Soft Law and Global Health Problems

Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis

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SOFT LAW AND GLOBAL HEALTH PROBLEMS

Various legal approaches have been taken internationally to improve global access to essential medicines for people in developing countries. This book focuses on the millions of people suffering from AIDS, tuberculosis and malaria. Beginning with the AIDS campaign for anti-retroviral medicines (ARVs), Sharifah Sekalala argues that a soft law approach is more effective than hard law by critiquing the current Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities within the WTO. She then considers how soft law has also been instrumental in the fight against malaria and tuberculosis. Using these compelling case studies, this book explores law-making on global health and analyzes the viability of current global health financing trends within new and traditional organizations such as the UN, WHO, UNAIDS, UNITAID and the Global Fund. This book is essential reading for legal, development, policy and health scholars, activists, and policymakers working across political economy, policy studies and global health studies.

SHARIFAH SEKALALA is a public international lawyer and development practitioner with experience in research and policy in resource-constrained settings. She has expertise on trade and development and global health, with particular emphasis on the HIV/AIDS pandemic. She is an assistant professor at the University of Warwick, where her research focuses on the intersection between international law and global health, particularly with regard to norms in global health financing. Previously, Sekalala worked in the International Bar Association in London and practised as an advocate in Uganda.

PREFACE

In 1999, a Ugandan woman, mother and friend called Sarah started to get sick. First it was the flu, then it was malaria. People got malaria every day so she was not unduly worried. She treated it with quinine, but it seemed to persist, so a doctor suggested mefloquine, which seemed to help. A few weeks later, there was a rash and the malaria was back and she was given chloroquine. She lost weight. She had a raspy cough. She took antibiotics. These seemed to make her feel a little better. However, before long, she was sick again. She went to one doctor and then another. Each took her money. No one could adequately diagnose her. She then opted for traditional medicines. Perhaps in them lay the cure. She did not get better. Eventually she contracted Kaposi's sarcoma. She had lesions on her neck and skin, which seemed to turn from blue, to black, to purple. She could not move her neck and she was in agony. She guessed then the cause of her sickness. She had seen it many times before. She went to her local clinic and took the test. She was HIV positive!

At the time, a lot of knowledge on AIDS revolved around prevention. Uganda after all was an AIDS success story; the government had rolled out a national education programme in schools, hospitals, at trading centres and on billboards. The prevention message was everywhere. As a society, Uganda had broken the taboo of talking about AIDS. Condom use, faithfulness, abstinence, even the dangers of blood transfusion were general knowledge. But what this campaign did not deal with was what happened to the people who already had AIDS. It was clear that you died, that it was a long, agonizing death and that there was suffering. There were some vague mutterings of medicines that made you better for a while, but that had not really registered because all the messages revolved around prevention. You tried not to get AIDS. What happened after you got it was less clear.

Sarah went to the national referral hospital in Mulago. They knew about the drugs, but they did not have any. The hospital at the time was implementing the Structural Adjustment reform programmes

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recommended by the IMF, which had led to the introduction of user fees that were supposed to make the hospital pay for itself. Patients had to bring their own gloves and their own syringes. The doctors worked in private clinics to augment their income, and everything for some reason took a very long time. She queued religiously for a most days, but in vain. She went to another hospital run by an international organization, but she was not eligible to receive drugs from them. The only drug programme they ran was for members of the army. A relative later told her about the mission hospital in Nsambya. It was rumoured that there were drugs there. You had to pay for them, but at least while you were on them you were not in pain, you did not suffer so much and most importantly you would not die.

So Sarah went to the mission hospital. It was true they did have drugs, but the drugs were expensive. She had to pay about 800,000 Uganda shillings every fortnight. This was approximately 800 US dollars. She did not even earn that in a month. It was expensive, but what was expense when faced with the choice of a long, tortuous death? She paid at the time for the first batch. She used up her meagre savings and she borrowed against her salary. Later her relatives chipped in; her friends did too as well but for how long could they continue to do so? Soon it dawned on her: she could not afford the drugs. At the time, she had begun to feel a little better, so she discontinued treatment. Within 6 months, she was critically ill again. Her relatives rallied once more, collected the money and the hospital put her back onto the drugs. But it was too little, too late. She was grateful that her relatives were looking after her, that they were helping her so she could live, but she knew as well as they did that they could not do it forever. Three weeks later she stopped taking the drugs.

By this point, she had tuberculosis, the malaria was back and she was in agony from the rasping cough that racked her emaciated body. The doctors could no longer find her veins to attach IV drips. She was continuously in agony. Death, when it came, was a release. She was only 33 years old.

Sarah's experience was not unique. Coming from Uganda, I knew this experience to be shared by thousands of others in the country and I believed millions in Africa and around the world. This made me realize the double burden which AIDS sufferers had to endure. Not only had they to deal with the trauma of the disease, and all its manifestations, but they also had to find the means to pay for the only treatment that would help them. And of course treatment was and remains available. Antiretroviral (ARV) drugs can and do offer relief. They can and do save

lives. They can and do reduce the impact of the disease and the level of pain a sufferer has to experience. There are also increasingly sophisticated medicines to cure malaria and even drug-resistant tuberculosis.

But the problem is one of access. It was obvious that this was conditioned not by need but by wealth. If you had money, you could be treated and probably survive free of the most severe effects of the disease. If you did not, then you were doomed to long periods of suffering and an inevitably agonizing death.

But why, I wondered, was this issue of access to drugs so bound up with individuals having the means to pay? Even a cursory review of the nature and source of the drugs gave one answer: they were invented and produced by international pharmaceutical corporations that operated for profit. These companies would not simply develop, manufacture and distribute treatments for nothing; someone had to pay for them, and they were and are expensive. Of course, governments around the world could meet these costs, but the majority of sufferers exist in the poorest regions of the world, in countries like Uganda in sub-Saharan Africa. Could these countries afford the seemingly endless bill for free and unlimited treatment for all when other diseases and other problems of impoverishment also needed attention? Perhaps, instead, these poor countries could produce their own drugs but it was not as simple as that. ARV drugs were protected by international patents. If countries were allowed simply to ignore these, what incentive would there be for the big pharmaceutical companies to develop more and better drugs, maybe in time, even a cure?

The international spread and threat of AIDS has drawn considerable attention to this conundrum of access to ARV drugs. There has been greater awareness of the dilemma faced by people such as Sarah and of those poor countries in which they live. Various approaches have been taken internationally in order to help. The central aim of this book is to explore those which operated within law. It looks at two general approaches that have developed. I have termed these the 'hard law' and 'soft law' approaches. The hard law involves enforceable legal regimes, which are derived from the TRIPS Agreement, and created minimum standards for intellectual property rights, which allowed pharmaceutical companies to exclude other people from using their inventions. This allowed them to set higher prices during the period of exclusion, thus leading to exorbitant costs for patients who needed them. Attempts to use this hard law to create access to ARVs could never be free of market considerations. Some money has to change hands and for people like

Sarah, in developing countries, even a little money (when it is for the rest of your life) becomes a lot of money.

The soft law approach, on the other hand, has evolved continuously in order to create greater access to ARVs. This book argues, therefore, that soft law has a greater chance of addressing the access conundrum and delivery of larger quantities of ARV drugs and also addressing the secondary opportunistic infections of malaria and tuberculosis, which afflict many sufferers such as Sarah. For Sarah, this approach came too late, but for many people in developing countries it has been a game changer. This book attempts to look at the evolution, merits and potential problems of this soft approach in creating access to essential medicines for AIDS, malaria and tuberculosis.

ABBREVIATIONS

ACT	Artemisinin Combination Therapy
AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-Retroviral Drugs
BCG	Bacillus Calmette–Guérin
DDT	Dichlorodiphenyltrichloroethane
DOTS	Directly-Observed Treatment, Short-course
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Commission
EMR	Exclusive Marketing Rights
EU	European Union
FDA	Food and Drug Administration
GATT	General Agreement on Trade and Tariffs
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFPs	Global Fund Programmes
HAART	Highly Active Anti-retroviral Therapy
HIV	Human Immunodeficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic Social and Cultural Rights
ICJ	International Court of Justice
IDP	Internally Displaced Person
ILC	International Law Commission
ILO	International Labour Organization
IMF	International Monetary Fund
LDC	Least Developed Country
MDG	Millennium Development Goals
MMV	Malaria Medicines Venture
MSF	Médecins Sans Frontières (Doctors Without Borders)
NATO	North Atlantic Treaty Organization
NGO	Non-Governmental Organization
OECD	Organisation of Economic Cooperation and Development
OPEC	Organization of Petroleum Exporting Countries

PLWHA	People living with HIV/AIDS
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
Reg	Regulation
Res	Resolution
SAP	Structural Adjustment Programme
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration on Human Rights
UK	United Kingdom
UNAIDS	United Nations Program on AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
UNFPA	United Nations Population Fund
UNGA	United Nations General Assembly
UNGASS	United Nations General Assembly Special Session
UNGC	United Nations General Compact
UNHCR	United Nations High Commissioner for Refugees
UNTS	United Nations Treaty Series
USTR	Office of the United States Trade Representative
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CONTENTS

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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.

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