

CANADIAN TREATMENT ADVOCATES COUNCIL



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AIDS – Twenty Years Later

by Enrico Mandarino

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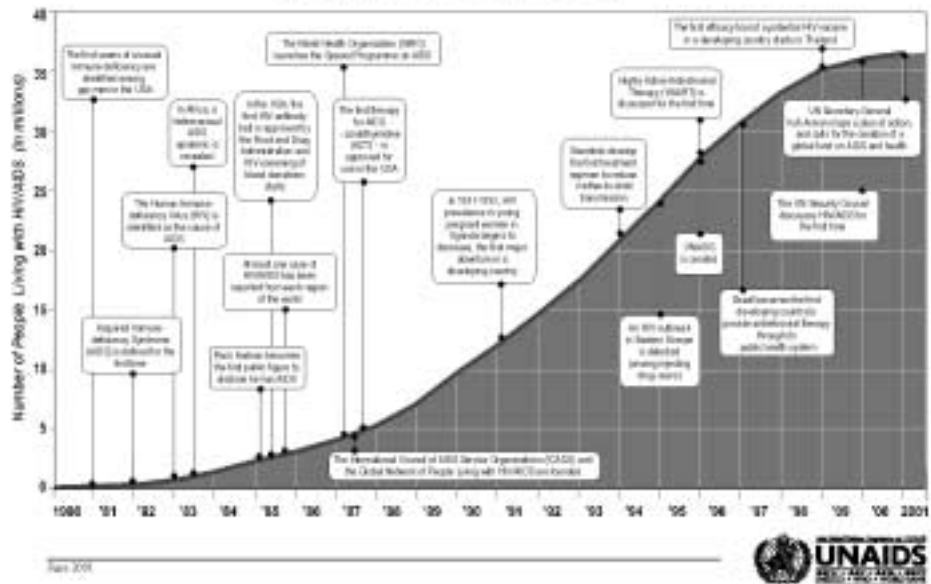
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20 years of HIV/AIDS



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On June 5, 1981, the Centers for Disease Control in Atlanta published the first report of a strange opportunistic infection among several young gay men in LA. Although seemingly healthy, the young men had contracted a rare, opportunistic infection usually associated with cancer patients.

By early 1982, there was an understanding that somehow this disease was related to sex. Soon, the syndrome was then linked to blood and identified also in women, injection drug users, hemophiliacs, blood transfusion recipients and babies. From an obscure beginning, HIV would become the worst public health disaster of all time. Early preventions methods were targeted around limiting the number of sexual partners and making sure your partner was “healthy”. In 1984-85, as more was understood about HIV, studies started to show that the number of partners didn’t matter and that unprotected sexual intercourse was the strongest factor in getting

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3RD SYMPOSIUM: Mission Accomplished!

by Christian LaForce

The 3rd HIV/AIDS Skills Building Symposium was held from July 6-9 at the Delta Hotel in Montreal and presented a unique opportunity for exchanging, creating and maintaining networks for the fight against HIV/AIDS.

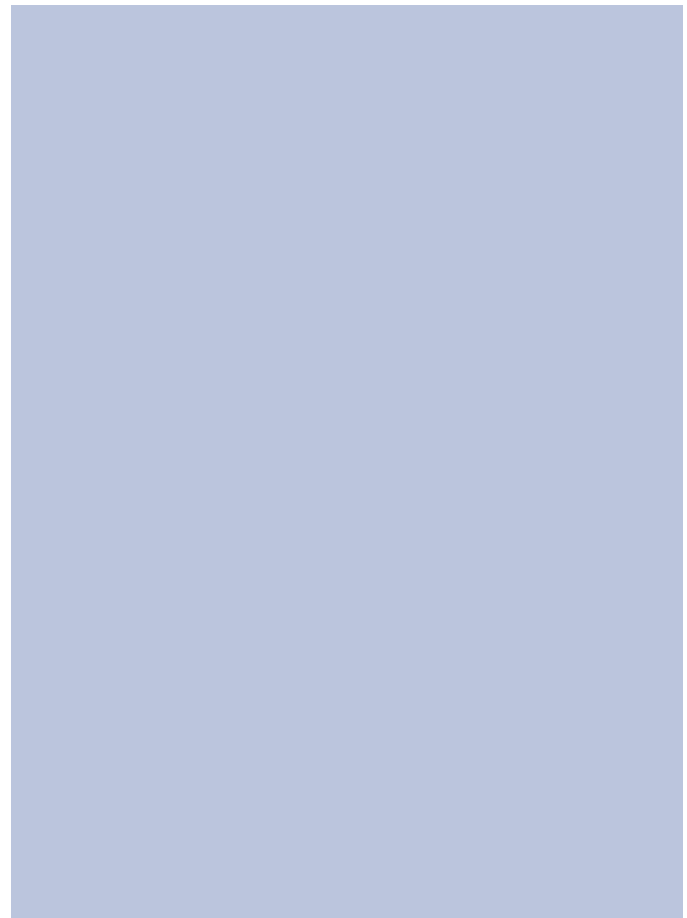
Certain satellites led to interesting meetings. In my opinion, the parallel meetings were the most productive, especially the meeting that followed the PLWHIV/AIDS forum, where a few of the organizations representing PLWHIV/AIDS met to discuss the steps needed to improve the circulation of information, and to give PLWHIV/AIDS a national voice. Although ambitious, this project is indispensable if our action is to overcome all the bureaucratic intricacies because, let's face it, sometimes we wonder why we are fighting...

A press conference was held on Thursday, July 5th with a familiar theme: "Double the money - Double the strategy." This meeting with the media was set up by the Canadian Aids Society (CAS) and was presided over by Michael Yoder. Guests included Daniella Boulay, Director of the CASM - Women, and CAS Representative of Quebec AIDS Organizations; Christian LaForce, Director of the CPAVIH; and Janet Connors. A clear message was sent to Allan Rock: renew the strategy and double the amounts invested, because the current amount is truly insufficient to pursue our fight against HIV/AIDS. Nearly two hundred symposium participants joined the demonstration in front of the Canada Health offices at the Guy-Favreau Complex, where they yelled out various slogans to make the government realize that after almost 20 years, AIDS continues to kill and, according to statistics, it's not over yet. What was remarkable about this demonstration was the spontaneity and energy manifested by the participants, who did not hesitate to join the ranks to denounce the government's attitude towards the fight against AIDS. It was a moving, encouraging and

inspirational moment for everyone.

My time was mostly filled with interviews and organization; nevertheless I presented a workshop on the media, occupational bias, and was able to attend a few workshops, including HIV and Aging, which truly gripped me. I attended it for the good and simple reason that if the trend continues, we will live longer lives and will be faced with different types of problems. We will perhaps have to take on the role of mentors, once again, in retirement homes and hospices for the other residents ...

Overall, there were nearly 800 participants and over 80 workshops at this 3rd symposium. And that created quite a buzz. ■



THE UNITED NATIONS GENERAL ASSEMBLY Special Session on HIV/AIDS

by Bob Mills

Official photo of the UN building in New York with the Red Ribbon during the UN Special Session on HIV/AIDS



Credit: UN Photo Unit

The United Nations General Assembly Special Session on HIV/AIDS (UNGASS) was the first ever UN Special Session called to deal with a health crisis. The meeting concluded June 27th in New York, with the historic consensus of 189 countries on a declaration to fight the HIV/AIDS epidemic globally. The gathering was a significant collective recognition of the urgency in dealing with the scourge of the epidemic by the global community. What is important is that the world now has a Global Declaration of Commitment on HIV/AIDS.

Firstly, it was an honor to be chosen by my colleagues for nomination and then by the Government of Canada to participate in the UNGASS on HIV/AIDS. Representing the views of the Canadian civil society on the government mission to the UN was challenging. Both Ralf Juergens and I worked long into the night on many occasions to make this declaration complete, using the strongest language that consensus can bring to such a document. The rewards for us were seeing some of our suggestions included in the wording of the final document and in knowing that we actively participated in such a historically significant undertaking.

On the final day, Ralf and I were invited by the Canadian

mission to assume the two government seats directly behind the CANADA sign on the General Assembly floor. This invitation was symbolic of Canada's role throughout the UNGASS process. Canada demonstrated it was truly all-inclusive of civil society participation by:

- including a NGO representative on the Canadian delegation as early as the first preparatory meeting in February, and by including two NGO representatives (including a person living with HIV/AIDS) on the delegation that attended the May and June meetings;
- organizing a consultation meeting in Ottawa to obtain the input of civil society and other interested parties;
- sponsoring an electronic UNGASS discussion forum;
- challenging other member countries to provide meaningful civil society participation at every meeting, culminating in a Canadian-led political battle for inclusion of a representative from the International Gay and Lesbian Human Rights Commission on the human rights roundtable panel;
- supporting Canadian civil society participation and encouraging feedback from all interested parties.

What we, as Canadians, gained from the Declaration of Commitment was recognition of the importance of the empowerment of women in fighting the AIDS epidemic worldwide. Canada also negotiated with some of the more conservative countries a compromise by listing in the document factors that lead to vulnerability to HIV. What Canada, the European Union, Australia and New Zealand were hoping for was a full listing of vulnerable groups included in the document; we settled for less. We tried, but did not fully succeed in getting a specific reference to the International Guidelines on HIV/AIDS and Human Rights. However, we were successful in getting general references to human rights throughout the document. The references were no small feat considering that not all countries fully support human rights for all people, gender equality or religious freedom. In hindsight, the UNGASS Declaration of Commitment on HIV/AIDS is the best that Canadians could expect as participants in an exercise of consensus by the global community.

The Global Declaration of Commitment can be found at: <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html> ■

WHAT DOES THE UNGASS DECLARATION Mean for Treatment Access?

by Richard Elliot,
Canadian HIV/AIDS Legal Network

At an historic “Special Session on HIV/AIDS” in June 2001, the member countries of the United Nations General Assembly unanimously adopted a “Declaration of Commitment on HIV/AIDS: Global Crisis – Global Action.”¹ What does it mean for access to treatment, and for treatment advocates? It means only what we can make it mean; without advocacy, it will mean little.

The Declaration offers treatment advocates a limited, imperfect, but nonetheless important, tool. While it creates no binding legal obligations on countries, it does represent commitments they themselves have adopted, meaning we can use the Declaration to hold governments accountable in the court of public opinion.

Importantly, countries recognize in the Declaration’s preamble that access to affordable drugs (including anti-retrovirals) is needed for effective prevention, care and treatment strategies, and that the lack of affordable drugs and adequate health systems hinders an effective response in many countries, especially for the poorest people. They also recognize that “resources devoted to combating the epidemic both at the national and international levels are not commensurate with the magnitude of the problem,” and that increased and sustained resources are required.

Each country declares that by 2003, it will implement “national strategies and financing plans that...fully promote and protect all human rights and fundamental freedoms, including the right to the highest attainable standard of physical and mental health.” These strategies are to include strengthening health care systems and “addressing” factors such as drug pricing and affordability (including “differential pricing” in different countries).

Whether these commitments translate into measures to improve access to treatment – both in terms of funding and at the level of government policy – will likely depend largely on treatment advocates.

On the resources front, treatment advocates should use the Declaration to push governments for increased national and global funding. Countries pledged to ensure “adequate” allocations in national budgets for HIV/AIDS programmes, and to ensuring that resources for a global response are “substantial, sustained and geared toward achieving results.” Yet independent researchers recently concluded that “the largely static \$42.2 million investment in the Canadian Strategy is neither adequate nor appropriate.”² So far, Canada has pledged only US \$98 million (over 3 years) to the new Global AIDS & Health Fund – less than \$2 per year per Canadian. And Canada still only allocates 0.29% of its gross domestic product to official development assistance, less than half of the 0.7% the world’s wealthy countries promised years ago. The Declaration also calls for enhanced debt cancellation in return for developing country commitments to direct monies freed up from debt servicing to eradicating poverty and to prevention, care and treatment for HIV/AIDS and other diseases.

On the policy front, countries have committed to addressing drug pricing (including differential pricing in different regions), in their national strategies by 2003, providing an opportunity to engage governments on these issues. However, the Declaration leaves lots of “wobble room” that governments can (and will) use to avoid or delay addressing the issue of international patent laws, saying only that the “impact of international trade agreements on access to or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated.” Treatment advocates’ national efforts to address drug pricing issues should include a global perspective and should complement ongoing international advocacy regarding international trade agreements in forums such as the World Trade Organization.

1. United Nations General Assembly. *A/5-26/L2* (26 June 2001), available on-line via: www.unaids.org.

2. Martin Spigelman Research Associations & The Project Group. *Taking Stock: Assessing the Adequacy of the Government of Canada Investment in the Canadian Strategy on HIV/AIDS*. Prepared for the Championing Committee, Ministerial Council on HIV/AIDS, January 2001.

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NEXT MOVES: BC's Glen Hillson Looks Back to the Future of Treatment Activism

by David March,
volunteer and AIDS Walk publicist since 1997



Glen Hillson,
Chair of BCPWA
and CTAC's BC
representative

BC's Glen Hillson is tearing a page from his activist history book before making his next moves as a treatment advocate – a strategy he feels necessary for a movement that's still relevant, but stalled in recent years from reduced enthusiasm of people living with HIV/AIDS and threats of a new wave of government cost cutting.

According to Hillson, the next wave of treatment issues will require a different approach that's more reminiscent of the early days of the epidemic than what we've become accustomed to of late.

"I don't necessarily see a wholesale return to marching in the streets, but I do see us getting louder and working more closely with other grassroots health advocates," says Hillson, who, as Chair of the BC Person's With AIDS Society and a member of the Canadian Treatment Advocates Council, has been a community activist for nearly 30 years.

Hillson sees a resurgence of interest in advocacy as a direct result of the new sense of urgency from people living with HIV/AIDS. "Rising infection rates, more treatment failures and diminished access to new treatments will force people to not take for granted what has been achieved so far. It will be hard enough to hold on to gains made years ago."

He also sees opportunity in broader coalitions that are showing signs of success elsewhere and have much to offer people living with HIV/AIDS.

Even the next phase of treatment issues confronting

people living with HIV/AIDS will go beyond mere access to the latest therapies. Monitoring and surveillance of therapies to ensure their safety and effectiveness will be at the top of the agenda.

"People have become a little too complacent about HIV treatment issues," explains Hillson. "At least until they find something doesn't work for them, and by that time, they're too sick to advocate for something better."

Fundamental to Hillson's activities as a health advocate is the tenet of "empowerment" of those living with the disease. "Demoralizing" is how he views government attempts to seize more control over treatment services.

One of Hillson's biggest priorities is that people living with HIV/AIDS remain their principal advocates and maintain control of the organizations that provide services to the community. He fears there is an increasing bureaucratization of service organizations by government. Hillson argues that community services will become less accountable to people living with HIV/AIDS if government takes over.

It's a silencing of people living with HIV/AIDS that he cites as the main cause behind the fewer number of people living with HIV/AIDS willing to get involved in treatment advocacy.

"Government controlled service providers are accountable only to government – not to PWAs," claims

Hillson. "In grassroots, consumer-owned organizations we are accountable to each other. In the early days of the epidemic, this is how organizations like ACT UP maintained their legitimacy."

Hillson recalls that there was a stronger sense of community action and desire for coalition building back in his early days as an activist for the gay community in the early '70s .

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"I don't necessarily see a wholesale return to marching in the streets, but I do see us getting louder and working more closely with other grassroots health advocates."

"Today it's not such a big deal, but I came out as a gay man and activist in an environment that was politically charged," he explains. "We were fighting for what then appeared as basic human rights." Hillson was 21 years old when he joined up with a Vancouver group of lawyers and labour activists to confront the Vancouver Sun in the Supreme Court of Canada over the paper's refusal to run a gay ad. He lost that battle, but his career as an advocate continued.

Throughout the '80's and early '90s, Hillson went on to become a successful union organizer and labour negotiator. He highlights his first key success as the deal breaker for 1,200 staff of the Vancouver School Board when he led a heated contract dispute into binding arbitration.

It was this successful stint as a negotiator that taught Hillson how to effectively work with diverse groups of people, something he feels is essential to leading any successful advocacy strategy.

As Hillson puts it, "I try to avoid pissing off too many people." After more thought, he does admit to learning about understanding and forgiveness, among both the people he lobbies and those he works with.

"Stigmatization and illness have contributed to a very difficult constituency. We show each other a greater level of compassion, understanding and forgiveness less evident in other arenas. We are a healthier movement because of this. To take an environment of frustration and turn it into one of generosity is an accomplishment in itself."

The cut and thrust of labour negotiation also prepped Hillson for his next challenge as Chair of BCPWA in 1996, an organization whose membership has grown over the years to nearly 3,500 people living with HIV/AIDS.

Perhaps Hillson's greatest achievement to date has been the long-awaited deal between people living with HIV/AIDS with the BC government for health benefits to which they are entitled, a battle known locally as the fight over "Schedule C." After four years of near unanimous tribunal rulings, people living with HIV/AIDS have finally convinced the provincial officials to stop denying them access to monthly allowances for health supplements such as vitamins and water.

Hillson shrugs at his recent success when compared to the battles that lie ahead. "It's quite discouraging," he says. "Governments have to realize the value of enabling PWAs to lead productive lives and, in turn, provide fair access to health services."

When asked of immediate goals, Hillson refuses to be pinned down to the short term and simply adds that, "We have to keep the doors of discussion open. Governments need to be reminded that we are relevant in both social and economic terms."

His goal is not just to remind government, but also people living with HIV/AIDS as to why there are treatment advocates in the first place.

"We overestimate our progress towards social understanding. The stigmas attached to this disease still exist. People are still scared to disclose their HIV status. We should by now be in a society where people can disclose HIV status in any situation without fear."

As to what role he plans to play in this chapter, Hillson admits that his personal health will be the critical factor. Alone, his passion for the cause is not enough to pin his or anyone else's hopes on. But then again, it was the driving force that got him started in the first place, and is likely to carry him forward for the immediate future. ■

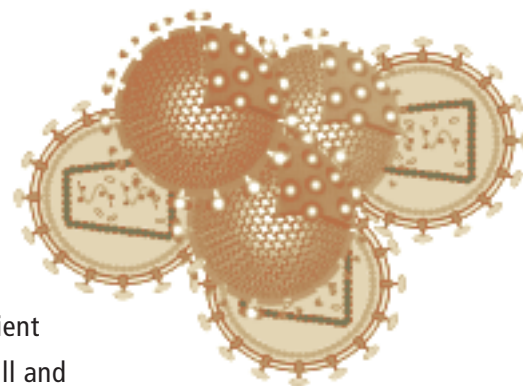
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Finally, countries have committed to conducting "national periodic reviews" of their progress achieved in realizing these commitments, and at the global level, to devote at least one full day of the annual session of the UN General Assembly to reviewing and debating a report on progress

toward globally realizing the commitments in the Declaration. This provides another opportunity for treatment advocates to keep the pressure on governments for both national and international action on access to care and treatment. ■

MICROBICIDE RESEARCH INCHES FORWARD

by Louise Binder



In the December 2000 CTAC newsletter, there was a long article about microbicides. You will recall that microbicides are chemicals that kill microbes. Research has been underway for some time to find microbicides that will be a safe and effective product to protect against HIV and other sexually transmitted diseases (STDs). Ideally some should also be used for birth control and some should be for vaginal and / or anal intercourse. Such products would be invaluable for both men and women as a preventative measure against infections and re-infections.

To date, research has involved topical gels, suppositories, foams, films and sponges. They allow the users greater control over their sexual health without the requirement to negotiate their use, a drawback with condoms. In addition to being invisible, the ideal microbicide would be stable, easy to store, fast acting, long lasting, inexpensive, available over the counter, and safe for multiple use.

It is exciting to report that Phase III trials are beginning on some microbicides. One is Carraguard (PC-515), a non-contraceptive gel derived from seaweed. It is inexpensive and relatively stable. 700 women in South Africa will take part in the trial which will measure efficacy against HIV and STDs, long term safety and acceptability for use. It will also be studied in New York on a cohort of men who have sex with men.

A second trial involves a polymer, Pro 2000, and an acid buffer, Buffergel. Between 8000 and 10,000 women will be involved in a Phase III multi-centre, international trial with four arms, i.e. Pro 2000 or Buffergel or condoms or abstinence.

We will watch the results of these trials with great interest; however, we know that in order to find one successful candidate microbicide, it may take the development and trials of many options. It costs between \$50 and \$100 million to do research on each new compound. Yet, despite the fact that scientists have determined that

with sufficient political will and investment, there could be an effective microbicide in five years, investment in microbicide research is woefully inadequate. Governments have made some investment in this work, no doubt recognizing the cost to the health care system of treating STDs and HIV. Large pharmaceutical companies, however, have not invested in microbicide research, concerned about profitability and issues of liability. The argument about profitability is somewhat surprising given that market research done in 1998 by the Alan Guttmacher Institute in the U.S. involving a large number of sexually active women found that a substantial number of women would be interested in microbicides. Perhaps this reluctance in the face of an overwhelming health need is an argument for at least some research decisions to be made by others outside the pharmaceutical companies, although paid for by them. The liability issue is one that exists in any new drug development and is surely factored into the costs of such work.

It is interesting that at least one study is taking place to test the use of ddl as a prevention mechanism compared to a placebo. This does seem at least as risky as microbicide research. It is also a much less desirable result to study expensive, toxic antiviral drugs for prevention, rather than trying to find a safe, effective and inexpensive microbicide.

Advocacy must continue to get microbicide research on the agenda of the large drug companies and to increase support by governments for this work. Many thousands, if not millions of men's, women's and children's, lives could be saved with this product. ■

WOMEN'S ISSUES

Update

by Shari Margolese



“Healthy Women-Healthy World”

CTAC’s Chair, Louise Binder, and Women’s Representative Shari Margolese recently attended the Global Health Council conference entitled “Healthy Women -HealthyWorld” in Washington D.C. where approximately 50% of the presentations featured information related to HIV/AIDS. Ms. Binder and Ms. Margolese presented a poster highlighting treatment-related recommendations from the Canadian Women and HIV/AIDS Conference. Highlights of the conference included keynote remarks by Koffi Annan and Melinda Gates. A session held on Microbicides was very well attended (see update on page 8). CTAC’s International and U.S. colleagues brought the issue of “the Global Gag Rule” to their attention.

The “Global Gag Rule”

Endangering Women’s Health and Democracy

What is The Issue?

On January 22, 2001, U.S. President George W. Bush re-imposed restrictions known as the “Global Gag Rule” (or the “Mexico City Policy”). Simply put, the Global Gag Rule, with limited exceptions, restricts foreign non-governmental organizations (NGOs) that receive U.S. family planning funds from using their own, non-U.S. funds to provide legal abortion services, lobby their own governments for abortion law reform, or even provide accurate medical counselling or referrals regarding abortion. The 1973 Helms Amendment already prohibits U.S. funds from being used for these activities. It is also important to note that these NGOs will not receive U.S. funds for ANY family planning programs if they do not adhere to the U.S. imposed regulations. For more information, please visit the Global Health Council’s website at www.globalhealth.org. You may contact the CTAC office to find out what Canadians can do to help.

Canadians Brainstorm Gender Research Priorities

CTAC participated, along with over 70 researchers and community members, in a brainstorming meeting in Vancouver hosted by the Canadian Institutes of Health Research (CIHR) Institute of Gender and Health (IGH).

The major objective of the meeting was to brainstorm ideas and suggest priorities for strategic research initiatives for the IGH. The IGH stated that these priorities should cross the full spectrum of health research (i.e., biomedical, clinical, health services,

population health/health promotion) and involve collaboration with other CIHR Institutes. A second objective of the meeting was to discuss the implications of these priorities for training and capacity building. An upcoming “Day Focusing on Women’s Health Research” will expand on the brainstorming session.

This meeting provided an opportunity for CTAC representatives to recommend inclusion of the following objectives in the IGH strategic research plan:

- Female controlled and initiated prevention technologies, particularly Microbicides that are both anti-STD and HIV, as well as pregnancy barriers.
- Research on the impact of HAART on women’s monthly and life cycles, and vice versa, as well as other gender specific impacts of HAART.
- The ways in which gender inequality and discrimination stand in the way of medical interventions.
- The role that violence plays in women’s health outcomes and specific interventions to combat these.
- Research into the development of programs for women and girls that seek to reduce HIV infection risk and improve reproductive health.
- Research into the use of acetic acid as a low cost, low technology method to test for cervical cancer.

New Brunswick Women’s Retreat

HIV+ women living in New Brunswick met as a group for the first time earlier this year for skills building, needs assessments and support. The women in attendance concluded that regular peer interaction would help them in effectively dealing with their HIV infection. Women made suggestions to representatives of local ASO’s to achieve this goal, including a recommendation that a provincial telephone support group be developed. ■

REPORT FROM THE 1st International AIDS Society Conference on HIV Pathogenesis and Treatment



by Louise Binder and Ron Rosenes

Buenos Aires, July 8-11, 2001—

This first IAS Conference focused exclusively on basic and clinical science. More than 700 abstracts were presented in either oral or poster format. Antiviral drugs, immune-based therapy, vaccines and microbicide research were the main general topics.

ANTIRETROVIRAL RESEARCH

There are approximately fourteen antiretroviral drugs presently available in Canada. These drugs fall into three classes. Although they have provided significant health benefits for many people, they also have many limitations. Adherence, durability, potency and adverse events are limiting factors. Development of new agents is important to both treatment experienced and treatment naïve patients.

PROTEASE INHIBITORS (PIs)

Tipranavir (TPV)

Tipranavir is a novel protease inhibitor that may offer a unique resistance profile, making it effective against both wild type and mutant strains of HIV. This drug has been in development for several years and is now being combined with low dose ritonavir to overcome poor TPV bioavailability and short half-life.

Adverse events included diarrhea = 59 %, nausea = 31 % and vomiting = 17 %.

Forty eight week data were presented from a study comparing different doses, formulations and combinations of TPV and left unanswered questions about the optimal dosage, drug interactions and adverse events. Further dose-ranging studies are required before pivotal, large-scale Phase III trials can be undertaken. This means it will still be some time before it could be licensed. Expanded access is not expected until at least 2003.

Atazanavir (TAZ, BMS 232632)

This protease inhibitor was compared to Nelfinavir in a 48 week, Phase II, randomized open label trial (TAZ dose ranges were blinded). In treatment naïve patients, TAZ was given once daily in combination with two reverse transcriptase inhibitors (RTIs).

After 24 weeks, the median viral load (VL) drop was 2.6 logs across regimens and >50 % of study subjects had an undetectable viral load of < 50. Triglycerides and cholesterol for TAZ did not change from baseline and were significantly lower than Nelfinavir by week 32. However bilirubin was elevated 32% in the TAZ 400 arm and 52% in the TAZ 600 arm, compared to 2% in the Nelfinavir arm.

In other studies TAZ demonstrated some ability to overcome HIV strains with limited PI resistance.

NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS

Tenofovir DF

(Tenofovir disoproxil fumarate) (TDF)

TDF has demonstrated viral load decreases of approximately .6 logs in RTI experienced patients. It has a unique resistance pattern and long half-life. TDF offers once daily dosing.

At 96 weeks, study subjects showed infrequent development of NRTI mutations associated with TDF.

CTAC is working with Gilead Sciences, the manufacturer, to assure an expanded access program for TDF in Canada by late 2001.

FUSION (ENTRY) INHIBITORS

T-20 and T-1249

These drugs are the first in a new class of drugs that inhibit HIV entry into human cells. New classes of drugs are especially

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important for treatment experienced patients because of cross-resistance between drugs in existing classes. T-20 and T-1249 are potent suppressors of HIV. Development of T-20 is further advanced but T-1249 may be more potent. Because they have slightly different target sites, they may not be cross-resistance with each other and could potentially offer synergy if used in combination. Daily subcutaneous injection of these drugs is a significant drawback. In addition to causing small, hard nodules under the skin, other reported side effects included mild to moderate headache, nausea and fever.

It appears that resistance to T-20 and T-1249 can develop quickly. As with other classes of drugs, the clinical significance of resistance is not fully understood.

The metabolic disregulation and organ damage associated with existing classes of HIV drugs have not been observed in these fusion inhibitors. T-20 is presently in Phase III trials and T-1249 is in Phase I/II trials. CTAC is working with Hoffman LaRoche to ensure limited access to Tipranavir and T-20 in Canada later this year.

STRUCTURED TREATMENT INTERRUPTIONS (STIs)

Clinical investigation to prove the concept of STIs has focused on the following questions:

1. In patients who respond to antiretroviral therapy (ARV), can time off therapy boost HIV-specific immune responses and stimulate control of viral replication?
2. In patients who are failing on ARV, can STIs stimulate a reversion to drug sensitive, wild type virus and a depletion of resistant HIV strains?
3. What is the potential impact of STIs on adherence, reduction of toxicities and ultimately health care costs?

Dr. Anthony Fauci, of the US National Institutes of Health (NIH) is a proponent of STI research. To date, he has conducted two trials in which patients discontinue and resume therapy at predetermined intervals. In one trial, now discontinued, the cycle was two months on treatment followed by one month off. In the other, which is still ongoing, the cycle is one week on and one week off.

In the "month off" trial, VL rebounded as expected during

interruption but always returned to undetectable when therapy was resumed. However, the study was too short to alleviate concern that repeated interruptions might eventually lead to the emergence of drug resistance. There is also concern that viral load rebounds increase infectivity during treatment interruption. Changes in CD4 and CD8 t-cell counts were observed in this study group. In the "week on week off" trial, t-cell counts remained stable during interruption. VL rebound was also less frequent and less pronounced in this group and patients returned to undetectable VL when treatment was resumed.

Dr. Franco Lori and colleagues presented interim results on the RIGHT Study 901 which compared 60 antiretroviral naïve patients who were randomized to receive two different courses of treatment continuously for 12 weeks before going onto three week cycles of STI for a total of 36 weeks. Results thus far are inconclusive, but suggest that VL decrease and CD4 increase are similar to continuous treatment. However, the long-term impact of transient CD4 loss and VL rebound on patient clinical endpoints is unknown.

Other studies suggest that in newly infected patients, enhanced immune control as demonstrated by lower VL setpoints can be achieved through STIs. So far the evidence provided by these two studies does not support the theory that similar effects can be achieved in chronically infected HIV patients.

Although 'drug holidays' can be a welcome reprieve for patients from the burdens of pill taking and side effects, rigorously structured interruptions may further add to the complexity of combination therapy.

Dr. Fauci stressed that "the long-term effect of interruption on the emergence of resistant mutations and on the ultimate clinical course of patients remains to be determined" and patients should not experiment with STIs on their own.

TREATMENT SIMPLIFICATION Indinavir (TID) versus Indinavir + Ritonavir (BID)

Indinavir has been a very useful protease inhibitor for the past five years. Its rigorous regimen of every eight hours on an empty stomach poses serious adherence challenges. The BEST study

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compared safety and efficacy of Indinavir 800 mg every eight hours (empty stomach) to mg 800 Indinavir/100 mg Ritonavir twice daily (with or without food). The effect on VL was comparable in the two arms although the dropout rate was higher in the Indinavir every eight hours arm.

CTAC will continue to advocate for simpler, effective and durable regimens.

SWITCHING STUDIES

Antiretroviral drugs are associated with many unwanted side effects - all of which affect quality of life and some of which are severe - even life threatening. Protease inhibitor use is thought to be associated with lipodystrophy syndrome. Lipodystrophy results in redistribution of body fat and is disfiguring. Elevated lipids (cholesterol and triglycerides) are also associated. Studies that examined switching the protease inhibitor component of drug combinations in patients on stable HAART were updated at this conference. NNRTIs are substituted for PIs in these experiments. Generally, it appears that viral suppression can be maintained but results are varied when it comes to reversal of lipodystrophy. The causes and mechanisms of lipodystrophy are not well understood. Disease state as well as other drug classes could also play a role. What remains clear is that some old rules still seem to apply. Firstly, drug therapy should be tailored to individual patient needs. Secondly, if it ain't broke – don't fix it!

HIV DRUG ADVERSE EFFECTS

Dr. Pablo Tebas and his researchers at Washington University, St. Louis, Missouri have been studying the high incidence of osteopenia and osteoporosis in HIV+ patients. Some studies show accelerated loss of bone mass density (BMD) among patients on HAART, but no link to specific drug classes, e.g. PIs, has been established. Preliminary data indicate there may be some correlation between osteopenia/osteoporosis, total duration of NRTI therapy and degree of NRTI-related lactic acidosis. Because these studies are cross-sectional, it is difficult to isolate other common risk factors including history of wasting, poor nutrition, past steroid use, or hormonal deficiencies. In other words, is it AIDS, is it age or is it AIDS drugs?

The answer is probably all three, and additional studies are

required to answer the question. People with HIV appear to have significant abnormalities in bone metabolism whether or not they are receiving ARV. It is important to understand bone as living tissue and treatment similar to HIV- patients with nutritional supplementation of Calcium and Vitamin D and weight bearing exercise is recommended. Hormonal replacements and medications that aid the formation of bone may also be indicated.

A poster presentation by C. Heiser and researchers at Creative Clinical Solutions, Geneva, Illinois, presented results of a prospective study of 20 men to test the effect of acidophilus, soluble fiber and L-Glutamine on Nelfinavir related diarrhea. The control group used Loperamide (LOP) alone to control diarrhea. The 12-week study showed that natural products and dietary methods were effective in controlling diarrhea not only in the group receiving them, but in patients who were unable to control diarrhea with LOP alone. CTAC continues to advocate for larger clinical trials to build the evidence base for these interventions.

The issue of sexual dysfunction (SD) was examined by Dr. J. Rueda and colleagues at the Center for Infectious Diseases and AIDS Assistance (CIAS) in Argentina. This is a well known but little discussed side effect of life with HIV. 72 HIV+ males and 19 HIV+ females were interviewed using a comprehensive questionnaire during a period of 4 months. As with bone loss, there may be underlying conditions which affect the general population, e.g. cardiovascular disease or the use of medications such as anti-depressants. In the HIV literature, SD is reported in regimens containing RTV, SQV, IDV, NFV, all PIs. It was found that patients reported SD manifestations consistently after initiating HAART. The study concluded that 1 of every 3 HIV+ patients experiences SD. The incidence between males and females was insignificant. Men complained most of erectile dysfunction (ED) and diminished libido (DL), while DL was the most frequent problem for women. Data were analyzed between the subjects and non-AIDS statistics which showed the significance of SD in the HIV and HAART groups. In the general population, SD is known to affect less than 5% of men under 40, however, in this study, that percentage was significantly higher at 67%. This study made no mention of how treat patients with SD, but further studies are clearly required.

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IMMUNE BASED THERAPIES

The jury is still out on whether STIs can stimulate HIV immunity and several presenters stressed the general need to acquire more knowledge about the immune system. Dr. Brigitte Autran of Hôpital Pitié-Salpêtrière, France spoke of the limits of immune reconstitution with ARV therapy alone. Although viral load reduction allows reversal of immune suppression related to HIV infection and restores defenses against opportunistic infections (OIs), immunity against HIV itself does not appear to be improved.

The French have long been proponents that the immune system ought to be a prime therapeutic target. One of the most studied immunotherapeutic agents is Interleukin-2 (IL-2), and several studies provided new information. Dr. Autran's work suggests that one effect of IL-2 is to stimulate the activity of the remaining thymus in HIV-infected individuals. This may restore immune capacity with repertoire diversity (broader capacity for fighting disease).

Dr. Christina Katlama presented week 80 data on the ILSTIM Study, the goal of which was to evaluate the capacity of IL-2 to increase the CD4 count in patients on HAART with CD4<200/mm³ and thereby reduce the likelihood of OIs. 72 patients were randomized to receive HAART or HAART + IL-2 in cycles of treatment. After 24 weeks, IL-2 was offered to all participants. During the first 24 weeks, the IL-2 group experienced a statistically significant increase in CD4 cells compared to the HAART alone group with 81% vs. 33% achieving over 200 CD4s. Dr. Katlama said the trial was not designed to determine if clinical benefit was associated with higher CD4 increases. That question is being addressed in other trials (SILCAAT and ESPRIT).

One study by Dr. Albert Wu from John Hopkins University looked at the tolerability of IL-2. This study assessed quality of life (QOL) for 150 patients on HAART alone or in combination with IL-2. As expected, QOL scores in the IL-2 group dipped at 5 days when patients experienced fever, body pain and flu-like symptoms. They improved over time, however, to a point where the researchers concluded that a significant QOL benefit was seen in the IL-2 group at the end of 40 weeks of intermittent therapy. Patients, not surprisingly, preferred this to the alternative of an AIDS defining illness. Wu suggested that patients either became more accustomed to the side effects over time, or managed them better.

Dr. Anne Sullivan presented data from a subset of the UK Vanguard Study. While too small a study to be reliable, her group showed that viral load increases during treatment with IL-2 were temporary. Once again, further investigation is warranted.

On other fronts, Dr. R. Pomerantz spoke of upcoming trials to test Prostratin, a Samoan plant derivative, which may act as a stimulatory agent for latent virus in reservoirs. This was discussed in the context of the challenges of HIV eradication.

SUMMARY

This report attempts to summarize highlights from the first IAS conference on HIV Pathogenesis and Treatment. CTAC is engaged in regular discussions with pharmaceutical companies involved in HIV drug research and development. CTAC advocates on issues of research priorities and methods as well as issues affecting access to drugs. The companies who are developing the experimental drugs discussed in this article are as follows: Tipranavir (TPV) - Boehringer Ingelheim, Atazanavir (TAZ, BMS 232632) - Bristol Myers Squibb, Tenofovir DF (Tenofovir disoproxil fumarate) - Gilead Sciences, (TDF) T-20 and T-1249 - Hoffman La Roche and Interleukin-2 (IL-2) - Chiron Sciences. CTAC will continue to work with these and other companies for the development of better treatments and for access to those treatments by those who need them. Our attendance at the Conference was assisted by an unrestricted education grant from GlaxoSmithKline and Shire BioChem and we thank them for their support.

For further information about the conference, visit www.aids2001IAS.org. ■

MATERNAL HIV TRANSMISSION In Ontario

by Enrico Mandarino

In November 2000, The Canadian Treatment Advocates Council (CTAC) invited treatment activists from across Ontario to come together to decide on treatment advocacy issues in Ontario and priorities to work on for 2001.

One of four committees formed was a Formularies Committee. This committee will look at issues relative to the Trillium Drug Program, including access to medication, and timely approval of drugs on the formulary.

CTAC Ontario Network's Formularies Committee has organized representatives from ACT, CATIE, OAN, Voices of Positive Women, Sick Children's Hospital and The Toronto Hospital, and other treatment activists across the province, to join forces to develop an advocacy plan to help expedite the process of getting medication to HIV positive pregnant women.

In January 2001, Dr. Sharon Walmsley and Mr. Bob Burgoyne from The Toronto Hospital sent a letter to the Ontario Minister of Health regarding maternal HIV transmission. Many women in Ontario are diagnosed with HIV during pregnancy and need HIV medication right away. Not only do these women have to cope with all the implications and struggle with the crisis stage of their diagnosis, they must also deal with the cumbersome application process and gather proper documentation. In addition, many of these women have to wait several weeks before being able to access urgently needed medication. The letter asked the Ministry of Health for assistance to fast-track newly diagnosed HIV positive women and expediting the application process. The response from the Health Minister did not address the concerns raised in the letter, so it was agreed that advocacy work needed to be done on this issue.

"There has been an increase in maternal HIV transmission in Ontario," state Drs. Stan Read and Susan King at The Hospital for Sick Children in Toronto. One possible reason for this may be that there are multiple care providers in Ontario and no one seems to be connected to the proper channels in order to prevent this from happening. Other factors preventing women from getting the proper medication may be how care is provided and communication problems. Statistics from the last 10 months

show that there are 8 new infected babies in Ontario, and most of the mothers are African or Caribbean born.

The issue was brought forward to the Pre-Natal Testing Committee, of which Dr. Stan Read is a member. Dr. Read then brought the issue forward to The Ontario Advisory Committee on HIV/AIDS (OACHA). He, along with Dr. Anita Rachis and Frank McGee (**IS HE STILL THE ONTARIO MIN OF HEALTH? INCLUDE HIS TITLE**) then met with people at the Trillium program who were very sympathetic to the issue of maternal HIV transmission. After the meeting, the Trillium Program agreed to facilitate a fast tracking protocol / process which can be initiated through a doctor's office. Once an HIV positive pregnant woman is identified and eligible for Trillium coverage, she will be able to access medications within 24 hours of submitting the completed application. The AIDS Bureau is planning to produce a flowchart which will categorize the different factors for Trillium eligibility and steps to follow in order to obtain Trillium coverage.

The next step for the committee is, once it is received from the Trillium Program and the AIDS Bureau, communicating the new protocol throughout Ontario. In addition, a major issue on which the committee will continue to work is policy changes at the ministerial level. While the committee has been successful in obtaining quicker access to medications for women who are eligible, there are still many women who remain ineligible for Trillium coverage, yet still need the medications, including those who do not have immigration status.

If you would like more information on the work that has been done or are interested in getting involved in this issue, please contact the CTAC office at 416-410-6538. ■

COMMITTEE AND PROVINCIAL REPORTS

COMMUNICATIONS COMMITTEE

by George Clark-Dunning

The Communications Committee is one of CTAC's busiest committees, and encompasses both the Newsletter and Website committees. The Newsletter Committee meets once a month and produces this newsletter four times a year. The committee is currently seeking an editor to assist with the production of the newsletter. In addition, the Website committee has begun the process of the development of a website and is confident that the CTAC website will be launched within this calendar year.

TERRITORIES

by Lelah Ngeruka

The local AIDS service organization in Yukon has changed its name from AIDS Yukon Alliance (AYA) to Blood Ties Four Direction Centre. This organization has grown and now receives funding for HIV/AIDS and Hepatitis C work. The name change allows the Centre to incorporate future work related to other blood born diseases into its work plan. It has been difficult networking with people in the North West Territories and all of the organizations that I have contacted are no longer functioning. My work continues as I try and find connections in the NWT. At this point I am forwarding pertinent information to Blood Ties or the Communicable Disease Unit.

ALBERTA

by Bob Mills

CTAC, along with the Alberta Community Council on HIV (ACCH), HIV Edmonton, Living Positive and Central Alberta AIDS Network Society (CAANS), held a media conference on Tuesday August 21st at the Fairmont Macdonald Hotel in Edmonton. The theme of the media release was increasing the Canadian HIV/AIDS Strategy.

The Federal Liberal Caucus, numbering 200, met in Edmonton the week of August 20th with the first event being the announcement of opening of a Canadian International Development Agency (CIDA) Regional Office here in Edmonton. Our media conference took place one hour before opening remarks by the Honorable Anne McLellan and the Honorable Maria Minna, and was held in the same venue. This was a first in a series of public media campaigns to increase the strategy from its stagnant \$42.2 million commitment.

I attended the CIDA Regional Office event that included a number of workshops aimed at educating the Edmonton public and Non-Governmental Organizations regarding how to access individuals and resources in the new office. There were introductions to staff and to the new director of CIDA Regional Office in the Prairies.

I also attended a Liberal Caucus sponsored BBQ at Fort Edmonton Park on August 22nd, 2001, where there was a further program of announcements of Federal support projects for Alberta and the Edmonton region. Most of the Federal Liberal Ministers were in attendance. I took every opportunity I could to mention our media conference that occurred the day before.

The ACCH's quarterly meetings will take place October 1-4, 2001, at a retreat venue outside of Red Deer. Kevin Midbo is the new chair of ACCH.

NEWFOUNDLAND AND LABRADOR

by Philip Lundrigan

The Newfoundland and Labrador PWA Network (NLPWAN) will hold its 3rd annual meeting on the weekend of Oct. 5-7, 2001. The meeting will be held in St. John's, Nfld. and is open to all people in the province who are living with HIV/AIDS. The weekend will include a treatment workshop presented by the Canadian AIDS Treatment Information Exchange (CATIE), as well as guest speakers. The major advocacy issue for discussion by the Network will be the Provincial AIDS Strategy. For more information, contact Philip Lundrigan, CTAC provincial representative, at the numbers listed, or by calling the CBN HIV/AIDS Interest Group at (709) 596-4433 or toll-free in Nfld. and Lab. (877) 596-4433.

ONTARIO

by Enrico Mandarino

On Sunday November 4th, 2001, CTAC, working together with the Ontario AIDS Network, have designed a one-day workshop which includes skills building sessions and an opportunity to work on advocacy issues in Ontario. People who attended last year's inaugural joint workshop between the OAN & CTAC formed four working committees: Ontario AIDS Strategy, Formularies, Care Shortage and Dental Care committees. There will be an opportunity for these working groups to connect and discuss the issues on

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CHAIR'S REPORT

by Louise Binder

Since the last newsletter, CTAC's Board has been working on some structural changes that we believe will enhance the effectiveness and efficiency of our work. One of these is a move to a Chair and Vice-Chair Executive structure rather than a Co-Chair approach. This decision coincided with Tom McAulay's decision to step down as Co-Chair. As his Co-Chair, I was asked by the Board to assume the position of Chair until our Annual General meeting in October, which I was honoured to accept. On behalf of all of the CTAC Council and its partners, we would like to thank Tom for his foresight in recognizing the need for an organization like CTAC and his ongoing support to get it up and running. Bob Mills has assumed the new position of Vice-Chair, Darren Greer has taken over from Bob as Secretary and Tony Di Pede remains our Treasurer. On behalf of the Council, I thank them for taking on these positions in the organization.

The Board is considering some other structural changes based on constructive feedback received from Health Canada during its most recent funding process. Additional information focusing on additional changes will be forthcoming.

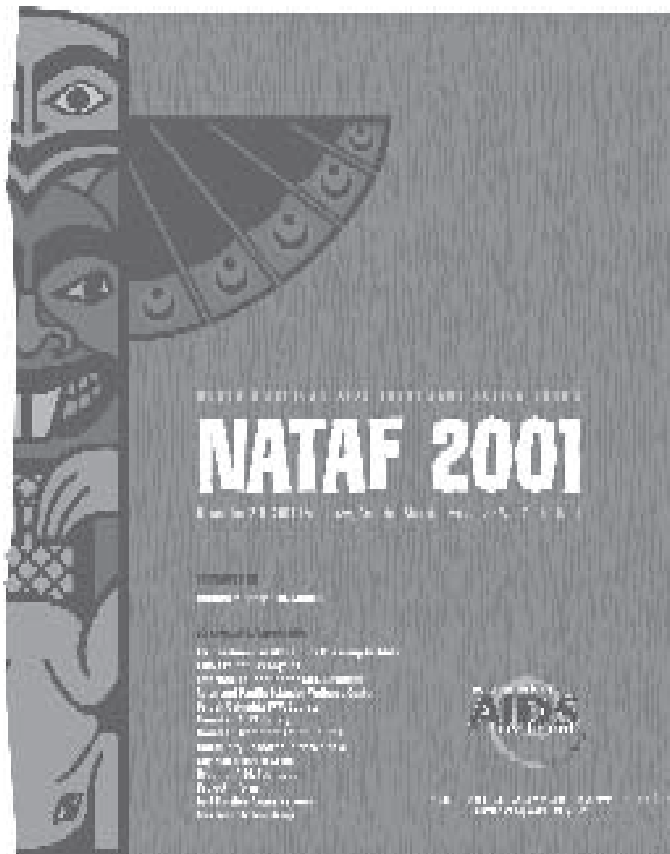
CTAC has been busy on a number of fronts since the last newsletter. Its policy paper on drug pricing has been completed and is available to all of you who have not yet received it. This paper will form the basis for CTAC's work in the area of policy development and education.

In addition, CTAC has received a substantial amount of the funding required to launch its research project on methods for obtaining post drug approval information from consumers about their experiences with antiviral and other drugs. This information will inform CTAC's policy development work in the area of what a consumer-centred post approval surveillance system for Canadians should contain.

Many of CTAC's Board members attended the Canadian HIV/AIDS Skills Building Symposium which was held in Montreal in July. CTAC had an information table where copies of our latest newsletter and policy papers were made available.

Another exciting experience for CTAC was its accreditation to participate in the United Nations General Assembly Special Session on HIV/AIDS. In fact, Bob Mills was a member of the Canadian government delegation to the UN. The Declaration of Commitment on HIV/AIDS, agreed to on the General Assembly floor, will form part of the policy work of the Canadian HIV/AIDS community, including CTAC, to ensure that Canada commits to the necessary resources to meet its obligations in the Declaration.

That's a brief update of some of our recent work. Please feel free to contact me through our CTAC office if you have any comments or want to get involved in any of our many programmes and projects. ■



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which they have been working, and to formulate priorities for next year. There will also be a session on "telling your story," the pros and cons, do's and don'ts of using your story to educate and to advocate. Part of the day will also include the election of the Ontario CTAC Representative. To find out more information about this day, register or apply for scholarship, please contact: phaprog@interlog.com, ricom@attcanada.ca or 1-800-839-0369 x 304. Thank you to the Formularies Committee who have put a lot of work into helping pregnant women in Ontario get quicker access to HIV medication. Please see full report in this issue. ■

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A television show has been produced about Louise and its first air date is October 29 10:00 pm-10:30 pm EST on Vision TV. Be sure to tune in!

CALENDAR OF EVENTS – FALL/WINTER 2001/2002

● October 1st, 2001**Alberta Community Council on HIV Meeting and Skills Building (retreat)**

Sylvan Lake, Alberta

Contact: Jennifer Vanderschaeghe at jen.acch@home.com or (403) 314-0892

● October 5th-7th, 2001**Newfoundland & Labrador PWA Network (CTAC Nfld. & Lab.) Meeting**

St. John's, Nfld.

Contact: Philip Lundrigan at philip_1@nf.sympatico.ca

● October 13th-16th, 2001**Canadian Treatment Advocates Council Annual General Meeting and Skills Building**

Montreal, Quebec

Join CTAC for a day of skills building on October 15th! Contact us for more information at ctac@sympatico.ca or (416) 410-6538

● October 27th-31st, 2001**10th International Conference for People Living with HIV/AIDS**

Port-of-Spain, Trinidad

Contact: website at www.gnp-plus.net/trinidad/index.html

● November 2nd-3rd, 2001**Ontario AIDS Network (OAN) PHA Caucus Meeting**

Toronto, Ontario

Contact: phaprogs@interlog.com or 1-800-839-0369 x 304

● November 4th, 2001**CTAC/OAN Skills Building day**

Toronto, Ontario

Join CTAC and the OAN for a day of skills building in Toronto!

Contact: phaprogs@interlog.com, ctaontario@home.com or 1-800-839-0369 x 304

● November 5th-6th, 2001**Ontario AIDS Network (OAN) Membership Meeting**

Toronto, Ontario

Contact: phaprogs@interlog.com or 1-800-839-0369 x 304

● November 16th, 2001**Canadian AIDS Treatment Information Exchange (CATIE) Annual General Meeting and Gala Dinner****November 17th-18th, 2001****Natural and Holistic Approaches to the Treatment of HIV/AIDS**

Toronto, Ontario

Contact: CAMConference@catie.ca or 1-800-263-1638 x 291 (French x 390) to receive scholarship information and a conference kit

● December 1st, 2001**World AIDS Day**

Contact your local ASO for events in your region.

● December 2nd-5th, 2001**National AIDS Treatment AIDS Advocates Forum 2001**

Vancouver, British Columbia

Contact: website at www.nmac.org/nataf/2001/welcome.htm

● February 5th-8th, 2002**Alberta Community Council on HIV Meeting and Skills Building**

Edmonton, Alberta

Contact: Jennifer Vanderschaeghe at jen.acch@home.com or (403) 314-0892

● March 14th-15th, 2002**Alberta Harm Reduction Conference**

Red Deer, Alberta

Contact: Phil Rauch at edcaans@look.ca or (403) 346-8858

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