Pin Lean Lau

Comparative Legal Frameworks for Pre-Implantation Embryonic Genetic Interventions



Comparative Legal Frameworks for Pre-Implantation Embryonic Genetic Interventions

Pin Lean Lau

Comparative Legal Frameworks for Pre-Implantation Embryonic Genetic Interventions



Pin Lean Lau Central European University Budapest, Hungary

ISBN 978-3-030-22307-6 ISBN 978-3-030-22308-3 (eBook) https://doi.org/10.1007/978-3-030-22308-3

© Springer Nature Switzerland AG 2019

This work is subject to copyright. All rights are reserved by the Publisher, whether the whole or part of the material is concerned, specifically the rights of translation, reprinting, reuse of illustrations, recitation, broadcasting, reproduction on microfilms or in any other physical way, and transmission or information storage and retrieval, electronic adaptation, computer software, or by similar or dissimilar methodology now known or hereafter developed.

The use of general descriptive names, registered names, trademarks, service marks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant protective laws and regulations and therefore free for general use.

The publisher, the authors, and the editors are safe to assume that the advice and information in this book are believed to be true and accurate at the date of publication. Neither the publisher nor the authors or the editors give a warranty, express or implied, with respect to the material contained herein or for any errors or omissions that may have been made. The publisher remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

This Springer imprint is published by the registered company Springer Nature Switzerland AG. The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Foreword

When the human genome program was completed and we started to understand the genetic makeup of human beings, the theoretical possibility of manipulating the genetic structure also emerged. In the debates on how much and what kind of interventions are ethically acceptable, only a few resulted in widespread agreement, and one of them was on the prohibition of modifying the genome of future generations. In Europe, under Article 13 of the Oviedo Convention, an intervention seeking to alter the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if its aim is not to change the genome of descendants. The Oviedo Convention is more than 20 years old, but its ethical principles are considered the standard setting even beyond the European continent. With the introduction of preimplantation gene editing, it seems that the distinction between germ line and somatic line is getting blurred. Therefore, it is crucial to explore and take stock of the manifold legal challenges of preimplantation genetic interventions on a global scale.

Pin Lean Lau's book provides an excellent review of this field, and it is unique in that it discusses preimplantation genetic interventions in a multidisciplinary and comparative context. Many layers of analysis complement each other: besides discussing the philosophical understanding of reproduction and enhancement, the book also explores the ethical principles formed in the debates on the status of the human embryo, on abortion, on early prenatal testing technologies, and on genetic interventions, and it engages with various legal theories as well on the fundamental rights and constitutional rights and on the role of regulation. Pin Lean Lau's work also challenges the notion that European or Western ethical principles and moral values are considered universally valid. The traditional focus on European bioethical discourses is reframed within a rich comparative ethical and legal context: the book analyzes a wide landscape of jurisdictions, including Malaysia, Thailand, and Australia, besides the United States and the United Kingdom. As the field of biomedical research itself becomes more and more global and new technological advances are reported increasingly from Asian countries, it is essential that the philosophical, ethical, and legal analysis of genetic research and interventions also develops a comparative on a global focus.

vi Foreword

As Sheila Jasanoff stated in her work *Reframing Rights: Bioconstitutionalism in the Genetic Age*, "Two encyclopedic bodies of writing—one social, the other scientific—define the meaning of life in our era. Encompassing, respectively, law and biology, these intertwined, mutually supporting, indeed coproducing textual projects frame the possibilities, limits, rights, and responsibilities of being alive—most especially for the species we call human." In the above quote, Sheila Jasanoff distinguishes between the two bodies of writing, the social and the biological, and claims that the two are now linked more than ever before. Although the two domains, law and science, have developed separately, the new textuality of genetics brings much closer the two disciplines than ever before. Now, we simply cannot escape the multidisciplinary studies in this field.

This multidisciplinary and comparative perspective is clearly shown in the structure of the book: after a rich introduction, it discusses the legacy of eugenics in contemporary law, the legal and ethical debates in embryo selection, the regulatory framework in biomedical technologies, the international biomedical laws in the field of genetic, and also the dynamics of basic constitutional rights in different jurisdictions. The bibliography also reflects this multidisciplinary approach, and the references to the American, British, Australian, Malaysian, and Thai legal doctrines promise to be a rich source of material for further research.

Pin Lean Lau eloquently demonstrates that working in the field of contemporary biomedical law and bioethics requires passion and patience: passion to understand the multiplicity of philosophical, ethical, and legal issues related to genetic research and the technologies of genetic interventions and patience to develop a consistent comparative analysis of a wide variety of ethical values and legal jurisdictions. Without such passion and patience, it would not be possible to work in this dynamic field, where new scientific challenges can shake the existing normative framework every day. The book shows that science, law, and ethics consist of not just dry texts that need to be collected, assessed, and compared, but it could also be formulated eloquently. I believe that it will be an important source book for lawyers, scientists, professors, students, and different kinds of stakeholders within the biomedical industry.

Central European University Budapest, Hungary Judit Sándor

Center for Ethics and Law in Biomedicine Budapest, Hungary

Acknowledgments

My warmest gratitude:

To my mentor, Professor Judit Sandor, without whom this book would not be possible. No words are enough to express my gratitude for your support, kindness, and friendship.

To my mother, Champi, who encouraged me to follow my dreams, spread my wings, and seek my passion beyond my comfort zone and who taught me how to be strong, resilient, and free-spirited and to embrace the world and my own abilities. To my late father, KB, whom I will always love until the end of my days. To my daughter, Emilie, the center of my universe, the only human being who will ever know what my heart sounds like from the inside. You have taught me so much more than I expected to learn, for the love you bestow upon me and the privilege I've been given to be your mother. I love you beyond the infinite universe. To my brother, Chin Wei, whose strong and silent presence throughout reminds me why I am grateful to you.

To my wonderful friends from home and those in my adopted home who have become my family. All of you, whose names are forever etched in my heart, I love that the breadth and depth of oceans and skies between us have never changed what we mean to each other; every one of you beyond the confines of our geographical borders, I am thankful to call you my dearest friends.

To my colleagues in the Central European University Legal Studies Department, my brothers and sisters now, thank you for the love, the camaraderie, the endless flow of coffee and chocolates in our lab, and the fellowship; the privilege has been mine to know each and every one of you. For my doctoral program directors, Professor Csilla Kollonay-Lehoczky and Professor Mathias Möschel, for your words of wisdom, kindness, continuous support and understanding. To Professors Károly Bárd, Renáta Uitz, Tibor Tajti, Eszter Polgári, and Petra Bárd, all of whom have extended advice and support in one way or other. To the effervescent Ms. Lea Tilless, for all your support, advice, easy friendship, and encouragement throughout these years. To Ms. Natalia Nyikes, who always has time to give me hugs and spur me on with words of wisdom and encouragement. To all the other wonderful people

viii Acknowledgments

at the Central European University, for being part of my daily life and giving me the privilege of knowing you.

To Professor Jane Kaye, Dr. Michael Morrison, Dr. Harriet Teare, Miranda Mourby, Imogen Holbrook, and Fiona Coldwell at the Center for Health, Law and Emerging Technologies (HeLEX), University of Oxford, my sojourn at HeLEX and all your encouragement and scholarly feedback have impacted my research studies in ways that allowed me to explore beyond what I knew, and I am grateful for that.

To Dr. Aurelie Mahalitchmy and Dr. Michael Morrison, whose invaluable advice and feedback have enabled me to undertake a richer and more comprehensive reflection of my research, for your encouragement, support, and continued future collaborations.

To my publisher and editor, Anke Seyfried, who took a chance on my work and has supported and encouraged me throughout, and to Springer International, for making this a reality.

Thank you.

Budapest, Hungary May 2019 Pin Lean Lau

Contents

1	Intr	oductio	n		1	
	1.1	Theoretical Background				
	1.2	Why Is This Work Important?				
	1.3					
	1.4	Globa	Blobalization and the Main Concerns			
		1.4.1	Socio-L	egal and Ethical Concerns of PGD		
			and Gen	ome Editing	13	
		1.4.2	Differen	ces in Legal/Regulatory		
			Framew	orks & Attitudes	17	
		1.4.3	An Inter	national Regulatory Benchmark?	22	
	Refe	erences.			24	
2	The Legacy of Eugenics in Contemporary Law					
	2.1			igenics in the Contemporary Genetic Debates	30	
	2.2			ets and Paradigms of Eugenics Movements	32	
		2.2.1		Theory of Heredity as the Birth		
				Eugenics	32	
		2.2.2	•	s Laws of Inheritance and Their Relationship		
			with Ear	'ly Eugenics	33	
		2.2.3	Beyond	Historical Conceptions: A Violation of Rights		
			nics Practice	35		
			2.2.3.1	Forced Sterilization as a Form		
				of the Early Eugenics Movements		
				in the United States (US)	35	
			2.2.3.2	Eugenic Policies in Nazi Germany	41	
			2.2.3.3	State-Supported Eugenics Movements in Asia	44	
	2.3	The T	heory of '	Liberal' Eugenics: Autonomy and Freedom		
	from State Intervention					
		2.3.1	Liberal l	Eugenics: A Recognition of Autonomy?	48	
		2.3.2	A Re-in	terpretation of Autonomy in Liberal Eugenics	61	

x Contents

		Eugenic Legacies in Contemporary Genetic Debates	66 69			
3	The Legal and Ethical Debates in Embryo Selection.					
	3.1	Infertility and the Journey to Embryo Selection	73 76			
	3.2	Genetic Screening Technologies: Pre-implantation Genetic				
		Screening (PGS) and Pre-implantation Genetic				
		Diagnosis (PGD)	84			
		3.2.1 Distinctions Between PGS and PGD	85			
		3.2.2 Current State of the Laws/Regulation for PGD				
		in the Selected Jurisdictions	88			
		3.2.2.1 The United States	88			
		3.2.2.2 The United Kingdom	91			
		3.2.2.3 Australia	94			
		3.2.2.4 Malaysia	97			
		3.2.2.5 Thailand	100			
	3.3	The Predominant Debates in the Selected Jurisdictions	103			
		3.3.1 Political and Socio-Legal or Legal Debates	104			
		3.3.2 Religious and Cultural Debates	106			
		3.3.3 Ethical and Philosophical Debates	108			
	3.4	Comparisons of the Debates: Shaping the Framework				
		of Regulation	111			
	3.5	Reprogenetics As an Influence in Regulation Shaping	115			
	Refe	erences.	117			
4	The Regulatory Framework in Biomedical Technologies					
	4.1	Regulatory Theory in the Field of Biomedical Technologies	125			
		4.1.1 Why Should Biomedical Technologies Be Regulated?	125			
		4.1.2 The Foundations of Regulatory Theory	129			
		4.1.3 Regulatory Approaches in Biomedical Technologies	132			
	4.2	The Challenges of Regulating Biomedical Technologies	139			
		4.2.1 Legitimacy	140			
		4.2.1.1 The Bioethical Triangle	141			
		4.2.1.2 Informed Consent	143			
		4.2.1.3 Pluralism	145			
		4.2.2 Effectiveness and Enforceability	147			
		4.2.3 Legal Pluralism/Cosmopolitanism	150			
	4.3	Analogies of Regulatory Design	153			
		4.3.1 The Abortion Debates	154			
		4.3.2 Prenatal Testing Technologies	159 162			
	4.4	• • • • • • • • • • • • • • • • • • • •				
	4.5					
	Rete	eferences 17				

Contents xi

5	International Biomedical Laws in the Field of Genetic					
	Inte	rventions	175			
	5.1	Existing International Biomedical Laws				
		5.1.1 Biomedical Laws: Public Law or Private Law? 1	178			
		5.1.2 Principles of International Biomedical Laws	181			
	5.2	Selected International Human Rights Instruments				
		in Biomedicine	186			
	5.3	Shortcomings of the International Instruments in Current				
		Bioethical Issues	191			
		5.3.1 Human Dignity as a Grounded Normative Value	194			
		5.3.2 Germ-Line Genetic Interventions	199			
		5.3.3 The Impact of the Shortcomings on Human Rights				
			203			
	5.4	Guidelines/Recommendations for Genetic Interventions:				
			205			
	Refe	rences	207			
6	The	Dynamics of Basic Constitutional Rights in Selected				
_			213			
	6.1		216			
		6.1.1 The Human Rights Approach in the Field of Genetic				
			220			
		6.1.2 Entry Points of Regulation: Genetic Interventions				
		· · · · · · · · · · · · · · · · · · ·	222			
	6.2	The Role of Human Rights As Constitutional Rights				
			227			
	6.3					
		Jurisdictions (The Human Rights Components)	230			
		6.3.1 Group One (1): The United States	231			
		6.3.2 Group Two (2): United Kingdom and Australia	237			
		6.3.2.1 The United Kingdom	237			
		6.3.2.2 Australia	252			
		I v v v v v v v v v v v v v v v v v v v	260			
		· · · · · · · · · · · · · · · · · · ·	263			
			266			
	6.4	The Entry Points of Regulation in Pre-implantation Genetic				
			271			
	Refe	rences	275			
7	Con	clusion	285			
	7.1		285			
	•		285			
			287			
	7.2		290			
			290			

xii Contents

		7.2.2	Implications on Reproduction and Reproductive/Maternal		
			Health	292	
		7.2.3	Implications on Scientific/Medical/Healthcare Research		
			and Development	295	
	7.3	Reboo	ting the Future	297	
	Refe	erences.		298	
Ref	References				

Abbreviations

AHEC Australian Health Ethics Committee
AHRC Australian Human Rights Commission
AHRD ASEAN Human Rights Declaration
ARTs Assisted Reproductive Technologies
ASEAN Association of Southeast Asian Nations

CEDAW Convention on the Elimination of All Forms of Discrimination

Against Women

CRISPR Clustered Regularly Interspaced Short Palindromic Repeats

DNA Deoxyribonucleic Acid

ECHR European Convention on Human Rights
ECtHR European Court of Human Rights
EMA European Medicines Agency

EU European Union

FSA Fertility Society of Australia GDP Gross Domestic Product

HFEA Act Human Fertilization and Embryology Authority Act HFEA Human Fertilization and Embryology Authority

HLA Human Leukocyte Antigen HRA Human Rights Act 1998 HRBA Human Rights-Based Approach

HRCM Act Human Rights Commission of Malaysia Act 1999

IBC International Bioethics Committee

ICCPR International Covenant on Civil and Political Rights

ICESCR International Covenant on Economic, Social and Cultural Rights ICPD International Conference on Population and Development IDHGD International Declaration on Human Genetic Data 2003

IVF In Vitro Fertilization

JRC Joint Research Centre for Science and Policy

LF Legal Foresighting

NHMRC National Health and Medical Research Council

NHRC National Human Rights Committee

xiv Abbreviations

NHSCB National Health Service Commissioning Board

NIH National Institutes of Health

OECD Organization for Economic Co-operation and Development

OHCHR Office of the High Commissioner for Human Rights

PGD Preimplantation Genetic Diagnosis
PGS Preimplantation Genetic Screening
RRI Responsible Research Innovation

RTAC Reproductive Technology Accreditation Committee

SUHAKAM Human Rights Commission of Malaysia

UDBHR Universal Declaration on Bioethics and Human Rights 2005

UDHG Universal Declaration on the Human Genome and Human Rights

1997

UDHR Universal Declaration on Human Rights 1948

UN United Nations

UNESCO United Nations Educational, Scientific and Cultural Organization

WHO World Health Organization
WMA World Medical Association