CANADIAN TREATMENT ACTION COUNCIL

Common Drug Review: Slow – or slower?

by Louise Binder

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IN THE FALL OF 2002, the federal Minister of Health and her provincial counterparts (other than Quebec) signed an agreement to develop and implement a common drug review process for recommendations for provincial formulary coverage.

The federal Canadian Coordinating Office for Health Technology Assessment (CCOHTA) was selected as the agency to manage this process.

Since then, CCOHTA has set up a Common Drug Review department (CDR) and has developed its structure, policies and processes. It is set to go into force in September 2003.

The theory of one recommendation-making authority for formulary coverage is a good one, based on aims of making the process faster, more effective and efficient and more equitable across the country.

The problem is that the Common Drug Review department of CCOHTA as described does not appear to achieve any of these aims. In fact, it may well add substantial delays to the formulary approval process and can be overridden at the provincial level, so it may not create equity, either. There is also no true consumer involvement so the lived experience of people's needs will not be taken into account.

Let me explain. The process, as described to consumers in a briefing by CDR, is as follows: first of all, CDR will do its own drug review which may take up to six months, at best. Secondly, it will send its decision to each of the provinces involved as a recommendation. Thirdly, the province decides whether or not to accept the recommendation. It should be noted that none of the provinces have agreed to disband its present review apparatus. Thus, we have a new tier added to the review process that really just adds six months to the present process, possibly to no purpose. If CDR says add it to the formulary, the province may agree or it may not. So what is the value added of this CDR review?

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Common Drug Review: slow or slower?

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In addition, CDR plans to rely only on the information provided by the drug company submitting the application to decide whether this drug has an important place in drug treatment and whether its cost to the province justifies putting it on the formulary. We have seen in the past that these submissions do not always tell the entire story about the value of a drug to the consumer. A case in point is ddI EC. Ontario turned it down for formulary coverage because it was approximately $3.00 more per pill than the original formulation. Consumers and doctors had to explain that real life experience proved that there was an additional cost to the original formulation i.e. the cost of drugs to deal with its side effects. As well, lack of ability to adhere also cost the system because we had to stop taking the drug and move to something more expensive that we could tolerate. Only then did the government put this drug on its formulary. Without a consumer advisory panel or some other effective consumer involvement process, CDR will lack real life experience about the cost of drugs to the system and the importance of new drugs that may appear on the face of the application to be the same as other drugs already available.

CDR may well be a sound concept for a more efficient, effective, well informed and equitable approach to formulary coverage decision-making. Unfortunately, as proposed, it does not appear to meet that challenge. As a result, we will lose by potentially having an even longer wait for drugs we desperately need. We cannot allow that to happen.

You can make a difference. Write to CDR to let them know you are not satisfied with the system as proposed; go to the CTAC website to review the joint letter to which it signed on and tell CDR you endorse it; join the CTAC drug review committee to work on this issue. This is a crucial issue for all of us. ■

International AIDS Society Conference Treatment Update

by Louise Binder

Paris, 2003

The 2nd International AIDS Society Conference was held in Paris in July 2003. Reports included new drug development for both treatment-naïve and treatment-experienced people, opportunistic infections, and co-infection with HIV/Hepatitis C. This report will cover a few of the highlights.

New drugs for treatment-experienced people

On the drug development front, there was 48-week data on the drug enfuvirtide (T-20), one of the new class of fusion inhibitor drugs in heavily treatment experienced people. The drug continues to hold up well, both in terms of virologic suppression and immunologic response. More people who had sensitivity to two or more other drugs in their background regimen did well; but even some people, who only had sensitivity to one drug or none, did well on both counts.

This drug is administered by subcutaneous injection. The most often reported side effect was injection site tenderness in 50% of people, with 20% of people reporting moderate pain. 1-2% reported severe pain requiring an analgesic.

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International AIDS Society Conference Treatment Update

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Another adverse event reported was a higher incidence of bacterial pneumonia of 6.6% for those on enfuvirtide versus 0.6% on an optimized background regimen only. For people with CD4s below 200, the incidence was 9-10%.

The company reported that it will have more drug available for its expanded access programme in 2004, with 18,000 spots versus 15,000 in 2003. It is yet to be known whether this will mean more spots for Canada but CTAC will be following up with the company about this.

T-1249, the second generation drug in this new class, will be in Phase II trials shortly. It appears to be sensitive to enfuvirtide resistant virus, which is very exciting. Time will tell about its long-term safety and efficacy profile.

Another interesting new drug for both naïve and treatment-experienced people is atazanavir, a protease inhibitor. It does not appear to increase lipids (fats) in the blood including triglyceride and cholesterol associated with lipodystrophy and heart problems.

In a 24-week treatment-experienced trial comparing atazanavir boosted with 100 mg of ritonavir or taken with saquinavir to Kaletra and added to an optimal background drug regimen, the atazanavir/ritonavir arm was equally potent to Kaletra but trigylicerides remained the same while increasing 31% in the Kaletra arm. Total cholesterol went down in both atazanavir arms but went up 3% in the Kaletra arm. Only 7% of the study participants on atazanavir/ritonavir were on lipid lowering agents versus 15% on the Kaletra arm.

Co-infection HIV/Hepatitis C

On the co-infection front, a small pilot study showed that co-infected people may well respond more slowly to Hepatitis C therapy than mono-infected people. Thus, the rule that Hepatitis C therapy should cause a one log drop in viral load at 12 weeks may be inappropriate to determine end-of-therapy response. Rather, one should look at the slope of the viral load decline in co-infected people to determine whether they should remain on therapy.

Another study showed that overall sustained treatment response rates with pegylated interferon plus ribavirin are lower in co-infected people than in mono-infected. Genotype 2 and 3 generally have a favourable response rate. As well, an early response generally predicts end-of-treatment response in the former as well as in the latter group.

In brief

Studies generally suggest caution in choosing a three nucleoside regimen as a first line therapy, especially abacavir/3TC/tenofovir which has a poor viral suppression rate.

The non-nucleoside efavirenz induces central nervous system side effects which generally seem to resolve for many people over time. However, people with a history of psychiatric disorders are at greater risk of these side effects, especially severe depression, aggressive behaviour, suicidal ideation and paranoid or manic reactions.

The protease inhibitor Kaletra (lopinavir/ritonavir) still does not appear to have resistance mutations after 96 weeks and remains safe, durable and potent. ■

Congratulations!

CTAC is delighted to announce that Dr. Mark Wainberg is the recipient of the Research Category of the Prix Galien Award 2003! Dr. Wainberg's tireless work in the area of HIV research has benefited the lives of many Canadians living with HIV, and CTAC is pleased to see that Dr. Wainberg's achievements have been recognized with such a prestigious award. Congratulations, Dr. Wainberg!

Remembering the activists' activist

by Ron Rosenes and Louise Binder

One of the few disappointments of Glen Hillson's life was not being able to pick up his Canadian AIDS Society (CAS) Leadership Award in person. We all knew he would have used the occasion as an outlet for the kind of sardonic hilarity that distinguished his column "The Last Blast" in the British Columbia Persons with AIDS Society (BCPWA) magazine *Living +*.

With the death of Glen Hillson, the AIDS community has lost a truly great leader. It is very difficult to summarize a life in a few words, but Glen Hillson fought every day for the rights, respect and dignity of people who are among the most marginalized in our society. Comfortable in rooms full of researchers, politicians, bureaucrats and people from the pharmaceutical industry, Glen never hesitated to speak out forcefully for the rights of people with HIV and other disabilities. As Chair of the BCPWA Society, he successfully fought for higher government payments for people with disabilities to cover their unique needs for nutritious food and vitamins. As Vice Chair of CTAC, he was equally successful in leading the effort that saw the federal government put 190 million new dollars into improving the drug review process and ensuring timely access to life-saving medications for all Canadians. It may have been Glen's gift to see the larger picture, but that never prevented him from putting in thousands of thankless hours behind the scenes to strategize, scrutinize, organize, and jolly his friends and colleagues through the tough times. But as tough as Glen was on his political opponents, he was a mother lion when it came to protecting his cubs – his friends, his family and the vulnerable. Those who were invited to share the memorable cuisine of Glen and his loving partner of more than 10 years, Gerald Obre, considered themselves fortunate indeed.

Glen Hillson has a future. Glen stood for the rights of all of us to social justice and equal access to first rate health care. His last battle may have been fought to save his own life, but it was also to ensure that others like him have the same opportunity to be listed for a liver transplant. Many of us feel he was denied that opportunity because of his HIV status and his co-infection with Hepatitis C. He never complained about his own situation, but he continued to rail against a system that continues to discriminate against people with HIV despite encouraging medical evidence of successful transplants in people like Glen.

In the end, Glen was surrounded by friends and family – they were the same to him – people who responded to his lifelong perseverance and loyalty with boundless love and around the clock care.

Glen Hillson is still our leader and we are honoured to continue the fight in his name. ■

Status Check

Another barrier to accessing treatments

by Ken Monteith

There is no population more vulnerable in Canada than those who live in the shadow of illegality with regard to their immigration status. These are people who have crossed the border undetected or who have stayed beyond the expiry of their visas. The very nature of this population means that there are no statistics to quantify the problem.

That these people can survive is a testament to their resourcefulness – they must find work "under the table" and look for services for which they are able to pay or which can be supplied by generous individuals working in the social services system. If they have children, they have no access to education unless their teachers are willing to furnish it without mentioning their presence to school authorities. It is only in the most difficult times of their lives, those moments of absolute vulnerability, that they come face to face with the authority of the state and risk losing all through deportation.

This is the case for a person without status diagnosed with HIV who seeks treatment. The cost of anti-retroviral therapy is easily beyond the means of a person without stable employment and without recourse to welfare. The informal network of people and organizations providing support to people living with HIV/AIDS is only able to help a small number of people, and cannot guarantee access to medication on a regular basis. The only choice can be to wait for an opportunistic infection which requires hospitalization, which entails great cost to the health system and often leads to the involvement of immigration authorities. Deportation becomes almost inevitable and the health of the individual can be irreparably compromised.

It seems that the only means by which these people can stay in Canada is to make a claim for refugee status based on discrimination against people living with HIV/AIDS in their country of origin, if there is no other basis for a claim for that status.[1] Proof of that discrimination can be difficult to obtain for a person diagnosed in Canada (without experience of living as a person living with HIV/AIDS in the country of origin) and expert witnesses are only available for those countries in which there has been Canadian aid experience related to HIV/AIDS.[2]

A more humanitarian solution can be found in the laws of France. Every person who is a resident of France, whatever the nature of their immigration status, has the right to receive medical care.[3] The person can obtain a certificate to this effect, giving access to medical treatment restricted to hospitals for those who have lived in France for less than three years, or unrestricted access for others. In addition, there is protection against the deportation of foreigners who are ill if they do not present a danger to public order, if they are residents of France and if they need treatment which would not be available in their country of origin.[4] People living with HIV/AIDS have easy access to this status. An attempt to abolish these measures by the current government was repelled by widespread and vigorous opposition from human rights and foreign workers' groups. ■

The only choice can be to wait for an opportunistic infection which requires hospitalization, which entails great cost to the health system and often leads to the involvement of immigration authorities.

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1. "Immigration et personnes séropositives ou sidéens," Boullé, Denis-Daniel and Saint-Pierre, Noël, Saint-Pierre, Grenier, Attorneys. (unpublished article). The fact that the life of a person may be threatened by lack of available medical treatment in the country of origin is not recognized as a reason to claim asylum in Canada.
2. Ibid.
3. *Code de la sécurité sociale*, Art. L 380-1.
4. "Étrangers en France : comment se soigner ?" *Remaides*, No. 40, June 2001, pp. 22-24.

CTAC supports access to medicinal marijuana

by Enrico Mandarino

Today, almost 600 Canadians with life threatening illnesses such as HIV/AIDS, cancer, MS and epilepsy are licensed to use marijuana to help alleviate symptoms of disease. In late 2000 Health Canada announced a compassionate access program that would make marijuana available to such Canadian exemptees for medical purposes, but to date the federal government continues to erect barriers preventing many of these people from obtaining their medicine without breaking the law.

The current Health Canada policy, Marijuana Medical Access Regulations (MMAR), which allows Canadians authorization to possess and cultivate marijuana for medical purposes, is seriously flawed: it asks Canadians with life threatening illness to try and grow their own medicine. Obviously, poor health, lack of horticultural expertise (marijuana isn't easy to grow), and a lack of financial and other resources can often prohibit the undertaking of what is a complicated operation. None of the expenses related to this process are recoverable through Revenue Canada, or through claims to public or private health plans.

CTAC, in its support of access to traditional, complementary or alternative treatments, wrote the Minister of Health in December, 2002, asking for a seat on the Special Advisory Committee to the Medical Marijuana Program. Unfortunately, CTAC was not invited to sit on this committee. However, CTAC continues to follow the issue as well as work with the Canadian AIDS Society (CAS) and other organizations, and to write letters to Members of Parliament asking for no less than comprehensive medical marijuana legislation that provides patients with easily and legally accessible medicine.

In January, 2003, the MMAR were successfully challenged on the basis that it is against the "principles of fundamental justice" to allow for a compassionate access program to marijuana for sick Canadians without supplying the medicine. The Ontario Supreme Court gave the government until July 9, 2003 to fix the regulations or they would be declared unconstitutional and have "no force or effect." As the July deadline approached, the government scrambled to create a new "interim" policy for distributing marijuana to ill Canadians.

It is a huge disappointment to medicinal marijuana users that the government came through at the last minute with only an interim measure marginally better than dealing with the black market. Raising further barriers, the government now says that doctors must first agree to also do the work of pharmacists and distribute the marijuana through their offices, and that people wishing to access the government supply of medicinal marijuana must pay lawyers to sign affidavits declaring their need. The government also plans to cancel this interim policy if they win their appeal.

The Special Advisory Committee to the Medical Marijuana Program was not consulted on this interim policy. Dr. Greg Robinson, who served on this committee, resigned after the new interim policy was introduced. The large advocacy initiative has been aided by newspaper headlines across the country declaring that the government has not been "compassionate" in allowing access to medicinal marijuana.

On August 26, 2003, Jari Dvorak, a strong, passionate advocate and a plaintiff in the Supreme Court case against the MMAR, was amongst the first people to receive a legal supply of his medicine from the government. While this a huge victory for medicinal marijuana users, much advocacy work still needs to be done to remove the barriers to access.

CTAC continues to advocate comprehensive legislation that will replace this haphazard series of interim regulations. Advocacy efforts focus on a safe, legal and a free supply of the medicine, the removal of barriers to access, and a better distribution process for medicinal marijuana. ■

There is a group of advocates working on medicinal marijuana issues. If you would like to be part of this group or receive updates, please forward your email to Clarie Checkland at clairec@cdnaids.ca or Enrico Mandarino at enrico@ctac.ca.

So, you want to have a baby?

Fertility issues facing people with HIV

by Shari Margolese

So, you want to have a baby? Considering the majority of people with HIV in Canada are of reproductive age (15-44), it comes as no surprise. Advances in HIV care and treatment have many people with HIV looking toward the future and deciding to have the babies they always wanted.

The good news is that, with treatment, the rate of mother-to-child transmission can be reduced from 25 % to below 2 %. In addition, studies have shown that being pregnant will not make HIV progress faster.

The bad news? Recent research reveals that HIV+ women may find it more difficult to conceive than their HIV- counterparts. HIV, its treatment or co-infection with other sexually transmitted diseases may all contribute to infertility.

Conception (getting pregnant) is also of particular concern for sero-discordant (+/-) couples. Safe sex is recommended, which of course, prevents pregnancy. In many cases, access to reproductive technologies such as *in vitro* (test tube) fertilization, donor eggs and sperm washing are required in order to conceive.

When the woman is HIV+, it is possible to collect semen from the HIV- man for artificial insemination. This can usually be done at home, but may require the assistance of a doctor. When the man is HIV+ and the woman is not, the process becomes more complicated. Semen, which contains sperm, also contains HIV. In order to reduce the risk of transmission of HIV, the sperm must be isolated from the semen and "washed." Sperm washing must be done in a laboratory.

Unfortunately, it is not possible to remove all viral particles from washed sperm.

However, research, including that of Dr. Mark Sauer of Columbia University, shows that transmission is unlikely. Dr. Sauer found that, in 350 couples who underwent more than 1,000 inseminations of washed sperm, there were no cases of infection in either the women or their babies.

HIV+ couples who require the assistance of reproductive technologies to conceive are very limited in their access to care. Until recently, the Special Program of Assisted Reproduction (SPAR), a program of the American Centers for Disease Control and Prevention, only permitted *in vitro* fertilization of HIV+ washed sperm. The procedure costs about US$7,000 per ovulation cycle. In 2002, the recommendations were updated to include the *intrauterine* (in the uterus) method of insemination.

Many medical facilities refuse to implant an embryo in an HIV+ woman fearing infection of the child, or, in the case of a negative woman, infection of the woman. Access to information regarding the availability of reproductive technologies for HIV+ Canadians is very limited; however, reports indicate that Canada prohibits access to most reproductive technology for HIV+ people for ethical reasons. One clinic known to provide fertility services in Canada is Southern Ontario Fertility Technologies (SOFT), located in London, Ontario (www.soft-infertility.com).

Other countries that may offer this technology, on a limited basis, to Canadian couples include Italy, Spain and the United States. ■

Selected resources:

- Mark V. Sauer, M.D., *Addressing the Fertility Needs of HIV Serodiscordant Couples*, January 13-14, 2003 www.blsmeetings.net/1729/Speaker%20Presentations/Mark%20Sauer.pdf
- *Reducing the Risks of Conception: Getting Pregnant When One or Both Partners is HIV+* (available at www.positivewords.com, search for "conception")
- *HIV and Pregnancy* www.bcpwa.org/issue6/HIVPreg.htm
- CBC News Indepth: *Genetics and Reproduction* www.cbc.ca/news/indepth/background/rgtech.html

PROVINCIAL UPDATES

Through its Provincial/Territorial Network Development Program, CTAC has worked towards linking with existing persons with AIDS networks where they exist and to the establishment of networks where none exist. These networks employ democratic election processes to select representatives to CTAC's Council and policies have been established to identify roles, responsibilities and reporting processes. In addition, these networks feed into the national agenda and are a conduit through which bi-directional communication occurs between membership and management.

CTAC is committed to continuing to work with its provincial, territorial and First Nations affiliates towards policy development at these levels, including the development of pan-Canadian standards of care.

ONTARIO

by Enrico Mandarino

Once again, CTAC is collaborating with the Ontario AIDS Network (OAN) to hold a skills building day focusing on continuing and emerging access to treatment issues in the province.

On December 6th, a new CTAC representative for Ontario will be elected. For more information on the roles and responsibilities of the Ontario representative as well as a nomination form, please contact the CTAC office.

I have been the Ontario Representative for the past 4 years, and I am very proud of the work we have done in Ontario, but the work continues. There are 116 CTAC members in Ontario and I encourage others to get involved with this dynamic group of people committed to addressing access to treatment issues in Ontario.

NEWFOUNDLAND AND LABRADOR

by John Baker

Our Provincial Network continues to monitor treatment access issues in Newfoundland and Labrador. Videx EC is now available with special authorization.

The Newfoundland and Labrador Persons with AIDS Network held its annual meeting and educational conference in mid-September in Port Rexton, Newfoundland. Some agenda items included workshops on HIV and Human Rights, HIV/ Hepatitis C co-infection and treatment/clinical information. A new Board for the network and also the Nfld. & Lab. representative to CTAC were elected on September 14, 2003.

The network continues to participate in the development of a Provincial HIV/AIDS Strategy through ongoing consultations with a broad range of stakeholders. The province of Nfld. & Lab. has developed various collaborative documents in the past but has never had a coordinated Provincial HIV/ AIDS Strategy. The final document is expected to be completed by late winter or spring of 2004.

NOVA SCOTIA

by John Arenburg

I am happy to report that the Nova Scotia Network is now in operation. It has held two meetings during the past two years and a skills building session during CTAC's face-to-face Board in Halifax in March 2003.

The Nova Scotia Network will meet in the very near future to discuss the process of creating a CTAC Provincial Network newsletter for Nova Scotia. The Network also hopes to form a partnership with the Community Advocates Network to work on accessing universal pharmacare coverage in Nova Scotia for those not able to afford it.

PRINCE EDWARD ISLAND

by George Clark-Dunning

The PEI Network continues its work at an even pace. At a recent gathering of people living with HIV/AIDS in the province, it was decided that several issues must be addressed by the group and brought to AIDS PEI for action. The first is the outdated Provincial AIDS Strategy which is close to 10 years old. Many of the items in the strategy are no longer needed or have been addressed and are working.

Other issues which the Network will address include access to housing, drugs (combination and other), and back-to-work eligibility. As a new government is now in place in PEI, the

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PROVINCIAL UPDATES

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Network hopes to facilitate the collaboration of the government, AIDS PEI and the positive community as a whole to address access to treatment and other issues in the province facing people living with HIV/AIDS. Time will tell, and much work will be needed.

QUEBEC

by Ken Monteith and Line Carreau

The Bulletin ITI, a treatment information newsletter in French produced by the Coalition des organismes communautaires québécois de lutte contre le sida (COCQ-Sida) and distributed to people living with HIV/AIDS in Québec and across North America, will publish two special editions. These will be Québec adaptations of publications produced by the organization AIDES in France about treatment and the management of side effects.

COCQ-Sida continues to work to support observance of treatments with a committee on observance and sexual health for people living with HIV/AIDS. The committee's mandate is to guide the member organizations of COCQ-Sida on these subjects.

A first series of workshops on the basics of treatment for newly diagnosed people or those who are considering beginning treatment will be presented this fall in Montréal. The one-day workshop will be offered four times between now and December, alternating in English and French. The programme was inspired by similar workshops offered in Toronto and is led by two Montréal doctors with financial support from GlaxoSmithKline and collaboration from the Comité des personnes atteintes du VIH (CPAVIH) and AIDS Community Care Montreal (ACCM). The doctors have expressed an interest in taking the workshops to other regions in Québec and in developing a workshop for people considering changing their treatment. ■

CTAC at 4th Canadian Skills Building Symposium

November 20-23, 2003 - Calgary, Alberta

CTAC will be hosting a satellite at the upcoming Skills Building Symposium in Calgary, and is also offering, on its own and in conjunction with other individuals and organizations, several workshops. Details are below. We hope to see you there!

Satellite

Climbing the Treatment Decision Tree: How to Save Your Life and Change the System

The Canadian Treatment Action Council is very pleased to host this highly interactive satellite symposium. The overall theme of the symposium will be "What you should know about HIV/AIDS treatment decision making." This symposium will be of greatest interest to people living with HIV/AIDS and those who, either formally or informally, provide support, treatment education or other services to people living with HIV/AIDS.

This symposium will take participants through the process of climbing the "Treatment Decision Tree" and will contribute to empowering people living with HIV/AIDS to become informed participants in their health care.

Workshops

Managing on Meds: Short Term Side Effects of ARV

Ron Rosenes, (CTAC), Kath Webster, (BCPWA)

Side effects of Anti-Retroviral therapies (ARVs) pose significant barriers for people initiating and adhering to treatments. This

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CTAC at 4th Canadian Skills Building Symposium

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workshop will explore the range of short-term side effects encountered, from the annoying to the dangerous, and focus on strategies and interventions to manage and minimize them. The goal is better management of side effects and greater adherence to regimens. Topics covered include: peripheral neuropathy, muscle aches, appetite loss, nausea, diarrhea, fatigue, sexual dysfunction, neurological/sleeping difficulties, headache and skin problems.

Women and HIV: Treatment, Research and Action

Louise Binder, (CTAC), Shari Margolese (CTAC)

More than twenty years have passed since the first diagnosis of HIV. While there were a handful of women among the first cases, AIDS was thought to primarily affect gay men. As the years progressed, more and more HIV+ women began to emerge. Until recently, very little research had been done on women and HIV. While many questions remain unanswered, we do have some information about how HIV can be different for men and women. This workshop will review differences in care and treatment for men and women (including gynecological issues), discuss the importance of women-specific research in HIV, and will also provide a forum for participants to identify gaps in treatment, treatment information and research in Canada.

Pregnancy and HIV

Ainsley Chapman (CAS), Kim Johnson (VOPW), Shari Margolese (CTAC)

This workshop is designed to offer participants an inside look into the unique treatment issues faced by HIV+ women about pregnancy. Participants will learn about up-to-date treatment and advocacy information regarding HIV and pregnancy. This workshop aims to assist women considering pregnancy in making informed choices for themselves and their children. It will enhance the capacity of AIDS service organizations and their staff to provide information on HIV and pregnancy to their clients and to advocate for necessary services on their behalf at the local, provincial and national levels. This workshop will also provide the opportunity for network building amongst community members who have a mutual interest in HIV and Pregnancy.

Medicinal Marijuana: What a Trip!

Claire Checkland (CAS), Enrico Mandarino (CTAC), Derek Thaczuk (TPWAF)

Many people with HIV/AIDS are using marijuana as an integrated part of their therapy to help alleviate symptoms and side effects from other medications. This workshop will look at the history of Marijuana to the present day. Participants will learn about the marijuana origins, composition, uses, types of plants, side effects and clinical trials. We will explore access regulations and access barriers faced by people living with HIV/AIDS. With a thorough exploration of the Medicinal Marijuana Access Regulations (MMAR), participants will be empowered to make informed choices about marijuana and to help them overcome the barriers to access. Recent court rulings and legislation changes around possession of marijuana will also be examined. ■

Dear Minister, are we there yet?

by Patrick McIntyre

The 2003 Canadian AIDS Society (CAS) People Living with HIV/AIDS Forum dinner on June 19, 2003 had a little more 'spice' than usual this year. Canada's Health Minister, the Hon. Anne McLellan, made an appearance and finally confirmed publicly that she has heard the Canadian AIDS community's call for a renewed Canadian Strategy on HIV/AIDS (CSHA) with a larger funding allocation. The CSHA was originally created in 1998 with an annual funding allocation of $42.2 million. However, funding has remained at the same level since 1993. CAS has been advocating for an increase in the strategy for several years, on its own and in partnership with many other organizations, including CTAC.

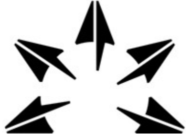
"You want the Government of Canada to step up to the plate, to demonstrate greater leadership and take action on key issues, such as supporting national and community-based infrastructures, developing and sharing knowledge and making information available to all Canadians," remarked the Minister (a link to the Minister's full speech as delivered can be found on the CAS website at www.cdnaids.ca.). Those in attendance commented that it seems like the Canadian AIDS movement has been waiting a long time to hear these words.

As a person living with AIDS and as an advocate, I have participated in many activities over the years which supported our collective call for increased investment and broader participation by government departments in the CSHA. As a National Programs Consultant for CAS since November, 2002, my participation became "professional" and intensified. I came to know first-hand the work CAS and its partners such as CTAC have done and continue to do to open the eyes of bureaucrats and politicians who previously thought of HIV and AIDS as "just a health issue." For example, this past June the Parliamentary Standing Committee on Health released a report recommending that the annual funding allocation to the CSHA increase to $100 million. The committee's report was based on testimonies from key stakeholders in the CSHA including community-based AIDS organizations, researchers and people living with HIV/AIDS. CAS was one of the organizations that offered testimony to the committee. Over the past year, CAS staff and board have held several (and sometimes repeated) meetings with many MPs and government departments inside and outside of Health Canada. For this advocate, the Minister's speech confirmed that this work and that of others across Canada has not gone unnoticed, that the community has effectively laid a solid foundation for continued movement towards our ultimate goal.

As long time advocates can attest, this work is never truly finished. As rewarding as it may have been on that June night in Montreal to have confirmation that our concerns have been heard, we must continue to articulate the need for an increased and more broadly-based strategy for HIV/AIDS in Canada. We must continue informing our elected representatives and federal public service workers of this need, and must continue this work until our goal is achieved. By the time this article gets to press, Health Canada will have completed a five-year review of the CSHA and will have initiated the development of a strategic plan for the CSHA for the next five years. The October 31st deadline for the delivery of Minister McLellan's memorandum to cabinet regarding the CSHA will be looming on the horizon. We are closer than we have ever been, but as the saying goes, don't count your chicks until all the eggs have hatched. ■

Patrick McIntyre recently returned to Montreal to begin studies in the BSW program at McGill's School of Social Work. He misses his friends and colleagues at CAS and in the AIDS movement, but figures you never really leave the AIDS movement, do you?

Clinical Trials – Update



by Jim Boothroyd, Communications Manager at the Canadian HIV Trials Network

Enrollment is nearing completion for an international trial of an innovative method for reducing the side effects of anti-HIV drugs among HIV+ people who have not previously had antiretroviral therapy.

The NRTI-Sparing Pilot Study (CTN 177) compares a drug combination without a nucleoside reverse transcriptase inhibitor (NRTI)(Kaletra plus nevirapine) with two other regimens that include this class of drug (Combivir plus nevirapine and Combivir plus Kaletra). The aim is to determine which one is least toxic and produces the fewest side effects.

Common side effects of NRTIs, such as Combivir (AZT plus 3TC), include muscle pain, numbness, tingling and burning sensations, pancreatitis and loss of body fat from areas of the body. Less common side effects include very high levels of lactic acid in the blood and liver damage.

NRTIs are the backbone of conventional HIV-regimens; however, many physicians now prescribe combinations that substitute non-nucleoside reverse transcriptase inhibitors, NNRTIs. A small series of studies indicate that this approach is safe and effective.

The 48-week NRTI-sparing trial opened in March with a target enrollment of 60 at sites in Canada, France, Spain and Argentina. As of mid-August, investigators had recruited 40 participants, 14 at sites in Ontario, Quebec and British Columbia.

Early indications are that the experimental regimen is safe and tolerable, according to Dr. Marianne Harris, one of a team of researchers led by principal investigator Dr. Julio Montaner of St. Paul's Hospital in Vancouver. Results are expected in the fall of 2004.

For details, check out the CTN trials database at www.hivnet.ubc.ca/ctn.html or call Sophie Geeraerts toll-free at 1-800-661-4664. ■

Visit us at
www.ctac.ca

PASS STUDY UPDATE

On behalf of the PASS Research Study team, we would like to extend our sincere thanks to everyone who participated in this important research project. A particular thanks goes to all the people living with HIV/AIDS who helped test out the various methods of reporting side effects of their medication, either by phone, mail, fax, in person or in focus groups. The PASS Research Study also would like to thank survey staff at Comité des personnes atteintes du VIH du Québec, Voices of Positive Women and British Columbia Persons with AIDS Society, the toll-free survey line and the facilitators for the focus groups. Thanks also to the Ontario HIV/AIDS Treatment Network and our pharmaceutical partners for their support of this study.

The data collection phase was completed at the end of July and the research team is presently analyzing the data. The PASS Advisory Committee will be meeting in early November, 2003, to discuss the results of the study and prepare the final report of the Research Study findings. We anticipate having the final report available at the beginning of 2004. ■

CHAIR'S REPORT

FALL 2003

by Louise Binder

As our AGM approaches, it is time to reflect upon the message we will want to deliver to our general members, Council and Board members, committees, other volunteers and staff.

The main message I want to deliver is that our work is never done – vigilance and the demand for meaningful citizen engagement through community organizations in the decisions that affect our lives every day must be paramount ongoing.

There have been a number of major political processes undertaken, some encouraging and some very discouraging.

The most encouraging is the recent Health Canada multistakeholder think-tank. Its role is to develop a method to overhaul the Therapeutic Products Directorate review process for drugs intended for sale in Canada. The impetus for this action was the newly allocated $190 million in the winter federal budget to provide faster drug reviews. The stakeholder message was loud and clear: the current system is irreparably broken in its present process and structure and needs an entirely new structure, immediately. Although the Minister of Health promised quick action by her department and her Deputy Minister of Health agreed to carry out her wishes, we are still waiting – again.

The new Common Drug Review Process under the federal Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is another case in point. This group, which will be up and running soon, has virtually no meaningful consumer involvement, although there have been repeated calls for it. More details about this process and its shortcomings are explored in "Common Drug Review," page 1.

The provincial drug formularies continue to be problematic and inequitable in terms of treatment accessibility.

Drug pricing is one of the hottest issues of the day with Canadians. The Canadian governments complain that it is the major burden on the budgets. The U.S. governments and pharmaceutical industry, on the other hand, complain that our prices are so low that Americans are rushing up here, physically or virtually, to buy their drugs. Both of these issues means big trouble for drug access in the future.

It is time to renew our call to politicians to take a stand on these issues of profound importance to people with HIV/AIDS and many other Canadians. Voices must continue to be raised. ■

CALENDAR OF EVENTS

FALL 2003

● **October 16th-18th**
5th Canadian Aboriginal AIDS Network AGM and Gathering
Canmore, Alberta
Contact: info@caan.ca or 1-888-285-2226

● **October 25th-29th**
9th European AIDS Conference (EACS)
1st EACS Resistance & Pharmacology Workshop
Warsaw, Poland
Contact: eacs2003@kit-group.org
or +49 30 24603 270

● **October 26th-27th**
Canadian Treatment Action Council AGM and Skills Building
Toronto, Ontario
Contact: ctac@ctac.ca or 416-410-6538
Join CTAC for a day of skills building in Toronto! All are welcome to attend. Please visit www.ctac.ca for details.

● **October 26th-30th**
11th International Conference For People Livng With HIV/AIDS
Kampala, Uganda
Contact: kampalaconference@gnpplus.net
or +31 (0) 20 423 4114

● **November 3rd-4th**
Ontario HIV Treatment Network Research Conference
Toronto, Ontario
Contact: 1-877-743-6486 or info@ohtn.on.ca

● **November 20th-23rd**
4th Canadian HIV/AIDS Skills Building Symposium
Calgary, Alberta
Contact: infoshaleena@cdnaids.ca
or 1-877-998-9991

● **December 10th-12th**
1st International Workshop on HIV Persistence During Therapy
Saint Martin, French West Indies
Contact: hiv2003@club-internet.fr
or +33 4 94 22 77 40

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BOARD OF DIRECTORS

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2003/2004 FUNDERS

Health Canada

Ontario HIV Treatment Network (OHTN)

Abbott Laboratories • Agouron Pharmaceuticals • Boehringer Ingelheim • Bristol-Myers Squibb • Gilead Sciences • GlaxoSmithKline in partnership with Shire BioChem • Hoffmann-La Roche • Merck Frosst • Schering Canada

CTAC POSITION PAPERS AND SKILLS BUILDING VIDEOS

Papers

- 2001 - "Improving our Health: The Need to Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada", author: David Garmaise.
- 2001 - "Making Treatments Accessible: A Policy Paper on Determining Appropriate Pricing for Brand-name Pharmaceutical Treatments for HIV/AIDS in Canada", author: Glen Brown.
- 2000 - "Position Paper on Direct To Consumer Advertising (DTCA) of Prescription Medications", author: Phillip Lundrigan.
- 1999 - "Timeliness and Transparency: Assessing the Review Process for HIV Drugs", author: David Garmaise.

Video Tapes

- 2001 - "New Drug Reviews and Research: What's the Rush?" - $9.00
- 2001 - "Making Room for CAM: Advocacy Issues regarding Complementary and Alternative Medicine (CAM)" and "How to Lobby Politicians and Bureaucrats Effectively" - $11.00

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Organizational Mandate

The mandate of the Canadian Treatment Action Council (CTAC) is to work with the prublic and private sectors to:

1. **Support access to therapies and treatments** for people living with HIV/AIDS by informing research and public policy, and by promoting public awareness
2. **Provide mentoring and skills building** in these areas to people living with HIV/AIDS
3. **Encourage and facilitate the exchange** of related information to stakeholders

MEMBERSHIP

Membership applications are available by contacting the CTAC office or by visiting the CTAC web site.

Full Membership

- Person living with HIV/AIDS
- Group, organization and/or project with a substantive HIV/AIDS mandate

Associate Membership

- Any individual
- Group, organization and/or project whose substantive mandate coincides with the objectives of the Corporation

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