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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