HUMAN GERMLINE GENOME MODIFICATION AND THE RIGHT TO SCIENCE

The advent of gene therapies and genome editing tools (ZFN, TALEN, CRISPR) are transforming not just science and medicine but also law. When the genome of germline cells is modified, the modifications could be inherited with far-reaching effects in time and scale. Legal systems are struggling with keeping up with the CRISPR revolution, and both lawyers and scientists are often confused about existing regulations. This book contains an analysis of the national regulatory framework in eighteen selected countries. Written by national legal experts, it includes all major players in bioengineering, plus an analysis of the emerging international standards and a discussion of how international human rights standards should inform national and international regulatory frameworks. The authors propose a set of principles for the regulation of germline engineering, based on international human rights law, which can be the foundation for regulating heritable gene editing both at the level of countries as well as globally. A companion website contains the legal instruments regulating human germline genome modification internationally and in each country surveyed in this book: www.freedomofresearch.org/ggel

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Human Germline Genome Modification and the Right to Science

A COMPARATIVE STUDY OF NATIONAL LAWS AND POLICIES

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To Maya, who came along on a lucky day (A.B.)
To Bourbon, who kept me company and waited for me patiently while I was writing yet another sentence (C.R.)
To Sebi, for always trying to see the best in everything around us, and to Rebe, for constantly striving for all of us to do better (J.A.)

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Foreword

Human Germline Genome Modification and the Right to Science: A Comparative Study of National Laws and Policies by Andrea Boggio, Cesare P. R. Romano, and Jessica Almqvist constitutes a tour de force resource for those seeking more explicit normative guidance on this controversial subject. Indeed, what distinguishes this book is not only the quality and rigor of its comparative, legal methodology, but the human rights lens it employs as its conceptual framework. The "right to science" is both the leitmotif and the lens through which the current laws and policies of eighteen countries, spanning North America, Asia, Europe and other Western countries, and the European regulatory framework, are filtered. The common template of analysis applied to each chapter addresses the questions and issues raised by human germline modification throughout the translational pipeline from basic, animal, and clinical research to possible clinical applications thereby allowing for cross-country comparisons. Moreover, the international discussion of this hitherto largely dormant human right to science has the power to refocus the current largely "prohibitive" stance found across the world. Indeed, even today proscriptive and technique-specific language has effectively shut down debate on human germline modification. The issue was seen as settled, since largely banned and accompanied by criminal sanctions justified by reference to human genetic identity, integrity, and immutability. And then came Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).

Hopefully, this awakening of the right to science – its freedoms and its benefits – will serve to place the debate on germline modification outside the binary and polarized clichés of "slippery slopes" and "playing God." It can catalyze, activate, and shape the contours for radical innovation. It can move the debate away from imagining hypothetical, harmful applications to considering evidence-based benefits. Perhaps somatic gene therapies will lead the

way and help develop the quality and safety foundations for the acceptability of clinical research into germline modifications. Most importantly, the legal actionability of the right to science could begin immediately with the creation of national and international governance structures that guide public debate and receive and monitor applications. Reflexive governance could also provide the common ethical guideposts for a responsible translation of the rights of its citizens, both individually and collectively, to say nothing of the rights of future generations.

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Preface

As this book's manuscript was finalized, the media announced that twin girls, whose DNA had been genetically modified with CRISPR tools, were born. The news was shocking, not only because this was the first case of human germline genome modification resulting in a birth, but also because it happened outside the boundaries of the law.

The scientist who made the shocking announcement on the eve of an international conference in Hong Kong on CRISPR, Dr. He Jiankui, of the Southern University of Science and Technology, in Shenzhen, People's Republic of China, said he and his colleagues altered embryos for seven couples during fertility treatments, with two female volunteers becoming pregnant as a result. One gave birth to female twins, named Lu Lu and Na Na, and the other is still pregnant. He said his goal was not to cure or prevent an inherited disease but to try to bestow a trait that few people naturally have – an ability to resist possible future infection with HIV, the AIDS virus. Dr. He Jiankui declared to Associated Press: "I feel a strong responsibility that it's not just to make a first, but also make it an example. Society will decide what to do next."[1] What we now know is that Dr. He's experiments involved serious violations of national regulations and international standards.

When we launched this book's project, we knew the application of CRISPR to human germline cells was going to take place, somewhere, somehow. We certainly did not foresee that it would happen so soon and within an overall legal framework that almost invariably prohibits clinical applications of germline genome modification. Dr. He's stunt will certainly jolt lawmakers across the globe, and that is good and overdue. However, the risk is that the scientific and human rights implications of this extremely complex field of scientific

[1] M. Marchione, "Chinese Researcher Claims First Gene-Edited Babies," Associated Press, November 26, 2018.

research will be glossed over in the vain search for quick and easy solutions. We hope our project can help in shaping the debate that will certainly take place in the coming years.

Like many projects, this one is largely the result of personal connections and intersecting research agendas. For a few years, Cesare had been litigating a case (communication) regarding research on human embryos before the Committee on Economic, Social and Cultural Rights together with the Associazione Luca Coscioni for the freedom of scientific research. Andrea had been a member of the board of the Associazione for years, supporting its work with a project mapping indicators of freedom of research. The two had become interested in the topic of the right to science and the rights of science, starting work on a book together. Cesare had worked with Jessica on international justice in New York, at New York University, at the Project on International Courts and Tribunals in the early 2000s. When Jessica contacted Cesare saying she intended to apply for a research grant and was shopping for ideas, Cesare had just finished discussing human genome modification with Andrea. Andrea reached out to Bartha Knoppers, the Director of the Centre of Genomics and Policy, Faculty of Medicine, Human Genetics, of McGill University. Bartha kindly gave us access to her vast professional network. The rest, as they say, is history.

At the outset of the project, it became apparent to us that, as it often happens with disruptive technological breakthroughs, states are struggling to keep up with developments and to regulate research and applications, creating a patchwork of national legislations. Some have equipped themselves with fairly sophisticated legislation and regulatory bodies to ensure research can advance but within acceptable limits. Others have instead opted to restrict research and applications as much as possible to ward off any dangers. Many have not yet adopted any national legislation, and keep on relying on outdated legislation that is unsuitable to regulate gene editing in general, and surely germline editing in particular. They are waiting to see in which direction most other states are going. Often, the boundaries of what is legally permitted are unclear. Gaps and unresolved legal issues abound. The only clear pattern is that clinical research is prohibited or under a moratorium in all countries. In fact, so far, no law seems to permit the implant of a genetically modified embryo (or an embryo created by using genetically modified germ cells) in uterus, whether for research purposes or to start a pregnancy.

At the international level, bar the Oviedo Convention and the European Clinical Trials Regulation, there are no clear, global legal standards on germline genome editing. However, international human rights standards, as codified in the Universal Declaration of Human Rights and the twin Covenants

(civil and political rights, and economic, social, and cultural rights), do provide the four corners within which regulatory frameworks of heritable gene editing must be placed and developed.

Within this fragmented and incomplete regulatory environment, this book explores both levels of regulation (domestic and international) and makes a case for using the human right to "benefit from advances in science and technology" (the right to science) and to "freedom indispensable for scientific research" (the rights of science) as a guiding framework to regulate germline engineering. The book accomplishes these goals in three steps. First, it maps national legislation of germline engineering in eighteen states and one region (Europe). The mapping exercise is not only descriptive but also normative, to the extent that it allows for the identification of best practices and the guidance of states that are still in the process to adapt their national legislation.

Second, the book provides a comparative analysis of the laws of the chosen jurisdictions. This analysis identifies patterns and trends as well as areas where policy work needs to be done. Our findings show a pattern of prohibition of any form of clinical research and clinical applications of germline genome modifications. With regard to basic research, the picture is much more fragmented with regulations taking a number of different paths. However, for the most part, these regulations are obsolete, incomplete, and unclear about what research can and cannot accomplish lawfully.

Third, the book connects national legislation to the core international obligations all states have as a matter of international human rights law. In particular, it puts at the center of the discussion the so-called right to science as a source of normative guidance in this complex area.

Although the "right to science" and the "rights of science" are some of the oldest human rights, dating back to the late 1940s, they are probably the least known, discussed, and enforced of all international human rights. However, over the past few years, they have been the object of much renewed attention. The Committee on Economic, Social and Cultural Rights is in the process of drafting a General Comment on them, and a number of nongovernmental organizations and scholars are busy organizing symposia and writing books on the matter.

No book, however, has applied the right to science and the rights of science to germline engineering. Our argument as to how human rights law applies to germline genome modifications is twofold. First, the current patchwork of national legislation infringes upon scientists' freedom to engage in basic research that has the potential to revolutionize how disease is construed and treated. Second, the right to science mandates that the material benefits of science are shared. Our reading is that a blank prohibition against clinical

research infringes upon the right of patients to have access to the benefits of science. These arguments are novel and readers will certainly benefit from a deeper understanding of the extent to which international human rights law can inform debate on germline engineering.

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Abbreviations

ABM	Biomedicine Agency (Agence de la Biomédecine) (France)
ACC	Animal Care Committees (Canada)
ACHR	American Convention on Human Rights
AHRA	Assisted Human Reproduction Act (Canada)
ANM	National Academy of Medicine (Académie Nationale de Médecine) (France)
ANR	National Research Agency (Agence Nationale de la Recherche) (France)
ARCs	Assisted Reproduction Centres
ART	Artificial/Assisted Reproductive Technologies
ASRM	American Society for Reproductive Medicine
AUGMENT	AUtologous Germline Mitochondrial ENergy Transfer
BAC	Bioethics Advisory Committee (Singapore)
BMBF	Federal Ministry of Education and Research (Bundesministeriums für Bildung und Forschung) (Germany)
BOE	Official Gazette (Boletín Oficial del Estado) (Spain)
BSA	Bioethics and Safety Act (Republic of Korea)
BVerfG	Federal Constitutional Court (Bundesverfassungsgericht) (Germany)
C. civ.	Civil Code (Code civil) (France)
C. pén.	Criminal Code (Code pénal) (France)
C. rur.	Rural Code (Code rural) (France)
CAHBI	Ad hoc Committee of Experts on Bioethics (Council of Europe)
Cas9	CRISPR associated protein 9

CBER	Center for Biologics Evaluation and Research (United States)
CCAC	Canadian Council on Animal Care
CCMO	Central Committee on Research involving Human Subjects (Centrale commissie voor medisch-wetenschappelijk onderzoek op mensen) (Netherlands)
CCNE	National Ethical Consultative Committee for Life and Health Sciences (Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé) (France)
CDA	Christian Democratic Appeal (Het Christen-Democratisch Appèl) (Netherlands)
CDBI	Steering Committee on Bioethics (Council of Europe)
CEC	Clinical Ethics Committees (Mexico)
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CENATRA	National Centre for Transplants (Centro Nacional de Trasplantes) (Mexico)
CEPAFIC	Spanish Committee for the Protection of Animals Used for Scientific Research (Comité español para la protección de los animales utilizados con fines científicos) (Spain)
CFDA	Chinese Food and Drug Administration (PRC)
CIBIOGEM	Inter-Secretariat Commission on Biosecurity of Genetically Modified Organisms (Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados) (Mexico)
CIHR	Canadian Institutes of Health Research
CINVESTAV	Centre for Research and Advanced Studies (Centro de Investigacion y Estudios Avanzados) (Mexico)
CJEU	Court of Justice of the European Union
CNDH	National Commission of Human Rights (Comisión Nacional de los Derechos Humanos) (Mexico)
CNRS	National Center for Scientific Research (Centre National de la Recherche Scientifique) (France)
CNTS	National Centre for Blood Transfusion (Centro Nacional de Transfusión Sanguínea) (Mexico)
CoE	Council of Europe
COFEPRIS	Federal Commission for the Prevention against Sanitary Risks (Comisión Federal de Prevención Contra Riesgos Sanitarios) (Mexico)

COGEM	Commission on Genetic Modification (Netherlands)
CONACYT	National Council for Science and Technology (Consejo Nacional de Ciencia y Tecnología) (Mexico)
CONBIOÉTICA	Comisión Nacional de Bioética (National Commission of Bioethics) (Mexico)
CPEUM	Political Constitution of the Mexican United States (Constitución Política de los Estados Unidos Mexicanos) (Mexico)
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSP	Public Health Code (Code de la santé publique) (France)
CSTI	Council for Science, Technology and Innovation (Japan)
D66	Democrats 66 (Democraten 66) (Netherlands)
DCC	Civil Code (Burgerlijk Wetboek) (Netherlands)
DH-BIO	Council of Europe's Committee on Bioethics
DHHS	Department of Health and Human Services (United States)
DIA	Drug Inspection Administration (PRC)
DNA	Recombinant Deoxyribonucleic Acid
EC	European Council
ECHR	European Convention on Human Rights and Fundamental Freedoms
ECJ	European Court of Justice
ECtHR	European Court of Human Rights
EGE	European Group on Ethics in Science and New Technologies
ELSI	Ethical, Legal and Social Aspects
EMA	European Medicines Agency (EU)
EPC	European Patent Convention
EPO	European Patent Office
ERC	European Research Council
ERLC	Embryo Research Licensing Committee (Australia)
ERRIH	Ethical Review of Research Involving Humans (Lag om etikprövning av forskning som avser människor) (Sweden)
ESchG	Embryo Protection Act (Embryonenschutzgesetz) (Germany)
ESHRE	European Society for Human Reproduction and Embryology
EU	European Union

FCCyT	Consultative Body on Science and Technology (Foro Consultivo de Ciencias y Tecnología) (Mexico)
FDA	Food and Drug Administration (United States)
G20	Group of 20
GAP	Good Animal Practice (Canada)
GDP	Gross Domestic Product
GenTG	Genetic Engineering Act (Gentechnikgesetz) (Germany)
GfH	German Society of Human Genetics (Deutsche Gesellschaft für Humangenetik)
GG	Grundgesetz (Basic Law) (Germany)
GHC	General Health Council (Mexico)
GHL	General Health Law (Mexico)
GIA	Genetic Integrity Act (Lag om genetisk integritet) (Sweden)
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GT Act	Gene Technology Act 2000 (Australia)
GTR	Gene Technology Regulator (Australia)
HBRA	Human Biomedical Research Act (Singapore)
hESCs	Human Embryonic Stem Cells
HFC	Health and Family Planning Commission (PRC)
HGRMO	Human Genetic Resources Management Office (PRC)
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HSA	Health Sciences Authority (Singapore)
IACHR	Inter-American Commission of Human Rights
IACtHR	Inter-American Court of Human Rights
IBC	Institutional Biosafety Committee
ICB	Italian Committee for Bioethics (Comitato Italiano di Bioetica) (Italy)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICH	International Conference on Harmonisation
ICSI	Intracytoplasmic Sperm Injection
IIJ-UNAM	The Institute for Legal Research at the National Autonomous University of Mexico (Instituto de Investigaciones Jurídicas de la Universidad Nacional Autónoma de México)

IMSS	Mexican Social Security Institute (Instituto Mexicano del Seguro Social) (Mexico)
INAI	National Institute for Transparency and Access to Information (Instituto Nacional de Acceso a la Información) (Mexico)
IND	Investigational New Drug (United States)
INEGI	National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía) (Mexico)
INMEGEN	National Institute for Genomic Medicine (Instituto Nacional de Medicina Genómica) (Mexico)
INSERM	Ethics Committee of the French National Institute for Health and Medical Research (Institut National de Santé et Recherche Médicale) (France)
IPN	National Polytechnic Institute (Instituto Politécnico Nacional) (Mexico)
iPSCs	Induced Pluripotent Stem Cells
IRB	Institutional Review Board
ISSCR	International Society for Stem Cell Research (United States)
ISSFAM	Institute for Social Security and the Mexican Army Forces (Instituto de Seguridad Social para las Fuerzas Armadas de México) (Mexico)
ISSSTE	Institute of Social Security and Services for Civil Servants (Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado) (Mexico)
IVF	In Vitro Fertilization
IVG	In Vitro Gametogenesis
IVM	In Vitro Maturation
JSOG	Japan Society of Obstetrics and Gynecology
LAA	Laboratory Animal Act (Republic of Korea)
LAGH	Federal Act on Human Genetic Testing (Loi fédérale sur l'analyse génétique humaine) (Switzerland)
LANGEBIO	National Laboratory of Genomics for Biodiversity (Laboratorio Nacional de Genómica para la Diversidad) (Mexico)
LBOGM	Biosafety Law on Genetically Modified Organism (Ley de Bioseguridad de los Organismos Genéticamente Modificados) (Mexico)

LGG	Federal Act on Non-Human Gene Technology (Loi fédérale sur l'application du génie génétique au domaine non humain) (Switzerland)
LPA	Animal Welfare Act (Loi fédérale sur la protection des animaux) (Switzerland)
LPMA	Federal Act on Medically Assisted Reproduction (Loi fédérale sur la procréation médicalement assistée) (Switzerland)
LRCS	Federal Act on Research Involving Embryonic Stem Cells (Loi fédérale relative à la recherche sur les cellules souches embryonnaires) (Switzerland)
LRH	Federal Act on Research involving Human Beings (Loi fédérale relative à la recherche sur l'être humain) (Switzerland)
MAR	Medically Assisted Reproduction
MDFS	Ministry of Drug and Food Safety (Republic of Korea)
ME	Ministry of Economy (Mexico)
MEXT	Ministry of Education, Culture, Sports, Science, and Technology (Japan)
MHLW	Ministry of Health, Labour, and Welfare (Japan)
MMT	Mitochondrial Manipulation Techniques
MoH	Ministry of Health (PRC) (Mexico) (Singapore)
MoHW	Ministry of Health and Welfare (Republic of Korea)
MoST	Ministry of Science and Technology (PRC)
MRT	Mitochondrial Replacement Therapy
mtDNA	Mitochondrial DNA
NAFTA	North American Free Trade Agreement
NEK/CNE	Swiss National Advisory Commission on Bioethics (Commission nationale d'éthique dans le domaine de la médecine humaine) (Switzerland)
NHC	National Health Commission (PRC)
NHI	National Health Institutes (Institutos Nacionales de Salud) (Mexico)
NHMRC	National Health and Medical Research Council (Australia)
NHS	National Health Services (Mexico)
NICE	National Institute for Health and Care Excellence (Belgium)
NIH	National Institutes of Health (United States)

NOMs	Official Mexican Norms or Standards (Normas Oficiales Mexicanas) (Mexico)
NPC	National People's Congress (PRC)
NRT	New Reproductive Technologies
NSERC	Natural Sciences and Engineering Research Council of Canada
NWO	The Netherlands Organization for Scientific Research (Nederlandse organisatie voor Wetenschappelijk Onderzoek)
OAGH	Ordinance on Human Genetic Testing (Ordonnance sur l'Analyse Génétique Humaine) (Switzerland)
OAS	Organization of American States
OClin	Ordinance on Clinical Trials in Human Research (Ordonnance sur les essais cliniques dans le cadre de la recherche sur l'être humain) (Switzerland)
OECD	Organisation for Economic Co-operation and Development
OFSP	Federal Office of Public Health (Office fédéral de la santé publique) (Switzerland)
OPAn	Animal Welfare Ordinance (Ordonnance sur la Protection des Animaux) (Switzerland)
OPECST	Parliamentary Office of Evaluation of Scientific and Technological Options (Office Parlementaire d'Évaluation des Choix Scientifiques et Technologiques) (France)
OPMA	Reproductive Medicine Ordinance (Ordonnance sur la procréation médicalement assistée) (Switzerland)
ORCS	Ordinance on Research involving Embryonic Stem Cells (Ordonnance relative à la recherche sur les cellules souches embryonnaires) (Switzerland)
OSAV	Federal Food Safety and Veterinary Office (Office Fédéral de la sécurité alimentaire et des affaires vétérinaires) (Switzerland)
OUC	Ordinance on Handling Organisms in Contained Systems (Ordonnance sur l'utilisation des organismes en milieu confiné) (Switzerland)
PAA	Pharmaceutical Affairs Act (Republic of Korea)
PAHO	Pan American Health Organization
PAN	National Action Party (Partido Acción Nacional) (Mexico)
PatG	Patent Act (Patentgesetz) (Germany)
PEMEX	Mexican Petrol (Petróleos Mexicanos) (Mexico)

PGD	Pre-implantation Genetic Diagnosis
PHCR Act	Prohibition of Human Cloning for Reproduction Act 2002 (Australia)
PMI	Precision Medicine Initiative (PRC)
PNT	National Platform for Transparency (Plataforma Nacional de Transparencia) (Mexico)
PRC	People's Republic of China
PRI	Institutional Revolutionary Party (Partido Revolucionario Institucional) (Mexico)
PvdA	Labour Party (Partij van de Arbeid) (Netherlands)
R&D	Research & Development
RCOG	Royal College of Obstetricians and Gynaecologists (Belgium)
REC	Research Ethics Committee
RF	The Instrument of Government (Regeringsformen) (Sweden)
RIHE Act	Research Involving Human Embryos Act 2002 (Australia)
RNEC	National Registry of Clinical Trials (Registro Nacional de Estudios Clínicos) (Mexico)
ROK	Republic of Korea
S&T	Science and Technology
SAMR	State Administration for Market Regulation (PRC)
SC	State Council (PRC)
SCJ	Science Council of Japan
SCJN	Mexican Supreme Court (Suprema Corte de Justicia de la Nación) (Mexico)
SCNT	Somatic Cell Nucelear Transfer
SCOC	Stem Cell Oversight Committee (Canada)
SEP	Ministry of Education (Secretaria de Educación Pública) (Mexico)
SNI	National System of Researchers (Sistema Nacional de Investigadores) (Mexico)
SSHRC	Social Sciences and Humanities Research Council of Canada
STA	Science and Technology Act (Mexico)
StGB	Criminal Code (Strafgesetzbuch) (Germany)
Swissmedic	Swiss Agency for Therapeutic Products (Swissmedic, Institut suisse des produits thérapeutiques) (Switzerland)

TAB	Office of Technology Assessment at the German Parliament (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag)
TALENS	Transcription Activator-like Effector Nucleases
TCART	Toronto Center for Assisted Reproductive Technologies (Canada)
TCPS 2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canada)
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
TIARAS	Tissue and Research Application System
TierSchG	Animal Protection Act (Tierschutzgesetz) (Germany)
TierSchVersV	Animal Protection – Experimental Animal Ordinance (Tierschutz-Versuchstierverordnung) (Germany)
UDHR	Universal Declaration on Human Rights
UN	United Nations
UNAM	National Autonomous University of Mexico (Universidad Nacional Autónoma de México)
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNRISD	United Nations Research Institute for Social Development
US	United States of America
USD	United States Dollars
VDI	Association of German Engineers (Verein Deutscher Ingenieure) (Germany)
VVD	People's Party for Freedom and Democracy (Volkspartij voor Vrijheid en Democratie) (Netherlands)
WB	World Bank
WHO	World Health Organization
WMA	World Medical Association
WMO	Medical Research on Human Subjects Act (Wet wetenschappelijk onderzoek met mensen) (Netherlands)
ZFN	Zinc-Finger Nuclease
ZON	Dutch Healthcare Research (ZorgOnderzoek Nederland) (Netherlands)