

BC Taxpayers Paying Millions for High Cost, High Risk, Inappropriately Prescribed Drugs

By Janet C. Currie

Recently released BC Pharmacare data has revealed that, in 2005, over 51 million dollars was spent by BC taxpayers to purchase atypical antipsychotic drugs such as olanzapine (Zyprexa), risperidone (Risperdal) and quetiapine (Seroquel). Prescriptions of Zyprexa accounted for twenty six million dollars alone. The three drugs were the 2nd, 8th and 9th most costly drugs paid for by BC Pharmacare.

Such high costs are not surprising considering that treatment with the atypicals typically BC taxpayers from \$100-1000 per patient per month, depending on the dose, drug and formulation. A Canadian study of antipsychotic drug costs found that the number of elderly Ontarians using antipsychotics increased by 35% between 1993 and 2002. This translated into a 230% increase in total antipsychotic prescriptions and a 749% increase in costs (from 3.7 million in 1993 to 31.4 million in 2002).

In 2005 Zyprexa was the fourth most profitable drug in the world and in 2003 became Eli Lilly's top seller earning the company 4 billion dollars. Ironically, Lilly's second best seller in 2003 was a group of drugs used to treat diabetes, grossing 2.51 billion. Ironic because Zyprexa has been clearly shown to cause insulin dependent diabetes in a significant number of patients. Risperdal, marketed by Janssen, has 2.1 billion in global sales.

The "atypical" antipsychotics are indicated for schizophrenia and severe psychosis but these conditions are relatively uncommon, particularly among the elderly. Instead the drugs are being widely prescribed "off label" to seniors and children for unapproved and untested purposes - for sedation, to "manage" behavioural or conduct problems, for treating anxiety, attention deficit or to address dementia related effects in the elderly. None of these drugs have been tested or approved for any type of use (including schizophrenia) in children or adolescents. Although BC data on the prescribing of antipsychotics to children is not publically available, recent US studies indicate that antipsychotic drug prescribing to children increased five-fold between 1993 and 2002. The average age of children who received an antipsychotic was 12.9 years and most were boys.

The most common reason children are being prescribed atypical antipsychotics in the US is for "attention deficit, hyperactivity or conduct disorder" – both unapproved and untested uses. According to Dr. John March, a professor of child and adolescent psychiatry at Duke University,, "we are using these medications and don't know how they work, if they work, or at what cost...it

amounts to a huge experiment with the lives of American kids” whose brains are still developing.

Atypical antipsychotics are also widely and frequently inappropriately prescribed to seniors in nursing homes or care facilities. A US study on the quality of antipsychotic prescribing in nursing homes found that of the 693,000 residents, almost 30% of residents received antipsychotics in 2001-2002 and over 50% of these prescriptions were inappropriate

Atypical antipsychotics are associated with a range of serious even fatal side effects including:

- A higher risk of cardiovascular events such as stroke, transient ischemic attack cardiac dysrhythmias and sudden death due to heart failure;
- Elevated blood sugar and a confirmed association between these drugs and the risk of developing diabetes (The incidence among Zyprexa users may be as high as 10%).
- Significant weight gain which may lead or contribute to other health problems
- Inability to sweat or withstand high or low temperatures –these drugs affect the body’s temperature regulation centre..
- Involuntary movements of the hands, fingers, arms or legs
- Sedation, confusion, restlessness, nervousness, euphoria. Increased sedation and confusion may lead to falls and fractures in the elderly and diminish communication capabilities and activity levels.
- Parkinsonian type motor impairment - symptoms such as loss of balance, difficulty swallowing, shuffling walk.
- Neuroleptic Malignant Syndrome – characterized by muscle stiffness, rapid or irregular heart beat, high fever, blood pressure problems and death if left untreated.
- Unbearable restlessness or akathisia

Lilly has already agreed to pay \$1 billion to settle 10,500 legal claims by Zyprexa users who have alleged they suffered diabetes-related injuries from the drug. Other claims and lawsuits are underway or expected.

The atypical antipsychotics are **not** approved for treating behaviour disorders in elderly patients with dementia or for the treatment of dementia-related psychosis. The US Food and Drug Administration and Health Canada have issued warnings that treatment of behavioural disorders in elderly patients with dementia with atypical antipsychotic medications is associated with increased mortality. A recent study has also concluded that up to 75% of those taking the drug, even for indicated purposes such as schizophrenia, stop taking the drug within months because of intolerable side effects or lack of benefit.

Many questions have been raised about the effectiveness of the atypical antipsychotics. Large scale recent research has found that even for *indicated* uses such as schizophrenia these drugs are no more effective or safer than older drugs that have been largely discontinued. In many cases atypicals performed worse than their cheaper, non-patented precursors and caused more serious side effects.

Because of their high cost and profitability drug companies have consistently promoted atypical antipsychotics for off-label (non-approved) uses. In July 2006 the state of Mississippi launched a lawsuit against Eli Lilly claiming that it had engaged in a “calculated marketing plan to defraud the state Medicaid program out of millions of dollars for off-label uses of Zyprexa,” including unapproved uses for children. At least five other states in the US have taken action to restrict prescribing antipsychotics because the costs are bankrupting their Medicaid systems. Although in BC, Zyprexa requires special authority to be prescribed, this is not monitored and has not affected prescribing levels or overall costs.

Canadians are rightfully concerned about maintaining a health care system that provides safe, effective and cost effective care. For this reason questions need to be raised about the enormous amount of funding being spent on a class of drugs that is high cost, causes serious and often permanent side effects, is being prescribed inappropriately and where questions about effectiveness, in many cases, have not been answered.

BC Pharmacare 2005 Chemical Description and Ingredient Paid by Pharmacare

Sabine et al(2004) Antipsychotics and the Risk of Sudden Cardiac Death. Arch Intern Med. 164:1293-1297

Rapoport, M. et al (2005) Antipsychotic use in the elderly: shifting trends and increasing costs Int J Geriatr Psychiatry, 20(8):749-753

Tanner, Lindsey (March 16, 2006) More kids are getting anti-psychotic drugs. New York Times

FDA Public Health Advisory – Deaths with Antipsychotics in Elderly Patients with Behavioural Disturbances. April 11, 2005

Cooper, W. et al (2006) Trends in Prescribing of Antipsychotic Medications for US Children. Ambulatory Pediatrics, Vol 6(2):79-83

Pringle, Evelyn (August 3, 2006) Zyprexa Lawsuits- Eli Lilly May Lose Insurance Coverage (Lawyers and Settlements www.lawyersandsettlements.com)

Swiatek, Jeff (July 25, 2006) Mississippi sues Lilly over Zyprexa Use (IndyStar.com)

Harris, G. (2003) States try to limit drugs in Medicaid but makers resist. New York Times.

BC Pharmacare Limited Coverage Drugs – Special Authority Criteria. Last revised June 21, 2006

Pringle, Evelyn (August 19, 2005) Why are atypical drug users angry? Health Online (www.onlinejournal.com/health)

Lieberman, J et al (2005) Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia. E Engl J Med 353:12: pages 1209-1223

Wolfe, S et al. (2005) Worst Pills Best Pills. Pocket Books,

Pringle, E. (2006) Zyprexa Lawsuits-Eli Lilly may lose insurance coverage (<http://lawyersandsettlements.com>)