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THE AIDS CRISIS ISN'T OVER !

A BRIEF SUBMITTED TO THE PARLIAMENTARY AD HOC COMMITTEE ON AIDS

NOVEMBER 1992

AIDS ACTION NOW!

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WHO WE ARE

AIDS ACTION NOW! is a Toronto-based organization which represents people living with AIDS and HIV. We fight for improved treatment, care and support for people living with AIDS and HIV infection. We work to transform HIV infection into a chronic manageable illness by ensuring that the research, health care and social service systems deliver optimal care.

Its Treatment Access and Research Committee, which has developed this brief, studies drug research, licensing and access in Canada.

AIDS ACTION NOW! receives no government funding.

1.0 Introduction

We are pleased that the Ad Hoc Parliamentary Committee is examining the federal response to the AIDS crisis. Canadians continue to die every day from AIDS--mostly young people who, had they lived would have been able to contribute greatly to Canadian society. And every day more Canadians become infected by the HIV virus at the same time as community groups are not funded to deliver vital prevention education. Patients and doctors alike lack adequate information on treatment options and access to treatments remains a serious problem. The high costs of AIDS drugs remains a very significant barrier to access to adequate treatment. Canada's research initiatives, both in basic science and clinical studies, are weak compared to most developed countries. Many people with HIV are made particularly vulnerable by poverty, youth, gender, geography, and sexual orientation. The federal government has it within its power to address most of these problems but its efforts have been sadly inadequate to date. We are hopeful that the end result of your examination will be a revitalized National AIDS strategy, supported by adequate financial resources to confront a continuing crisis.

This committee's efforts were very important in the development of Canada's National AIDS Strategy, reflected in the documents "HIV and AIDS: Canada's Blueprint" and "Building an Effective Partnership: The Federal Government's Commitment to Fighting AIDS". The committee's report on "Confronting A Crisis" contains many valuable recommendations. However many of these recommendations have not been implemented. We attach a list of those recommendations in your report which we feel have not been adequately implemented (Attachment 1) and would encourage you to ask those expert witnesses who appear before you to provide answers to the questions which we have raised. **We would urge the federal government to implement the outstanding recommendations of the committee's report**

In this paper we will address the crisis that has been allowed to develop and detail key problems in research, treatment access and management, and other federal issues. We will outline an action plan

of concrete recommendations which we believe should be incorporated into a revitalized strategy.

2.0 Research

The amount and direction of HIV/AIDS research is a continuing problem. Little basic research is conducted in Canada; clinical research is directed solely by pharmaceutical agendas; and the needs of PLWA/HIV are largely neglected.

2.1 Basic Research

Most basic research in AIDS is done outside of Canada.We have few immunologists and virologists in Canada and fewer still with an interest in AIDS. Moreover there is little funding available for these few experts. The Medical Research Council of Canada pays only lip service to AIDS research and the National Health Research and Development Programme is underfunded but expected to do everything, including funding students to become our pool of experts in the future. **We would recommend that the federal government provide sustained and dedicated funding to the Medical Research Council and the National Health and Development Programme for AIDS research.**

The Canadian Association for HIV Research recently released a publication entitled "Towards an HIV/AIDS Research Agenda for the 1990's" which identified the lack of long term funding as the major obstacle to conducting HIV/AIDS research in Canada. The report states the Canada is spending 60% less on research and other key areas on a per HIV capita basis than the US and Australia, surely an embarrassment to all Canadians. The report points out that there is little private sector financing available in Canada and correspondingly more need for government to make a significant commitment to AIDS research. **We strongly support their call for Canada to make a clear commitment to long-term sustained funding to AIDS research at least proportionate to the population base and scale of the epidemic in Canada.**

2.2 Clinical Research

2.2.1 Canadian HIV Trials Network (CTN)

The CTN was established and funded by the federal government to facilitate the development and implementation of clinical trials of HIV therapies and vaccines. Its mandate includes working in close cooperation with the people affected by HIV and involving them in all aspects of the CTN's operations. AIDS Action Now! has in fact had few dealings with the CTN but the following recital of our experiences may be instructive with respect to how well the CTN has fulfilled its mandate.

We first approached the CTN in August 1991 asking them to review a draft publication on clinical trials and we subsequently requested financial assistance for its publication. A copy of this publication, available in both official languages, is attached for your information (Attachment 2). While the CTN did provide us with some comments on the draft they were unwilling to provide us with $2000 from their budget for its publication unless we were willing to give up editorial control. The result was that we had to obtain funds elsewhere. The booklet has been a great success and we are now proceeding with a third printing.

At a workshop in October of 1991 we proposed establishing a working group of CTN and community representatives to develop a set of ethical principles which would govern clinical trials and requested the views of the CTN on their overall priorities. The CTN responded that they would seek steering committee input on the working group proposal but there has been no further communication from them on this subject. Some of our concerns on research ethics are set out below.

As to the development of priorities, the CTN indicated that it could support all valid and worthwhile protocols and did not yet need a mechanism of determining priorities. Recent discussions with CTN representatives confirm that even today the CTN is an organization with, in their words, "no vision".

Our relationship with the CTN has improved recently. In May 1992 the CTN sponsored a skills development workshop on protocol

development and design, and drug licensing. This provided us with an opportunity to present a series of recommendations to them. We have recently responded to their Ad Hoc Group on Informed Consent, a subject which, as outlined below, merits attention. Finally, we have been involved in discussions with the CTN on a workshop for next winter on research priorities from a global perspective with presentations on local initiatives.

A serious problem with the CTN, which we are hopeful will soon be addressed, is the lack of meaningful community representation on its committees. There have been three community representatives on the steering committee and scientific advisory committee of the CTN, but they perceive their participation, in their words, as largely "tokenistic" and this is how they are perceived by the HIV community at large. While in 1989 the US AIDS Clinical Trials Group created a community constituency working group and followed this in 1990 by expanding each and every committee and working group to include patients and community constituents, the CTN is only now creating a Community Advisory Committee. We hope that this committee will result in CTN initiatives that are in touch with community needs and expectations. Ideally we would like to see such a committee operate independently from the CTN and offer advice to the CTN, community initiatives and pharmaceutical companies that elect not to conduct trials through the CTN. **We would recommend that the federal government should re-allocate the monies for this committee so that a truly independent committee might be established.**

Some of the pharmaceutical companies with whom we have met have expressed views that they see the CTN as an additional layer of bureaucracy providing them with few benefits. In your questioning of pharmaceutical company witnesses we would suggest that you ask them what they see as the value of the CTN and how trials can best be coordinated and facilitated.

We understand that the US offer for Canada to join the ACTG was never acted on. Notwithstanding the many problems with the ACTG, it is an intriguing option. How does it help people in Canada with HIV to be isolated from North American research efforts? Are there ways in which Canadian efforts can be tied in more closely with those elsewhere in the world? An excellent example of this is the community research network discussed in the next section. What

are the views of agencies like the ACTG and leading researchers on the contribution CTN trials make to the advancement of science?

We recommend that your committee study the costs and benefits of the CTN and potential alternate vehicles. You should address what measures the CTN might take to better perform its mandate.

2.2.2 Community Research Initiatives

We are fortunate in Toronto to have the Community Research Initiative of Toronto(CRIT). The American Foundation for AIDS Research provided the original funding for CRIT and continues to provide them financing. CRIT brings together twenty primary care physicians treating about 3000 patients. Its goal of CRIT is to conduct trials of promising treatments that are ethically acceptable. CRIT attempts to engage the community in determining its research priorities through its community advisory board and by participation in our Treatment Access and Research Committee. Among its innovative projects are an observational database, a directory of clinical trials in Toronto, and a treatment/trials counsellor. With its 50 American counterparts it participates in the Community-Based Clinical Trials Network.

We would recommend that the federal government consider CRIT as a model for other community research initiatives elsewhere in Canada. We would also recommend that federal financing be provided to support such initiatives.

1.2.3 Research Ethics

One of the greatest difficulties we encounter in meetings with pharmaceutical companies on the design of trials is to persuade them that it is not ethical to coerce participants into trials by denying them access to the treatment in question through EDRP or compassionate arms. There is only one good reason to join a trial and that is to assist all of us to learn whether a drug is efficacious. People who are forced into trials because they see the trial as the only way to access the drug do not make good participants. In order to ensure that they get the drug they may share their drugs with others, change their dose, test the drug to see what they are getting, drop out of the trial when

something else comes along or take other drugs at the same time without informing the researchers. All of this is well documented in the United States. This behaviour may render the trial results useless with serious cost consequences to the drug company and of course more serious results for the HIV community. We want to see trials designed so that they attract and retain participants who will seriously follow the protocol so that valid information will be generated.

We would recommend that the federal government guarantee that people are not coerced into trials in a desperate attempt to receive treatment. Phase 2 trials should not be permitted unless compassionate access is provided at the same time to anyone who seeks access to the therapy in question. A company which fails to comply could have its approval to market other drugs in Canada suspended. Such a guarantee could be provided through the federal government's drug regulatory powers.

Another ethical problem in clinical research is the failure to obtain truly informed consent from trial participants. Consent forms are often in too complicated language, there is too much variability between institutions, there is a need for languages other than English and French, etc. One of the biggest problems is that patients are not made aware of their options in accessing the treatment they wish. In our opinion the consent form should clearly spell out these options. We have expressed these views to the CTN ad hoc working group. Again, **we would recommend that the federal government's regulatory powers be used to ensure participants give truly informed consent.**

2.3 Research Priorities and Coordination

Any organization needs to orchestrate its resources and establish its objectives, goals and priorities. As we indicated above, the CTN is an organization without a vision. Clearly they should be at work establishing a research agenda. For any organization involved in AIDS research we might ask: What attention is being given to immune boosters, opportunistic infection prophylaxis and treatments, developing a better understanding of the pathogenesis of the disease, the treatment of neglected populations, and non-

allopathic treatment options? Should neglected research areas such as wasting, neurology and immune-based therapies receive special support? What should Canada's role be in searching for cytokine inhibitors and synthetic immune modulators? What is the point of developing prophylaxis and better treatment for opportunistic infections when these measures simply allow someone to survive long enough to develop lymphoma, visceral Kaposi's sarcoma, wasting syndrome or neuropathology?

The failure to develop a research strategy is unfortunately not unique to Canada. An enormous number of new leads, insights and opportunities have been uncovered in recent years, but nowhere does there seem to be a body responsible for the big picture and making sure the new leads and insights are followed up. Who is taking the steps to avoid duplication and who makes sure that the questions raised in international conferences are pursued and answered? Dozens, if not hundreds, of promising leads generated by recognised scientists get published every year in journals and then sit unused because there is no mechanism to research them further. University scientists can seldom afford to move a drug into clinical development, and usually no company chooses to do so. Pharmaceutical companies will choose to develop agents which they perceive to be of significant commercial value. What is needed is an unbiased professional team that can scan these leads and make sure that the promising leads get attention.

Coordination of research efforts is another serious problem. Different disciplines need to better communicate with each other. We are looking to the scientific community to minimize suffering and pain, to keep people alive with a reasonable quality of life and to cure a disease -- and in the process make a giant leap forward in the treatment of all diseases. ACT-UP New York and other bodies have proposed the creation of a global facility to take leadership in the fight against AIDS. **We would urge the federal government to endorse and take a lead role in facilitating and funding the establishment of a global facility that would perform this oversight and coordination function.**

Another failing of the Canadian research effort should be highlighted. The CTN does not have sufficient funds to conduct trials independently. The kinds of substantial private research funds that are available to other diseases are not allocated to HIV. We believe that if industry sponsorship cannot be found for trials which are high

priorities for HIV communities, then the CTN or other appropriate bodies should be in a position to help them go ahead. The ACTG provided financing for a comparative trial of septra and pentamidine as a prophylaxis for PCP. Both drugs were known to be efficacious but this trial demonstrated that septra was significantly more effective and have resulted in changes to treatment regimens that undoubtedly have extended and improved the quality of living for many. **We would urge the federal government to provide this support to the CTN or other appropriate body.**

Finally we would note that there is a serious problem in the failure of organisations like CTN, CRIT and the Toronto HIV Project Centre, as well as hospital-based researchers, to communicate and coordinate initiatives within the same city, not to mention on a national and international level.

3.0 Treatment Access

Significant barriers continue to exist in making treatments available to people who need them. These include inadequate funding, particularly to cover the costs for the more expensive treatments which are not covered by health insurance, ineffective EDRP mechanisms and the refusal of pharmaceutical companies to release experimental treatments.

3.1 Emergency Drug Release Program (EDRP)

Since Canada is a small country it is critical that a mechanism like EDRP exist to ensure that Canadians can access drugs under development in other countries. EDRP should function to make any experimental treatment in use elsewhere in the world available to any Canadian who would like to use it. There are, however, several obstacles to making this mechanism as effective as it should be.

EDRP does not have adequate resources to perform its job. We know of one of our members who wished to obtain thymosine-alpha one from Italy. Although he had provided extensive references in the medical literature, the EDRP officer in charge told him that he didn't have time to go to the library to satisfy himself with respect to the drug because he was required to spend the day answering the telephone. Complaints to a senior officer ultimately brought results

after a two month wait. It appears that there is a problem with respect to training and allocation of EDRP staff. We understand that the unit in which EDRP is located is staffed by 4 persons and that the comparable unit within the Food and Drug Administration in the US consists of 87 people. A recent regulatory change providing for block release of EDRP drugs should help in making some of these drugs available. **We would recommend that increased resources be provided to the EDRP so that its staff may adequately perform its duties and that priority be established for life-threatening diseases.**

A major problem with the EDRP as it is currently structured is that it is essentially a passive vehicle. It acts as an intermediary between a drug manufacturer who has agreed to make the drug in question available and a person with HIV (through their physician) who wishes to use the drug for treatment. What is needed is an advocacy power so that EDRP may be more aggressive in making experimental treatments available to people who want them. There were instances in the past where Abbott Laboratories refused to release clarithromycin, an antibiotic used in the treatment of MAC (and now approved) despite indications that EDRP would approve requests for it. **We would recommend that an advocacy power be added to the EDRP mandate and that some disciplinary mechanism, such as suspension of a company's marketing approval for other drugs, be provided to give pharmaceutical companies incentive to comply with an EDRP request for release of an experimental treatment.**

There have also been instances of doctors refusing to prescribe experimental drugs or make efforts to obtain them due to lack of familiarity with how EDRP works. **We would recommend that EDRP continuously communicate its services and also produce regular updates on HIV/AIDS drugs available through the EDRP.** It is a mechanism with tremendous potential to improve the lives of people with AIDS/HIV. Too few patients understand how to access treatments through the EDRP and it is simply not working to its full potential. It would also be helpful if provincial medical associations and colleges urged members to make greater use of the EDRP.

Finally, there have been instances where the cost of drugs obtained through the EDRP has been prohibitive. Again clarithromycin is an example. **We would therefore recommend**

that EDRP be given the authority to oblige pharmaceutical companies to release experimental treatments free of charge. Alternatively, the federal government should pay for these treatments.

3.2 Drug Regulation

For the reasons indicated above **we urge the federal government to make its approval of investigational new drugs conditional on the provision of a compassionate arm coincident with the Phase 2 of the scientific trial. The compassionate arm should be available to anyone who wishes to obtain the drug but does not wish to participate in the formal trial.**

We are pleased that the drug regulatory process in Canada is undergoing review. We have provided our views on this review to Dr. Gagnon (attachment 3) who was expected to submit a report to the Minister by June 1992. To our knowledge this report has not yet been released. One of our principal recommendations is that **the federal government should take a lead role in bringing about the international harmonization of the drug approval process.** Any unnecessary delay in processing drug patents and licenses slows access and discourages pharmaceutical investment. However, while looser standards might ease access for some, the potential for exploitation of a vulnerable population is immense. Canada must strike a delicate balance of rationalizing the process while maintaining scientific rigor and adequate standards.

There is a growing amount of scientific evidence that early intervention (i.e. in people with T counts above 500) provides significant benefit. AIDS Action Now! wrote to the Bureau of Human Prescription Drugs in May 1992 concerning the effect of the labelling of approved drugs on the access of immuno-competent people with HIV to the treatments they desire. Labels on azt and ddi indicate that these antiretrovirals should be used by people who are HIV positive with T counts under 500. A survey we conducted of Toronto primary care physicians indicated that half would not prescribe these drugs to immuno-competents. Accordingly **we would urge the federal government to re-label these drugs without reference to particular T counts.**

We are also concerned about the lack of medical expertise within the senior bureaucracy of Health and Welfare. Indeed the overall capability of the Department to perform its role should be examined, particularly if, as a result of the regulatory review, expedited approval is introduced. Should this occur, increased resources may well be necessary to provide the necessary approval and then to monitor the drug's continuing performance. **We would urge the committee to review the medical expertise of senior bureaucrats within Health and Welfare Canada and ensure that the department has the necessary resources to perform expanded duties as a result of any future regulatory reform.**

3.3 Drug Funding

The cost of drugs constitutes an enormous barrier to equitable access to treatments. For example, a month's supply of high dose acyclovir used as a prophylaxis for CMV costs about $700. A month's supply of fluconazole used as a prophylaxis for fungal diseases costs $270. The first month's supply of ganciclovir to treat CMV costs $1800. Bear in mind that a person with a low T count will be taking antivirals, opportunistic infection prophylaxis, and immunemodulators --perhaps 10 or 15 drugs-- as well as possibly treating a particular condition, and you can see that the total costs become exorbitant. Needless to say this burden puts most people in situations where they must make difficult choices-- give up work to go on welfare in order to have a health benefits card, use up savings or sell their house, choose between spending money on food or drugs, etc.

Many people with HIV and AIDS currently participate in trials or benefit from compassionate access for drugs under investigation. As these drugs get market approval some will undoubtedly have such high costs that many people with HIV or AIDS are denied treatments unless they receive government assistance. It is a paradox that once that these people who participated in the drug company's trial find themselves denied the drug once it has received market approval.

While we recognize that pharmaceutical companies spend enormous sums on the development of new therapies and must receive fair remuneration for these costs, it is not clear to us that these prices are reasonable. **We would encourage the federal**

government to satisfy itself through the Patented Medicines Prices Review Board that the prices of approved AIDS drugs are fair.

While we recognize that health is primarily an area of provincial jurisdiction, the Canada Health Act requires that health care be made available on a comprehensive basis to residents of Canada on uniform terms and conditions. At the moment Canadian provinces have different approaches to this problem. In Quebec the "malade sur pied" programme enables people suffering from chronic manageable diseases such as diabetes, cancer, cystic fibrosis and tuberculosis to receive needed medication from an external clinic at a cost of $2 per month per drug. This programme covers Kaposi's sarcoma, lymphoma and tuberculosis in AIDS patients but should be expanded to include other AIDS conditions. While most Canadian provinces do cover the cost of antiviral drugs, we fare poorly in comparison to European countries such as Denmark, Germany, France, Holland and Italy where the state covers 100% of all AIDS drugs. Accordingly **we would urge the federal government to work with the provinces to establish a mechanism so that 100% coverage can be provided to all Canadians living with AIDS. As drugs receive approval for marketing, assistance must be provided so that all people with AIDS have access to the treatments that they need.**

4.0 Treatment Management

PLWA/HIVs and their care-givers need and deserve up to date, culturally appropriate information on treatment options and strategies. Health care professionals need efficient, credible systems to update their knowledge and practices.

4.1 Treatment Information

One of the greatest disappointments in Canada's response to the AIDS crisis has been the failure to complete the AIDS Treatment Information System.(ATIS). It is truly scandalous that ATIS has been so mismanaged. This was a service which this committee recommended be developed on a priority basis. Unfortunately many who might have benefitted from this service are no longer with us. We remain even more strongly convinced that doctors and patients

need this service. **We would urge your committee to do whatever it can to ensure that ATIS becomes a reality.**

Federal government support to the National Network of Organizations of People Living with HIV/AIDS would enable it to coordinate treatment information initiatives among its members. Federal support of community groups is indispensable in providing information to people with HIV and AIDS. **We would encourage the federal government to provide financial support to the National Network of Organizations of People Living with HIV/AIDS and to local community-based initiatives like the Community AIDS Treatment Information Exchange of Toronto.**

4.2 Treatment Standards.

One of the problems we face is to encourage physicians to become aware and adopt the best practices and standards. It is important, for example, to adopt new diagnostic tools as they are developed. PCR is now available to measure viremia. A Dutch technique that measure syncytia inducing and non-syncytia inducing strains of virus was discussed at some length at the Amsterdam conference. Neither of these tools seems to have been adopted in Canada to assist physicians in planning patients' drug regimens. It is important as well to anticipate the direction of future treatments and ensure that Canada has the necessary facilities to provide these treatments. For example, CD8 expansion is a promising treatment for Kaposi's Sarcoma but there is no laboratory facility in Canada to do the necessary processing for this treatment. **We would urge the federal government to establish a mechanism whereby new diagnostic tools and necessary facilities for new treatments are available to patients and their physicians.**

It is important that patients also be aware of the best treatment and prophylaxis standards so that they may ask their doctors appropriate questions and ensure that they are getting the best possible care. AIDS Action Now! has developed a health care management document which outlines the best practices of leading HIV physicians. We hope to release this document in both official languages in mid-December. Treatment standards evolve and change as new drugs are tested and become available and as we learn more about how the immune system works. Living with HIV and AIDS sometimes means having to make important treatment decisions

based on incomplete information and adjusting those decisions over time. We have developed this document because we perceive a need for such information and because of the lack of leadership taken by the authorities.

Two federal authorities that have not measured up to our expectations are the Expert Advisory Committee on HIV Therapies and the National Advisory Committee on AIDS (NAC-AIDS). The terms of reference of the Expert Advisory committee make it clear that this committee should not only give advice to the Health Protection Branch on therapies but also develop guidelines on AIDS conditions like Kaposi's Sarcoma. We have no knowledge of this committee having accomplished anything to date. The NAC-AIDS committee is held to secrecy and there is under-representation of PLWA/HIV. Again we have no knowledge of what this committee has accomplished. These committees should be providing leadership. **We would recommend that you review the effectiveness of these committees and their contribution in leading Canada's fight against AIDS.**

5.0 Prisons

Sexual activity in prisons has finally been acknowledged and distribution of condoms has begun. This is a positive step. However much more needs to be done. The closed environment of prisons dangerously accelerates the risk of transmission through unclean needle sharing. Additionally, there are difficulties with access to testing, confidentiality, and basic care and support. What is needed now is a comprehensive strategy to effectively confront AIDS in the prison system. **We strongly endorse the strategy developed by Prisoners with HIV and AIDS Support Action Network (PASAN) and would encourage you to adopt their recommendations.**

6.0 Discrimination

In April 1991, the federal government announced that visitors with HIV would be treated as any other visitors to Canada. However lack of clarity has already led to cases where people with HIV have been arbitrarily denied entry. **A clear policy and education of immigration officials is urgently needed.**

Canada's practice of prohibiting immigration for people with HIV has been under review for two years. Arbitrary rejection of immigrants solely on the basis of HIV and any introduction of mandatory testing is unwarranted and discriminatory, and would be counter-productive to Canada's own education efforts. **Again a clear policy and education of immigration officials is urgently needed.**

The social stigma attached to AIDS deeply affects the lives of people infected with HIV and creates barriers to effective education. Despite repeated promises from the government since 1986, the Canadian Human Rights Act has not been amended regarding sexual orientation and the "duty to accommodate" people with disabilities. These changes would provide urgently needed leadership to counter prejudice and misinformation. **The Canadian Human Rights Act should be so amended.**

7.0 Financing

Providing adequate financial resources to implement a revitalized National AIDS Strategy involves making difficult choices in an environment of fiscal restraint and deep recession. And for people with AIDS inadequate support from government means limited access to treatments, inadequate care, and misery.

Finding the financial resources to fund the National AIDS Strategy means making choices among competing national goals. Is it absolutely necessary that the federal government spend $5 billion a year on subsidies to businesses of all sizes? Could some of these funds not be allocated to the National AIDS Strategy? What about the $4.0 billion spent on Armed Forces helicopters?

The NIH budget in the United States for AIDS programmes stood at $873,377,000 for 1993. The New York-based Treatment Action Group presented a detailed analysis of the US research effort at the Amsterdam conference. They found that significant underfunding was crippling the US government's efforts to develop treatments for AIDS/HIV and concluded that the AIDS budget should be doubled to $1.6 billion immediately. If Canada were to make a comparable contribution its AIDS budget should be approximately $160 million, a far cry from current levels.

8.0 Conclusion--Report Card

AIDS ACTION NOW! released a report card evaluating government response on ten key issues shortly before the National Strategy was first announced (Attachment 4). We gave Minster Beatty a generous passing grade on a National Treatment Registry and PLWA/HIV accountability, for a total of two out of ten. Since then the government has failed to fulfil its promise of speedy implementation of a National Treatment Registry and gets a failing grade on this item. Some progress has been made on travel restrictions, giving the government a total again of two out of ten. Clearly the National AIDS Strategy still fails people living with AIDS.

The deliberations of this committee provide the Minister and his officials an opportunity to indicate whether Canada will seriously commit itself to confronting the issues and needs posed by this deadly disease or face expanding tragedy for years to come.

9.0 Action Plan

Our recommendations provide a comprehensive framework for the government to take up its responsibilities.

The federal government should:

1. implement the outstanding recommendations of the Parliamentary Committee's "Confronting a Crisis" report.

2. provide sustained and dedicated funding to the Medical Research Council and the National Health Research and Development Programme for AIDS research.

3. make a clear commitment to long-term sustained funding of AIDS research at least proportionate to the population base and scale of the epidemic in Canada.

4. reallocate monies for the establishment of a Community Advisory Committee of the Canadian Trials Network(CTN) to a truly independent advisory committee which could provide advice to the CTN, community research initiatives and pharmaceutical companies that elect not to conduct trials through the CTN.

5. review the costs and benefits of the Canadian HIV Trials Network and alternate vehicles and address how the CTN might better perform its mandate.

6. adopt the Community Research Initiative of Toronto(CRIT) as a model for the establishment of community research initiatives elsewhere in Canada and provide financing to support CRIT and other initiatives.

7. endorse the principle that patients should not be coerced into clinical trials in order to obtain treatments and require, through drug regulation, that Phase 2 of a clinical trial should not be permitted unless compassionate access is provided at the same time to anyone who seeks access to the therapy in question. In addition, any company which fails to comply with this provision should have its approval to market other drugs in Canada suspended.

8. ensure that the informed consent form used in clinical trials in Canada clearly spell out the patient's options (EDRP, compassionate arms) in accessing the treatment s/he wishes.

9. endorse and take a lead role in facilitating and funding the establishment of a global facility of unbiased professionals that would take an overview of world research efforts, pursue new leads and insights, and assist in coordinating research efforts.

10. provide financing to the Canadian HIV Trials Network or other appropriate body to conduct trials independently of pharmaceutical companies with respect to questions which are of high priority to the HIV and scientific communities.

11. increase resources to the Emergency Drug Release Programme (EDRP) so that staff may adequately perform its duties, and establish priority to life-threatening diseases.

12. give an advocacy power to the EDRP and develop a disciplinary mechanism, such as suspension of a company's marketing approval for other drugs, to encourage companies to comply with an EDRP request for the release of an experimental treatment.

13. provide adequate resources to the EDRP to continuously communicate its services and to produce regular updates on available HIV/AIDS drugs.

14. give EDRP the authority to oblige pharmaceutical companies to release experimental treatments free of charge or alternatively provide funding to patients for these treatments.

15. take a lead role in bringing about the international harmonization of the drug approval process.

16. ensure that labels on antiretrovirals, including azt and ddi, do not specify any particular T-cell count maximum in order to ensure that immuno-competent persons with HIV who wish to take these drugs may have access to them.

17. review the medical expertise of senior bureaucrats within Health and Welfare Canada and ensure that the department has the resources available to perform its duties, particularly as these duties change as a result of regulatory reform.

18. satisfy itself that the prices of approved AIDS drugs are fair.

19. work with the provinces to establish a mechanism so that 100% coverage of drug costs can be provided to all Canadians with HIV and ensure that drugs are approved for marketing only if assistance is available so that all persons with HIV have access to the treatments that they need.

20. ensure that the AIDS Treatment Information System soon becomes a reality.

21. provide financial support to the National Network of Organizations of People Living with HIV/AIDS and local community-based initiatives like the Community AIDS Treatment Information Exchange of Toronto.

22. establish a mechanism whereby new diagnostic tools and necessary facilities for new treatments are available to patients and their physicians.

23. review the effectiveness of the Expert Advisory Committee on HIV Therapies and the NAC-AIDS committee and assess their contribution in leading Canada's fight against AIDS.

CONFRONTING A CRISIS

QUESTIONS ON THE IMPLEMENTATION OF THE RECOMMENDATIONS OF THE PARLIAMENTARY AD HOC COMMITTEE ON AIDS

(Numbers refer to recommendation numbers)

1 Why was no Special Joint Committee of Parliament ever established?

2 What consultative process was set up to advise on the implementation of the national strategy?

4 How many meetings of the Federal\Provincial\Territorial Advisory Committee have taken place since 1990? What has been accomplished?

8 Was the Departmental Working Group chaired by the Senior Assistant Deputy Minister of National Health and Welfare made responsible for co-ordination of the Departments AIDS¦HIV related activities?

9 Has their been greater consultation with PLWA groups since 1990?

10 Was the NAC-AIDS mandate changed to include public advocacy?

13 Was the recommended "comprehensive social and behaviourial research study" completed? If so what were the results?

14 Has there been an increase in Federal funding for biomedical research since 1990?

16 What present targeted education programmes presently have priority? Women? Youth? Ethnocultural communities?

20 What is the present state of the proposed National AIDS Education Strategy?

21, 26 Was Federal funding provided to the CPHA and community based groups for educational efforts?

23 Where is the Treatment Registry?

24 What is the state of Federal Provincial consultations on the provision of all AIDS/HIV drugs free of charge?

25 What Federal funding was provided to community based groups?

27 Did the Department of Health and Welfare produce a policy position on catastrophic rights?

28 Why has no conditional approval system been implemented?

30 What incentives have been provided to pharmaceutical companies to make experimental drugs available in Canada?

31 What has been done about liability questions facing doctors and companies around patients access to experimental drugs?

32 Sexual orientation has still not been added to the Canadian Human Rights Act?

36 Have all provinces established needle exchange programmes?

37 Have the 1989 NAC-AIDS prison recommendations been implemented?

38 Are bleach, needles and condoms presently available in all Federal Prisons?

40 What funding was provided to community groups for prison AIDS awareness programmes?

41 Did the Department of the Solicitor General address questions of the advantages of outside health care for prisoners?

43 What federal monies were provided to NGOs for participation in international forums?

44 What initiatives has the Federal government taken around international collaboration on drug trials?

45 Have immigration restrictions on HIV positive visitors been lifted?

46 What has been the Federal Government's funding commitment to the struggle against AIDS since 1990?

47 What funding proposals are planned for post March 1993?

48 Was CAS funding indexed to inflation?

September 1992

June, 1990

DEMONSTRATE!

National AIDS Strategy Announcement

Minister of Health Perrin Beatty will reveal his long-awaited National AIDS Strategy on Thursday, June 28, 1990 here in Toronto.

Has he listened to the demands of People Living with AIDS and HIV?

Join AIDS ACTION NOW! to grade Beatty's report.

Harbour Castle Westin Hotel
Bay & Queen's Quay Streets
THURSDAY, JUNE 28, 12:00 noon

PLWHIVs HAVE DEMANDED THAT THE NATIONAL STRATEGY INCLUDE:

	PASS	FAIL
National Treatment Registry Plans for the Registry should include adequate funding for immediate implementation	☐	☐
Government testing of promising treatments Promising treatments must be tested even though they might be unprofitable for pharmaceutical corporations	☐	☐
Ethical access to treatments Catastrophic rights and access to drugs independently of clinical trials	☐	☐
Accelerated care Promotion of accelerated care for PLWHIVs among health care professionals	☐	☐
Accountability PLWHIVs on all HIV boards and committees	☐	☐
Core funding for community groups Funding for these groups must be ongoing	☐	☐
Special needs in terms of education, prevention and treatment Programs for women, children, IV-drug users, prisoners and minority communities	☐	☐
Non discrimination Inclusion of sexual orientation in Human Rights Code	☐	☐
Anonymous HIV testing Support for anonymous testing in all provinces	☐	☐
No travel restrictions Support for removal of travel restrictions against PLWHIVs both coming into Canada and travelling internationally	☐	☐

LE GROUPE D'ACTION-SIDA

AIDS ACTION NOW!

517 College St., Suite 324, Toronto (Ontario) M6G 1A8 / (416) 944-1916

For more information please also refer to AIDS Action Now!'s AIDS and HIV Drug Trials in Canada: What You Need To Know. This booklet is available for $1.00 through AIDS Action Now!, 517 College Street #321, Toronto M6G 1A8, (416) 928-2206.