DIGNITAS

Canada: Fulfill Your Commitment to Increase Access to Medicines
Streamline CAMR

Dignitas International: Submission on Canadian Access to Medicines Regime (CAMR), Standing Committee on Industry, Science and Technology

Dignitas International was co-founded in 2003 by Dr. James Orbinski and James Fraser, Canadian medical humanitarians, health experts, and citizens indignant about the lack of access to medicines for millions of people. In collaboration with the Malawi Ministry of Health in Zomba District, Dignitas works to dramatically increase access to effective HIV/AIDS-related prevention, treatment, care, and support in resource-limited settings through medical programs and health systems strengthening. Dignitas has started more than 13,000 people living with HIV (10% of whom are children) on life-prolonging antiretroviral treatment (ART), tested more than 84,000 pregnant women for HIV, and trained hundreds of health care workers.[1] From 2010-13, Dignitas will scale its model of HIV services – integrated with primary care, health systems strengthening, and operations research – to five additional districts in Malawi, expanding its reach to 3.1 million people – a quarter of Malawi's population. CIDA and USAID are among Dignitas's donors, as are Canadian and US private donors, local and international foundations, and national and global research funding agencies. Dignitas has an operating budget in 2010 of CAD5.4million.

Let a streamlined regime maximize Canadian commitments at the WTO, to the Millennium Development Goals, and to The Global Fund to Fight AIDS, TB and Malaria, Dignitas and others – not work against these commitments.

The Global Fund, with contributions from donors including Canada, has put over 2.8 million people on AIDS treatment and seven million on TB treatment. Today, many more patients are ready to access life-prolonging antiretroviral treatment, and many more women are ready to access Prevention of Mother-to-Child Transmission (PMTCT) services – all of this is possible because of effective and affordable medicines, the will of the Canadian government and partners to provide universal access to treatment, and commitments of donor money to make it happen. Such progress is under threat, in part because of a lack of successful implementation of WTO TRIPS flexibilities and continued excessive patent protection, which leads to high drug prices, lack of needs-based drug development, and current underfunding of HIV/AIDS, TB and malaria – despite the recent laudable yet insufficient pledges from donor countries such as Canada. Meanwhile, of the 33 million people infected with HIV today, 42% of those in need of life-prolonging HIV treatment have access to it; 14 million people need these drugs now.[2]

We urge Canada to streamline CAMR and fix the flaws identified[3] so that the mechanism is simple and effective and can contribute to access to medicines for all.

Malawi is one of the world's least developed countries and has an HIV prevalence of 11.9% (UNAIDS, 2009) and 807 maternal deaths per 100,000 births (UNICEF, 2009), one of the highest rates on the African continent and in the world. From direct experience, Dignitas has an acute understanding of the need for a steady and reliable flow of affordable, quality medicines, including ART for HIV/AIDS and a range of treatments for HIV's twin epidemic, TB. We also know the life and death implications that result from governments' decisions regarding their commitments to global health. These decisions relate not only to funding to tackle global infectious diseases such as AIDS, TB and malaria; they also involve concrete judgments of whether to prioritize patients' lives over patent protection – a commitment that all World Trade Organization member states made in the Doha Declaration of 2001.[4]

Daily, we witness the positive impact of access to medicines on the lives of thousands of our patients and their families. We know that trade flexibilities, generic competition, and the availability of new and more effective medicines reduce mortality. They enable people to live longer lives and to contribute to their families, and their society and economy. We

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[1] See Annex I for more details on Dignitas's program.
[2] http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf.
[3] Bill C-393 is a Private Member's Bill introduced in the 40th Parliament, 2nd Session, to reform Canada's Access to Medicines Regime. Canadian HIV/AIDS Legal Network: "Making CAMR Work: Streamlining Canada's Access to Medicines Regime – Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-393," http://www.aidslaw.ca/EN/camr/documents/CHLN_BillC-393_INDUbrief_21Oct2010_EN.pdf; Professor Fred Abbott's November 19 submission to Senate Standing Committee on Banking, Trade & Commerce, http://www.aidslaw.ca/EN/camr/documents/Abbott_SenateBillS-232_ENG.pdf.
[4] The Doha Declaration, http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html.

also see how improving access to TB and HIV treatment directly improves maternal and child health, and empowers countries to build health systems that are capable of meeting other health challenges.

HIV/AIDS has impacts beyond the health of those populations most disproportionately affected by AIDS. The United States and others have already acknowledged HIV/AIDS as a threat to global health and security,[5] and UNAIDS has documented how AIDS and global insecurity "co-exist in a vicious cycle"[6]. HIV/AIDS also has a devastating impact on economies. It is believed that the impact of AIDS on the gross domestic product (GDP) of the worst affected countries is a loss of approximately 1.5% per year; this means that after 25 years the economy will be 31% smaller than it would otherwise have been.[7] The AIDS epidemic also adds to food insecurity in many areas, as agricultural work is neglected or abandoned due to household illness. In Malawi, where food shortages have had a disastrous effect, HIV/AIDS is diminishing the country's agricultural output. By 2020, Malawi's agricultural workforce will be 14% smaller than it would have been without HIV/AIDS. In other countries, such as Mozambique, Botswana, Namibia, and Zimbabwe, the reduction is likely to be over 20%.[8]

In six short years, however, Dignitas has seen the impact of accessible HIV treatment on a population's well-being, including declining morbidity concurrent with decentralized HIV treatment at health centres in Zomba District, Malawi.[9] Evidence from across Africa and the world has shown that effective HIV/AIDS interventions have numerous positive spin-off effects on the broader health sector.[10] Dignitas, in cooperation with the Ministry of Health in Malawi, has shown positive results with treatment, care, and prevention for people living with HIV/AIDS and their communities. However, the war is not won; less than half of people who need ARVs in Malawi have access to them. As we scale up programming, and as Malawi prepares to implement new World Health Organization guidelines to initiate ART earlier[11], the need for more affordable new medicines is clear. As more people access treatment, and at an earlier stage, more lives will be saved, resulting in more people remaining on treatment for longer periods of time. To cope with drug resistance and side effects, we need expanded access to new, affordable, high-quality medicines.

The current trend of abandoning people with HIV/AIDS, TB and malaria by cutting funds committed[12] to this fight means that we are again in the dismal situation we were in more than 10 years ago when people died needlessly and without dignity due to HIV/AIDS. This is not inevitable, and now is the time to avert further backtracking and affirm efforts to increase access to medicines.

Pass Bill C-393 so an effective CAMR can meet its objective to ensure greater access to medicines for AIDS and other public health needs in developing countries.

Through our experience in Malawi and our work in global health, we note:

•Demonstrable positive health outcomes associated with decentralized, community-centered HIV/TB care[13];

•Strengthening health systems and health care workforces, and integrating HIV care into primary care, can help countries respond to new health issues and crises such as influenza pandemics;

•A robust response to AIDS can improve other global health priority areas – including maternal and child health.[14] Maternal health cannot be tackled without HIV treatment and care. Prevention of Mother-to-Child Transmission programming can be an entry point for other maternal and health services[15];

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[5] Bonventre, Eugene V., Kathleen H. Hicks and Stacy M. Okutani. U.S. National Security and Global Health: An Analysis of Global Health Engagement by the U.S. Department of Defense; A Report of the CSIS Global Health Policy Center, Center for Strategic & International Studies, April 2009.
[6] UNAIDS, "Security and humanitarian response to AIDS," http://www.unaids.org/en/AboutUNAIDS/PolicyAndPractice/SecurityHumanitarianResponse.
[7] Greener R. et al, "The Impact of HIV/AIDS on Poverty and Inequality", The Macroeconomics of AIDS, November 2004.
[8] "Malawi issues food crisis appeal," bbc.co.uk (October 2005); "The impact of AIDS on people and societies," Report on the global AIDS epidemic, UNAIDS (2006).
[9] http://www.dignitasinternational.org/articles.aspx?aid=404.
[10] "No time to quit: HIV/AIDS treatment gap widening in Africa," Médecins Sans Frontières, Belgium, May 2010.
[11] New WHO guidelines call for the enrollment of patients on treatment when CD4 count is <350 cells/mm. In Zomba, Malawi, non-pregnant adult patients with a CD4 count of <100 cells/mm are initiated on treatment first (rather than <250 cells/mm, the standard for initiation of treatment in Malawi). All non-pregnant adult patients with a CD4 cell count of >100 cells/mm are put on a waiting list. All Stage IV non-pregnant adult patients are initiated on ART.
[12] Donors announced funding of US $11.7 billion for the Global Fund to Fight AIDS, Tuberculosis and Malaria for 2011-2013. "HIV/AIDS: Record contributions to Global Fund "not enough"," IRIN, 6 October 2010, http://www.irinnews.org/report.aspx?Reportid=90689. Global Fund Executive Director Michel Kazatchkine noted if this amount "were to be the last word from donors…it is not enough to reach the Millennium Development Goals".
[13] http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3156.2010.02503.x/full.

•AIDS is a chronic disease, and responding to it requires affordable, new, and contextually adapted medicines, such as second- and third-line ARVs; we urgently require access to existing pediatric ART formulations that are more child-friendly and easy to store and transport in developing country settings;[16]

•Competition between and among generic and brand name companies and multiple suppliers means lower prices and thus larger markets and more people receiving treatment;

•Health programming and drug procurement requires flexibility and rapidity of response. The country-by-country, order-by-order processes associated with compulsory licensing are unrealistic and cumbersome for health care planning and health system responses. Drug procurement must be a simple, straightforward, uncomplicated process;

•The current funding crisis for HIV and its effect of drug stockouts places vast populations at risk, and imperils all the progress made to date in tackling HIV/TB[17];

•Disruption in drug flows, and the need to substitute sub-optimal treatment or to delay treatment can do harm and drive up the price of treatment, and must be avoided[18];

•Malawi has the staff, infrastructure, willingness, and readiness to scale up universal access to treatment – the excuse of inadequate infrastructure to weaken or obstruct TRIPS flexibilities in CAMR or chronically underfund the AIDS, TB and malaria response is not valid or tolerable;

•The global response must correspond to the scale of the need or we will be faced with a greater social and economic costs due to HIV-related deaths and morbidity; these costs include risks to global security.

Living Results: Our Patients

As medical humanitarians, we have witnessed first-hand the enormous gains in the fight against AIDS, TB and malaria in developing countries. We have seen how generic competition and a spectacular fall in the price of first-line medicines – won by the hard work of people infected with and affected by HIV/AIDS, developing countries and supporters of access to medicines – has meant many more people can access treatment, orphanhood can be prevented, many people's lives can be regained, and people can go back to work and care for their families. We have seen the impact of the fruits of needs-based research and drug development, and we know the urgent need for this to continue. These gains, advances that have taken 23 years[19] and over $10 billion to achieve, must be leveraged in resource-limited countries, not undermined.[20],[21]

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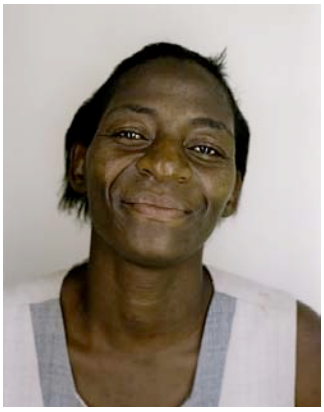
[14] No Time to Quit: HIV/AIDS Treatment Gap Widening in Africa, MSF, May 2010.
[15] AIDS remains the leading cause of death for women of child-bearing age and poses an impediment in reducing maternal and child mortality, particularly in sub-Saharan Africa. The International AIDS Society (IAS) calls on governments and donors to accept that success in improving the health of pregnant women and children under five is interdependent with the battle against HIV. http://www.iasociety.org/Default.aspx?pageId=483.
[16] "Recently the WHO released their annual Towards Universal Access Report [http://www.who.int/hiv/pub/2010progressreport/report/en/index.html]. On the ground, we are seeing the impact of a push for identifying and diagnosing HIV in children earlier. The good news is that there was a 29% year-on-end increase in the number of children on ART. The bad news? Only 28% of children in need of life-saving antiretroviral therapy worldwide are estimated to have access to ART. In addition to support for prevention of new infection with aggressive evidence-based PMTCT interventions, and investment in early diagnosis of HIV infection in exposed infants, pediatric ART access can be improved by further development of pediatric specific formulations, and, more importantly, making the more expensive 'second-line' regimens affordable for children who were exposed to first-line treatment during the perinatal period through PMTCT and may have developed resistance, which make them sitting ducks for early treatment failure and death." – Dr. Adrienne Chan, Dignitas Medical Advisor, 20 October 2010.
[17] Dignitas experienced serious stockouts of HIV medicines in 2009, directly linked to lack of funding gaps or delays in funding disbursements. The under-funded Global Fund is the sole provider of ARVs in Malawi. Lack of adequate drug supply for patients who are on treatment can mean substitution of sub-optimal treatment regimes are necessary and treatment is delayed. This may induce toxicity or ART drug resistance, increasing poor health outcomes, vulnerability to other diseases or causing treatment failure and premature death. "Deadly Rationing: G8/G20 Leaders Must Continue to Fund AIDS Response: Dignitas International's Experience with Drug Stockouts", June 2010, http://www.dignitasinternational.org/articles.aspx?aid=412.
[18] In managing 2009 stockouts, Dignitas notes that substituting sub-optimal treatment regimes risked exposing patients to rashes, anemia, hepatotoxicity.
[19] "The Global HIV/AIDS Epidemic Fact Sheet," Kaiser Family Foundation, November 2009, http://www.kff.org/hivaids/upload/3030-14.pdf (accessed 10 June 2010).
[20] "The Global Fund to Fight AIDS, Tuberculosis and Malaria," AVERT, http://www.avert.org/global-fund.htm.
[21] "Scaling up access to ARV drugs will soon become an impossible task if prices proposed by pharmaceutical firms for new first-line and second-line ARV regimens (respectively US$610 and $1,660 on average per person-year in 2008) remain prohibitive compared with those of the old generation of first-line treatment ($88). Since the full implementation of TRIPS by the WTO in 2005, supply of



"Gertrude *[at left]* and her son receive life-prolonging ART in Dignitas's clinics. Gertrude's oldest son Chifundo has HIV, but her younger child does not. If highly active antiretroviral treatment (HAART) was accessible for all pregnant women, the risk of transmission would drop to less than 1%." – Dr. Adrienne Chan, Dignitas Medical Advisor; Dignitas Medical Coordinator, Malawi Country Program, 2007 to May 2010.

"We need access to affordable, more effective second-line medicines so patients like Rodrick *[at left]* don't suffer awful side effects. No more double standards. Rodrick developed side effects to d4T (lipodystrophy)...we would have switched him earlier if access to more expensive alternative first-lines were available. With newer, less toxic regimens, stigmatizing lipodystrophy doesn't have to occur. In addition, d4T can cause pancreatitis, debilitating peripheral neuropathy and life-threatening lactic acidosis. In North America, I have not seen anyone on d4T since I was a medical student in 1998, and we know from our data that patients who have been on ART for more than 18 months and have a side effect are eight times more likely to default than those who don't have a side effect. And in our cohort, 91% of whom are on stavudine (the low-cost solution forced on poor countries who have to scale up treatment quickly with limited and increasingly shrinking funds), we know that these side effects are all attributable to the mitochondrial toxicity caused by stavudine." – Dr. Adrienne Chan, Dignitas Medical Advisor; Dignitas Medical Coordinator, Malawi Country Program, 2007 to May 2010.

Photos © Ian Brown

"Malawi has just submitted an ambitious, evidence-based proposal to the Global Fund, to ask for fund replenishment to adopt the newest minimum standard-setting WHO Guidelines. These guidelines, which came out in November 2009, recommend starting patients who are HIV-infected at a higher CD4 level, recommend using a less toxic ART regimen, and also suggest starting all pregnant women on combination highly active antiretroviral therapy (HAART). The potential impact is that people will get on ART earlier and we will have fewer side effects; that should improve both morbidity and mortality. More importantly, major strides will be made in the fight to have an HIV-free generation, as HAART is far more effective than the previously recommended forms of PMTCT adopted in resource-limited settings. For the first time, we are striving towards solutions that are equitable with evidence-based standards of care offered in resource-rich settings. The Malawian government has more than met its commitment to a human rights approach to universal access to ART by putting forward a plan that endorses all of the WHO recommendations. It is now up to donor governments to meet their fair share of financial contribution to the Global Fund, and also to ensure that low-cost generic formulations are available and exportable, to enable countries like Malawi to meet these standards."
-Dr. Adrienne Chan, Medical Advisor, Dignitas International.

"Dignitas is building a set of tools for countries like Malawi to build a highly effective system of care at the frontline, in the most remote clinics, in a practical, sustainable way. This is an argument for continuing to provide HIV care, especially including ARVs, and doing it in a way that uses the most urgent problem as a gateway to improve care for other infectious diseases, mental health, maternal health, TB. These are themselves vital, but it is simply criminal to set up a duality in which it is falsely suggested that only one or the other can be provided – AIDS versus everything else. In fact, Dignitas is showing that it can most easily and sustainably be done by doing HIV and everything else."
-Dr. Merrick Zwarenstein, Dignitas Board Member, Senior Scientist, Sunnybrook Research Institute, University of Toronto

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generic drugs for new ARVs has no longer been possible, unless through the use of compulsory licensing systems…the use of such systems in their present form remains not only complex but also unattractive…Securing access to ART therefore implies urgent measures such as: (1) the re-establishment of the conditions for competition among drug producers, through the re-introduction of generic supply for new ARVs included in the WHO list of Essential Medicines, and simplification of the existing rules of compulsory licensing…" From "Call for action to secure universal access to ART in developing countries," Fabienne Orsi et al., The Lancet, Volume 375, Issue 9727, 15 May 2010, http://www.thelancet.com/journals/lancet/article/PIIS0140673610607374/fulltext?rss=ye.

ANNEX I

Dignitas outcomes as of October 2010:
-13,603 adults and children started on HIV treatment.
-Of those ever enrolled, 7,397 are still followed directly or at a Dignitas-supported site.
-6,901 patients have been decentralized.
-14,000+ patients are under active care.
->12,500 HIV tests administered per quarter with over 200,000+ HIV tests administered ever.
-6,900+ pregnant women tested for HIV per quarter with 84,000+ pregnant women ever tested for HIV – 12% HIV positive.

Health Systems Strengthening:
-HIV treatment decentralized to 25 rural health centres, of which five are now functioning independently, and an additional four are providing ART initiation services.
-29 PMTCT sites, 41 HIV Testing & Counseling (HTC) sites established.
-161 Clinical Officers, Medical Assistants and Nurses trained in HIV treatment, with 100 retained and working in the District health system.
-87 nurses trained in PMTCT.
-103 counsellors trained to administer HIV Tests and counsel on results, prevention and refer to care.

CAMR and Dignitas:
2003-2007: Dr. James Orbinski, Co-Founder of Dignitas (2004), provided input on draft legislation during the development of CAMR (Bill C-9 & JCPA) in his capacity with Médecins Sans Frontières (MSF). With others, he identified flaws in the draft legislation and helped mobilize support from health care organizations and workers, students, HIV-positive groups in Canada and internationally, and others to urge Canada to make a workable 'solution'. NGOS were consulted in the creation of CAMR[22] and some of the recommended changes were adopted into the legislation, but the long-standing major problems, clearly articulated by the Canadian HIV/AIDS Legal Network, Professor Fred Abbott[23] and in Bill S-232 and C-393 remain and still must be changed for the Regime to be workable. Then and now, many organizations, including Dignitas, and the public urged Canada to fix the legislation to be effective.

2009: Dignitas provided input from our experience providing integrated AIDS/TB care in Malawi to the Canadian HIV/AIDS Legal Network report "Delivering on the pledge, treating the most vulnerable: Ensuring affordable AIDS drugs for children in the developing world by streamlining Canada's Access to Medicines Regime", noting the need for more affordable and effective child-friendly HIV ARV treatments, and endorsed efforts to promote CAMR reform. On December 1, 2009, Dr James Orbinski was one of 59 Canadian VIPs urging parliamentarians to amend CAMR. On December 2, Canada's House of Commons voted narrowly in favour to move forward with a Private Member's Bill to streamline CAMR.

2010: Dr. James Orbinski submitted (unsuccessfully) to be a witness before the Industry Committee on Bill C-393 for Oct. 26, 2010.

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[22] http://www.camr-rcam.gc.ca/countr-pays/ngo-ong/index_e.html.
[23] supra, footnote 4.