

**Submission to the Standing Committee on Community Services**  
**Bill 31: Mental Health Amendment Act**

I'm very concerned about the "unintentional consequences" of Bill 31.

In terms of my special interest area, the collateral damage is very likely going to include an increase of both chemical and physical restraints, instead of adequate and appropriate care, for elderly persons whose dementia results in inconvenient or risky behaviours. This will become increasingly obvious with the current shift of care for seniors with chronic illness and impairment into the community.

I'm going to begin this submission with a brief summary of my own experience in this regard. For a dozen years my mother suffered increasing cognitive impairment – classed as “psychogeriatric illness” – as a result of a series of “little” strokes. Her judgment and behaviour were seriously affected. Not one of the various antipsychotic drugs or cocktails of drugs prescribed by all the doctors, including psychiatrists and geriatric specialists, relieved her distress; indeed, most simply added to the problems, increasing agitation, confusion and fear.<sup>1</sup> The favorite drug, Risperdal (Risperidone), is recognized as increasing the risk of further strokes<sup>2</sup> – so we'll never know whether the continuing strokes were indeed caused by, or aggravated by, the prescribed cure.

One of the few studies attempting to justify the increased use of Risperidone (and, by implication, other atypical antipsychotics) for this purpose was published in 2004<sup>3</sup>. Without once mentioning the considerable health risks or quality-of-life consequences of Risperidone, or whether the use was justified by medical diagnoses and licensed use of the drug, it concluded that use was justified because it "reduced the nursing burden".

Risperidone is manufactured by Janssen Pharmaceutica, and its products include Haldol and other atypical antipsychotic drugs. Funding for the “nursing burden” study was provided by Janssen Medical Affairs; one of the authors was an employee of Janssen, one was a consultant to Janssen, and the others were on contract with Janssen.

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<sup>1</sup> The Quality of Antipsychotic Drug Prescribing in Nursing Homes; Briesacher et al, Arch Intern Med. 2005;165:1280-1285; <http://archinte.ama-assn.org/cgi/reprint/165/11/1280.pdf>

*“Conclusions: This study detected the highest level of antipsychotic use in (nursing homes) in over a decade. Most atypicals were prescribed outside the prescribing guidelines and for doses and indications without strong clinical evidence. Failure to detect positive relationships between behavioral symptoms and antipsychotic therapy raises questions about the appropriateness of prescribing.”*

<sup>2</sup> Risperidone (Risperdal): increased rate of cerebrovascular events in dementia trials  
CMAJ • NOV. 26, 2002; 167 (11): *“The burden of dementia is staggering — over 8% of the population over the age of 65 is affected — and behavioural disturbances that often accompany dementia (including physical aggression, hallucinations, wandering, yelling, throwing and vocalizations) are distressing for caregivers and patients alike. . . However, a recent analysis by the drug’s manufacturer of trials involving patients with dementia suggests that **the use of risperidone may be associated with increased rates of cerebrovascular adverse events, including stroke and transient ischemic attacks**, when compared with placebo.”* (emphasis added)

<sup>3</sup> The Effect of Risperidone on Nursing Burden Associated with Caring for Patients with Dementia, Frank et al, Journal of the American Geriatrics Society, JAGS 52:1449–1455, 2004

*“The quality of care for cognitively impaired residents in long-term care is a matter of great concern to families, staff, and policy makers. Staff burden is one key factor among the multiple factors identified that may affect care quality. . In this trial, risperidone treatment for residents with dementia reduced some of the burden nursing staff perceive in caring for such individuals. Any improvements that can positively affect nursing staff in their performance of their job are likely to ultimately improve the care individuals with dementia receive.”*

Risperidone (Risperdal) is an atypical antipsychotic, developed and licensed to treat schizophrenia and bipolar disorder, and tested in otherwise healthy persons (not including seniors with multiple medical diagnoses). It has been the subject of both FDA<sup>4</sup> and Health Canada<sup>5</sup> warnings about use of risperidone in elderly dementia patients. The most recent concerns involve the increased risk of strokes and related events.

Yes, some of these drugs did sedate Mom sufficiently so that the behaviours which were the symptoms of her distress weren't quite so inconvenient for others. They also caused increased confusion and anxiety, agitation, dysphagia, weakness, and coordination problems. She died, eventually, of yet another "cerebrovascular accident". I can't prove that her "treatment" hastened her death, but I know all too well that it damaged both our lives.

This story is relevant to Bill 31 on four counts.

The first has to do with "informed consent".<sup>6</sup> Not once in those dozen years did a doctor, pharmacist or nurse advise us of the possible benefits and risks of the prescribed drugs. That I had to learn by my own research in an attempt to explain the problems I saw. Not once was either Mom or I asked if we consented to this treatment. Even after I had forbidden the use of these drugs, or indeed of any medication I had not expressly approved, they remained on the care facility list of drugs prescribed for Mom, and were on occasion administered without my knowledge.

The second has to do with safety. None of the health care professionals or care staff involved with my mother's care were aware of the possible side-effects, and none recognized or reported the changes in her behaviour or health that resulted. Not once, even after I had identified the signs of problems to the care staff or health professionals, did they initiate an effective monitoring process for the documented possible side-effects. And, during several periods when I had directed that the drug be discontinued, the well-established and documented procedures for withdrawal of these dangerously addictive drugs were simply ignored. These drugs, and others, are typically used as restraints. There is no doubt that the use of restraints, whether physical or

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<sup>4</sup> <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a694015.html>

"Risperidone is not approved by the Food and Drug Administration (FDA) for the treatment of behavior problems in older adults with dementia." <http://www.fda.gov/cder>

<sup>5</sup> Canadian Adverse Drug Reaction Newsletter, Volume 11, Number 4 October 2001, Health Canada Therapeutic Products Directorate  
Health Canada Health Products and Food Branch; Updated Safety Information for Risperdal\* (Risperidone) in Elderly Dementia Patients, Announced in Canada October 17, 2002  
"Data were analyzed from four clinical studies in elderly, dementia patients. In two of these studies, a higher proportion of patients taking RISPERDAL experienced strokes or related events than did those who received placebo (sugar pill). **Patients or their caregivers should immediately report to their doctors any signs and symptoms of potential strokes such as sudden weakness or numbness in the face, arms or legs, and speech or vision problems. Patients or their caregivers should inform their doctors of their past and present medical history, including history of stroke or stroke-like events, and should also consult their doctor prior to making any changes in their medication.**" (emphasis added)

<sup>6</sup> Accountability in Health Care and Legal Approaches, Ries and Caulfield, Canadian Policy Research Networks, 2004; How do Current Common Law Principles Impede or Facilitate Change? Caulfield, University of Alberta, Discussion Paper for the Commission on the Future of Health Care in Canada, 2002; Ethical Choices in Long-Term Care: What Does Justice Require? World Health Organization, 2002; Out of the Shadows at Last, Transforming Mental Health, Mental Illness and Addiction Services in Canada; the Standing Senate Committee on Social Affairs, Science and Technology, 2006; The Texas Medication Algorithm Project, at <http://psychrights.org/Drugs/AllenJonesTMAPJanuary20.pdf>

chemical, is risky. The decreased use of physical restraints coincides with the increased use of chemical restraints, which – while less obvious and less visually distressing to the onlooker – can cause much more harm.

The third has to do with the “nursing burden”.<sup>7</sup> The emphasis for care has shifted, particularly with mental illness, to controlling specific behavioural manifestations. This can be a critical intervention, when there is a serious risk of imminent harm to self or others. But indeed, and especially with dementia in elderly persons, there are more effective and safer options. These options (appropriate physical facilities; adequate skilled nursing and personal care; attention to issues of self-respect and self-worth; suitable activities and human contact) are, apparently, seen as “too expensive”. I would argue that any such assessment ignores the real costs of the harm that is done to patients, their families, and the community.

The fourth has to do with choice. We value our right to make our own choices; theoretically, our Government is concerned that we have choices.<sup>8</sup> In the situation I described, there weren't any choices – other than suggestions that if I didn't like the care being provided, I could take Mom out of care. This “choice” culminated, a month before her death and just after a particularly devastating “little stroke”, in an ultimatum that either I agree to the administration of an antipsychotic or remove Mom from the facility, because they simply did not have enough staff (let alone qualified staff) to provide alternative care. (I refused; my son and I spent at least 40 hours a week caring for Mom, with very good effect for her – and disastrous consequences for my own health.)

There is a difference between psychiatric illnesses like schizophrenia and Alzheimers, dementia illnesses and stroke damage; someone who is mentally impaired or brain damaged and lives to grow old. We need to recognize these differences – and so do the medical professionals and health care workers – and respond appropriately to these differing needs for treatment and care.

As a society, we owe a duty of care to those who cannot care for themselves. While I believe this Bill was initially drafted to enable care for psychiatric illness, it doesn't provide the protections or the treatment options that recipients of this “care” should have. It's not good enough to rely on civil litigation, long after the damage has been done, for redress.<sup>9</sup> Perhaps we should take some time to understand and define that duty of care.

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<sup>7</sup> Potentially inappropriate prescriptions for older patients in long-term care

BMC Geriatrics 2004, 4:9 doi:10.1186/1471-2318-4-9. Rancourt et al. (Note: 2 of the 6 researchers were employed by Merck Frosst Canada at the time of the preparation of this article.)

*“Inappropriate medication use is a major healthcare issue for the elderly population. This study explored the prevalence of potentially inappropriate prescriptions (PIPs) in long-term care in metropolitan Quebec. Conclusions: Inappropriate prescribing is highly prevalent in the elderly long-term care population in metropolitan Quebec. The use of an explicit criteria list to identify PIPs is a first step towards identifying most critical issues and implementing strategies to improve quality of care and patient safety. Identifying predictors of PIPs may help to target problems and prioritize interventions that are most needed in the rapidly expanding older population.”*

<sup>8</sup> Caring and Responsibility, A Statement of Social Policy for Alberta 1988; A Framework for Reform, Report of the Premier's Advisory Council on Health 2001; the Broda reports; Building a better public health care system 2002; Alberta's Healthy Aging and Seniors Wellness Strategic Framework 2002 – 2012; Health Policy Framework 2006; Health Authority Accountability in Alberta's Health System, Alberta Health and Wellness 2006; et cetera.

<sup>9</sup> Muir v. The Queen in right of Alberta 132 D.L.R. (4th) 695 Court File No. 8903 20759 Edmonton Alberta Court of Queen's Bench Veit J. January 25, 1996  
Remarks of the Right Honorable Beverley McLachlin, P.C.; Medicine and the Law: the Challenges of Mental Illness, February 17 and 18, 2005  
[http://www.scc-csc.gc.ca/aboutcourt/judges/speeches/medecine\\_law\\_e.asp](http://www.scc-csc.gc.ca/aboutcourt/judges/speeches/medecine_law_e.asp)  
Competence and Human Reproduction, Institute of Law Research and Reform, Edmonton. 1989

The underlying problem is mainly the failure of “community support services”. The closure of the mental treatment facilities started nearly 50 years ago. The theory was fine: most folks with mental illness could be better cared for in the community, rather than in institutions. The problem is not with the theory, but the planning and implementation. There have never been enough resources, including professional and caregiver workforce training, research, or funding. Society, not the unfortunate individuals affected by mental illness, is responsible for the consequences of these failures. We need medical, legal, income security, housing, personal care, and social supports for persons who are mentally impaired, and for their families. A traumatic illness doesn't just affect one person; the family is devastated as well. We've been shifting far too much responsibility to the individual and their families and friends without providing them with the resources to cope.

We do have one example of a project which attempts to improve community care for seniors, in the CHOICE<sup>10</sup> programs Capital Health has initiated. That is considered to be quite successful, in making coordinated professional care, home care services, income subsidies, and social supports available to individuals – but it is very limited. That may be a model that can be adapted to minimize the need for “last resort” measures like those proposed in Bill 31.

When the State, or an agency or person with delegated authority, assumes the right to force treatment on its citizens, it has an obligation to ensure that this treatment is a last resort; it is the least risky of all the options; the social benefit far outweighs potential individual harm; the individual is afforded every possible protection and recourse to representation. Our history includes embarrassing examples of situations where these precautions were not in place.<sup>11</sup>

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<http://www.law.ualberta.ca/alri/docs/fr52.pdf>

Suits allege Lilly, Janssen kept risks of drugs quiet by [James Goodwin](#)

“*St. Louis Business Journal* - October 27, 2006

*Dozens of people are suing [Eli Lilly and Co.](#) and [Janssen LP](#) in St. Louis Circuit Court, saying anti-psychotic drugs the companies make carry risks that were previously unreported.*

*The suits allege that Indianapolis-based Lilly and Titusville, N.J.-based Janssen knew of but failed to warn patients of possible links to hyperglycemia and diabetes. . . .*

<http://www.elwx.com/risperdal-class-action-lawsuit.html>

*“Johnson and Johnson is the maker of Risperdal, a drug linked to hyperglycemia, a prelude to Ketoacidosis, coma and death. Not to mention anemia, diabetes and stroke, and sometimes Bipolar episodes. This drug was originally approved by FDA as a treatment for schizophrenia, acute mania and dementia, attention deficit disorder or behavioral disorders in the elderly. But it managed to reach the innards of children with anxiety, depression and even autism. Other serious effects associated with Risperdal include neuroleptic malignant syndrome, pancreatitis, gynecomastia or growing breasts in male and female children and adults, dizziness, rapid heart beat, fainting, seizures, problems swallowing, painful penile erection, vision problems, suicidal thoughts and uncontrollable movements. For every drug there are lawyers forming Risperdal class action lawsuits for redress in this new business of drugs which are more ready to provide patients with more harm, if not more deadly illnesses than they already suffer. If you are among such sufferers there are myriad of attorneys to be found on the internet.”*

<sup>10</sup> **CHOICE** (Comprehensive Home Option for Integrated Care of the Elderly) is a coordinated care program for older people living at home. Full range of medical, social and supportive services including: a day centre, medical monitoring and treatment, medication dispensing, rehabilitation, transportation, 24 hour phone number, in home personal care assistance.

<sup>11</sup> The Residential Schools; the sterilization of “mental defectives” in Alberta; the Canadian military and Defence Research Board sponsored LSD tests at McGill University and studies of even more powerful hallucinogens in secret experiments in rural Alberta (1960s)

See *Hidden from History: The Canadian Holocaust* by (Rev.) Kevin Annett; references to the 1946 Project Paperclip, the 1928 Sexual Sterilization Act in Alberta.

<http://canadiangenocide.nativeweb.org/intro2.html>

I would rather not see this piece of legislation go down in history like the 1928 Sexual Sterilization Act and the 1937 and 1942 amendments, which included persons with neurosyphilis, epilepsies with psychosis, mental deterioration, and Huntington's disease. That legislation was proposed to reduce the growing burden of taxpayers in caring for mentally disabled persons, and for the benefit of society. It did not require the consent of the person or that person's family, it did not consider the harm it would cause, it did not allow for any appeal. It had a particular impact on women and Aboriginal citizens. It took a change of government in 1972 to get the Act repealed. We don't need to repeat the experiment.

It is distressing that this removal of citizen rights with government-mandated treatments and confinement is not accompanied by any plan for adequate follow-up and reassessment of the consequences. There have been major shifts in the government's "interpretation" of our shared responsibility to fund and provide health care supports for affected individuals and families, particularly in the area of seniors' care and mental health, in the last quarter century. There has never been a competent assessment of the effectiveness of the new regime. In particular, assessments of the quality of clinical care, and the fate of folks and their families who have fallen through the cracks, have not even been considered. The failure of responsibility regarding hospital-acquired infection in our hospitals reached critical proportions before getting attention; we should learn from that, as well.

I would hope that the Committee would research and consider the provisions and the experience with similar legislation in other jurisdictions – particularly whether the health outcomes of the treatments ordered are successful, and the response of those concerned with civil and legal rights.

Once again, although I appreciate that the Committee has invited public presentations and posted submissions with respect to this Bill, it's too little too late for any meaningful public discussion and for an exploration of the alternatives to resolve an important problem. These amendments present significant ethical implications<sup>12</sup>, which need to be thoroughly considered and decided by an informed public. Reliance on "stakeholder" input has once again failed to represent many of the interests and concerns of the public.<sup>13</sup>

Thank you for your consideration.

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<sup>12</sup> Review of Bill 31, the Provincial Health Ethics Network, September 2007: notes that their review did not allow for participants in different discussions to have the benefits of reflecting on each other's comments. The Committee has not made the comments of PHEN, or other consultants, available to the public on the website related to consideration of Bill 31

<sup>13</sup> My submission to the Standing Committee on Government Services, Bill 1, the Lobbyists Act, September 28, 2007 discussed problems with the current public consultation process, despite the minor improvements in process recently introduced.