canada was filed as evidence in the Inquiry. It reads as follows:

> Health Canada advises consumers about important safety information on atypical antipsychotic drugs and dementia
> **Advisory**
> 2005-63
> June 15, 2005
> For immediate release
>
> **OTTAWA** - Health Canada is advising Canadians about the risks to elderly patients suffering from dementia, who take second-generation antipsychotic medications, also referred to as atypical antipsychotics.
>
> The advice is based on recent studies showing that elderly demented patients prescribed second-generation antipsychotic medications had a 1.6 greater death rate than those patients taking placebos (sugar pills)
>
> The studies examined risperidone (Risperdal), Quetiapine (Seroquel) and Olanzapine (Zyprexa). There were no studies with clozapine (Clozaril) in elderly demented patients. However, because Clozaril is in the same family, this advisory applies to all four drugs.
>
> Seroquel, Zyprexa and Clozaril are not approved for treating behavioural disorders in elderly patients with dementia. These three drugs as well as Risperdal are approved for the treatment of schizophrenia. Risperdal is also approved for the short-term treatment of aggression and/or psychosis in patients with severe dementia.
>
> Based on the findings in the studies, Health Canada is requesting that all manufacturers of these drugs include a warning and description of this risk in the safety information sheet for each drug.
>
> Patients should continue to take their medication as prescribed, as discontinuing any medication could pose health risks and should be discussed with a physician. If patients have any concerns they should contact their doctor

Extracts from the Compendium of Pharmaceuticals and Specialties - the Canadian Drug Reference for Health Professionals (2009) were also entered as exhibits, specifically the pages dealing with Zyprexa and Seroquel. Each page contains an entry which was referred to in evidence as a “black box warning”. Those warnings read as follows:

> Serious Warnings and Precautions
> Increased Mortality in Elderly Patients with Dementia: Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared with placebo. Analyses of thirteen placebo controlled trials with various atypical antipsychotics (modal duration of 10 weeks) in these patients showed a mean 1.6 fold increase in death rate in the drug-related patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg heart failure or sudden death) or infectious (eg. pneumonia) in nature. (See Warnings and Precautions, Special Populations, Use in Geriatric Patients with Dementia).

A number of the witnesses were asked about Zyprexa, Seroquel and these warnings.

Dr. Bannach who identified the cause of death as NMS described NMS as a rare, potentially life-threatening neurological disorder caused by an adverse reaction to a class of medications called neuroleptics which include atypical anti-psychotics. He said NMS is not dose related; it is caused by an adverse reaction to the drug itself and not the quantity.

Dr. Bannach described Zyprexa as an anti-psychotic used for schizophrenia and bi-polar disorder, but which can also be used for dementia and agitation.

Dr. Bannach was not aware of the Health Canada warnings. He reviewed the CPS warnings but was not able to speak to their significance. Dr. Bannach is not a treating physician and does not prescribe medications.

Graham Jones identified Zyprexa as a drug used to treat various types of psychoses including schizophrenia and bipolar disorder and occasionally agitation. He is aware that warnings come out from Health Canada and other American agencies relating to drugs, but said that, ultimately, the question of whether to prescribe the drugs becomes a matter of clinical judgement.

Dr. McDermott testified that medications are often used "off label" - for purposes for which they have not been specifically recommended. He said that Zyprexa, Seroquel and Risperdal have been approved specifically to manage psychosis in the context of psychiatric disease such as schizophrenia, but they are also used quite commonly to manage behavioural disturbances in patients with dementia, recognizing that there is a risk of complications. He said there are few alternative choices - pharmaceutical and non pharmaceutical - for management of symptoms where a patient's agitation relates to dementia.

The black box warning speaks of increased risk relating to cardio vascular events or infections in elderly patients. Dr. McDermott said that NMS is not a cardiovascular condition or an infection.

Dr. Sereda, referring to the Health Canada warnings, said all physicians receive them. He said that a lot of medications are used off label. Dr. Sereda was aware of the CPS warnings and acknowledged that there are risks to those drugs and to other drugs used in treating the elderly, but that there are not many options.

Dr. Sereda described NMS as a very rare condition. He had seen one such case before. He said it can be caused by any neuroleptic.

Susan Haggarty said she was familiar with NMS which she described as rare and which is a side effect of anti-psychotic drugs regardless of whether dementia is present.

Dr. Chea was aware of the CPS warnings when he treated Ms. Pifko. He said there are not a lot of options when dealing with agitation in elderly patients.

Dr. Brahim was familiar with the warnings relating to Seroquel and Zyprexa. He said they do not mean those medications should not be prescribed, but that one must be very careful when prescribing them and explain their side effects. He said it is necessary to weigh the pros and cons of prescribing medications as compared with side effects. He has prescribed Zyprexa to other elderly patients. He described NMS as very rare, and not age-specific - it can happen to anyone.

Dr. Faulder was aware of the warnings associated with Seroquel and Zyprexa. He said that those drugs treat hallucinations. The drugs do treat dementia; they are used in connection with dementia to reduce its symptoms.

IV. RECOMMENDATIONS FOR THE PREVENTION OF SIMILAR DEATHS:

This Inquiry is empowered to make recommendations, where appropriate, directed at preventing similar deaths. In considering whether to make recommendations, there are several things that must be borne in mind.

Any recommendations from this Inquiry should be useful. To be useful they must go beyond the specific facts of this case and have a broad, systemic application. They must be based on evidence. The Inquiry must consider the potential for future unforeseen adverse consequences which could arise from any recommendations.

This Inquiry involved highly trained professionals including physicians, nurses and pharmacists. Their activities and scope of practice are governed by statute, and by their professional organizations. Professional and civil consequences may flow from a failure to carry out their professional obligations.

Their activities relative to a given patient may overlap, but the professionals play separate and distinctive roles.

Physicians, nurses and other health care professionals care for their patients in accordance with their professional training and judgement.

With hindsight it is not difficult to identify things which, if done differently, might have had the potential to alter the course of events.

Counsel for Jodi invited me to make a number of recommendations as described below. I have carefully considered the proposed recommendations. They are set out below together with my comments.

Suggested Recommendation No. 1

> "a. In long term care facilities, nursing staff or physicians should disclose the Health Canada Advisory and the black box warnings to their patients with dementia and to the patients' legal representatives/involved family members if it is proposed that the patients be given Seroquel, Zyprexa or Clozaril.
>
> b. This disclosure must be documented."

This recommendation addresses how nursing staff and physicians practicing in long term care should communicate with their patients. It engages the concept of informed consent which is addressed in common law and in professional standards. To the extent that the recommendation would require nurses to discuss risks and side effects of medications, it is not clear that such a discussion would fall within their scope of practice. To the extent that it would require physicians to communicate with their patients in a specific way using specific documents, it would seem to fetter a physician in how he or she deals with a patient and exercises his or her professional judgement. That would be an unintended adverse consequence.

Clearly not knowing about her mother's medications was distressing to Jodi and understandably so. However, the physicians and others who testified appear to be aware of the requirements of informed consent. I do not feel that any recommendation could add to those existing obligations.

Suggested Recommendation No. 2

> "a. Continuing Care Standard 1.16(f) must be implemented so that patients and their legal representatives/involved family members are provided clear and easy to understand information about the risks and side effects of their medications.
> b. Patients and their legal representatives/involved family members must be given an opportunity to give or withhold informed consent with respect to anti-psychotic medications.
> c. If informed consent is given and anti-psychotic medications are newly prescribed, there needs to be more extensive daily documented monitoring by not only nurses, but also physicians on the effects of the medications.
> d. Doctors must assess the patients more frequently than once per month if their patients are on anti-psychotic medications.
> e. The disclosure of risks and adverse effects to the patients or their legal representatives/involved family members must be documented."

The evidence was that Norwood was audited for its compliance with the Continuing Care Standards. A Compliance report dated June 18, 2009 found Norwood non-compliant in certain respects. Changes were made with the result that the auditor found Norwood to be compliant.

To the extent that this set of proposed recommendations relates to informed consent, my comments on informed consent are set out above.

It is not clear what "more extensive daily documented monitoring" by nurses and physicians means and a general recommendation in those terms would be vague and ambiguous. This Inquiry has not heard evidence about optimum monitoring periods so as to be able to make a recommendation about what those periods should be.

It is not clear how documenting disclosure could operate to prevent similar deaths.

Suggested Recommendation No. 3

"a. A psychiatric assessment should be done by a psychiatrists [sic]. Jan Barton thought that Dr. Brahim was a psychiatrist, but he is not.
b. Anti-psychotic drugs should not be recommended by a Psychiatric Consultant unless the physician has seen the patient and reviewed the patient's chart."

This proposed recommendation invites this Inquiry to venture into the realm of determining who is qualified to practice certain types of medicine. There is no evidence before the Inquiry to indicate that a person with Dr. Brahim's qualifications is not or should not be able to conduct the type of assessment which he testified he conducted. It was not suggested to him or any other witness that this was the case.

Further the proposed recommendation that a psychiatric consultant cannot recommend anti-psychotic drugs on its face purports to restrict the way in which a psychiatric consultant could communicate with a physician. Open communications between professionals involved in the treatment of a patient should be encouraged, not restricted.

Suggested Recommendation No. 4

"a. Patients and their legal representatives/involved family members must be told immediately about any incorrect doses of medication, and this notification must be documented.
b. The Patient's physician must be notified immediately by means other than the Orange Card, and this notification must be documented by the staff person giving the notification and the doctor receiving it."

The double dose was discovered and a report prepared. It was documented on the orange Physician/Team Communication Record which was part of the material which would have been brought to the attention of the physician on rounds the following day. It was not a part of the file which accompanied Ms. Pifko to the RAH. Because she was sent to the RAH the following day, it was not discovered until later.

As a result of Penny Reynolds' investigation, changes were made respecting reporting of medication errors. The care manager on the unit, as well as pharmacy, must now be notified of any medication errors. The concern about an error not coming to the attention of the unit was addressed by that change.

The evidence from Penny Reynolds was that as soon as she became aware of the medication error she took steps to notify the family.

Penny Reynolds implemented a change to address the concern that the double dose was not discovered. No further recommendation in that regard is necessary.

Suggested Recommendation No. 5

"a. When patients are transferred from one facility to another, information about incorrect doses must be communicated to the receiving facility.
b. A transfer letter from the attending physician at the sending facility must be sent to the receiving facility outlining the patient's medical history, current condition and concerns.
c. The "Patient Transfer Information" (Tab 17, Doc. 786-787) should be completed by the attending physician or alternatively the charge nurse.
d. The "Patient Transfer Information" should identify the specific medical information sent along with the patient."

The evidence was that when a patient is being transferred to another facility information which would be necessary and useful to the receiving facility is sent with that patient. The medication error was not known to those preparing the documents for transfer when Ms. Pifko was transferred. It was not on her chart. I have no reason to believe that, had that information been available and a part of her chart when Ms. Pifko

was transferred it would not have been sent with her. The circumstances giving rise to that situation where the note was not a part of the chart have been addressed by the change implemented by Penny Reynolds.

The document at Tab 17 (p. 786 - 787) was completed. No witnesses testified about this document or its use. I would be reluctant to make any recommendations respecting paperwork without hearing about its use. From the evidence I heard, it is important that documentation giving complete and accurate information be transferred with patients. The witnesses who testified about this issue were aware of the importance of this.

Suggested Recommendation No. 6

a. All missed doses must be documented, with the reasons given.

Counsel notes that Capital Care's Medication Administration policy requires nurses to record on the Medication Flow sheet routine medication doses that are withheld, omitted or refused and the reason for not administering the medication. There is no dose of Zyprexa recorded for the morning of April 27. Helen Wellsbury testified that usually if a dose is not given an Unusual Incident Report would be made - that is the normal practice. She was not able to say whether an incident report was made in relation to that apparently missed dose. No one else testified about this issue.

It appears that the recommendation being suggested tracks the Capital Care Medication Administration policy. No recommendation is necessary.

Suggested Recommendation No. 7

"a. All incorrect doses must be recorded immediately in the Nurses notes and in the Medication Flow Chart.

b. In addition, an Incident Report from both the Pharmacy and the Nursing Staff must be placed immediately on the Patient's Chart."

Penny Reynolds discovered that the Incident Report for the double dose was sent to pharmacy and a copy was not sent to the unit. She instituted a new policy whereby a copy is sent to the care manager as well.

The recommendations under this heading refer to "charting deficiencies". A recommendation that nurses chart better would not be meaningful. Clearly in this case it would have been preferable that the double dose information be available to the physicians dealing with Ms. Pifko on April 28 - at Norwood and at the RAH. All the individuals who testified were aware that this was important and a policy change has been instituted with this in mind. Very specific instructions as to how and what to record are best left to the trained individuals and the institutions for whom they work.

Suggested Recommendation No. 8

"a. When incorrect doses are discovered, there should be documented evidence that the patient is being monitored and assessed and that the patients [sic] vital signs are taken.

b. In the event of a serious dosing error such as in Mrs. Pifko's case, a physician should assess the patient immediately and notify the family/legal representative of the assessment."

The evidence was that Susan Haggarty asked Helen Wellsbury to monitor Ms. Pifko, although Ms. Wellsbury did not recall that conversation. The evidence indicates that Ms. Wellsbury completed a Behavioural Observation Record for the evening of April 27 showing that Ms. Pifko settled and exhibited no odd behaviour after 1700 hours. It does not appear that her vital signs were taken that day.

There is no evidence before the Inquiry upon which the Inquiry could base the specific directions suggested to nurses and physicians.

Suggested Recommendation No. 9

> "If a DNR is considered, it must be discussed with the patient or involved family member/legal representative and that person must sign the DNR confirming there [sic] were advised of the DNR and agree with it."

A two-page Do Not Resuscitate order formed a part of the RAH chart. It was apparently completed and signed by Dr. Savage. Dr. Savage did not have a recollection of speaking with Jodi about it.

Jodi indicated that she wished to have all steps taken to save her mother. There is no evidence that that did not happen, and nothing before this Inquiry to suggest that care was withheld or steps were not taken as a result of the existence of the DNR order. There is no need for a recommendation respecting the DNR because it would have no bearing on prevention of similar deaths.

Moreover, there is no evidence about practice respecting DNR orders and personal directives. Any recommendation respecting how physicians and other health professionals should conduct themselves relative to DNR orders is beyond what this Inquiry has heard.

Neither counsel for the physicians nor counsel for AHS made any suggestions respecting recommendations.

The Inquiry makes no recommendations.

DATED June 26, 2013,

at Edmonton, Alberta.

Original signed by

The Honourable Elizabeth A. Johnson
A Judge of the Provincial Court of Alberta