REGULATORY VIOLENCE

International case studies on regulation and science collaboration show how competition and economic pressures on the national regulators of biomedicine condition the development of jurisdictive regulations. But regulation that fails to guarantee a jurisdiction's optimal protection of patients and scientific research in favour of other interests commits foreseeable and avoidable 'regulatory violence'. Even when well-intended, regulation gets caught up in the intense international competition to support public health and generate national wealth, with real-world implications. Evidence from Asia, Europe and the US challenges the belief that regulation improves ethical practices in regenerative medicine, connects practitioners with good science and protects patient safety. This book explains why this is so and points to ways in which science could help us address healthcare issues in greater solidarity. This title is also available as Open Access on Cambridge Core.

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CAMBRIDGE BIOETHICS AND LAW

This series of books – formerly called Cambridge Law, Medicine and Ethics – was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law's complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law. It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy and bioethics debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. With that in mind, we seek to address how legal analysis might have a trans-jurisdictional and international relevance. Organ retention, embryonic stem cell research, physician-assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

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A list of books in the series can be found at the end of this volume.

REGULATORY VIOLENCE

The Global Dynamics of Regulatory Experimentation in Biomedicine and Health

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CAMBRIDGE
UNIVERSITY PRESS

Shaftesbury Road, Cambridge CB2 8EA, United Kingdom

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

477 Williamstown Road, Port Melbourne, VIC 3207, Australia

314–321, 3rd Floor, Plot 3, Splendor Forum, Jasola District Centre, New Delhi – 110025, India

103 Penang Road, #05-06/07, Visioncrest Commercial, Singapore 238467

Cambridge University Press is part of Cambridge University Press & Assessment,
a department of the University of Cambridge.

We share the University's mission to contribute to society through the pursuit of
education, learning and research at the highest international levels of excellence.

www.cambridge.org
Information on this title: www.cambridge.org/9781009461764

DOI: 10.1017/9781009461757

First published 2025

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

A Cataloging-in-Publication data record for this book is available from the Library of Congress

ISBN 978-1-009-46176-4 Hardback
ISBN 978-1-009-46179-5 Paperback

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ACKNOWLEDGEMENTS

Discussions on the human genome and embryonic stem cell research at the beginning of the noughties were accompanied by government investment into public discussion on the ethical regulation of scientific innovation. These discussions increasingly included social science expertise, as it became clear that social, political and economic conditions influence the ethics of scientific research in societies in different manners. This fundamental interconnectedness between science and society became a challenge, as internationally, scientists have increasingly called for regulatory harmonisation at a global level: regulations impact countries differently. Generally, scientific institutions opened up to visitors and to discussion, and here I would especially like to express my gratitude to them. Of course, I am indebted to all who have made possible and contributed to the research for this book. There are more than I can name.

Funders

First of all, the research would not have been possible without long-term research support. This was provided by the European Research Council (ERC: 283219), the Economic and Social Science Research Council (ESRC: RES-350-27-0002; ES/E00542X/1; ES/I018107/1) and the British Academy/ Leverhulme Foundation (SRF20\200078). Similarly, without UK Research and Innovation (UKRI) funding, the publication would not have been Open Access.

Co-researchers in Projects and University Colleagues

Ideas for this book have developed over a long time span, during which I have benefitted from various project collaborations. In 2007, a two-year ESRC fellowship (RES-350-27-0002) in the Stem Cell Initiative: Capacity Building Awareness Raising (CBAR) Phase II Fellowships, headed by

Andrew Webster on stem cell research and society in China and Japan, gave me the opportunity to learn about the governance of regenerative medicine. This fellowship happily coincided with my representation of the University of Sussex as a member of Bionet, a 6th EU Research Framework Programme entitled Ethical Governance of Biological and Biomedical Research: Chinese European Co-operation (2006–2009 [Contract no.: 036788], led by Nikolas Rose). I am much indebted to both CBAR and Bionet for facilitating the organisation of countless meetings and generating a platform that enabled sometimes difficult, but in the end, fruitful conversations and debate.

At around the same time, the project International Science and Bioethics Collaborations, co-led by Cambridge, Durham and Sussex Universities, was awarded ESRC funding (ISBC, January 2007–December 2009). This project helped me to develop research on the drivers and practices of science collaborations in the context of stem cell research. Project meetings of CBAR and Bionet, which partly coincided with ISBC, had a synergetic effect on the research of the governance of biomedical science and international science collaborations in East Asia. I am much indebted to co-investigators Monica Konrad, Bob Simpson and Marilyn Strathern and researchers Seyoung Hwang, Achim Rosemann, Prasanna Kumar Patra, Salla Sariola, Rachel Douglas-Jones, Birgit Buergi and Adele Langlois for their stimulating discussions on science collaboration and bioethics in a diversity of regional and scientific contexts.

ISBC was followed up by an ESRC (December 2011–November 2014, ES/I018107/1) and ERC projects (February 2012–January 2017, ERC: 283219) related to 'bionetworks' in the University of Sussex, where a team of European and Asian researchers explored collaborative networks of biobanks (ESRC) and stem cell therapy clusters (ERC) in the field of regenerative medicine. I would like to thank Prasanna Patra, Masae Kato, Suli Sui, Achim Rosemann, Jessica Hung-Chieh Chang, Nattaka Chaisinthop, Adrian Ely, Carolyn Heitmeyer, Choonkey Chekar, Yeyang Su, Xinqing Zhang and Marina Marouda for turning the exploration of the stem cell research initiatives in Asia into a fruitful co-production of insights into bionetworks.

Five years after the end of the ESRC project, I was awarded a BA-Leverhulme Senior Research Fellowship, which allowed me to develop research materials and ideas gathered on science collaborations and the regulation of regenerative medicine over a period of over fifteen years into this book on regulatory violence. The application for funding for the

publication of the book has further been supported by the library of Sussex University, without which I would have been lost in the world of Open Access. And, finally, I am also thankful to the Anthropology department of the University of Sussex, which has accommodated my research for many years.

Colleagues, Friends and Experts in the Field

In the course of this period, I have received hospitality and advice from countless colleagues and researchers, to whom I feel greatly indebted. In the People's Republic of China (PRC), I am in particular grateful to Renzong Qiu, Xiaomei Zhai, Guangxiu Lu, Duanqing Pei, Peng Xiang, Qi Zhou, Ole Doering, Wolfgang Hennig, Yali Cong, Huanming Yang, Ruipeng Lei and Wei Zhu, who have kindly introduced me to colleagues and collaborators. In Japan, I am particularly grateful to help received from Tohru Masui, Kazuto Kato, Ryuichi Ida, Koji Kawakami, Shin Kaneko, Norio Nakatsuji, Azumi Tsuge, Yoko Matsubara, Shin Enosawa, Akihiro Umezawa, Shinichi Nishikawa, Masayoshi Murakami, Shin Kawamata and Doug Sipp. I would also like to thank experts in Thailand for their helpful introductions to fellow experts, in particular Hongeng Suradej, Nipan Israsena and Pruksananonda Kamthorn. In India, the introductions by Anish Majumder, Nandini Kumar and Sachin Chaturvedi to their institutions, regulators, medical professionals and patient organisations are very much appreciated. In Europe, I would like to thank Christine Mummery, Nick Medcalf and Clare Blackburn for bringing me in contact with other experts.

Experts and Lay Experts

Without the help of archives, scientists, managers, patients and regulators, attendants of conferences, workshops and other meetings I would not even have been able to begin to understand the importance of drivers of regulation and international collaboration. I therefore would like to express my gratitude to numerous pseudonymised people in Thailand, Singapore, India, Japan, China, The Netherlands and the UK, including international and national patient/health groups. I thank them for allowing me to learn from them, for their generosity and patience in explaining their views and for taking an interest in my exploration of international science collaboration and the regulation of regenerative medicine. I would particularly like to thank the pseudonymised

gatekeepers of scientific institutes, companies and hospitals, who opened their doors for me widely and on trust. I am much indebted to all who took the trouble to speak with me, and I am grateful for what they taught me. Of course, there may be much in the book to disagree with, and I take responsibility for any erroneous views that remain.

Journals, Authors, Comments on Chapters and Institutions

Some sections of chapters draw on published work. In providing the global historical background of the book, Chapter 2 draws for a large part on an article published as 'Comparing national home-keeping and the regulation of translational stem cell applications: An international perspective' in *Social Science and Medicine* (2016), 153: 240–249. I would like to thank the co-authors Choon Key Chekar, Alex Faulkner, Carolyn Heitmeyer, Marina Marouda, Achim Rosemann, Nattaka Chaisinthop, Hung-Chieh (Jessica) Chang, Adrian Ely, Masae Kato, Prasanna K. Patra, Yeyang Su, Suli Sui, Wakana Suzuki and Xinqing Zhang for their comments on it. The argument of Chapter 3 partly draws on the notion of regulatory capacity building, introduced in a publication entitled 'Regulatory capacity building and the governance of clinical stem cell research in China' in *Science and Public Policy* (2018), 45(3): 416–427. The first, re-written case study derives from this. I would like to thank Haidan Chen and Achim Rosemann for providing comments on a draft of it. In Chapter 4, the first example of Beike Biotech draws on a case published in an article entitled 'The large grey area between "bona fide" and "rogue" stem cell interventions – ethical acceptability and the need to include local variability' in *Technological Forecasting and Social Change* (2016), 109: 76–86. I use the notion of regulatory brokerage and examples in the first half of Chapter 8 that I introduced in 'Regulatory brokerage: Competitive advantage and regulation in the field of regenerative medicine', published in *Social Studies of Science* (2019), 49: 355–380. I would like to thank Nattaka Chaisinthop for identifying the international scientific collaboration around the robotic machine and for her insightful comments on Chapter 5. I would also like to thank the (anonymised) health organisation representatives and other participants in the international network workshop in Brighton. The ensuing conversations and discussions were the main reason for writing Chapter 7. I am particularly grateful to Masae Kato, Hung-Chieh (Jessica) Chang, Komal Kamra, Louis Stanislas, Suli Sui, Yeyang Su and Tammy Sun who commented on this chapter and a former version of it.

Reviewers and Readers

Many thanks also to Cambridge University Press's Cambridge Bioethics and Law series editors for their advice and guidance. I also would like to thank the anonymous reviewers and Joy Zhang, Yeyang Su, Doug Sipp and Alex Faulkner for their comments on various stages of the manuscript. Alex's encouragement and support have been invaluable to the writing of this book.

ACRONYMS AND ABBREVIATIONS

AABB	American Association for Blood Banks
ACTO	Asian Cellular Therapy Organisation
AJS	All Japan System
AMD	age-related macular degeneration
AMED	Agency for Medical Research Development
ARM	Alliance for Regenerative Medicine
ASEAN	Association of Southeast Asian Nations
ATMP	advanced therapy medicinal productsBM-MSC-s bone marrow–derived mesenchymal stem cells
CD	Crohn's disease
CDB	Centre for Developmental Biology
CFDA	China Food and Drug Administration
CGTs	cell and gene therapies
CiRA	Centre for iPS cell Research and Application
CITIC	China International Trust and Investment Corporation
CPC	Cell Processing Centre
CU	Chulalongkorn University
DBT	Department of Biotechnology (India)
DM	diabetes mellitus
DMD	Duchenne muscular dystrophy
DN	dopamine neurons
EMA	European Medicines Agency
FBRI	Foundation for Biomedical Research and Innovation
FIRM	Forum for Innovative Regenerative Medicine
FTCM	free-to-choose medicine
GCTP	good gene, cell and tissue practice
GLP	good laboratory practice
GMP	good manufacturing practice
GvHD	graft versus host disease
HE	hospital exemption
hESC	human embryonic stem cell(s)
HICs	high-income countries

HLA	human leukocyte antigens
HOs	health organisations
HSCs	hematopoietic stem cells
IANR	International Association of Neurorestoratology
ICMR	Indian Council for Medical Research
ICMS	International Cellular Medicine Society
ICSI	International Stem Cell Initiative
IFMS	Institute for Frontier Medical Sciences
IHOs	international health organisations
IND	investigational new drug
IPR	intellectual property rights
iPSCs	induced pluripotent stem cells
IRB	institutional review board
ISCBI	International Stem Cell Banking Initiative
ISCT	International Society for Cell Therapy
ISSCR	International Society for Stem Cell Research
JSRM	Japanese Society of Regenerative Medicine
JST	Japan Science and Technology Agency
KFDA	Korean Food and Drugs Administration
KHI	Kawasaki Heavy Industry (Japan)
KUH	Kyoto University Hospital (Japan)
LMICs	low- and middle-income countries
MAPPs	Medicines Adaptive Pathways to Patients (EMA)
MCT	Medical Council of Thailand
MD	muscular dystrophy
MEMG	Manipal Education and Medical Group (India)
METI	Ministry for Economy, Trade and Industry (Japan)
MEXT	Ministry for Education, Culture, Sports, Science and Technology (Japan)
MHA	minor histocompatibility antigen
MHC	major histocompatibility complex
MITI	Ministry of International Trade and Industry (Japan)
MoHLW	Ministry of Health, Labour and Welfare (Japan)
MOU	memorandum of understanding
MSCs	mesenchymal stem cells
NAC	National Apex Committee (India)
NEDO	New Energy and Industrial Technology Development Organization (Japan)
NGOs	non-governmental organisations
NHFPC	National Health and Family Planning Commission (PRC)
NHS	National Health Service (UK)
NIH	National Institutes of Health

NPOs	non-political organisations
OA	osteoarthritis
ODD	Orphan Drug Designation
PD	Parkinson's disease
PIM	Promising Innovative Medicine (UK)
PMD Act	Pharmaceuticals, Medical Devices, and other therapeutic products Act (Japan)
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRC	People's Republic of China
PSCs	pluripotent stem cells
R&D	research and development
RCT	randomised control trials
REGROW	Act named Reliable and Effective Growth for Regenerative Health
Act	Options that Improve Wellness (US)
RM Act	Act on the Safety of Regenerative Medicine (Japan)
RMP Act	Regenerative Medicine Promotion Act (Japan)
RPE	retinal pigment epithelium
SCI	spinal cord injury
SCI-Net	Stem Cell International-Net (US based)
SCNT	somatic cell nuclear transfer
STS	science and technology studies
TFDA	Thai Food and Drug Administration
TPA	Thai Physician Association
WHO	World Health Organization
WPI	World Premier International Research Centre Initiative