REGULATING ASSISTED REPRODUCTIVE TECHNOLOGIES

Reproductive science continues to revolutionise reproduction and propel us further into uncharted territories. The revolution signalled by the birth of Louise Brown after IVF in 1978 prompted governments across Europe and beyond into regulatory action. Forty years on, there are now dramatic and controversial developments in new reproductive technologies. Technologies such as uterus transplantation, that may enable unisex gestation and babies gestated by dad, or artificial wombs that will completely divorce reproduction from the human body and allow babies to be gestated by machines, usher in a different set of legal, ethical and social questions to those that arose from IVF. This book revisits the regulation of assisted reproduction and advances the debate on from the now much-discussed issues that arose from IVF, offering a critical analysis of the regulatory challenges raised by new reproductive technologies on the horizon.

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This series of books 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. Since the early 1990s, 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 and 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 debates in the UK, Europe and the international community involve 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 healthcare.

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New Horizons

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FOREWORD

On 25 July 1978, a much-wanted little girl was born in the small Lancashire town of Oldham. As she lay in her cradle, Louise Brown would have been blissfully unaware that her birth signalled a revolution not just in reproductive medicine but in society as a whole. Louise was of course the first baby to be born as a result of *In Vitro Fertilisation* (IVF); or, as the media preferred to say, she was the first test-tube baby. Since that day a whole generation (including the author of this book, Amel Alghrani) has grown up taking IVF for granted. Infertility is no longer something that must simply be accepted as a vicissitude of life. An embryo could now be created outside the body of a woman and then implanted in the mother to be gestated as normal. Louise's mother, who could not conceive naturally because of an obstruction in her Fallopian tubes, was able to give birth to Louise, and later to a second daughter.

Looking back forty years and knowing what we know now about the subsequent developments in the reproductive technologies, Louise's birth after IVF using her married parents' gametes does not seem so earth shattering. Other more dramatic and controversial developments were to follow. To give but a few examples: Dolly, the most famous sheep in the world, offered the prospect of cloning human beings; Pre-Implantation Genetic Diagnosis (PGD) enabled doctors to screen embryos for serious genetic disease and paved the way for 'saviour siblings'. In 1978, the news of the birth was amazing, prompting great celebration and heart-warming media coverage rejoicing for the Browns and other couples unable to have a child. But at the same time the birth gave rise to prophecies of doom and condemnation of unnatural practices. In particular, the ability to create a child outside the womb and the potential for research on in-vitro embryos led to attempts to ban embryo research and effectively stop IVF in its tracks. Enoch Powell's Unborn Child Protection BiIl came very close to becoming law.

Governments across Europe and beyond were slow to respond, fearful of the moral debates that raged around IVF and the opposition of the Catholic Church and other religions. In the United Kingdom, a Committee of Inquiry chaired by Dame Mary Warnock reported in 1984 and the Human Fertilisation and Embryology Act was enacted in 1990, by which time Louise Brown was 12 years old. Nonetheless, the United Kingdom legislated much more swiftly than many other states and, as Dr Alghrani explains, the Human Fertilisation Act 1990 came to be seen as a model for regulation abroad, albeit often denigrated in the United Kingdom itself. The central problem with the 1990 Act was that no sooner than Royal Assent had been granted, the Act became outdated. Research and developments in the reproductive technologies gave rise to ethical dilemmas and legal questions that the lawmakers had never envisaged. The law could only play 'catch up', aided by judges ready to give imaginative interpretations of the Act, leaning towards the spirit of the Act rather than the letter of the law.

At the heart of this book is a plea that the law relating to the reproductive technologies should, as far as possible, be proactive rather than constantly reactive. Amel Alghrani seeks to look to the new horizons in relation to how we should regulate assisted reproductive technologies on and beyond the horizon today. Thus, in Chapters 3 and 4 of Part II, she explores the questions that will be posed by ectogenesis (artificial wombs), venturing into a field that until very recently was much more the concern of literary scholars and science fiction. Few of us will not have read Aldous Huxley's *Brave New World*. In the final two chapters of the present book, the focus is on uterus transplantation and the prospect that a uterus could be transplanted into a man. Uterus transplantation illustrates vividly just how formidable a task Dr Alghrani faced in writing this book. When she began her work, the possibility of a successful uterus transplant seemed some years away. Then, in September 2014, a Swedish team announced the first live birth to a woman who had received a donated womb from a living donor. In a sense, the Swedish success demonstrates the importance of the message at the heart of this book – legislators and regulators cannot afford to sit on their hands and say to themselves, 'don't bother about ectogenesis or male pregnancy yet: it won't happen till tomorrow'. Unlike the promise of jam in *Alice through the Looking Glass*, in the field of the reproductive technologies 'tomorrow' becomes today at a frightening speed.

The reader fascinated by how the frontiers of research to develop the reproductive technologies are changing society may be tempted to rush

straight to Part II and the exciting, brave new world of babies gestated by 'dad', or by machines. They should avoid that temptation. Understanding the context within which radical developments in science, law and ethics may come about is crucial to an informed assessment of regulating new reproductive technologies. Part I sets the scene, giving a critique of the principles of regulation and addressing the fundamental problems arising when gamete donors disagree. The clash of claims by A to a right to reproduce and B to a right not to reproduce is poignantly demonstrated in the sad case of Natalie Evans. On her recovery from cancer, Ms Evans sought to have embryos implanted: embryos that had been created with her eggs and fertilised with sperm from her then partner before Ms Evans underwent chemotherapy. The couple's relationship had broken down and her ex-partner successfully blocked her access to what she saw as 'her' embryos.[1] Ectogenesis will exacerbate the questions around who is entitled to decide about the fate of embryos and fetuses. Imagine that an embryo is created with gametes from A and B, and the couple celebrate the placement of their 'child to be' in the ectogenic chamber. Some weeks later A and B fall out, and B asks for the chamber to be switched off. A objects and wants the fetus to be allowed to develop and be 'born' at the due time. Does it matter if A is the 'mother' or 'father'? Do words such as mother and father continue to have any meaning? Is it relevant how many weeks the fetus has been gestated? If a uterus is successfully transplanted into a man, and he changes his mind against the wishes of his partner, do laws designed to address termination of pregnancy in a woman apply?

By beginning the book with a strong account of the framework of regulation of the more established reproductive technologies, Amel Alghrani ensures that, in moving on to the more dramatic possibilities on the horizon, her argument is well grounded. She considers ethical and social perspectives, as any work on this subject must. The principal focus of this book, however, is the law. All too often in debates about the regulation of healthcare and biomedical science, law is depicted as rather boring and simplistic. Other 'experts' are prominent in the arguments about what society should do; the lawyers are just there to work out how to enforce the outcome. Dr Alghrani demolishes such an attitude. She shows that law is far from dull or simple. And necessarily she contends with the reality that the 'experts' vary rarely, if ever, agree. Lawmakers, legislators and judges confront the dilemma of how to develop laws

[1] *Evans* v. *United Kingdom* (Application no 6339/05); [2007] 22 BHRC 190 [54] (ECtHR).

within a society that includes divergent views on, for example, matters of the status of the fetus, payments for gametes or surrogacy and gendered roles in parenting.

Exploring new horizons in the reproductive technologies is exciting. The future of human reproduction is of interest to most if not all humans. This is a book that will make the reader think; it challenges prejudices and at some points prompts concern about where the journey to the future is taking us. Readers will disagree about the solutions to the dilemmas that Dr Alghrani presents. Some readers will challenge her conclusions. No one will be bored by this book, and very many of us will be much better informed.

Professor Margaret Brazier

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I would like to thank my son and family for their patience and support while I wrote this manuscript. I love you, and perhaps now this is complete we can enjoy spending more time together!

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TABLE OF CASES

TABLE OF STATUTES AND STATUTORY INSTRUMENTS

ABBREVIATIONS

ARTs	Assisted Reproductive Technologies
CCG	Clinical Commissioning Groups
CoP	Code of Practice (HFEA)
CQC	Care Quality Commission
DoH	Department of Health
ECtHR	European Court of Human Rights
HCSTC	House of Commons Science and Technology Committee
HFE Act 1990	Human Fertilisation and Embryology Act 1990
HFE Act 2008	Human Fertilisation and Embryology Act 2008
HFE Act	Human Fertilisation and Embryology Act 1990 (as amended)
HFEA	Human Fertilisation and Embryology Authority
HTA	Human Tissue Authority
IVF	In Vitro Fertilisation
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
PGD	Preimplantation Genetic Diagnosis
PND	Prenatal Diagnosis
RCOG	Royal College of Obstetricians and Gynaecologists
VLA	Voluntary Licensing Authority