A Womb of One’s Own? –

The Legal Implications of Ectogenesis

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Abbreviations

ART – Assisted Reproductive Technologies
ECtHR – European Court of Human Rights
ECHR – European Convention on Human Rights
HFEA – Human Fertilisation and Embryology Act 1990
HTA – Human Tissue Act 2004
IVF – In Vitro Fertilisation
RCOG – Royal College of Obstetricians and Gynaecologists
NICU – Neonatal Intensive Care Unit
REC – Research Ethics Committee
MHRA – Medicines and Healthcare products Regulatory Authority
OAPA – Offences Against the Person Act 1861
RCPCH - Royal College of Paediatrics and Child Health
UK – United Kingdom
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Abstract

This thesis seeks to explore the legal implications of the development of ectogenesis. Although this technology does not currently exist, indirect research into ectogenesis and the pace of reproductive medicine indicates that this technology is something that is inescapable from further research. The driving force behind this thesis is that ectogenesis needs to be thoroughly explored prior to any clinical research on human embryos and foetuses. Following an introduction in Chapter I, Chapter II addresses the ethics and legality of such research towards this technology. Chapter III and IV both examine the application of the current law to ectogenesis. Chapter III focuses upon viability and birth for the ectogenic foetus, whilst Chapter IV addresses whether it is ever permissible to ‘switch off’ the ectogenic chamber. What becomes evident is that the new technology cannot be made to ‘fit’ the old law. As a result of this, Chapter V proposes recommendations for a future regulatory framework for this technology.
Declaration

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Dedication and Acknowledgments

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Chapter One: Introduction

We are such stuff,
As dreams are made on
and nightmares.²

Ectogenesis has been at the back of biologists’ minds for almost one hundred years. In 1923, the evolutionary biologist J B Haldane lauded the technology as one of the most important biological discoveries mankind could ever make.³ One year later he gave extra-uterine babies a name: ‘ectogenesis’,⁴ literally meaning ‘external in origin’.⁵ However, many people were introduced to the idea of artificial wombs through Huxley’s dystopian novel,⁶ Brave New World,⁷ which proposed a world of engineered bottle-grown babies, ‘hatched’ to fulfil their predestined social roles. His title is a quotation from Shakespeare’s The Tempest: ‘O brave new world, that hath such people in it’.⁸

It is described as a dangerous masterpiece of speculation,⁹ however, despite its terrifying predictions, the radical feminist Shulamith Firestone brought its ideas centre stage in the 1970s.¹⁰ She was excited by the prospect of ectogenesis because she believed it to be the only way to achieve the ultimate feminist revolution: an androgynous society.¹¹ Two years before Huxley died,

¹ W. Shakespeare, The Tempest, Act 4, Scene 1, pp. 148
⁴ J B S Haldane, Daedalus; or science and the Future (1924)
⁵ Concise English Dictionary (Wordsworth Editions Ltd, 2007)
⁸ W. Shakespeare, Supra, fn. 1, Act 5, Scene 1.
⁹ Ibid, introduction by Margaret Atwood, p. xvi
he expressed caution over this ‘ectogenic desire’, stating that although society is ‘getting more and more into a position where these things can be achieved…for heaven’s sake be careful about it’.

While the ethical arguments in favour of ectogenesis have entertained curiosity, more pertinent are the profound dangers presented by the practical reality of safely starting, and then continuing, the journey to developing ectogenesis. Weaving an equally complex web of questions are the legal conundrums that may arise out of the development of ectogenesis. What becomes apparent is that exploring the legal implications of ectogenesis is akin opening Pandora’s box, and it is impossible to cover the wealth of legal issues that may arise as a result of ectogenesis. Instead, I have focused upon two main issues: firstly exploring the research phase and safety concerns regarding this emerging technology and secondly, ensuring that the ectogenetic foetus is adequately protected during the gestational phase in the artificial womb. Showing how present legislation will not easily accommodate this new technology will highlight the importance of drafting new legislation to regulate complete foetal gestation in the ectogenic chamber.

1.1 Tomorrow’s Politics - Why Now?

Following the birth of Louise Brown – the world’s first in vitro fertilisation (‘IVF’) baby - Patrick Steptoe said: ‘[t]his is not the beginning of an end, but only the end of the beginning’. Since Brown’s birth in 1978, the pace of reproductive medical advances has been accelerating exponentially, with the advent of technologies including reproductive cloning, three-parent embryos and human-animal hybrids. Welin describes ectogenesis as the ‘obvious next step’, a

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12 The belief that most research in Ectogenesis is driven by the promises and dynamics of an ectogenic desire stated in Aristarkova, Irina, “Ectogenesis and Mother as Machine” Body Society 2005; 11; 43 found at http://bod.sagepub.com/cgi/content/abstract/11/3/43 accessed December 12th 2009
13 Introduction to Brave New World. Pg. xiii A. Huxley, Brave New World (Longman Group Ltd, 1991)
16 Britain has become the first country in the world to allow mitochondrial transfer, (otherwise known as babies with three parents) Z. Williams, “Are three-parent babies the first step towards a Blade Runner future?” The Guardian
question of ‘when’ rather than ‘if’, and the third and final stage of the reproductive revolution. Gelfand observes that it is surprising that so little has been published on artificial wombs, given that some scientists predict that safe, reliable, and complete ectogenesis will be available within the next thirty years, and perhaps within as little as ten or five years.

Recent breakthroughs in reproductive medicine have brought ectogenesis away from science fiction to a potential reality. Researchers have already achieved small steps through successfully keeping foetal goats alive for three weeks using an artificial placenta, developing the world's first mother-to-daughter uterus transplants and sustaining pregnancies in brain-dead women. In addition to these advances, on June 15, 1993, the United States Patent Office granted a patent for a placental chamber. The proposed device is a ‘[l]ife support system for a premature baby in which the baby remains attached to its placenta through its umbilical cord,’ and would support a foetus after as little as ten weeks of in utero female gestation.

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17 D. Bainbridge Supra fn. 6 p.251-252
18 S. Welin, “Reproductive ectogenesis: The third era of human reproduction and some moral consequences” Science and Engineering Ethics (2004) 10, 615-626. In this article, Welin describes the “first era” as normal conception inside the woman and female uterine gestation for nine months. The second era is In Vitro Fertilisation (IVF). “The fetus starts outside the woman as a fertilised egg, moves to the body of the woman and spends nine month there, where the body of the woman and the fetus travel together in space-time to separate at birth”. Ectogenesis represents the third era of reproduction where the fetus spends its gestational time entirely outside the woman’s body. At p.617 Also see P. Singer and D. Wells, The Reproduction Revolution: New Ways of Making Babies (Oxford University Press: Oxford, New York, Melbourne, 1984); A. Smajdor “The Moral Imperative for Ectogenesis” (2007) 16 Cambridge Quarterly of Healthcare Ethics 336-345
19 S. Gelfand, “Ectogenesis and the Ethics of Care” in Gelfand and Shook, Supra fn. 19 at 89.
25 Ibid at [1]. Such a device would not enable complete ectogenesis because it would still require that the embryo spend the first ten weeks of development in utero. However, such a drastic decrease in the amount of time the embryo or fetus spends in a natural womb would still raise the some of the same legal questions surrounding foetal status, viability and birth. See Hyun Jee Son, Artificial Wombs, Frozen Embryos, and Abortion: Reconciling Viability’s Doctrinal Ambiguity, 14 UCLA Women’s Law Journal 213 (2005). Son uses ectogenesis to explore the vulnerabilities in the viability standard arising from the ambiguity of the term “viable.” Id. at 215.
1.2 ‘First of all, do no harm’

Although it is likely to be a number of years before the technology of ectogenesis is fully developed, the legal questions surrounding this process are sufficiently complex to require consideration sooner, rather than later. Hibbert states that it is irresponsible to wait until the first ectogenetic baby is born before discussing how the law will deal with the wide-ranging aspects of ectogenesis. As Morgan and Been argue: ‘[i]n a new age of medical products...there will always be those legislatures that try to pre-empt perceived disasters...and there will be those that limp behind and deal with the aftermath.’ However, to begin thinking about ectogenesis today is akin to asking legislators who can scarcely keep up with today’s technologies to begin thinking about tomorrow’s possibilities. It is asking Parliament for proactive legal regulation rather than reactive late additions. In 1984, when the Warnock Commission had the opportunity to consider the legal implications of ectogenesis, the Committee made the following comments:

*We appreciate why the possibility of such a technique arouses so much anxiety. There are however two points to make about this. First, such developments are well in to the future, certainly beyond the time horizon within which this inquiry feels that it can predict. Secondly, our recommendation is that the growing of a human embryo in vitro beyond fourteen days should be a criminal offence.*

In its momentary consideration of ectogenesis, the Warnock Committee asserted both its inability to make judgments for the future of ectogenesis and recommended that gestation be made illegal.

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26 Primum non nocere is a time-honoured maxim essential to sound medical practice. Literally translated it means ‘first of all do harm’. The origin of the phrase is uncertain but it is most often attributed to Hippocrates who is quoted as saying ‘As to disease, make a habit of two things: to help, or at least do no harm’. In W. S. Haubrich, *Medical Meanings: A Glossary of Word Origins* (United States: American College of Physicians, 2003).


outside the fourteen-day time limit. Yet, the central crux of this thesis is that ectogenesis is a matter that is inescapable from scientific research and a legislative response ought to be considered prior to any human research into ectogenesis.

At present, there are no UK laws which expressly cover research into ectogenesis, although research on an embryo in vitro beyond the fourteenth day of fertilisation is prohibited under s.3 of the Human Fertilisation and Embryology Act 1990 (‘HFEA 1990’) as amended in 2008. Therefore, a key preliminary question is how this ban could be lifted, if indeed it should be. Although current guidelines regarding research with living humans and research with IVF embryos may offer some insight, it will become evident throughout this thesis that there are certain aspects of legislating for artificial wombs that are completely new.

1.3 Definitional Issues

For the purposes of this discussion, I will be focusing upon the legal implications of ‘complete ectogenesis’, where the female body is no longer involved in the gestation of the child at any stage. To qualify as a ‘complete ectogenesis’, this process would involve the creation of an embryo (via IVF), which would then be implanted in an artificial womb and fully developed, completely independent of the female body. For this reason, I will not be discussing ectogenesis as a response

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31 The reasoning behind this decision will be further explored in Chapter One.
33 Ibid.
34 S. Coleman, The Ethics of the Artificial Uterus: Implications for Reproduction and Abortion (Hants: Ashgate Publishing Ltd) 2004. In fact, the opportunity to provide a regulatory framework was bypassed in 2007 for the following reasons: “It has been suggested that in the long term, further developments of current techniques could result in the maintenance of developing embryos in an artificial environment (ectogenesis) for progressively longer periods with the ultimate aim of creating a child entirely in vitro...we appreciate why the possibility of such a technique arouses so much anxiety. There are however two points to make about this. First, such developments are way into the future, certainly beyond the time horizon within which this inquiry feels it can predict. Secondly, our recommendation is that the growing of a human embryo in vitro beyond 14 days should be a criminal offence” Mary Warnock, “A Question of Life: the Warnock Report on Human Fertilisation and Embryology” (Ox: Basil Blackwell, 1985)
35 HFEA 1990 s.3 “No person shall bring about the creation of an embryo except in pursuance of a licence.”
36 (3) A licence cannot authorise—
(a) keeping or using an embryo after the appearance of the primitive streak...(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.”
37 Raskin, Joyce and Mazor, Nadav, “The Artificial Womb and Human Subject Research” in S. Gelfand and R. Shook, Supra fn. 19
or answer to the abortion debate.\textsuperscript{37} Partial ectogenesis, which refers to gestation in the female womb and then in an artificial womb, is also beyond the scope of this thesis.

Although partial ectogenesis already exists through the incubation of extremely premature babies (from as early as twenty-one weeks gestation)\textsuperscript{38} and the use of embryos up to fourteen days old under the HFEA 1990,\textsuperscript{39} these two avenues are yet to converge. Complete ectogenesis is therefore seen as representing ‘the logical end of a continuum’\textsuperscript{40} which has already been developing, and may one day fully develop into the full panoply of incubators and equipment for the full gestation of embryos and foetuses.

1.4 Chapter Outline

In 1978, when the first IVF baby was born, proactive legislation did not exist. Chapter Two uses past lessons that need to be learnt from the early days of developing IVF, to create a compelling case for proactive legislation for ectogenesis. In \textit{The Mother Machine},\textsuperscript{41} Corea refers to evidence suggesting that the early IVF attempts were highly experimental\textsuperscript{42} and that corners were cut in terms of safety in order to win the ‘IVF race’.\textsuperscript{43} Also discussed is the first IVF baby, which had to

\textsuperscript{37} The social implications alone are far-reaching and complex, and numerous works have attempted to address this topic in a myriad of ways. See, generally, F. Simonstein, \textit{Could Artificial Wombs End the Abortion Debate?} In C. Kaczor, \textit{The Edge of Life} (2005)

\textsuperscript{38} Although it is important to note this is an extremely rare occurrence: ‘Most-premature baby allowed home’, 21 February 2007, at http://news.bbc.co.uk/1/hi/world/americas/6377639.stm (accessed January 25th 2010)

\textsuperscript{39} HFEA 1990 s.3 (3) A licence cannot authorise (a) keeping or using an embryo after the appearance of the primitive streak. This is defined in s.3(4) For the purposes of subsection (3)(a) the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with [the day on which the process of creating the embryo began], not counting any time during which the embryo is stored.

\textsuperscript{40} J. Bard ‘Immaculate Gestation? How will ectogenesis change current paradigms of social relationships and values? Chap. 11, p.150 in S. Gelfand and J. Shook, \textit{Supra} fn. 19

\textsuperscript{41} G. Corea, \textit{Supra} fn. 14

\textsuperscript{42} \textit{Ibid.} Two years before the first IVF baby was born an interviewer from \textit{Contemporary Ob/Gy} asked Steptoe, “If a woman became pregnant by this method [IVF] would her baby be normal?” Steptoe replied (one year after he had begun IVF with the Browns) “We don’t yet have enough experience with humans to answer with confidence that all-important question.” \textit{Contemporary Ob/Gyn}, October 1977. When three months after the birth of Louise Brown, \textit{The Washington Star} questioned Steptoe about an increase in birth defects due to external fertilisation he replied, “We do not really know yet what the full risks are...” (Interview in \textit{Star}, Oct 13, 1978)

\textsuperscript{43} \textit{Ibid.} Dr Pierre Soupart thought Steptoe and Edwards had bypassed a crucial step in their research by failing to test whether the embryo might be damaged by the IVF process. When asked, “Were you or your colleagues...concerned that they might be cutting some corners in order to win the race? Soupart replied, “Well, quite obviously they had already cut one...Short of that, there isn’t much more corner that they could cut” (McMullen, 1979). It is also worth
be aborted at ten weeks due to severe abnormalities.\textsuperscript{44} This raises a host of important issues for the early research stages of ectogenesis, such as, how should early research on the ectogenetic embryo and foetus be regulated? Furthermore, the issues raised by the development of IVF are not entirely settled. In 2009, a French study\textsuperscript{45} found that children born from IVF have a sharply increased risk of serious congenital malformation.\textsuperscript{46} The reasons for the defects are not known, but it is thought that the fertilisation process may damage embryos.\textsuperscript{47} The main concern is that not only will ectogenesis involve the IVF procedure, but that with so little certainty surrounding the conditions needed for healthy foetal development, if problems are evident in the process of fertilisation, how much more amplified will those problems be through artificial gestation for nine months?

Chapter Two will therefore address whether, if ectogenesis is allowed to go ahead, what new guidelines or legislation will need to be drafted to enable the process of ectogenic research to begin. This involves moving beyond the current restrictions contained in the HFEA 1990, which prohibit research on embryos beyond the fourteen-day limit, to allow for ectogenetic research on both living embryos and foetuses. This is not an easy task since the current research guidelines rest primarily noting that this was possible because explicit legal regulation governing IVF did not exist until thirteen years after the first IVF baby despite the uncertainty of the procedure.

\textsuperscript{44} The foetus contained sixty-nine chromosomes - three, rather than two sets. This may have been because two or more sperm entered the egg.

\textsuperscript{45} The study looked at the births of more than 15,000 children who were conceived at 33 major fertility centres across France. The study found that more than 4\% of these children were born with some sort of major congenital malformation, which included heart disease and urogenital abnormalities.

\textsuperscript{46} S. Bosely, “Doctors should warn of IVF detect risk, says report”, http://www.guardian.co.uk/lifeandstyle/2010/jun/13/ivf-malformation-risk-doctors-warn/print (last accessed June 28th 2010) The research was led by Dr Geraldine Viot, clinical geneticist at the Maternite Port-Royal hospital, Paris, into the health of 15,162 babies born after assisted conceptions found that 4.24 per cent had serious malformations, roughly double the rate for all children. The study, carried out in France, is the largest of its kind.

\textsuperscript{47} “It remains unclear whether these problems come from the parental infertility or the IVF procedure itself”. http://www.councilforresponsiblegenetics.org/blog/post/Malformations-in-IVF-Births-are-a-e2809cPublic-Health-Issuee2809d-According-to-French-Scientists.aspx (accessed July 5th 2010). Also see J. Leake, “IVF doubles risk of abnormal babies” http://www.timesonline.co.uk/tol/news/uk/health/article7149082.ece (accessed June 28th 2010).
on the Polkinghorne Code of Practice\textsuperscript{48} and the Human Tissue Authority Codes of Practice,\textsuperscript{49} neither of which ‘canvass even the possibility of ectogenesis’\textsuperscript{50}.

The origins of Chapters Three and Four arise from a British Medical Association quotation which states that ‘although at first sight anticipation of risks seems far superior to the trial and error of reactive legislation...very often our understanding of hazards is most readily advanced by analysis of actual events, sometimes involving accidents.’\textsuperscript{51} In these chapters, I use the hypothetical thought experiment of ‘Louise Smith’, who I will ask readers to imagine is the world’s first ectogenic foetus. The impetus for this stems from the points addressed in Chapter Two, wherein Louise Brown, the world’s first IVF baby was born prior to \textit{any} legislative framework for ART. On account of the greater risks involved with ectogenesis and the greater implications of artificial gestation, this scenario demonstrates the enormity of the task of adequately regulating this potential future development. Whilst artificial gestation gives rise to basic legal questions, the use of the thought experiment illustrates far more nuanced issues raised by the ectogenic foetus’ unknown status, such as: what if the ectogeneic foetus appears to be developing abnormally? Can the machine be switched off? What becomes clear from this is that there is no blueprint for ectogenesis; every single decision of the current law in relation to the living foetus has been made in the context of female pregnancy, wherein the intrinsic status of the foetus has been avoided. Therefore, there are no clear answers to any of the legal questions for ectogenesis.

It is important to note that the thought experiment removes the context of research governance provided in Chapter Two. It posits the appearance of ectogenesis without considering the research


\textsuperscript{49} In particular, Code of Practice 9 sets out the consent and licensing requirements relevant to the research community and offers guidance on what tissue falls under the remit of the HTA.

\textsuperscript{50} Brazier and Alghrani, “What is it? Whose it? Re-Positioning the Fetus in the Context of Research?” - \textit{The Cambridge Law Journal}, 70 [2011], pp 51-82,

\textsuperscript{51} Mclean, Sheila, \textit{Old Law, New Medicine} (Pandora, Rivers, Oram London, 1999)
phases and rules of research governance that would be necessary for this medical device. It imagines that ectogenesis occurs in a similar way to IVF, where scientists announce to the world’s press that a *Brave New World* of artificial gestation has begun. As a result of this, it presumes that the current law is the only law in place to deal with the legal problems presented by Louise Smith’s gestation in the ectogenic chamber.

Ultimately, these two chapters will address the key legal and practical problems that may arise as a result of ectogenesis. The principal concern is that applying the old law to ectogenesis will not work. As I will evidence, attempts to stretch the current legislative framework to this new and novel technology may cause more problems; raising more questions than providing answers. Therefore the case for new legislation is compelling, if ectogenesis is to go ahead. However, despite the problems with the current law, I will use this model to determine what the law on ectogenesis needs to encompass. Whilst Chapter Three explores viability and birth for the ectogenic foetus, Chapter Four looks at whether it is ever permissible to ‘switch off’ the ectogenic chamber. However, the theme of the inadequacy of the current law permeates both chapters.

Finally, Chapter Five uses the arguments formed throughout this thesis to form proposals for legal provisions to regulate the future development of ectogenesis, if it goes ahead. As the previous chapters will have evidenced, effective regulation for ectogenesis is complex and presents a multitude of practical difficulties. Consequently, there is a clear need for a Committee of Inquiry to address whether this technology is too medically risky for ectogenesis to ever be permissible and if it is allowed to go ahead, what new legislation will be required. Therefore, this chapter forms proposals to adequately address the legal issues this technology raises prior to any research into this technology.
1.5 Conclusion

Advances in biotechnology alone will not plunge us irrevocably into the depths of Huxley’s nightmare. A technology is only a tool. How a society chooses to use a tool will be influenced by the characteristics of the society in question.\textsuperscript{52}

The birth of Louise Brown, silenced much of the debate that had raged over the IVF procedure. It appeared that those who had warned of the appalling consequences of this technology had been proven wrong. However, recent studies indicate that the confidence inspired by her birth was misplaced, and that children born as a result of the various forms of assisted reproductive technologies (‘ART’) may be exposed to an increased risk of birth defects.

With striking similarity to the IVF debate over thirty years ago, some opponents of ectogenesis intrinsically feel that ‘this is the wrong thing to do’; they worry about where and when it will all end and talk of slippery slopes and moral nightmares ending in a place not too dissimilar from Huxley’s \textit{Brave New World}.\textsuperscript{53} However, the point of Huxley’s tale was to remind us of the human impulse to change and improve nature, which can have unforeseen consequences.\textsuperscript{54} In the words of Jackson, ‘we must not stifle scientific inquiry...for fear of its consequences’.\textsuperscript{55} Nonetheless, to accept this future technological progress without due regard to its wide-ranging legal implications raises the potential for a significant amount of litigation and enormous risks for all potential parties. Ensuring a comprehensive legal framework is in place prior to the first ectogenetic foetus is therefore absolutely critical. Ultimately, the ‘dream’ of many proponents of ectogenesis needs to be assessed, evaluated and regulated to guard against the antithesis becoming true.

\textsuperscript{55} E. Jackson, ‘Degendering Reproduction’ \textit{Medical Law Review} 346 (2008) 10
Chapter Two: The Road to Ectogenesis

‘Ex ovo omnia’

From an egg, everything

2.1 Introduction

An extrapolation of technology developed to save the lives of those born prematurely and those unable to gestate their offspring, ectogenesis has the potential to have a profound impact upon future generations. It is billed as changing society in ways difficult to imagine, no longer making future generations ‘human’ in the same way they once were and potentially having everlasting ‘unforeseen consequences’. Opponents of ectogenesis are concerned that science will never be able to mimic the womb because there are elements that are integral to the healthy development of the foetus currently unknown to scientists or simply incapable of being replicated. Concerns also centre around how complete ectogenesis will be developed, due to the fact that it will require research on living embryos (beyond the current fourteen day time limit) and clinical research on ex utero living foetuses. This also which represents a new dilemma for legislators. The legal bases for such uses of embryos and foetuses have rarely been explored, as the majority of academics have focused upon the ethics of these practices rather than their legality.

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56 W. Harvey, *Exercitationes De Generatione Animalium* (London: Typis Du-Gardianis, 1651)
57 As will be explored later in this chapter, concerns centre on the psychological effects of being born and gestated via a machine rather than the female body.
58 C. Rosen, *Supra* fn. 54
59 Ibid.
60 S.3(3) HFEA 1990 prohibits the use of embryos beyond the primitive streak. s.3(4): “For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo no later than the end of the 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.”
This chapter will address these matters through attempting to explore the regulatory aspects of developing ectogenetic technology and assessing the potential risks such research may give rise to. Firstly, I will set out the case for regulating the research phase proactively rather than reactively.\textsuperscript{63} I will shed light on the need for legislative reform through an exploration of the history of previous regulation for ART. In particular, I will focus upon the early debates and concerns surrounding \textit{in vitro} fertilisation (‘IVF’),\textsuperscript{64} which highlights the scarcity of legislation in the IVF research phase. Parallels will be drawn with the development of ectogenesis today, and I will show that dealing with the aftermath is an option that ought to be avoided at all costs.\textsuperscript{65} I conclude that further inquiry is required prior to any research into ectogenesis, which explores the ethical and scientific concerns raised in this chapter.

It is important to note from the outset that no explicit legal regulation exists for governing ectogenesis. The legislation governing embryo and foetal research rests primarily on the Polkinghorne Code of Practice,\textsuperscript{66} the HFEA 1990\textsuperscript{67} and the Human Tissue Act 2004,\textsuperscript{68} none of which mentions the possibility of ectogenesis. Despite this, the existing regulation restricting embryo and foetal research\textsuperscript{69} presents a number of hurdles for ectogenetic research. The first hurdle relates to justifying practices that allow experimentation on embryos beyond the ‘primitive


\textsuperscript{63} Whilst research beyond fourteen days is currently prohibited, advances in neo-natal technology have reduced the amount of time that the foetus needs to spend in the mother's womb resulting in viability being pushed back from the normal 40 weeks, down to 24 weeks. See Chapter Two for further information on foetal viability.

\textsuperscript{64} IVF is explained by Robert Winston as "the process by which egg and sperm are mixed in a small plastic or glass container outside the body and then placed in a woman's uterus after fertilisation. It usually involves the removal of eggs from the woman's ovary and the collection of sperm from her partner. The embryo, which results from fertilisation in the laboratory, is transferred to the woman's uterus about two to five days later" R. Winston, \textit{The IVF Revolution: The Definitive Guide to Assisted Reproductive Techniques} (Vermilion Publishing, 1999)

\textsuperscript{65} Although, I will show that there are also many differences.


\textsuperscript{67} Amended in 2008 (hereafter ‘HFEA 1990’)

\textsuperscript{68} In particular, Code of Practice 9 sets out the consent and licensing requirements relevant to the research community and offers guidance on what tissue falls under the remit of the Human Tissue Act 2004. (hereafter HTA 2004)

\textsuperscript{69} Via the HFEA, HTA and Polkinghorne Report.
streak’,\textsuperscript{70} which is currently illegal under the HFEA 1990.\textsuperscript{71} However, moving beyond fourteen
days requires one to challenge existing regulations and legislation in order to allow the process of
ectogenetic research to begin.

The second hurdle for research into ectogenesis is caused by the lack of regulations and guidance
relating to research on the \textit{ex utero} living foetus.\textsuperscript{72} It is problematic that the ectogenetic foetus does
not fall within any current definitions of unborn entities\textsuperscript{73} or within any research guidelines or
legislation. This calls for a new level of discussion regarding foetal status in the artificial womb.
However, this matter is only briefly explored in this chapter since the majority of discussion on the
status, rights and protections that should be afforded to the ectogenic foetus is explored in Chapters
Three and Four.

The discussion begins from the point of regulating the (potential) human research phase of
ectogenesis. At present, many new pharmaceutical drugs and medical devices are tested on animals
prior to progressing onto the clinical phase.\textsuperscript{74} Although a Research Ethics Committee (‘REC’) may
expect some data from animal studies before it is prepared to consider allowing research to progress
onto a clinical trial, it is not a necessary requirement.\textsuperscript{75} Instead, the clinical research phase into
ectogenesis may proceed without any animal trials in the UK. I therefore shall proceed on the basis
that a REC is satisfied that ectogenesis ought to progress onto human research subjects either on the

\textsuperscript{70} Primitive Streak: a groove which develops in the embryonic disc about 14-15 days after fertilisation, into
which a third layer of cells, the upper ectoderm layer invaginates the disc to form the three germ layers. The primitive
streak is taken to be the first sign than an embryo will develop; if the primitive streak does not form, embryonic
development does not progress and there will be no foetus. The legal significance of this in the HFEA 1990, ss.11(1)(c)
and 3(3).

\textsuperscript{71} HFEA 1990 s.3(a) \textit{Supra} fn. 35

\textsuperscript{72} I will specifically be focusing upon the foetus from the moment it becomes a foetus (at 8 weeks) to the point it
is deemed medically viable (from 24 weeks). I have chosen this framework because there is relatively little discussion
on the intrinsic status of the alive foetus which is external to the female.

\textsuperscript{73} Raskin, Joyce and Mazor, Nadav, “The Artificial Womb and Human Subject Research” in S. Gelfand and J.
Shook, \textit{Supra} fn. 19

\textsuperscript{74} E. Jackson, \textit{Law and the Regulation of Medicines} (Oregon: Hart Publishing, 2012)

\textsuperscript{75} Ibid.
basis of animal research trials,\(^\text{76}\) which are likely to attract huge controversy, or without the need for such trials.

### 2.2 Rationale for primary legislation on ectogenesis

As the development of ectogenesis looms on the horizon\(^\text{77}\) and the Government reasserts its commitment to specialist regulation for ART,\(^\text{78}\) it is difficult to see why little has been done to regulate this future technology. The United Kingdom (‘UK’) is a world leader in human reproductive technologies and the law relating to these technologies. It was one of the first countries to introduce legislation governing IVF and human embryo research through the HFEA 1990. This Act was enacted on the basis that activities involving human embryology outside the female body through the storage and use of gametes, demanded active regulation and clear legal limits.\(^\text{79}\) Since the 1990 Act, the Government has outlined its commitment to the specialist regulation and legislation of ART. It stated in the 2007 Human Tissue and Embryology Draft Bill:

> [T]he force of law remains justified in the distribution of permissions, rights, responsibilities and prohibitions for the development and use of human reproductive technologies. Law and active regulations are necessary to set out and monitor a system of public accountability, taking account of the principles of good regulations.\(^\text{80}\)

The principal aims in reviewing the 1990 Act\(^\text{81}\) in 2007 were to ensure that the law was fit for purpose, to promote public confidence in the development and use of human reproductive

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\(^{\text{76}}\) The Animals (Scientific Procedures) Act 1986 makes provision for the protection of animals used for experimental or scientific purposes. Projects may only be carried out by persons who have obtained a specific scientific licence. The Animals (Scientific Procedures) Act 1986 Amendment Regulations SI 2012 No. 3039 came into force in December 2012, implementing European Directive 2010/63/EC.

\(^{\text{77}}\) For further information on the timeframe of the future development of ectogenesis, see Introduction, pp. 2-4

\(^{\text{78}}\) See Human Tissue and Embryology Draft Bill, May 2007, Cm 7087

\(^{\text{79}}\) Ibid.

\(^{\text{80}}\) Ibid at para 4.6

\(^{\text{81}}\) Human Tissue and Embryos (Draft) Bill 2006-2007 (Joint Committee on the Human Tissue and Embryos (Draft) Bill [2007 HFEA]
technologies and to secure regulatory controls through a revision of the existing framework.\footnote{Ibid.} However, despite clear arguments surrounding the importance of reform and of the need to remain abreast with recent medical advances to respond to these developments, Alghrani questions whether the government missed a ‘vital’ opportunity to include and set parameters for ectogenetic research within the 2008 HFEA Act.\footnote{A. Alghrani, “The Human Fertilisation and Embryology Act 2008: a missed opportunity?” \textit{Journal of Medical Ethics} 2009 Vol 35 No 12} This Act had the foresight to consider and regulate future technologies such as human chimeras, crybrids and hybrids but it chose to dismiss ectogenesis.\footnote{Ibid.} In the five years since the Act’s inception, ectogenesis has also been briefly mentioned before being quickly dismissed by the Horizon Scanning Panel,\footnote{Human Fertilisation and Embryology Authority, Scientific horizon scanning at the HFEA, Annual Report 2006, para 2.2: “the area of science and medicine regulated by the HFEA is fast-paced”, requiring regular review of new medical developments.} which was set up in 2006 to act as an early-warning system to identify new scientific and clinical developments in assisted reproduction. As a result of this, there has been no discussion of the regulation of this future development.\footnote{The most comprehensive discussion thus far was in 1984 when the Warnock Committee had the opportunity to consider the legal implications of ectogenesis but chose to dismiss it. For further details see introduction p.4.}

As the science of ectogenesis develops, the law needs to form a clear framework for the research phase of ectogenesis. As early as the 1980s, indirect research into partial ectogenesis began when Thomas Schaffer, an American neonatal physiologist, began developing an artificial amniotic fluid, which would help extremely premature babies survive longer.\footnote{In 1996 clinical trial, 13 infants, born after 23-34 weeks with severe breathing difficulties, were given oxygenated liquid for between four hours and three days. Seven were discharged from hospital and appeared to be healthy and normal several months later. C. L Leach et al., \textit{Partial Liquid Ventilation with Perflubron in Premature Infants with Severe Respiratory Distress Syndrome}, 335 \textit{New England Journal of Medicine} 761-67 (1996), cited in J. Knight, \textit{Artificial wombs: An out of body experience}, 419(12) \textit{Nature}106, 107 (2002).} In 1988, a research team in Italy headed by Dr. Carlo Bulletti implanted surplus IVF embryos into artificially perfused uteruses obtained from women who underwent a hysterectomy, as a result of cervical cancer.\footnote{Carlo Bulletti et al, “Early Human Pregnancy \textit{in vitro} utilising an Artificially Perfused Uterus,” \textit{Fertility and Sterility} 49 (1988): 991-996.} The
researchers successfully implanted an embryo in the wall of the artificial uterus, where it grew for fifty-two hours before they removed it for dissection. Research has also taken place into the creation of an artificial placenta. In 1990, ectogenetic research on animals began in Japan. Yoshinori Kuwabara, a Professor of Obstetrics at Juntendo University, reported that he had created an artificial womb using an acrylic tank filled with a fluid similar to amniotic fluid, which successfully developed goat foetuses to term. However, the goat foetuses had to be given muscle relaxants because they were pulling the catheters out as they twisted and moved around in the tank, and due to this, they were unable to develop muscle tone, stand or breathe unassisted. When the researchers removed the ventilator after four weeks, the goats died within hours.

Research has also taken place into the beginning of gestation. In 2001, researchers at Cornell University attempted to grow an artificial uterus using cells removed from a woman’s uterus, hormones and growth factors. In an unpublished piece of work, Dr. Lui’s team found that when they placed ‘surplus’ embryos obtained from fertility clinics into this womb, they attached themselves to the plugs of the endometrial cells six days after fertilisation, just as they would do in a natural womb. In 2003, Dr. Liu grew a mouse embryo close to full term in three-dimensional engineered endometrial tissue, although it died days later.

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89 The embryos were only left to grow for 52 hours as a result of problems with the uterus, not with the embryos. Ibid., 995.
90 Ibid.
92 Ibid.
In 2008, research was published in the *International Journal of Biomedical Engineering and Technology* evidencing the research of scientists who had the goal of creating an artificial womb that replicated the acoustical state of a woman’s abdomen.\textsuperscript{98} The purpose of this research was to test foetal monitoring systems as opposed to conducting clinical testing on pregnant women. Therefore, whilst it was not an attempt to create an artificial womb capable of the entire gestation process, because this research aimed to find a stand-in chamber for a pregnant woman, it represents an important part of the history of the scientific development of artificial wombs.

What each part of the historical development of artificial wombs tells us is that, globally, research into ectogenesis has been under way for over thirty years. Some of this research may either prove to be useful on the road to developing a full ectogenic chamber, or it simply may not come to fruition. However, what the aforementioned studies display is that, despite the topic of ectogenesis being dismissed by the Horizon Scanning Panel,\textsuperscript{99} scientific research into ectogenesis has actually been happening for some time. It is also reasonable to believe that, given the pace of reproductive medicine, further research towards achieving ectogenesis may occur in the future. Therefore, it is surprising that so little has been done or discussed in relation to legislating the research phase of this technology, particularly when steps towards achieving the first ectogenic baby have already been made. If any ectogenetic human research is to go ahead in the UK, it is vital to start thinking about the legal implications of ectogenesis and set the boundaries and perimeters of research on embryos and foetuses. As the IVF analogy will demonstrate in the next section, a careful assessment of the risks of this technology ought to be made before it progresses onto the clinical phase involving research with human embryos and foetuses.


\textsuperscript{99} Supra fn. 86
2.3 IVF Technology - too big a risk?

Louise Brown, the world’s first IVF baby, changed the nature and process of reproduction forever. In the late 1970s and early 1980s, Brown’s conception and birth sparked a flurry of concerns regarding ‘test-tube babies’. Initially, IVF was described as a monstrous venture, reminiscent of Frankenstein-type experiments,\textsuperscript{100} threatening the very essence of “who we are and where we’re headed; what it means to be human.”\textsuperscript{101} The Warnock Report captured this zeitgeist:

\textit{Society’s views on the new techniques were divided between pride in the technological achievement, pleasure at the new-found means to relieve...the unhappiness of infertility, and unease at the apparently uncontrolled advance of science.}\textsuperscript{102}

Before Brown’s birth, scientists raised concerns and doubts about the safety of this procedure. These early concerns in relation to IVF technology are reminiscent of the current concerns surrounding artificial wombs. However, it is important to note that although there are similarities, the road to developing ectogenesis may be significantly more fraught with risk than that which was initially presented by IVF. Consequently, although we may learn lessons from IVF, the physical risks to ectogenic children are significantly greater. Therefore there is a heightened need to conduct a careful assessment of the risks versus the benefits of clinical research into ectogenesis. Ultimately, the aim of this section is to understand and learn from the lessons of IVF in order to think about developing legislation for ectogenesis, if it is allowed to go ahead at all.

\textsuperscript{100} F. Simonstein, ‘Artificial Reproduction Technologies (RTs) – All the way to the Artificial Womb’, Medicine, Healthcare and Philosophy (2006) 9 395-365 p.362
\textsuperscript{101} R. Marantz Henig, Pandora’s Baby. (NY: Houghton Mifflin, 2004) p.6
\textsuperscript{102} Ibid. fn. 3 at Para 1.1
2.4 ‘Test-tube Babies’: A Cause for Concern?

The absence of a clear protocol or methodological framework raises the question of whether Louise Brown was the result of an experimental coincidence rather than a carefully developed technique or experiment. 103

Prior to Louise Brown’s birth, concerns were expressed by doctors and researchers about the safety and experimental nature of IVF. Corea’s work, The Mother Machine104 analyses the development of reproductive technologies and refers to evidence which strongly suggests that the early nature of IVF attempts were highly experimental,105 and that corners were cut in terms of safety in order to win the ‘IVF race’.106 Also discussed is the first IVF baby, which had to be aborted at ten weeks due to severe abnormalities.107 Critics questioned how such an abnormality could be allowed to occur in the first place. Dr. Pierre Soupart (a fellow IVF researcher) thought that Steptoe and Edwards (who pioneered the first IVF baby) had bypassed a crucial step in their research through failing to test whether the embryo might be damaged by the IVF process. When asked, ‘[w]ere you or your colleagues...concerned that they might be cutting some corners in order to win the race?’ Soupart replied, ‘[w]ell, quite obviously they had already cut one...Short of that, there isn’t much more corner that they could cut’. This issue is further evidenced by Thatcher and Decherney who described the birth of Louise Brown’s as ‘the culmination of a sound knowledge of reproductive science...and ten years of trial and error’.108

This information raises numerous ethical and legal conundrums for both IVF and ectogenesis. For example, what if the mother of the first IVF foetus had refused to terminate her child, even in the

104 Corea, Supra fn.14
106 Ibid (McMullen, 1979).
107 The foetus contained sixty-nine chromosomes - three, rather than two sets. This may have been because two or more sperm entered the egg. Corea, Supra n.14
face of such severe abnormalities? Whilst the mother could never have been forced to terminate her child against her wishes, the continued gestation and birth of a severely disabled child would have had wide ranging repercussions for the development of IVF. However, further circumstances surrounding the decision to terminate this foetus are unknown.

For ectogenic children, this occurrence raises a number of important issues for early research regulation such as: could the ectogenetic chamber be switched off if the foetus appeared to be developing abnormally and who could make such a decision? The answers to these questions ought to be considered before ectogenesis is developed on human subjects on account of the ethical and legal complexities of ending developing life in an ectogenic chamber. This particular issue was highlighted at a symposium on ‘fabricated babies’ over forty years ago, where the Nobel Prize Winner James Watson addressed Edwards directly:

You can only go ahead with your work if you accept the necessity of infanticide. There are going to be mistakes. What are you going to do with your mistakes?

Prior to Brown’s birth, Watson and Perutz, a former colleague of Robert Edwards, expressed concerns that if even one baby was born with abnormalities, and had to be kept alive as an ‘invalid’ for the rest of its life, the idea that it could happen globally and on a larger scale was horrifying. They described it as being ‘a new thalidomide catastrophe’. Furthermore, Kass believed that it

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109 Protection of a pregnant woman's bodily autonomy includes her right to decide whether or not she has a baby: see E. Jackson, Medical Law: Texts, Cases and Materials (Oxford, OUP, 2010) pp.654-710
110 The issue of the developing disabled ectogenetic foetus will be discussed in Chapter Two.
111 For a discussion of the potential means of obtaining embryos for research into ectogenesis (including the use of surplus embryos obtained from IVF or termination) see Brazier and Alghrani, Supra fn. 50.
112 J. Van Dyke, Supra fn. 103 p.46
113 S. Coleman, Supra fn. 34 at 41. Thalidomide, which led to “the greatest drug tragedy of our time” (“The Thalidomide Children and the Law”, report by the Sunday Times was discovered in 1953 by Ciba, a West German pharmaceutical company. Preliminary animal tests indicated that the drug had little pharmacological effect, so the company did not continue with its development. Chemie Gruententhal, also a West German company, marketed the drug as a sedative and allowed other companies to produce and sell thalidomide. The first report of suspected damage to the foetus was published in that country in 1961; most notably “flippers” and absence of the limbs. Thalidomide was marketed in Britain by Distillers Co. (Biochemicals) Ltd as a treatment for morning-sickness. In December 1961, a British doctor wrote to The Lancet, noting the appearance of birth defects in mothers who had taken thalidomide. In
did not matter how many times a baby was tested, the medical profession could never be certain that an IVF baby would be born without a defect and many obstetricians wondered who would care for these babies if this experiment with nature went disastrously wrong. David Callaghan, one of the founders of the Hastings Centre, argued that the first case of IVF was probably unethical since there was no guarantee that Louise Brown would be born ‘normal’. This is further corroborated by an interview with Steptoe, two years before Louise Brown’s birth, where the following question was posed to Steptoe, ‘[i]f a woman became pregnant by this method [IVF] would her baby be normal?’ Steptoe replied, one year after he had begun IVF with the Browns: ‘[w]e don’t yet have enough experience with humans to answer with confidence that all-important question.’ Approximately three months after the birth of Louise Brown, The Washington Star questioned Steptoe about an increase in birth defects due to external fertilisation. He replied: ‘[w]e do not really know yet what the full risks are.’ Later, these arguments were acknowledged by Dr. Edwards, who mentioned the back-up methods of monitoring abnormalities after IVF and implantation in order to avoid incidents of abnormalities. It would therefore appear that prior to the first IVF baby, scientists were significantly concerned about the ethics of such experimentation and what would happen to the resulting children.

Yet, to all appearances, those who had warned of the appalling consequences of tampering with the origins of human life were proved wrong by the birth of a healthy baby girl. Nevertheless, the

total, 430 British children were injured as a result of their mother taking the drug. In Germany, thalidomide had been taken by so many women that virtually every paediatric clinic in Germany had at least one child affected. (Teff and Munro, *Thalidomide: The Legal Aftermath* (Farnborough, Hants, Saxon House, 1976) p.5)


115 P. Singer and D. Wells, “In Vitro Fertilisation: The Major Issues” 9(4) *Journal of Medical Ethics* 192

116 D. Callahan, WT Times, July 27, 1978, p.A16 in Coleman *supra* fn. 34 at p.42 Though he did suggest that after this first healthy birth it would be ethical to proceed with IVF.

117 Contemporary Ob/Gyn, October 1977 in G. Corea *Supra* fn.. 14

118 Ibid.

119 T. Iglesias, *Supra* fn. 19. This risk was also implicitly recognised in the report on IVF by the Royal College of Obstetricians and Gynaecologists in Great Britain; Report of the Royal College of Obstetricians and Gynaecologists Ethics Committee on IVF and Embryo Replacement or Transfer, March 1983.

120 It is important to note that Louise Brown has since had healthy children of her own: C. Moreton, “World's first test-tube baby Louise Brown has a child of her own” *The Independent* 14 January 2007. Available at:
issue is not quite settled and the confidence generated by the birth of Louise Brown may have been misplaced. In 2009, confidence in the IVF procedure was potentially undermined through the publication of a study in France\textsuperscript{121} that revealed that children born from IVF have a sharply increased risk of serious congenital malformation, which is roughly double the rate for all children.\textsuperscript{122} The reasons for these defects are not known but it is thought the fertilisation process may damage embryos.\textsuperscript{123} This study is not alone in a growing body of evidence indicating that children born from IVF may be exposed to a significantly increased risk of suffering from major birth defects.\textsuperscript{124} The concern is that with so little known of the conditions needed for healthy foetal development, if problems are evident in the process of fertilisation, how much more amplified will those problems be through artificial gestation for nine months?

Singer and Wells argued in 2006 that these studies prove that scientists were not justified in taking the IVF risk in the first place because, although the birth of a healthy baby girl proved critics wrong, ‘[w]inning a gamble does not always show that taking the gamble was wise in the first place’\textsuperscript{125} Additionally, following from the results of the French study, it does not appear that this ‘gamble’ was entirely won and some of the earlier concerns about the safety of the IVF procedure were not completely unfounded.

\textsuperscript{121} The study looked at the births of more than 15,000 children who were conceived at 33 major fertility centres across France. The study found that more than 4\% of these children were born with some sort of major congenital malformation which included heart disease and urogenital abnormalities.

\textsuperscript{122} S. Bosely, Supra fn. 46

\textsuperscript{123} “It remains unclear whether these problems come from the parental infertility or the IVF procedure itself”. See http://www.councilforresponsiblegenetics.org/blog/post/Malformations-in-IVF-Births-are-a-c2809cPublic-Health-Issuee2809d-According-to-French-Scientists.aspx (accessed July 5th 2010). Also see J. Leake, “IVF doubles risk of abnormal babies” http://www.timesonline.co.uk/tol/news/uk/health/article7149082.ece (last accessed June 28th 2010).


Singer and Wells, “Ectogenesis” in S. Gelfand, Supra fn. 18 at 21.
Whilst I am advocating a note of caution for any future development and have outlined the risks involved in the development of IVF, with hindsight it would appear that the concerns raised were not as well-founded as they first appeared. IVF in humans was based upon widespread experience of the commercial use of the technique in farm animals and laboratory observation of human embryos which had been kept alive in a petri dish for one or two days. Both Edwards and Steptoe had also gained a wealth of knowledge and insight into the human reproductive process through decades of research. This culminated in a revolutionary treatment that has since resulted in the births of millions of healthy children. Prior to the birth of Louise Brown, infertility caused great shame to many childless couples who had struggled to conceive naturally. The development of IVF changed all of this. Since Brown’s birth, IVF has become a routine alternative to natural conception, and approximately 9,000 IVF babies have been born per year in the UK with an estimated four million babies born worldwide collectively, as a result of ART. These well-documented benefits of IVF were all part of Steptoe and Edwards’ aims because ‘[t]he plight of infertile couples gave [their] work crucial meaning.’ Therefore the apparent risks of IVF, although significant, were outweighed by the huge benefits of alleviating infertility for millions of couples.

2.5 Early IVF Legislation

Despite the concerns about the practice of IVF, a legislative framework was not in place until twelve years after the first IVF baby was born in Oldham District General Hospital. In the

126 J. Van Dyke, Supra fn. 103
127 Brinsden, Supra fn. 15
129 In vitro fertilisation, intracytoplasmic sperm injection, cryopreservation, intrauterine insemination, artificial insemination by donor, super ovulation, embryo flushing and transfer and surrogacy.
130 R. Winston, Supra fn. 68
research prior to Louise Brown’s birth, scientists were free to choose who they experimented upon and how they conducted their experiments in order to achieve the world’s first IVF baby. As I will demonstrate, although voluntary regulation and the world’s first ethics committee were initially established to assist clinical staff in this practice, this was by no means legal regulation, which only began in 1990.

2.5.1 The Warnock Report

The first steps towards some sort of legislative framework for IVF and ART were made in 1982 when the UK Government commissioned a Committee of Inquiry chaired by Dame Mary Warnock, entitled: *A Question of Life: The Warnock Report on Human Fertilisation and Embryology* (‘the Warnock Committee’). The purpose of this inquiry was to study the social, ethical and legal implications of issues raised by new and potential ART. It published its report in 1984 and declared that new technological developments needed closer and more formalised regulation than the existing professional codes could offer. It suggested that regulatory and licensing procedures were required for the research, treatment and storage of human embryos and gametes, which ought to be undertaken by a dedicated body, which became known as the Human Fertilisation and Embryology Authority (‘HFE Authority’).

In 1990, after lengthy debates in Parliament, the HFEA 1990 was passed. Based largely on the recommendations of the Warnock Report, this Act was the world’s first statute which regulated

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133 Although the UK was still the first country to impose strict legal regulation of the practice of ART; Brinsden, *Supra* fn. 15

134 The date of which, is unknown.


136 *Ibid.* The exact remit was defined as "to consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical, and legal implications of these developments; and to make recommendations."


138 In the interim period, a Voluntary Licensing Authority was established in 1985 (which later became the Interim Licensing Authority in 1986 during the period leading up the the start of the HFE Authority) to regulate work on human *in vitro* fertilisation. This was coordinated by the Medical Research Council whilst working in close association with other relevant associations such as the Royal College of Obstetricians and Gynaecologists and the General Medical Council.
ART. With the creation of the HFE Authority, it ensured the regulation of human embryos outside the body through licensing their creation, including their use in treatment and research, and the use and storage of gametes and embryos.

It has since been noted that unrestrained research on IVF technology was only possible due to the lack of explicit legal regulation governing IVF in the stages preceding and following the development. During this time, research into complete ectogenesis would have been considerably easier than it is at present, due to the lack of restrictions on embryo research. However, such restrictions may be viewed as necessary in light of the grave consequences that ectogenesis may have for future embryos, foetuses and infants, particularly when the extent of the harm is entirely known. As I will demonstrate in the next section, ectogenesis is significantly different from any other ART development thus far, which requires a careful assessment of the potential risks of starting this technology.

2.6 Assessing the harms of ectogenic research

Following the birth of Louise Brown, Steptoe was quoted as saying, ‘I am not a wizard or a Frankenstein. All I want to do is to help women whose child-producing mechanisms are slightly faulty.’ However, ectogenesis is much more than helping those with ‘slightly faulty’ fertility problems. If IVF is described as being the small step in reproductive technology, ectogenesis represents a giant leap. An obvious difference is the reality of the increasing developmental complexity of the growing human versus the fertilised ovum that may not implant correctly if abnormal. IVF is a reproductive technology limited to fertilisation or conception; if not implanted the embryo will naturally die. In contrast, ectogenesis is a development not limited by time and the

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139 Ibid. Interestingly, Robert Edwards and David Sharpe wrote about these issues as early as 1971 in a paper entitled, “Social values and research in human embryology” Nature 231, no.5298 (1971): 87-91
140 T. Iglesias, Supra 16 at 6.
142 Coleman Supra fn. 34 at p. 104
ectogenetic foetus is on its way to becoming much more recognisable as a human being.\footnote{Raskin and Mazor \textit{Supra} fn. 36 at p.165} Unlike the IVF embryo in a petri dish, which is a mass of undifferentiated cells, the ectogenetic foetus will develop body organs, the capacity to breathe and have a beating heart. As a result of this, all parties may find it much more difficult to terminate the life of the foetus or make other complex decisions surrounding foetal life and rights when the ectogenic foetus can be clearly seen developing in the ectogenic chamber and will appear much more like a human being than an embryo in a petri dish does. This alone creates enormous implications for the future welfare of children born from this procedure, particularly in the human research trial phase.

Furthermore, ectogenesis presents far more unknown risks to future infants due to the lack of knowledge surrounding the conditions needed for healthy foetal development. In light of evidence available prior to the first IVF baby, scientists believed children born from the procedure were at no greater risk of deformity than children born by normal unaided sexual reproduction.\footnote{Callahan, \textit{Supra} fn. 42} Yet for ectogenesis, indications to the contrary exist due to the lack of complete knowledge surrounding the science of the female womb and the problem of how to accurately predict the outcome of complete ectogenesis. Current understanding of the female womb is imperfect and a key area of concern is the potential psychological and physical effects that artificial wombs may have on future babies.

Scientists believe that the conditions needed for healthy foetal development in the womb are integral to the future health of that person.\footnote{P. Nathanielz, \textit{Life in the Womb: The Origin of Health and Disease} (US: Promethean Press, 1999)} Begley’s research on ‘fetal [sic] programming’ suggest that conditions during gestation, ranging from the torrent of hormones to how well the placenta delivers nutrients, shape the health of the adult that the foetus becomes.\footnote{S. Begley, “Shaped by Life in the Womb” \textit{Newsweek} 134: 13 (9 Sept 1999) p.57} These same scientists are convinced that foetal programming affects one’s health for the rest of their life.\footnote{The associations with healthy adult life are thought to be consequences of ‘programming’, whereby a stimulus or insult at a critical, sensitive period of early life has permanent effects on structure, physiology and metabolism.}
Dr. Nathanielsz has argued: ‘[t]he script written on the genes is…altered by the womb environment’ and the seeds of health are planted before one even draws their first breath.

Recent guidelines produced by the Royal College of Obstetricians and Gynaecologists (‘RCOG’) further expands this theory. These guidelines warn that exposure to large amounts of chemicals during pregnancy has been linked to health problems in children, including birth defects. Growing concerns over the risk of chemicals in everyday products relate to the effects on the body's hormone system, particularly on growing babies in the womb. In its report, the RCOG expressed ‘considerable uncertainty’ surrounding the risks relating to chemical exposure for pregnant women, thus advocating ‘a safety-first approach to chemical exposure’. In the guidelines, it advises that pregnant women should avoid food in plastic containers or cans, and reduce their use of personal care products such as moisturiser, sunscreen, shower gels and fragrances, to ‘minimise harm’ to their babies. This report sparks the concern that if there is such great medical precaution surrounding healthy gestation in the female womb, how much more exacerbated will this concern be for artificially gestated foetuses who are located in an experimental environment, far removed from ‘natural’ gestation?

Furthermore, due to insufficient knowledge of the exact conditions required for healthy foetal development, and the clear importance of this, ectogenesis could have wide-ranging consequences for the future psychological health of any children born from this technology. Concerns centre on the impact of being born from a machine, rather than a human being. As Rosen argues, ‘[w]hether it is the sound of a human voice, the beating of a human heart, the temperature and rhythms of the Programming of the foetus may result from adaptations invoked when the materno-placental nutrient supply fails to match the fetal nutrient demand. Although further research is required into these factors that impair fetal development, there are strong pointers to the importance of maternal body composition and dietary balance during pregnancy: KM Godfrey and DJ Barker, “Fetal programming and adult health” Public Health Nutr. 2001 Apr;4(2B):611-24.

P. Nathanielsz, Supra fn. 145


Ibid at p.2

Ibid.
human body...it is difficult to imagine that science will ever find a way’ to mimic the female womb.\textsuperscript{152} Therefore, the essential issue is whether or not scientists are justified in bringing about a procedure that carries a high risk of future harm, such as risk of the creation of a disabled child.\textsuperscript{153}

Ireland’s first surrogacy case, \textit{M.R & Anor -v- An tArd Chlaraitheoir & Ors}\textsuperscript{154} rebuts some presumptions about the health impact of artificial gestation. It represents the first time that the courts have heard detailed expert evidence surrounding the conditions of the womb. This case concerned twins born to a gestational surrogate who was the sister of the genetic mother. After the birth, the parents applied to have the birth certificates amended to reflect the biological reality of the twins’ parents. However, the Chief Registrar refused to allow any exception to the current policy that the birth mother is the legal mother.\textsuperscript{155} The central legal issue was: who in law, is entitled to be treated as the parents of the twins, and who, in particular is the mother? Assisted reproduction remains entirely unregulated in Ireland, hence the need in this case to seek a court order. Substantial expert evidence was placed before the court in relation to epigenetics. Epigenetics is the study of changes in gene expression or cellular phenotype caused by the womb environment rather than the underlying DNA sequence or structure. The Respondents sought to use this evidence to prove that the impact of the mother on the foetus during pregnancy has a sufficiently substantial effect on the physiology of the child, to justify the presumption of \textit{mater semper certa est}.\textsuperscript{156}

However, Abbott J. was not convinced by this argument. Instead, he relied upon a number of expert opinions on epigenetics, including the fact that epigenetic influences do not interfere with the inheritable characteristics of the child. In other words, while the womb environment is important, it

\begin{itemize}
\item \textsuperscript{152} C. Rosen, \textit{Supra} fn. 54
\item \textsuperscript{153} Although, as Chapter Four demonstrates, in certain circumstances, foetuses evidencing severe disabilities, may be aborted.
\item \textsuperscript{154} [2013] IEHC 91 (2013)
\item \textsuperscript{155} This was based on the presumption of \textit{mater semper certa est} – the mother is always certain.
\item \textsuperscript{156} \textit{Ibid.}
\end{itemize}
will never trump ‘the deterministic quality of chromosomal DNA’\(^ {157}\) because the environment in which the foetus develops is ‘largely dependent on the chromosomal input of the cells of the foetus from embryo stage’,\(^ {158}\) rather than on the environment itself. However, his conclusions were caveated by the fact that genetic and epigenetic research is likely to develop further in the future\(^ {159}\) and more research in this sphere may be required before a final conclusion on this subject is reached. This therefore reiterates the conclusion that, in the context of human embryology and the conditions needed for healthy foetal development in the womb, a significant amount remains unknown.

Since the medical knowledge about the womb environment is insufficient, greater consideration and research is required to determine whether ectogenesis is safe enough to be allowed to go ahead. Singer and Wells argue that allowing this ‘experiment’ to run its full course is an extremely dangerous scenario due to the lack of knowledge about the outcome of the procedure and because given the lack of complete knowledge of the conditions needed for healthy children, ‘any attempt to nurture a child entirely outside the womb would be experimentation with human life’.\(^ {160}\)

### 2.7 How can we begin human research into ectogenesis (If allowed to go ahead at all)?

Today, the artificial womb is a developing technology, and, in this period, it remains experimental. Animal research has already begun into this technology, but it remains to be seen whether it will be developed onto human research subjects. In this section I will assess potential avenues of direct research into complete ectogenesis on human embryos and foetuses.

\(^{157}\) [2013] IEHC 91 (2013) at 98

\(^{158}\) Ibid at 99.

\(^{159}\) Ibid at 98.

\(^{160}\) Raskin Supra fn. 36 at 172
2.7.1 From Animal Research to Human Embryos

Whilst it is difficult to imagine that the technology of ectogenesis can be improved and become safe enough to be used for human embryos and foetuses, this section will consider potential ways in which scientists may overcome the shortfalls in research on animal species to allow this technology to become safe enough to use on human beings. At present, Singer and Wells present this leap between animal research and human research into ectogenesis as a ‘catch-22’ style scenario. It seems that the only way to see if a child could develop healthily through artificial gestation would be to produce babies through ectogenesis, in the same way that Louise Brown was born, and monitor their advancement to see if they developed normally. However, this is presented as a ‘catch-22’ scenario because, ‘if it is unethical to attempt ectogenesis in humans until we have a reasonable assurance that it is safe and we can have no reasonable assurance that it is safe [on human species] until it has been carried out...work on ectogenesis will remain forever unjustifiable.’ As Coleman states:

*The success or failure of such attempts and the negative effects on the psychology of the ectogenic child could really only be assessed in a human being as there is really no comparison between the psychology of humans and other species.*

For IVF, numerous studies had been conducted to compare the outcomes of singletons conceived by IVF compared with the outcomes of those following natural fertilisation. The same empirical research is often suggested for ectogenesis due to the belief that the success or failure of attempts and the unknown effects on the psychology of the ectogenic child could only really be assessed in a human being. A possible solution to bridging the gap between animal research and human

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161 Ibid.
162 Singer and Wells Supra fn. 61 at 22
163 Coleman, Supra fn. 34 at 44
165 Coleman, Supra fn. 34 at 44
research is to carry out preliminary trials on a small number of babies and then wait six or seven years to compare the results against other children who were not ectogenic babies.

It is worth noting that there are inherent risks involved with all clinical trials for developing pharmaceuticals or technologies, and it is impossible to know whether a medicine is safe and effective for use in humans, unless trials have taken place. Medical progress therefore depends on balancing the risk of harm to protect participants’ welfare with the need to develop innovate treatments.

Consequently, what may justify the decision to go ahead with the development of ectogenesis in human subjects is a careful assessment of the risks as they appear in animal research and use such knowledge as the basis for the belief that the offspring of ectogenesis would not have significantly more defects than children conceived by the natural method.166 Therefore, any framework through guidelines or legislation which allows research on embryos must be clear that all of the necessary data and information for ectogenetic research is obtained, before it progresses onto humans.

A safer possible alternative is presented by Singer and Wells. They argue that if scientists gradually push back the boundaries of the age at which premature babies can be saved, we will eventually reach the point where the human embryo produced through IVF can be kept alive ex utero: ‘[t]he essential point is to work up to ectogenesis very gradually.’167 This would mean that research into complete ectogenesis would not take place until scientists pushed the boundaries of partial ectogenesis towards complete ectogenesis. However, since the focus of this thesis is on research into complete ectogenesis, a discussion of pushing back the boundaries of partial ectogenesis is beyond its scope.

166 Ibid.
167 Singer and Wells, Supra fn. 18 at p.22
2.7.2 Would research towards ectogenesis be ethical?

The essential issue for any clinical research into artificial womb technology is: what should constitute lawful research and is it even possible to research towards ectogenesis without unfortunate consequences, such as severely disabled children? Would such a trial be ethical, and would it get through an ordinary REC? It must be noted that RECs are central to research governance and since the first IVF baby, research governance has significantly developed to include a complex framework of guidance and regulations, which may offer the necessary protection required to adequately regulate this technology. Any research into ectogenesis must take place within an established regulatory framework based on ethical guidelines such as the Clinical Trials Regulations 2004 (implementing the 2001 directive) or the ethical review of research protocols issued by the Department of Health.

However, although research governance will apply to ectogenesis, it is unclear as to exactly how it will apply. Who would fall under the subject of research and the appropriate guidance is of central importance. Would it be the embryo or foetus (who may never exist external to the womb) or would it be the gamete providers? At present, any clinic conducting embryo research must obtain a licence granted by the HFE Authority. The Authority may only licence a research project if it is satisfied that the research being carried out is ‘necessary or desirable’ for one of the purposes listed in the

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169 A number of RECs have been established in the UK. There are now more than 70 ‘clinical ethics’ committees established in NHS hospital trusts. Their composition is regulated by guidelines issued by the Department of Health and brought together in 2012 under *Governance Arrangements for Research Ethics Committees*. Matters are also overseen by the National Research Ethics Services (NRES) which is now under the auspices of the Health Research Authority; Health Research Authority Regulations 2011/2341 and Health Research Authority (Amendment) Regulations 2012/1108. Also see *Standard Operating Procedures for Research Ethics Committees* (March 2012) which outlines factors to be considered by ethics committees. Approval for research must also be sought by the MHRA
170 The development of a research governance framework has been haphazard affair, since there was no single piece of legislation directed towards the regulation of human research conduct, prior to the Clinical Trials Regulations 2004
171 SI 2004/1031. The Regulations implemented the EU Clinical Trials Directive (Clinical Trials Directive 2001/20 into UK law. See also E. Cave “Seen But Not Heard? Children in Clinical Trials” (2010) 18(1) *Medical Law Review* 1–27. Furthermore, is it unclear whether the regulations must relate to ectogenesis since the research must “directly to a condition from which the minor suffers” and must not be able to be done on any other group of subjects.
172 See Department of Health, *Local Research Ethics Committees, HSG 91(5)*.
173 Under section 3(1) of the 1990 Act if a licence is not granted then any such activity will be a criminal offence.
Act. Initially, there were five purposes,\(^{174}\) which were then expanded in 2001 and 2008 to the present eight purposes.\(^{175}\) It would appear that under the current legislation, the medical basis for research into ectogenesis would fall under the category of ‘increasing knowledge about the development of embryos’.\(^{176}\) This would be of great benefit to scientists researching into human embryology. However, since the purpose of the HFE Authority, and the HFEA, is to regulate research into embryos up to fourteen days old, research beyond the fourteenth day is unlikely to fall under this regulation or under the remit of the HFE Authority.\(^{177}\) Furthermore, as I will explore later in this chapter, there is also no exact regulatory regime for research on living foetuses.\(^{178}\) Therefore, in Chapter Four, I discuss how regulation may necessitate the drafting of a specialist statute in order to regulate ectogenesis and what provisions that statute may contain.

There is also the question of the artificial womb machine. Any research into complete ectogenesis will require the creation of an ectogenic chamber or ‘medical device’, including appropriate drugs and pharmaceutical products replicating amniotic fluid, hormones and \textit{in utero} nutrients. Since 1998, all medical devices must comply with the Medical Devices Directive\(^{179}\) and the rules on the supply, sale and administration of pharmaceuticals, which is regulated by the Medicines Act 1968 and the statutory instruments made under it. However, as further discussed in Chapter Three, some critics may suggest that the device ought to be treated as a Neonatal Intensive Care Unit (‘NICU’), but on a larger scale. Therefore it remains to be seen whether an ectogenic device will fall under the above research guidance or whether it will be regulated on the premise that it is a device which

\(^{174}\) These were: (a) promoting advances in the treatment of infertility, (b) increasing knowledge about the causes of congenital disease, (c) increasing knowledge about the causes of miscarriages, (d) developing more effective techniques of contraception, or (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation: The HFEA Act 1990, Sch 2, Para 3.

\(^{175}\) HFE (Research Purposes) Regulations 2001/188 and the 2008 Act.

\(^{176}\) HFEA 2008 Schedule 2, Para 3A(2)(h)

\(^{177}\) Section 3 of the 1990 Act defines research activities that are beyond the powers of the HFE Authority to Licence. This includes the Authority’s inability to authorize the use or retention of a live human embryo after the appearance of the ‘primitive streak’ under s.3(3)(a)

\(^{178}\) See pages 28-31 of this chapter.

\(^{179}\) (SI 1994) No 3017). On that date, the Medical Devices Regulations 1994 came into force and as a result of this, manufacturers of devices must comply with the directive.
bears similarity to a NICU, thus falling under the Medicines and Healthcare products Regulatory Agency (‘MHRA’). As a result of this, research governance in relation to artificial wombs remains to be determined and it is imperative that further inquiry is undertaken to determine the appropriate regulatory authority for such research.

2.7.3 Risk versus benefit

Despite the existence of research governance and ethical frameworks, as with most medical progress, research towards ectogenesis will involve inherent risks to human embryos, foetuses and potential children born from this procedure. An assessment of the risk versus the benefits of artificial womb technology is therefore necessary as part of the ethical considerations. As Steinbock eloquently reminds us, any foetal research involves experimentation with human life, because:

Like human corpses, human foetuses [sic] are human. Like trees, they are alive. Like flags, they have, for many people symbolic significance. All of these features may give rise to moral reasons for treating them or not treating them in certain ways.\(^{180}\)

However, all medical progress depends upon some exposure to risk. As Jackson argues, ‘if no one was ever subjected to the risks of being among the first people to take a new drug, it would be impossible to develop innovative ways to treat disease.’\(^{181}\) Weighing the balance of some of the known risks that I have highlighted in relation to developing this technology requires an assessment of the desirability and need for human research into the development of ectogenesis. One of the most basic questions for regulation in emerging technologies is how to strike the right balance between the need to generate useful data and the need to protect research participant’s welfare.\(^{182}\)

\(^{180}\) B. Steinbock, Life Before Birth (NY, OUP, 1992)
\(^{181}\) E. Jackson, Law and the Regulation of Medicines (Oregon: Hart Publishing, 2012) p.21
\(^{182}\) Ibid.
Some of the arguments, which might be used for a particular piece of research of this kind, will now be outlined. The purpose of which is to balance against the risks and draw comparisons with the risks that were taken in the early stages of IVF:

Raskin and Mazor argue that in the context of research on the early embryo, research with *in vitro* foetuses would carry its own benefits to our society: ‘A major benefit of such research would be to increase knowledge of fetal development, understanding genetic deformities and treating horrible diseases.’¹⁸³ Ectogenesis would provide scientists with the complete control of the developing embryo throughout the forty weeks of gestation.¹⁸⁴ In other words, the knowledge gained from research into ectogenesis could potentially be an integral step towards gaining greater understanding of the foetus and its development in the womb.

The existence of ectogenesis would allow those who cannot gestate their own children such as women who have had a hysterectomy, Mayer Rokitansky Küster Hauser syndrome¹⁸⁵ or a medical history which places a woman at a high risk if she wishes to become pregnant, to use an artificial womb. Where once a woman’s uterus was required for gestation, an artificial womb would be available to gestate children, thus making the option of reproduction available to increasing numbers of people. For example, at present for a homosexual male couple, who wish to reproduce, they must use an egg donor and find a suitable surrogate mother in order to have a child. Whereas, as a result of ectogenesis, a homosexual male couple would only need to procure the former, thus simplifying the process of reproduction.

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¹⁸³ Raskin *Supra* fn. 36 at 177
¹⁸⁵ MRKH syndrome is a congenital (born with) abnormality, characterised by the absence of the vagina, cervix and the uterus (womb). The ovaries are usually present and function in the same way as any other woman’s by producing eggs and female hormones. This condition affects approximately one in every 5000 women.
For those who cannot gestate their own children, ectogenesis therefore represents an alternative to surrogate motherhood, since it avoids all of the well-rehearsed pitfalls of surrogacy. A surrogate mother may develop an attachment to the baby she is carrying, which leads to complications with the arrangements made with the commissioning couple. Removing the surrogate from the equation would alleviate the problems and uncertainties of using a surrogate. However, it is important to note at this juncture that the cost of ectogenesis is likely to be prohibitive and it is most likely that it would only be available to those wealthy enough to afford it.

Other critics argue that a valuable goal of ectogenesis is that women would no longer have to endure pregnancy. Pregnancy carries significant health risks for a woman such as high blood pressure, pre-eclampsia, nausea and even death as a consequence of childbirth. Artificial wombs would eliminate the need for pregnancy, or at least provide an alternative option for women.

It is also not possible to mention the benefits of ectogenesis, without making reference to the feminist debates on this topic. A number of feminists cite their desire for ectogenesis for social

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186 Reasons against surrogacy include a multitude of risks by all those involved. These are well-rehearsed and well documented in M Brazier, S Golombok, A Campbell, Surrogacy: Review for the UK Health Ministers of current arrangements for payments and regulation; Hum Reprod. Update. 1997 Nov-Dec;3(6):623-8.
189 L. Donnelly and J. Clayton, “Deaths in childbirth rise amid struggle with complex cases” The Telegraph 28 Apr 2012. Available at: http://www.telegraph.co.uk/health/healthnews/9233608/Deaths-inchildbirth-rise-amid-struggle-with-complex-cases.html (Last accessed 20th June 2013.) The research, found maternal mortality in London rose from fewer than 10 deaths per 100,000 maternities in 2005/2006 to 20 deaths per 100,000 in 2010/2011. The figures compare with an average in the UK outside London of 8.6 fatalities per 100,000 maternities. There were 31 maternal deaths in London in 2010-11, with the total reducing to 22 in 2011-12.
and professional reasons. Most notably, the radical feminist Shulamith Firestone believed that female oppression could only be overcome when technology enables babies to be incubated outside the womb. Firestone believes that ‘the ultimate goal of the feminist revolution is an androgynous society to obliterate sexual ones’. In her eyes, the moment that biological realities of reproduction are overcome, the fact that some persons have wombs and others have penises will ‘no longer matter culturally’.

From this perspective, the prospect of ectogenesis shatters the biologically constructed roles of men and women in society; it would vanquish the only valid distinction between the sexes because, ‘[o]nce women no longer have to reproduce, the primary rationale for keeping them at home disappears’. Artificial wombs would equalise the roles that males and females perform in reproduction, and, thus, the subsequent responsibilities of childcare. If women are not gestating their own children then their careers would no longer be impeded as a result of the health implications of pregnancy, such as those who have to take a break from their vocational careers in professions such as athletics or manual labour or those who, as a result of pregnancy suffer health complications that require significant leave from work. Nor would women be required to take maternity leave that may cause delay in their careers, leaving them behind their male contemporaries. Ectogenesis therefore signifies the potential end to a large faction of the feminist debate because, ‘a woman who wants to have a child might not necessarily have to slow down her career because of a pregnancy’. Therefore the development of artificial wombs represents the ultimate equalisation of gendered reproductive roles.

S. Firestone, Supra fn. 10
Tong, Supra fn.193 p. 74

However, understandably, some feminists are reluctant to accept Firestone’s view. Radical feminists fear that with the advent of new technology, women will become ‘de-humanised’ and the medical and legal profession will usurp even greater control of female reproduction with unfortunate consequences. Liberal feminists also argue that reproductive technologies infringe upon women’s self-determination and ‘brain wash’ them into believing that their appropriate role is to exist as ‘mother as machine’. Feminism also portrays the artificial womb as an ‘escape from the dark and dangerous place’ that is a woman's womb, towards the medically regulated sanctuary of an artificial womb. Ectogenesis therefore carries with it the negative implication that the maternal body is a source of danger: women are not to be trusted with the serious role of gestating future generations because man-made machines can do better; ‘[s]afe in a bottle [the foetus] would be spared the ignorance or carelessness of its parent.’

### 2.7.4 Ectogenic Research: Moving Beyond Fourteen Days

In light of the many benefits that the development of ectogenesis may bring, if this technology is to go ahead, lawyers and ethicists should be prepared to think about how the current restrictions on embryo research beyond fourteen days could be removed. I now turn to the issue of embryo research in order to attempt to move beyond the legislative limit, which, if not undertaken, will prohibit any clinical research into ectogenesis. This is an area that is now heavily regulated, and it is important to briefly consider some of the debates regarding experimentation prior to the enactment of the HFEA 1990.

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197 For example, liberal feminists assume a definitional equality between the male and female experience. This theory emphasises the value of individual and autonomous personal development - the pursuit of the extension of choices to free women from the constraints of domesticity. It stresses that biology should not determine destiny. Through these principles, liberal feminists have sought to claim reproductive rights on the grounds that they are a necessary precondition for self determination: if women are to compete with men, they must first be enabled to control their own fertility. This right is also defended as a straightforward extension of the basic liberal principle that individuals are entitled to do what they want with their own bodies and live their lives free from unnecessary state intervention.


200 Ibid at p.250

201 E. Jackson, Supra fn. 55 at 350
The HFEA 1990, although not commonly seen in this way, was a major piece of restrictive legislation.\textsuperscript{202} It imposed limits on embryo research where none had operated before. As a result of this legislation, if clinical research into complete ectogenesis is ever allowed to go ahead, it would seem that primary legislation is required to remove the fourteen day time limit on embryo research. At the outset, therefore, there exists an enormous legal challenge for the development of ectogenesis; exactly when, how, and if, the fourteen day ban should be lifted.

At this point, I must briefly return to the recommendations of the Warnock Report, which proposed the time limit of fourteen days for embryo research, before the appearance of the ‘primitive streak’ which appears at around fifteen days. This point was adopted by the Warnock Committee because it was viewed to be the point when human life begins to matter morally.\textsuperscript{203} Braude and Johnson suggest that the importance of choosing a point before the ‘primitive streak’ appears is threefold:

(i) It is the time at which the precursor cells for the basic body tissues are laid down in the correct relative position;
(ii) It is the first time at which the embryonic disc has a front and back, left and right and top and bottom; and
(iii) It is likely that this is the last stage at which twinning of the conceptus can occur, the number of embryos being determined by the number of primitive streaks that develop.\textsuperscript{204}

It is important to note that in most other countries, research on embryos beyond day fourteen, is also banned. In particular, Canada has expressly prohibited any ‘experimentation which may lead to

\textsuperscript{202} R. Lee & D. Morgan, \textit{Human Fertilisation and Embryology: Regulating the Reproductive Revolution} (Blackstone Press, 2001) p.80
\textsuperscript{203} Warnock, \textit{Supra} fn. 77 para 11.2-0
\textsuperscript{204} A. McLaren, ‘Can we Diagnose Genetic Disease in Pre-Embryos?’ \textit{New Scientist} December 10, 42-47 (1987) p.213
ectogenesis’. Similar committees to Warnock were established in many countries to address the unique situation that IVF presented and the new ability to produce embryos in vitro for research. Many reached the same conclusion as the Warnock Committee on account of the potential status of an embryo, which required a measure of dignity in its treatment. However, as a number of critics have pointed out, this response tells us nothing about how to treat the embryo since the adoption of fourteen days is not any more significant a scientific marker than the beginning of brain life. Other critics have described the fourteen day cut-off point as an uneasy compromise to what had been a vociferous debate.

Warnock prefaces this conclusion with the reiteration that ‘the objection to using human embryos in research is that each one is a potential human being.’ However, this compromise has been rejected by a number of critics. As Mason stated in 1988, ‘[e]ither the in vitro embryo of Homo sapiens is a human being with rights that are absolute in themselves, and which only become comparative when they are in conflict with those of human beings...or it is an artifact to be regarded in the same light as any other biological product of the laboratory.’ Harris further highlights the contradiction of the potentiality argument and use of the primitive streak when he states:

...if the potentiality argument is sound, then human potential is present quite as much before 14 days as it is after that limit. And if, as I have suggested, the potentiality argument is unsound, the development of the primitive streak operates on nothing of moral importance.

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206 Raskin, Supra fn. 36
209 Warnock Report, Supra fn. 77, para 11.22
210 J. K Mason, Human Life and Medical Practice, Edinburgh University Press, 1988, at p.94
211 J. Harris, Supra fn. 208 at p.93
Furthermore, it is not clear how the embryo’s potential status is more protected through being destroyed at fourteen days than it would be through implantation in an artificial womb. The Warnock Committee concluded that the early embryo has a ‘special status’ but not one that justifies according the embryo absolute protection. Without becoming embroiled in the circular debate of embryo status, the prohibition on research beyond fourteen days could be removed if the embryo were to be implanted in an artificial womb resulting in the embryo’s survival rather than its destruction. After all, would this not protect its ‘special status’ and recognise its potentiality to become a human being more than its destruction? If this position is accepted, and the prohibition on ectogenetic research is removed, primary legislation would need to be enacted, either through an amendment to the HFEA 1990 or through specific legislation for ectogenesis (such as, ‘The Ectogenesis Act’). However, it is more than likely that the latter will be required due to the enormity of the task of legislating for ectogenesis.

Yet the point still remains that the allowance of any form of research beyond this stage of development is highly controversial, and it would be a difficult hurdle to overcome. Following the 2008 review of the HFEA, the Government made it made clear that the fundamental principles of the Act, including ‘the permissibility of the creation and use of embryos for research within limits and subject to regulatory oversight’, were not to be debated again.212 Therefore, at the moment, the Government has made its stance on moving beyond fourteen days clear. However, this position may change if the need and desirability of this technology acts as an impetus for legislative change.

An example of such an occurrence is the recent government ‘U-turn’ in relation to the ban on human-animal hybrids.213 In December 2006, the Government’s White Paper on the Review of the Human Fertilisation and Embryology Act stated that: ‘[t]he Government will propose that the

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creation of hybrid and chimera embryos in vitro should not be allowed.\textsuperscript{214} However, after much lobbying, the Government reversed its decision six months later. The publication of the \textit{Human Tissue and Embryos (Draft) Bill} proposed to allow legislation, for categories of inter-species embryos. Later, this was placed in statutory form through Section 4A of the Human Fertilisation and Embryology Act 2008, which permits licences to be granted for the creation of human-admixed embryos.\textsuperscript{215} The 2008 amendments therefore represented a significant reversal on this ban. At the time, scientists argued that the research could help people with incurable conditions, such as motor neuron disease and Alzheimer’s, and their well-rehearsed reasoning successfully persuaded the Government to allow research on human admixed embryos.\textsuperscript{216}

This further supports the notion that there are no firm barriers for protecting the embryo, and, if scientists researching into ectogenesis can prove that there is a compelling case to allow such research, a reversal of the fourteen day ban may one day occur. Whilst the previous sections have established that extensive regulation is needed from the outset, the key concern in this chapter is whether such research can adequately prevent unnecessary casualties in terms of foetal death and injury. Even if research towards ectogenesis is deemed to be ethical and appropriate, and knowledge is gained in order to bridge the gaps between animal and human research into artificial wombs, a precautionary approach is still necessary. Unlike many other medical procedures, ectogenesis includes risks towards a third party: the child born as a result of this technology. This risk lies in the unknown; the fear is not of particular anticipated consequence but of the consequences that no one can foresee. Therefore, in the event that this ban is lifted and this technology is allowed to progress to allow for the gestation of ‘future human beings’, before any research is conducted, an inquiry must take place to address the myriad of ethical and legal questions that loom over research into this technology.

\textsuperscript{215} A term for an embryo that contains both human and animal material including chimeras, hybrids and cytoplasmic hybrids or “cybrids”. See The Human Fertilisation and Embryology Draft Bill Explanatory Notes Para 33 for more information.
\textsuperscript{216} Batty, \textit{Supra fn} 213
2.7.5 A New Warnock Committee for Ectogenesis?

As I have evidenced in this chapter, it is unclear as to whether ectogenesis involves unjustifiable medical risks for ectogenic embryos and foetuses, and whether the profound risks and concerns outweigh the benefits. At this stage, it is impossible to know whether or not the development is feasible and any final conclusion would be presumptive since the medical risks involved with ectogenesis cannot be determined in this thesis alone.

An appropriate solution at this juncture would be to conduct a meticulous and detailed inquiry into ectogenesis, which is similar in scope to the Warnock Committee. However, in contrast to Warnock, this inquiry would take place prior to any research into ectogenesis in order to determine whether technology and knowledge is advanced enough to enable research to be ethically permissible. This inquiry would involve detailed discussions with ethicists, doctors and other members of the medical profession. If ectogenesis is deemed to be medically too risky for the future welfare of human embryos and foetuses, then the inquiry would recommend that either nothing be done in terms of allowing research to move beyond fourteen days, or that explicit legislation should be enacted which would ban any clinical research into ectogenesis. If it is determined that science is advanced enough to enable research into the first human ectogenic chamber, then a second inquiry would be necessary in order to explore the wide ranging legal and ethical implications of such research. Further details of stages and decisions involved in this ‘ectogenesis inquiry’ will be explored in Chapter Five.

2.8 Research on the living ex utero foetus

Ectogenesis gives rise to new concerns, for which the possible use of live human foetuses does not fall within the remit of any legislation or consultation document thus far. Understandably, the sensitive issues that this form of experimentation raises requires further consideration. At the heart
of previous legal discussion involving the foetus has been the problem of involving human subjects that are ‘not nothing’ but equally, are not bestowed with full legal rights. The concern is: what value should be attributed to the foetus in this new context, based upon the foetus’ potential for further development? As Seymour argues, ‘[w]hile the law is adept at indicating what the fetus is not, it throws little light on what the fetus is’. The law has determined that the foetus has ‘special status’ as a ‘unique organism’, yet it can also be destroyed. This produces a contradictory and conflicting conclusion as to how the law regards the foetus. Therefore, one of the biggest challenges for the law in relation to ectogenesis is how to reconsider these complex issues that are fraught with difficulties and have yet to be discussed in this new context. This will be further explored in more detail in Chapter Three in relation to when it is ethically permissible to ‘switch off’ the ectogenic chamber.

2.8.1 Foetuses in research

The current guidelines relating to foetal research fall under the 1989 Review of the Guidance on Research Use of Foetuses and Foetal Material (also known as the Polkinghorne Report or Guidelines). The Committee recommended a professional code of practice, as opposed, to legal regulation, for the use of foetuses and foetal material in research and treatment. These guidelines state that the foetus merits ‘profound respect based upon its potential for development into a fully-formed human being’ and thus should not be treated instrumentally for mere investigation or use.


219 J. Raskin and N. Mazor, Supra fn. 36 at 165.

220 J. Seymour, Childbirth and the Law (Oxford University Press, 2000) at p.184

221 The Polkinghorne Report, Supra fn. 8 at para 2.4

222 Per Lord Mustill in Attorney-General’s Reference (No.3 of 1994) [1996] 2 All E.R 10, C.A

223 J. Harris, Supra fn. 208 at 84


225 The Polkinghorne Report, para 2.4
Despite changes to other relevant areas of law such as the Human Tissue Act 2004 (‘HTA 2004’), which makes no reference to the use of living foetal material, and the HFEA 1990, which specifically applies to the use of gametes and embryos up to fourteen days old, these guidelines have remained the main regulatory guidance for the use of foetal tissue in research. This has since been criticised as out of date and not adequately addressing maternal and paternal consent in relation to research on foetal tissue.

Another question in relation to foetuses in research, is whether live aborted foetuses could be used to conduct research into ectogenesis? With regards to abortion and the use of foetal materials, the Polkinghorne report states: ‘The decision to carry out an abortion must be reached without consideration of the benefits of subsequent use. The generation or termination of pregnancy to produce suitable material is unethical.’ Therefore, a woman may not become pregnant with the sole intention of aborting the foetus in order to use it solely for research purposes. However, Keown criticises this lack of clarity in the report, which finds abortion ethically permissible, yet states that it is unethical to generate a pregnancy in order to provide tissue.

With regards to live foetuses obtained through premature birth, foetal guidance from the report states that in the case of ‘the live whole fetus [sic] beyond fourteen days after fertilisation, whether inside or outside the womb’, research or other use should only take place if it carries ‘only minimal risk of harm or, if a greater risk than that is involved, the action is, on balance, for the benefit of the fetus.’ Furthermore, for the live foetus, the Polkinghorne Report recommended that it be accorded a status ‘broadly comparable to that of a living person.’

226 This legislation applies to dead foetuses or ‘foetal tissue’
228 The Polkinghorne Report, para 3.1.
229 Keown, Supra fn. 226 at 118.
230 The Polkinghorne Report, paras. 2.4 and 3.2.
231 Ibid, para 3.1
2.8.2 Foetuses in utero

The only other context in which the rights and protections afforded to the living foetus has been discussed are the rights of the foetus in utero. It is a well-established principle of English law that the foetus does not have legal status per se, although it may have legal interests, which warrant protection. However, this is interpreted as the legal status of an embryo and foetus that develops in the female body. Therefore, the key issue for ectogenesis is how should we determine the status of a living foetus that develops in an artificial womb, physically separated from a female body and all the rights that that body envelops? After all, in the artificial womb, the foetus is both removed from the inalienable rights of the female body and yet not placed in a research laboratory as a born-dead foetus, thus falling under the aforementioned research guidelines. Instead, the ectogenic foetus would be both ‘alive’ and ‘independent’ whilst not directly conflicting with any other person’s rights. This calls for a final determination on the ectogenetic foetus’ intrinsic status, removed from the maternal body. As I will further demonstrate in Chapter Three and Four, removing the foetus from the female body and gestating it in an independent ectogenic chamber changes the status of the foetus entirely, with the end result of additional rights and protections for the ectogenic foetus. These issues will be further explored in Chapter Three in relation to the circumstances in which it may be permissible to ‘switch off’ the ectogenic foetus in the artificial womb.

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233 Such as those under the Congenital Disability (Civil Liability) Act 1976 which allow the foetus a right to bring an action in tort for damages inflicted negligently while in utero – provided that the injured foetus survived as a neonate for at least forty-eight hours.

234 In particular, a pregnant woman has the absolute right to refuse medical treatment needed by the foetus; Re MB [1997] 2 FLR. And the law of abortion permits pregnancy to be terminated by a registered medical practitioner if two of such practitioners of the opinion, formed in good faith, that the four main defences under s1(1) to the OAPA are met; Abortion Act 1967, as amended by the HFEA 2008 s.37. For further discussion of the abortion law provisions see p. 89-90 of this thesis. In addition, whilst pregnant women are also an exception to the rule that pre-natal claims ‘crystallise’ upon birth; The Congenital Disabilities (Civil Liability) Act 1976.

235 As Chapter Four will discuss, this ‘separate’ status means that the foetus in this setting cannot fall within the provisions of abortion jurisprudence.
The law in relation to the ectogenic foetus is a complex field, in which I have briefly attempted to demonstrate that the current legislation and guidelines are inadequate to regulate research on the ectogenic foetus. It is clear that primary legislation or new guidelines will have to be drafted to determine the status, rights and protections accorded to the ectogenic foetus on account of the separate status of the foetus removed from the female body.

2.9 Conclusion

*The types of question that normally arise about any new and dramatic technological procedure fall into the categories of: can man, will man and ought man.*\(^{236}\)

In this chapter, I have indicated a precautionary approach towards the development of ectogenesis in light of the concerns surrounding the risks of this technology. Nevertheless, there are two main problems with this position.

Firstly, whilst the current technology and lack of scientific knowledge on human embryology and the womb environment may prevent ectogenesis, this position may change as it has done with many other areas of medicine. After all, there are inherent risks involved with the beginnings of all medical research but this does not mean that the technology of ectogenesis should be rejected forever. It is not the technology of ectogenesis that raises concern but the known (and unknown) risks that starting this technology might raise. As Harrison reminds us (in a different context), ‘we don’t want to hold up research...we want research to prosper’\(^ {237}\). However, the conclusion of this chapter is that ectogenesis should only be developed if it safe to do so or where, after careful scrutiny it has been deemed that the benefits outweigh the risks posed and such research will only

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\(^{236}\) W. Gaylin, "The Frankenstein Myth Becomes a Reality: We Have The Awful Knowledge to Make Exact Copies of Human Beings" *New York Times Magazine* 1972 March 5; Section 6, Part 1; p. 12-13,

take place within clear perimeters and guidelines. Therefore, I recommend further enquiry in order to decide if ectogenesis should be allowed to go ahead at all.

Secondly, the legal problems raised and highlighted in this thesis will not subside if one simply hopes that ectogenesis will never happen. As with other reproductive technologies, the desire for couples to have a genetically related child and for scientists to push medicine and research towards new horizons may overcome concerns that were initially raised by lawyers and ethicists. Beem and Morgan argue that often one finds that the pace of medicine and the willingness of society to allow couples to have a genetically related child outstrip any concerns raised because:

The desire for a child sometimes seems all consuming. IVF and its myriad cousins might seem to offer entitlement to a child; that every woman…who wants a child deserves a child…there is an emergent notion that IVF will deliver what nature or nurture has not.\textsuperscript{238}

As the next chapter will demonstrate, if the development of ectogenesis is to go ahead, it is vitally important to retain some form of regulatory control over the development and use of this new technology. Ectogenesis generates new problems for the regulators to grapple with and whilst the development reignites controversial debates on embryo and foetal research, finding law-based answers to these issues cannot be found in the current legislation or quasi-official regulations. As a result of this, in Chapter Three and Four I seek to demonstrate that the current legal system is wholly inadequate for the development of ectogenesis, and that new legislation will have to be drafted to address the numerous and wide-ranging issues which may arise. This is a complex area, and, as the next two chapters demonstrate, the potential range of legal conundrums and problems

raised by regulating are almost endless; a ‘glittering constellation of legal and ethical questions’. 239

239 M. Brazier, “Regulating the reproduction business” (1999) Medical Law Review 166
Chapter Three

Square pegs and round holes? – Viability and Birth for the Ectogenic Foetus

I begin with a thought experiment:

On 14th February 2026, Jane and Henry Smith file an interim injunction with the High Court to prevent the termination of Louise, an eighteen-week-old ectogenic foetus and their ‘last chance’ of genetic parentage. They argue that under s1(1) of the Infant Life (Preservation) Act 1929 (‘The 1929 Act’) it is an offence for any person, with intent, to destroy the life of a child ‘capable of being born alive’. They contend that a foetus of eighteen weeks gestation in an ectogenic chamber is viable from the moment of implantation and therefore switching off the chamber would amount to the crime of child destruction. In the alternative, they argue that Louise is in fact already ‘born’, since her existence is entirely separate to that of her mother’s, and any attempt to ‘switch off’ her ectogenic chamber would equate to the crime of murder.

The Defendant, The Ectogenic Research Centre, dispute both of the Applicants’ claims. They contend that the artificial womb is to be treated in line with the current law on female gestation; the foetus is not viable at eighteen weeks and is not born alive until removed from the chamber. They further contend that due to clear evidence of the ‘substantial risk’ of ‘physical or mental abnormalities’ were Louise to be born, the Abortion Act 1967 s.1(d) permits terminating the life of the foetus in these circumstances. ‘Switching off’ the chamber also falls in accordance with the Centre’s consent policy on developing ectogenesis, which the Smiths were informed of when they agreed to the procedure.

This case represents the first time the court has had to consider these issues in relation to artificial chambers and ectogenic foetuses.
This chapter seeks to determine the issues of viability and birth that are raised in the thought experiment. The use of this scenario highlights the nuances of artificial womb technology. Through thinking about the ectogenic foetus ‘Louise Smith’, one can begin to imagine a whole host of issues within the law of viability and the ‘born alive’ rule that demonstrate that issues of viability and birth for the ectogenic foetus are not clear-cut.

If one considers this dilemma from both perspectives, it is clear that these issues need to be considered sooner rather than later. In this scenario, Louise represents the Applicants’ last chance to have genetic offspring. At eighteen weeks gestation, she looks like a human being, with fingers, toes and eyelashes. ‘Switching off’ the machine would cause her inevitable death, which the Applicants wish to avoid at all costs, regardless of her severe disabilities. In contrast, for the Defendant, the Applicants represent participants in a clinical trial to develop ectogenesis (assuming that such a trial would ever be allowed to take place).\textsuperscript{240} Louise is severely disabled and ‘switching off’ the chamber falls in accordance with both the research consent provisions\textsuperscript{241} and the law on termination of pregnancy for serious foetal handicap.\textsuperscript{242} They argue that Louise is not viable at this stage because once the machine is switched off, the lack of surfactant in her lungs means that she will die. An additional concern for the clinic is the potential claim for damages if Louise is born alive. In 2026, due to the lack of forward-planning in relation to the development of ectogenesis, the law is unclear as to whether the provisions of the Congenital Disabilities (Civil Liability) Act 1976 will apply.

\textsuperscript{240} Whilst the topic of research governance is beyond the scope of this thesis, it is important to note that such a trial would require regulation through the Medicines and Healthcare products Regulatory Authority (‘MHRA’). For further details see M. Brazier, Medicine, Patients and the Law (Penguin: London, 2011) Chapters 10 and 15.

\textsuperscript{241} That is, on the assumption that such consent provisions would be legally binding or enforceable. This matter will be further explored under question 3, ‘Can the ectogenic foetus be switched-off?’

\textsuperscript{242} s.1(1)(d) Abortion Act 1967 states where “there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped” then the pregnancy may be terminated, subject to the provisions of s.1(1). As noted in the introduction to this chapter, this thought experiment begins with the discussion that the current law is the only legislative framework in place to deal with ectogenesis and therefore before I turn to a criticism of the inapplicability of the Abortion legislation for ectogenesis, I proceed on the basis that this is the only legislation which the parties may use.
Through deconstructing the current law in relation to this thought experiment, it is clear that the new technology of ectogenesis is not accommodated by present legislation such as the Offences Against the Person Act 1861 or Abortion Act 1967 (as amended), which was developed for female gestation. This is further illustrated by the fact that much of the legislation that I will discuss in this chapter was written at a time when medical science had not even achieved artificial fertilisation for the first time. To date, few commentators have explored the legal and regulatory aspects of ectogenesis, mainly focussing upon the ethics of artificial gestation and ectogenesis as a potential answer to the abortion debate. However, in this chapter, my main focus will be on the substantive law, which, unlike philosophy or ethics, does not have the luxury of equivocation. As Foley states, ‘the law must answer when it is asked: Is X alive?...Maybe is not an option’. As I will demonstrate, unless these substantive legal questions are explored prior to the development of ectogenesis, numerous disputes regarding control over and interest in in vitro foetuses may ensue.

This chapter is structured into two parts. It seeks to answer the following questions:

(i) When is the ectogenic foetus viable; and

(ii) When is the ectogenic foetus born?

These two questions display the numerous problems that will arise once ‘the theatre of gestation becomes seeable and its players accessible’. It causes conflict between the legal status of the

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244 This matter is beyond the scope of this thesis. For work discussing this see: V. R. Randall & Tshaka C. Randall, Built In Obsolescence: The Coming End to the Abortion Debate, 4 J. Health & Biomed. L. 291, 307-08, 309 (2008); P. Singer and D. Wells, Supra fn.18 -20 (1985); M. Buckley, Current Technology Affecting Supreme Court Abortion Jurisprudence, 27 N.Y.L. SCH. L. REV. 1221 (1982); M. A. Goldstein, Supra fn. 243 K. Martyn, Comment, Technological Advances and Roe v. Wade: The Need to Rethink Abortion Law, 29 UCLA L. Rev. 1194, 894 (1982).

245 E. Foley, The Law of Life and Death (USA, 2011) p.8

246 J. Raskin and N. Mazor, Supra fn. 36 at 159
foetus\textsuperscript{247} and even the satisfactory nomenclature to be applied. For instance, the legal definitions of the terms ‘viability’, and ‘birth’ all struggle to fit into the intricacies of artificial womb technology. After all, a child of ectogenesis will never be ‘born’ or gestated in the traditional legal sense. Instead, in \textit{Brave New World} Huxley prefers to use the term ‘decanting’.\textsuperscript{248}

\textbf{PART I: Viability}

Viability and the correct meaning of the phrase ‘capable of being born alive’ have been subject to varying definitions and interpretations. English law uses the term ‘capable of being born alive’\textsuperscript{249} rather than ‘viability’ to describe the point at which to afford additional legal protection\textsuperscript{250} to the foetus’, although in \textit{Rance v Mid-Downs},\textsuperscript{251} Brooke J held that the two terms were synonymous.\textsuperscript{252}

In this chapter, I use both terms interchangeably to illustrate the difficulties that might ensue from retaining viability as a stage from which to grant partial legal protection to the ectogenic foetus.

Pursuant to the doctrine of viability, a foetus is not entitled to legal protection until he or she is developed enough to be ‘capable of’ surviving outside the female womb, albeit with medical assistance. Viability is an important construct, since it acts as the legal demarcation for abortion in many jurisdictions.

If one considers the issues raised in the thought experiment, it is evident that the development of ectogenesis requires a re-examination of the meaning of the phrase ‘capable of being born alive’.

\textsuperscript{247} Under current scientific nomenclature, an ‘embryo’ technically refers to a zygote from conception to twelve weeks of development. A foetus is the appropriate term for an immature human at any stage of development between approximately twelve weeks to birth. M. Brazier and E. Cave, \textit{Medicine, Patients and the Law} (Penguin Books, London 2011) p.403-404 For the sake of simplicity, I refer to both entities as a ‘foetus’ in this chapter.

\textsuperscript{248} Aldous Huxley, \textit{Brave New World} 1 (Harper Perennial Modern Classics, 2006), p. 5.

\textsuperscript{249} \textit{C v S} [1998] 1 All ER 1230 per Sir John Donaldson MR and \textit{Infant Life (Preservation) Act 1929}

\textsuperscript{250} Although, it is important to note that although a foetus does not have legal personality before birth and is not awarded protection prior to the point it is ‘capable of being born alive’ under the \textit{Infant Life (Preservation) Act 1929}, a duty of care is owed. As Lord Hope stated in \textit{Attorney General’s Reference} (No.3 of 1994) [1998] Cr App R 91 “For the foetus, life lies in the future, not the past. It is not sensible to say that it can never be harmed.” (at 116)

\textsuperscript{251} \textit{Rance v Mid-Downs} [1991] 1 QB 587

\textsuperscript{252} \textit{Ibid} at 93 where Brooke J stated that the statutory application of the word ‘viable’ was ‘simply used [by Parliament] as a convenient shorthand for the words, ‘capable of being born alive’.”
This is something entirely new that the courts have not yet had to consider. Alghrani argues that ectogenesis complicates matters because it challenges what we think we might mean when we use the expression ‘viable’, because ‘it might simply mean capability of survival outside of a mother’s womb’. Raskin and Mazor argue that under the legal definition of viability, there is a strong case to suggest that the ectogenic foetus is viable from implantation, with all the rights that this status envelopes. The crux of this argument is centred on the idea that through growing in an artificial womb, the foetus has the actual potential, rather than a philosophical potential, to develop into a fully formed human being. This reasoning is focused upon the fact that the entirety of foetal development would take place take in the ectogenic chamber; unless a catastrophic error occurs, the foetus may develop independently, until he or she is ‘decanted’ from the artificial womb.

Therefore, the fundamental points of these interpretations of the term ‘viability’ is that ectogenesis could render a foetus viable from implantation, albeit with the technological assistance of the artificial womb, with the consequence that the foetus will acquire the legal protection of viability (as outlined in the introduction to this section). However, these claims demand further inquiry as to the exact meaning of the terms ‘capable of being born alive’, and what it really means to be viable. This lack of certainty surrounding the term extends to the medical and legal profession. As Dr. Easterling, states, ‘[v]iability is a legal term. It’s not a medical term. Who really knows what it means?’ Whilst this is an issue that is fraught with difficulties, if ectogenesis is to be adequately regulated, it is imperative that thorough consideration is given to what viability might mean in this new setting. The starting point for this can be found through exploring the legal meaning of the term ‘viability’ in the context of female gestation.

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253 Ibid.
254 A. Alghrani, Supra fn. 243 at 7
255 J. Raskin and N. Mazor, Supra fn. 36. Also suggested by S. Zimmerman Supra fn. 91
256 Although, see Chapter Three for a full exploration of “switching-off” the ectogenic foetus.
3.1 Foetal Viability: A Legal Analysis

To answer the question of when the ectogenic foetus ought to be considered viable, it is necessary to look at the remit of the current law surrounding the term ‘capable of being born alive’ in order to ascertain the exact meaning behind this phrase. Section 1(1) the 1929 Act introduced the offence of child destruction causing the death of a child ‘capable of being born alive’.\(^{258}\) This was later placed on a statutory footing and amended to a twenty-four week presumption by the HFEA 1990.\(^ {259}\) However, this wording provides little clarity as to what the phrase means and it is necessary to look at the legislative purpose to determine at what point the ectogenic foetus should be granted similar protection (if the distinction should remain at all).

The 1929 Act itself gives a potential indicator of the meaning of this term under s.1(2), which creates a presumption that a twenty-eight-week-old foetus is ‘capable of being born alive’.\(^ {260}\) However, this is no more than a presumption, and the exact interpretation of this statutory phrase is not clear. Instead, exploring the legislative purpose behind the Act, Keown suggests that the mischief of the legislature was to protect the ‘viable child’ because parliamentary history reveals that the concern was for the ‘safety of the child at and around the time of the birth’.\(^ {261}\) On this interpretation, it could be suggested that the narrow sense of viability such as surviving for several minutes after birth, was not part of the intention of Parliament.\(^ {262}\) Instead, ‘substantial viability’,

\(^{258}\) “Any person who, with intent to destroy the life of a child capable of being born alive, by any wilful act causes a child to die before it has an existence independent of its mother, shall be guilty of felony, to wit, of child destruction”. A proviso to the sub-section states that a person will not be guilty of this offence if it was done in “good faith for the purpose of preserving the life of the mother” ILPA 1929 s.1(1). The purpose of this Act was to close a loophole between the law against abortion and the law against murder (which protected a foetus once it was ‘born alive’). Prior to the introduction of this offence, it was not a crime to destroy a child during delivery: E. Jackson, Medical Law: Texts, Cases and Materials (OUP, Oxford 2010) p. 667. The 1929 Act created the offence of child destruction in order to protect the child during birth. But it also went further, protecting a child before delivery had begun (once it was ‘capable of being born alive’). The offence overlaps with abortion, as it is not restricted to acts done while the child is in the process of being born and also covers the causing of a miscarriage of a child ‘capable of being born alive’. Abortion is also an alternative verdict to child destruction (Infant Life (Preservation) Act 1929 s.2(3)).

\(^{259}\) s.37 HFEA 1990. This time limit was introduced by the Abortion Act 1967; s.1(1) (a) which states that a person shall not be guilty of an offence under the law relating to abortion as long as the pregnancy has not exceeded its twenty-four week.


\(^{262}\) Ibid.
such as reaching a significant point of development in order to stand a ‘substantial’ chance of survival, ought to be interpreted in its place. This is further demonstrated by the fact that the 1929 Act was enacted to close a loophole between the law against abortion\textsuperscript{263} and the law against murder,\textsuperscript{264} thus protecting the child which had reached the point at which it would be born and could survive.

However, the Act also went one stage further through protecting a child before delivery had begun, once it was ‘capable of’ being born alive,\textsuperscript{265} and it is the examination of these words that may be of some relevance to drafting legislation for ectogenesis. After all, what does it mean to be ‘capable of’ doing something? Is the ectogenic foetus’ capability to survive with the assistance of the artificial womb enough to classify him/her as viable? The crux of this issue was explored in the Northern Irish\textsuperscript{266} case of \textit{R v McDonald}.\textsuperscript{267} In his analysis of s.25 of the Criminal Justice Act 1945 (which is equivalent to s.1 of the ILPA 1929), Girvan J explained that the words ‘capable of’ could be ‘open to different interpretation in different contexts’.\textsuperscript{268} In order to explain this, he used an analogy:

\begin{quote}
To say that a given person is capable of achieving an honours degree means that that person has the qualities which could lead on to his achieving such a degree. It does not mean that he will inevitably do so.\textsuperscript{269}
\end{quote}

\textsuperscript{263}Which protected a foetus once it was ‘born alive’. (As contained in Sections 58 and 59 of the Offences Against the Person Act 1861.
\textsuperscript{264}Prior to the introduction of this offence, it was not a crime to destroy a child during delivery: E. Jackson, \textit{Medical Law: Texts, Cases and Materials} (OUP, Oxford 2010) p. 667\textsuperscript{265}The offence overlaps with abortion, as it is not restricted to acts done while the child is in the process of being born and also covers the causing of a miscarriage of a child ‘capable of being born alive’. Abortion is also an alternative verdict to child destruction (Infant Life (Preservation) Act 1929 s.2(3)). Emphasis added.\textsuperscript{266}Note that the law in Northern Ireland is not governed by the Abortion Act 1967, the Infant Life (Preservation) Act is confirmed in the Criminal Justice Act (Northern Ireland) 1945 s25; however there are several judgments in case law which modify this position somewhat.\textsuperscript{267}[1999] NI 150 In Northern Ireland, the law relating to the termination of pregnancy is contained in sections 58 and 59 of the Offences Against the Person Act 1861, and in section 25(1) of the Criminal Justice Act (Northern Ireland) 1945\textsuperscript{268}[1999] NI 150 per Girvan J at 156\textsuperscript{269}\textit{Ibid.}
This illustrates the important legal distinction that ought to be made between being ‘capable of’ doing something and actually achieving it. Implanting an embryo into an ectogenic chamber does not necessarily mean that the foetus will survive until live birth and thereafter. It may be ‘capable of’ doing so, but this is no more certain than being capable of completing a marathon, simply because one has legs. Various things could go wrong in the lengthy process of running the marathon, which means that the participant is unable to complete it. Any assumption that completion will definitely and inevitably occur would be just that, an assumption. Even a presumption that a pregnancy will result in a live birth is sadly often incorrect, with one in four pregnancies ending in miscarriage or stillbirth.\textsuperscript{270} I therefore, aim to display that without the full developmental support of the artificial womb, the foetus is not ‘viable’ until it reaches approximately twenty-four weeks gestation.

At this juncture it is necessary to add a note of caution in relation to the legal presumption of viability. As the medical meaning of viability will demonstrate, this term is defined by reference to current medical technology, which places great importance on the availability of technology required to keep the foetus alive. Moreover, the law treats viability as if it were a quality inherent in the foetus which is capable of surviving from the twenty-fourth week, whereas, viability is merely a point at which technology has been able to maintain neonatal life. In some cases, neonates have survived earlier than twenty-four weeks, such as Amilia Taylor, born at twenty-one weeks and six days.\textsuperscript{271} This therefore illustrates the elasticity of the concept, since in rare situations neonates born prior to the twenty-four week time limit may survive. Consequently, as I will demonstrate, viability becomes very difficult to pinpoint as it arises from individual neonatal developmental and circumstance.

\textsuperscript{271} This is reported to be one of the world’s most premature babies: J. Moorhead, “Against All Odds” Wednesday February 21, 2007, The Guardian. Accessible at <http://www.guardian.co.uk/society/2007/feb/21/health.lifeandhealth>
3.2 Medical Viability

Despite advances in neonatal care and rare cases such as Amilia Taylor, the medical threshold of foetal viability remains at approximately twenty-four weeks. Medical studies indicate there has been no significant increase in the number of babies born below twenty-four weeks surviving and care for infants born at twenty-two or twenty-three weeks is not always successful. This is mainly due to foetal lung development, because an infant whose lungs lack surfactant cannot survive, and medical science thus far has not been able to push beyond this hurdle. This position is supported by the British Medical Association, the EPIcure studies, the Neonatal Survey Report and the Nuffield Council on Bioethics, all of whom recommend that the gestational limit for abortion under s.1(1)(a) remains at twenty-four weeks. The British Association of Perinatal Medicine (BAPM) has suggested that, ‘those working in perinatal care...in general, do not believe that the survival for babies born below 24 weeks of gestation has improved.’ Furthermore, for neonates who survive after being born on the cusp of viability, such as at twenty-three weeks gestation, very few leave hospital without severe disabilities.

Despite the medical profession continuing to use the twenty-fourth week as the medical point of foetal viability, it is important to recognise that it is, in itself, a fluid concept which differs

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272 The Royal College of Obstetricians and Gynaecologists (RCOG) have also suggested that the “minimum stage of development, with structural integration of peripheral nerves, spinal cord, brain stem, thalamus and, finally, the cerebral cortex, [does not begin] before 26 weeks’ gestation”: Royal College of Obstetricians and Gynaecologists. Fetal Awareness. Report of a Working Party. London: RCOG press, 1997: 3.


275 The EPICure 2 study showed that the survival rate of premature babies has increased at twenty-four weeks and above but there are insignificant improvements at 23 weeks or below. http://www.epicure.ac.uk/overview/overall-outcome/ The EPICure study group Petrou S, Henderson J, Bracewell M, Wolke D, Marlow N. Early Human Development 2006; 82:77–84 Outcome following extremely preterm birth.


278 Notwithstanding this, the development of 4D ultrasound images of foetus pioneered in 2003 by Professor Stuart Campbell created calls for limits to be lowered in light of this.


280 Alghrani, and Brazier, Supra fn. 50
depending on factors such as location, birth weight and availability of technology.\textsuperscript{281} Therefore whilst twenty-four weeks is the current benchmark for viability, this point may be reached earlier. This is reflected in the British Association of Perinatal Medicine who have introduced the concept of a ‘threshold of viability’. This is a period from twenty-one to twenty-six weeks of gestation where a baby born at that stage is potentially, but not definitely, viable.\textsuperscript{282} This further demonstrates the nuances of a fixed and specific point in which to determine foetal viability.

### 3.3 When is the ectogenic foetus ‘viable’?

Looking at both the medical and legal definitions of viability, the term requires a significant chance that the foetus can maintain an independent life outside the uterine environment. This distinction must remain for ectogenesis. Mere implantation in the artificial womb is not sufficient to establish viability\textsuperscript{283} because life inside the ectogenic chamber does not truly reflect ‘the common understanding of viability’.\textsuperscript{284} In other words, the ectogenic foetus should not be deemed ‘viable’ until he or she could stand a significant chance of independent survival outside the artificial womb. This would require the ectogenic foetus to reach a significant point in its development, wherein it could survive outside any womb. This is further illustrated by a thought experiment adapted from George Annas:\textsuperscript{285}

> If a fire broke out in an ectogenesis laboratory and there was only time to save a visiting one month old baby in a bassinet or a developing twenty-two week old foetus in an artificial womb, most people would save the baby without hesitation.


\textsuperscript{283} J. Raskin and N. Mazor, Supra fn. 36 at o,179.

\textsuperscript{284} Ibid.

This scenario shows that there is a distinction between a pre-viable foetus that is on its way to becoming a potential newborn and a baby, which we know has full legal personality. In the event of fire or mechanical failure (assuming that no other ectogenic chamber is accessible), a foetus of at least twenty-four weeks gestation could survive once placed on life support. Whereas, for the pre-viable foetus, no amount of life-saving support could enable that foetus to live; it is entirely dependent on a female host or machine for its development and survival. Therefore, the true meaning of viability in the artificial womb ought to take these factors into account and the point at which the ectogenic foetus ought to be deemed legally viable should be at between twenty-one and twenty-six weeks.\textsuperscript{286} Support for this proposal can also be found in the discussion for the 1979 Abortion (Amendment) Bill where the then Solicitor-General, Sir Ian Percival QC, stated:

\begin{quote}
As a matter of law it would be held that ‘capable of being born alive’ means more than simply being born alive in the sense that the body may draw one breath or make one sound. In law it would be held to mean more than that and something very akin to the concept of “viable foetus”.\textsuperscript{287}
\end{quote}

Hyun Jee Son calls this the ‘naturalist approach’ because it requires a baby to survive ‘naturally’ in order to be ‘viable’ and warrant legal protection.\textsuperscript{288} Alghrani refers to it as the ‘middle ground’ since it is in line with both medical technology for foetal development and the current law.\textsuperscript{289} However, it is important to recognise that this stance on ectogenic foetal viability is not without difficulty. There are two main problems that this position raises which need to be addressed accordingly: firstly, the argument of biological geography highlights the problems with using the term ‘surviving naturally’ and secondly, the use of a NICU may cause criticisms due to its similarity with an ectogenic chamber.

\begin{footnotes}
\textsuperscript{286} This removes the difficulties presented by evidence of live-births from as early as 10 weeks, where although the foetus was capable of being expelled from the womb, it was unable to exist beyond a few hours. E Rigby, \textit{A System of Midwifery} (Lea & Blanchard, 1841) 87
\textsuperscript{287} \textit{Hansard}, HC Standing Committee C 369 (1979)
\textsuperscript{288} Hyun Jee Son, \textit{Supra} fn. 25
\textsuperscript{289} Alghrani \textit{Supra} at fn. 13, p.8
\end{footnotes}
1. Biological geography

The first problem with classifying an ectogenic foetus as viable from the twenty-fourth week of gestation is that viability is essentially a criterion which is an imprecise determinant of human life: ‘[a] premature fetus may survive in a hospital neonatal intensive care unit while one of similar or greater maturity and health will die if born under a hedgerow’.\textsuperscript{290} This is otherwise known as the argument of ‘biological geography’,\textsuperscript{291} which centres on the claim that ‘while some foetuses may become at some point transplantable, no fetus is actually viable’\textsuperscript{292} (unless at the very late stages of pregnancy). Jackson argues that if we define viability as a stage in foetal development at which the foetus can survive with minimal assistance, ‘we would have to acknowledge that hardly any babies born very prematurely can survive with minimal assistance’.\textsuperscript{293} This leads onto the second problem of viability for ectogenic foetuses.

2. NICU

Life-saving assistance for neonates born as early as twenty-four weeks (and earlier) comes in the form of mechanical life support in the NICU,\textsuperscript{294} and it may be possible to argue that the technological assistance that the ectogenic chamber provides bears striking similarity to that of a NICU. In other words, because the premature baby is deemed ‘born alive’ once placed in a NICU, why should the ectogenic foetus' implantation in the artificial womb be viewed any differently? After all, they are both in ‘chambers’ which keep their inhabitants alive, regardless of the differences in their stage of development. This highlights the nuances of both ectogenesis and the argument of viability.

\textsuperscript{291} R. Gillon, “Is there a New Ethics of Abortion?” Journal of Medical Ethics 27 (2001)
\textsuperscript{292} R. Petchesky, Abortion: Woman’s Choice (Longman, 1984): xii
\textsuperscript{293} E. Jackson, E., “Degendering reproduction” Medical Law Review 16(3) (2008) p.364
\textsuperscript{294} Simonstein, F., “Artificial reproduction technologies – all the way to the artificial womb?” (2006) Medicine, Health Care and Philosophy, pp. 1386–7423, 1572–8633
However, although in theory ectogenesis could be seen to represent a more sophisticated version of the NICU system, this does not take into the account the extent of the gestational support that the artificial womb would provide. This technology would aim to replicate the female body and the placenta, providing the full developmental assistance required to enable an embryo to develop into a foetus and then a live baby. In contrast, the NICU resembles ‘ordinary life support, but on a smaller scale’. Without this important developmental phase in the ectogenic chamber or the female placenta, any attempts to place a baby that has not reached at least the twenty-fourth week of gestation on life support via the NICU will either result in severe disabilities or death for that child. Furthermore, the argument of viability is centred on the claim that if removed from the womb, a foetus would stand a reasonable chance of survival (with medical assistance). It therefore encompasses the possibility that such a child would need ‘life support’ assistance from the NICU. As a result of this, the words ‘surviving naturally’ ought to be avoided and interpreted in its place should be the requirement that the ectogenic foetus may survive after the point of viability, with medical assistance via NICU.

3.4 Is Louise ‘viable’?

Revisiting the scenario posed in the introductory thought experiment, Louise ought not be deemed viable at eighteen weeks’ gestation on account of the medical and legal definitions of this term. In the event of technical failure, fire in the laboratory or deliberate or accidental ‘switching off’, Louise would not survive once external to the artificial womb even if placed in a NICU. Furthermore, on the legal construction of the term alone, she would not stand a ‘significant chance’ of being ‘born alive’ at this point.

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295 From a life support perspective, a successful artificial womb would have to be able to perform the functions of the placenta, as well as protect the fetus with something akin to amniotic fluid: S. Coleman, The Ethics of Artificial Uteruses: Implications for Reproduction and Abortion (2004) at 7 (“The amniotic fluid acts to regulate foetal temperature, to prevent dehydration, and as a barrier to infection.”).


297 Statistics show that of all the babies born at the borderline of viability which The Nuffield Council on Bioethics term below 25 weeks 6 days gestation, a proportion of those who survive will have severe disabilities: Nuffield Council on Bioethics, Critical Care Decisions in Fetal and Neonatal Medicine (2006)

However, as alluded to earlier, it is important to note that, although Louise is not viable at eighteen weeks, she ought to be afforded some additional protections. Traditionally, a foetus’s protection, especially that of a pre-viable foetus, has been inextricably linked with that of its mother, which has, in certain circumstances, enabled the mother’s rights to trump that of the foetus. However, since there are no longer female rights involved in the ectogenic foetus, this is one reason for granting additional protections. In other words, whilst in utero foetuses have the ancillary protections of their mothers' legal personhood, ectogenic foetuses would not have these safeguards. (Although it remains to be seen whether there would be parental rights.) Therefore, as will be explored in Chapter Five, primary legislation ought to be established which recognises the need for these additional protections or regulations to address this lack of protection for the pre-viable ectogenic foetus. This will be also explored in Chapter Four in relation to whether it is permissible to ‘switch off’ the ectogenic chamber and the legal status of the developing ectogenic foetus.

PART II: Birth

[Birth is] the complete extrusion of a newborn baby from the mother’s body.

The next question to consider is: when is an ectogenic foetus considered ‘born alive’? However, to define birth in the context of artificial wombs, we must firstly look at ‘why birth is important?’ Both the common law and statute declare that a foetus only acquires full legal personality once he or she is ‘born alive’. From this moment, the baby cannot be actively killed; only a baby, rather

300 Although there are burdens too. For example, the mother may still terminate grave risk to health and may refuse to have a caesarean.
301 This will be further explored in Chapter Four.
304 Although foetuses lack legal personality there are legal protections that require consideration: Adrian Whitfield, ‘Common Law Duties to Unborn Children’ (1993) 1 Medical Law Review
than a foetus, can be the victim of homicide, the crime of which requires the death of ‘a person in being’ (or in rerum naturae).\textsuperscript{305} Whilst if a child is injured in utero but is later born alive and dies of that injury, the person who inflicted the injury is guilty of murder or manslaughter, should the necessary required \textit{mens rea} exist.\textsuperscript{306} Furthermore, there are practical legal consequences of birth, such as being able inherit money, having a bank account and a birth certificate, and any person with parental responsibility can authorise treatment in the best interests of the child.\textsuperscript{307}

Whilst the traditional moment of birth is clearly marked by the act of departing the womb, Raskin and Mazor question: should the equivalent to birth be the moment of complete departure from the artificial womb?\textsuperscript{308} In this sub-section I will explore whether ‘birth’ should remain the same as uterine gestation (in other words, complete departure from the artificial womb) or whether the distinction between viability and birth should be removed altogether, thus rendering the ectogenic foetus ‘born’ from the moment he or she is ‘capable of being born alive’ or ‘viable’. This is illustrated through adapting the thought experiment from the introduction (imagining that Louise Smith has now developed to the point of viability):

Louise Smith was implanted in an artificial womb twenty-four weeks ago. She is presenting clear, visible symptoms of severe disabilities and the Ectogenic Research Centre wish to “switch off” her chamber. Her parents argue that she is fact already born - under the legal definition of birth - since she is separate from her mother’s body and ending her life would amount to the crime of murder. They also wish to begin legal proceedings for damages for the birth of a child suffering from disabilities.

\textsuperscript{305} \textit{Rance v Mid-Downs} per Brooke J who stated that the child must be fully extruded from the mother’s body and is ‘breathing and living by reason of its breathing through its own lungs alone’


\textsuperscript{307} All births must be registered within 42 days. Children Act 1989, s. 3(1) defines “Parental Responsibility” as “all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.” Parental responsibility includes the right to consent to medical treatment on behalf of a child, but the Children Act 1989 demands that parental responsibility must lawfully be exercised in the “child’s best interests” (s. 1).

\textsuperscript{308} J. Raskin and N. Mazor, \textit{Supra fn. 36} at 159
This scenario demonstrates the importance of determining exactly when the ectogenic foetus is considered ‘born’. In addition, to the aforementioned consequences of birth, the thought experiment illustrates a further consequence; that the child may claim damages (or its parents’ may claim on his or behalf) whilst in the artificial womb. Prior to the Congenital Disabilities (Civil Liability) Act 1976 (herein ‘the 1976 Act’), the common law in Burton v Islington held that a child born suffering from disabilities caused by medical negligence before birth could sue for breach of duty of care because the interests materialise at birth, whereupon the child is clothed with a right of action. Statute has come to the same conclusions via the 1976 Act, which states that a child who is born alive but disabled as a result of an occurrence before its birth may in certain circumstances have a cause of action against the person responsible for the child’s disability. The reality of this legislation is that the child in the womb is protected just as if it had been born, but any claim cannot be advanced before the child is actually born. However, applicability of both the common law and statute to ectogenesis may prove difficult.

Under s.1A of the 1976 Act, an extension has been placed to cover infertility treatments. Section 1A(1)(b) and (c) state that where the congenital disability results from an act or omission, it may be actionable as a result of the wrongful act of the person, who is ‘answerable’ to the child. However, applicability of both the common law and statute to ectogenesis may prove difficult. In particular, the interpretation of this section of

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309 However, it is not clear whether the parents could recover damages under negligence law through either the common law or statute.
310 This applies to all children born after 22nd July 1976. Furthermore, s.44 HFEA 1990 extents this to cover negligently inflicted disability in the course of licensed fertility treatment.
312 Congenital Disabilities (Civil Liability) Act 1976
314 S.1A(1)(c): “A person is under this section answerable to the child in respect of the act or omission, the child’s disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.”
the statute is to be construed in accordance with section 1(1) of the HFEA 1990. Whilst this section does not make specific reference to the use of an embryo beyond the appearance of the primitive streak, section 3 refers to ‘activities governed by the Act’ and specifically excludes any application of the Act to ectogenesis under section 3(3)(a), as explored in Chapter Two. As a result of this, it is unlikely that the 1976 Act will apply to ectogenesis. This also further evidenced through the defence in the Act that the affected parent ‘knew of’ the risk of their child being born disabled (that is to say, the particular risk created by the act or omission). Therefore, if the Smiths were informed of the act which resulted in Louise’s disabilities, and continued with her gestation, then their claim in damages would fail under the 1976 Act. Taken together, it would appear that both section 1A and the section 3(5) defence evidence the inapplicability of the 1976 Act to ectogenesis.

However, what can be taken from this exploration of the Act is that this is just one of many examples in which the legal implications of being ‘born alive’ bears enormous ramifications for all parties involved in ectogenesis. As explained previously, birth represents the highest level of protection for the ectogenic foetus or neonate, since from the moment it is achieved the child is no longer dependent upon a womb, natural or artificial, to exist or develop. Therefore, it represents the most important stage of development for the ectogenic foetus and careful consideration is required when considering the point at which the ectogenic foetus should be ‘born alive’.

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316 There are also difficulties in the common law with regards to whether the principles laid down in Bolam v Friern Hospital Management Committee [1957] 2 All ER 118 would apply.
317 Plus, any regulations under section 1(6).
318 As detailed in Chapter One, the creation of an embryo is a criminal offence without a licence (s.3(1) HFEA 1990 and a licence cannot authorize “keeping or using an embryo after the appearance of the primitive streak.” (S.3(3)(a))
319 Congenital Disabilities (Civil Liability) Act 1976, s. 3(5) provides: “Compensation is not payable in the child’s case if the injury to the parent preceded the time of the child’s conception and at that time either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the injury).”
320 A further issues is whether Louise could or should be able to sue her parents for not following the clinicians advice. Whilst the importance of law of informed consent in relation to ectogenesis cannot be underestimated, a full exploration of this area, when applied to artificial wombs is beyond the scope of this thesis.
3.5 When is the ectogenic foetus ‘born alive’?

The born alive rule is from the common law and holds that a person cannot be held responsible for injuries inflicted on a foetus in utero unless and until it is born alive. In English law, the rule dates back to the fourteenth century, though its roots can be traced back to Roman law, under which an unborn child was regarded as part of its mother. Generally, it consists of two parts: that the foetus must be completely separate from the mother, and that the infant must be alive at birth. Under the first element of the rule, a child is not considered to be in being until its whole body has been removed from the body of its mother. Whether or not the child has an independent existence generally turns upon whether it has independent circulation.

However, these numerous definitions cause various difficulties when applied to the ectogenic foetus because if a baby is only differentiated from a foetus by its removal from the mother’s body (through its ‘separate existence’ and ‘independent circulation’) then the point at which a developing ectogenic foetus is considered ‘born’ could be considered to be much earlier. In *Paton v B.P.A.S Trustees* Sir George Baker P stated: ‘[t]he foetus cannot...have a right of its own at least until it is born and has a separate existence from its mother.’ On this interpretation, it could be argued that

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323 Davis, Colleen, “Conjoined twins as persons that can be victims of homicide” Medical Law Review, 19, Summer 2011, pp. 430-466

324 In *R v Poulton* (1832) 5 C this was expressed as the moment when “the whole body is brought into the world” 330; quoted in *Rance v. Mid-Downs Health Authority* [1991] 1 QB 587. ‘Born’ in the context of the Congenital Disability (Civil Liability) Act 1976 has been taken to mean reaching the point at which the child has a life separate from its mother: S.4(2)(a) 1976 Act states: (a) “born” means born alive (the moment of a child’s birth being when it first has a life separate from its mother), and “birth” has a corresponding meaning; Also see *R v Brain* 172 Eng. Rep 1272 (1834) which held that the child must be “wholly in the world in a living state to be the subject of a murder charge”. *R v Trilloe* 174 Eng. Rep 674 (1842) held that the strangled infant (once fully produced from her mothers body) but before the umbilical chord had been severed was sufficient for complete birth. In *R v Tait* [1990] 1 QB 290 a threat against the life of an unborn child was not considered an offence under S16 of the Offences Against the Person act 1861.

325 *R v Enoch* (1833) 5 C & P 539; *R v Wright* (1841) 9 C & P 754. In the former, the court held that a complete birth was necessary before a child could be sufficiently alive, which was to be determined through the establishment of “independent circulation in the child”.

326 1 Q. B. 276

327 This was also raised in *Re F (in utero)* [1988] 2 All ER 193 where May LJ spoke of the ‘insuperable difficulties’ in enforcing any order to protect the foetus against its mother concluding that ‘[u]ntil the child is actually born there must be an inherent incompatibility between any projected exercise of warship jurisprudence and the rights of the welfare of the mother...[b]ecause the court cannot care for a child or order that others do so, until the child is born...[A]n unborn child has ex hypothesis, no existence independent of its mother’. At p.201 Whilst in *St George’s*
the independently growing ectogenic foetus, which is physically separate from his or her mother is in fact already born alive. However, independence from the womb and separate status are just two of the factors that the current law uses to determine whether a baby has been born alive. Therefore, in order to reach a conclusion, both elements of the ‘born alive’ rule must be discussed. In other words, in ‘order to be a legal person, an infant must not only be born [it must be]...born alive.’

However, although there is a clear definition of ‘birth’, I will show that the legal meaning of ‘life’ or ‘being alive’ is less than certain.

Traditionally, the courts have considered the ‘live-born’ question on the salient facts of each individual case, an approach that has produced differing results. Consequently, the common law position was described as ‘ambiguous’ in C v S. In this case, Heilbron J determined that a foetus of eighteen to twenty-one weeks’ gestation could show ‘signs of life’ though little explanation was given as to what was meant by this term. Heilbron J explored earlier judicial decisions and concluded that some assistance could be found in nineteenth-century cases, such as R v Handley.

In this case, Brett J directed the jury that a child was considered to have been ‘born alive’ when it existed as a live child, breathing and living by reasons of its own lungs without connection with the mother. However, in Rex v Poulton this was rejected as inconclusive proof of life after birth. In this case, the defendant strangled her baby to death and it was not clear from the facts, whether the child had died before or after the birth. The Court at the Old Bailey began its summation to the jury by holding that a conviction of homicide could not occur unless the subject was alive at the time of strangulation. The court concluded that being ‘born alive’ requires that the ‘whole body is brought into the world; and it is not sufficient that the child respires in the process of the birth.’

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Healthcare NHS Trust v S; R v Collins and Others ex parte S [1998] 3 All ER 673 the Court of Appeal stated, "Although human and protected by the law...an unborn child is not a separate person from its mother. At p.746

Davis Ibid fn. 323, p.438


Although it was unable to perform the function of lung respiration.

R v Handley (1874) 13 Cox CC 79.

(1832) 5 C & P 539,

Ibid at 998
Little clarification of the law was provided in the case of *Re A (Children) (conjoined twins: surgical separation)*.\(^{334}\) This case concerned conjoined twins, one of whom, Jodie, had a normal heart and lungs, whereas the other, Mary, had a ‘virtual absence of functional lung tissue’.\(^{335}\) Despite the opportunity to determine what was meant by the term ‘alive’, Ward LJ declined to comment, stating it would be ‘contrary to common sense and to everyone’s sensibilities’ to suggest that Mary was not ‘born alive’. He argued that she had clearly showed signs of life, even though she was incapable of breathing on her own.\(^{336}\) Davis concludes that this signals a move towards a ‘broader standard’ of life, which includes independent circulation and the child showing signs of life through breathing, crying or a heartbeat rather than through simply breathing alone.\(^{337}\)

Therefore, English law on ‘life’ provides little clarity as to when the ectogenic foetus may be deemed ‘alive’. At present, the law is a complex amalgam of ambiguous decisions, which present a lack of definitive answers. However, without any conclusive decision, how can one determine when an ectogenic foetus is ‘alive’ under the second strand of the ‘born alive’ rule?

It seems that in the absence of a clear and definitive answer to the legal meaning of ‘life’, one possible alternative is to look at the legal definition of still-born.\(^{338}\) This particular method was used in *Re A*,\(^{339}\) where Ward LJ and Robert Walker LJ explored the Births and Deaths Registration Act 1953, which defines a ‘stillborn child’ as ‘a child which has issued forth from its mother after the twenty-fourth week of pregnancy and which did not at any time, breathe or show any other signs of life: s 41 (amended by the Still-Birth (Definition) Act 1992 s 1(1)). A non-viable foetus expelled at a stage of pregnancy whereby a ‘separate existence’ would have been impossible, also does not fall under the definition of a ‘body’. However, body under the Coroners and Justice Act 2009 does include body parts (s.48(1))

\(^{335}\) Ibid at 975
\(^{336}\) Ibid at 1053 (Robert Walker LJ)
\(^{337}\) Davis, Ibid fn. 70 p.440-441
\(^{338}\) Inquiry into still-birth is also not a matter for the coroner unless there is doubt as to whether or not a separate existence has been achieved which once reiterates the importance of physically being detached form the female body. (Where a registrar is given information of an alleged still-birth and he has reason to believe that the child was born alive, he must report the matter to the coroner.) In the Births and Deaths Registration Act 1953, ‘still-born child’ means a child which has issued forth from its mother after the twenty-fourth week of pregnancy and which did not at any time after being completely expelled from its mother breathe or show any other signs of life: s 41 (amended by the Still-Birth (Definition) Act 1992 s 1(1)). A non-viable foetus expelled at a stage of pregnancy whereby a ‘separate existence’ would have been impossible, also does not fall under the definition of a ‘body’. However, body under the Coroners and Justice Act 2009 does include body parts (s.48(1))
\(^{339}\) [2000] 4 All ER 961; [2001] 2 WLR 480; [2001] 1 FLR 1; [2001] 57 BMLR 1
life’. Therefore, this definition attached importance to the twenty-fourth week of female gestation and indicated that after this point, the child must also show ‘any other signs of life’, although this has never been judicially defined.

As my next section will demonstrate, stretching the current legislation and case law to artificial gestation in order to determine when Louise Smith is ‘born’ may produce absurd results. As a result of this, the thought experiment presents a compelling case for specific and tailored legislation for ectogenic birth and the point in which it is necessary to grant the ectogenic foetus full legal personality.

3.6 When is Louise ‘born alive’?

Through exploring the case law and legislation in relation to the ‘born alive’ rule, there is a great deal of evidence to suggest that, when revisiting the scenario posed at the outset of this chapter, twenty-four week old Louise Smith could be determined to be ‘born alive’ from the point at which she is ‘viable’, rather than the point at which she would be decanted from the artificial womb at forty weeks. The reasoning behind this is as follows: from the point of the twenty-fourth week, she would survive in the event of having to be extracted from the artificial womb, she would be physically separate from her mother, and her circulation would not be dependent upon the circulation of another human being; thus falling under the elements of the current ‘born alive’ criteria.

However, this serves to demonstrate both the need for these issues to be carefully considered by a committee set up for this purpose and later the need for primary legislation to regulate ectogenesis, since any attempt to apply the current law causes confusion and incongruous results. Through consideration of the practical realities of birth, it would be nonsensical to suggest that, once Louise

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340 See the Registration of Births and Deaths Regulations 1987, SI 1987/2088, reg 33(1); and registration concerning the individual vol 39(2) (Reissue) para 540.
reaches approximately the twenty-fourth week of gestation (and is still developing in the artificial womb), she is ‘born alive’ and becomes a full legal person with legal rights. This would mean that Louise would be three months old at the point she was ‘decanted’ from the artificial womb. In the same way that Holland’s article begins with the idea that ‘a fortnight of my life is missing’\textsuperscript{341}, Louise would effectively lose the first three months of her life; she could inherit money, have a bank account opened in her name, and her birth would have to be officially registered whilst she was still developing in the ectogenic chamber.\textsuperscript{342} Yet at no point would independent breathing have taken place external to the chamber. At twenty-four weeks, she would still remain entirely dependent on the ectogenic chamber for full developmental support and might not survive to the point in which she lived external to the womb. On this basis, it seems incongruous to suggest that the bright line has been crossed towards full legal status for the ectogenic foetus.\textsuperscript{343}

3.7 Conclusions

It is important to remember that all of the authorities and statute discussed in this chapter remain of limited application to ectogenesis. In none of the decisions were the courts considering the question of ‘life’ in an ectogenic chamber, which is an entirely different question to that of life in the female womb. Being ‘born alive’ does not solely depend on legal and medical determinations about the beginning and end of life, but also stems from social and cultural views of what it means to be a person.\textsuperscript{344} An example of this can be found in the Warnock Report,\textsuperscript{345} which was created by the government to consider the ‘social, ethical and legal implications of recent and potential developments...relating to human fertilisation and embryology’.\textsuperscript{346} This went beyond legal and

\textsuperscript{342} Supra fn. 69
\textsuperscript{343} Alghrani and Brazier discuss the ‘bright line’ between the law’s classification of foetuses and babies: Alghrani, and Brazier, Supra fn. 50 at 52
\textsuperscript{345} Report of the Committee of Inquiry into Human Fertilisation and Embryology, (Cmd 9314, 1984)
\textsuperscript{346} Ibid.
medical stances on human embryology, and included oral submissions from the Chief Rabbi.\textsuperscript{347} This highlights the practical, legal, ethical and philosophical challenges of this area, and suggests that it is impossible to pursue a course of action merely through focussing upon the substantive law without consideration of the scene as a whole; the law does not operate in a vacuum.

However, despite the apparent problems with declaring Louise to be ‘born’ from the twenty-fourth week, an exploration of the law in this area indicates that, post-viability, there is some argument in granting the ectogenic foetus higher status than an \textit{in utero} foetus, although this should not amount to full legal personality. As I have demonstrated in this chapter, there are various stages in the development of the embryo and foetus, which affect the foetus’ protection such as implantation,\textsuperscript{348} viability and birth that contribute to making it worthy of varying levels of protection. Ultimately, it must be recognised that what the ectogenic foetus is classified as will affect the value and status conferred by the medical and legal profession. In turn, this will have wide-ranging consequences for viability and birth. As the next chapter will demonstrate, the location of the ectogenic foetus alters the level of protection, since the rights of the female body are no longer involved. In other words, once the dependency on a person for development and survival has been removed, the ectogenic foetus requires additional protections such as the right to not be ‘switched off’.

Consequently, this reiterates that the time is ripe for a new committee of inquiry to be established into ectogenesis. In light of the high degree of complexity surrounding the term ‘birth’, and the legal status it affords to the foetus, this would address the legal, ethical and social issues raised by ectogenesis. It should encompass both legal discussions on what it currently means to be ‘born alive’, how this might be adapted and developed for artificial wombs, and also a consideration of the philosophical, ethical and religious discussions.

\textsuperscript{347} \textit{Ibid} at p.95
\textsuperscript{348} Once an embryo implants in the uterine wall, any decision to terminate that life must fall under the abortion legislation, as discussed in Chapter Three.
Chapter Four: Square Pegs and Round Holes – Switching off the Ectogenic Chamber

4.1 Introduction

The removal of artificial gestation is perhaps the starkest of the issues discussed in this thesis, in that it involves the inevitable death of the foetus. At this point, it is not clear how artificial wombs will react to abnormalities in foetuses who naturally, might have miscarried in female pregnancy, although this does not always occur. Nor do we know if the chamber itself will cause abnormalities. The central issue addressed in this chapter is under what circumstances, if any, could the progenitors and/or the Ectogenic Clinic ‘switch off’ the chamber and thus end the life of the foetus? Such circumstances giving rise to this need include: in the event of parental disagreement, the progenitors changing their mind, or instances of the foetus developing abnormally.

English law has always protected the foetus; even today, termination of pregnancy is only lawful if it falls within one of the limited defences of the Abortion Act 1967. Yet, although abortion remains a heavily debated notion, the question of foetal rights to life versus negative reproductive interests\(^\text{349}\) has, thus far, not been answered in the context of artificial wombs. Perhaps the biggest challenge for ectogenesis is that it requires one to rethink arduous points that have already been decided upon, but in very different contexts. However, as Chapter Two demonstrated, thorough knowledge of the legal response to the dilemmas of living \textit{ex utero} foetuses is scarce, and ectogenesis represents the first time that the issue of the \textit{intrinsic} status of the foetus, removed from the female body will have to be fully explored and decided.

\(^{349}\) In other words, the right not to be a parent.
Ectogenesis raises complicated legal questions for abortion law. At present, little discussion has taken place as to the legal intricacies of ending the life of an ectogenic foetus which has been external from the female body at all developmental stages. Instead, most of the discussion has focused upon ectogenesis as a means ending the abortion debate. These arguments have focused upon the immoral act of insisting upon the death of a foetus when doing so is not necessary to protect anyone’s rights. Rosalind Hursthouse reminds us that it is important to remember that termination represents the destruction of new life:

[which] connects with all our thoughts about human life and death...To disregard this fact about it, to think of abortion as nothing but the killing of something that doesn’t matter, or as nothing but the exercise of some right or some rights one has...is to do something callous and light-minded.

The existing literature recognises that artificial wombs could end the abortion debate, because, if abortion is to be understood as the evacuation of the foetus from the mother’s womb, then removing the foetus and placing it in an artificial womb would provide a resolution to what has been a long-standing and vociferous debate. As Thomson states, ‘while I am arguing for the permissibility of abortion in some cases, I am not arguing for the right to secure the death of the unborn child.’ In her infamous violinist analogy she argues, ‘if I detach myself from the violinist and miraculously

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354 “You wake up in the morning and find yourself back to back in bed with an unconscious[famous] violinist... He has been found to have a fatal kidney ailment, and the Society of Music Lovers has canvassed all the available medical records and found that you alone have the right blood type to help. They have therefore kidnapped you, and last night the violinist's circulatory system was plugged into yours, so that your kidneys can be used to extract poisons from his blood as well as your own...To unplug you would be to kill him. But never mind, it's only for nine months. By then he will have recovered from his ailment, and can safely be unplugged from you.” Thomson argues that you may unplug yourself from the violinist even though this will cause his inevitable death because the right to life does not entail the right to use another person’s body. For the same reason, Thomson argues that abortion does not violate the fetus's right
he lives, I do not have the right to cut his throat.' Similarly, Warren too insists that there is no right to insist upon the foetus’s death in the same way one cannot insist that a viable infant be killed. Consequently, these philosophers believe that artificial wombs could end the abortion debate because if abortion represents the evacuation of the foetus from the mother’s womb, then the foetus could be removed and placed in an artificial womb.

However, for the small amount of empirical research that does exist for women’s attitudes towards ectogenesis, few would consider artificial wombs as a realistic response to an unwanted pregnancy. In the same way that adoption has failed to provide a resolution, ectogenesis will not resolve the abortion debate. In other words, women in favour of abortion rights believe that evacuating a foetus to an artificial womb represents abandonment, in a similar way to a woman who ‘relinquishes her child for adoption.’ For some women, due to their belief in the moral difference between a foetus and a baby, whilst they may be willing to terminate their foetus, they would be unwilling to give up a baby even if the pregnancy was unwanted. As Cannold argues, ‘[a]rtificial wombs do not remove [parental] responsibility from the mother, since her child would exist somewhere even if she did not have to care for him or her’ and it is precisely avoiding this ‘responsibility’ that causes women to exercise their choices. Therefore, the right to choose whether or not to become a mother gives rise to the right to terminate the foetus and artificial wombs as a means of ending the abortion debate cannot be stripped down to such simplicity.

Whilst these arguments need to be noted, as they have dominated debate on ectogenesis, I will be focusing upon the substantive law in relation to abortion as it may or may not apply to a foetus developing in the ectogenic chamber in this chapter. A key question when one considers ‘switching


355 Ibid.
356 Warren, Supra n.351
358 Ibid at 10.
off’ the ectogenic chamber in any circumstance is exactly how the creation of independent gestation will alter the way we think about the ectogenic foetus and what rights the ‘parents’ will have. Most crucially, foetal status has been discussed mainly in the context of female gestation. In this chapter, I explore these issues by attempting to place past and analogous debate about embryo and foetal status into the new context of ectogenesis. I contend that, growing in the artificial womb, the ectogenic foetus’ naturally determined status is entirely different to that of an in utero foetus and there may be some argument in the above claims that the progenitors do not always have the right to insist upon the ectogenic foetus’ death. However, it remains to be seen whether they have a right to keep him or her ‘alive’.

4.2 The Law on Abortion: The Offences Against the Person Act 1861

Son argues that the existence of artificial wombs requires legislators to revisit and revise existing abortion legislation since ectogenesis causes women’s interests and rights to be conflict with the state’s interests to keep the ectogenic foetus alive. Simonstein also agrees that ectogenesis could have significant consequences for abortion legislation, because existing abortion rights could be eroded due to the fact that abortion rights are rooted in women’s rights to bodily autonomy. This therefore demonstrates the inapplicability of the current legislation when examined in light of the development of ectogenesis because the rationale for ‘abortion’ is removed once the foetus is externally gestated.

There are a number of key preliminary points to make on the manner in which abortion legislation operates in England and Wales in order to rule out the possibility of any applicability to ectogenesis. The current law is regulated by several Acts of Parliament, which have developed over the past one hundred and fifty years, most notably before the term ‘ectogenesis’ had ever been

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360 Hyun Jee Son, *Supra* fn. 25
Firstly, the Offences Against the Person Act 1861 (‘OAPA’) criminalised the ‘procuring of miscarriage’. Its scope is broad, applying the offence not just to a woman who procured her own miscarriage but to ‘whosoever shall supply or procure’. The Act also places emphasis on who the offence occurs to (‘of any woman’). Therefore, under the current law, whether the ectogenic chamber could be switched off depends upon whether the act of ‘switching off’ would fall within the offence of ‘procuring a miscarriage’ contrary to s.59 of OAPA. This provides, so far as it is relevant:

[w]hosoever shall unlawfully supply or procure any poison or other noxious thing, or any instrument or thing whatsoever, knowing that the same is intended to be unlawfully used or employed with intent to procure the miscarriage of any woman...shall be guilty of a misdemeanour.

From the outset, it appears that applying the current law of abortion to ectogenesis poses significant legal problems. The central issue is whether ‘switching off’ the ectogenic chamber could fulfil the legal criteria for the offence of ‘procuring a miscarriage’. However, it is clear from the statute that, to violate the criminal law, the offence must occur to ‘any woman’; which closes down any possibility of this provision applying to ectogenesis since the act of ‘switching off’ would apply to a machine, rather than a ‘woman’. To fall within the wording of the criminal offence, the very scope of the OAPA would need to be creatively interpreted or amended to include the words, ‘to procure the miscarriage in an artificial chamber’. However, as I will further demonstrate, the entire legislative provisions in relation to abortion and ectogenesis are so different that new legislation is required.

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363 Which replaced earlier legislation.

364 The Act sought in broad terms to criminalise termination of pregnancy; providing a maximum sentence of life imprisonment for a woman who procured her own miscarriage, and a five-year sentence for a third-party who knowingly assisted.

365 There is no definition of miscarriage in English law, either in statute or in case law.
For example, there are further problems between the interplay of ectogenesis and the abortion legislation when one explores other legal provisions. Whilst it is worth noting that in 1929, Parliament passed a second statute in this area, (the Infant Life (Preservation) Act 1929), which introduced the offence of child destruction, this will not be further explored beyond what has already been stated in Chapter Three.

4.3 The Abortion Act 1967

The Abortion Act 1967 (‘The 1967 Act’) came into effect in April 1968 and fundamentally changed the law in this area. The 1967 Act, as amended by the HFEA 1990 provides limited statutory defences to the charges under sections 58 and 59 of the OAPA. As I have demonstrated, it is unlikely that the OAPA will apply to ectogenesis. Therefore, further exploration of the 1967 Act serves two purposes. Firstly, it bears significance for the central theme running throughout Chapter Three and Four, of the inadequacy of the current legislative framework. Secondly, when drafting legislation and ethical guidance for ectogenesis, it is important to consider the analogy of abortion in order to determine what the law with regards to ‘switching off’ the ectogenic chamber ought to entail.

4.3.1 Abortion Act 1967 s.1(1): ‘...a pregnancy is terminated...’

The wording of s1(1) of the 1967 Act states that the ‘pregnancy’ must be ‘terminated’. It does not explicitly state that the pregnancy must be a woman’s pregnancy, although it can clearly be inferred from the legislation that it is referring to the female body. This is further illustrated by the medical interpretations of the word ‘pregnant’, which Webster's Dictionary defines as ‘having conceived’

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366 Through causing the death of a child ‘capable of being born alive’.
367 Where new legislation for ectogenic foetal viability was recommended. It is worth noting that whilst the Infant Life (Preservation) Act 1929 forms part of the law in this area through imposing restrictions on the destruction of “viable” foetuses, for the purposes of avoiding repetition I will not be exploring the inapplicability of this legislation to ectogenesis since this has been fully dealt with in question one.
368 The Act was introduced in response to widespread evidence of unsafe illegal abortions and the maternal mortality and morbidity that inevitably result from this.
369 Section 37 of the HFEA 1990 amends the law relating to termination of pregnancy.
(or ‘the state of a female who has conceived’), whilst *Black’s Medical Dictionary* defines the term ‘pregnancy’ as ‘when a woman carries a baby in her uterus’. For artificial gestation in an ectogenic chamber that is completely removed from the female body, it is difficult to see how, or if at all, the legislation may be applicable. To fall within the wording of the current legislation, the Act would need to be amended to include the words ‘the termination of the foetus within the ectogenic chamber’. However, on the face of it, this would stretch the 1967 Act far from its original purpose, which was to pay attention to women’s needs through eradicating illegal, unsafe abortions.

Furthermore, the huge distinctions between abortion and ‘switching off’ the artificial chamber become even more apparent when one applies the defences within the 1967 Act to artificial gestation. The Act permits pregnancy to be terminated by a registered medical practitioner if two of such practitioners of the opinion, formed in good faith, that the four main defences under s1(1) to the OAPA are met. These are:

(a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to *the physical or mental health of the pregnant woman* or any existing children of her family; or

(b) that the termination is necessary to prevent grave permanent injury to *the physical or mental health of the pregnant woman*; or

(c) that the continuance of the pregnancy would involve *risk to the life of the pregnant woman*, greater than if the pregnancy were terminated; or

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370 Webster’s Revised Unabridged Dictionary (1913 and 1828); 1913
372 Without this legislation practitioners who ‘switch’ off the ectogenic chamber may remain open to prosecutions under the Offences Against the Person Act 1861 and the 1929 Act on the basis that the aborted foetus was ‘capable of being born alive’.
(d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.\(^ {374}\)

At present, the ‘social ground’ under s.1(1)(a), is the most common ground with, 98 per cent of abortions being performed under this basis in 2011.\(^ {375}\) Yet this ground also requires consideration to the pregnant woman and her risk of injury to her physical or mental health, or that of her existing children. Without the existence of female gestation, once again, the issue arises as to whether the rationale for the sections (a)-(c) disappears in light of ectogenesis.\(^ {376}\) Alghrani notes that the legislature and the court have only considered these phrases in the context of natural pregnancy,\(^ {377}\) and it seems that the whole thrust of provisions will have to be redrafted to apply to artificial wombs. In particular, it is difficult to see how this ground, or s.1(1)(b) or (c), will remain applicable to artificial wombs, which will not directly risk ‘injury’ to the physical or mental health of the mother if the gestation is continued, since she will no longer be carrying the child. This is further alluded to by the fact that the 1967 Act gives no right to a father to have any say in either the continuation or termination of the pregnancy since it is not his bodily autonomy which is at stake.\(^ {378}\)

Instead, the precedents make it clear that it is impossible for a father to mount a legal challenge to prevent abortion,\(^ {379}\) as the sole decider in any case (which fulfils the 1967 Act defences), is the pregnant woman.\(^ {380}\)

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\(^ {374}\) Emphasis added.


\(^ {376}\) S.1(1)(d) will be further explored later in this chapter. Unless being a mother in itself, even if she was never pregnant, would harm her.


\(^ {379}\) Ibid. International cases on this matter also include: Kelly v Kelly [1997] 2 F. L. R 828 and X v United Kingdom (Appl. No 8416/79, Commission decision of 13 May 1980) Where the Commission considered an application by a man complaining that his wife had been allowed to have an abortion on health grounds. The Commission ruled out any interpretation which would recognise an absolute right of the life of the foetus but avoided a decision as to whether the foetus had no rights or partial rights.

Although it is worth noting that the 1967 Act gives no specific right to the mother, her decision is at the heart of the matter for the doctors who are forming their decision in ‘good faith’, since any abortion performed against her will would amount to the crime of assault.\textsuperscript{381} Whilst critics claim that abortion is available on demand since gynaecologists may perform an abortion at the request of the pregnant woman, it is important to note that the woman has no right to demand an abortion. Instead, the law affords the right to doctors, who have the decision-making authority to decide whether a woman’s situation falls within the terms of the 1967 Act.\textsuperscript{382}

4.4 Foetal Rights and the Female Body

In order to understand the above arguments and the inapplicability of the abortion legislation to artificial wombs, it is also important to understand the context in which the current case law and statute has developed. The status of the foetus, removed from the female body, has been avoided as a discussion point in judicial debate due to the potential to infringe upon the rights of the female body. However, as I will demonstrate, despite a lack of discussion on the intrinsic status of the foetus, some arguments may be drawn from past debate. These indicate that, once removed from the female body, the foetus begins to have some rights per se as an independent rights-bearing human being, although the full determination of these rights remains to be explored later in this thesis.

The central premise of this argument rests in the dictum of Sir George Baker P in \textit{Paton v BPAS}\textsuperscript{383} where he stated ‘[t]he foetus cannot, in English law, in my view, have any right of its own at least until it is born and has a separate existence from its mother.’\textsuperscript{384} Implicit in this precedent is the view that ‘unless separate’ from the female body, the foetus does not have independent legal rights nor a

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\item[381] Whether the necessary opinions were formed in good faith is a question for the jury; \textit{R v Smith} [1974] 1 All ER 376, 58 Cr App Rev, 196, CA Anything done with intent to procure a miscarriage is unlawfully done unless authorised by the \textit{Abortion Act 1967}, section 1.
\item[382] This was made clear in \textit{Re T (adult: refusal of medical treatment)} [1992] 4 All E.R 649 where it was stated that a competent adult woman has a right to refuse treatment so that no third party can compel a woman to undergo a termination against her will.
\item[383] [1978] 2 All E.R. 987; [1979] Q.B. 276; [1978] 3 W.L.R. 687
\item[384] \textit{Ibid} at 279.
\end{itemize}
\end{footnotesize}
legal status. For ectogenesis it may be argued that the independently gestated and ‘separate’ foetus begins to establish that the foetus has having some rights which require legal protection. Ford aptly summarises this argument where she states:

[i]mplicit in the jurisprudence of pregnancy is a sense that things would likely be different… if the embryo or foetus was located elsewhere…the insurmountable obstacles of the woman’s body and her fundamental legal rights could be avoided, the kaleidoscope of interests and rights would shift to an entirely different picture.385

In this section I argue that re-positioning the foetus from the female body to the artificial womb creates a different picture; ‘a kaleidoscope’ of new interests and new rights which cannot simply be disregarded in the event of one progenitor (or both) changing their minds. Instead, further exploration of the rights of the ectogenic foetus needs to take place in order to determine what status this new setting affords the foetus, and whether its life may ever be terminated.386 However, it is important to note that it is difficult to predict exactly how the law will determine ectogenic foetal status, since there are no direct legal precedents for artificial wombs.

4.4.1 A Foetal Right to Life? – Vo v France

Vo v France387 concerned a twenty-week pregnant Vietnamese woman who was living in France and went into hospital for a routine antenatal appointment. Following an astonishing line of gross errors, she was negligently treated for the removal of a non-existent contraceptive coil and during the process her amniotic sac was ruptured. A week later, the pregnancy was terminated on health grounds. Mrs Vo sued the hospital and the doctor in both the civil and criminal jurisdictions alleging unintentional homicide of the child. The applicant’s petition alleged that the Cour de

386 Ibid
387 [2005] 40 EHRR
Cassation, the French court of last instance, had violated Article 2 in its refusal to treat the foetus as a person and thus prosecute the doctor for unintentional homicide of her 20-21 week old.\textsuperscript{389}

At the European level, this case was welcomed as the first opportunity for the European Court of Human Rights (‘ECtHR’) to directly determine the status of the foetus in a non-abortion setting.\textsuperscript{390} It also raised a new issue; whether, ‘harming a foetus should be treated as a criminal offence in light of Article 2’\textsuperscript{391} of the European Convention on Human Rights (‘ECHR’), when the pregnancy had been terminated as a result of the negligence of a doctor. Most importantly, it represented the first time in which the court had to directly confront the question of whether foetuses enjoyed a right to life because the issue here was not whether or not the mother had a right to an abortion but rather, whether the foetus was protected through the convention.

However, the ECtHR failed to reach an unequivocal decision as to whether Article 2 applied to the foetus. Instead, the court held that the issue fell within the ‘margin of appreciation’,\textsuperscript{392} thus refusing to determine the status of the foetus outside of abortion jurisprudence. This demonstrates that, even in a non-abortion contentious situation, the court still declined to interfere in the debate as the importance of female bodily autonomy was reasserted. The Court stated that, even if a foetus did enjoy a right to life, this would always be ‘implicitly limited by the mother’s rights and interests’.\textsuperscript{393}

By addressing the issues of the ethical debate and the current law on foetal status, the Court brought

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\item Article 2, European Convention on Human Rights; “Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided for by law.”
\item Expert evidence at the trial varied on the gestational age of the foetus, assessed to be between 20 and 21 weeks old and possibly older. One of the expert witnesses, Dr. G, said that the age of the foetus was ‘very close to that of certain foetuses that have managed to survive in the United States.’
\item For example, in Paton v United Kingdom (1980) 3 EHRR 408 At European level, the (now defunct) European Commission of Human Rights declined to express a view on the broad question of whether Article 2 recognises the right to life of the foetus at any later stage before birth because the foetus’s right to life did not outweigh the interests of the pregnant woman ‘s rights. The Commission ruled that Art 2(1) of the European Convention on Human Rights, the 'right to life', is subject to an implied limitation justifying termination of a pregnancy in its early stages in order to protect the life and health of the woman.
\item This decisions was based upon the following grounds: (i) the issue of the extent of protection has not been resolved within many of the states, and (ii) there was no European consensus on the scientific and legal definition of the beginning of life.
\end{itemize}
the issue of a foetal right to life to the forefront of the case and yet disappointingly failed to reach a conclusion. It represented the possibility of a landmark decision, however, ‘the troubling conclusion...is that there is no clear resolution to the status of the foetus.’ 394

However, the dissent of Judge Ress further reminds us that life, one of the main values of society, must be addressed and protected accordingly.395 He notes ‘specific laws on abortion would not have been necessary if the foetus did not have a life to protect.’396 Furthermore, the separate opinion of Judge Rozakis questions, ‘does the present inability of ethics to reach a consensus on what is a person and who is entitled to the right to life prevent the law from defining these terms? I think not.’397 The Convention is described as a living instrument, therefore criticism placed on the lack of a definitive conclusion in Vo has centred on the need for Article 2 to develop in light of modern technologies and ‘confront the real dangers now facing human life’.398 The foetus in this case was very close to the point of viability,399 and Judges Caflisch, Fischbach, Lorenszen, Thomassen and Rozaki thought that life had not been protected and thus Article 2 had been violated. They believed that even if the foetus did not have legal personality until birth, this should not mean that the foetus is not entitled to any right to life. This moves towards recognising unborn life as something that should be protected, but not to the same extent as ‘born’ children.

4.4.2 Context is Everything: Nothing and ‘Not Nothing’

One thing that can be inferred from Vo v France and the other case law and discussions on foetal status, is that there is a definite sense of sensitivity displayed towards the foetus. In H v Norway400 the European Commission stated that it would not exclude the possibility that, in certain

395 Ibid at fn. 299, per Judge Ress
396 Ibid
397 Ibid at fn. 299, per Judge Rozakis
398 Ibid at fn. 299, per Judge Ress
399 At 20-21 weeks old, see p.5-6 of the case
circumstances, Article 2 offers protection to the foetus, but it did not indicate what these were. It seems that although the courts are reluctant to conflict with female bodily autonomy, they are also reluctant to assert that the foetus is ‘not nothing’. Instead, case law and statute demonstrate that, whilst the foetus can be terminated (in accordance with the provisions of the 1967 Act), it is also viewed as having has ‘special status’ as a ‘unique organism’. In the context of research, the Polkinghorne Committee argues that foetuses should be treated with ‘profound respect based upon their potential to develop into a fully-formed human being’. Even Dworkin, who denies that there is a moral legal basis for protecting the life of the human embryo in the early part of the pregnancy, concedes that as the human embryo acquires sentience and the capacity for an independent existence it becomes morally entitled to legal protection.

There is a body of opinion that believe that foetal life is entitled to respect. However, in the context of natural pregnancy, this view cannot be imposed upon a woman on account of her right to bodily integrity. As a result of this, there has been a lack of coherent judicial discussion on the intrinsic status of the foetus, removed from the female body. However, what is evident from looking at the context of the aforementioned cases, is that the future technology of ectogenesis shifts the focus away from the female body and its inalienable rights, to that of the foetus. Without digressing too much on the circular debate of embryo and foetal status, it is possible to suggest that the loss of the pregnant body removes the foetus’ lack of legal standing, since life in the ectogenic chamber shifts the foetus’ rights and interests to an entirely different picture; a ‘kaleidoscope of new rights and interests’. In other words, liberating the foetus from the female body allows a

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Note: This text does not include the references cited in the document.
stronger argument that foetal life demands the aforementioned respect.\textsuperscript{409} The end result is that causing the death of an ectogenic foetus is not simply a right which the genetic progenitors may assert regardless of the foetuses rights and interests, even before the point in which I have argued that it is viable.

Instead, explicit legislation, which prohibits withdrawing consent from ectogenic gestation is required. This would prevent couples from ending the life of their ectogenic foetus mid-way through the process of artificial gestation. This is by no means advocating the principle that the foetus is ‘viable’ from implantation; instead, it is stating that reproductive choice remains fully autonomous up until the point that the life begins to develop in the artificial womb. From this point it is exactly that; life, and ought to be treated as such.

For ectogenesis, the parents of the foetus would have deliberately made the decision to create the ectogenic embryo and then gestate it in an artificial womb. To deliberately and intentionally create a human life and then end the process before completion would undermine the aforementioned special status granted to human embryos and foetuses. It would treat a foetus as a mere commodity; as something that can simply be created then subsequently destroyed. Preventing parents from switching off would also recognise the moral worth of embryos and foetuses. In other words, it could be argued that the state is justified in forcing a parent to bring an ectogenic foetus to term in order to assert the importance of developing foetal life, which requires state protection.

However, I do accept that there are a number of problems with the ‘point of no return’ model. It may be unjust to impose parenthood on reluctant parents, particularly considering the financial and emotional investments involved in raising a child. Steiger notes that if ‘point of no return’ situations did occur, it would be necessary to determine who pays for the foetus’ development and also who is

\textsuperscript{409} Ibid.
responsible for the child in the event that neither party could insist upon the termination of foetal life.410 Another problem is the issue of removing reproductive choice and control; in the sphere of natural conception and gestation, it is hard to imagine a society in which choice and reproductive liberty does not exist for. As Sheldon argues, ‘...it is unjust to impose responsibility where there is no ability to exercise control.’411

However, the main argument in opposition to this claim can be found in Blackstone’s Commentaries on the Laws of England, where it is stated that by choosing to beget a child that person has entered into a ‘voluntary obligation to endeavour that the life which they have bestowed shall be supported’.412 Robertson also contends that certainty about consequences is necessary in reproductive choice.413 Thus, for assisted conception, a situation in which individuals have carefully planned and decided to undergo a complex and sometimes costly medical procedure, there is some argument in claiming that the parties have entered into a ‘voluntary obligation’ to continue with that procedure until it reaches its natural end point. To look at the decision any other way, would, I believe, lessen the importance of both foetal life as a whole and the gestation of developing foetal life as something that does not matter.

Although disagreements about continuing the gestation of an ectogenic foetus may represent a rare scenario, Evans v United Kingdom414 shows that there is the potential for similar disputes in the future of ectogenesis, where one party wishes to avoid the legal, financial and emotional responsibilities that parenthood entails, whereas the other is fighting for the chance of genetic parenthood, in what may be their ‘last hope’ for a child. This would be particularly useful if the parties broke up during the process of artificial gestation. Without clear guidance before the parties

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410 E. Steiger, Supra fn. 27 at.143
413 J. Robertson, “Procreative Liberty and Harm to Offspring in Assisted Reproduction” 30 (2004): 7-40 American Society of Law, Medicine & Ethics
414 Evans v United Kingdom Application No. 6339/05, Judgment of 10 April 2007 (Grand Chamber) (Evans GC.)
embark upon ectogenesis, this may lead to tragic situations where one party feels their reproductive wishes and desires have been ignored. A possible resolution would be to create an agreement beforehand which fully informs the parties of the ‘point of no return’ from the moment of implantation.

4.5 The ‘point of no return’ model

English Law is not a stranger to parental disputes, with cases such as Paton v BPAS\textsuperscript{415} exhibiting conflict between pregnancy and reproductive rights. However, this issue has never been discussed in the context of artificially gestated foetuses removed from the female body. For independently stored embryos, Evans represents the closest decision to that relating to an artificial womb. The facts of this case are particularly tragic. In October 2001, Ms Evans was told that due to the presence of tumours, her ovaries would have to be removed and she embarked upon fertility treatment with her partner, Mr Johnston, to maintain her chance to have a genetically related child. However, their relationship later ended and Mr Johnston wrote to the clinic to inform them of his withdrawal of consent to the use and storage of the embryos. In the High Court, Wall LJ held that consent to the use of gametes could be withdrawn after fertilisation. The Court of Appeal upheld this judgment and leave to appeal to the House of Lords was refused. The majority of the Grand Chamber also agreed that there had been no violation of Articles 2, 8 and 14 of the ECHR, and therefore Miss Evans was not entitled to use embryos created with her oocytes and Mr Johnston’s sperm.

Critics have argued that this case begins to show ‘what might happen if the bodily autonomy of the woman…is not automatically decisive of the legal outcome - as they are in pregnancy cases - but are simply weighed in the balance’.\textsuperscript{416} As Arden LJ states, the wider issue to be considered is that in a world in which many people have come to accept a woman’s right of choice as to whether or not

\textsuperscript{415} This case involved a dispute regarding termination of pregnancy whereby Mr Paton sought an injunction to restrain the defendants from terminating his estranged wife’s pregnancy.

\textsuperscript{416} M. Ford, \textit{Supra fn. 385}
she should have a child, it appears that now, the genetic father should have that equivalent right.\textsuperscript{417}

This particular point bears some significance later, in discussions on foetal disability under s.1(1)(d) of the Abortion Act 1967.

Whilst \textit{Evans} held that consent may be withdrawn after fertilisation, and that equal weight ought to be given to each progenitors decision, for ectogenesis I argue that once the embryo is implanted, consent cannot be revoked. Draper advocates a similar premise in her ‘point of no return’ model.\textsuperscript{418} She argues that in the context of disputes over embryos there is merit in having binding agreement that creates a ‘point of no return’ once the decision has been made to fertilise the embryo.\textsuperscript{419}

However, for ectogenesis, the act of implantation would justify continuing with the ectogenic process, thus creating a ‘point of no return’ once the decision has been made to implant the embryo. This would serve a number of purposes; firstly, it would underline the seriousness of the act of implantation and prevent the iniquity of ‘switching off’ a perfectly healthy foetus, which would have otherwise survived. Secondly, it would create certainty for couples and their reproductive choices when embarking upon ectogenesis. Finally, it also serves the purpose of recognising the change in status for the \textit{ex utero} foetus and it is in accordance with the aforementioned laws on foetal status. However, the key issue that remains is whether couples could be forced to continue with the artificial gestation of their offspring, when it is against their express wishes. As Himmeltwelt reminds us, forcing progenitors to continue the gestation of an unwanted foetus is ‘cruel’ when parties are ‘unwilling and reluctant.’\textsuperscript{420}

The current law under the HFEA 1990 provides guidance and regulation regarding the consent provisions for embryos. It provides that embryos that have been created \textit{in vitro} can only be used

\textsuperscript{417} Evans (C.A.), at 89.
\textsuperscript{418} H. Draper, “Gametes, consent and points of no return” \textit{Human Fertility} 10(2): 105-109 (2007)
\textsuperscript{419} Ibid.
\textsuperscript{420} Himmeltwelt in R. Rowland, \textit{Living Laboratories: Women and Reproductive Technology} (USA, 1992) p.284
within the terms of ‘an effective consent’ from each of the parties whose gametes were used to create it.\textsuperscript{421} It provides that this consent can be varied or revoked at any time preceding the moment that the embryos are used for implantation via IVF.\textsuperscript{422} The courts will also employ the common law relating to consent when interpreting the statutory principles. Therefore, under the present law, consent for storage of embryos can be varied or revoked at any point until the embryo is implanted in the female body.

However, to develop the above principles for application to artificial wombs may be seen as detrimental to reproductive choice and ‘abortion’ rights. A potential criticism of removing parties’ consent is that this may this may lead to infringements upon a woman’s right to choose to have an abortion. Such issues coalesce around the discussions raised earlier in this chapter regarding ectogenesis as a means of ending the abortion debate and whether reproductive ‘choice’ would be diminished as a result of ectogenesis. However, this choice would also include a father’s choice, as earlier demonstrated in the discussion of Evans,\textsuperscript{423} which was about the right to bring life into being, and not just the right to life.\textsuperscript{424}

In spite of these criticisms, the ‘point of no return’ is the most effective way of protecting the rights of all participants, including the foetus. This is on the premise that if the progenitors are fully informed of the consequences of implantation and agree to this via express and written consent, it

\textsuperscript{421} Schedule 3, para 6(3): “An embryo the creation of which was brought about \textit{in vitro} must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose and the embryo is used in accordance with those consents.”

\textsuperscript{422} Schedule 3, para 4(1): “The terms of any consent under this Schedule may from time to time be varied and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant.” Although it further adds under para 4(2): “The terms of any consent to the use of an embryo cannot be varied, and such consents cannot be withdrawn, once the embryo has been used (a) in treatment services, or (b) for the purposes of research.”

\textsuperscript{423} The ratio of this case demonstrated that both parents have an equal say as gamete donors which justifies either party withdrawing consent prior to implantation in the woman’s body. This is also on account that the embryos were not in the female body which further warrants equal say.

\textsuperscript{424} \textit{Ibid} at [19]. This entitled the father in this case to withdrawn his consent. With regards to the applicants claims that the embryos had a right to life under Article 2, Thorpe L.J. in the Court of Appeal stated, ‘there can be no independent right…no Convention jurisprudence extends the right [to life] to an embryo’. (Para 19) Similarly, in the Grand Chamber it was held unanimously, that there had been no violation of Article 2, because in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of the right to life came within the margin of appreciation: There had been no violation. (para 54-55)
would be clear to both parties throughout the process that the act of implantation represents a significant milestone. After all, this is not something that can happen accidentally, by virtue of not giving it much thought. The process to gain access to an artificial womb is likely to be complex, costly and full of safeguards including consent forms, detailed advice and discussions with the medical profession. It is unlikely that the progenitors would take the decision to implant an embryo in the ectogenic chamber lightly, and a decision to switch off the ectogenic chamber on account of change-of-heart scenarios is not something that ought to be permitted in the circumstances discussed above. Despite this, implementing the point of no return in practice may prove tricky and cause future litigation in circumstances similar to Evans, where one party feels that their reproductive choice is being ignored.\textsuperscript{425}

\textbf{4.5.1 Pre-and Post-Conception Arrangements: A Panacea?}

Booth states that a resolution to any ART dispute can be found in ‘the appropriate consents before embryo transfer or insemination takes place.’\textsuperscript{426} At present the current consent provisions for IVF are contained in the HFEA 1990, which contains specific terms of consent for the use of any embryo.\textsuperscript{427} This must include specification as to the purpose of any conditions subject to which the human embryo may be so used\textsuperscript{428} and any maximum period of storage (if less than the statutory period). In particular, consent to the use of a person's cells may be varied, or the consent may be withdrawn in accordance with Schedule 3 generally, or in relation to a particular embryo or embryos.\textsuperscript{429} The paragraph further provides that consent may not be varied or withdrawn once the

\textsuperscript{425} It is also likely that such a rule may also cause claims that it is not compliant with the Human Rights Act 1998, although this is beyond the scope of this thesis.


\textsuperscript{427} (1) use in providing treatment services to the person giving consent, or that person and another specified person together; (2) use in providing treatment services to persons not including the person giving consent, (3) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques; or (4) use for the purposes of any project of research, and may specify conditions subject to which the embryo may be so used. As contained in HFEA 1990, Schedule 4 para 2.

\textsuperscript{428} Human Fertilisation and Embryology Act 1990 Sch 3 para 2(1A)

\textsuperscript{429} The person giving consent must be informed that 'the terms of any consent … may from time to time be varied, and the consent may be withdrawn, by notice to the person keeping the relevant gametes or embryo'.
embryo has been used, either in providing treatment services, or for the purposes of any project of research.

Some criticism may be placed on these provisions which lack certainty for the parties embarking on reproductive technologies whilst the embryo is in storage, since at any point either party may change their mind and revoke consent prior to the use of that embryo in ‘treatment services’. This particular issue was challenged in the aforementioned case of Evans. The key question was whether consent given to IVF treatment was like consent to any other form of medical treatment, in that it can be withdrawn at any stage prior to completion of the treatment or course of treatment. The applicants sought to establish that consent to IVF treatment was a different form of consent order, moving towards the ‘point of no return’ model because the nature of a promise for IVF could not be revoked.

In his analysis of the consent provisions, Wall J began by reaffirming the centrality of the 'twin pillars' of the HFEA 1990 which are the principles of the welfare of any child born by treatment under its provisions, and the requirement of consent from those participating in the treatment. He held that the only consent given by each of the defendant male gamete providers had been for treatment ‘together’ with his partner, which, since they had separated, did not occur together. There was, therefore, no effective consent by the male gamete providers to the continuing treatment of the claimants on their own. The requirement that couples embarking on IVF treatment were in agreement about the treatment, and that it should be possible for either party to withdraw from it at any time before implantation in the female gamete provider, was deemed to be entirely appropriate in the circumstances. This upheld the principles of the HFEA 1990, since it was held that the wider public interest of the proper operation of the scheme did not allow giving unequivocal consent to

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430 'Treatment services' means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children. HFEA 1990 s.37
431 per Wall J at 2
432 Ibid at 37.
433 Ibid at [133], [134], [136], [137], [147], [149].
the use of embryos, irrespective of any change of circumstances. It would not be unconscionable to allow a male gamete donor to withdraw consent, particularly given the observation that each of them would be liable to maintain any children born under s.1(1) of the Child Support Act 1991. Wall J recognised that the right of either party to withdraw consent to infertility treatment together is not only fundamental to the scheme of the 1990 Act, but is also protected by Article 8 ECHR.

However, ectogenesis represents a different scenario to that of IVF, which requires new legislation to permit pre-conception arrangements once the embryo has been used in ‘treatment services’. This is in line with the current model via the HFEA 1990, although the rationale behind withdrawing consent on this basis is entirely different. For IVF, consent cannot be withdrawn once an embryo has been used, because a woman cannot be forced to undergo a termination. However, in the context of ectogenesis, I am arguing for a pre-conception agreement, which would be legally binding once the embryo has been implanted in the artificial womb. This would serve to protect the rights and interests of the embryo and foetus and provide certainty to the parties embarking upon this technology. However, as previously stated, this could impact upon the abortion debate due to granting some rights and status to the ectogenic foetus.

Rebuttal to these criticisms can be found in an analysis of the differences between artificial gestation and pregnancy. Creating a pre-conception arrangement and preventing parties from ‘switching off’ the ectogenic chamber is an entirely different scenario to a woman’s pregnancy and her rights to bodily autonomy. Firstly, artificial gestation would be deliberately created. There would be no cases of rape, unwanted pregnancy or where continuing with the pregnancy would damage the woman’s physical or mental health. Secondly, artificial gestation would not trigger any claim of bodily autonomy on account of the fact that a woman’s body will not be involved in the gestation of the child. As a result of this, the interests and rights of the ectogenic embryo and foetus ought to be protected and the moral worth of developing life ought to be recognised.
4.5.2 *A B and C*: ‘This is not a case of dry legal contract’

It is therefore necessary to put certain measures in place to fully inform the parties as to the consequences of implantation, and to create agreements which clarify the parties’ intentions when embarking upon artificial gestation. Although raised in the context of parental responsibility, the judgment of *A v B and C*[^434^] highlights the difficulties of applying any pre-conception arrangements once parties change their mind. In this case, B and C wanted to have a child and A offered himself as a sperm donor. The parties’ intentions were that any child would be born into the household of B and C who would be the primary care givers; A would be welcomed and acknowledged as the biological father but his relationship with his son would be secondary. Soon after conception, the parties began to have fraught discussions about contact arrangements for M (the child). Two years later, A applied for a defined contact order and B and C responded with an application for both a joint residence order and a specific issue order relating to A’s exercise of parental responsibility.

At first instance HHJ Jenkins increased A’s contact hours but substantially upheld B and C’s case. He held that A's role in M's life should be secondary; enough for M to know who his father was but not so much as to fracture the ‘nuclear family’. A appealed. The appeal was unanimously allowed and Thorpe LJ chose to ignore such an arrangement, adding that ‘[w]hat happened here shows graphically how plans change over time...No matter how detailed their agreement, no matter what formalities they adopt, this is not a dry legal contract...human emotions are powerful and inconstant’.[^435^] He held that the father's right to play a role in his son's life had to be recognised despite the women's desire to create ‘a two-parent lesbian nuclear family’.[^436^]

This judgment therefore highlights the complexity of creating strict and prescriptive law in relation to this area. Whilst it is evident that a basic framework is needed to allow couples embarking on ectogenesis to have reproductive certainty, relying upon any form of pre-conception agreement is

[^434^]: [2012] EWCA Civ 285
[^435^]: Ibid, Lord Justice Thorpe at 27.
[^436^]: Ibid.
‘fraught with risk’.\textsuperscript{437} Furthermore, the legislature has made it clear that prior agreements made between the parties will not be enforced and are not currently legally binding.\textsuperscript{438} Despite this, the need for certainty in pre-conception arrangements for ectogenesis exists, and, it will be necessary to clearly inform the parties when embarking upon artificial womb technology in order to avoid future litigation in this area.

\textbf{4.5.3 Exceptions to the ‘point of no return’ rule: The Disabled Foetus}

Whilst I am not arguing for the permissibility of termination for genetic progenitors who have changed their mind or who wish to exercise reproductive choice, in certain circumstance ‘switching off’ the abnormally developing foetus or the foetus with innate genetic abnormalities may be permissible. The question of whether the possibility of the ‘disabled ectogenic foetus’ may ever arise is also an important one, particularly for the first child ‘decanted’ from the artificial womb. However, if errors do occur in the laboratory or during the development of the embryo or foetus, ‘pulling the plug’ in the process of ectogenesis would raise problematic questions in light of the change of status that I have advocated. Furthermore if ectogenic foetuses cannot be switched off from the moment of implantation due to parental disputes or ‘change of heart’ scenarios on account of the incompatibility of the abortion legislation with ectogenesis, is it possible to ‘switch off’ the ectogenic chamber at all? Can newly drafted provisions allow for the termination of severely disabled ectogenic foetuses? Or should any legislation move towards the current guidance and case law for withholding and withdrawing life sustaining treatment for neonates born with severe impairments?

Considering the thought experiment adapted from Chapter Three, Louise Smith demonstrates the problems caused by research towards the first ectogenic foetus. This scenario imagines that Louise

\textsuperscript{437} ML and AR v RWB and SWB [2011] EWHC 3431 (Fam)
\textsuperscript{438} Schedule 3 of The Human Fertilisation and Embryology Act 1990 provides both gamete progenitors with the statutory right to withdraw or vary consent to the use of an embryo created through IVF up until the moment of implantation in a woman.
has progressed to the point of twenty-eight weeks’ gestation. However, it is becoming increasingly clear that her development has gone horribly wrong and any further treatment in the ectogenic chamber would be medically futile:

At twenty-eight weeks gestation, Louise Smith’s disabilities are clearly evident in the artificial womb. Her brain, heart and lungs are significantly under-developed, and all efforts by the medical team at the Ectogenic Research Centre to rectify this situation have come to no fruition. It is likely that she will die once decanted from the artificial womb, and if not, will lead a life blighted with disabilities of the utmost severity. Can the doctor advise her parents to “switch off” the chamber in Louise’s best interests?

Key preliminary issues are raised, such as whether Louise could be ‘switched off’ before she even had chance to ‘exist’ external of the womb, or whether she should be allowed to continue to develop abnormally, despite clear evidence of severe disabilities? Imagining the scenario from a number of perspectives, it is clear that any decision to ‘switch off’ in these circumstances is difficult. If Louise is not ‘switched off” it is difficult to see whether continuing to sustain her life is in her best interests. However, her parents (who had anticipated the arrival of a healthy baby) are now faced with the difficult dilemma of ending the life of their child, which they wish to avoid at all costs, regardless of the evidence of severe disabilities.

At present, many parents are faced with a similar dilemma under s.1(1)(d) of the 1967 Act which allows for the termination of the foetus’ life at any point until birth if the practitioner believes that ‘there is substantial risk that if the child were born it would suffer from physical or mental abnormalities as to be seriously handicapped’ (and the pregnant woman consents to the termination).\footnote{The relevant part of s. 1(1) of the Abortion Act 1967 as amended by the HFE Act 1990 reads:}  

\footnote{The relevant part of s. 1(1) of the Abortion Act 1967 as amended by the HFE Act 1990 reads:}
development of ectogenesis, analysing the provisions in relation to s.1(1)(d) acts as an analogous situation in which the rights of the disabled foetus have been discussed by both academics and legislators.

At present, s.1(1)(d) is a rare outcome, both in terms of the total number of pregnancies and the total number of abortions; approximately one per cent of all abortions in England and Wales are carried out solely under this sub-section. Access to abortion on this ground depends upon two doctors agreeing that a particular handicap is ‘serious’ and that the risk of it materialising is ‘substantial’. There is no time limit, nor a specific requirement to take into account the rights of the female, (other than the mother’s consent). In fact, although there is guidance from the RCOG, there is a lack of clarity as to what amounts to a ‘substantial risk’ of serious foetal handicap and difficulties are caused by the assessment and estimation of these terms when attempting to observe the foetus via ultrasound examination. As Wicks illustrates:

The more difficult question arises where an abnormality is seen which raises the possibility of handicap, but where the chances of the handicap being serious are uncertain, for example, with an apparently isolated cleft lip, or a minor abnormality of the hands or feet. The point here is that... the ultrasound scan could represent the first signs of a serious handicap which might not present itself until after birth.

“Subject to the provisions of this section, a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by a registered medical practitioner if two registered medical practitioners are of the opinion, formed in good faith ... (d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped”.

R. Scott, Ibid.
E. Wicks, Human Rights and Healthcare (Oxford, 2007) 185
Ectogenesis represents an obvious solution to this dilemma because these observational difficulties may be resolved when the disabilities evidencing themselves in the foetus can be clearly seen in the artificial womb. In his book, Designing Babies: The Brave New World of Reproductive Technology, Gosden describes the difficulties of foetal observation in the female womb and the changes the new viewpoint of artificial gestation may bring:

Although much research has been done on fetal gestation, we have not yet been able to directly and continuously observe development of the fetus from birth. Even using the variety of new observation technologies, such as fiber optic photography, thermocameras, ultrasound and computer generated imaging, the womb is still a fundamental barrier to the accessibility to, and observability of, the fetus.

Evidently, one consequence of increased accessibility and visibility of the foetus developing in the womb, is the fact that any physical abnormalities will be detected and clearly observed. One of the key problems with using s.1(1)(d) (or a similar model) for ectogenic foetuses, is that it is intended for situations where disabilities are ‘potential’ due to the inability to clearly observe disabilities in the female womb. This particular issue was brought to the fore in Jepson v. The Chief Constable of West Mercia Police Constabulary where Reverend Joanna Jepson asked the West Mercia Police to investigate doctors who had authorised an abortion for cleft lip and palate at 28 weeks. Although no prosecution was brought, the case received a huge amount of publicity on late
Abortions for what has been termed ‘eugenic practices’.\textsuperscript{449} Despite calls for cleft lip and/or cleft palate to be excluded from being classified as a ‘serious handicap’, the RCOG’s view is that in some cases, cleft palates are symptoms of more serious conditions which are difficult to assess prior to birth.\textsuperscript{450} In particular, research has shown that children with cleft lip and palate often have associated malformations such as problems with brain development\textsuperscript{451} or congenital heart disease,\textsuperscript{452} and it is on this basis that seemingly minor abnormalities such as ‘cleft lip’ are able to fall under the current scope of s.1(1)(d). However, for artificial wombs it is difficult to find any application of s.1(1)(d) without allowance of some form of eugenic practice. This is due to the combination of the broad basis of the application of ‘serious handicap’ and the ability to clearly observe the whole spectrum of the foetus’s disabilities in the artificial womb.

For ectogenesis, it is much more likely that doctors will be able to accurately and precisely predict disabilities and monitor the foetus’ development. As a result, clear guidance is required to determine what may happen in situations in which the ectogenic foetus is clearly disabled. Since the current abortion legislation cannot be applied, creating legislation akin to s.1(1)(d) of the Abortion Act is inadequate for the ectogenic device. Instead, guidance may be found in the current ethical guidelines for severally disabled neonates whose lives are medically futile. Instead of focusing upon vague concepts such as ‘substantial’ and ‘serious’ abnormality, focus should be upon the concepts of ‘intolerable’ suffering where the continuing life sustaining treatment is medically futile\textsuperscript{453} and not in the foetuses ‘best interests’.\textsuperscript{454} This viewpoint is also shared by Sheelagh McGuinness who

\begin{itemize}
  \item \textsuperscript{449} McGuinness, Sheelagh. "Law, Reproduction and Disability: Fatally ‘Handicapped’?" \textit{Medical Law Review} 0 (2013) pp.1
  \item \textsuperscript{450} Royal College of Obstetricians and Gynaecologists, “Abortions for fetal abnormality and sydromatic conditions indicated by cleft lip and/or palate” Available at: http://www.rcog.org.uk/what-we-do/campaigning-and-opinions/briefings-and-qas/-human-fertilisation-and-embryology-bill/abort#_ftn6 (last accessed April 12th 2013)
  \item \textsuperscript{453} Ibid.
\end{itemize}
criticises the legitimacy of section of s1(1)(d). She suggests that it is currently operating beyond any plausible legitimate interpretation of that ground, and that if the 1967 Act was drafted today, ‘it would be difficult to justify the inclusion of a broad ‘disability’ indication [since]...the way in which disability is framed in the Act is inconsistent with other areas of medical practice.”

Instead, she concludes that we should ‘reject the language of handicap and focus instead on concepts like suffering’, as we have with other areas. Scott also argues for consistency between the treatment of foetuses and neonates on the basis that, ‘if it is in the best interests of a neonate to withdraw treatment, it must also be justifiable to terminate the life of a fetus [sic] with a condition of the same degree of severity.’

Therefore, a suitable way to frame ectogenic foetal terminations due to severe abnormalities is to permit ‘switching off’ on a similar basis to that of severely disabled children and neonates. Similar decisions to that of Louise Smith are routinely made in the care of terminally ill children. In NICU it has been estimated that up to seventy per cent of deaths, are preceded by discussions about limiting or withholding treatment. The Royal College of Paediatrics and Child Health (‘RCPCH’) have issued guidance about the circumstances when decisions to withhold or withdraw life-prolonging treatment are justifiable. Yet, despite this guidance, a number of cases have come before the courts concerning parental disagreement with the medical profession over whether the child’s situation is unbearable or their treatment is futile.

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455 Mcguinness, Supra fn. 449.
456 Ibid at p.2
457 Ibid at p.30
460 Ibid. These recommendations are fully documented in Chapter Five.
The test that the courts apply when faced with applications is the ‘welfare principle’, which requires that the child’s best interests be the paramount concern. However, this is a difficult principle to apply, when one considers that it may be viewed to always be in a child’s best interest to continue living. Some judges have asked whether continued life would be an intolerable burden to the child. In Re B (A Minor) Templeman LJ suggested that the child’s life must be ‘demonstrably awful’ before non-treatment can be contemplated. In this case, it was held that Down’s syndrome does not lead to such a life, whereas profound brain damage accompanied by paralysis and deafness does. Jackson argues that what seems evident through the wealth of case law is that the courts are guided by medical evidence and will not order doctors to treat children contrary to their clinical judgment, as occurred in Re Wyatt (A Child) (Medical Treatment: Parents’ Consent). In this case, in light of the medical evidence, it was held that the baby’s interests were to be kept comfortable and should she stop breathing, she should be allowed a peaceful death. However, it is important to note that in Glass v UK, the Court endorsed a strong presumption in favour of the parents’ claim to have a voice in the outcome of their children’s care. It was held that only in a genuine emergency should doctors override parental wishes without a court order and where agreement is not reached, doctors may not unilaterally override the wishes of a child’s parents since courts retain the authority to do so. There must be a hearing in court or before some independent tribunal for the final arbitration of otherwise irresolvable disputes.

463 [2008] EWHC 1998 (Fam)
465 Supra fn. 461
466 [2004] 1 FLR 1019, ECHR.
467 Recent court decisions have also upheld this, such as Re OT (A Baby) [2009] EWHC 635 (Fam), [2009] EWCA Civ 409 this case involved a nine-month old child who suffered from mitochondria, a progressive neuro-metabolic genetic condition that meant he was unable to swallow and was dependent on a ventilator. He had also suffered irreversible brain damage. Despite doctor advice that continued treatment was futile and would cause further distress, both parents strongly disagreed. However, the court accepted the expert evidence and made the declarations sought by the hospital trust, which sadly resulted in the child’s immediate death. Also see Nuffield Council on Bioethics, Supra 297 for guidelines in relation to withholding or withdrawing treatment and GMC Guidance, Treatment and care towards the end of life: good practice in decision making (1 July 2010). Available at: http://www.gmc-uk.org/guidance/ethical_guidance/end_of_life_care.asp
4.6 Can Louise be ‘switched off’?

Through exploring which appear to be similar on some of the facts to that of Louise Smith⁴⁶⁸, it may be possible to attempt to reach a determination as to what decision the courts may make in the present case. In Re C (A Minor) (Wardship: Medical Treatment),⁴⁶⁹ C suffered from an extremely severe hydrocephalus, and her brain was poorly formed. She appeared to be blind and virtually deaf and, at sixteen weeks, she was significantly underdeveloped and the size of a four-week-old baby. The damage was irreparable and the prognosis for the child’s life was ‘hopeless’: death was inevitable within a matter of months. At first instance, Ward J declared that it would be lawful for C’s life to be ended to allow her to die peacefully with the greatest dignity.⁴⁷⁰ In the Court of Appeal the decision was upheld, although this phrase was deleted from the judgment. Lord Donaldson MR distinguished C’s case with that of Re B because C was inevitably dying and her life offered her no pleasure, only suffering. Consequently, it would appear from cases containing some similar facts to that of Louise Smith (although this is by no means a perfect analogy), the courts would allow ‘switching off’ of the chamber to end Louise’s life.⁴⁷¹ However, it is important to note at this juncture that any decisions involving palliation rather than continuation of life-enabling treatment are profoundly difficult and contentious. Nevertheless, providing a clear, reasoned and compassionate approach for the medical profession to follow in the event of problems with the artificial womb process is necessary.⁴⁷² In Chapter Five, I will demonstrate that for severely disabled ectogenic foetuses, a similar framework than that of neonates whose lives are medically

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⁴⁶⁸ Although I recognise that there are a number of differences between these cases and my thought experiment.
⁴⁷⁰ Fam 35, All ER 787
⁴⁷¹ For jurisdiction it is most likely for UK based clinics, the claim would be brought in a UK High Court in accordance with Civil Procedure Rule 7.1 and the Practice Direction 7A, paragraph 2.4(2). It may be that to protect themselves from actions brought in a patient’s home court, the Ectogenic clinics could insert a jurisdiction clause in their documentation stipulating that any litigation must be pursued in the same country as the clinic.
⁴⁷² “The framework is not a prescriptive formula to be applied in a rigid way in all cases but an attempt to guide management in individual cases with the fundamental aim to consider and serve the best interests of the child.” Taken from Royal College of Paediatrics and Child Health: Withholding or Withdrawing Life Sustaining Treatment in Children: A Framework for Practice (second edition) 2004. Available at: http://www.rcpch.ac.uk/system/files/protected/page/Witholding%20...pdf last accessed April 4th 2013.
futile ought to be applied. This would justify the withdrawal or withholding of treatment for the severely disabled ectogenic foetus.

However, what if, despite being given a clear explanation of Louise’s prognosis, Jane and Henry Smith (Louise’s mother and father) choose to reject the doctor’s advice and refuse to sign the parental consent form required to ‘switch off’ Louise? Can the doctors proceed anyway on the basis of the research consent form (as outlined in the introductory thought experiment to Chapter Three?) Under the current law, parents are invested legally with the proxy power to consent to medical treatment on behalf of their children.473 However, this power must be exercised reasonably in the best interest of the child and it is likely that in the present circumstance, the doctors will seek a decision from the courts.474

Although it could also be argued that on account of the ectogenic foetus’ significant change in status from approximately the twenty-first to the twenty-sixth week of gestation in the artificial womb, the courts may be prepared to make the foetus a ward of court. The attitude of the courts to this possibility can be seen in Re F (in utero).475 In this case, a local authority was concerned that a mentally disturbed, nomadic woman who was pregnant would not take care of or provide appropriate medical attention for her child at and after birth. The local authority made an ex parte application to have the foetus made a ward of court. Hollings J. refused the application, holding that the Court had no wardship jurisdiction over an unborn child since it would be ‘repugnant to think of applying the principle of paramountcy in favour of the child’s welfare at the expense of the welfare and interests of the mother.’476 The Court of Appeal unanimously affirmed this decision. Agreeing with Hollings J., May L.J. was of the opinion that there would be ‘insuperable difficulties if one

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473 With regards to who is the legal parent of the ectogenic foetus see p. 130-131
474 Withholding or Withdrawing Life Saving Treatment in Children: A Framework for Practice (London, 1997), para. 2.5. Earlier in the report the RCPCH states that parents should decide whether treatment is withdrawn ‘unless clearly acting against the best interests of the child’ (para. 2.3.2.3). In these circumstances, a decision will be taken to court.
476 Ibid. at 131
sought to enforce any order in respect of an unborn child against its mother, if that mother failed to comply with the order.\textsuperscript{477} The court’s reluctance to impinge on female bodily autonomy prevented the application to make the foetus a ward of court. However, without the female body, it is difficult to see why the court would not grant such an application and similar applications may be granted in relation to decisions regarding neonatal care.\textsuperscript{478}

However, let me alter the scenario slightly. After significant deliberations with doctors, Henry Smith decides that it is in Louise’s ‘best interests’ to ‘switch off’ the chamber due to the intolerable burden that her life would have on her if she were to exist outside the artificial womb. He therefore permits the doctors to switch off the machine and agrees to sign the consent form. Is Henry’s sole consent enough? As demonstrated earlier in this chapter, the case law on termination of foetal life in the event of parental disputes focuses upon the female body and reproductive autonomy, regardless of the wishes of the putative father.\textsuperscript{479} However, it is important to note that in the context of ectogenesis, issues of female reproductive choice and bodily integrity will not be taken into account since the foetus will not be located in the female body. On this basis, the answer as to whether Henry’s sole consent is permissible may be found via guidance for foetuses external to the female body. At present, the only guidance available is that of dead foetuses via the Polkinghorne Guidelines.\textsuperscript{480} This requires that written, general consent must be given by the mother before research can be undertaken on both aborted and miscarried foetuses. No consent is required by the father.\textsuperscript{481} Similarly the HTA Code of Practice states:

\textsuperscript{477} \textit{Ibid.} at 138
\textsuperscript{478} In other words, where decisions involve a conflict between foetal rights and the female body, for the future technology of ectogenesis, which will remove the insuperable difficulties of such a conflict, it is likely that an application to make a foetus a ward of court may be granted.
\textsuperscript{480} \textit{Supra} fn. 144
\textsuperscript{481} The written consent of the mother must be obtained before any research or therapy involving the fetus or fetal tissue takes place. Sufficient explanation should be offered to make the act of consent valid. The Polkinghorne Report, note 144 above, para. 4.1.
The law does not distinguish between fetal tissue and other tissue from the living – fetal tissue is regarded as the mother’s tissue...However, because of the sensitivity attached to this subject, it is good practice to always obtain consent for the examination of fetal tissue and for its storage or use for all scheduled purposes.\(^{482}\)

Although the Polkinghorne Guidelines state that it is desirable to ‘consult the father’, his consent is not a requirement nor does he ‘have the power to forbid research or therapy making use of foetal tissue.’\(^{483}\) As Brazier and Alghrani state, with regards to the genetic father’s input in the context of foetal research materials, his say is very ‘little’.\(^{484}\) Furthermore, It must also be noted that the courts have consistently held that where some major or irreversible procedure is proposed and/or the parents disagree about treatment of the child, either parental consent is required from both parents, or a ruling must be sought from the courts.\(^{485}\) Therefore, it is unlikely that Henry’s sole consent\(^{486}\) for the termination of Louise’s life is enough and in these circumstances, a court’s decision would be required, as is normal practice for disputed medical decisions for neonates.

4.7 Parental Responsibility: who is the legal mother or father of the ectogenic child?

Further complexities arise when one considers Louise’s new status and the matter of ‘parental responsibility’,\(^{487}\) which entitles parents to make decisions about their children’s welfare.\(^{488}\) Current legislation for parental responsibility for Henry would be granted from the moment of Louise’s birth, since he is married to Louise’s mother, Jane. However, two problems arise with this

\(^{482}\) The Human Tissue Act Code of Practice – Consent, Code 1 September 2009, paras. 157
\(^{483}\) The Polkinghorne Report, see note 144 above, para. 4.3.
\(^{484}\) Brazier and Algrani, Supra fn. 50 at p. 59
\(^{485}\) Re J (Specific Issue Order: Muslim Upbringing and Circumcision) [2000] 1 F.L.R 571 Butler-Sloss P spoke of “a small group of important cases made on behalf of a child” which “should only be carried out where the parents together approve of it or, in the absence of parental agreement, where a court decides that the operation is in the best interests of the child”. Male circumcision is stated to be one example, as is immunisation Re C (Welfare of Child: Immunisation) [2003] E.W.C.A Civ 1148.
\(^{486}\) On the flip-side a mother’s sole consent is also not enough in these circumstances since the courts require both consent for serious medical decisions. Ibid.
\(^{487}\) Parental responsibility is defined as “all the rights, duties, powers, responsibilities, and authority that the law gives to a parent. Children Act 1989, s. 3.
\(^{488}\) Children Act 1989, s2(7) provides: “Where more than one person has parental responsibility for a child, each of them may act alone and without the other (or others) in meeting that responsibility; but nothing in this Part shall be taken to effect the operation of any enactment which requires the consent of more than one person affecting the child.”
legislation for ectogenesis. Firstly, Louise is not considered to be legally ‘born’ until she is decanted
from the artificial womb. Secondly, the current legislation provides for the legal definition of a
child's mother\textsuperscript{489} to be a woman who is carrying or has carried a child as a result of IVF and the
woman who gives birth to the child is treated as the mother of that child.

In the context of ectogenesis, the foetus will not be ‘born’ via a woman, thus rendering the child
motherless (and fatherless) in the eyes of the law. At present, under the current statutory regime if a
woman other than the genetic mother has gestated the child, the commissioning couple may apply
for a parental order pursuant to HFEA s.54, in order to be recognised legally as the child’s
parents.\textsuperscript{490} However, this order is only recognised once the child is ‘born’ and, therefore, if this
were to be applied to ectogenesis, a curious situation would arise where the ectogenic foetus could
potentially be viewed to be ‘motherless’ and ‘fatherless’ in the eyes of the law. On the other hand,
s.33 of the HFEA defines the mother of the child as ‘the woman who is carrying or has carried a
child as a result of the placing in her of an embryo or of sperm and eggs’ and therefore this
legislation could not apply to ectogenesis. However, what is clear, is that the HFEA and the law
surrounding parental responsibility, particularly for non-biological parents, was intended to cover
situations where the foetus is gestated in the female host. As such, confusion arises when applied to
ectogenesis. Legislative measures must therefore be introduced which specifically state who the
legal mother and father of the ectogenic child would be (this could be the genetic parents, or in
some circumstances, gametes may have been donated), and from which point they would be
deemed to be the child’s mother or father.

The final matter to be considered in relation to consent provisions for ectogenesis is whether it is
possible to avoid all of the above complexities and, instead, create consent agreements for

\textsuperscript{489} Human Fertilisation and Embryology Act 2008 s 33(1) defines the “mother” of the child as the “woman who
is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other
woman, is to be treated as the mother of the child”.

\textsuperscript{490} However, problems arise when this application is not made within the first six months of the child’s birth, as
required by s.30(2) HFEA.
ectogenesis, allowing for the termination of severely disabled ectogenic foetuses. It is worth noting that the mother of the ‘test-tube’ baby agreed in advance to an abortion, should the foetus have proven abnormal.  

However, the exact details of this consent form, especially whether it would have any legal effect, are unclear.

For ectogenesis, there are a number of issues to consider in relation to the legality of such an agreement. Firstly, would this be lawful? Secondly, could the gamete progenitors renege on this consent and later decide that they no longer wished for the severely abnormal ectogenic baby to be aborted? Whilst the topics of informed consent and the ability to create such agreements are important to the development of ectogenesis, I have specifically chosen to focus upon the rights and status of the ectogenic foetus at various stages in its development and therefore a detailed exploration of the admissibility of such agreements is beyond the scope of this chapter. However, it is worth noting that although such agreements may alleviate some of the complexities discussed, this is an emotional area of law where ‘dry legal contract’ will not be rigidly applied.

As one judge recently commented, where unconventional means are involved in creating a family, ‘depths of emotion are engaged and feelings released that come as a surprise and shock, not only to others, but in particular to the participants themselves.’

As a result of this, it is not always possible to inform and agree on an exact cause of action as to what will happen in the future or how the parties may feel when their ectogenic foetus is clearly visible and developing in the ectogenic chamber. As Lady Justice Black noted in *A v B and C*.

No matter how detailed their agreement, no matter what formalities they adopt, this is not a dry legal contract. Biology, human nature and the hand of fate are liable to undermine it and to

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491 “Ectogenic Human Being: A Problem Child of Our Time” Uni of Western Ontario Law Review 18 p.241. This article does not explicitly clarify who agreed to this potential procedure, where it was made or the year in which this occurred. For further information see p.241-242
492 Ibid.
493 Supra fn 434 at 44 per Black LJ
494 TJ v CV and S v BA [2007] EWHC 1952 (Fam), para.15.
495 Supra fn. 434
confound their expectations. Circumstances change, and adjustments must be made. And above all, what must dictate is the welfare of the child and not the interests of the adults.\textsuperscript{496}

\textbf{4.8 Conclusion}

Looking at the circumstances of Jane and Henry Smith’s interim injunction to prevent Louise from being ‘switched off’, it is likely to fail, although further exploration of the law in relation to the ethics of ectogenesis and abortion is to be necessary. In Chapter Three, I analysed the law in relation to foetal viability and birth, concluding that whilst the point of viability ought to be at a similar point to maternal gestation, the moment of birth is markedly different, due to the need to grant certain legal protections to the ectogenic foetus. Whilst this ought to prohibit ‘switching off’ foetal life for social reasons, I have advocated certain situations where it is permissible to ‘switch off’ foetal life for medical reasons in accordance with the current law and guidelines for severely disabled neonates.

I have noted the difficulties of applying the current law of abortion to ectogenesis. In attempting to explore these issues, I have used the hypothetical scenario of Louise Smith, the world’s first ectogenic foetus to establish that stretching the current legal model to ectogenesis is incompatible. Inevitably, new legislation will have to be drafted to address the numerous and wide ranging issues which I have discussed in these chapters. Clearly, applying the current legislative framework to ectogenesis is akin to applying square pegs to round holes.

Ultimately, this legal regulation for ectogenesis needs to protect clinicians, progenitors and the scientists, not only from legal malpractice action, but also to give them a shield against accusations of malpractice, as long as they act with the specified legal parameters.\textsuperscript{497} As the previous sections have evidenced, effective legislation for ectogenesis is complex and presents a multitude of

\textsuperscript{496} Ibid at paras.44 and 48
\textsuperscript{497} Deech suggests a similar methodology for IVF and other ART’s in Deech, Ruth and Smajdor, Anna, \textit{From IVF to Immortality: Controversy in the Era of Reproductive Technology} (Oxford University Press, Oxford, 2007) p.2
practical difficulties. Yet there is a clear need for substantive provisions in relation to the status of
the foetus, its protection at various decided points, and its birth. The legal complexities regulating
the development of artificial wombs raises a host of issues that urgently require consideration.
Naturally, no single statute or policy can address all of the concerns that ectogenesis raises. In fact,
some will not even have been thought of. However, through deconstructing each answer to the
above three questions, we can begin to find our way to the future with some anticipation of meeting
the needs of all parties who may embark upon this development.
Chapter Five: Drafting a regulatory framework for the development of ectogenesis

5.1 Introduction

The development and use of ectogenesis raises complex social, legal and ethical questions that go to the heart of how we should treat living human embryos and foetuses. In deciding whether to conduct research into ectogenesis, I have demonstrated the importance of proactive legal regulation in this field, whilst enabling science and medical research to prosper, but within clear parameters. The preceding chapters have demonstrated that ectogenesis gives rise to significant concerns about whether the development should be allowed to go ahead at all, and how the law should respond to some of the challenges posed by the capacity to create a child outside a woman’s body.

In this final chapter, I outline some practical recommendations to address the growing possibility that, within the next decade or two, scientists and doctors will seek to embark on research into ectogenesis in the UK with the eventual aim of incorporating it into clinical practice. In Chapter Two, I highlighted the legal and ethical problems that may arise on the road to developing ectogenesis. In Chapters Three and Four, I deconstructed the current law and attempted to apply it to ectogenesis, thus demonstrating that current legislation and case law cannot be made to ‘fit’. Instead, it is clear that if ectogenesis is to go ahead, new legislation is required (herein referred to as ‘The Ectogenesis Act’). The Ectogenesis Act would aim to provide a robust regulatory framework that is ‘fit for purpose’. It would be supportive of innovation, medical research and the development of ectogenesis whilst recognising the need for safety and a clear framework of regulation to the benefit of patients, parents and healthcare professionals. It would represent a comprehensive piece of legislation, tailored to ectogenesis and the legal problems highlighted in this thesis. However, it is important to note that the scope of this legislation is almost endless, and not every issue will be
covered. Instead, the aim is to conclude the arguments and themes running throughout this thesis through making practical recommendations for the development of ectogenesis.

5.2 Legal Elements of the Proposal

Definitions and scope of recommendations
The scope of the proposed recommendations would correspond to the development of an ectogenic chamber, which would have the ability to gestate an embryo created \textit{in vitro} and subsequently implanted in an ectogenic device for forty weeks’ gestation.

My proposals do not extend to:

(a) partial ectogenesis\textsuperscript{498}
(b) Neonatal Intensive Care Units; or
(c) the creation of an artificial uterus intended to be implanted into a human body.

Territorial extent/jurisdiction
If approved by Parliament, the proposed legislation would apply throughout the UK. The remit would cover the whole of the UK within the same remit of the HFEA 1990, thus covering England, Wales and Northern Ireland and matters reserved to the UK Parliament in Westminster. It would therefore be able to assist the relevant authorities in Scotland.

5.2 Recommendations
I addressed some of the substantive legal issues in relation to the research phase of ectogenesis in Chapter Two. What is apparent is that, in order to address the technological feasibility of this development, further medical and scientific information is required. At this stage, it is impossible to know whether the medical risks and potential harms for embryos and foetuses outweigh the benefits

\textsuperscript{498} Although this would also require regulation, the issue of partial ectogenesis is beyond the scope of this thesis.
of ectogenesis. A committee of inquiry (herein referred to as the ‘Ectogenesis Inquiry’) is required to fully assess the risks and benefits of ectogenesis and determine if any research into ectogenesis should be permitted in the UK. This Inquiry would conduct a meticulous assessment, which would be similar in scope to the Warnock Committee. However, in contrast to the Warnock Committee, it would take place prior to any research into ectogenesis. It would determine whether the current technology and knowledge is advanced enough to enable research into ectogenesis to be ethically permissible. It would be broken down into two possible stages.

5.2.1 (1) Stage I

The first phase of the Ectogenesis Inquiry would address whether the risks posed by the development are outweighed by the benefits. The full purpose of this inquiry would be to study the social, ethical and medical implications of ectogenesis; to weigh up the risks involved with developing this procedure. Ectogenesis must be shown to have a valuable objective that, when weighed in the balance of the known and unknown physical and psychological risks, produces a valuable benefit which justifies the research proceeding. Stage I would involve taking the evidence of ethicists, doctors and other members of the medical profession. It would reach a conclusion based upon various consultations regarding the medical risks for the future welfare of human embryos and recommend either:

(1) The current technology of ectogenesis carries too many medical risks that are not outweighed by profound benefits, and either:

a. research into ectogenesis should be banned for the foreseeable future. This prohibition could follow the Canadian model, which has banned any clinical research into ectogenesis; and

b. no steps should be taken to remove the fourteen day ban; therefore research into

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ectogenesis would remain illegal.

(2) In the alternative, the committee may decide that research into complete ectogenesis, in principle, should be allowed to go ahead. As a result of this, the Ectogenesis Inquiry would proceed onto stage II.

5.2.2 Stage II

If it is determined that science is advanced enough to enable research into the first human ectogenic chamber, then a second inquiry would be necessary. Stage II of the Inquiry would involve a detailed determination of the legislation and ethical considerations required to adequately regulate this technology. This would represent the culmination of an extensive process of consultation, discussion and reflection, including the findings of Stage I of the Inquiry, followed subsequently by public consultation and vigorous parliamentary debate.

Stage II would also discuss the primary legislation that is required to enable research into ectogenesis to begin. As a preliminary matter, the fourteen day ban on embryo research would need to be removed to allow for embryo research to progress towards the gestation of an embryo for forty weeks in an ectogenic chamber. Any changes made through the Ectogenesis Act would act as an exception to the general rule under s.3 of the HFEA, which prohibits keeping or using an embryo after the appearance of the primitive streak. Stage II would also consider whether an independent regulator would be required to oversee the use of gametes and embryos in ectogenic research or whether this would fall under the remit of a current regulatory body, such as the Human Fertilisation and Embryology Authority.500

500 Taking into consideration the enormous costs of setting up an independent body.
Finally, stage II of the Ectogenesis Inquiry would also consider the necessary elements of the legislative framework that must be in place prior to any research into ectogenesis. I will now turn to these components. In the following pages, I indicate that the principle factors need to be addressed. I will also make my own recommendations regarding possible solutions to some of the legal questions placed before the Inquiry.

5.3 Chronological timeline of the embryo and foetal status:
The existence of ectogenesis will undoubtedly spark debate surrounding the concepts of viability and birth and the availability of abortion. Within these issues, the legal meanings of the terms ‘ectogenic embryo’ and ‘ectogenic foetus’ are also crucial in determining the scope of regulation. As explained in Chapters Three and Four, birth is the point at which the highest level of legal protection is accorded to a human being. This continues at that same level throughout that person’s life. However, for the independently gestated ectogenic embryo and foetus, certain protections are required from the outset in order to recognise the dignity and respect that ought to be granted to developing human life.

5.3.1 Implantation
I recommend that once the embryo is implanted in the ectogenic chamber, the parties cannot terminate the life of that foetus through ‘switching off’ the ectogenic chamber. However, in circumstances where continuing gestation is an exercise of medical futility, exceptions are set out in Annex I. The legal implications of implantation should be clearly disclosed to the parties prior to embarking upon the technology of ectogenesis. This would take into consideration the emotional and financial consequences of creating a ‘point of no return’ agreement for artificial wombs. It would also include express, written consent from both of the parties involved with the gestation.
5.3.2 From implantation to the twenty-third week of gestation

Until the twenty-fourth week of gestation, it is my recommendation that the foetus is not viable on account of the medical and legal interpretations of the term ‘capable of being born alive’. Despite this, it is important to recognise that the foetus is still owed a duty of care and in accordance with my earlier recommendations the ectogenic foetus cannot be switched off at any point past implantation in the artificial womb, unless it falls within the guidelines in Annex I.

5.3.3 Viability

There should be no distinction between viability outside a woman’s uterus and viability outside the artificial womb; if the child can survive outside either womb at as little as twenty-two weeks in NICU, then it should be deemed to be viable. As I have demonstrated in the previous chapters, the elasticity of the concept of viability requires that no specific demarcation should be given for the ectogenic foetus. Rather, the point of viability ought to range from as early as twenty-one weeks to twenty-six weeks, depending on the circumstances of each case (factors including birth weight and lung development). This new definition of viability should also include the requirement that the ectogenic foetus may survive after the point of viability, with medical assistance via NICU. This would take into account that the ectogenic foetus cannot survive naturally, and, if decanted at twenty-three weeks, may need life-support assistance via NICU.

5.3.4 Birth

The law in relation to the birth of the ectogenic foetus is a complex field. No clear consensus has emerged from the existing literature as to how to legislate for the birth of the ectogenic foetus and the status that should be accorded at this point. Primary legislation will have to be drafted to determine the status, rights and protections accorded to the ectogenic foetus on account of the separate status of the foetus removed from the female body. However, it is clear that some change
of status ought to be recognised from the point which must be deliberated and discussed prior to the Ectogenesis Act.

I recommend that legislation should clearly define the status of a developing foetus from the point of viability. Once the foetus reaches this point, I recommend that he or she be classified as an ‘interim’ human being, which is neither a foetus nor a baby person. This would resolve the complexities surrounding the consequences of being ‘born’ whilst granting some legal status and protections to the in vivo foetus without granting full legal personality. A similar model can be found internationally, through the American case of *Davis v Davis* where the Tennessee Supreme Court heard the unsuccessful appeal of the ‘tiny persons’. In this case, the court suggested that fertilised frozen eggs occupied an ‘interim category’ between full, legal persons and non-entities that entitled them to special respect because of their potential for human life. U.S. scholars have also coined a new term, the ‘fetal infant’, while Spanish law has an interim category of ‘human beings’ which are neither foetuses nor babies.

A similar term ought to be enacted through legislation for ectogenesis which would recognise the unique legal status of the foetus in the artificial womb and grant him or her additional rights which require legal protection. The full scope of these rights will need to be explored in light of ethical, social and religious considerations to fully determine the status that should be afforded to the viable ectogenic foetus.

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502 842 S.W.2d 588 (Tenn.),

503 The court was asked to rule on the disposition of frozen embryos which had become the subject of a bitter divorce. The applicant, Mary Davis asked the court for control of the embryos so that she could achieve a post-divorce pregnancy. (Although this was later modified to embryo donation). Her soon-to-be ex husband objected, arguing that the embryos should be discarded. The court held that in the absence of a prior agreement, the party wishing to avoid the procreation should prevail, assuming the other party had a “reasonable prospect of achieving parenthood by other means”.

504 *Ibid* at 597


506 Alghrani, Amel and Brazier, Margaret, *Supra* fn. 50
5.3.5 Congenital Disabilities

As with many other examples of applying the current legislative framework to ectogenesis, applying the 1976 Act in its current format is not possible. Therefore, an amendment must be placed in the 1976 Act which would cover ectogenic gestation and enable parties who fulfilled the requirements of the legislation, to be granted redress through this Act.

5.3.6 Status and legal parenthood

The Ectogenesis Act should contain provisions about the parenthood of children born following artificial gestation. This should clearly set out who has the legal status of ‘mother’ and ‘father’ of the ectogenic foetus. These provisions are crucially important since they affect matters ranging from an individual’s sense of self, to practical matters such as rights of inheritance and determining who will have parental rights and responsibilities towards the child. I propose the following:

(a) the genetic mother and father of the child ought to be treated in law as the legal mother or father unless;

(b) where donor gametes (or an embryo created from them) are used, the law should recognise the parties who express clear and written intention to be the legal parent of that child as the legal father or mother of that child.

5.3.7 Consent Agreements

Any embryo used in the initial clinical phases of ectogenic research should be obtained with the full, written consent of both parents. This would include disclosure of all known risks of ectogenic research and standard information with regards to taking part in a clinical research trial. Parties should be fully informed that, once implanted in the artificial womb, this represents the point of no
return in terms of withdrawing their consent.\textsuperscript{507} Once used in regular clinical practice (‘ectogenesis clinics’), written agreements should be created for parties embarking upon ectogenesis. The Inquiry should consider the provisions of such agreements including who would look after the child in the circumstances wherein one or both parents is unable to do so.

5.3.7 Research on the living \textit{ex utero foetus}

Other matters for consideration by the Ectogenesis Inquiry would be the creation of new guidelines with regards to research on the living \textit{ex utero} foetus and the means of obtaining research embryos and foetuses for such trials.

5.4 Annex I: Situations in which it is permissible to ‘switch off’ the ectogenic foetus

Whilst I propose legislation to grant the foetus protection to prohibit the chamber being ‘switched off’ beyond the point of implantation, there are certain circumstances where it may be permissible to end the life of the ectogenic foetus. Clear guidance is required to determine what may happen in situations in which the ectogenic foetus is clearly disabled. On account of the higher status for the ectogenic foetus, I propose that some guidance may be found in the ethical guidelines for severally disabled neonates whose lives are medically futile. This recommendation moves towards recognising a uniformity of treatment between both foetuses and neonates through using the current framework of the RCPCH. This identifies five situations in which life-sustaining treatment can be withheld or withdrawn from severely disabled neonates and children. These are:

\textbf{The Brain Dead Child:}\textsuperscript{508} Here, it is agreed within the profession that once the criteria of brain-stem death is agreed by two practitioners\textsuperscript{509} treatment in such circumstances is

\textsuperscript{507} (Although see Annex I for the general exceptions to this rule.)

\textsuperscript{508} Brain death is defined as when a child has sustained either (i) irreversible cessation of circulatory and respiratory functions or (ii) irreversible cessation of all functions of the entire brain including the brain stem. A determination of death must be made in accordance with accepted medical standards. \textit{Ibid} at p.10

futile and the withdrawal of current medical treatment is appropriate.

The Permanent Vegetative State: \(^{510}\) This situation applies to the child who develops a permanent vegetative state and is reliant on others for all care and does not react or relate with the outside world. In this situation, it may be appropriate to withdraw or withhold life-sustaining treatment from the ectogenic foetus. Such situations would encompass instances where the ectogenic child falls under the aforementioned definition of a Permanent Vegetative State and the medical profession view this situation as unlikely to change.

The ‘No Chance’ Situation: This applies to the child who has such severe disease that any life-sustaining treatment simply delays death without significant alleviation of suffering nor improvement of life’s quality or potential. In this situation, the current guidelines state that “[t]reatment to sustain life is inappropriate.” \(^{511}\) Needlessly prolonging treatment in these circumstances is futile and burdensome and not in the best interests of the patient; hence there is no legal obligation for a doctor to provide it. In fact, if futile treatment is done knowingly, this may constitute an assault or “inhuman and degrading treatment” under Article 3 of the European Convention on Human Rights. \(^{512}\)

The ‘No Purpose’ Situation: Although the patient may be able to survive with treatment, the degree of physical or mental impairment will be so great that it is

\(^{510}\) The vegetative state – guidance on diagnosis and management. *A Report of a working party of the Royal College of Clinical Medicine* (2003): 249-254. Defines the vegetative state and uses the terms “persistent” to mean a vegetative state that has persisted for four weeks or more and “permanent” when the vegetative state is deemed to be permanent and it is predicted that awareness will never recover. “The persistent vegetative state.” Conference of Medical Royal Colleges and their Faculties of the United Kingdom. *Journal of the Royal College of Physicians, London.* (1996)30: 119-121.

\(^{511}\) *Supra* fn. 172 at 10

\(^{512}\) *Pretty v United Kingdom* (2002) 35 EHRR 1, para 52: "As regards the types of ‘treatment’ which fall within the scope of article 3 of the Convention...The suffering which flows from naturally occurring illness, physical or mental, may be covered by article 3, where it is, or risks being, exacerbated by treatment, whether flowing from conditions of detention, expulsion or other measures, for which the authorities can be held responsible." As Cazalet J succinctly summarised it in *A National Health Service Trust v D* [2000] 2 FLR 677, 695: "Article 3 of the Convention, which requires that a person is not subjected to inhuman or degrading treatment includes the right to die with dignity."
unreasonable to expect them to bear it.

The ‘Unbearable’ Situation: The child and/or family feel that in the face of progressive and irreversible illness further treatment is more than can be borne. They wish to have a particular treatment withdrawn or to refuse further treatment irrespective of the medical opinion that it may be of some benefit.

The Nuffield Council on Bioethics also recommends the use of the term ‘intolerability’ which would embrace all three situations recognised by the RCPCH, as well as those that have features of more than one of these categories.\(^{513}\) On their definition ‘intolerability’ encompasses ‘an extreme level of suffering or impairment which is either present in the baby or may develop in the future, and may be given more weight in the judgement of parents or doctors.’\(^{514}\)

Using both the RCPCH and Nuffield Council recommendations, this collective guidance covers the broad spectrum of situations where life for the ectogenic foetus would be an intolerable burden on that child. Under these circumstances it is my submission that support from the ectogenic chamber should be withdrawn and the life of the foetus would be ended.

5.5 Summary and conclusion

The proposals in this chapter represent the first attempt in English law to provide some form of a framework for the development of ectogenesis. The final stage of the ‘reproductive revolution’ brings in its wake profound and difficult questions, raising a wealth of legal, ethical and social conundrums. I have attempted to answer some of these questions through proposing legislation for

\(^{513}\) ‘Critical Care Decision Making in Fetal and Neonatal Medicine: ethical issues’ 9.16 (Nuffield Council on Bioethics, 2006) Available at: http://www.nuffieldbioethics.org/sites/default/files/CCD%20web%20version%2020June%202007%20(updated).pdf. accessed 14 April 2013 at 2.16. This was adopted by the Nuffield Council to describe situations where it would not be in a baby’s best interests to insist on the imposition or continuance of life-sustaining treatment when doing so imposes an intolerable burden upon the baby.\(^{513}\)

\(^{514}\) Ibid. However, they note that in each case an assessment must be made of the individual baby.
ectogenesis. It is clear that boundaries must be set to ensure that any research into ectogenesis is ethically permissible; the more we understand what artificial wombs involve, the more informed our choices will be with regards to whether this technology should ever be allowed to go ahead.

In this thesis, I have argued that although the development of ectogenesis may have many advantages, further consideration is required to assess the potential harms this technology may inflict upon future generations of children. In Chapter Two I have suggested that an inquiry ought to be established to explore the medical, ethical and social implications of ectogenesis. This would establish whether research should progress onto the clinical phase. In the event that this technology is allowed to proceed onto human subjects, a broader discussion is necessary to consider the entire spectrum of issues ectogenesis raises in order to develop appropriate legislation. I have demonstrated in Chapter Three and Four that the old law cannot be made to ‘fit’ the new technology of ectogenesis. Instead, it is clear that new legislation is required to regulate the law’s treatment of the ectogenic embryo and foetus. Finally, I have attempted to draft some proposals for a tailored regulatory framework to deal with these matters in Chapter Five.
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