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Framing International Legal Responses to Global Health

> I've been out there on the ground talking to sufferers. I've seen the situation in parts of Africa where I've visited AIDS patients in villages, where you see a grandmother and lots of grandchildren but no mother, no father. For me it's not statistics. I've seen the human suffering and the pain. What is even more difficult is when you see somebody lying there dying who knows that there's medication and medicine somewhere else in the world that can save her, but she can't have it because she's poor and lives in a poor country. Where is our common humanity? How do you explain to her that in certain parts of the world AIDS is a disease that can be treated, that one can live with and function, but in her particular situation it's a death sentence?[1]
>
> Kofi Annan

1.1 The Current State of Global Health

This should be the golden era of global health. We now have the science to screen and test for diseases and so identify them much earlier, which can help to negate their deadly impact. We have vaccines to prevent the killer diseases of childhood and antibiotics to deal with the most dangerous pathogens. Increasingly, we have better medicines, which can treat the most common and deadliest diseases. As a result, many people in the world are experiencing better health than ever before, but this is not universal. If you are born in Europe, you can expect to live well into your 80s, but in sub-Saharan Africa life expectancy is only 57 years. For many of the world's poorest people, global health remains in constant crisis as infections spread across borders. Diseases like cholera, yellow fever, Acquired Immune Deficiency Syndrome (AIDS), swine flu, Severe Acute Respiratory Syndrome (SARS) and tuberculosis continue to take advantage of increasingly porous borders in a highly networked world

[1] Kofi Annan, Secretary General, United Nations; Interview with the BBC (28 November 2003). http://news.bbc.co.uk/1/hi/world/africa/3244564.stm last accessed 20 May 2005.

that relies on vast movements of people and goods across the globe to facilitate global trade. Less infectious diseases, such as malaria, are also continuing to devastate parts of the developing world.

Despite the existence of medicines that can treat most of these diseases, access in many parts of the developing world remains a lottery. It is estimated that one-third of the global population, almost two billion people, lack regular access to essential medicines.[2] In many parts of Asia and Africa this figure rises to almost half of the population.[3] One of the principal reasons for this inequity is the existence of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which grants pharmaceutical manufacturers the right to patent medicines, allowing them to exclude other manufacturers from making the same medicines within a set period of time. In the absence of competition, the pharmaceutical companies can set higher prices, ostensibly in order to recoup their research and development costs. Millions of people, especially those from the developing world, simply cannot afford to pay these prices. This massive inequity has meant that people from developing countries are dying of treatable diseases.

This book examines the international legal response to this problem by asking how law in the international realm has either contributed to or prevented greater access to Anti-Retroviral Medicines (ARVs). It explores this by considering legal initiatives as elements of two general categories: 'hard' or 'soft' law. Hard law can be defined as 'legally binding obligations that are precise (or can be made precise through adjudication or the issuance of detailed regulations that delegate authority for interpreting and implementing the law)'.[4] Soft law, by contrast, may be described as 'normative agreements that are not legally binding'.[5] Although the definition of these terms is justified and set out in detail in Chapter 2, this is the

[2] The WHO defines essential medicines as 'the minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost–effective medicines for priority conditions.' Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf last accessed 5 November 2015.

[3] World Health Organization, *WHO Medicines Strategy: Countries at the Core 2004–2007* (WHO, Geneva, 2004) 3.

[4] Kenneth W Abbott, 'Hard and "soft law" in international governance', *Int'l Org*, 54 (2000), 421 [DOI: 10.1162/002081800551280].

[5] Francis Synder, '"Soft law" and international practice in the European community' in Stephen Martin (ed), *The Construction of Europe: Essays in Honour of Emile Noel* (Kluwer Academic Publishers, Dordrecht, 1994) 197, 198.

fundamental distinction adopted in this book. The underlying argument then advanced is that soft law mechanisms provide a better option for achieving greater access to ARVs for those living in the developing world.

Starting with the AIDS crisis, the book argues that a hard law response was unsuited to creating greater access to ARVs (the essential medicines needed for treating HIV/AIDS), as relying on hard law meant prioritizing patent rights, which invariably led to cost implications for the consumer. This is because the predominant hard law initiatives arose within the context of existing international legal structures that are constructed around the protection of private property or individual rights, furthering the dominant northern hegemony at the expense of the majority of people in the developing world.

By contrast, the book argues that a soft law approach has been more effective. The non-binding nature of soft law, unlike its hard law counterpart, makes it quicker and easier for States to reach agreement. This makes it preferable when dealing with public health pandemics, such as HIV/AIDS, where speed is of the essence. Soft law is also more flexible and easier to supplement, amend or replace when circumstances change.

In pursuing this argument, the book looks at the World Trade Organization (WTO) regime and the United Nations (UN) regime from which the majority of conceptual responses to the issue of access have originated. This book suggests that soft law initiatives have developed a humanitarian norm of access to ARVs so as to enhance the prospect of universal access programmes that give free ARVs to those who would have been unable to afford them otherwise.

This book will argue that the success of a soft approach in response to the HIV/AIDS pandemic ought not to be examined in isolation. A softer approach can also be invaluable when looking more generally at the broader problems of global health. Thus, the book will look at how a soft law approach has been used in creating successful global health responses to malaria and tuberculosis in the developing world. However, before clarifying the argument, this chapter provides an overview of the subject at issue. In Section 1.2, the links between AIDS, malaria and tuberculosis are sketched out. Section 1.3 analyzes why AIDS is exceptional in global health matters and attempts to explain why, despite the existence of malaria and tuberculosis, international responses have largely focused on it. Section 1.4 introduces the legal context of this response. Section 1.5 moves on to describe the nature of ARVs, and explains their importance for the pandemic and how their accessibility has been affected by law. Section 1.6 returns to the central

arguments that will be explored through this book, while Section 1.7 of the chapter deals with the parameters of the research.

1.2 AIDS, Tuberculosis and Malaria: Complex Interlinkages; Human Suffering

HIV/AIDS, tuberculosis and malaria are three major global, public health threats, which cause immense suffering and the deaths of close to five million people every year. These diseases disproportionately impact the developing world, with sub-Saharan Africa bearing the brunt of these three interrelated pandemics.

AIDS is a disease caused by the Human Immunodeficiency Virus, which leads to a wide variety of clinical conditions. HIV belongs to a class of viruses called retroviruses, which attach themselves to a host cell without immediately destroying it, using it to multiply rapidly through other cells, before eventually destroying the entire immune system.[6] AIDS is transmitted from an infected person by sexual contact, sharing needles or syringes (primarily for drug injection) or, less commonly, through transfusions of infected blood or blood clotting factors. Babies born to HIV-infected women may become infected before or during birth, or through breastfeeding. The nature of its transmission puts several groups of people particularly at risk: women, children and homosexual men.[7]

The process of infection begins much like a common cold. However, the virus rapidly multiplies, causing flu-like symptoms – muscle ache, diarrhoea, mild fever and sore throat. The virus then becomes dormant, while mutating very quickly. Eventually, it starts killing healthy immune cells, paving the way for opportunistic infections, because at that point the body's natural defences are ineffectual. In the advanced stages, the body's immune system is so weakened that sufferers are vulnerable to all sorts of conditions, such as tuberculosis, pneumonia, malaria, toxoplasmosis, esophagitis, tumours and cancers.[8]

[6] See John Iliffe, *A History of the African AIDS Epidemic* (Ohio University Press, Ohio, 2006) 3–10 for a useful account of the earliest convincing evidence of HIV.

[7] R M Anderson et al., 'The spread of HIV-1 in Africa: Sexual contact patterns and the predicted demographic impact of AIDS', *Nature*, 352 (1991), 581–9 [DOI: 10.1038/352581a0] [PubMed: 1865922].

[8] M A Jacobson and M French, 'Altered natural history of AIDS-related opportunistic infections in the era of potent combination antiretroviral therapy', *AIDS Journal*, 12 (1998), 157–63.

Of the three diseases, AIDS is the most infectious, with Africa as its epicentre.[9] It has killed thirty-nine million people so far, leaving serious implications not only for those with the disease, but for their loved ones who care for them, often watching helplessly as the sick die of the lingering disease with its multiple secondary infections, their bodies wasting away and in constant pain due to acute shortages of palliative treatment.

Tuberculosis is the second most infectious disease worldwide. It is caused by *Mycobacterium tuberculosis* and is an airborne disease, making it very contagious. There are 9.2 million new infections every year.[10] Tuberculosis also presents the most common opportunistic infection affecting HIV-positive people, leading to 700,000 new infections and 200,000 deaths every year amongst people who are HIV positive. Like AIDS, the burden of tuberculosis is disproportionate, with sub-Saharan Africa and Asia reporting the most cases. Fifty per cent of people with HIV/AIDS will develop tuberculosis, and having HIV/AIDS makes it more likely that a primary infection will develop into a case of active tuberculosis. The spread of tuberculosis has been compounded by the increase in drug-resistant tuberculosis, which once again raises issues about access to essential medicines. Although the incidence of disease is concentrated in the developing world, there is evidence to suggest a new resurgence in industrialized countries, with some cities such as London showing an increase of 80 per cent in tuberculosis cases.

Malaria is an endemic disease that affects over 189 million people annually, many of whom come from the developing world. Malaria is caused by the *Plasmodium* parasite, which is spread by female *Anopheles* mosquitoes that have bitten an infected person. Malaria causes 881,000 associated deaths each year, 91 per cent of which are in sub-Saharan Africa. There are well-documented links between HIV/AIDS and malaria, with studies showing that being HIV positive makes individuals more susceptible to the parasites that cause malaria.[11] Additionally, the weak immune systems of people living with HIV/AIDS makes it harder

[9] Iliffe, *A History of the African AIDS Epidemic*.
[10] WHO, '2008 tuberculosis facts', www.who.int/tb/publications/2008/factsheet_april08.pdf last accessed 9 January 2016.
[11] Neil French, Jessica Nakiyingi, Eric Lugada et al., 'Increasing rates of malarial fever with deteriorating immune status in HIV-1 infected Ugandan adults', *AIDS*, 15 (2001), 899–906.

for them to fight malaria, and research has shown that when treating both AIDS and malaria, some of the medications interact with each other and may lead to toxicity. This creates public health dilemmas in sub-Saharan Africa, where both these diseases are prevalent.[12]

Both tuberculosis and malaria are common secondary infections for people suffering from HIV/AIDS, and cause untold suffering. Many AIDS patients struggle with recurrent episodes of tuberculosis that spreads not only to the lungs, but throughout the body to the brain, lymph nodes, spinal cord and bone marrow, leading to extreme fatigue that renders many patients bedridden and socially and economically unproductive. Some patients suffer with severe chest pain that leaves many struggling simply to breathe and coughing up blood. For many HIV/AIDS sufferers, tuberculosis becomes a life sentence, and many of them die within 5–6 weeks of infection. What makes tuberculosis as a secondary infection particularly harmful is its unresponsiveness to treatment, and even when treated many AIDS sufferers are more likely to relapse. There have been harrowing stories of patients who have struggled through multiple six-month courses of treatment to no avail. Their constant suffering is made worse by the fact that active tuberculosis is very visible due to the fatigue and loss of weight which sufferers face, creating considerable stigmatization within communities.

The symptoms of malaria mimic those of HIV/AIDS, with many patients suffering from flu-like symptoms, headaches, vomiting, jaundice, blood in the urine, convulsions and extreme fatigue. Malaria can cause serious complications, including respiratory distress, which occurs in 25 per cent of reported cases in adults and 40 per cent in children with severe *Plasmodium falciparum* malaria. AIDS sufferers are particularly prone to cerebral malaria.

AIDS patients who are co-infected with malaria or tuberculosis also struggle with the number of drugs that are necessary to combat them successfully, as well as with drug interactions. AIDS, tuberculosis and malaria are all diseases of poverty, as they affect young, able-bodied individuals, who can no longer contribute to workforces and local economies. Women are disproportionately affected by all three diseases. They are more vulnerable to contracting HIV/AIDS, and by 2004, 53 per cent

[12] Paula E Brentlinger, Christopher B Behrens, James G Kublin, 'Challenges in the prevention, diagnosis, and treatment of malaria in human immunodeficiency virus infected adults in sub-Saharan Africa', *Arch Intern Med*, 167:17 (2007), 1827–36.

of people who were infected were women.[13] The disproportionate impact of HIV/AIDS infection in women is rooted in their lack of economic power, which shapes the life choices they make through marriage, formal or informal employment, commercial sex work, etc. In all these situations, women are disadvantaged due to low bargaining power for safe sex.[14] Moreover, in many developing countries motherhood is integral to women's identity, and so the idea of safe sex is a moot point. Thus, many women are increasingly falling victim to the AIDS pandemic within marriage.[15] Tuberculosis is among the top killers of women of reproductive age. Some 510,000 women died from tuberculosis in 2013. Women with tuberculosis are 300 times more likely to die with their unborn children during labour. They are also more likely to have babies who are premature and underweight.[16] Pregnancy also reduces a woman's immunity to malaria, making her more susceptible to infection and increasing the risk and severity of illness, which can lead to severe anaemia and death. Maternal malaria increases the risk of stillbirth, premature delivery and low birth weight, which is a leading predictor of child mortality.[17]

The impact on women of all three diseases is further heightened by the fact that many of these infected women not only struggle with the impact of the disease on themselves, but are also expected to provide care to others who are sick. Nelson Mandela talked about women who 'bear the burden of HIV infection, but also bear the burden of HIV care, with grandmothers looking after their children, women caring for their dying husbands, and children looking after dying parents and siblings'.[18] In the absence of social security mechanisms in the developing world, this care becomes an all-encompassing process provided in the home.[19] It often

[13] Alan Whiteside, 'The economic, social and political drivers of the AIDS epidemic in Swaziland: A case study' in Amy S Patterson (ed), *The African State and the AIDS Crisis* (Ashgate, Aldershot, UK, 2006) 97–126.

[14] Patricia Siplon, 'Aids and patriarchy: Ideological obstacles to effective policy making' in Patterson (ed), *The African State and the AIDS Crisis*, 17–36.

[15] Carolyn Baylies, 'HIV/AIDS and older women in Zambia: Concern for self worry over daughters towers of strength', *Third World Q*, 23:2 (2002), 351–75.

[16] WHO, 'Tuberculosis in women', www.who.int/tb/publications/tb_women_factsheet_251013.pdf last accessed 5 November 2015.

[17] WHO, 'Lives at risk pregnancy in malaria', www.who.int/features/2003/04b/en/ last accessed 5 November 2015.

[18] Nelson Mandela, From 46664 HIV/AIDS awareness concert, March 2005, as quoted in VSO (2006), 'Reducing the burden of HIV & AIDS care on women and girls'.

[19] Aashar Kapura Mehta and Seroshi Gupta, 'The impact of HIV/AIDS and women care givers in situations of poverty', (2004) www.chronicpoverty.org/uploads/publication_files/CPRC-IIPA_31.pdf last accessed 9 January 2016.

involves bathing, toilet assistance, turning patients to avoid bed sores, as well as the carer still being required to provide food for not only the patient, but also the rest of the household. Many of these families live in places with inadequate sanitation facilities, which makes the job much harder.[20] Furthermore, in many cases, the lack of basic health infrastructure makes these women helpless, as they often have neither the resources nor the knowledge to help the AIDS sufferers deal with the painful effects of the disease. Caring, therefore, becomes a constant sap on the carer's energy, underlined by the certain knowledge that they too will shortly face the same fate. Moreover, the traditional nature of this caregiving means that women's roles as caregivers are so ingrained within communities that they are mostly unsupported, unrecognized and, above all, unremunerated.[21]

Tuberculosis and malaria are not new diseases and their medicines are not as expensive as ARVs, but there are still problems for the poorest people in the world gaining access to them. According to the World Health Organization (WHO),

> Essential medicines are one of the most cost-effective elements in modern health care and their potential health impact is remarkable. This year [2015] alone, there will be over 40 million deaths in developing countries, one-third among children under age five. Ten million will be due to acute respiratory infections, diarrhoeal diseases, tuberculosis, and malaria – all conditions for which safe, inexpensive, essential drugs can be life-saving.[22]

This situation is exacerbated by the fact that a failure to access full dosages of these essential medicines is leading to resistant strains of malaria and tuberculosis, which have even more unaffordable medicines.

As we will see in Chapter 8, there were international programmes that preceded the current programmes for AIDS, tuberculosis and malaria. This book will argue that the reliance on hard law mechanisms within these programmes means that these medicines still remain unaffordable.

Several scholars have rightly queried whether HIV/AIDS is diverting the attention of the international community to the detriment of dealing with other diseases that kill even more people in the developing world.

[20] Id at 15. [21] Id at 16.
[22] WHO, 'Essential medicines and health products', available at www.who.int/medicines/services/essmedicines_def/en/ last accessed 5 November 2015.

In some cases it has, but this book argues that rightly or wrongly this focus on the AIDS pandemic gave the international community the impetus to address wider access issues. In order to fully understand access to medicines, it is therefore necessary to look at the AIDS crisis, which brought the issue of access to the consciousness of the international community.

1.3 Background to the AIDS Crisis: Making a Case for an Exceptional Response

There is a consensus among global health experts that there are interconnected aspects of the HIV/AIDS pandemic that make it exceptional. First, the modality of its transmission puts certain already vulnerable groups at particular risk, i.e., women, children, commercial sex workers, gay people, etc. Second, HIV/AIDS has profound and lasting social and cultural effects on the societies that it affects, which include the impact on development prospects, human and national security and the balance of political power, and the link with international economic and financial relations and global governance. Together these dimensions demonstrate why it is that AIDS has attracted greater concern from the international community than other diseases.[23] The fact that AIDS has no cure has compounded these effects, and with few signs of the pandemic abating, communities remain in a continuous state of crisis.

The United Nations Program on AIDS (UNAIDS), the specialized UN body that deals with HIV/AIDS, has estimated that over 60 million people have been infected with HIV so far, and 30 million of these have prematurely lost their lives due to HIV/AIDS-related illnesses. Mortality was so high that in a single year between 1999 and 2000, more people died of AIDS in Africa than all the wars that ravaged the continent at the time.[24] By 2005, many developing countries experienced extremely low

[23] The divide is stark between the developed and developing world. Although sub-Saharan Africa contained only 10 per cent of the world's population, by 2001 it accounted for over two-thirds of the 40 million people living with HIV/AIDS. Sixty-eight per cent of new infections originated in this region; 77 per cent of all deaths and over 90 per cent of AIDS orphans could be found in this part of the world. While HIV prevalence amongst pregnant women was very rare outside this region, sentinel surveillance has shown it to be greater than 40 per cent in various parts of Botswana, Zimbabwe and Swaziland. See UNAIDS, *Report on the Global HIV/AIDS Epidemic*, Geneva, June 2000. Also see A Buve, K Bishakwabo-Nsarhaza and A Mutugadur, 'The spread of HIV-1 infection in sub Saharan Africa', *The Lancet*, 359 (2002), 2011–17.

[24] Victoria Brittain, '"More die of AIDS than war in Africa," says Kofi Annan', *The Guardian* (14 March 2000).

life expectancy rates. Five sub-Saharan African countries (Botswana, Central African Republic, Lesotho, Zambia and Zimbabwe) all faced life expectancies of below 40 years.[25] Three African countries (Lesotho, Swaziland and Botswana) experienced negative population growth rates for the first time, due in large part to the AIDS pandemic.[26] The rate of mortality put increased pressure on communities; for instance, in Durban, the city council authorities ran out of space to bury the dead, leading to widespread anxiety in a community that believed in the sacrosanct nature of the funeral as a journey into the next life.[27] In Uganda at the height of the epidemic in the 1990s, there were not enough grave diggers in Rakai District, leading to fears that people would go unburied.[28]

Morbidity was particularly severe in children below five years of age. Because AIDS passes from mother to unborn child, many children were born only to die before they could reach adulthood. Between 1990 and 1995, the infant mortality rate in Zimbabwe was 50 per cent; in the first five years of the next decade, the rate had risen to 62 per cent. In Kenya, infant mortality for the same period rose from 63 per cent to 68 per cent, which was at odds with a forecasted decline to 60 per cent that had not taken into account the AIDS pandemic.[29]

The high mortality rate is only one of the consequences of the AIDS pandemic. John Iliffe states that 'HIV/AIDS was not one pandemic but four: first the virus, then disease, next death and finally societal decomposition, each superimposed upon its predecessors'.[30]

Amidst this crisis, ARVs initially offered hope. Although they were never represented as a cure, ARVs relieved the symptoms of the disease and prolonged the lives of sufferers. But the initial euphoria that accompanied their invention turned out to be premature. Their high prices meant that many people in developing countries could not afford them. The pharmaceutical companies argued that such prices were essential in

[25] United Nations Population Division, 'The impact of AIDS', *ST/ESA/SER/A/229* (United Nations Publications, New York, 2004).
[26] Id.
[27] Marine Veith, 'What about the ancestors?', *South African Times* (10 October 2010). www.iol.co.za/news/south-africa/kwazulu-natal/what-about-the-ancestors-1.684934 last accessed 20 August 2011.
[28] This led to the development of groups like Bataka Twezike, which can be literally translated as 'let us bury ourselves'. See Paul Mugyenyi, *Genocide by Denial* (Fountain Publishers, Kampala, 1999) 69–71.
[29] UNPD, 'The impact of AIDS'. [30] Iliffe, *A History of the African AIDS Epidemic*, 112.