Mood Disorders Society of Canada
La Société Pour **Les Troubles de L'Humeur** du Canada

Medications and Mental Illness

Brief presented to: the Standing Committee on Health - study of Prescription Drugs (Common Drug Review)

By: Phil Upshall, National Executive Director, MDSC

The Mood Disorders Society of Canada calls for:

- ***meaningful consumer and family involvement in the drug approval process. This involvement is essential to the goal of transparency.***

- ***appropriate and necessary access to medications for all Canadians suffering from a mental illness. Choice is essential to recovery. Limiting choice limits access and only adds to the stigma of mental illness.***

The Mood Disorders Society of Canada believes that "cost savings," as envisaged by the CDR, may not in fact be "cost savings" for the Canadian health care system or for the economy of Canada and is definitely not a cost saving for consumers And their families and caregivers.

The Mood Disorders Society of Canada urges the Standing Committee on Health to recommend a "streamlining" of the drug approval process in Canada that will eliminate delays in making new medications available to consumers and patients.

Summary of recommendations

Recommendation 1

Health Canada must give the same priority to the approval of medications for mental illnesses as it gives to medications for physical illnesses.

Recommendation 2

If Health Canada is truly patient-centred and dedicated to promoting "the effective use of the public health care system,"[1] then it must appoint consumers and family members to the appropriate drug approval boards so that their knowledge is taken into account right from the outset.

Recommendation 3

There must be an increased profile for consumers and family members specifically in the Canadian Expert Drug Advisory Committee (CEDAC) review and decision-making processes, including 2 additional committee memberships reserved for mental health consumer and family representatives.

Recommendation 4

Access is extremely important to the disability community – including those with a disabling mental illness. Reference based pricing and therapeutic substitution neither improves access nor saves money – a prominent goal of the National Drug Strategy. The human and economic costs of people being forced to take improper, inadequate or ineffective medications are too high.

Recommendation 5

Access issues include "timely access" and the drug approval process is far too long in Canada and requires streamlining and elimination of duplicate approval processes.

The impact of mental illnesses in Canada

[1] Health Canada's mission statement. Available at: http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index_e.html#mission

In May 2006, the Senate Standing Committee on Social Affairs, Science and Technology (Kirby/Keon Committee) published its historic report, *Out of the Shadows at Last,*[2] following the most extensive investigation into the impact of mental illness ever conducted in Canada. The report made it clear that one of the most substantial barriers to obtaining quality care for mental illness is stigma. Canadians state that the stigma associated with mental illness is harder to bear than the illness itself. Stigma is all-encompassing, affecting the ability to obtain work, maintain housing, keep relationships and access health care. In a national conference on stigma, hosted in October 2006 by the Mood Disorders Society of Canada, delegates identified the stigmatizing attitudes held by health care professionals towards people with mental illness and their families as their number one priority for change.

Among the many effects of stigma is the lack of awareness among Canadians of the impact of mental illness, despite the fact that one in five will experience a mental illness in their lifetime. Lack of awareness leads to lack of attention – on the part of political leaders, policy makers, media and other influential decision-makers.

The basic facts [3]

- Mental disorders contribute more to the global burden of disease than all cancers combined.
- Depression is the leading cause of years lived with disability in the world.
- Five of the 10 leading causes of disability worldwide are mental or nervous disorders.
- Suicide is the most common cause of violent death in the world.
- Canadians are the highest per capita users of psychiatric medications in the world.
- Canadians are the second highest users of sedatives and the fourth highest users of prescription narcotics in the world.
- Rate at which the costs for anti-depressant medication have risen in Canada:
    - 1981 ($31.4 million)
    - 2000 ($543.4 million)
    - estimated costs for 2005 ($1.2 billion)

Medication and mental illness

Recovery from mental illness is multi-faceted and involves treatments and activities that go well beyond medical care and medications. These components of recovery are typically referred to as the determinants of

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[2] Kirby, M. & Keon, W. (2006). Out of the Shadows at Last: Report by the Standing Senate Committee of Social Affairs, Science and Technology. Available at: http://www.parl.gc.ca/39/1/parlbus/commbus/senate/com-e/soci-e/rep-e/rep02may06-e.htm

[3] Quick facts: Mental illness and addiction in Canada. The Mood Disorders Society of Canada. Available at: www.mooddisorderscanada.ca

health and include housing, employment and education opportunities, freedom from violence, social inclusion and community participation.

However, the capacity for people with mental illness to live full lives depends on quality medical care, including accurate and timely diagnosis, access to helpful treatments and the right medication – at the right level - to control symptoms.

Despite its impact, mental illness is not accorded the same level of health resources that physical illnesses are. Across Canada, access to mental health care is limited with many people waiting sometimes years to see a psychiatrist. [4] Others are unable to find a family doctor. In this atmosphere of neglect, and in the shadow of the all encompassing stigma of mental illness, people can be mis-diagnosed, improperly medicated, and left without recourse as their illness gets worse and worse – despite the fact that research [5]has shown that people who are able to obtain timely, high quality, mental health care can recover – findings that are consistent with consumers' experience.[6]

Medication is a cornerstone of mental health care and consumers and patients must have access to the latest pharmacological discoveries including what some "experts" dismissively call "me too" drugs. While it is an acknowledged travesty to deny cancer patients newer and more effective drugs, people with mental illness may easily find themselves prescribed older or inappropriate anti-psychotics or anti-depressants for a number of reasons:

1. Their practitioner is not well trained in prescribing practices for mental illnesses,
2. The medication they need is only covered for in- or out-patients of hospitals,
3. Many people with mental illness depend on social assistance and the medication that works best for them may not be listed on provincial or territorial formularies,
4. They are not informed of the various choices available, the relative benefits of each choice and the expected side effects,

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[4] Mood Disorders Association of British Columbia – interview regarding wait times for mental health services.

[5] Recovery literature is extensive. As one example only: Harrison, G. et al (2001). Recovery from psychotic illness: A 15- and 25-year international follow-up study. British Journal of Psychiatry, Vol 178, p. 506-517. Abstract available at: http://bjp.rcpsych.org/cgi/content/abstract/178/6/506

[6] See www.copelandcentre.com and www.mentalhealthrecovery.com for full information on recovery strategies.

5. Access to their practitioner is limited so that they are unable discuss problems with their medication and obtain another type or a different dosage level,
6. Consumers and families also report that health care providers discount their views and ignore their stated medication preferences.

The right medication at the right dosage level is as important to the wellbeing, recovery and effective functioning and contribution to society of people with mental illness as insulin is for diabetics.

While it is abundantly clear that tragedy will result if people with diabetes are inadequately or inappropriately medicated, the consequences of neglecting or ignoring the medication needs of people with mental illness are of little interest – but they are just as dire. Furthermore, if the issue is considered through the "disability lens" as recommended by the Kirby/Keon Committee, access to appropriate medications becomes a matter of civil rights of access to necessary supports. When dealing with physical disabilities "access" issues refer to wheelchair ramps, Braille elevator buttons, enlarged doorways, etc. In the context of disabling mental illnesses "access" refers to appropriate medications that facilitate illness management and recovery as well as access to health care professionals, access to hospital services, and access to special aids in the work place such as "flex hours", etc.

People with mental illness who do not have access to, or who are not prescribed the right medication, experience frequent relapses that interrupt lives and productivity. Estimating the high personal cost is impossible, however it is very high.They may spiral into chronicity and hopelessness. Some become involved with the law. Others become homeless. Many die by suicide --- the only real health care epidemic confronting Canada today.

***Recommendation 1*: Health Canada must give the same priority and attention to the approval of medications for mental illness as it gives to medications for other chronic illnesses.**

Empowerment and choice

Over the past decade, consumers and families have taken a much more prominent role in their own health care. They have also obtained places at federal, provincial and territorial decision-making tables where they are shaping the way that mental health care is delivered in Canada. They have pressured media to report on mental illness in a more balanced and less stigmatizing manner.

On a system-wide basis, the positive results of their advocacy are beginning to materialize. What is also clear is that empowerment, in and of itself, is good for mental health.

An aspect of empowerment is choice and, in the context of this brief, choice means the ability of consumers to choose a medication that works for them and to have their views and preferences respected by health care providers, government decision-makers and pharmaceutical companies. This choice must include what some "experts" call "me too" drugs as these drugs often provide the right combination of a reduction of the symptoms of a mental illness together with the mildest side effects.

Choice leads to:

Greater compliance – People who participate in their own medication decisions are more likely to take their medications as prescribed and enjoy the benefits. They must also be actively encouraged to report problems and assured that changes can and will be made if they experience discomfort of lack of relief of symptoms or if they find a particular type or dosage level to be ineffective. Meaningful participation of course implies that alternative medications are available.

Professional oversight when discontinuing medication - People with mental illness do not necessarily require medication for the rest of their lives. Some are able to stop taking medications once their illness has stabilized. If they and their health care provider are working in partnership, the medication can be gradually reduced and their reactions monitored. If their health care provider is unable or unresponsive to their desire to reduce, stop or change medication, consumers take matters into their own hands and risk relapse through rebound effects (a return of symptoms due to suddenly stopping medication).

Cost savings – The sheer amount of psychotropic medication prescribed and then left to age in medicine cabinets because it is ineffective or people cannot tolerate the side effects represents staggering costs to the public health care system. Consumers who participate in the choice of medication are much more likely to use what is prescribed.[7]

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[7] Meuser, K. et al (2004). Illness management and recovery: A review of the research. American Psychiatric Association. Vol 2, p. 34-47. Abstract available at: http://www.focus.psychiatryonline.org/cgi/content/abstract/2/1/34

Medication approval in Canada

"It is difficult, perhaps impossible, to evaluate the integrity of a process when you can't get basic information about it." [8]

The complexity of Canada's drug approval system means that only bureaucrats and industry insiders have an understanding of exactly what goes on.[9] Critics argue that the lack of public scrutiny leads to perceptions of undue pharmaceutical company control of the approval process and of course with the previously discussed stigma of health care professionals, it is of concern that the CEDAC panel, composed primarily of physicians may, as they search for "cost savings" give less than the appropriate attention to the needs of consumers and patients living with or suffering from a mental illness

Even more alarming is the disregard for public safety leading to physicians prescribing medications without knowing about recent findings on risks or contra-indications. For example, the finding that the use of Selective Serotonin Reuptake Inhibitors (SSRIs) for people under the age of 19 showed evidence of harm went unreported by manufacturers or Health Canada, resulting in thousands of Canadian teenagers and children being prescribed SSRIs.[10]
Responsible pharmaceutical companies support the need for full and transparent disclosure of information to the public - but there are concerns with the present situation:

- Ninety percent of drug trials are designed and funded by the same pharmaceutical companies that intend to market them. Canadian research funders such as CIHR must support more research and independent drug trials. Research and clinical trials should not be left solely to be undertaken by pharmaceutical companies. Many mental illnesses do not attract research by the private sector because the

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[8] Silversides, A. (2005). Transparency and the drug approval process at Health Canada. Available at: http://www.whp-apsf.ca/pdf/transparency.pdf
[9] For an accessible step-by-step explanation of the drug review process in Canada, see the Canadian Pharmacists Association pamphlet available at: http://www.pharmacists.ca/content/hcp/resource_centre/drug_therapeutic_info/pdf/DrugApprovalProcess.pdf
[10] Silversides, A. (2006). Women and health protection policy brief. Available at: http://www.whp-apsf.ca/en/documents/trans_policy.html

incidence of the illness is not sufficiently large to warrant private sector attention.

- There is an increase in off-label prescribing, meaning that physicians prescribe drugs for uses other than approved by Health Canada.
- If a pharmaceutical company applied – and was refused – permission to market their drug for a new use, this fact is not made public. [11]

<u>Recommendation 2:</u> If Health Canada is truly patient-centred and dedicated to promoting "the effective use of the public health care system," [12] then it must appoint consumers and family members to the appropriate drug approval boards so that their experiential expertise and knowledge is taken into account right from the outset.

Canadian drug approval bodies

In response to criticisms centred on lack of transparency, Health Canada has moved to reform its drug approval process, setting up a number of bodies that are designed to have more independence and less secrecy.

Some terms:

It is helpful to understand who the players are in the Canadian drug review process.

The Canadian Agency of Drugs and Technologies in Health (CADTH): CADTH, formerly called the Canadian Coordinating Office for Health Technologies Assessment, is "an independent, not-for-profit agency funded by Canadian federal, provincial, and territorial governments to provide credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies to Canadian health care decision makers." [13]

CADTH programs:

The Health Technology Assessment (HTA): HTA provides "high-quality information about the clinical effectiveness, cost-effectiveness, and broader impact of drugs, medical technologies, and health

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[11] ibid

[12] Health Canada's mission statement.
Available at: http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index_e.html#mission

[13] Source: www.cadth.ca

systems." This group looks as broader health questions such as how will a product affect the health of Canadians, is it cost-effective, are there alternatives that do a better job, and are there other health services implications to take into account?

The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS): COMPUS is a program of CADTH and it "identifies evidence-based best practices in drug prescribing and use. Strategies, tools, and services are provided to encourage best practices among health care providers and consumers." The stated manadate of COMPUS it to influence prescribing practices in Canada so that people receive the most effective medication and achieve the most positive health outcome – at the best price.[14]

The Common Drug Review (CDR): Established in 2003, CDR was intended to replace the individual provincial, territorial and federal drug review bodies charged with the responsibility of evaluating drugs for potential listing on their respective public formularies (after approval by Health Canada). CDR was designed to speed up the drug review process and recommendations to formularies but critics claim that this goal has not been met. In fact, the drug review process has slowed, become less transparent, and recommendations are far too infrequent. Furthermore, after recommendation still more "red tape" must be completed before provincial drug programs agree to list the recommended product and many provinces even after the CDR recommendation do not list the product at all. This must change!!!

The Canadian Expert Drug Advisory Committee (CEDAC): CEDAC is part of the Common Drug Review and is responsible for providing scientific evidence and advice to provincial, federal and territorial formularies. Its advice can affect what drugs are, or are not listed. Its members are appointed by the CADTH Board of Directors. CEDAC has 13 members, two of whom are appointed as representatives of the "general public."

CEDAC's definition of "expert" favours physicians, pharmacists and researchers although in a truly "patient centred" system patients, consumers and their experiential expertise would be highly sought after and given great weight in the decision to recommend or not. Presently, none of the committee members' biographies identify experience with prescribing psychotropic medication or research in this area of practice. This is quite inappropriate, given both the numbers of anti-psychotic and anti-

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[14] ibid

depressants listed on provincial and territorial formularies and the high incidence and cost to the health care system and to the Canadian economy of mental illnesses.

Consumers and patients are the end users and beneficiaries of the many drugs that CEDAC must review and their views are invaluable because they provide "real world" expertise and experience on the positive results of effective medication - and the harm that can result from ineffective products or delayed access to new discoveries. The lack of attention to mental health consumers and their concerns, notwithstanding their desire for engagement in this important aspect of the health care system, reflects attitudes of stigma within Health Canada and the medical professions. Combined with the delays in approvals for new medications, this inattention has a dramatic and costly impact on consumers, their families and Canadian Society.

Research into issues surrounding mental illness is sadly under-funded even in light of the efforts of the CIHR Institute of Neurosciences, Mental Health and Addictions. Pharmaceutical companies make an important contribution to the overall knowledge base. They must continue their work as it is vital for our community. If they are impeded, the economic and human consequences would be far greater than any real or imagined cost savings supposedly to be achieved by the CDR.

***Recommendation 3*: There must be an increased profile for consumers and family members specifically in the Canadian Expert Drug Advisory Committee (CEDAC) review and decision-making processes, including 2 additional committee memberships reserved for mental health consumer and family representatives.**

Cost containment strategies

Drug costs are identified as a primary driver of health care expenditures in Canada. The last several decades have seen unprecedented growth, setting new spending records. Canadians are being prescribed more drugs than ever, and more expensive drugs.[15] Companies that handle drug card transactions for Canadians with employee health benefits report that 21% of these costs are attributable to psychotic and non-psychotic psychotropic medication, second only to cardiovascular drugs at 23%. The average annual cardholder cost was $653.28, with a recorded 8 – 10% increase year- over-year since 2000. [16]

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[15] Morgan, S. (2005). Canadian prescription drugs costs surpass $18 billion. Canadian Medical Association Journal, 172(10). Available at: http://www.cmaj.ca/cgi/content/full/172/10/1323

[16] Emergis (2005). The current prescription drug landscape. Presentation to industry.

Alarmed by these cost increases, governments have proposed two strategies to achieve containment.

> **Referenced-based pricing**: Similar drugs are grouped into one category and people are reimbursed only at the level of the least expensive drug in this group.
>
> **Therapeutic substitution:** A drug judged to be therapeutically equivalent can be substituted for a more expensive one. If people want the more expensive drug, they are required to pay the difference between it and the therapeutic substitute. [17]

The mental health community has several concerns with both reference-based pricing and therapeutic substitution:

1. How drugs are assigned to categories for the purposes of reference-based pricing can be inconsistent, depending on the classification system used. [18]
2. Drugs listed as therapeutically equivalent may not be experienced that way by consumers – with disastrous results. As a simple example, consumers react differently to Aspirin, Tylenol and Advil – yet they could be judged to be therapeutically equivalent. [19]
3. Many people with mental illness live on fixed incomes and cannot afford to pay the difference between a drug that works for them – and the least expensive in its category or its therapeutic equivalent.
4. Drugs that work for consumers and patients not only facilitate speedier recovery, they keep us out of hospital. Limiting access through reference based pricing and therapeutic substitution is, we believe, a costly mistake for the healthcare system and an even costlier one for the patient whose recovery is impeded. Allowing doctors and scientists to determine "therapeutic equivalents" without input from consumers and patients, is discriminatory.

Canadians with mental illness have often struggled for years to find the right medication at the right dosage level so that they can live productive

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[17] Source: Best Medicines Coalition, National Pharmaceuticals Strategy: Issues paper. March 2006. Available at: www.bestmedicines.org

[18] The classification system may be obtained from Medispan which is a North American industry standard. Alternatively, there is the Hospital Formulary System (HFS) which is the government classification standard. These two are not equivalent.

[19] Example from presentation by Lembi Buchanan in response to Ontario's Bill 102. Consultations, July 25th 2006.

lives. The risk of changing medications to conform with cost-containment strategies is costly in both human and economic terms. Relapses can be devastating to consumers, their friends and families. They can be accompanied by loss of work or, in the most severe cases, involvement with the law. They are certain to be associated with hospitalizations – the most costly of all mental health interventions.

Further, both these cost containment strategies interfere with consumers' hard won empowerment. They will also reduce the benefits (health-wise and cost-wise) associated with choice and a full partnership with health providers.

Recovery

The Mood Disorders Society of Canada is in agreement with the need to spend taxpayers' dollars efficiently in the provision pharmaceuticals to the citizens of this country. *Where we differ is on strategy.*

For centuries, people with mental illness were considered incurable and the only government solution was to lock them away in locations where it was assumed they would be protected from society and society would be protected from them.

Today, we know that people can and do recover from mental illness. However, they could recover in greater numbers if they had access to effective treatment – one major component of which is the right medication at the right dosage level.

The costs of ignoring the potential for recovery

Governments need to examine the cost of limiting access to effective medications.

What mental illness costs the Canadian health care system. [20]

- Of all hospitalizations in Canada, 33% are due to mental illness as either a primary or secondary diagnosis.

[20] Quick facts: Mental illness and addiction in Canada. The Mood Disorders Society of Canada. Available at: www.mooddisorderscanada.ca

- People with mental illnesses spend twice as long in hospital relative to other diagnoses.
- The cost of supporting someone with serious mental illness to live in the community is $34,418 per year (*all costs*)
- The cost of keeping someone with serious mental illness in the hospital is $170,820 per year.

What mental illness costs the Canadian workplace [21]

- The unemployment rate among people with serious mental illness is 70 – 90%, constituting a huge social cost.
- Annual losses to the Canadian economy due to mental illness in the workplace are $33 billion.
- Of all short term disability claims related to mental illness in Canada, 75% are related to mental illness.
- Of all long term disability claims related to mental illness in Canada, 79% are related to mental illness.
- The fastest growing category of disability costs to Canadian employers is depression.
- Ninety percent of people who are depressed *never* access treatment, however, research finds that 80% of depressed people who seek treatment respond well.
- For those who get treatment, employers will save, per employee per year, from $5000 - $10,000 in average wage replacement, sick leave and prescription drug costs.

What mental illness and homelessness costs the Canadian health care system

- From 30 – 35% of people who are homeless also have serious mental illness. of homeless women, 75% have serious mental illness. [22]
- Homeless people, on average cost $4,714.00 year per person in health costs while the average Canadian costs $2,633.00. [23]

What mental illness costs in policing and incarceration

- There has been a 100% increase in mental illness among offenders in the last decade.
- There has been 100% increase in police time spent responding to calls about the mentally ill in London Ontario.[24] In 2001, it cost up to 2.4 million to respond to calls from 835 individuals with serious mental illness.[25]

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[21] ibid

[22] CMHA, Ontario Fact sheet: Homelessness and mental illness. Available at: http://www.ontario.cmha.ca/content/reading_room/factsheets.asp?cID=3975

[23] No way home: The cost of homelessness. Fifth Estate. Broadcast in 2004. Available at: http://www.cbc.ca/fifth/main_nowayhome_cost.html

[24] Trends in police contact with people with serious mental illness in London Ontario. Available at: http://www.lhrionhealth.ca/PDF/press_releases/news_10_02_02.pdf

[25] Source: Annual report 2004 – 2005 of the Correctional Investigator of Canada. Available at: http://www.oci-bec.gc.ca/reports/AR200405_e.asp#1

- It costs $240.18 daily (or $87,665 per year) to keep an offender in federal prison. It costs $141.75 per day (or $51,738 per year) in provincial facilities. [26]

***Recommendation 4**: Access is extremely important to the disability community – including those with a disabling mental illness. Reference based pricing and therapeutic substitution do not improve access and do not save money – a prominent goal of the National Drug Strategy. The human and economic costs of people being forced to take improper, inadequate or ineffective medications are too high. We urge this Committee to recommend streamlining of the drug approval process to make it more transparent, more timely and more patient-centred, particularly for patients and consumers with mental illnesses whose issues have been so frequently ignored by the process due to stigma and discrimination.*

Conclusion

The Mood Disorders Society of Canada calls for meaningful consumer and family involvement in the drug approval process. This involvement is essential to the goal of transparency.

The Mood Disorders Society also calls for appropriate and necessary access to medications for all Canadians suffering from a mental illness. Choice is essential to recovery.

The Mood Disorders Society suggests that "cost savings," as envisaged by the CDR, may not in fact be *"cost savings"* for the Canadian health care system or for the economy of Canada and certainly won't be a "cost saving" to consumers in economic or psychological terms

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[26] Statistics Canada (2005). Adult correctional services. Available at: http://www.statcan.ca/Daily/English/051216/d051216b.htm

About the Mood Disorders Society of Canada

The Mood Disorders Society of Canada is one of the leading national, voluntary health organizations in the fields of depression, bipolar illness, and associated mood disorders. MDSC's website - www.mooddisorderscanada.ca is one of the most visited mental health websites in Canada for information about mental illnesses.

The Mood Disorders Society of Canada is a member of the Canadian Alliance on Mental Illness and Mental Health (CAMIMH), the Global Alliance of Mental Illness Advocacy Networks (GAMIAN), and other national and international mental health bodies.

The Mood Disorders Society of Canada publishes materials for consumers and patients living with depression, bipolar illness, and related mood disorders. The publication "Quick Facts: Mental Illnesses and Addiction in Canada" is one of the most widely distributed publicly available data sources on mental illnesses (over 100,000 copies distributed by print and electronically).

Phil Upshall, the National Executive Director of the Mood Disorders Society of Canada, is the former National Executive Director of Canadian Alliance on Mental Illness and Mental Health, CAMIMH; a past member of the Institute Advisory Board for the Institute of Neuroscience, Mental Health and Addiction (CIHR), a member of the Advisory and Editorial Boards for the Health Canada publication "The Human Face of Mental Illness in Canada 2006", a member of the Expert Advisory Group for the Canadian Population Health Initiative's current undertaking involving "mental illness in vulnerable communities"; and is an adjunct professor in the department of Medicine, Dalhousie University.

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