



**MEMORANDUM ADDRESSING THE NEED
FOR A TREATMENT AGENDA
TO BE INCLUDED IN THE PROPOSED WORLD BANK-FINANCED
SRI LANKA NATIONAL AIDS PREVENTION PROJECT**

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[HIV/AIDS] ... does not discriminate my dear friends, learn something from South Africa and Brazil ... the virus is wiping out ... entire civilizations immaterial of whether [a person] is a doctor, lawyer, engineer, man, woman or infant ...I do not want to see that happen to my people and my country!

Aruna H., HIV-Positive Sri Lankan

STATEMENT OF NEED

Sri Lanka has a US\$10 million funding request for its National AIDS Prevention Project (“Prevention Project”) pending before the World Bank.¹ A decision on the request is expected by May 2002. We urge the World Bank and the government of Sri Lanka to incorporate funding for human immunodeficiency virus (“HIV”)/acquired immunodeficiency syndrome (“AIDS”) treatment into the pending proposal.

We are an international coalition of nongovernmental organizations (“NGOs”) working on behalf of HIV-positive individuals in Sri Lanka.² We bring expertise in HIV/AIDS treatment and law, as well as in international human rights and intellectual property law. We share the commitment of the government of Sri Lanka and the World Bank to address the challenges posed by HIV/AIDS. We believe that heeding our recommendations will increase the likelihood that Sri Lanka can avert the high level of HIV infection increasingly common in other countries in South Asia. In addition, our ongoing participation in the planning process and implementation of an HIV strategy is essential to ensure that the process responds to the needs of the HIV-positive community.

There is growing consensus among scientists, public health professionals, human rights scholars, activists, representatives of international organizations as well as political leaders of the indivisibility of HIV prevention and HIV treatment. In the absence of treatment, high-risk populations have little incentive to take advantage of HIV testing, which in turn reduces

opportunities for health professionals to encourage behavior change among high-risk individuals as well as opportunities for individuals to make informed decisions about their health. Sri Lanka's Prevention Project, while ambitious, focuses solely on outreach and prevention. Unless it is amended to address treatment as well, we believe that the Prevention Project will fall well short of its goal of halting the spread of HIV/AIDS in Sri Lanka.

Not only are treatment options necessary for the future success of Sri Lanka's prevention agenda, but they are also necessary to alleviate the immediate suffering and deprivation of human rights of the thousands individuals who are HIV positive, lacking treatment, and without hope. There is a growing consensus among international jurists that in the specific context of HIV/AIDS, the right to essential treatment is incorporated into the human rights obligations of governments progressively to realize the right to health. Thus, governments have a duty to provide treatment to the extent feasible. In the case of Sri Lanka, we believe that with the requested World Bank funding, the robust public health system and the proven feasibility of HIV treatment programs in resource poor countries, the government of Sri Lanka has both the opportunity and the affirmative duty to provide treatment to its HIV-positive constituents.

We urge Sri Lanka to include funding for the following treatment components in its pending World Bank funding proposal. Consistent with World Bank operational procedures, we request a meeting with the appropriate officials in the Sri Lankan government, and the World Bank respectively, to discuss our recommendations set forth below.³

RECOMMENDATIONS

- **Remove domestic legal barriers that obstruct access to antiretrovirals (“ARVs”) by adding ARVs and other essential HIV/AIDS drugs to the National Formulary.**
- **Place essential HIV/AIDS medicines on the Essential Drugs List (“EDL”) to provide access to them for Sri Lankans who cannot otherwise afford these medications. Drugs on the EDL should include:**
 - **nevirapine to prevent mother-to-child transmission of HIV;**
 - **medications to treat opportunistic infections; and**
 - **two or more antiretroviral (“ARV”) combinations.**
- **Develop short- and long-term strategies to procure affordable ARVs and other HIV/AIDS medications.**
- **Strengthen the Sri Lankan public health system’s capacity to deliver comprehensive services for persons with HIV/AIDS by equipping hospitals and treatment centers with improved HIV/AIDS testing and diagnostic systems and improving the training of personnel.**
- **Create and support a planning council of local NGOs including associations of people living with HIV/AIDS, international health organizations, donors, government, and private sector government representatives, to participate in all stages of strategic planning, project development, program evaluation, and long-term monitoring.**

These recommendations are based on our analysis of the nature and scope of HIV infection, the medical infrastructure of Sri Lanka, the country’s legal obligations, its capacity to finance HIV/AIDS medications, and the present opportunities for procurement and distribution of these medications. We are willing to assist the government in its efforts to identify and access

additional funds and procure affordable HIV/AIDS medications. In our capacity as NGOs, we hope to provide the World Bank and the government of Sri Lanka with important information, analyses and perspectives that will amplify the potential impact of the Prevention Project. We look forward to an ongoing dialogue with you about the complex public health and human rights issues raised by the need to provide access to treatment and care for people living with HIV/AIDS.

We begin with an analysis of the risk factors and estimated rates of infection in Sri Lanka. We discuss the literature regarding the integration of treatment and prevention and note the negative impact of HIV on economic growth and development. Subsequently, we set forth Sri Lanka's obligations under international human rights law to provide HIV treatment. Finally, we address the technical and practical feasibility of our recommendations.

I. THE GOVERNMENT OF SRI LANKA'S GOAL OF HALTING THE SPREAD OF HIV REQUIRES A COMMITMENT TO WIDESPREAD ACCESS TO HUMAN IMMUNODEFICIENCY VIRUS ("HIV") TREATMENT⁴

The U.N. General Assembly recently urged states to acknowledge that “prevention, care, support, and treatment for those infected and affected by HIV/AIDS are mutually reinforcing elements of an effective response and must be integrated in a comprehensive approach to combat the epidemic.”⁵ Although large-scale prevention programs can reduce the spread of HIV/AIDS, as demonstrated in Cambodia and Thailand,⁶ national responses that lack treatment provisions have failed to stop the spread of the virus.⁷ Of the forty million individuals living with HIV at the end of 2001 worldwide,⁸ an estimated six million individuals contracted the disease between 1999 and 2001.⁹ For those persons who contracted the disease despite prevention efforts in their communities, this one-sided approach to HIV has failed. As anthropologist and professor of medicine at Harvard University, Dr. Paul Farmer, points out:

[G]lobally, billions of dollars have been invested in AIDS prevention and treatment, but the epidemic marches on. AIDS prevention efforts have failed in precisely those areas where they are needed most. And yet in these very areas—poor communities in developing countries—we are encouraged to restrict our “AIDS-related activities” to prevention alone.¹⁰

An effective response to HIV/AIDS must include treatment for individuals already infected in addition to primary prevention for those not infected. Treatment maximizes the efficacy of prevention efforts in two ways. First, it encourages participation in voluntary counseling and HIV testing—essential for reducing risky behavior that facilitates the spread of HIV.¹¹ Second, treatment reduces the viral loads of infected individuals, thereby reducing the likelihood that they will transmit HIV to others.¹²

In addition, treatment is crucial to preventing public health and economic disasters that have afflicted the developing countries currently experiencing HIV/AIDS pandemics.¹³

Treatment averts rapid increases in overall mortality, illness, and hospitalization rates which decrease economic productivity and drain health care resources.¹⁴

As set forth immediately below, the existence of certain risk factors in Sri Lanka indicate the country's high vulnerability to an epidemic similar to those in other resource-constrained countries where HIV/AIDS has spiraled out of control. To prevent this, the Sri Lankan government needs both a treatment and a prevention plan in order successfully to combat the spread of HIV/AIDS.

A. The Availability of Treatment Increases Participation in Voluntary Testing Programs that Provide Opportunities for Counseling About Behavior Modification to Reduce the Risk of Contracting and Transmitting HIV, Thereby Optimizing Prevention Efforts.

1. The modification of behaviors that increase the spread of HIV is critical to prevention efforts.

As of December 2000, Sri Lanka had an estimated 8,500 people living with HIV and an infection rate of 0.07 percent among adults between the ages of 15 and 49.¹⁵ Although these numbers appear relatively low, Sri Lankan National STD (sexually transmitted disease) /AIDS Control Program ("NSACP") official Dr. Sujatha Samarakoon stated that the reported HIV prevalence in Sri Lanka is only "the tip of the iceberg,"¹⁶ suggesting that the national figures do not provide a realistic assessment of the national incidence of HIV. Despite the low national averages, data regarding the behavior patterns of high-risk populations indicate that Sri Lanka is highly vulnerable to an HIV/AIDS epidemic. Such data has led the United Nations Development Program ("UNDP") to make an alarming projection: without effective intervention that dramatically lowers the incidence of high-risk behaviors, the number of HIV-infected individuals in Sri Lanka will increase exponentially to 80,000 by 2005 (an 841 percent increase) and HIV

prevalence will increase to 5.4 per 1,000 among those aged 15 to 64.¹⁷ As set forth below, treatment is a necessary component of a national strategy to forestall the UNDP's dire projection.

Among other benefits, the provision of treatment can reduce various risk factors and behavior patterns that make Sri Lanka highly vulnerable to an HIV/AIDS pandemic.¹⁸ These risk factors include the commercial sex industry, low condom use, high rates of sexually transmitted diseases (STDs), high rates of injecting drug use, and population mobility. Sri Lanka's HIV/AIDS strategy must seek to reduce these risk factors and encourage changes in behavior. Provision of voluntary counseling and testing ("VCT"), linked with treatment and other services, will help to achieve both goals.

a. Sri Lanka's sex industry creates vulnerability to an HIV epidemic.

Available data indicate that the main route of HIV transmission in Sri Lanka is through sexual intercourse, to which approximately seventy-three percent of all infections may be attributed.¹⁹ The World Bank estimates that approximately 30,000 women and girls and 15,000 men and boys work in the commercial sex industry in Sri Lanka.²⁰ These sex workers are vulnerable to HIV infection because they often lack the ability or power to negotiate condom use with clients or to seek treatment for sexually transmitted diseases. For example, an often-overlooked group among sex workers is that of children known as "beach boys,"²¹ boys as young as nine, who have little ability to request that their older clients use condoms.²² Despite being at high risk of HIV infection, these children are difficult to educate about HIV transmission because most do not attend school and many are made inaccessible by their pimps.²³

b. Low condom use and a high rate of sexually transmitted diseases ("STDs") in Sri Lanka create vulnerability to an HIV/AIDS epidemic.

Low condom use and high prevalence of STDs heighten the risk of the transmission of HIV/AIDS among those engaged in sex work. Although research on sexual behaviors in Sri

Lanka has been limited, a few studies conducted in urban areas suggest there is low condom use among men. This pattern increases the likelihood that high-risk behavior such as unprotected sex will result in greater rates of STD infection among the general population.²⁴ In addition to serving as an indicator for condom use (or lack of use), STDs are a recognized co-factor for HIV transmission because the genital lesions caused by illnesses such as syphilis and herpes facilitate the spread of HIV between sexual partners.²⁵ For example, Cambodian female sex workers—who have the highest HIV prevalence of any high-risk group—report high STD prevalence and low condom use with their male customers.²⁶ These figures are sobering news for Sri Lanka, where estimates of detected STD cases vary annually from approximately 60,000 to 200,000, of which only ten to fifteen percent are seen in government clinics.²⁷ One recent study revealed that forty-five percent of Sri Lankan female sex workers had experienced multiple STDs, and seventy percent of patients at STD clinics reported engaging in sex with commercial sex workers.²⁸ Given the proven connection between STDs and HIV transmission, these figures suggest that the prevalence of HIV infection in Sri Lanka already is higher than the official figures indicate and likely will increase further.

c. Injecting drug use in Sri Lanka creates vulnerability to an HIV epidemic.

Injecting drug use is also a risk factor in the spread of HIV. In Sri Lanka heroin, which is consumed by approximately 240,000 to 300,000 casual users and addicts,²⁹ has become the most commonly-used drug.³⁰ Of Sri Lanka's estimated 30,000 heroin and other drug addicts, approximately two percent inject drugs and are at high risk for contracting HIV through needle sharing.³¹ A study of heroin users conducted in Sri Lanka in the early 1990s found that forty percent of injecting drug users shared needles and syringes.³² Additionally, this study found that injecting drug users frequently engaged in sexual intercourse with multiple partners and that

sixteen percent performed sex for money.³³ Although there have been no official reports of HIV infection through injecting drug use thus far, one report estimates that twenty-one percent of the total HIV infections in Sri Lanka may be attributed to this method of drug use.³⁴

d. Migration between Sri Lanka and countries with high HIV rates creates vulnerability in Sri Lanka to an HIV epidemic.

Each year, thousands of Sri Lankans leave their communities in search of employment opportunities in countries like India where HIV prevalence is high.³⁵ Evidence suggests that such mobility increases the transmission of HIV: 146 of the 385 Sri Lanka AIDS cases officially reported in 2001 were those of women, half of whom had been employed abroad.³⁶ Thousands of Sri Lankan migrant workers live abroad in the free trade zones³⁷ where rates of commercial sex, multiple-partner casual sex and sexual abuse of women and children are high and increase the likelihood of HIV transmission.³⁸ As a comparison, one survey of Nepalese migrants found that ten percent of migrants returning from India were infected with HIV compared to two percent of non-migrants.³⁹ The occurrence of significant migration in and out of the country is another risk factor that suggests the official estimate of the number of HIV cases is low and that numbers likely will increase.

It is estimated that four million of the forty million HIV-positive people in the world reside in Sri Lanka's closest neighbor, India.⁴⁰ Given the proximity of these two countries (separated by approximately twenty kilometers) and the economically-driven migrations from Sri Lanka to India, the number of HIV cases in India should serve as an indicator for what may lie ahead for Sri Lanka.

2. The availability of treatment increases participation in voluntary HIV counseling and testing (“VCT”).

Given the depth and breadth of risk factors described above, the government’s prevention policy must be comprehensive. VCT provides a proven method for reducing the risky behaviors that facilitates the transmission of HIV in a population. More individuals seek VCT when it is offered together with HIV/AIDS treatment.⁴¹

Scientists, public health professionals, and representatives of international organizations recently have acknowledged the synergistic relationship between treatment and prevention.⁴² According to Dr. Brundtland, Director-General of the World Health Organization (“WHO”), access to affordable medicines is a key element in improving the efficacy of prevention efforts.⁴³ Dr. Brundtland confirms that greater use of VCT is an important method to encourage changes in risky behavior and thus to reduce HIV infection.⁴⁴ Among other benefits, VCT provides those who test positive for HIV the ability to make an informed decision not to spread the virus to their sexual partners. However, the lack of perceived benefit from VCT alone (because a positive result can appear as “nothing more than a death sentence” if antiretroviral medication is inaccessible)⁴⁵ creates a barrier to individuals seeking testing and counseling. This barrier is heightened in Sri Lanka where there is a prevailing stigma and fear of being identified as HIV positive.⁴⁶

However, if VCT is linked with adequate medical services, individuals will have a powerful incentive to ascertain their HIV status.⁴⁷ For example, a 1999 study in Botswana surveyed adult patients waiting for services at government clinics and found that more than ninety percent of study participants reported a willingness to seek VCT if medical therapy were offered to those found to be HIV-positive. However, fewer than fifteen percent of those

surveyed reported that they had undergone VCT because HIV-specific treatments were not widely available.⁴⁸

B. Treatment Further Optimizes Prevention Efforts Generally by Reducing HIV Viral Load, Thereby Reducing the Likelihood of HIV Transmission.

We wish to emphasize the link between *suppression* of HIV viral load and prevention of HIV infection. Specific ARV regimens known as highly active antiretroviral therapy (“HAART”) reduce the risk of HIV transmission by significantly lowering the level of HIV in an infected individual’s blood.⁴⁹ A study in Uganda found that HIV transmission probability increased significantly as an individual’s viral load increased.⁵⁰ The study concluded that interventions (such as ARV therapy) that reduce viral load could reduce transmission of HIV.⁵¹ In particular, ARV intervention has proven particularly effective in preventing perinatal transmission. ARVs administered during labor and delivery have been shown to reduce maternal-to-newborn transmission of HIV by well over fifty percent, saving thousands of infants from the complications and early death associated with AIDS.⁵² For many patients, ARV therapy has transformed HIV infection from a “death sentence” into a chronic condition that frequently remains without symptoms for many years, with resultant gains in life expectancy.⁵³ Accordingly, providing treatment (ARV therapy, in this case) can significantly benefit prevention efforts and improve the quality of life of HIV-infected individuals.

C. Treatment Will Avert a Rapid Increase in Mortality Rates and Resultant Negative Public Health and Economic Effects.

In countries where access to treatment is not provided, the AIDS epidemic has driven average households into poverty and condemned the poor to inescapable destitution as a result of reduced productivity.⁵⁴ HIV/AIDS is now the leading cause of death in sub-Saharan Africa.⁵⁵ The WHO reports that the agricultural sector in sub-Saharan Africa has experienced up to a fifty

percent reduction in productivity in certain areas as a result of AIDS-related illnesses and deaths.⁵⁶ For example, one sugar estate in Kenya reported a fifty percent drop in productivity between 1995 and 1997 due to HIV/AIDS related illnesses among its employees and increased expenditures in overtime payments to workers filling in for sick colleagues.⁵⁷ Subsistence agriculture is also affected: a study in the northwestern region of Tanzania found that women with sick husbands spent sixty percent less time on agricultural activities than they would have otherwise.⁵⁸ In Zimbabwe, maize production on communal farms fell by fifty-four percent between 1992 and 1997 due to illness and death as a result of AIDS.⁵⁹

Following the lead of developing countries such as Brazil that have provided treatment and reduced HIV infection rates, Sri Lanka can avoid the devastating toll that HIV epidemics exert on public health and economic development. A 1996 Brazilian policy to provide universal, free access to antiretroviral therapy (ARV) has resulted in improved and longer lives for all persons living with HIV, even those with incomes well below those in Europe and North America. Since the introduction of ARV therapy, Brazil has observed a striking fifty percent reduction in the number of AIDS deaths,⁶⁰ a sixty to eighty percent reduction in the incidence of opportunistic infections among HIV infected patients⁶¹ and a fourfold reduction in hospitalization rates of HIV-positive patients.⁶²

The success of Brazil's program also demonstrates that treatment of HIV-infected individuals not only saves lives, but also can be cost effective and provide significant economic benefits.⁶³ Due to the reduction in mortality, morbidity and hospitalization rates of HIV-positive patients, Brazil's ARV access policy has resulted in an overall governmental savings of US\$472 million from 1997 to 1999.⁶⁴

D. Without Access to Treatment, Thousands of Sri Lankans Suffer Despite the Existence of Medicines that Would Alleviate Their Suffering.

The estimated 8,500 HIV cases in Sri Lanka represent physical and mental suffering on a staggering scale because the vast majority of individuals have no access to treatment. The personal stories of the isolation and despair that many of these individuals have endured are too numerous to detail individually here. We share the stories of three individuals to illustrate the experience of HIV-infected individuals in Sri Lanka.

Aruna H. was diagnosed with HIV on February 15, 1998, after he was admitted to a hospital for continued chest pain. When he learned of his condition, Aruna felt as though he had been sentenced to death. At first, he did not tell his family and friends about his diagnosis, but the burden of silence was too much for him to bear. When he finally confided to his inner circle about his medical condition, those closest to him abandoned him and his family told Aruna that he had shamed them. The emotional toll of his diagnosis was matched by his physical symptoms, which included the loss of mobility and coordination, pain throughout his body, inability to concentrate, and intense muscular spasms. His physical and mental suffering was made infinitely worse by the knowledge that existing and effective treatments to alleviate his pain and prolong his life were out of his reach.⁶⁵

Rose, a member of the AIDS Coalition in Sri Lanka, tells a similarly tragic story about herself and her deceased husband.⁶⁶ In July 2000, Rose's husband, Tilak, was hospitalized. The doctors advised Tilak that he had AIDS and shortly thereafter, Rose was diagnosed with HIV. Although Tilak wanted his diagnosis to remain confidential, a staff person at the hospital disclosed his diagnosis to a member of Tilak's village. Soon, much to Tilak's shame, the whole village knew about his illness. The village ostracized Tilak's family. Rose's relatives advised her to leave Tilak immediately, and Tilak's relatives advised Rose to leave their home because

they were afraid the villagers would burn it down. Several months later, Tilak attempted suicide. Rose decided she would take care of him regardless of the consequences to herself. Yet fearing for the safety of their two children, Rose sent them to live with relatives. Tilak made a second attempt at suicide. He was taken to a hospital in Colombo where he died several days later. Rose's troubles continue since Tilak's death: the villagers have humiliated the family, threatened them and recently burned their house. Rose states that she is desperate for some treatment so that she can live long enough so see her children settled in life.

The stories of Aruna, Rose, and Tilak exemplify the struggle and danger faced by Sri Lankans living with HIV. As discussed below, the government of Sri Lanka has a duty to protect and treat HIV-positive individuals, and adequate and effective measures are within immediate reach.

II. THE GOVERNMENT OF SRI LANKA'S OBLIGATION TO RESPECT, PROTECT AND FULFILL THE RIGHT TO HEALTH CANNOT BE MET WITHOUT IMPLEMENTATION OF A TREATMENT PLAN

Twenty years into the HIV/AIDS epidemic, the international community has begun to condemn the inherently unfair practice of providing comprehensive HIV care only to those fortunate enough to live in the developed world. Peter Piot, Executive Director of the United Nations Special Programme on AIDS, states, "The new paradigm [of AIDS care] recognizes the ethical impossibility of denying to the majority of people living with HIV the life-saving treatment that has been available to the minority."⁶⁷ There is an emerging consensus among international legal experts that not only is this practice unfair, but that governments have legal obligations in the context of human rights to provide HIV/AIDS treatment. Conceptualizing the problem of access to treatment for HIV/AIDS in terms of unfulfilled human rights, not just unmet human needs, highlights the legal aspects of the HIV/AIDS crisis.⁶⁸

Sri Lanka has a legal obligation progressively to realize the right to health.⁶⁹ Given Sri Lanka's solid public health infrastructure, the proven viability of antiretroviral and other medical treatments, and the government's capacity to obtain these medicines, we believe that the government has an affirmative obligation to make HIV drugs available to HIV-positive individuals in Sri Lanka. In this section, we analyze the nature and content of the government's obligations under international law to fulfill the right to health.

A. Sri Lanka's Obligation Progressively to Realize the Right to Health Includes the Provision of Treatment for HIV/AIDS.

The right to health belongs to the family of economic, social and cultural rights enumerated in the International Covenant on Economic, Social and Cultural Rights ("Covenant") and in other international instruments⁷⁰ ratified by the Sri Lankan government.⁷¹ Each state party to the Covenant is required "to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights [enumerated in the Covenant],"⁷² and to achieve "progressively the full realization of the rights recognized in the Covenant [...] to the maximum of its available resources."⁷³ According to the United Nations body charged with monitoring the Covenant, the Committee on Economic, Social and Cultural Rights:

The concept of progressive realization constitutes recognition of the fact that full realization of all economic, social and cultural rights will generally not be able to be achieved in a short period of time.⁷⁴

However, a scarcity of resources does not relieve the responsibility of the state to meet certain minimum obligations.⁷⁵ Further, state parties must take steps necessary for "the prevention, treatment, and control of epidemic, endemic, occupational and other diseases."⁷⁶

Access to health care and the prevention and treatment of diseases are recognized by major international human rights treaties and covenants as essential components of the right to health.⁷⁷ Specifically, in the context of the HIV/AIDS pandemic, the U.N. Commission on

Human Rights, an important U.N. human rights body composed of representatives from fifty-three member-states elected by the Economic and Social Council, has declared that “access to medication is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”⁷⁸ This Commission has called upon states

to pursue policies, in accordance with applicable international law... which would promote:

(a) The availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them; [and]

(b) The accessibility to all without discrimination, including the most vulnerable sectors of the population, of such pharmaceuticals or medical technologies and their affordability for all, including socially disadvantaged groups.⁷⁹

Moreover, Sri Lanka has assumed the legal responsibility under the Covenant “[t]o provide essential drugs, as defined by the WHO Action Programme on Essential Drugs.”⁸⁰ The current WHO Model List of Essential Drugs (“Model List”) includes the antiretrovirals nevirapine and zidovudine, as well as several drugs for the treatment of opportunistic infections associated with HIV/AIDS.⁸¹ Inclusion of these drugs on the Model List in itself does not legally bind national governments to provide them. However, it establishes a benchmark of progressive realization that Sri Lanka should strive to achieve given its ability to do so as discussed further below. Thus, Sri Lanka is obligated under the Covenant to include these medicines, as soon as possible, on its National Formulary and Essential Drugs List.

Concrete approaches to ensure the respect, protection and fulfillment of human rights in the context of HIV/AIDS have been set out in some detail in the United Nations international guidelines on HIV/AIDS and human rights.⁸² The next section presents an overview of how these approaches apply to and should be incorporated into Sri Lanka’s HIV/AIDS policies.

B. In Order to Uphold the Right to Health Sri Lanka is Obligated to Seek Funding for Treatment and to Provide Treatment to the Maximum Extent of Resources on a Non-Discriminatory Basis.

1. Sri Lanka is obligated to seek funding for HIV/AIDS treatment.

As the General Assembly of the United Nations has noted, “[i]ncorporating human rights in the response to HIV/AIDS implies recognizing that [the] three elements of adherence to rights standards—to respect, to protect, and to fulfill—are essential, interdependent, and indivisible.”⁸³ Even in “resource-restrained settings,” international human rights standards call for government recognition that “access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”⁸⁴ If limited resources present an obstacle to the implementation of specific rights, states have an obligation under the Covenant to seek international assistance and cooperation.⁸⁵

The U.N. General Assembly, recognizing the synergistic relationship between prevention strategies and the provision of treatment in the context of the AIDS pandemic, has pointed out that “greater levels of funding for other care and prevention activities, public health infrastructure and training in clinical care” must accompany any large-scale effort to provide access to HIV treatments, including antiretroviral therapy.⁸⁶ Additionally, United Nations Secretary-General Kofi Annan and seven pharmaceutical companies recently emphasized the need to adopt such comprehensive strategies in a jointly issued communiqué stating that: “Effective care calls for reliable and accessible diagnosis, and without the potential for care, increasing the impact of prevention is extremely difficult.”⁸⁷

There is little room to dispute the contention that “[a] comprehensive approach to prevention, care and support is essential if we are to halt the HIV/AIDS pandemic.”⁸⁸ The U.N.

Commission on Human Rights has urged states “to adopt all appropriate positive measures to the maximum of the resources allocated ... to promote effective access to ... preventive, curative or palliative pharmaceuticals or medical technologies for all.”⁸⁹ Therefore, Sri Lanka should make available affordable HIV/AIDS medications to the greatest extent permitted by resources that are directly available to the government or that could be sought from outside sources.⁹⁰ The government’s pending request for funding from the World Bank provides an opportunity to seek such resources. Domestic policy and existing resources alone will not necessarily suffice to progressively realize the rights to health and access to health care for all; therefore, the Sri Lankan government has a duty to devise plans and seek resources domestically and internationally in order to fulfill these rights.⁹¹

2. Sri Lanka is obligated to provide HIV/AIDS treatment to the maximum extent of resources.

Several U.N. bodies as well as national courts have recognized that a government’s obligation progressively to fulfill the right to health includes a duty to provide essential HIV medicines to the maximum extent of the state’s resources.⁹² The High Court of South Africa recently held that its constitution (which, like that of Sri Lanka, explicitly incorporates international human rights laws and standards) “imposes the duty to achieve a progressive realization of the right to health care as an ongoing obligation.”⁹³ To the extent that pregnant women’s access to medications that help prevent mother-to-child transmission of HIV may depend upon available resources, the Court found that “[t]he resources will have to be found progressively. The availability or [*sic*] resources can only have an influence on the pace of the extension of the program. But there must be a plan for a further roll out.”⁹⁴ Similarly, in 1999 the Venezuelan Supreme Court of Justice recognized that access to antiretroviral medicines is a

component of the right to life, the right to health, and the right to the benefits of scientific progress for HIV-positive persons.⁹⁵

Thus, Sri Lanka has a current obligation to provide HIV/AIDS treatment to those within its borders. The proposed Prevention Project offers a unique opportunity to expand the government's ability progressively to realize its HIV/AIDS treatment obligations. In fact, with World Bank funding, we submit that Sri Lanka has the capacity to provide effective treatment for all those infected with HIV living within the country. A wide variety of factors, including the existence of Sri Lanka's public and private health care infrastructure, the possibilities for obtaining ARVs at an affordable rate,⁹⁶ and the participation of well-informed members of civil society and the international community demonstrate that Sri Lanka is well-positioned to go *beyond* the minimum standards and provide medicines to prevent mother-to-child transmission as well as ARV combinations to treat infected individuals. The government's failure or refusal to provide access to essential HIV/AIDS treatment—especially when resources would permit it to do so—would be inconsistent with its obligation to respect, protect and fulfill the fundamental human rights of persons suffering from HIV/AIDS.⁹⁷

3. The right to health includes a duty of nondiscrimination that requires HIV/AIDS treatment be provided to individuals regardless of socioeconomic status.

In recent years, the international community has paid increasing attention to the human rights implications of significant and rising “disparities and inequities regarding access to antiretroviral therapies and other forms of care for HIV-positive people.”⁹⁸ The observable disparate impact of the disease on poor and vulnerable populations serves as a striking reminder that the principles of non-discrimination, equality, and participation in relation to strategies to reduce the incidence of HIV/AIDS and its impact on individuals are central to the government's obligations to promote and protect health and human rights.⁹⁹

The principle of nondiscrimination applies to all rights enunciated in the Covenant, including the right to health.¹⁰⁰ Therefore, states not only must implement laws that prohibit discrimination against persons living with HIV/AIDS by private and state actors, but also must adopt measures to ensure that all persons infected with HIV/AIDS have access to basic treatment, including antiretroviral medications. The latter obligation is twofold: (1) states must refrain from denying equal access to existing health care/treatment to individuals or populations on the basis of their HIV status; and (2) states must take affirmative steps to establish access to care and treatment for such individuals and populations where none exists.¹⁰¹

The government of Sri Lanka currently is addressing these obligations and already has committed itself to increasing education programs to promote social acceptance of and nondiscriminatory attitudes towards people living with HIV and highly vulnerable groups.¹⁰² This is an area that requires further and sustained attention since the reduction of stigma is necessary to encourage treatment.¹⁰³ Moreover, “appropriate treatment [not only can] prevent infected individuals from succumbing to life-threatening illnesses from AIDS but may play a major role in prevention both by reducing the viral load of those under treatment and by reducing behaviors that transmit the disease.”¹⁰⁴ Thus, treatment that is selective and/or discriminatorily narrow will be insufficient to treat, and could further stigmatize, HIV-infected or vulnerable populations. The combination of stigmatization and lack of access to affordable treatment will discourage individuals from seeking testing. In contrast, by acknowledging and valuing the lives and suffering of those living with HIV/AIDS, policies that increase access to treatment for all HIV-infected persons regardless of their socioeconomic or other status can help reduce stigma, denial, and other negative attitudes facing these individuals within the health care system and society at large. As discussed in our Recommendations section below, we submit that to provide

non-discriminatory HIV/AIDS treatment, Sri Lanka must begin by placing essential HIV/AIDS medicines on its national Essential Drugs List.

In the next section, we respectfully recommend some concrete actions and policies that we believe will bolster Sri Lanka's prevention efforts and advance the progressive realization of the right to health for HIV-infected persons and vulnerable populations in Sri Lanka.

III. RECOMMENDATIONS

The Sri Lankan government has the opportunity to avert an AIDS epidemic similar to that which has ravaged neighboring countries. The Prevention Project proposal pending before the World Bank evidences the government's appreciation of the risks and opportunities it faces in battling the spread of HIV/AIDS. Building upon this prevention-focused proposal, we provide our companion recommendations for an HIV/AIDS treatment agenda and timeline. We are confident that the government and, in particular, the National STD/AIDS Control Program ("NSACP") share our sense of urgency in developing an effective, strategic plan to combat the spread of HIV/AIDS. With an effective strategy, Sri Lanka hopefully will avoid becoming another example of a low-prevalence country that did not respond aggressively enough to the disease to prevent the onset of an epidemic. Thus, with urgency, we turn to our specific recommendations.

We encourage the Sri Lankan government to capitalize on the present opportunity to obtain funding from the World Bank to develop and implement an affordable and effective HIV/AIDS policy that supports prevention through treatment, testing and long-term strategic planning activities. Our guidelines for an effective Sri Lankan HIV/AIDS policy are based on the Panos Institute's guidelines, which in turn, are modeled on WHO and Joint United Nations

Programme on HIV/AIDS (“UNAIDS”) guidelines.¹⁰⁵ Following these guidelines, the Sri Lankan government should:

- provide access to essential HIV/AIDS medicines by removing the legal barriers to importation;
- place essential HIV/AIDS medicines on the Essential Drugs List (“EDL”) to provide access to them for Sri Lankans who cannot otherwise afford these medications;
- develop short- and long-term strategies to procure affordable ARVs and other HIV/AIDS medications;
- strengthen the medical infrastructure by equipping hospitals and treatment centers with HIV testing and diagnostic systems and training personnel to perform HIV testing and other diagnostic prevention and treatment regimens; and
- create and support a local planning council of government representatives and non-governmental organizations from pertinent sectors of civil society, including associations of people living with HIV/AIDS, the private sector, donors and others to participate in formulating and monitoring an appropriate prevention and treatment program to combat the spread of HIV.

Below, we set forth our reasons for focusing on these steps.

A. Remove Domestic Legal Barriers that Obstruct Access to Antiretrovirals (“ARVs”) by Adding ARVs and Other Essential HIV/AIDS Drugs to the National Formulary.

Currently, the absence of ARVs from Sri Lanka’s national drug formulary (the “Formulary”)¹⁰⁶ prevents lawful dispensation and importation of HIV medications. We request that the government place all HIV drugs, including ARVs and medications to treat secondary infections, on the Formulary.¹⁰⁷ Once the medications are placed on the Formulary, these drugs

may be imported into the country and medical professionals lawfully can prescribe them, thereby eliminating a significant barrier to accessing the medications. This action also will convey to the national and international community that the government of Sri Lanka is committed to reducing the barriers that prevent individuals from accessing HIV medicines.

B. Add ARVs and Other Essential HIV/AIDS Drugs to the Essential Drugs List (“EDL”) to Provide an Effective Prevention and Treatment Program and Fulfill the Duty of Non-Discrimination.

At this time, Sri Lanka has no ARVs on its Essential Drug List (“EDL”), the subset of legally importable drugs which the government makes available to those who otherwise could not afford them. Our research indicates that Malaysia is the only country in Asia currently with ARVs on its EDL (zidovudine and didanosine). We encourage the Sri Lankan government to follow Malaysia’s example.¹⁰⁸ As set forth in Section I above, effective treatments are required for effective prevention. And, as set forth in Section II.B.3 above, Sri Lanka’s duty of non-discrimination under the right to health partially can be fulfilled by placing ARV medicines on the EDL.

We understand that the decision to place drugs on the EDL requires weighing numerous factors including the pattern of prevalent disease, treatment facilities, training and experience of prescribers, cost, and safety.¹⁰⁹ Taking these factors into account, we believe that Sri Lanka’s national AIDS strategy will be most effective if it makes ARVs and other essential HIV/AIDS drugs available to those who cannot afford treatment. As noted in Section I.C. above, countries like Brazil already have found this strategy to be an extremely effective aspect of a national HIV/AIDS plan. We acknowledge that ARVs are expensive and we are committed to working with the government, the World Bank and other future funders to help develop short-and long-

term strategies for providing affordable access to ARVs for the people of Sri Lanka. Below we discuss the particular medications that we believe must be included immediately on the EDL.

1. Place nevirapine on the Essential Drugs List to prevent mother-to-child transmission and progressively to realize the right to health.

As a first step, we recommend that Sri Lanka adopt the WHO's Model Essential Drugs List¹¹⁰ and place nevirapine on the EDL. The WHO has concluded that the prevention of mother-to-child transmission ("MTCT") of HIV should be part of the minimum standard package of care for HIV infected women and their exposed newborns; the benefit of nevirapine in reducing MTCT greatly outweighs any potential adverse effects of drug exposure.¹¹¹ Researchers have found that two doses of nevirapine, one for the mother in labor and the other for the infant after birth, can reduce MTCT by at least fifty percent (to approximately twelve percent).¹¹² The cost of this treatment is less than US\$10.¹¹³ The WHO recently recognized Cipla as a safe producer of the generic version of nevirapine.¹¹⁴ Further, it may be possible to purchase a generic copy of this medication at a reduced rate or to negotiate its donation.¹¹⁵

Nevirapine is a cost-effective solution to MTCT. A study evaluating the effectiveness of five different MTCT treatment programs using a hypothetical group of sub-Saharan African women found that the most expensive program – a targeted treatment program for an area with thirty percent HIV-1 seroprevalence – cost US\$141,922.00.¹¹⁶ As Sri Lanka's prevalence rate is far lower, approximately 0.07 percent, the cost of implementing an MTCT program would be much lower. The sub-Saharan study concluded that "[i]n lower seroprevalence areas, when multidose regimens are not cost-effective, nevirapine therapy could have a major public health impact at a reasonable cost."¹¹⁷

The WHO provides further guidance for incorporating a comprehensive MTCT program and implementing nevirapine treatment as part of a national AIDS strategy.¹¹⁸ It is important to

emphasize that, in order to be effective, nevirapine must be implemented as part of a complete treatment program that addresses the special needs of HIV-positive mothers and their children. For example, HIV-positive nursing mothers need reliable, accessible information about the risks of breastfeeding so that they can make educated decisions about how to feed their newborns. Also, to reduce the number of potential orphans, mothers should be provided with ARV therapy after they have given birth. Thus, nevirapine and other ARV treatments are critical to the health of HIV-positive women and an essential component of public policy to reduce the number HIV-infected infants and potential orphans.

2. Place ARVs on the EDL to provide effective treatment and prevention and progressively to realize the right to health.

We recommend that the government place a combination of ARV therapy on the country's EDL. While the choice of therapy and the number of combinations is within the NSACP's discretion, we believe that the government must begin to offer some treatment and, by extension, some hope to Sri Lankans living with HIV/AIDS. Providing ARV therapy constitutes concrete action by the government progressively to realize the right to health as well as to promote an effective strategy to combat the spread of HIV/AIDS.¹¹⁹ We direct the government to the Harvard Consensus Statement and the Panos Institute for guidance on choosing medications:

The ideal regimen should be potent and well tolerated; should have low drug toxicity; should be simple for the patient to take; and should not be prone to development of drug resistance. There are as yet no proven data that one particular regimen is best for initiating therapy, and therefore, several treatment regimens should be available for use in poor countries.¹²⁰

The Panos Institute recommends a combination such as Combivir® and Crixivan®.¹²¹

We believe that NSACP can negotiate significantly reduced prices for the patented medications.

In addition, generic versions of this popular combination therapy, and other ARVs, currently are available from multiple manufacturers at lower cost.

3. Place medicines to treat opportunistic infections on the EDL to provide effective HIV treatment and prevention and progressively to realize the right to health.

The Sri Lankan government can improve the quality and increase the length of life for an individual living with HIV/AIDS by providing access to medicines to treat opportunistic infections that are the result of HIV-related immunosuppression. In addition, providing treatment for these debilitating illnesses likely will increase the efficacy of prevention programs such as VCT. The greater the opportunities to receive life-enhancing treatment, the more likely are high-risk individuals to seek counseling and testing.¹²²

These medicines may be provided at relatively little cost—UNAIDS estimates that comprehensive prophylaxis and palliative care, for example, costs less than US\$20 per patient per year.¹²³ WHO provides a list of the most commonly used anti-infective agents to treat people living with HIV/AIDS¹²⁴ and many are already included on the WHO's model EDL.¹²⁵ Given the ability of drugs to (1) protect the health and extend the quality of life of people with AIDS and to (2) maximize the results of prevention programs, these medicines should be integrated into the government's strategy for addressing HIV/AIDS.¹²⁶

C. Formulate Short- and Long-Term Strategies to Procure Affordable ARVs to Provide an Effective Prevention and Treatment Program and Progressively to Realize the Right to Health.

ARVs can be costly and the implications of international intellectual property treaties on access to these pharmaceuticals are complex. However, several options exist for the Sri Lankan government to procure medicines at a price that it can afford, and in a manner consistent with ongoing treatment needs and international and domestic intellectual property rules. For example, Sri Lanka can begin immediately to increase access to ARVs by importing affordable and

successful generic drugs and by negotiating discounts with manufacturers of patented medicines. In the longer term, it is likely that Sri Lanka will be able to take advantage of language within international intellectual property agreements that ensures the rights of nations to protect the public health of their citizens by permitting governments to license domestic generic manufacturing of patented medications or to import newly developed generic medicines produced in other countries.¹²⁷

The Trade-Related Aspects of Intellectual Property (“TRIPs”) Agreement, signed by the member countries of the World Trade Organization (“WTO”) in Marrakesh, Morocco in April 1994, set out minimum standards for protection, general principles of enforcement and uniform dispute settlement procedures for intellectual property rights in all WTO nations.¹²⁸ Sri Lanka, as a signatory to this treaty and a country classified by the WTO as “developing”, had to draft compliant patent laws by January 1, 2000 and has until January 2005 to enforce fully patents on pharmaceuticals.¹²⁹ However, the TRIPS Agreement does not affect the ability of Sri Lanka to import generic ARVs that currently are produced or to negotiate with companies for donations of lower prices on patented drugs. Thus, several strategies exist for the Sri Lankan government to obtain continued access to safe, legal and affordable treatments for those living with HIV.

1. Purchase generic versions of medicines.

The Sri Lankan government is able to provide affordable and safe medicines for the prevention and treatment of HIV/AIDS while complying with its responsibilities under the TRIPs Agreement by purchasing available generic medications. Generic manufacturers based in India¹³⁰ currently sell generic versions of both nevirapine and popular combination therapies used successfully by many people battling HIV/AIDS.¹³¹ In WHO’s first list of manufacturers of safe AIDS drugs, Cipla was deemed a safe supplier of the antiretrovirals nevirapine, ziduvudine

and lamivudine, as well as acyclovir, ciprofloxacin, vinblastine and vincristine sulfate for treating secondary infections common in HIV positive individuals.¹³² Although TRIPs mandates that after January 2005, Sri Lanka must not import any generic pharmaceuticals that are covered by a patent application or have been granted patent protection since Sri Lanka's TRIPs compliance period ended on January 1, 2000, nothing in the TRIPs Agreement prevents the government from importing generics that currently are available and were not covered by patent protection before January 1, 2000.¹³³ Since generic forms of newer generations of ARVs will be harder to import due to TRIPs compliance, the Sri Lankan government should seize its opportunity to legally import affordable generic versions of HIV/AIDS medications that currently are successful in fighting the virus.

2. Negotiate with pharmaceutical companies to purchase affordable patented medicines.

Under TRIPs, the Sri Lankan government also can import patented, name-brand HIV/AIDS medications. While patented drugs normally are more expensive than generics, countries such as South Africa and Brazil have successfully negotiated reduced prices with pharmaceutical companies.¹³⁴ A negotiated discount may be attractive to a pharmaceutical company that is eager to bolster its public image or seeks to avoid future compulsory licensing. WHO representatives can assist the government in negotiating directly with pharmaceutical companies to import nevirapine, other ARVs and drugs for opportunistic infections. Such importation of patented medications provides Sri Lanka with another option to access new and effective treatments to prevent HIV and care for those that are infected.

D. Strengthen the Sri Lankan Public Health System's Capacity to Deliver Comprehensive Services for Persons with HIV/AIDS.

Sri Lanka has a solid health infrastructure that could form the basis for effective HIV/AIDS testing, treatment and monitoring.¹³⁵ The Sri Lankan health program is noteworthy

for its provision of holistic services to all socioeconomic classes of society and for its close interaction between public health workers and patients in urban and rural areas.¹³⁶ The Sri Lankan health system utilizes an advanced service structure in which family health workers act as liaisons between the community and the formal health care delivery system. This structure cultivates community participation through village leaders and voluntary health workers.¹³⁷ With the infrastructure, organization and the capacity to meet the primary health care needs of the whole family, Sri Lanka is in an excellent position to support integrated HIV/AIDS sites that would provide proper prevention, testing and treatment programs.¹³⁸

1. Leverage Sri Lanka's existing health infrastructure for the prevention and treatment of HIV/AIDS.

Sri Lanka should leverage its existing health infrastructure to create an effective HIV/AIDS strategy that incorporates prevention education, testing and treatment.¹³⁹ We understand that the government already has a national STD services infrastructure with HIV-specific services¹⁴⁰ and products, including a basic training manual for healthcare providers on HIV/AIDS treatment.¹⁴¹ Further, Sri Lanka has medical resources beyond the public health system including an excellent public university system with six medical schools. Moreover, the country has over 600 hospitals.¹⁴² Although some of those hospitals are private, most of them are government-run.¹⁴³ Sixteen are teaching hospitals,¹⁴⁴ many of which would be excellent sites for integrated HIV/AIDS treatment and care pilot programs that also could function as research projects.

In addition, Sri Lanka can look to examples of effective ARV treatment programs in developing countries such as Haiti¹⁴⁵ and Guatemala.¹⁴⁶ These programs could serve as models for developing treatment sites in Sri Lanka. Many international health organizations with expertise in providing HIV care and treatment are active in Sri Lanka, including the well-known

NGO Médecins Sans Frontières, which has been working in Sri Lanka since 1986.¹⁴⁷ The Sri Lankan government should take advantage of the expertise and resources of these NGOs and request their assistance in the creation of prevention and treatment programs.

2. Equip hospitals and treatment centers with improved HIV/AIDS testing and diagnostic systems and provide training for personnel.

As stated above in Section I.A.2, we believe that access to treatment will encourage individuals to participate in voluntary counseling and testing (“VCT”). A recent study evaluated VCT programs in Kenya and in Tanzania and found that the annual program costs to serve 10,000 patients were US\$266,500 and US\$289,300, respectively.¹⁴⁸ This study concluded that VCT programs are “highly cost-effective” for several reasons, including the fact that the cost of HIV infections averted is substantially less than the cost of treatment.¹⁴⁹ However, the success of VCT as a prevention strategy requires accurate, reliable and widely available HIV testing laboratory services. Thus, pursuing VCT as a prevention strategy requires investment in diagnostic systems and training personnel to use them. The WHO, recognizing the importance of available HIV testing sites, has implemented a project to provide member states with HIV testing kits at approximately half the market price.¹⁵⁰

As stated above in Section I.A.2, VCT programs are only effective if combined with treatment programs. Sri Lanka has limited microbiology facilities.¹⁵¹ However, the current lack of appropriate microbiology services should not be viewed as an insurmountable barrier to providing ARV treatment. We urge the Sri Lankan government to upgrade its microbiology services so that HIV-positive patients can receive accurate assessments of the disease progression based on viral load counts and CD4 (T-lymphocyte white blood cell) cell counts.

Recent research indicates that sophisticated and expensive testing to monitor a patient’s HIV viral load and CD4 cell count are not required to implement effective ARV treatment

programs.¹⁵² For example, in one program without access to HIV viral load and CD4 testing equipment, patients assessed for ARV treatment are those with chronic enteropathies or other forms of HIV-associated wasting, patients with presumed neurological complications of HIV, those with repeated opportunistic infections unresponsive to antibacterials and antifungals, and patients with severe leukopaenia, anemia or thrombocytopenia. Two physicians, one with infectious-disease training, assess each patient.¹⁵³ As stated in Section III.D.I., there are local and international resources available if Sri Lanka were to seek training regarding the clinical diagnosis of HIV and treatment of the accompanying opportunistic infections for its healthcare providers. Thus, we recommend the government incorporate into the Prevention Plan a proposal to appropriately equip and fund pilot treatment sites.

E. Create and Support a Planning Council of Local Non-Governmental Organizations (“NGOs”) Including Associations of People Living with HIV/AIDS, International Health Organizations, Donors, Government, and Private Sector Representatives to Participate in All Stages of Strategic Planning, Project Development, Program Evaluation, and Long-Term Monitoring.

Based on its proposed Prevention Project we believe that Sri Lanka is committed to the declaration issued after the 2001 United Nations General Assembly Special Session on HIV/AIDS (“UNGASS Declaration”). This document encourages governments to combat HIV/AIDS by forming collaborations with civil society, the business community and the private sector.¹⁵⁴ The participation of NGOs has been recognized by the World Bank in its own operational procedures as a crucial element in the formulation of sound policy and the preservation of transparent governance. GP 14.70, Section 10 of the World Bank Operational Manual¹⁵⁵ states that:

[B]ank staff should investigate concerns voiced by NGOs regarding projects and the application of policies, provide timely and substantive responses, and meet with NGOs and affected parties when possible. Similarly, the bank encourages

borrower governments to be responsive to local NGO requests and concerns that relate to the development policies and programs.

We urge the government to adopt this principle as its actions and omissions directly affect the lives of the individuals represented by these NGOs. Therefore, we respectfully recommend that the following steps be taken to create¹⁵⁶ a collaborative structure for addressing HIV/AIDS in Sri Lanka.

1. Convene an inaugural meeting with stakeholders.

In response to a World Bank-funded analysis of the health sector,¹⁵⁷ the government of Sri Lanka is formulating a long-term strategy for improving the provision of health services.¹⁵⁸ The Sri Lankan government has acknowledged that the World Bank analysis identified centralization of HIV policy within a single department as a major obstacle to combating HIV/AIDS.¹⁵⁹ To date, however, one governmental agency (the NSACP) has assumed sole responsibility for planning HIV/AIDS strategy in Sri Lanka, while other governmental departments and NGOs have remained largely outside the planning process.¹⁶⁰

As noted above, the government appreciates the need for wider collaboration to most effectively address the AIDS epidemic. As the government (and specifically the NSACP) recognizes, all members of global, national, and local communities have a responsibility to join in the fight against HIV. To this end, we urge the NSACP to convene a meeting with persons living with HIV/AIDS, doctors and public health professionals, representatives of other government departments, interested NGOs, religious leaders and community members to discuss the government's long-term strategy for confronting HIV/AIDS. Representatives of the AIDS Coalition and the Center for Policy Alternatives would like to attend this meeting. They are also willing to assist with its organization.

2. Circulate the national strategic plan for the provision of HIV/AIDS services covering the period from 2001-2006.

The NSACP describes a timeline in the Prevention Project for implementation of basic HIV-related health services, referred to as the “National Strategic Plan for 2001-2006.”¹⁶¹ To date, this document has not been made public. We look forward to reviewing a copy of the government’s strategic plan and express our hope that it includes a timetable and specific numeric targets for providing immediate access to antiretroviral and opportunistic infection therapies.

3. Create an HIV/AIDS services planning council.

To implement the UNGASS declaration, we believe that NSACP should create a planning body that includes individuals living with HIV/AIDS, representatives from the public health system and representatives from NGOs serving people living with HIV/AIDS. Including varied stakeholders in such a structure will increase transparency and accountability in national treatment and prevention programs, ensure the most effective allocation of funds (such as the World Bank funds) earmarked for AIDS services, and will allow the government and AIDS service organizations to avoid allegations—real or alleged—of misuse of funds.

One possible model for such a planning body may be the local Planning Councils mandated by the U.S. federal government to identify gaps in HIV care and services, set priorities, and allocate funds to provide a continuum of care for persons with HIV/AIDS.¹⁶² Planning Councils comprise volunteer members from the local community and facilitate strategic responses to the changing needs of the community.

4. Develop adequate long-term monitoring and information dissemination systems for all HIV/AIDS-related programs.

Developing a system to monitor the availability of expanded HIV services in Sri Lanka is crucial to the success of these services and will build on and strengthen the existing HIV and STD surveillance infrastructure. In any program that is established, the following services must be assessed:

- 1) the availability and utilization of voluntary counseling and testing services;
- 2) the availability, access and usage of antiretroviral medication and medications to treat opportunistic infections. The numbers of prescriptions for these drugs can be considered as a surrogate for the number of people accessing care; and
- 3) the awareness by high-risk populations of the availability of VCT and ARVs.

A brief form completed by staff of antenatal clinics and facilities serving patients with STDs and tuberculosis would provide information on the availability of VCT services and the number of patients who have used these services in the past month.¹⁶³ Monthly or quarterly reporting thereafter would indicate whether increased availability of services has resulted in increased use of VCT. A brief telephone or letter survey from pharmacies in government facilities would enable NSACP to determine what proportion of pharmacies have ARVs available and estimate the number of patients regularly receiving HIV therapy. Information from private and government laboratories regarding the availability of HIV testing services, the type of tests, and techniques used by the staff also is vital and could be collected through surveys. These services must be provided anonymously. Studies have shown that anonymity is essential in the performance of testing, data collecting, and reporting services because the safety of anonymity encourages individuals to seek testing earlier, thereby having the chance to start treatment earlier should the results be positive.¹⁶⁴

Anonymous post-testing surveys of patients who have used VCT services would enable NSACP to determine whether or not patients understood the information they received, felt they were treated with respect and compassion, would encourage others to get tested in the future, and were aware that treatment for HIV is available to them should they test positive. The results of these surveys would enable local staff to improve upon their services and would permit NSACP to assess which clinics and which strategies to pursue. Surveys of clientele attending STD clinics also would enable NSACP to assess whether high-risk groups were aware of the availability of treatment for HIV. Similar surveys of clientele at antenatal clinics would provide complementary information.

As opportunities to access ARVs increase, it is vital that general practitioners as well as staff in government clinics be aware of the increased availability of HIV treatment and that they receive accurate information which enables them to refer patients to obtain medicines. A bulletin sent out to health care providers directly by NSACP may be a relatively inexpensive method of disseminating reliable information to healthcare workers. The proposed Planning Council may suggest other dissemination methods.

F. Proposed Timeline for Implementation of Recommendations.

Below, we submit our proposed timeline for the implementation of the above recommendations.

Immediately

- 1) Amend the National Formulary to include all ARVs and other HIV/AIDS medications.

- 2) Amend the proposed Prevention Project to include a treatment agenda that provides nevirapine, medications for opportunistic infections and ARVs to individuals in Sri Lanka with HIV/AIDS.
- 3) Amend the EDL to include some ARVs and other HIV/AIDS medications.
- 4) Distribute the National Strategic Plan for provision of HIV/AIDS services covering the period from 2001–2006 to stakeholders including, the AIDS Coalition and the Center for Policy Alternatives.
- 5) Begin to create adequate long-term monitoring of the program.
- 6) Begin to develop appropriate institutions and trained personnel responsible for diagnosis and prescription of drugs.

May 2002

Convene a meeting of stakeholders in conjunction with the World Bank appraisal visit.

June 2002

Inform NGO stakeholders of the amount earmarked for treatment upon approval of the Prevention Project.

August 2002

Create a local planning council system to inform project design and strategy for implementation.

The proposed Prevention Project creates an immediate opportunity for Sri Lanka to make a quantum leap progressively to realize the right to health. With World Bank financing and modifications to the existing plan as outlined above, we believe Sri Lanka is poised to become a South Asian success story in the fight against HIV.

¹ The National AIDS Prevention Project (ID# LKPE74730) [“Prevention Project”] is a proposal drafted by the Sri Lankan Ministry of Health which requests US\$10 million for HIV prevention activities. The proposal is pending before the World Bank, at <http://www.worldbank.org>.

² Our collaboration consists of the following organizations:

- **The AIDS Coalition for Care, Education and Support Services (“the AIDS Coalition”):** The AIDS Coalition is a Sri Lankan NGO based in the capital city of Colombo. The AIDS Coalition provides a range of services to Sri Lankans living with HIV. For more information about the AIDS Coalition see: <http://www.companionsonajourney.com/aids.htm>.
- **AIDS Lanka:** Founded in October 2000, AIDS Lanka’s mission is to increase access to antiretroviral medications (“ARVs”) in order to improve the quality of life of those living with HIV/AIDS in Sri Lanka. The organization is a multi-disciplinary initiative of medical providers, lawyers and public health experts.
- **The International Human Rights Law Clinic at the University of California, Berkeley, Boalt Hall School of Law:** The International Human Rights Law Clinic works with human rights organizations and activists in the U.S. and abroad on innovative human rights projects.
- **The East Bay Community Law Center (“EBCLC”):** EBCLC provides free legal services to low-income residents of Alameda County in California. EBCLC’s HIV/AIDS Law Project is the primary legal service provider for people with HIV in the Alameda County.
- **The Samuelson Law, Technology and Public Policy Clinic at the University of California, Berkeley, Boalt Hall School of Law:** The Samuelson Clinic was the first clinic in the country to provide law students with the opportunity to represent the public interest in cases and matters on the cutting-edge of high technology law.

³ World Bank Operational Manual, GP 14.70, February 2000, available at <http://wbln0018.worldbank.org/Institutional/Manuals/OpManual.nsf/tocall/1DFB2471DE05BF9A8525672C007D0950?OpenDocument> (last visited April 9, 2002).

⁴ Address by the Honorable W.D.J. Seneviratne [Former] Minister of Health of the Democratic Socialist Republic of Sri Lanka at the Twenty-sixth Special Session of the United Nations General Assembly on HIV/AIDS (June 26, 2001), at <http://www.un.org/ga/aids/statements/docs/srilankaE.html> (last visited April 5, 2002).

⁵ U.N. GAOR, Special Session on HIV/AIDS, *Declaration of Commitment on HIV/AIDS: Global Crisis—Global Action*, U.N. Doc. S-26/2 (2001) [hereinafter Declaration of Commitment], para. 17.

⁶ UNAIDS MAP Report 2001, *The Status and Trends of HIV/AIDS/STI epidemics in Asia and the Pacific* (October 2001), at <http://www.unaids.org/hivaidinfo/statistics/MAP/index.html> (last visited April 9, 2002).

In Cambodia, concerted efforts, driven by strong political leadership and public commitment, lowered HIV prevalence among pregnant women to 2.3 percent at the end of 2000—down by almost one third from 1997. UNAIDS, *AIDS Epidemic Update* (December 2001), at http://www.unaids.org/epidemic_update/report_dec01/ (last visited April 9, 2002).

In Thailand, condom use among sex workers rose steadily from 10 percent in 1989 to 90 percent by the mid-1990s, contributing to overall reduction of new HIV infections. In the absence of intervention programs, Thailand today would have adult prevalence rates of 10 to 15 percent rather than the actual level of approximately 2 percent. Joan Stephenson, *Swift Action Needed to Prevent Explosive HIV/AIDS Epidemics in Asia*, 286 J. AM. MED. ASS’N 16 (2001), <http://jama.ama-assn.org/issues/v286n16/ffull/jmn1024-2.html>.

⁷ In Cambodia, for example, the number of HIV-infected individuals increased from 184,600 to 220,000 from 1998 to 1999 despite national prevention efforts. During this time, the overall HIV prevalence rate in those ages 15 to 49

years increased from 3.70 to 4.04 percent. UNAIDS 2000 Revised Update, *Epidemiological Fact Sheet on HIV/AIDS and Sexually Transmitted Infections: Cambodia* (December 2000), at http://www.unaids.org/hivaidsinfo/statistics/fact_sheets/pdfs/Cambodia_en.pdf.

⁸ UNAIDS, *AIDS Epidemic Update* (December 2001), at http://www.unaids.org/epidemic_update/report_dec01/ (last visited April 9, 2002).

⁹ UNAIDS, *Report on the Global HIV/AIDS Epidemic* (June 2000), at http://www.unaids.org/epidemic_update/report/index.html (last visited April 9, 2002); *supra* note 8.

¹⁰ Laura Tarter and Paul Farmer, *Confronting the Global HIV Epidemic: A Call for Equity*, 2 HARV. HEALTH POL'Y REV. 2 (2001), <http://hcs.harvard.edu/~epihc/currentissue/Fall2001/tater.htm> (last visited April 9, 2002).

¹¹ *Infra*, § I.A.2.

¹² *Infra*, § I.B.

¹³ *Infra*, § I.C.

¹⁴ *Id.*

¹⁵ World Bank Update, UN General Assembly Special Session on AIDS, *Regional Updates: South Asia Region: Sri Lanka* (December 2000), at <http://www.worldbank.org/ungass/srilanka.htm> (last visited April 9, 2002).

¹⁶ Feizal Samath, *Sri Lanka Health: Economic Cost of AIDS Complacency*, INTERPRESS NEWS SERVICE, October 5, 1997.

¹⁷ See TvT Associates, Inc., The Synergy Project, *Country Summary: Sri Lanka* (October 1999), at http://www.synergyaids.com/files.fcgi/571_Srilanka5.pdf (last visited April 9, 2002).

¹⁸ Former Sri Lankan Minister of Health, W.D.J. Senviratne, has pointed to factors that may help fuel an HIV/AIDS epidemic in the country. The factors include 1) fifty percent of the population in Sri Lanka is sexually active; 2) internal and external migration help fuel an epidemic of HIV/AIDS in the country; 3) displacement either for employment or on account of the ongoing conflict; 4) narcotics usage; 5) poverty; and 6) ignorance. See Honorable W.D.J. Senviratne, *supra* note 4.

¹⁹ Feizal Samath, *Island Fever*, POZ IN ASIA, Colombo, Sri Lanka, July 2000, <http://www.poz.com/archive/july2000/inside/srilanka.html> (last visited April 9, 2002).

²⁰ World Bank Update, *supra* note 15.

²¹ One agency estimated that there may be as many as 20,000 to 30,000 child prostitutes, the majority of whom are beach boys. UNICEF, *Profiting from Abuse: An Investigation Into the Sexual Exploitation of Our Children* (November 2001), at <http://www.unicef.org/pubsgen/profit/profit.pdf> (last visited April 9, 2002). In 1998, nongovernmental organizations working in the area of child prostitution estimated that 5 percent of 350,000 to 400,000 tourists arrive in Sri Lanka for the purpose of sex tourism. TvT Associates, Inc., *supra* note 17.

²² Tharuka Dissanaiké, YouandAIDS.org, South Asia Intercountry Programme office of UNAIDS, *Sri Lanka's Beach Boys: Soft Targets for HIV* (August 2002), at <http://www.youandaids.org/news/southasia/srilanka.asp> (last visited April 9, 2002).

²³ *Id.*

²⁴ For example, in 1997, only 4.7 percent of men between the age of 15-49 in Matale and 9.6 percent of men in Colombo reported ever having had used condoms. Among men who had sex with casual partners, only 26.3 percent

in Matale and 44.4 percent in Colombo reported using a condom in the past year. World Bank Update, *supra* note 15.

²⁵ See generally, Heiner Grosskurth, *Control of Sexually Transmitted Diseases for HIV-1 Prevention: Understanding the Implications of the Mwanza and Rakai Trials*, 355 THE LANCET 1981-1987 (2000).

²⁶ The highest HIV prevalence in Cambodia is observed among female sex workers, 42.6 percent in 1998. STDs are highly prevalent among female sex workers (61.3% in urban areas) and condom use is low among both female sex workers and their male customers (36%). UNAIDS 2000 Revised Update, *supra* note 7.

²⁷ Iyanthi Abeyewickreme & Kingsley de Silva, *Health Care Systems in Transition III. Sri Lanka, Part II. The Current Status of HIV-AIDS in Sri Lanka*, 22 J. PUBLIC HEALTH MED. 21, 22 (2000).

²⁸ *Id.*

²⁹ The Burnet Institute, The Centre for Harm Reduction, *Revisiting 'The Hidden Epidemic' – A Situation Assessment of Drug Use in Asia in the context of HIV/AIDS* (January 2002), at <http://www.chr.asn.au/Rapidassessment.pdf> (last visited April 9, 2002).

³⁰ United Nations, International Narcotics Control Board, *Regional Update: South Asia* (1995), at http://www.un.org/ecosocdev/geninfo/drugs/souasi_e.htm (last visited April 9, 2002).

³¹ World Bank Update, *supra* note 15.

³² The Burnet Institute, *supra* note 29.

³³ *Id.*

³⁴ Feizal Samath, *supra* note 19. Comparative data suggest that HIV rates among injecting drug users can grow very rapidly. For example, in the late 1980s during an eight-month period, in Bangkok, Thailand, HIV prevalence among injecting drug users grew from virtually nothing to almost 40 percent. In Manipur, India, prevalence grew from a few percent to 80 percent in only three to four years. UNAIDS MAP Report 2001, *supra* note 6.

³⁵ For 1998, 1999 and 2000 statistics on migrant labor in Sri Lanka, see the official Web site of the Sri Lanka Bureau of Foreign Employment at <http://www.slbfe.lk/> (last visited April 5, 2002).

³⁶ Xinhua News Service, *27 More AIDS Cases Reported in Sri Lanka in First Half of 2001* (July 16, 2001), <http://www.xinhuanet.com/english/20010716/430058.htm>. There is a substantial difference between the number of reported AIDS cases and estimates of HIV cases in Sri Lanka. The latter figure of 8,500 has been estimated by WHO epidemiologists who extrapolated from the number of actual, reported cases and considered the in-country risk factors. For a description of the methodology, see World Health Organization, *Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections 2000 Update (Revised)*, at 3 (2000), at http://www.who.int/emc-hiv/fact_sheets/pdfs/Srilanka_EN.pdf (last visited April 9, 2002).

³⁷ Free Trade Zones are areas established in South Asia with the goal of attracting foreign capital through preferential tax treatment and other government incentives. Library of Congress Country Studies, *Sri Lanka - A Country Study* (February 2002), at <http://leweb2.loc.gov/frd/cs/lktoc.html> (last visited April 9, 2002).

³⁸ World Bank Update, *supra* note 15.

³⁹ UNAIDS MAP Report 2001, *supra* note 6. In particular, Nepali women sex workers who had a history of working in India reported 50 percent HIV prevalence compared to 1.2 percent who had never worked in India. See *id.*

⁴⁰ World Bank Update, UN General Assembly Special Session on AIDS, *Regional Updates: South Asia Region* (December 2000), at <http://www.worldbank.org/ungass/sar.htm> (last visited April 9, 2002).

⁴¹ UNAIDS, Contact Group on Accelerating Access to HIV/AIDS-Related Care, *Voluntary Counseling and Testing (VCT)* (May 2001), at http://www.unaids.org/acc_access/contact_group/May2001/Session3a.pdf (last visited April 9, 2002); UNAIDS, *Fact sheet: HIV/AIDS Care and Support* (June 2001), at http://www.unaids.org/fact_sheets/ungass/html/FScare_en.htm (last visited April 9, 2002).

⁴² Partners AIDS Research Center, *Consensus Statement on Antiretroviral Treatment for AIDS in Poor Countries* (March 2001), at http://www.mgh.harvard.edu/depts/aids/images/consensus_aids_therapy.pdf (last visited April 9, 2002). The statement was signed by individual faculty of Harvard University. See also Gustavo Capdevila, *New WHO Model to Fight Infectious Diseases*, PAKISTANI DAWN, February 3, 2002, at <http://www.dawn.com/2002/02/03/int15.htm> (last visited April 9, 2002); and WHO, *Report on Infectious Diseases, Scaling up the Response to Infectious Diseases: A Way out of Poverty* (February 2002), at <http://www.who.int/infectious-disease-report/2002/> (last visited April 9, 2002).

⁴³ UNAIDS, *The UN Secretary General to Lead the Fight Against HIV/AIDS* (April 2001), at http://www.unaids.org/whatsnew/press/eng/pressarc01/amsterdam_050401.html (last visited April 9, 2002).

⁴⁴ *Id.* See also, Family Health International, *IMPACT ON HIV: LINKING CARE AND PREVENTION*, Vol. 1, No. 1 (October 1998), <http://www.fhi.org/en/aids/impact/iohiv/ioh11/index.html> (last visited April 9, 2002). This randomized, controlled trial conducted at counseling centers in Kenya, Tanzania and Trinidad found that voluntary testing, combined with professional pre- and post-test counseling, encourages people to change their behavior in order to prevent HIV transmission.

⁴⁵ The Panos Institute, *Beyond Our Means? The Cost of Treating HIV/AIDS in the Developing World* (December 2001), at http://www.panos.org.uk/aids/access_report_ext.htm (last visited April 9, 2002); Partners AIDS Research Center, *supra* note 42.

⁴⁶ World Bank Update, *supra* note 15. For more information on the stigma related to HIV, see also Report from Stigma and Discrimination Conference held in Colombo, Sri Lanka on December 28, 2001, on file with EBCLC; and Section II of this document.

⁴⁷ UNAIDS, *supra* note 41.

⁴⁸ E.A. Talbot et al., *Knowledge, Attitudes and Beliefs Regarding Tuberculosis Preventive Therapy for HIV-Infected Persons, Botswana*, 4 INT. J. TUBERC. LUNG DIS. 1156 – 1163 (2000).

⁴⁹ Partners AIDS Research Center, *supra* note 42.

⁵⁰ Ronald H. Gray et al., and the Rakai Project Team, *Probability of HIV-1 Transmission per Coital Act in Monogamous, Heterosexual, HIV-1-Discordant Couples in Rakai, Uganda*, 357 LANCET 1149-1153. (Abstract on file with EBCLC.)

⁵¹ *Id.*

⁵² Partners AIDS Research Center, *supra* note 42.

⁵³ *Id.*

⁵⁴ See generally, Mattias Ganslandt, et al., *Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal*, 24 THE WORLD ECONOMY 779, 783- 86 (2001), at <http://swopec.hhs.se/uiwop/abs/uiwop0552.htm> (last visited April 9, 2002).

⁵⁵ UNAIDS, *supra* note 8.

⁵⁶ WHO, *supra* note 42.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² The figures are current as of 1999. UNAIDS, Contact Group on Accelerating Access to HIV/AIDS-Related Care, *Universal Access to Antiretroviral Therapy: the Brazilian Experience* (December 2000), at http://www.unaids.org/acc_access/acc_care_support/DiscursoDrPauloARVContactGroup.doc (last visited April 9, 2002).

⁶³ *See generally*, WHO, Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development* (December 2001), at <http://www3.who.int/whosis/menu.cfm?path=cmh&language=english>. This report, presented to the WHO by the Harvard Professor Jeffrey D. Sachs, Chair of the Commission on Macroeconomics and Health, concluded that treatment of HIV-positive individuals not only saves lives, but also provides an essential boost to economic development. The report states that a recommended \$66 billion increase in global health investments will save 8 million lives per year and generate at least a US\$360 billion annual gain within 15 years, a sixfold return on the investment.

⁶⁴ *Id.*

⁶⁵ Recently, Aruna has received some HIV drugs through international donations; however, the supply is not a secure one.

⁶⁶ Rose's story is based on the experiences of a member of the AIDS Coalition who wishes to remain anonymous. The facts were provided by e-mail communication with the authors of this brief. Information about Rose is on file at EBCLC.

⁶⁷ WHO, *supra* note 42.

⁶⁸ Since the 1990s, there has been increased awareness of human rights as an important factor "in determining people's vulnerability to HIV infection and their consequent risk of acquiring HIV infection and chances of accessing appropriate care and support." Sofia Gruskin and Daniel Tarantola, *HIV/AIDS and Human Rights Revisited*, CANADIAN HIV/AIDS POLICY & L. REV., Vol. 6, No. 1/2 (2001), at 3, http://www.aidslaw.ca/Maincontent/otherdocs/Newsletter/vol6nos1-22001/discrimination.htm#_edn4 (last visited April 9, 2002). Even more recently, "human rights have come to be understood to be directly relevant to every element of the risk/vulnerability paradigm." *Id.* Response to the epidemic requires attention to the links between HIV/AIDS and international human rights law as contained in such human rights treaties as the International Covenant on Economic, Social and Cultural Rights ("ICESCR" or the "Covenant"), the Convention on the Elimination of All Forms of Discrimination Against Women ("CEDAW"), the International Convention on the Elimination of All Forms of Racial Discrimination ("CERD"), and the Convention on the Rights of the Child ("CRC"), all of which Sri Lanka has ratified. *See* Status of Ratification of UN Human Rights Treaties, *infra* note 71. The connections between HIV and the human rights articulated in these treaties have been reiterated and increasingly clarified in the normative statements of the U.N. General Assembly (*see, e.g.*, Declaration of Commitment, *supra* note 5); the World Health Assembly (*see*, <http://www.who.int/m/topicgroups/governance/en/index.htm> (last visited April 9, 2002) and, for an example of the exercise of this body's policymaking function, *see*, World Health Assembly Res. 54.10, *Scaling up the Response to*

HIV/AIDS, May 21, 2001); United Nations human rights treaty monitoring bodies, and by the U.N. Commission on Human Rights. For an example of one such statement by the Commission, see Res. 2001/33, *infra* note 78.

⁶⁹ *Infra* § II.A.

⁷⁰ See, e.g., Universal Declaration of Human Rights, G.A. Res. 217 A(III), U.N. Doc A/810 at 71 (1948), art. 25 (“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services [...]”); International Covenant on Economic, Social and Cultural Rights, Jan. 3, 1976, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. No. 16 at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, art. 12 [hereinafter ICESCR]: (“(1) The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for [...] (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases [and] (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”); International Convention on the Elimination of All Forms of Racial Discrimination (CERD), 660 U.N.T.S. 195, *entered into force* Jan. 4, 1969, article 5(e)(iv); and the Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW), G.A. Res. 34/180, U.N. GAOR Supp. No. 46 at 193, U.N. Doc. A/34/180, *entered into force* Sept. 3, 1981, arts. 11.1(f) and 12 (requiring, respectively, that State parties eliminate discrimination against racial minorities and women in health care policies and systems); Convention on the Rights of the Child (CRC), article 24 (providing that State parties are obligated to support the right to access to health care services, including facilities for treatment of illness and rehabilitation of health for children; take steps to reduce infant and child mortality; provide health care to children; combat disease and malnutrition; and develop preventive health care, medical assistance and health care for children).

In addition, the World Health Organization (WHO), of which Sri Lanka is a member state, defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” Constitution of the World Health Organization (preamble), *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185, *reprinted in* BASIC DOCUMENTS (WHO, 36th ed. 1986) (“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”). While this definition of health was not explicitly incorporated into article 12 of the ICESCR, “the reference in article 12.1 of the Covenant [on Economic, Social and Cultural Rights] to ‘the highest attainable standard of physical and mental health’ is not confined to the right to health care.” U.N. GAOR, *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, Committee on Economic, Social and Cultural Rights, 22nd Sess. (2000), U.N. Doc. E/C.12/2000/4, para. 4 [hereinafter General Comment No. 14].

⁷¹ See the Office of the U.N. High Commissioner for Human Rights, *Status of Ratifications of the Principal International Human Rights Treaties as of February 8, 2002*, at 8, at <http://www.unhchr.ch/pdf/report.pdf> (last visited April 9, 2002).

⁷² U.N. GAOR, *General Comment No. 3: The nature of States parties obligations (Art. 2, par. 1)*, Committee on Economic, Social and Cultural Rights, 5th Sess. (1990), U.N. Doc. E/1991/23, Annex III, para. 10 [hereinafter General Comment No. 3].

⁷³ ICESCR, *supra* note 70, art. 2(1).

⁷⁴ General Comment No. 3, *supra* note 72, para. 9.

⁷⁵ See Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, *reprinted in* International Commission of Jurists, ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A COMPILATION OF ESSENTIAL DOCUMENTS, at pars. 9-10 (International Commission of Jurists ed., 1997).

⁷⁶ ICESCR, *supra* note 70, art. 12.

⁷⁷ See, e.g., Universal Declaration of Human Rights, *supra* note 70, art. 25; ICESCR, *supra* note 70, art. 21.

⁷⁸ G.A. Resolution 2001/33, *Access to Medication in the Context of Pandemics Such as HIV/AIDS*, U.N. Human Rights Comm., 71st mtng., U.N. Doc. E/CN.4/RES/2001/33 (2001), para. 1 [hereinafter Res. 2001/33].

⁷⁹ Res. 2001/33, *supra* note 78, para. 2.

⁸⁰ General Comment No. 14, *supra* note 70, para. 12(a); *see also*, WHO Action Programme on Essential Drugs, Dept. of Essential Drugs and Medicines Policy, *Framework for Action: Objectives and Expected Outcomes for 2000-2003*, at <http://www.who.int/medicines/strategy/whozip16e/ch08.htm> (last visited April 9, 2002).

⁸¹ *See* WHO, 11th Model List of Essential Drugs, reproduced in WHO Drug Information 1999, Vol. 13, No. 4, § 6.4.2., <http://www.who.int/medicines/organization/par/edl/edl11.pdf> (last visited April 9, 2002). The Model List is designed for use as “an informational and educational tool for professionals and consumers... [and] an aid to developing treatment guidelines, national formularies, consumer drug information, and other measures to improve drug use.” Zidovudine and nevirapine were introduced for the specific treatment of HIV-infected pregnant women in order to reduce mother-to-child transmission and to protect the newborn baby. It is important to note that antiretrovirals are not the only drugs needed for the prevention and treatment of HIV/AIDS. As of October 2000, 75 out of 117 drugs recommended under then-existing UNAIDS and WHO guidelines for the treatment and prevention of HIV/AIDS were already on the WHO Model List of Essential Drugs. *See* Dr. Hans V. Hogerzeil, *The definition and selection process for an EDL*, WHO Dept. of Essential Drugs and Medicines Policy (technical briefing paper), October 27, 2000, at <http://www.who.int/medicines/organization/par/edl/infedltechbrief.htm>.

⁸² *See* HIV/AIDS and Human Rights: International Guidelines, HR/PUB/98/1, Geneva 23-25 September 1996 (U.N., New York and Geneva 2001), <http://www.unaids.org/publications/documents/human/law/JC520-HumanRights-E.pdf> [hereinafter International Guidelines] (last visited April 9, 2002). The guidelines were produced at the Second International Consultation on HIV/AIDS and Human Rights, jointly organized by the Office of the United Nations High Commissioner for Human Rights and UNAIDS. They offer concrete measures that could be taken to protect human rights and health, in line with Member States international human rights obligations. While in many resolutions the General Assembly has urged countries to implement the guidelines, they are not legally binding.

⁸³ U.N. GAOR, Special Session of the General Assembly on HIV/AIDS, *Roundtable 2: HIV/AIDS and human rights*, U.N. Doc. A/S-26/RT.2, June 15, 2001, para. 5 [hereinafter Roundtable 2]. *See also*, General Comment No. 14, *supra* note 70, para. 33. We do not address the Sri Lankan government’s compliance with the requirements to respect and protect the all the fundamental rights of HIV-infected persons in this memorandum, but rather the nature and content of the government’s obligation to *fulfill* the right to health.

⁸⁴ Declaration of Commitment, *supra* note 5, para. 15.

⁸⁵ ICESCR, *supra* note 70, art. 2(1).

⁸⁶ U.N. GAOR, Special Session of the General Assembly on HIV/AIDS, *Roundtable 1: Prevention and Care*, U.N. Doc. A/S-26/RT.1, June 15 2001, para. 27 [hereinafter Roundtable 1].

⁸⁷ Joint Communiqué from Secretary General and Seven Leading Research-Based Pharmaceutical Companies on Access to HIV/AIDS Care and Treatment, Press Release SG/SM/7982 AIDS/34, 4 October 2001, para. 5, <http://www.un.org/News/Press/docs/2001/sgsm7982.doc.htm> (last visited April 9, 2002).

⁸⁸ *Id.* at para. 28.

⁸⁹ Res. 2001/33, *supra* note 78 at para. 3(c).

⁹⁰ This obligation is further supported by the U.N. General Assembly’s *Declaration of Commitment on HIV/AIDS*, *supra* note 5, para. 55 (calling on State Parties “[i]n an urgent manner [to] make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including... [the] effective use of quality-controlled antiretroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance; and to cooperate constructively in

strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with international law.”) Further, the duty to adopt “a national strategy to ensure to all the enjoyment of the right to health, based on human rights principles” is discussed extensively by the U.N. Committee on Economic, Social and Cultural Rights in General Comment No. 14, *supra* note 70, para. 43(f). *See also*, Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 *IND. L. REV.* 1457, 1470 (2001).

⁹¹ General Comment No. 14, *supra* note 70, paras. 35-37.

⁹² *See* Res. 2001/33, *supra* note 78, para. 3(c).

⁹³ Treatment Action Center *et al.* v. Minister of Health, Case No. 21182/200, Transvaal Provincial Division, 18 December 2001, 42-43, at <http://www.tac.org.za/Documents/MTCTCourtCase/mtctjudgement.doc> (last visited April 9, 2002).

⁹⁴ *Id.*

⁹⁵ *See* Mandamiento de Amparo, Corte Suprema de Justicia Sala Político Administrativa, Dra. Hildegard Rondón de Sansó C. del V.S. y otros(as) v. Ministerio de Sanidad y Asistencia Social, 15 July 1999 [Injunctive Order, Supreme Court, Administrative Law Branch] (Venez.). ACCSI—Acción Ciudadana Contra el SIDA [Citizens’ Action Against AIDS], an NGO in Caracas, Venezuela, summarizes the holding on its Web site. *See* <http://www.internet.ve/accsi/htm/actual.htm>. Another example of courts affirming the right to HIV treatment is in Argentina. On June 2, 2000, the Supreme Court of Argentina affirmed the government’s obligation to provide free diagnostic care, medications, and other necessary treatment for HIV-infected persons in hospitals pursuant to Argentina’s national AIDS law (n° 23.798), the Constitution of the City and Province of Buenos Aires, and the National Constitution. *See* AIDS Network (“Red SIDA”), at <http://www.redsida.org.ar/corte.htm> (last visited April 9, 2002).

⁹⁶ *See* §III.C, *infra*, pp. 22-24.

⁹⁷ *See* General Comment No. 14, *supra* note 70, para. 47 (explicitly providing that a state party which “is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under article 12 [of the ICESCR]”).

⁹⁸ *See* Gruskin and Tarantola, *supra* note 68 at 3 (citing “Statement from the community AIDS movement in Africa,” presented at meeting of the International Partnership Against HIV/AIDS in Africa, held at U.N. headquarters, New York, 6-7 December 1999).

⁹⁹ *See* Joint United Nations Programme on HIV/AIDS (UNAIDS), *Framework for Global Leadership on HIV/AIDS*, UNAIDS/PCB (10)/00.3 (December 2000); and *The Global Strategy Framework on HIV/AIDS*, UNAIDS Pub. No. KM121 (June 2001), 2, at <http://www.unaids.org/publications/documents/care/general/JC637-GlobalFramew-E.pdf> (identifying as a fundamental principle that, “prevention methods, life saving treatments, and the results of scientific breakthroughs need to be equitably and affordably available to all”) (last visited April 9, 2002).

¹⁰⁰ *See* ICESCR, *supra* note 70, art. 2(2) (guaranteeing the rights enunciated in the ICESCR shall be exercised “without discrimination of any kind as to race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status”); International Covenant on Civil and Political Rights (“ICCPR”), G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. No. 16 at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, art. 2(1) (requiring each state party “to respect and ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the [Covenant], without distinction of any kind, such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status”).

¹⁰¹ *See*, General Comment No. 14, *supra* note 70, para. 34. We contend that the government must work, over time, to extend access to HIV treatment throughout the country. However, our recommendation that the government

begin with pilot programs to deliver HIV treatment at a few sites is consistent with the government's obligation progressively to realize the right to health. *See infra* §III(D).

¹⁰² *See* Prevention Project, *supra* note 1.

¹⁰³ *See* Dr. Michael Abeyaratne, "HIV/AIDS: A Story of Suffering," in *Stigma & Discrimination* (conference paper from Stigma and Discrimination Conference held in Colombo, Sri Lanka on December 28, 2001) (on file with EBCLC).

¹⁰⁴ Faculty members of Harvard University have released a blueprint calling for widespread availability of antiretroviral treatment to HIV-infected persons in poor countries, citing as one "compelling reason" that: "Treatment is necessary to optimize prevention efforts. When treatment is not available, less incentive exists for an individual to take an HIV test, since HIV-positive status not only is associated with social stigmatization but also is tantamount to a death sentence. It is only when HIV testing is coupled with treatment that people have an incentive to be tested, thus enabling a rational response to AIDS." Partners AIDS Research Center, *supra* note 42, at 4. The U.N. reaffirmed these principles in the Declaration of Commitment on HIV/AIDS, in which it urges State parties to: enact, strengthen or enforce, as appropriate, legislation, regulations and other measures to *eliminate all forms of discrimination against and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable groups, in particular to ensure their access to, inter alia, education, inheritance, employment, health care, social and health services, prevention, support and treatment, information and legal protection, while respecting their privacy and confidentiality; and develop strategies to combat stigma and social exclusion connected with the epidemic.* (emphases added)

Declaration of Commitment, *supra* note 5, para. 58.

¹⁰⁵ The Panos Institute, *supra* note 45, at 24.

¹⁰⁶ SRI LANKA HOSPITAL FORMULARY (R.L. Jayakody ed., 1994)

¹⁰⁷ For an example of a comprehensive drug formulary that addresses the needs of HIV-positive patients, refer to the AIDS Drugs Assistance Program ("ADAP") formulary for the State of California, at http://www.pmdc.org/California/English/Formulary_table.htm.

¹⁰⁸ Malaysia's Essential Drug List ("EDL"), at [http://www.pharmacy.gov.my/html/nedl.htm#ESSENTIAL DRUGS LIST](http://www.pharmacy.gov.my/html/nedl.htm#ESSENTIAL_DRUGS_LIST) (last visited April 9, 2002).

¹⁰⁹ Memorandum from Krisantha Weerasuriya representing the WHO's Action Programme on Essential Drugs ("DAP"), The WHO Essential Drug Concept ("EDC") From The Last Quarter Century To The Next Millennium, at <http://www.prn.usm.my/isdb/kris.html>.

¹¹⁰ WHO, 11th Model Essential Drugs List (1999), at <http://www.who.int/medicines/organization/par/edl/edl11.pdf> (on file with EBCLC) (last visited April 9, 2002).

¹¹¹ *See generally*, WHO, TECHNICAL CONSULTATION ON BEHALF OF THE UNFPA/UNICEF/WHO/UNAIDS INTER-AGENCY TASK TEAM ON MOTHER-TO-CHILD TRANSMISSION OF HIV (2000), at http://www.who.int/reproductive-health/rtis/MTCT/mtct_consultation_october_2000/index.htm (last visited April 9, 2002).

¹¹² Guay, L.A. et al., *Intrapartum and Neonatal Single-Dose Nevirapine Compared with Zidovudine for Prevention of Mother-to-Child Transmission of HIV-1 in Kampala, Uganda*, 354 LANCET 795-802 (1999).

¹¹³ *See, e.g.*, UNITED NATIONS CHILDREN'S FUND, ET AL., SOURCES AND PRICES OF SELECTED DRUGS AND DIAGNOSTICS FOR PEOPLE LIVING WITH HIV/AIDS (2001), at <http://www.accessmed-msf.org/upload/ReportsandPublications/3920012333116/Sources%20and%20prices.pdf> (last visited April 9, 2002).

¹¹⁴ WHO, *Suppliers Whose HIV-Related Medicines Have Been Found Acceptable, In Principle, For Procurement by UN Agencies*. Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality: Pilot Procurement Quality and Sourcing Project (March 20, 2002) at <http://www.who.int/medicines/organization/qsm/activities/pilotproc/suppliers.doc> (last visited April 2, 2002).

¹¹⁵ See, e.g., Letter from M.K. Hamied, Director, Cipla Limited, to the Indian Ministry of Health and Family Welfare, offering Nevirapine Donations (November 7, 2000) at <http://www.cptech.org/ip/health/c/india/ciplaindia11072000.html>; see e.g., Axios International, *About the VIRAMUNE® Donation Programme For the Prevention of Mother-to-Child Transmission of HIV-1*, at <http://www.viramune-donation-program.org/en/program/> (last visited April 4, 2002).

A GlaxoSmithKline spokesman said that “We believe the way to do this is to negotiate arrangements with governments and employers in the developing world, and in poorer countries we’ve said we will supply (medicine) at cost.” Donald G. McNeil, Jr., *New List of Safe AIDS Drugs, Despite Industry Lobby*, N.Y. TIMES, Mar. 1, 2002, at A3.

¹¹⁶ Elliot Marseille et al., *Cost effectiveness of single-dose nevirapine regimen for mothers and babies to decrease vertical HIV-1 transmission in sub-Saharan Africa*, 354 THE LANCET, 803 - 809 (1999).

¹¹⁷ *Id.*

¹¹⁸ Prevention of Mother-to-Child Transmission of HIV: Selection and Use of Nevirapine (Technical Notes) WHO. Selection and Use of Nevirapine (2001), at http://www.who.int/HIV_AIDS/MTCT/who_hiv_aids_2001.03.pdf (last visited April 9, 2002).

¹¹⁹ See *supra* §§ I.B. and I.D.

¹²⁰ Partners AIDS Research Center, *supra* note 42, at 10.

¹²¹ The Panos Institute, *supra*, note 45, at 7.

¹²² See *supra* §I.A.2.

¹²³ UNAIDS, Background Document from the Accelerating Access Contact Group, Mobilising Resources for Accelerating Access to HIV/AIDS Care, at 1 (May 29, 2001), at http://www.unaids.org/acc_access/contact_group/May2001/resources_en.doc (last visited April 9, 2002).

¹²⁴ See generally, UNAIDS, Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS, (May 2001) at <http://www.who.int/medicines/library/par/hivrelateddocs/sourcesandpricesmay.doc> (last visited April 9, 2002).

¹²⁵ As of October 2000, 75 out of 117 drugs recommended under then-existing UNAIDS and WHO guidelines for the treatment and prevention of HIV/AIDS were already on the WHO Model List of Essential Drugs. See Hogerzeil, *supra* note 81.

¹²⁶ As opportunities to access ARVs and other critical medications increase, it is vital that general practitioners as well as staff in government clinics are aware of the increased availability of HIV treatment and that they receive accurate information to enable them to refer patients to obtain medicines. A bulletin sent out to health care providers directly by NSACP may be a relatively inexpensive method of disseminating reliable information to health care workers.

¹²⁷ For a fuller discussion of the long-term procurement options available to the Sri Lankan government, please see Appendix: “Long-term Options for Procuring Generic ARVs in Compliance With International Intellectual Property Agreements.”

¹²⁸ Trade-Related Aspects of Intellectual Property Agreement, April 15, 1994. Please see full text of the TRIPs Agreement and other materials at the Web site of the *World Trade Organization* (last visited February 24, 2002) at http://www.wto.org/english/docs_e/legal_e/legal_e.htm (last visited April 9, 2002).

¹²⁹ Classification of member nations by TRIPs compliance date available at *World Trade Organization* (last visited February 24, 2002) at <http://www.wto.org>. Pharmaceutical process patent protection was required to be in place as of January 1, 2005 for “developing” nations.

¹³⁰ Such manufacturers include Cipla Ltd., Aurobindo Pharma Ltd. and Ranbaxy Laboratories Ltd.

¹³¹ Cipla produces a generic version of GlaxoSmithKline’s Combivir® drug and Merck’s Crixivan® drug. Please see Web site of Cipla at <http://www.cipla.com> (last visited February 24, 2002).

¹³² Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality Pilot Procurement Quality and Sourcing Project, *Suppliers Whose HIV-Related Medicines Have Been Found Acceptable, in Principle, for Procurement by UN Agencies*, March 20, 2002, at <http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotproc/suppliers.doc> (last visited April 2, 2002).

¹³³ Classification of member nations by TRIPs compliance date available at World Trade Organization at <http://www.wto.org> (last visited February 24, 2002). Pharmaceutical process patent protection was required to be in place as of January 1, 2005 for “developing” nations.

¹³⁴ Mattias Ganslandt et al., *Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal*, 24 THE WORLD ECONOMY 779, 786 (2001); ID21 Insights, *Model of Success: Universal Access to Treatment in Brazil* (Feb. 2002), at <http://www.id21.org/insights/insights-h02/insights-iss02-art07.html> (last visited April 9, 2002).

¹³⁵ *Id.* Ministry of Health, Sri Lanka, *Public Health Services*, at <http://www.lk/health/pub.htm> (last visited April 4, 2002).

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ National STD/AIDS Control Programme, Guidelines in HIV/AIDS Clinical Care For Medical Officers (1998).

¹⁴² See Ministry of Health, Sri Lanka, *Public Health Services*, at <http://www.lk/health/Med.htm> (last visited April 4, 2002) for a detailed description of Sri Lanka’s public health system.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ See generally, Paul Farmer et al., *Community Based Approaches to HIV Treatment: DOT-HAART in Resource Poor Settings*, 358 THE LANCET 404, 406 (2001).

¹⁴⁶ See generally, Médecins Sans Frontières (MSF), *AIDS Care in Guatemala* (January 12, 2001) at <http://www.msf.org/countries> (on file with EBCLC).

¹⁴⁷ For more information about MSF's office in Sri Lanka, see generally, MSF Activity Report 2000-2001 (December 13, 2001) at <http://www.msf.org/content/page.cfm?articleid=A4F473A3-0962-49E0-916AE99CC41C7CD7> (last visited April 4, 2002).

¹⁴⁸ Michael Sweat et al., *Cost-effectiveness of voluntary HIV-1 counselling and testing in reducing sexual transmission of HIV-1 in Kenya and Tanzania*, 356 THE LANCET 113-121 (2000).

¹⁴⁹ *Id.*

¹⁵⁰ Additional information on the program, "HIV Test Kit Bulk Procurement Scheme," is at http://www.who.int/bct/Main_areas_of_work/BTS/HIV_Diagnostics/HIV_Test%20Kit_Bulk_Procurement_Scheme.htm (last visited April 9, 2002).

¹⁵¹ This information is based on discussions the authors have had with members of the HIV/STD healthcare community in Sri Lanka.

¹⁵² Farmer, *supra* note 145. WHO, Laboratory Requirements for the Safe and Effective Use of Antiretrovirals (1998) at http://www.who.int/HIV_AIDS/antiretroviral_modules/indexar.htm. The WHO has collected information on alternative CD4 and viral load measurement technologies that are both established and less expensive than those customarily used in wealthy countries.

¹⁵³ Farmer, *supra* note 145.

¹⁵⁴ "Affirming the beyond the key role played by communities, strong partnerships among Governments, the United Nations system, intergovernmental organizations, people living with HIV/AIDS and vulnerable groups, medical, scientific and educational institutions, non-governmental organizations, the business sector including generic and research-based pharmaceutical companies, trade unions, media, parliamentarians, foundations, community organizations, faith-based organizations and traditional leaders are important." UNGASS Declaration of Commitment on HIV/AIDS (adopted Aug. 2, 2001), at <http://www.un.org/ga/aids/coverage/FinalDeclarationHIVAIDS.html> (last visited April 9, 2002).

¹⁵⁵ World Bank Operational Manual, *supra* note 3.

¹⁵⁷ The National AIDS Prevention Project, *supra* note 1.

¹⁵⁸ *Id.* at 1.

¹⁵⁹ *Id.* at 2.

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 3.

¹⁶² The Ryan White Care Act of 1990, The Ryan White Care Act Amendments of 1996 [Pub. L. 104-146].

¹⁶³ See Department of Health, Ministry of Public Health Thailand, Evaluation of Voluntary Counselling and Testing in the National Prevention of Mother to Child Transmission Programme in Thailand (October 2000) for examples of evaluation tools, at <http://www.unaids.org/publications/documents/health/counselling/jc699%2Dthai%2Dfinal%2De.doc> (last visited April 9, 2002).

¹⁶⁴ Lidia Wasowicz, *Benefits of Anonymous HIV Testing*, UNITED PRESS INT'L, October 27, 1998, <http://www.aegis.com/news/upi/1998/UP981008.html> (last visited April 9, 2002). See, e.g., Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *Anonymous or Confidential HIV Counseling and*

Voluntary Testing in Federally Funded Testing Sites – United States 1995–1997 (June 25, 1999), at <http://www.ama-assn.org/special/hiv/newsline/special/mmwr99/mm4824.htm> (last visited April 9, 2002); Johns Hopkins AIDS Service, Guidelines, *Revised Guidelines for HIV Counseling, Testing, and Referral: November 2001* (November 9, 2001), at http://www.hopkins-aids.edu/guidelines/ctr/gl_ctr.html (last visited April 9, 2002).

APPENDIX
LONG-TERM OPTIONS FOR PROCURING GENERIC ARVS IN COMPLIANCE
WITH INTERNATIONAL INTELLECTUAL PROPERTY AGREEMENTS

Section III.C outlined immediate strategies available to the Sri Lankan government to provide affordable ARVs and medicines for opportunistic infections to HIV-positive individuals. While the Sri Lankan government always has the option to attempt to negotiate lower prices with patent holders for medicines, and TRIPs does not affect importation of generic ARVs produced before 2000, provisions within TRIPs will require legislative effort to import generic forms of new ARVs. The Sri Lankan government can act to maintain its access to affordable, generic ARVs and medicines for opportunistic infections by:

- 1) authorizing and issuing a compulsory license for domestic production of ARVs and other HIV medicines;
- 2) authorizing and issuing a compulsory license to allow importation of newly developed generics produced under compulsory license in another country;
- 3) authorizing compulsory licenses and entering into a regional market arrangement for distribution of generic drugs; or
- 4) instituting broad parallel import language into the Sri Lankan laws.

A. Authorize and Issue Compulsory Licenses for ARVs and Bolster Domestic Pharmaceutical Manufacturing Capacity.

The Sri Lankan government can develop a sustainable supply of low-cost ARVs by authorizing and issuing compulsory licenses for the domestic manufacturing of ARVs.

Governments, including the United States,¹ have compulsory license provisions in their patent laws that allow the government to force the patent owner to permit the generic production of the pharmaceutical by the government or a third party in exchange for “adequate compensation.”²

The Sri Lankan government can amend its patent law to authorize the issuance of compulsory

licenses. In addition, Article 31 of the TRIPs Agreement allows for governments to issue a compulsory license without prior negotiation with patent owners in the event of “national emergency or extreme urgency.” On November 14, at the Fourth WTO Ministerial Conference at Doha, it was further clarified that public health crises such as HIV/AIDS constitute national emergencies.³

The Sri Lankan government should seriously consider the passage of legislation that would authorize the use of compulsory licenses and explore the issuance of these licenses for domestic production of ARVs. The World Health Organization review and analysis of access to drugs in Sri Lanka reported that over a decade ago, the Sri Lankan manufacturing sector had the capability to increase product range and production levels of domestically created pharmaceuticals.⁴ Particularly in light of the growing complexity of importing generic medicines under TRIPs, a system of compulsory licensing and an expansion of domestic generic manufacturing capacity might be the most efficient strategy to provide necessary treatment and assist in accomplishing the goals of the proposed Prevention Project to reduce the prevalence of HIV/AIDS.

B. Authorize and Issue Compulsory Licenses for Importation of Generic ARVs—Parallel Compulsory Licensing.

Sri Lanka also has the option to rely on a regime of parallel compulsory licensing in order to provide generic medicines to its population. Under this strategy, the compulsory license issued by Sri Lanka would not be used to permit domestic production, but would make it legal for the government to import generics from a manufacturer in another country that was producing generics under the authorization of an in-country compulsory license. However, for parallel compulsory licensing to be a viable strategy to secure generics, a country with manufacturing capacity must choose to issue a compulsory license that allows the company in its

country to produce the generic drugs. Additionally, Article 31(f) of the TRIPs Agreement requires that a manufacturer operating under a compulsory license must “predominately” supply the domestic market.⁵ Countries cannot currently issue a compulsory license and then export the majority of these drugs to other nations. Even if the country has an excess supply of drugs to export to Sri Lanka, the country might still choose to provide its drugs to another country. Participants at the Doha meeting recognized that the limitations on the export of pharmaceuticals produced under compulsory licenses might create difficulties for countries with little or no pharmaceutical manufacturing capacity to gain access to affordable medications. The Doha Agreement instructed the Council for TRIPs to “find an expeditious solution to this problem” by the end of 2002.⁶ The government should take an active role in crafting a solution that would assist Sri Lanka in accessing affordable ARVs.

While Sri Lanka potentially can authorize and issue compulsory licenses in order to import affordable generic medicines, particularly if the limitations for export are reduced in the coming year, parallel compulsory licensing still poses some difficulties as a strategy. Under the parallel compulsory licensing plan, Sri Lanka will have to find a willing and able supplier for each drug that it desires, and then issue its own compulsory license for each of those drugs. Accordingly, domestic production of pharmaceuticals discussed in the previous section, as well as the development of regional market arrangements and the inclusion of broad parallel import language discussed below, might be more feasible options.

C. Regional Market Arrangements.

Entering into a regional market arrangement could be a legally creative method of avoiding the current limitations on exports produced under compulsory licenses. Under TRIPs, the WTO allows nations to form customs unions, free trade areas and regional services

arrangements. Sri Lanka could structure a regional market arrangement with neighboring countries to jointly adopt and implement regional legislation with permission for compulsory licensing for pharmaceuticals.

Although we are not aware of a country that has acted to take advantage of this flexibility within TRIPs specifically to address the issue of access to generic medicines, this strategy is worthy of exploration, particularly if the Council for TRIPs fails to find an adequate solution to the export problem. By entering into a regional market arrangement, “the TRIPs agreement might be constructively interpreted to contemplate that a group establishing a common patent regime would be entitled to issue a common compulsory license with effect in all states of the arrangement, with the further understanding that supply of the group market under such arrangement constituted domestic supply within the meaning of TRIPs Article 31(f).”⁷

Establishing a regional market arrangement could be an extremely conducive method for Sri Lanka to acquire and maintain access to a supply of low-cost generic medications if it chose to partner with countries that have a larger generic manufacturing base. The regional market arrangement could also be profitable to Sri Lanka if it developed a manufacturing structure for ARVs and could export its own pharmaceuticals.

D. Broad Parallel Import Language.

In addition, Sri Lanka potentially could circumvent difficulties under a parallel compulsory licensing strategy by implementing broad parallel import language into its domestic laws. Under TRIPs, each country retains the power to develop its own patent exhaustion policies and decide the extent of the rights retained by the patent holder after initial sale.⁸ Countries like the United States limit the control that a manufacturer has over its products. A patent holder is said to have exhausted its control once the product has been sold to the first buyer. After

exhaustion, a manufacturer has no right to control what the buyer does with the product. The buyer is free to resell it, destroy it or keep it forever. Paragraph 5(d) of the Doha Declaration clarifies that each WTO nation has the power to establish “its own regime for ...exhaustion without challenge.”⁹ The Sri Lankan government could take advantage of its power over exhaustion rules to create a broad rule that patent rights were exhausted after first sale of a generic produced under compulsory license in a foreign country, thus making it lawful to import generics purchased from resellers in other nations.

Although it is not a settled point that parallel importation of compulsory licensed pharmaceuticals is allowed, it can be argued that if the non-predominant portion of pharmaceuticals produced under a compulsory license can be exported, then the process of a country like Sri Lanka importing these products would necessitate the validity of parallel importation.¹⁰ Unlike the strategy of compulsory licensing, which requires the government to issue a license for every drug before it can be imported, the insertion of broad parallel import language into the domestic patent laws could allow for the legal purchase of any generic from a reseller in another nation. If parallel importation of compulsory licensed products is available as a strategy, then Sri Lanka could take advantage of compulsory licenses issued in other countries and import these generic medications by “recogniz[ing] a broad doctrine of exhaustion and parallel importation.”¹¹

E. Summary of Intellectual Property Strategies for Securing Access to Affordable ARVs.

Currently, the Sri Lankan government has the power to provide affordable and safe medicines for the prevention and treatment of HIV/AIDS while complying with its responsibilities under the TRIPs Agreement. The government immediately can begin to import medications from generic manufacturers or negotiate to import patented medications at reduced

rates from a variety of drug companies. The Sri Lankan government can and should also ensure a sustainable supply of affordable ARVs to the country by investigating the options discussed in this Appendix. The government can work in the long-term to ensure continued access to generics through the growth of its domestic pharmaceutical manufacturing capacity and the issuance of compulsory licenses for ARVs, the use of parallel compulsory licensing, the development of regional market agreements or the inclusion of broad parallel import language into its domestic laws.

¹ 28 USC 1498. Under this statute the U.S. government does not have to seek a license or negotiate for use of a patent or copyright. The rightowner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. Text of U.S. code at Legal Information Institute (visited February 24, 2002) <http://www4.law.cornell.edu/uscode/28/1498.html> (last visited April 9, 2002).

² “[A]dequate compensation” is a flexible standard. It is based on the circumstances of the situation and might be a manageable royalty based on the local wholesale sale price. Frederick M. Abbott, Study Paper 2a: “WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries” 13.

³ Doha Ministerial Declaration, Nov. 14, 2001 [hereinafter Doha], Par. 5 (c) “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent national emergency or other circumstances of extreme urgency.” Please see *Consumer Project on Technology* <http://www.cptech.org/ip/wto/doha/overview.html> (last visited February 24, 2002) for an overview of the Doha Agreement and *World Trade Organization* for full text of Agreement at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (last visited April 9, 2002).

⁴ Sri Lanka Essential Drugs Project: Review and Analysis of the Current Drug Situation Proposal and plan of action for 1993-1998, 18.

⁵ World Trade Organization, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization: Agreement of the Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPs], Apr. 15, 1994, at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited April 9, 2002).

⁶ Doha, *supra* note 3, par. 6.

⁷ Abbott, *supra* note 2 at 21.

⁸ TRIPs, *supra* note 5, art. 6. “...nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

⁹ Doha, *supra* note 3, par. 5d.

¹⁰ Abbott, *supra* note 2 at 42.

¹¹ *Id.* at 44.