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978-1-107-04952-9 — Soft Law and Global Health Problems
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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.

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Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis

SHARIFAH SEKALALA
University of Warwick

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University Printing House, Cambridge CB2 8BS, United Kingdom

One Liberty Plaza, 20th Floor, New York, NY 10006, USA

477 Williamstown Road, Port Melbourne, VIC 3207, Australia

4843/24, 2nd Floor, Ansari Road, Daryaganj, Delhi – 110002, India

79 Anson Road, #06–04/06, Singapore 079906

Cambridge University Press is part of the University of Cambridge.

It furthers the University's mission by disseminating knowledge in the pursuit of
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www.cambridge.org
Information on this title: www.cambridge.org/9781107049529
DOI: 10.1017/9781107278950

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First published 2017

A catalogue record for this publication is available from the British Library.

Library of Congress Cataloging-in-Publication Data
Names: Sekalala, Sharifah, author.
Title: Soft law and global health problems : lessons from responses to HIV/AIDs,
malaria, and tuberculosis / Sharifah Sekalala, University of Warwick.
Description: Cambridge [UK] ; New York : Cambridge University Press, 2017. |
Includes bibliographical references and index.
Identifiers: LCCN 2016046858 | ISBN 9781107049529 (hardback : alk. paper)
Subjects: LCSH: Public health laws, International. | World health. | Right to health. |
Soft law. | Antiretroviral agents. | AIDS (Disease)–Law and legislation. |
Malaria–Law and legislation. | Tuberculosis–Law and legislation.
Classification: LCC K3570 .S45 2017 | DDC 344.03/21–dc23 LC record
available at https://lccn.loc.gov/2016046858

ISBN 978-1-107-04952-9 Hardback

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Sharifah Sekalala
Frontmatter
More Information

CONTENTS

Preface ix
List of Abbreviations xiii

1 Framing International Legal Responses to Global Health 1

1.1 The Current State of Global Health 1
1.2 AIDS, Tuberculosis and Malaria: Complex Interlinkages; Human Suffering 4
1.3 Background to the AIDS Crisis: Making a Case for an Exceptional Response 9
1.4 Framing an International Legal Response to HIV/AIDS 11
1.5 The Impact of Anti-Retroviral Medicines 15
1.6 An Outline of the Book 25
1.7 A Note of Caution 27

2 Hard Law and Soft Law in the Global Context 29

2.1 Introduction 29
2.2 Hard Law 30
2.3 Advantages of Hard Law 40
2.4 Critiques of Hard Law 44
2.5 Soft Law 50
2.6 Conclusion 69

3 Hard Law and Access to ARVs: Examining Intellectual Property Rights 70

3.1 Introduction 70
3.2 The TRIPS Agreement 71
3.3 TRIPS and Relevant Case Law 79
3.4 Hard Law Programmes 89
3.5 Conclusion 94

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CAMBRIDGE

Cambridge University Press
978-1-107-04952-9 — Soft Law and Global Health Problems
Sharifah Sekalala
Frontmatter
More Information

4 Hard Law and Access to ARVs: Examining the Right to Health 95

4.1 Introduction 95
4.2 The Human Right to Health 96
4.3 The Right to Health and Access to ARVs 106
4.4 Conclusion 117

5 The Soft Approach: The Doha Declaration on Public Health 118

5.1 Introduction 118
5.2 Background to the Doha Declaration 119
5.3 Compromise amidst Polarity: The Doha Declaration 127
5.4 The Pendulum Swings Back to Hard Law: Introducing Article 31 *bis* 139
5.5 Canada–Rwanda Case Study 149
5.6 Conclusion 154

6 The Soft Approach: Greater Access to ARVs within the United Nations 155

6.1 Introduction 155
6.2 The WHO within the UN Framework 156
6.3 Soft Law Tradition in International Health 157
6.4 Identifying Soft Law within the UN Context 165
6.5 Creating Greater Access to ARVs through Soft Law 167
6.6 Conclusion 183

7 Examining Soft Law in Action: The '3 by 5' Initiative and the Global Fund 184

7.1 Introduction 184
7.2 Soft Law Developments 185
7.3 The '3 by 5' Initiative 188
7.4 The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) 194
7.5 Analysis of the Impact of Soft Law on the Two Programmes 202
7.6 Conclusion 212

8 The Cases of Tuberculosis and Malaria 215

8.1 Introduction 215
8.2 Tuberculosis and Malaria: An Overview of Global Approaches 217
8.3 The Role of Soft Law in Creating Further Access to Medicines for TB and Malaria Control 232

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CAMBRIDGE

Cambridge University Press
978-1-107-04952-9 — Soft Law and Global Health Problems
Sharifah Sekalala
Frontmatter
More Information

8.4 Towards Hard Law Programmes: Disturbing Trends in the Development of New Medicines 240
8.5 Conclusion 244

9 Conclusion 245
9.1 Exceptional Diseases: International Responses 245
9.2 A Soft Law Approach: Evidence of Forum Shifting? 246
9.3 Preferring Soft Law in Gaining Access to Essential Medicines 247
9.4 Measuring Global Progress 252
9.5 Should We Still Be Wary? 253
9.6 Towards a New Dawn in International Health 255

Bibliography 258
Index 299

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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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Sharifah Sekalala
Frontmatter
More Information

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

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Sharifah Sekalala
Frontmatter
More Information

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

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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.

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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

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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

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