UNIVERSITÀ DEGLI STUDI DI PADOVA
DEPARTMENT OF POLITICAL SCIENCE, LAW, AND INTERNATIONAL STUDIES

Master's degree in
Human Rights and Multi-level Governance

ARTIFICIAL WOMB TECHNOLOGY: AN EXAMINATION OF HUMAN RIGHTS, ETHICS, AND LEGAL FRAMEWORKS

Supervisor: Prof. COSTANZA MARGIOTTA BROGLIO MASSUCCI

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Matriculation No. : 2039423

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ABSTRACT

As reproductive technologies advance, they prompt ethical and legal inquiries that challenge established definitions. The focus on Artificial Wombs Technology (AWT) has spurred debates surrounding ex-utero fetal rights, impacts on women's reproductive autonomy, and future prospects like full ectogenesis. This thesis extensively explores these concerns from human rights, bioethical, and legal standpoints. Employing a meticulous methodology, including a comprehensive literature review and meta-analysis, the study meticulously selects pertinent information. Findings emphasize the need for a nuanced analysis, encompassing psychological, ethical, sociological, and legal dimensions. The primary focus centres on exploring ongoing discourse and its implications concerning this topic. The hypothesis suggests that evolving debates, when approached from various perspectives and integrated methodologies, will illuminate critical implications for human rights, ethical guidelines, and legislative frameworks. By synthesizing fragmented sources and disparate viewpoints, the research aims to comprehensively analyze the topic and provide a holistic understanding. Crucially, these discussions not only influence perceptions and applications of the technology but also shape its ethical implementation, and societal impact, and contribute to this field's transition from theory to practical application.

Keywords: Artificial Wombs Technology (AWT), bioethics, ectogenesis, reproductive technology, gestation ex utero, women's rights.

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Abbreviations

AA	Abortion Act 1967
AG	Advocate General
AHR	Assisted Human Reproduction Act
AI	Artificial insemination
ART	Assisted Reproductive Technology
ASPA	Animals (Scientific Procedures) Act 1986
AWs	Artificial Wombs
AWT	Artificial Womb Technology
BIPOC	Black, Indigenous, and People of Colour
CDC	Centers for Disease Control and Prevention
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CJEU	Court of Justice of the European Union
CRISPR/Cas9	Clustered Regularly Interspaced Palindromic Repeats
DES	Diethylstilbestrol
ECHR	European Court of Human Rights
ECJ	European Court of Justice
ECMO	Extracorporeal Membrane Oxygenation
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
ExCG	Extracorporeal Gestation
FDA	Food and Drug Administration
FEMM	European Parliament's Committee on Women's Rights and Gender Equality
GIFT	Gamete Intrafallopian Transfer
HFEA	Human Fertilisation and Embryology Authority

ICPD	International Conference on Population and Development
ICSI	Intracytoplasmic Sperm Injection
ILPA	Infant Life (Preservation) Act 1929
IPSC	Induced Pluripotent Stem Cells
IRB	Institutional Review Board
IVF	In Vitro Fertilization
IVG	In Vitro Gametogenesis
LCIVF	Low-cost In Vitro Fertilization
LGBTQ2SIA+	Lesbian, Gay, Bisexual, Transgender, Transsexual, Queer and Questioning Two-Spirit, Intersex, Asexual, Plus people
NIC	Neonatal Intensive Care
OAPA	Offences against the Person Act 1861
OHRP	Office for Human Research Protections
PCR	Polymerase chain reaction
SRHR	Sexual and Reproductive Health and Rights
STI	Sexually transmitted infections
TFEU	Treaty on the Functioning of the European Union
TGA	Therapeutic Goods Administration
U.S.	United States
UK	United Kingdom
UTx	Uterus transplantation
WE	The Walking Egg
WHO	World Health Organization
ZIFT	Zygote Intrafallopian Transfer

Introduction

The emergence of Artificial Womb Technology (AWT) marks a significant milestone in the ongoing evolution of reproductive healthcare, offering unprecedented opportunities to revolutionize neonatal care, surrogacy alternatives, and prenatal therapy. Throughout history, humans have sought to improve our ability to conceive and nurture offspring, employing a variety of techniques and technologies to overcome reproductive challenges. From ancient fertility rituals to modern assisted reproductive technologies (ART), such as in vitro fertilization (IVF) and gamete donation, the quest for enhanced reproductive capabilities has been a constant theme in human civilization. Against this backdrop, AWT emerges as the latest frontier in reproductive innovation, promising to redefine our understanding of gestation and childbirth.

Recent breakthroughs in medical research have brought the concept of ectogenesis — the gestation of fetuses outside the human body — from the realm of science fiction to the forefront of scientific inquiry. While partial ectogenesis has become a feasible reality, with advancements in artificial womb technology enabling the incubation of premature fetuses, the prospect of complete ectogenesis looms on the horizon. This convergence of scientific progress and reproductive innovation raises profound questions about the intersection of technology, ethics, and human reproduction. By removing the fetus from the maternal womb and incubating it in an artificial environment, AWT challenges traditional notions of pregnancy, parenthood, and familial bonds. Ethical dilemmas surrounding ectogenesis include concerns about the status of the fetus, the rights of the pregnant individual, and the potential consequences of societal norms and values.

Bearing in mind these preliminary considerations, this master's thesis aims to answer two main questions: (i) How and to what degree will ectogenesis impact reproduction (as in how people perceive and experience reproduction, pregnancy and parenthood)? (ii) What are the consequences of the arrival of this piece of technology (especially for people who can get pregnant)? This piece of work then addresses the ethical challenges posed by ectogenesis within the framework of human rights, social justice, and ethical principles. Through a comprehensive analysis of the ethical, social, and legal dimensions of AWT, this study seeks to assess the ethical implications of ectogenesis within the context of reproductive autonomy, bodily integrity, and human rights; examine the societal implications of AWT, including its potential impact on gender equity, reproductive justice, and marginalized communities; analyze the legal

and regulatory challenges associated with the development and implementation of AWT; and propose ethical guidelines and policy recommendations for the responsible development and equitable distribution of AWT.

By examining the potential benefits, risks, and societal implications of AWT, this study aims to contribute to the ongoing discourse on reproductive ethics and healthcare policy. Specifically, the objectives of this research encompass a multifaceted exploration of AWT within the framework of human rights, ethics, and legal frameworks. Therefore, the present work is divided into three chapters, besides this introduction and the final considerations. The first chapter focuses on the historical background of ectogenesis, its future applications and the differentiation between partial and complete ectogenesis. Following this, the second chapter investigates the intricate interplay between reproductive rights, ART frameworks, and the regulation of AWT. This analysis primarily focuses on the legal framework within the European Union while also considering its implications globally, through comparative examinations and discussions of international standards and practices. Lastly, the third chapter delves into the ethical complexities inherent in AWT, tackling issues such as the ethics of human trials, the evolving concept of parenthood, and the intersection with women's rights, with a specific focus on its implications for abortion discourse. Furthermore, it underscores the imperative of ensuring equitable access to AWT by comprehensively examining the impact on marginalized demographics and its potential contribution to societal stratification.

This thesis will adopt an interdisciplinary approach, drawing upon insights from bioethics, feminist theory, legal studies, and social science research. A comprehensive review of the existing literature on AWT, reproductive ethics, and related fields will inform the analysis. Additionally, case studies and hypothetical scenarios will be utilised to illustrate key ethical dilemmas and policy challenges in the context of AWT. The research methodology will incorporate qualitative analysis, ethical reasoning, and policy analysis to achieve the stated objectives.

All analyses were based on legal instruments of international human rights law; publications from human rights bodies, international and non-governmental organizations, national legislations; statistical data; and articles from scholars and researchers who are references in the study field. It's crucial to clarify that despite the array of terms used to denote the technology (such as AWT, biobag, ExCG, ectogenesis—each carrying its own nuances), this thesis will treat them

interchangeably, considering them synonymous in meaning and application. Discussing and defining their similarities and differences is beyond the scope of this work.

Furthermore, important to mention that the thesis adopts a comprehensive approach that encompasses diverse perspectives, albeit with a recognition of its largely heteronormative nature. While it briefly touches upon LGBTQ2SIA+ considerations, for example, it does not extensively delve into these topics as its main focus. Acknowledging its limitations, this study endeavours to offer a comprehensive view of AWT and its implications through a human rights lens. By illuminating crucial debates surrounding ethical and sociological considerations, it adopts a holistic and intersectional approach to provide a nuanced understanding of the subject matter. This thesis also contributes significantly to the field by consolidating and synthesizing dispersed information on the topic, thereby providing a comprehensive overview that was previously fragmented across various sources.

Chapter 1 - Ectogenesis: history and evolution of a field

To understand the evolution of Assisted Reproductive Technology (ART) and the current pinnacle of the Artificial Wombs Technology (AWT) discussion, is imperative to go back to 1924 when the term "ectogenesis" was first coined by the prominent British biologist, geneticist and scientist J.B.S. Haldane. In his essay titled "Daedalus; or, Science and the Future." he envisioned a future in which the reproduction of human beings would be possible outside the female body and through artificial means. This was when artificial wombs and incubators were mentioned for the first time[1].

The word ectogenesis derives from "the words “ecto” (outside) and “genesis” (development), [...] this literally means “development outside”—i.e. outside the body. But since that is the norm in most of the biological world, the focus in practice is on the development of placental mammals—specifically humans—outside the maternal body, where this development would normally happen inside."[2]. In the realm of reproductive science, terminology sparks vigorous scholarly debate among experts. There's a division: some argue that ART is indeed a form of (partial) ectogenesis when taking into account IVF, for example - since it can be considered a form of embryonic development occurring outside the human's body, while others firmly oppose this notion. At present, Artificial Womb Technology (AWT) is hailed as a leading example of ectogenesis. Notably, both ART and AWT operate within the expansive landscape of reproductive technology, inviting rich discussions and ongoing exploration in the field, with AWT promising advances in prenatal medicine, improved neonatal intensive care, and the creation of a new path to biological parenthood.

The placement of AWT gets even more complicated considering how close partial ectogenesis and the research that has been developed around it is with the Neonatal Intensive Care (NIC) treatments that have been occurring nowadays. Many see AWs as an advancement over current Neonatal Intensive Care (NIC) methods, with some specialists affirming that neonatal incubation for prematurity is also a form of partial ectogenesis, assuming that AWT is a novel medical treatment.

In the history of reproductive technologies, the most famous to this day is, without a doubt, indeed the most notorious form of ART, IVF has grown into an

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[1] Rosen, C. (2003). Why Not Artificial Wombs? On JSTOR. *The New Atlantis*, 67. https://doi.org/43152051.
[2] Kingma, E., & Finn, S. (2020). Neonatal incubator or artificial womb? Distinguishing ectogestation and ectogenesis using the metaphysics of pregnancy. *Bioethics*, *34*(4), 354–363. https://doi.org/10.1111/bioe.12717.

acceptable and popular method of treating infertility. In 1978 the birth of Louise Brown became a landmark in ARTs' history, being the world's first baby born through *in vitro* fertilization (IVF), commonly known as the world's first 'test-tube baby'. However, it is only one of many procedures that it encompasses. In general, "Assisted reproductive technologies involve combining sperm with ova that have been surgically removed from a woman's body and returning the fertilized eggs to the uterus or donating the produced embryos to another woman or couple. [...] ART procedures include in vitro fertilization ("IVF"), gamete intrafallopian transfer ("GIFT"), zygote intrafallopian transfer ("ZIFT"), and intracytoplasmic sperm injection ("ICSI")."[3]

In time, important to briefly explain those techniques in a little more depth: "IVF involves the combination of the egg and sperm to achieve fertilization outside of the woman's body, usually under a microscope in a glass petri dish. The embryo is then placed in the uterine cavity for implantation. GIFT and ZIFT are variations of IVF that involve placement of the egg and sperm in the fallopian tubes, instead of the uterus. In GIFT, unfertilized eggs and sperm are placed in the fallopian tube and fertilization occurs inside of the body. ZIFT, on the other hand, involves placement of a pre-fertilized egg in the fallopian tubes. In ICSI, an embryologist uses a small pipet to inject a single sperm into the center of an egg; the fertilized egg grows in a laboratory for one to five days before being placed in the woman's uterus."[4] Moreover, crucial to mention that Artificial insemination ("AI") and surrogacy are not technically ART, but alongside it, are methods that also assist individuals and couples in achieving pregnancy.

Some forms of ART can be considered, therefore, the first stage of partial ectogenesis, with AWT covering the last part of it. When considering the infertility rates in the world that show that one in six couples worldwide experiences some form of infertility problem at least once during their reproductive lifetime, resulting in more than 80 million people globally, it is understandable the role that ART has in today's outline. According to the European Society of Human Reproduction and Embryology (ESHRE), "The current prevalence of infertility lasting for at least 12 months is estimated to affect between 8-12% worldwide of women aged from 20 to 44 years old. Also, 20-30% of infertility cases are explained by physiological causes in men and 20-35% by physiological causes in women, and 25-40% of cases are because of a problem in both

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[3] Casolo, J., Curry-Ledbetter, C., Edmonds, M., Field, G., O'Neill, K., & Poncia, M. (2019). ASSISTED REPRODUCTIVE TECHNOLOGIES. *Georgetown Journal of Gender and the Law*, *20*(2), 313+. https://link.gale.com/apps/doc/A584979735/AONE?u=anon~8f617f2e&sid=googleScholar&xid=5f4a76a2.
[4] Ibid.

partners. In 10-20% no cause is found. Infertility is also associated with lifestyle factors such as smoking, body weight and stress. The increasing age of the female partner is one of the most common explanations today. Most ART treatments take place in women aged between 30 and 39."[5]

Moreover, the majority of people who experience any kind of infertility reside in developing nations where infertility and ART services are either scarce or unavailable. Considering the high rates of pelvic tuberculosis or schistosomiasis, postpartum or postabortal infection, and sexually transmitted diseases (STIs) in these countries is noticeable a higher percentage of infertility arises, not only, but also as a consequence of these diseases and contributes to the substation increase of inferitily[6]. Additionally, important to mention that many times the infertility rates are in fact underestimated, so these numbers are possibly much higher. Consequently, there has been an increase in demand for ART services in both developed and developing nations over the past couple of years as a result of advancements in the area that have heightened the aspirations and wants of infertile people to end their struggle.

The most recent data on ART - especially regarding Europe - is from 2018, and it demonstrates that in between 39 counties in this region, 1 007 598 treatment cycles were reported; Japan was the most 'officially' active country in the world with 454 893 cycles in 2018 and in the US the number reaches 306 197 cycles; Australia and New Zealand were responsible for 84 064 of them in the same year. Nonetheless, more recent data, from 2022, determine that China is currently performing around 1,000,000 cycles per year (ICMART 2022) displacing Japan as number one. Worldwide, more than 3 million ART cycles are reported each year with 769 977 babies being born from it. There is a discrepancy between the number of cycles that were registered and the reality of it and since registry figures are thought to represent around 75% of all ART treatments, supposably, around 4 million ART cycles are estimated each year, with about 1,000,000 babies born[7].

Furthermore, since AWT comes, in its partial ectogenesis form, as an alternative to the conventional NIC treatments, with the intention of facilitating the process of gestation ex utero and enabling preterms to continue to develop, necessary to mention the rates of survival of NIC treatments. It shows that "Before 26 weeks [...] preterms remain unlikely to survive the common complications associated with

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[5] *Factsheet on ART*. (2023, November). Retrieved from https://www.eshre.eu/Europe/Factsheets-and-infographics.
[6] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[7] *Factsheet on ART,* op. cite.

prematurity and resulting from NIC. Only approximately 9% of preterms born at 22 weeks survive. One study reports that the survival rate increases to 33% at 23 weeks, and to 65% at 24 weeks. Complications in NIC include lung damage caused by ventilation, cardiac failure, and infection. Of preterms born at 26 weeks that do survive, 50% have a severe impairment following complications. This increases to 75% amongst preterms at 23 weeks. Despite overall mortality rates improving in NIC over time, outcomes for extremely preterm infants (< 28 weeks) have not meaningfully changed in the last two decades."[8]

Preterm births have diverse causes. While many occur naturally, some result from medical issues like infections or pregnancy complications, leading to early labour or a C-section. Factors behind preterm birth, similar to those affecting infertility, can be linked to limited healthcare access and untreated prior health issues. Additionally, where babies are born and their access to NIC and postnatal care significantly impact their chances of survival.

Clearly, these issues intersect with political, economic, and social dynamics, necessitating their consideration in discussions concerning Artificial Womb Technology (AWT). The disparities in healthcare access and the socioeconomic context profoundly influence the prevalence of preterm births and subsequent outcomes, highlighting the need for a holistic approach. Additionally, the introduction of AWT raises a plethora of ethical considerations in particular related to the protection of the rights at stake. Questions surrounding the right to life, parental rights, and equitable access to advanced medical technologies prompt critical ethical reflections in navigating the implications of AWT.

1.1 The future of Ectogenesis

After its first appearance in the works of Haldne, as previously mentioned, Ectogenesis gained *momentum* one more time in the 1970s and 1980s with a debate around the liberating versus oppressive features of reproductive technology proposed by the feminist movement of the time. Later, in the early 2000s, AWT discussion came

[8] Romanis, E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research? *Bioethics, 34*(4), 392–402. Retrieved from: https://doi.org/10.1111/bioe.12701.

back with a focus on the possibility of being used for the advancement of fetal surgery with the creation of a controlled environment for fetal development.[9]

There are still many debates in the scientific community around the terminology that should be applied to this type of extra-uterine support system. The focal point of the debate revolves around the distinction between partial and complete ectogenesis, introducing various nuanced perspectives, particularly concerning partial ectogenesis. Some experts assert that partial ectogenesis is already a tangible reality, citing examples from the realms of IVF to neonatal incubation. Basically, "The term “partial ectogenesis” is often used to refer to any period of embryonic or fetal development occurring outside the organic womb"[10], as mentioned above, "IVF involves partial ectogenesis; the embryo initially develops in a petri-dish rather than a mammalian body. At the opposite end of the process, the neonatal incubation of preterm infants also involves partial ectogenesis: the 28-week-old, 1 kg preemie undergoes development for many weeks to come that normally happens inside the womb."[11]. Partial ectogenesis, therefore, "can be divided into two interpretations. On one interpretation, ‘partial ectogenesis’ refers to the transfer of a partially developed embryo or fetus from the female body to an external womb for the remainder of the gestation period. On another interpretation, ‘partial ectogenesis’ refers to techniques already routinely practiced in neonatology through the use of incubators to sustain premature babies, as well as in reproductive medicine through, for instance, in vitro fertilization."[12]

Full or complete ectogenesis, which is not the focus of recent research, means complete artificial gestation, in simple terms, it is just ""“babies in bottles” vision often espoused in science-fiction: the complete development of a new human (or other mammalian) being outside the maternal body, from conception to babyhood"[13].

Another term that was coined and is relevant for ethical analyses is ectogestation. It is a more specific subset of partial ectogenesis and it is a "method of distinguishing between existing neonatal technologies that serve the needs of infants born prematurely, and emerging technologies aimed at providing an alternative site for

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[9] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[10] Kendal, E. S. (2022). Focus: Bioethics: Form, Function, Perception, and Reception: Visual Bioethics and the Artificial Womb. *The Yale Journal of Biology and Medicine*, *95*(3), 371-377. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9511943/.
[11] Kingma, E., & Finn, S. (2020). Neonatal incubator or artificial womb? Distinguishing ectogestation and ectogenesis using the metaphysics of pregnancy. *Bioethics*, *34*(4), 354–363. https://doi.org/10.1111/bioe.12717.
[12] Segers, S. (2021)., op. cite.
[13] Kingma, E., & Finn, S., op. cite.

fetal development. At its most basic, the difference is often that the former is air-based and the latter fluid-based [...]"[14].

To better understand this concept and the subjects involved in it, Elselijn Kingma and Suki Finn, inspired by the work of Romanis[15], decided to differentiate the following terminologies: fetuses, gestatelings and neonates. In the words of the authors "to be a fetus is to have a physiology characteristic of a fetus; and to be a neonate is to have a physiology characteristic of a neonate. To be a gestateling, then, is to have a physiology characteristic of a fetus, but to exist outside of a gestating mammal"[16]. Apart from that, another differentiation factor between fetus and neonates is that the latter misses an organ, for example, the placenta and other physical characteristics, such as the umbilical cord and amniotic fluid. A third important aspect that must be taken into account is the change of location of their bodies since "According to the parthood view, birth also marks the transition from being part of another organism, to no longer being such a part. But even without accepting the parthood view, [...] analysis shows that birth is not just a change of location, but involves topological, physical and physiological changes: the loss (and, possibly, gain) of body parts; the loss of topological, physical and physiological connections to the gestator; and an internal physiological transformation that includes changes to vasculature, heart, lungs, hemoglobin, etc."[17]

After clearing these concepts, the authors define in a more precise way what and where the gestatelings fit into this rationale, "First, gestatelings are treated as if they had never been born, not in the sense that they haven't left the maternal body—for they have—but in the sense that they haven't undergone the transition from a fetal physiology to a neonatal physiology. Thus they are only "born" in the sense that they have changed location from inside to outside the maternal body, i.e. "born-by-location-change". But they are not "born" in the sense that they have changed their physiology from fetus to neonate, i.e. "born-by-physiology-change." Second, this specifies the way in which gestatelings are "more ontologically similar" to fetuses than neonates: they retain fetal physiology (as they have not undergone the "born-by-physiology-change" from fetus to neonate)."[18]

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[14] Kingma, E., & Finn, S. (2020). Neonatal incubator or artificial womb? Distinguishing ectogestation and ectogenesis using the metaphysics of pregnancy. *Bioethics*, *34*(4), 354–363.
[15] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910
[16] Kingma, E., & Finn, S., op. cite.
[17] Ibid.
[18] Ibid.

To summarize the difference between neonatal intensive care (NIC) and ectogestation, "Incubators, as a non-ectogestative version of ectogenetive technology, support neonates, taking over, or assisting with, functions they cannot yet perform. They do so on the physiological blue-print of a “born-by-physiology-change” (as well as ‘‘born-by-location-change”) neonate. Ectogestative technologies, by contrast, support gestatelings; they take over, or assist with, functions that cannot be performed on the physiological blue-print of a fetus. Ectogestation—and here is our rough definition—is thus development after being “born-by-location-change” but before being “born-by-physiology-change”: i.e. development outside the maternal body that prevents the physiological transformation from fetus to neonate."[19]

So where do the AWT can be placed in this scheme? AWT, as current research indicates, can be identified as partial ectogenesis and according to the specialist teams that are developing this technology, it will improve and reinvent the current neonate treatments since these devices aim to facilitate the process of ex utero gestation, enabling the development of preterms, reducing their mortality and morbidity rates. This technology had been developed by two different research teams, in the U.S. and in Australia[20], that created "artificial womb devices" or biobags: the EVE platform and the EXTEND design, where "Both approaches successfully enabled the development of lamb fetuses in a sterile environment, using extracorporeal perfusion."[21]

These sterile containers for the fetus can be divided into two major categories, pump-driven systems and pumpless ones, "Pump-driven (venovenous) systems use a pump to control drainage of blood to an oxygenerator. Pumpless (arteriovenous) models for oxygenation use the fetus' heart to pump the fetal blood from the umbilical arteries."[22]. Both systems are considered feasible, and for a long time, the first one was considered more advantageous, but new research demonstrated that actually, the pumpless system provides longer chances of survival, since "The state of the art suggests that substantial departures from the uterine physiology are not optimal for clinical application. It has been reported that the ideal model for AWT should preferably

[19] Kingma, E., & Finn, S. (2020). Neonatal incubator or artificial womb? Distinguishing ectogestation and ectogenesis using the metaphysics of pregnancy. *Bioethics*, *34*(4), 354–363.
[20] Partridge, E. A., Davey, M. G., Hornick, M. A., McGovern, P. E., Mejaddam, A. Y., Vrecenak, J. D., Mesas-Burgos, C., Olive, A., Caskey, R. C., Weiland, T. R., Han, J., Schupper, A. J., Connelly, J. T., Dysart, K. C., Rychik, J., Hedrick, H. L., Peranteau, W. H., & Flake, A. W. (2017). An extra-uterine system to physiologically support the extreme premature lamb. *Nature communications*, *8*, 15112. https://doi.org/10.1038/ncomms15112.
[21] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[22] Ibid.

mimic the circulation as it occurs in the intact fetal umbilical-placental unit, with perfusion determined by fetal cardiac output."[23].

Most of the research that has been conducted for the past years is done with fetal lambs. Back in 2017, following the uterine incision and with the use of the EXTEND design, the extremely premature fetal lambs were placed in a closed 'Biobag' where "Catheters imitate umbilical cord access and facilitate water and nutrient provision and waste product removal. An oxygenator ensures oxygen provision but allows the subject's heartbeat to control circulation as in utero. The subject is sealed in (synthetic) amniotic fluid, facilitating sustenance delivery and protecting it from infection. The biobag was able to sustain preterm lamb foetuses, developmentally equivalent to 'just‐viable' human preterms, for 28 days. 100% of the biobag subjects survived and were successfully 'delivered'. All research subjects appeared healthy and to have developed (evidencing successfully continued gestation)."[24]

In 2019, another group of specialists "published the second trial of the EVE platform. The EVE device has a similar design [from the one mentioned above], sealing the subject in a warm amniotic fluid bath in a sterilized plastic bag. The subject's heartbeat, an oxygenator and catheters maintain circulation. In a 2017 study, the EVE platform sustained lamb foetuses for a shorter period than the biobag study and had a higher incidence of morbidity and mortality. The authors were reserved about the potential clinical application of EVE therapy and directed their conclusions towards redesign. In 2019, they published the results of a study using their redesign."[25]. In this trial, the EVE platform produced similar results to the EXTEND, demonstrating five-day survival of healthy fetal lambs, which was allegedly extended to 14 days in a subsequent set of unpublished experiments. The same five-day results were achieved once more by the same group of scientists, that kept more immature ewe fetuses in an ex vivo uterine environment and they also, as the ones before, presented normal somatic growth, cardiovascular performance and absence of infection and inflammation.

Despite the success of the usage of sterile containers for partial ectogenesis, research has also been developed in the area using bioengineered uteri or donated uteri. In 1988, the first in vitro culture of a human embryo was realized for a total of 52 hours in a hysterectomized human uterus, that was extracorporeally perfused with an

[23] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[24] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.
[25] Ibid.

oxygenated medium. Moreover, "A variant of using donated uteri for ectogenesis, is so-called xenopregnancy where an embryo or fetus is placed inside a uterine carrier belonging to a different species. This has been tried in non-human animals. As far as safety is concerned, there are at least risks of immune rejection of the fetus, inappropriate interactions between the fetal trophoblast and the endometrium of the carrier and cross-species transfer of infections."[26].

Furthermore, many advances can be seen in tissue engineering and, despite the focus of the research being the transplantation of organs, many believe it can be applied to ectogenesis in the future. Considering that tissue engineering is the creation of analogous biological organs using 3D bioprinting or 3D scaffolds using biomaterials, the development of uteri " “offer hope” to develop an artificial uterus that can be used not only for uterine transplantation, but also for ectogenesis"[27]. As mentioned before, the main goal of the research being conducted now is its usability in reproductive medicine, either as in vitro research applications for endometrial cancer cell studies and drug screening applications as well as its future application in *in vivo* transplantation studies, with the goal of curing uterine factor infertility. Important to mention that ectogenesis can take various forms, and does not completely overlap with AWT. Ectogenesis research can, but does not always, involve tissue or bioengineering.

There are many different researchers being developed around the world in this field, for example, in 2019 the EU program Horizon 2020 and a €2.9 million grant available for the development of an artificial womb by Professors Frans van de Vosse and Loe Feijs from Eindhoven University of Technology (TU/e) and professor Guid Oei from Máxima Medical Center (MMC) and TU/e that initiated the European consortium that received the grant declaring that they could create a working prototype in five years[28].

The researchers from the EVE platform and the EXTEND design despite admitting that the device needs to be improved and that their findings need to be validated further, were convinced that their device was ready for humans in the near future. The primary clinical target population of AWT would be a life support platform for extremely preterm infants considering the "improvements in extracorporeal circuit configuration and advances in oxygenator technology, significant progress has been achieved both in demonstrating the physiological effects of the artificial environment

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[26] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[27] Ibid.
[28] *Multimillion grant brings artificial womb one step closer*. (2019). https://www.tue.nl/en/news/news-overview/multimillion-grant-brings-artificial-womb-one-step-closer/.

and the feasibility of extra-corporeal support of younger animals biologically comparable to a 22–24-week gestation human fetus"[29], which can lead to a broader range of applications if successful.

By the end of September 2023, the Pediatric Advisory Committee, as an advisory committee that provides non-binding recommendations to the FDA, under the U.S. Food and Drug Administration (FDA), announced a meeting in order to discuss the appropriate development plans for establishing safety and effectiveness of artificial womb technology (AWT) devices, including regulatory and ethical considerations for first in human (FIH) studies as to the use of AWT as an alternative to current standard-of-care management of extremely premature infants in the Neonatal Intensive Care Unit[30].

Before such technology could be used on humans, the FDA committee agreed that scientists would need to determine the best animal model to test the artificial womb and according to experts, there may also need to be a discussion about what viability — the ability of a human to survive outside the womb — means. In the meeting, the committee debated the ethics of using the technology in depth, including what discussions doctors might have with parents about how successful such an intervention might be if tested on humans and they also wanted to ensure that if humans were used in the trials, they were inclusive. Furthermore, they said it was imperial the necessity of extensive follow-up to determine what long-term health effects, if any, children experienced. They also made remarks at potential clinical considerations to determine whether the new technology would be an improvement over current care.

These concerns are valid since many affirm that these studies are promising, but have limitations, considering that "The devices have only been tested on small sample sizes for short durations. Further validation of results is necessary for repeated, longer studies. Moreover, the outcome of these studies should not be considered sufficiently promising to allow use on human subjects without significant refinement. The EVE study had a survival rate of 87.5%, there was an incidence of brain damage, and several subjects displayed early signs of liver dysfunction. These risks *may* be no worse than those that routinely occur in NIC. It is important, however, that the specific risks and uncertainties are acknowledged. Finally, lambs have a different physiology

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[29] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

[30] *Pediatric Advisory Committee Meeting Announcement*. (2023). U.S. Food And Drug Administration. https://www.fda.gov/advisory-committees/advisory-committee-calendar/pediatric-advisory-committee-meeting-announcement-09192023.

from humans. Thus, the devices may be less successful when used on humans. Testing on animals, such as primates, with physiologies more similar to humans, is necessary to better understand the likelihood of AWs gestating humans."[31]

When it comes to ectogenesis and artificial womb technology, the outlook is both promising and ethically complex. The potential to revolutionize neonatal care, providing hope to premature infants and families, is accompanied by significant societal, ethical, and legal concerns. The realization of sustaining gestation outside the maternal body gets closer as research advances. The future holds the promise of improving these technologies, making them more accessible, and navigating the complex web of ethical and societal implications.

1.2 Partial Ectogenesis and the use of Artificial Wombs Technology

In accordance with the World Health Organization (WHO), approximately 13.4 million babies were born in 2020 before 37 completed weeks of gestation. The numbers for preterms across countries range from 4–16% of babies in the same year. A preterm is a baby born alive before 37 weeks of pregnancy are completed and they are sub-divided based on gestational age: the ones being born with less than 28 weeks are known as extremely preterm; very preterm are those born with 28 to less than 32 weeks and moderate to late preterm the ones born between 32 to 37 weeks.[32]

Preterm birth can occur for a number of reasons. The majority of them occur naturally, but some are caused by medical reasons such as infections or other pregnancy complications that necessitate early induction of labour or caesarean birth. In 2019, approximately 900,000 children died as a result of preterm birth complications and many survivors were disabled for the rest of their lives. These numbers show that prematurity is the leading cause of death in children under the age of 5 years. Although the majority of preterm births occur in southern Asia and Sub-Saharan Africa, preterm birth is a global issue. The survival rate of premature babies varies dramatically depending on where they are born. For example, more than 90% of extremely preterm

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[31] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

[32] *Preterm birth*. (2023, May 10). https://www.who.int/news-room/fact-sheets/detail/preterm-birth#:~:text=An%20estimated%2013.4%20million%20babies%20were%20born%20too%20early%20in,and%20visual%20and%20hearing%20problems.

babies (those born before 28 weeks) die within the first few days of life in low-income countries, while less than 10% die in high-income countries.[33]

Furthermore, there has been no discernible change in global preterm birth rates over the last decade, including in the highest-burden regions, "Preterm birth rates were 9.9% in 2020, compared to 9.8% in 2010. There was also no measurable change in preterm birth rates in the highest-burden regions (Southern Asia: 13.3% in 2010 and 13.2% in 2020, and sub-Saharan Africa: 10.1% in both 2010 and 2020). National-level preterm birth rates also changed little between 2010 (5.8%–16.5%) and 2020 (4.1%–16.2%)."[34] Only a few countries have reduced their preterm birth rates by 0.5% per year between 2010 and 2020: Czechia, Austria, Brunei Darussalam, Singapore, Spain, the Netherlands, Denmark, Hungary, Brazil and Sweden.

Moreover, "In 13 countries (Poland, Iceland, Croatia, United Kingdom of Great Britain and Northern Ireland, Bulgaria, Armenia, Bahrain, Ireland, Chile, Georgia, Colombia, the Republic of Korea and North Macedonia) the preterm rates increased by more than 5% in this period, although some of these increases may relate to improved data quality. In 52 other countries, the preterm birth rate showed no measurable change (absolute percentage increase <1%). The absolute number of babies born preterm decreased slightly from 13.8 million in 2010 to 13.4 million in 2020, primarily due to fewer births globally and in many regions. However, in sub-Saharan Africa, the number of babies born preterm increased, with 563,000 more babies born preterm in 2020 than in 2010. This relates to increases in the birth cohort in sub-Saharan Africa, as well as to the lack of reduction in preterm birth rates."[35]

In 2020, more than half of all preterm births were reported in eight specific countries and regions, maintaining the same top-ranking positions observed in 2010, albeit with minor fluctuations in their positions. India registered the highest count of preterm births (3.02 million), contributing to over 20% of global preterm births. Following India were Pakistan, Nigeria, China, Ethiopia, Bangladesh, the Democratic Republic of the Congo, and the USA. The prevalence of preterm births in these regions is influenced, in part, by their large population sizes, substantial total birth rates, and

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[33] *Preterm birth*. (2023, May 10). https://www.who.int/news-room/fact-sheets/detail/preterm-birth#:~:text=An%20estimated%2013.4%20million%20babies%20were%20born%20too%20early%20in,and%20visual%20and%20hearing%20problems.

[34] *Born too soon: decade of action on preterm birth*. (2023, May 9). https://www.who.int/publications/i/item/9789240073890.

[35] Ibid.

insufficient healthcare systems that struggle to provide comprehensive family planning, prenatal care, and birthing services to meet the needs of all individuals.[36]

As previously mentioned, preterm birth can be associated with many diseases and disorders even with the best procedures NIC can provide. "The biggest issues plaguing preterms include underdeveloped lungs and respiratory problems, circulatory problems causing low blood pressure and oxygen deprivation and an underdeveloped ability to swallow or suck. These complications are almost inevitable before 26 weeks. They can be managed by providing mechanical ventilation, administering oxygen, using external pumps to aid circulation and nasogastric feeding These functions are all interventions facilitated in infant incubators, and they each carry risks and limitations. Mechanical ventilation and the administration of oxygen can hinder further lung development or damage the lungs. External aids for circulation can cause heart failure by affecting imbalances in blood flow. Nasogastric feeding carries a high risk of necrotising enterocolitis (death and leakage of intestinal tissue) and infection."[37]

These can lead to "long-term detriments to respiratory and cardiac systems, especially with neurodevelopmental impacts on survivors. These range from major disabilities, such as diplegia, especially for those most preterm, to less severe outcomes. Importantly, new research shows that being born even a few weeks preterm can result in learning and behavioural spectrum disorders; since most preterm babies are born between 32 and 36.9 weeks, this is a more frequent outcome. Indeed, even those born between 37 and 39.9 weeks have a slightly elevated risk of adverse neurodevelopmental outcomes. It is important to recognize that many of these disabilities are preventable and are a sensitive marker of quality of care. A crucial example is blindness or visual impairment due to retinopathy of prematurity, which has been increasingly reported over the last decade, especially in Latin America and South-Eastern Asia, often in newborns who were only moderately preterm. Improving safe oxygen use (avoiding saturations above 95%) and scaling up screening and treatment is crucial to avoid a repeat of the epidemic of blindness seen in the United States in the 1960s."[38]

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[36] Ohuma, E. O., Moller, A. B., Bradley, E., Chakwera, S., Hussain-Alkhateeb, L., Lewin, A., Okwaraji, Y. B., Mahanani, W. R., Johansson, E. W., Lavin, T., Fernandez, D. E., Domínguez, G. G., de Costa, A., Cresswell, J. A., Krasevec, J., Lawn, J. E., Blencowe, H., Requejo, J., & Moran, A. C. (2023, October). National, regional, and global estimates of preterm birth in 2020, with trends from 2010: a systematic analysis. *The Lancet*, *402*(10409), 1261–1271. https://doi.org/10.1016/s0140-6736(23)00878-4.

[37] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910.

[38] *Born too soon: decade of action on preterm birth*. (2023, May 9). https://www.who.int/publications/i/item/9789240073890.

Due to the inherent risks and constraints associated with existing interventions, certain scientists posit that the clinical potentials of Neonatal Intensive Care (NIC) have reached their limits. They argue that medical interventions can only offer a finite scope of support for neonates lacking the ability for independent survival. Consequently, a significant percentage—between 60% and 80%—of NIC fatalities occur following the withdrawal of interventions.[39] This raises ethical quandaries within conventional NIC, where the withdrawal of treatment often results in the prolonged physical suffering of the neonate and emotional distress for their parent/s.

The exploration of potential alternative interventions presents challenges, as these approaches may entail similar risks and barriers to success as routine methods. Thus, researchers are exploring an innovative physiological strategy aimed at emulating the uterine environment more effectively. This approach seeks to sustain underdeveloped neonates by closely replicating gestation within an environment akin to an Artificial Womb (AW). Unlike traditional infant incubators used in NIC, which assist premature infants with bodily functions they struggle to perform independently, this proposed support system aims at fostering continuous development, almost as if the neonate had not yet been born. It's noteworthy that this approach seems to address the three most common complications—lung development, circulation, and infection—often encountered in conventional NIC.

When comparing two medical technologies that serve a similar purpose, they're often considered interchangeable unless their fundamental processes significantly differ. For instance, medical and surgical treatments are differentiated by their levels of invasiveness. Artificial Womb Technology (AWT) and conventional Neonatal Intensive Care (NIC) both aim to support underdeveloped humans. However, a fundamental difference in AWT is its provision of more comprehensive support compared to conventional NIC. Presently, current care for preterm infants relies on their ability to tolerate artificial ventilation, constrained by a natural threshold of lung development. This limitation doesn't apply to AWT, as it more closely resembles natural gestation and doesn't depend on lung function for gas exchange. This distinction implies that the AW isn't bound by the same limitations related to lung development. The long-term implications of artificial gestation remain uncertain and will continue to be a subject of

[39] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910.

research trials even after removal from the artificial womb. While the biobag remains a novel experimental treatment, conventional NIC operates as standard practice.[40]

Furthermore, another advance that could be seen with the rise of AWT is in the field of surgical procedures. Various authors propose that certain fetal treatments, such as specific surgical procedures, could be facilitated if conducted on a fetus outside the uterus. In utero fetal therapy involves risks like surgical complications for the pregnant individual and a potential risk of uterine rupture. Prevalent guidelines in neonatal care often advocate counselling to persuade pregnant individuals to undergo medical interventions for the benefit of viable fetuses. However, if ectogenesis extends the threshold of fetal viability (potentially rendering more or all fetuses viable), it could intensify pressures on pregnant individuals to opt for fetal removal during advocated fetal therapy. This risk impacts directly the pregnant person, due to the physical relocation of the fetus to the artificial womb: "An incision is made in the uterus—resembling a Caesarean—to expose the fetus, after which it is transferred to the sterilized container. It is likely that this intervention will be no less risky than a Caesarean section—with the potential to be significantly riskier. Caesareans are a form of major surgery and entail possible adverse consequences like risks of blood clotting and excessive bleeding, wound infection, and in cases of a previous Caesarean there is an expected increased risk of obstetric complications (e.g. heightened risks of hysterectomy, abnormal placentation, uterine rupture)."[41]

Moreover, some specialists have proposed a hypothesis suggesting that certain risks are indeed more probable for the ones bearing the fetus in cases of partial ectogenesis. They argue that performing a uterine incision during early pregnancy stages, when the uterus is less stretched compared to term pregnancies, may result in a relatively larger scar, potentially increasing future risks such as uterine rupture or abnormal placental implantation, besides possibly compromising a person's eventual later reproductive trajectory and it is often made more complex by the ethical dilemma of determining whether the drawbacks are justified by the expected clinical advantages.[42]

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[40] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910.

[41] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

[42] Segers, S., & Romanis, E. C. (2022). Ethical, Translational, and Legal Issues Surrounding the Novel Adoption of Ectogestative Technologies. *Risk management and healthcare policy*, *15*, 2207–2220. https://doi.org/10.2147/RMHP.S358553.

In delving into Partial Ectogenesis and Artificial Womb Technology (AWT), we uncover a realm of possibilities and complexities. Navigating the data on preterm births, the dynamics of Neonatal Intensive Care (NIC), and the nuanced advantages and drawbacks of AWT for both fetus and carrier, we confront an evolving frontier in reproductive science. As we grapple with ethical dilemmas and weigh medical advancements, the responsible and ethical application of this technology emerges as a crucial consideration in shaping the future of maternal and neonatal healthcare.

1.3 Complete Ectogenesis

Complete Ectogenesis and Artificial Womb Technology (AWT) have been longstanding subjects of exploration, extensively depicted in science fiction literature and cinematic works. Notable examples include 'The Matrix' and Aldous Huxley's 'Brave New World.' However, these technological concepts often evoke apprehension, predominantly due to their portrayal in dystopian narratives. Discussions surrounding Complete Ectogenesis or AWT commonly carry an undertone of fear, as they are often intertwined with speculative concerns regarding societal and ethical consequences.

In reality, many scholars believe that full ectogenesis may be developed by accident or as a consequence of the advancement of partial ectogenesis. Once AWs can consistently and safely support the survival of premature infants at the viability threshold, both medical professionals and parents will likely advocate for extending this technology to assist slightly fewer premature infants. Historical trends in conventional NIC have shown a similar progression leading to our current viability standard. Should the biobag function as intended, it is expected that infants supported by AWs will encounter fewer complications compared to those relying on traditional NIC. Consequently, healthcare providers are likely to view earlier interventions for preterms more favourably with the availability of AWs, as it promises improved outcomes. The motivation behind exploring biobag technology stemmed from the desire to aid 'almost surviving' preterm infants. If AW technology proves successful with older neonates, introducing younger infants into AWs would probably encounter little controversy, fostering a willingness to attempt novel interventions in neonatal care.[43] As a result, the

[43] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910.

logical progression of this technology involves its adaptation to cater to even younger fetuses.

On the other end of the spectrum, researchers have reported a recent achievement in cultivating fertilized mouse oocytes from the moment of conception for up to 11 days using an external culture system.[44] This research doesn't primarily aim to enhance care for preterm infants; instead, its focus lies in delving into the foundational understanding of embryonic development's earliest phases. This procedure aims to cover the gap between fertility treatments and AWs (as in partial ectogenesis for preterm births), focusing on embryonic development. It is seen as a groundbreaker because exploring how tissues and organs form during development is a key aspect of developmental biology. In mammals, this process occurs after the embryo attaches inside the uterus, making it challenging to observe and control. As a result, the series of events during the development stages from before gastrulation to organ formation remains not entirely comprehended and proves challenging to influence or modify.

Before this advancement, studies involving ex utero mouse embryonic development were constrained to brief periods of 24–48 hours and they couldn't commence from the pre-gastrulation phase, failing to capture the ongoing processes of both gastrulation and organ formation and they even couldn't accurately replicate normal gastrulation leading to proper organ development, and predominantly resulted in low-efficiency and abnormal embryo development.[45]

Nevertheless, with the ex utero mouse study mentioned above, on the 11th day of the embryo development, which is over halfway through a typical mouse pregnancy, the research team studied the lab-grown embryos—about the size of apple seeds—and compared them to embryos developing inside live mice. Remarkably, the lab-grown embryos were identical to those in the uterus. However, at this stage, the lab-grown embryos had grown too large to survive without a direct blood supply. While they had developed a placenta and a yolk sac, the nutrient solution they relied on for sustenance through diffusion was no longer adequate. The experts affirm that overcoming this challenge is their next objective and that they will explore options like a

[44] Aguilera-Castrejon, A., Oldak, B., Shani, T., Ghanem, N., Itzkovich, C., Slomovich, S., Tarazi, S., Bayerl, J., Chugaeva, V., Ayyash, M., Ashouokhi, S., Sheban, D., Livnat, N., Lasman, L., Viukov, S., Zerbib, M., Addadi, Y., Rais, Y., Cheng, S., Stelzer, Y., … Hanna, J. H. (2021). Ex utero mouse embryogenesis from pre-gastrulation to late organogenesis. *Nature*, *593*(7857), 119–124. https://doi.org/10.1038/s41586-021-03416-3.

[45] Oldak, B., Aguilera-Castrejon, A., & Hanna, J. H. (2022). Recent insights into mammalian natural and synthetic ex utero embryogenesis. *Current opinion in genetics & development*, *77*, 101988. https://doi.org/10.1016/j.gde.2022.101988.

more enriched nutrient solution or an artificial blood supply connected to the embryos' placentas.[46]

Being able to watch as early embryonic development occurs, means uncovering reasons behind miscarriages or unsuccessful egg implantation. It offers a new perspective in understanding how gene mutations impact fetal growth. This innovation could potentially enable researchers to observe how individual cells move to their final locations during the development of the organism.

In the context of full ectogenesis, the convergence of In Vitro Gametogenesis (IVG), In Vitro Fertilization (IVF), and Artificial Womb Technology (AWT) presents a transformative potential in revolutionizing human reproduction. IVG involves the creation of sperm and egg cells from induced pluripotent stem cells (IPSCs), allowing individuals without gametes to have their own genetically related offspring. IVF, a well-established technique, unites eggs and sperm in a lab dish, facilitating fertilization outside the body before implantation into the uterus. Integrating IVG with IVF might enable the creation of gametes in a lab for fertilization, particularly benefiting individuals with fertility challenges. AWT introduces the concept of gestating embryos/fetuses outside the human body, potentially allowing for full-term development within an artificial womb. The fusion of IVG's cell creation capability, IVF's fertilization process, and AWT's external gestation could reshape reproduction paradigms.

Moreover, genetic manipulation studies within this context (considering that these advancements could potentially be used in an integrative form) could offer insights into how altering specific genes influences the developmental trajectory during these artificial reproductive processes, potentially impacting the long-term health and development of offspring. This integration might offer solutions for infertility, enhance reproductive options for diverse circumstances, and challenge traditional notions of conception and pregnancy, fundamentally altering the landscape of human reproduction.

However, the advancements in merging IVG, IVF, and AWT also raise profound ethical and sociological considerations. These technologies challenge established ethical frameworks surrounding reproduction, parenthood, and the beginning of human life. The potential for selecting specific genetic traits or editing genes prompts ethical debates regarding the ethical boundaries of manipulating human genetic material. Societal concerns arise regarding equitable access to these technologies, potential commercialization, and the societal implications of altering traditional concepts of

[46] Kolata, G. (2021, March 17). *Scientists Grow Mouse Embryos in a Mechanical Womb*. The New York Times. https://www.nytimes.com/2021/03/17/health/mice-artificial-uterus.html.

conception, family structure, and parenting. Ethical deliberations are vital to navigating the ethical complexities, ensuring responsible use, addressing societal implications, and fostering inclusive discussions and policy frameworks that consider the ethical, legal, and social implications of these groundbreaking reproductive technologies.

While this integration holds promise for addressing infertility and expanding reproductive options, there are considerations regarding the potential human toll. The extensive utilization of these technologies might lead to unforeseen health risks or long-term consequences for the offspring, necessitating extensive monitoring and assessment of their safety and impact on individuals' well-being. Furthermore, the commercialization and accessibility of these technologies might exacerbate societal disparities, potentially creating divides in access to advanced reproductive options. Additionally, there are ethical concerns about the commodification of human life, where reproductive technologies may become a transactional endeavour rather than a means of fulfilling deeply personal desires for parenthood. It's crucial to weigh these potential outcomes against the benefits and ethical considerations, ensuring that the human price for advancing reproductive technologies is vigilantly evaluated and minimized through responsible and conscientious utilization.

The collaborative integration of multiple biotechnologies, such as the ones mentioned above, mirrors historical patterns of technological convergence seen in biotechnology advancements. For instance, the convergence of DNA sequencing technologies with computational biology has propelled breakthroughs in genomics and personalized medicine. Similarly, the fusion of CRISPR gene-editing technology with stem cell research has opened new avenues in targeted therapies and regenerative medicine. Just as these integrated biotechnological approaches have revolutionized healthcare, the coordinated application of IVG's cell creation abilities, IVF's fertilization methods, AWT's external gestation, and genetic modification's precision hold the potential to alter the course of human reproduction. This integration reflects a collective effort to address complex challenges in reproductive biology, aiming for inclusive solutions, enhanced reproductive healthcare, and a deeper understanding of early human development.

The potential applications and ethical considerations surrounding full ectogenesis invite us to contemplate the profound implications of these advancements. This transformative journey calls for careful ethical deliberation, inclusive discourse, and a conscientious approach to harnessing these technologies for the betterment of reproductive health and human understanding.

Chapter 2 - Understanding the impact of Reproductive Rights and ART frameworks on the regulation of Artificial Womb Technology: navigating the legal landscape in the EU and beyond

2.1 The initiatives of the United Nations concerning Reproductive Rights

Legislation concerning reproductive rights exhibit global variability, shaped by diverse factors like religious beliefs, cultural norms, and ethical principles. The distinctions in legal frameworks underscore the need for nuanced analyses and a comprehensive understanding of their intricate interplay.

The landscape of reproductive rights in Europe is significantly influenced by the actions of both committee and legislative bodies within the European Union, such as the European Parliament and the European Commission, which enact regulations and directives impacting reproductive health and rights across member states. Additionally, the Council of Europe, through its conventions and recommendations, and the rulings of the European Court of Human Rights in Strasbourg, play a pivotal role in shaping legal frameworks and standards concerning reproductive rights. However, it is crucial to recognize that the United Nations also exerts substantial influence in this domain. At the UN level, various guidelines and declarations, including those stemming from conventions like the International Conference on Population and Development (ICPD) and the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), serve to direct the policies of member states and international organizations regarding reproductive health, rights, and justice.

Reproductive rights, constituting a pivotal component of Sexual and Reproductive Health Rights (SRHR), encompass not only reproductive health but also sexual health and rights. At the international level, besides the ICPD - one of the instruments that helped to shape global discourse and policy frameworks concerning reproductive health and rights-, within the UN framework, the UNESCO Universal Declaration on Bioethics and Human Rights highlights the principle of informed consent, crucial in ensuring individuals' autonomy in reproductive decision-making. This principle resonates with Article 5 of the Oviedo Convention, a legally binding instrument adopted by the Council of Europe, emphasizing the importance of voluntary consent in healthcare matters, including reproductive choices.

Moving to the supranational level within the EU, entities such as the Committee on Women’s Rights and Gender Equality (FEMM) and instruments like the EU Charter

play instrumental roles in advancing reproductive rights. The FEMM Committee, in particular, serves as a forum for advocating gender equality policies, including those related to reproductive health and rights. Additionally, the EU Charter enshrines fundamental rights, including the right to dignity and integrity of the person, which are pertinent to reproductive rights issues.

At the regional level, the Council of Europe plays a significant role in shaping legal frameworks through instruments like the Oviedo Convention and decisions of the European Court of Human Rights (ECHR) in Strasbourg. The Oviedo Convention reinforces principles of autonomy and consent in healthcare, echoing the broader international consensus on these fundamental rights. Furthermore, the Strasbourg Court's rulings have a profound impact on member states' obligations to uphold reproductive rights, ensuring compliance with the European Convention on Human Rights (ECHR).

According to the FEMM Committee of the European Parliament, reproductive rights encompass the freedom to decide on the timing of childbirth, ensuring freedom from discrimination, coercion, and violence in family planning choices[47]. SRHR play a crucial role in securing the right to the highest attainable standard of physical and mental health, as highlighted in the 2003 resolution by the UN Commission on Human Rights[48] and the Programme of Action of the International Conference on Population and Development[49]. In line with the FEMM Committee's stance, the EU is urged to adhere to international human rights law and standards, including the 2003 UN Commission on Human Rights resolution and the Programme of Action.

The foundational framework for international consensus on Sexual and Reproductive Health and Rights (SRHR) is enshrined in the Programme of Action established during the 1994 International Conference on Population and Development (ICPD) in Cairo. Central to this Programme is the principle of respecting national laws, development priorities, and the diverse religious, ethical, and cultural values inherent to each country. A pivotal component of the Programme of Action is the dedicated section on reproductive rights and reproductive health, which delineates reproductive health as a holistic state encompassing physical, mental, and social well-being pertaining to the

[47] Anedda, L., et al. (2018). Sexual and Reproductive Health Rights and the Implication of Conscientious Objection (Policy Department for Citizens' Rights and Constitutional Affairs Report No. 11). Retrieved from https://eurogender.eige.europa.eu/system/files/post-files/eige_icf_sexual-and-reproductive-health-rights.pdf.

[48] UN Commission on Human Rights. (2003). Commission on Human Rights Resolution 2003/28: The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. Retrieved from https://undocs.org/E/CN.4/RES/2003/28.

[49] UN Population Fund (UNFPA). (1995). Report of the International Conference on Population and Development, Cairo, 5-13 September 1994 (A/CONF.171/13/Rev.1).

reproductive system. The objectives outlined within this Programme are multifaceted, aiming to ensure access to comprehensive and accurate information regarding SRHR, provide a wide array of reproductive healthcare services, facilitate accessibility, affordability, and convenience in family planning, and foster support for responsible voluntary decisions regarding child-bearing and family planning methods.

Furthermore, the Programme offers concrete recommendations delineating actionable steps to advance its objectives. These recommendations include advocating for improved accessibility to reproductive health services through primary healthcare systems, prioritizing maternal healthcare needs, and fostering community engagement in reproductive health initiatives. While highlighting the importance of tailoring interventions to local contexts, the Programme underscores the imperative of safeguarding maternal health and promoting women's participation in healthcare decision-making processes. It calls for enhanced community involvement, partnerships with local non-governmental organizations, and targeted support for transitioning economies facing reproductive health challenges. Moreover, the Programme urges the international community to acknowledge and address the distinct needs of vulnerable populations, including migrants, displaced persons, and individuals who have experienced trauma, such as survivors of sexual violence.

Recognizing and upholding the fundamental rights outlined in these international agreements, aiming at fostering collaboration and advocacy to advance reproductive health and rights for all individuals, entails not only acknowledging the principles enshrined in documents such as the ICPD and CEDAW, for instance, but also actively implementing policies that prioritize access to comprehensive reproductive healthcare services, including family planning and maternal care. Collaboration among nations, international organisations, and civil society is crucial in addressing the multifaceted challenges faced by communities worldwide, from ensuring access to accurate information about sexual and reproductive health to combating discrimination and violence in family planning choices, for example.

2.2 Exploring the regulatory framework in Europe: the EU

The Programme of Action acknowledges reproductive rights as inherent human rights, echoing sentiments expressed in national legislation, international human rights instruments, and consensus agreements, echoing the stance of the FEMM Committee.

Within the European Union, the Charter of Fundamental Rights[50] holds a central position in protecting the fundamental rights of European citizens. This comprehensive document enshrines various reproductive rights within its framework of fundamental rights. For instance, Article 2 of the Charter establishes the universal right to life, which inherently includes access to quality healthcare, as emphasized in Article 35, mandating Member States to ensure robust protection of this right.

Article 14 of the Charter guarantees the right to education for all individuals, with Article 14(3) acknowledging sensitivity to diverse beliefs, in alignment with Article 10 of the Charter on freedom of thought, conscience, and religion, reflecting the objectives of the Programme of Action. Member States must ensure access to education without disregarding diversities, a provision corresponding with the fundamental right of freedom of expression and information, emphasising the importance of education on reproductive rights. The EU initiated several policies in this domain to enhance European citizens' understanding and awareness regarding sexual health. The EU's approach to sex education in schools encompasses various models, including the abstinence-only approach, comprehensive sexuality education, and the more recent holistic sexuality education approach, each reflecting distinct perspectives on sexual health and relationships, with the holistic approach focusing on age-appropriate, culturally responsive, and rights-based education.

Additionally, the Charter upholds the right to marry and form a family, emphasizing the importance of respecting family life (Article 9) and privacy (Article 7). This includes the freedom to make decisions regarding family planning, with privacy surrounding these choices safeguarded by both societal norms and healthcare services. Article 3 of the Charter guarantees everyone's right to physical and mental integrity, aligning with SRHR principles by emphasizing the protection of individuals involved in reproduction and highlighting the role of reproductive health in overall well-being. Furthermore, Article 20 underscores the principle of equality before the law, emphasizing the prohibition of discrimination based on various grounds. While the UN Programme of Action recognizes the importance of equality, SRHR predominantly focuses on maternal well-being.

Reproductive rights, as enshrined in the EU Charter of Fundamental Rights - and as demonstrated above - form a comprehensive foundation for individual autonomy in family planning and healthcare decisions. While the specific regulation of ART often falls within the purview of national legislation, the guiding principles of

[50] Charter of Fundamental Rights of the European Union, 2012/C364/0. Retrieved from http://data.europa.eu/eli/treaty/char_2012/oj

reproductive rights from the EU Charter contribute to shaping a framework that acknowledges the evolving landscape of reproductive healthcare and the diverse needs of individuals across member states.

2.3 Council of Europe's impact on regulatory policies in Europe

With regards to reproductive medicine and biotechnology, in 1997, the Council of Europe adopted the Convention on Human Rights and Biomedicine[51], commonly known as the Oviedo Convention, which addresses many ethical and legal aspects of biomedicine that can impact human rights in Europe. Here, important to mention that this document has been updated with additional protocols. The Convention, which is the only international legally binding instrument in the field, possess as its main goal the protection of human rights and fundamental freedoms in the medicine, biomedicine and reproductive areas. It entered into force only on 1st December 1999 after it was ratified by a sufficient number of member states. It constitutes a comprehensive framework encompassing specific subjects such as transplantation, genetic research, and notably, ART. Although not an EU treaty, numerous member states ratified it, and it has served as a benchmark for the development of national policies and legislation. Additionally, the framework includes provisions ensuring that it does not adversely impact existing or future international instruments if deemed more favourable to individuals.

Important to mention that the treaty lacks an enforcement mechanism, resulting in the absence of an international court dedicated to enforcing the provisions outlined in the Oviedo Convention. However, the Strasbourg Court possesses the authority to utilize these provisions in interpreting the norms stipulated in the European Convention on Human Rights, thus indirectly safeguarding the principles articulated within the Oviedo Convention[52].

The Oviedo Convention draws upon principles derived from various treaties, conventions, and instruments, including the European Convention on Human Rights[53]

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[51] *Oviedo Convention and its Protocols - Human Rights and Biomedicine - www.coe.int*. Human Rights and Biomedicine. https://www.coe.int/en/web/bioethics/oviedo-convention.

[52] See *Demir and Baykara v. Turkey* (App. 34503/97) judgment of 12 November 2008 *Reports of Judgments and Decisions* 2008, par. 81.: "The Court took account, in interpreting […] the Convention, of the standards enshrined in the Oviedo Convention on Human Rights and Biomedicine of 4 April 1997, even though that instrument had not been ratified by all the States parties to the Convention".

[53] European Convention on Human Rights. (1950). Retrieved from https://www.echr.coe.int/european-convention-on-human-rights.

(ECHR), the UNESCO Universal Declaration on Bioethics and Human Rights and even the Charter of Fundamental Rights of the European Union. These foundational documents, in conjunction with the ECHR, laid the groundwork for the principles embedded in the Convention. Notably, it references rights such as the right to private and family life, the principles of non-discrimination and the best interest of the child, access to information, human dignity, respect for individual autonomy, reproductive choices, and informed consent.

The Oviedo Convention, as mentioned above, embodies the fundamental principles of bioethics, notably the principle of consent. According to the Convention, any medical intervention, and in the future also AWT, necessitates the explicit, informed consent of the individual, which can be revoked at any juncture (Article 5). In cases involving individuals with diminished capacity to consent due to mental disorders or illness, the intervention may only proceed with the authorization of a legally designated representative or authority, as specified by law (Article 6). Notably, the individual in question retains the right to participate in the authorisation process, which remains subject to withdrawal at any time (Article 6). Crucially, Article 9 stipulates that previously expressed wishes regarding medical interventions by patients who are unable to express their wishes at the time of the intervention must be duly considered[54].

Furthermore, the Convention emphatically prohibits financial gains from the human body, preventing the exploitation of any of its parts and substances. It also prohibits genetic manipulation, aiming to safeguard the integrity of the human genome and establishing ethical boundaries regarding human cloning and genetic manipulation, particularly in light of historical atrocities such as eugenics experiments conducted during the period of World War II. The convention, guided by principles of respect for human dignity and autonomy, imposes stringent limitations on these practices. Specifically, the convention prohibits human cloning and emphasizes the necessity of informed consent for any medical intervention, including genetic manipulation, in line with Articles 5 and 6, as already mentioned above. This stance underscores Europe's commitment to upholding ethical standards in biomedical research and healthcare as these restrictions reflect a collective response to the ethical dilemmas posed by advancements in biotechnology. Failure to adhere to such ethical guidelines could lead to dystopian scenarios, where the commodification of human life, loss of individual autonomy, and exacerbation of social inequalities become prevalent.

[54] Ruggiu D. (2018). *Human Rights and Emerging Technologies. Analysis and Perspectives in Europe*. Pan Stanford, Singapore, p. 345.

The regulation landscape on ART across Europe can be better visualized due to a 2020 survey conducted by the European IVF Monitoring Consortium of the European Society of Human Reproduction and Embryology (ESHRE), across forty-three European countries that revealed that while almost all countries (excluding Albania, Bosnia and Herzegovina, Ireland, Romania, and Ukraine) have specific legislation addressing ART, many substantial legal variations persist among them, with the most prominent discrepancies pertaining "access to treatment (based on age and relationship status), third-party donation, fertility preservation (whether for medical reasons or personal/social motivations), and public funding"[55].

Here, it is crucial to acknowledge the jurisprudential insights provided by the Strasbourg Court, particularly in contentious areas such as the legal status of embryos and reproductive policies. In instances where consensus is lacking, the Strasbourg Court grants member states a degree of discretion, often referred to as the "margin of free appreciation." A pertinent case illustrating this principle is the Open Door case[56], where the court upheld Ireland's restrictive abortion laws, citing the state's margin of appreciation in shaping its reproductive policies, underscoring the significance of judicial interpretation in navigating the complex legal terrain surrounding reproductive rights and ART regulations in Europe.

To exemplify, Denmark[57] has a considerably broad legal framework that fully covers any ART-related topics, including surrogacy, donor conception, and patient access. It is also renowned for its lenient ART policies, which permit treatment for single women and same-sex couples and provide accommodating legal frameworks for both patients and providers. Sweden, Spain, Belgium and the Netherlands also have very comprehensive legislation on ART procedures, and protection of the rights of those involved, including children and reproductive medicine in general.

On the other hand, some European countries are known for having either limited or extremely restrictive legislation on the subject. As a result of its constitutional and cultural elements, Ireland[58], for example, is the only EU country that does not have any type of Assisted Human Reproduction (AHR) regulation. A draft Bill has been with the Irish government for three years but has yet to be enacted. However, some

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[55] *ART in Europe*. https://www.eshre.eu/Press-Room/Press-releases-2020/ART-in-Europe.
[56] *Open Door and Dublin Well Woman v. Ireland*, App. No. 14234/88; 14235/88 (ECHR Oct. 29, 1992).
[57] Mohr, S., & Koch, L. (2016). Transforming social contracts: The social and cultural history of IVF in Denmark. *Reproductive Biomedicine & Society Online*, *2*, 88-96. https://doi.org/10.1016/j.rbms.2016.09.001.
[58] McDermott, O., Ronan, L., & Butler, M. (2022). A comparison of assisted human reproduction (AHR) regulation in Ireland with other developed countries. *Reproductive Health, 19*, 62. Retrieved from https://doi.org/10.1186/s12978-022-01359-0.

legislative progress in the area could be seen in 2018 when the referendum against the ban on abortion was passed, affecting the field of reproductive rights in the country. Lithuania[59] is another example of a member state with more stringent ART laws. Although the country has some regulations in place, its legal system may be less comprehensive than that of other EU members.

These disparities in legal frameworks and regulations governing reproductive rights and ART have led certain cases to be brought before the European Court of Human Rights (ECHR). For example, the case of *Vo v. France*[60] concerns an unintentional abortion resulting from the negligence of a French hospital. The applicant, Mrs Vo, alleged a violation of Article 2 of the European Convention on Human Rights (ECHR), which protects the right to life. Mrs Vo argued that the absence of criminal remedies in French law to punish the unintentional destruction of a fetus constituted a failure by the state to protect the right to life of the unborn. However, the European Court of Human Rights (ECtHR) held that France did not violate the ECHR, ruling that the Convention does not extend protection to the right to life of the unborn as it does not recognize them as legal persons. The court's decision highlighted the distinction between the protection of the right to life for born individuals and the absence of such protection for unborn fetuses under the ECHR.

The principal case addressing individual autonomy within the realm of biomedicine is the *Juhnke v. Turkey case*[61]. This case involved a female detainee accused of assisting an illegal organization, the Workers' Party of Kurdistan (PKK), who was subsequently subjected to a coerced gynecological examination[62]. The European Court of Human Rights (ECtHR) determined that compelling an individual to undergo medical procedures constitutes a violation of their right to privacy, particularly their autonomy as safeguarded by Article 8 of the European Convention on Human Rights (ECHR). Furthermore, in instances where there is no medical or legal justification for such interventions, the practice may amount to torture or inhuman treatment, as outlined in Article 3 of the ECHR, given the severity of the violation perpetrated.

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[59] Busardò, F. P., Gulino, M., Napoletano, S., Zaami, S., & Frati, P. (2014). The Evolution of Legislation in the Field of Medically Assisted Reproduction and Embryo Stem Cell Research in European Union Members. *BioMed Research International*, *2014*. https://doi.org/10.1155/2014/307160.

[60] *Vo v. France* (Application no. 53924/00), [2004] ECHR 254, (8 July 2004) 60 EHRR 27. Retrieved from https://hudoc.echr.coe.int/?i=001-61887.

[61] *Juhnke v. Turkey* (Appl. 1620/03), judgment of 23 September 2010, Reports of Judgments and Decisions 2010.

[62] Ruggiu D. (2018). *Human Rights and Emerging Technologies. Analysis and Perspectives in Europe*. Pan Stanford, Singapore, p. 346.

Another relevant case was *Tysiąc v. Poland*[63] centred on the reproductive rights of Alicja Tysiąc, a Polish woman experiencing health risks during pregnancy. Tysiąc, seeking a therapeutic abortion, faced challenges due to Poland's restrictive abortion laws. The ECHR, in its ruling, acknowledged the delicate balance between an individual's right to reproductive autonomy and a State's interest in protecting life. The decision held that Poland's stringent abortion laws interfered with Tysiąc's right to respect her private life, highlighting that the status of the embryo is protected under the ECHR, but it can never overcome the women's reproductive rights in the face of health considerations (as in their right to health).

The legal status of the embryo in the context of the ECHR has been subject to scrutiny in various cases, including *Evans v. the United Kingdom* and *Vo v. France*, as mentioned above. The *Evans v. the United Kingdom*[64] case, while primarily centred on the applicant's right to use frozen embryos created through IVF despite her former partner's withdrawal of consent, sheds light on broader questions surrounding the legal status of the embryo in the context of the ECHR. The applicant's pursuit of her reproductive autonomy underscores the tension between individual rights and the ethical considerations surrounding ART. While the Court's decision in the Evans case did not directly address the right to life of the embryo in vitro, it raises pertinent questions about the scope of protection afforded to embryos under the ECHR. The case highlights the complexity of balancing competing interests, such as the right to respect for private and family life under Article 8 of the ECHR, with broader ethical considerations regarding the status of the embryo. This shows that the determination of the embryo's right to life falls within the margin of appreciation of states, depending on national legislation. However, this limitation of the unborn's interest is typically recognized only in the context of protecting the right to health of another living subject, such as the mother. The ECtHR has held that the protection of the right to life of the fetus can be limited only to safeguard the life and health of the pregnant woman, based on a conception of dignity. Despite the absence of a general consensus in Europe on this matter, the majority of European countries do not recognize legal personhood for the embryo.

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[63] *Tysiąc v. Poland* (Application no. 5410/03), [2007] ECHR 204, (20 March 2007) 45 EHRR 42. Retrieved from https://hudoc.echr.coe.int/?i=001-79812.

[64] *Evans v. the United Kingdom* [Grand Chamber], App. No. 6339/05, judgment of 7 March 2006, Reports of Judgments and Decisions, 2007-I.

A, B, and C v. Ireland[65] brought forth the challenge of three Irish women against the restrictive abortion laws in Ireland. The case underscored the complex interplay between reproductive rights, women's health, and state regulations. The ECHR emphasized the importance of legal clarity and effective procedures in cases involving abortion. The decision held that Ireland's ambiguous laws and inadequate procedures violated women's rights, emphasizing the need for states to ensure clear legal frameworks that respect and protect women's reproductive autonomy.

An important case concerning medically assisted procreation is the *Costa and Pavan*[66] case. Costa and Pavan, an Italian couple afflicted with a genetically transmissible disease, sought access to IVF, which was prohibited by Law No. 40 on medically assisted procreation. The hospital's refusal resulted in the couple having to rely on natural procreation, necessitating the selection of healthy embryos through the procedure of abortion, causing unjustifiable suffering. This measure was deemed irrational and inadequate for safeguarding both the health of the fetus and the well-being of the mother, thereby violating their right to respect for private and family life under Article 8 of the ECHR.

These cases collectively reflect the evolving jurisprudence of the ECHR on reproductive rights, illustrating the delicate balance between individual autonomy and state interests in regulating reproductive technologies. The decisions highlight the importance of legal clarity, effective procedures, and the consideration of individual health circumstances in navigating the complex landscape of reproductive rights. Despite the trajectory of scientific progress in the field of reproductive science being challenging to predict with precision, the moment artificial uteri become viable for human application, the existing deficiency in addressing ethical and legal considerations will become evident. AWT arrives with the potential to challenge existing legal frameworks for its utilization and as technology advances, it is essential to address these issues before the integration of AWs into human reproductive practices.

[65] *A, B and C v. Ireland* (Application no. 25579/05), [2010] ECHR 2032, (16 December 2010) 51 EHRR 11. Retrieved from https://hudoc.echr.coe.int/?i=001-102332.
[66] *Costa and Pavan v. Italia*, App. No. 54270/10, judgment of 28 August 2012.

2.4 Fetal viability, Reproductive Technology, and Ectogenesis: legal and ethical analysis

Given these considerations, it becomes imperative to examine the legal standing of the foetus. While certain facets of this discourse have been previously addressed in the preceding chapters, the legal status of the foetus holds paramount importance, influencing various dimensions of the ongoing discussion and defining the path of others. Essentially, the legal protection afforded to a foetus hinges on its designated legal status, posing a fundamental ethical dilemma related to its viability and the juncture at which it transforms from a cluster of cells into a recognized human being.

Although the EU has sidestepped explicit definitions, viability emerges as a potential threshold for establishing when the foetus merits protection as a human life. This concept could signify the onset of human life, analogous to the stance taken in the historic *Roe v. Wade*[67] case, where the U.S. Supreme Court refrained from a definitive determination but identified the foetus's viability commencing the third trimester. Acknowledging the State's interest in the foetus's life post the second trimester (between 24 and 28 weeks), this decision shaped U.S. law. Conversely, the European Union's stance on viability and the onset of human life appears less definitive, primarily due to the freedom afforded to individual member states to determine their own policies on this matter Despite the European Parliament commissioning a study on reproductive health rights, offering a comparative analysis of EU Member States' implementations, there is a notable absence of a unified legal framework within the EU.

The crux of the matter lies in balancing the foetus's interest in life against a woman's freedom to choose abortion, a fundamental aspect of Sexual and Reproductive Health Rights (SRHR). Presently, within the EU, the prevailing perspective attributes paramount importance to the mother's rights, considering the foetus as an integral part of the mother. The linchpin is the mother's fundamental right to bodily autonomy, enshrined in Article 3 of the Charter of Fundamental Rights. This underscores the mother's protected bodily integrity, affirming her freedom to make decisions about her body, including the developing foetus within her womb.

However, a pivotal ruling by the Court of Justice of the European Union in the case of *Oliver Brüstle v. Greenpeace eV*[68] introduced a nuanced layer to this narrative. In this case, the ECJ was tasked with interpreting Article 6(2)(c) of Directive 98/44/EC,

[67] *Jane Roe, et al, Appellants, v. Henry Wade* (1973) 70-18 (U.S. Supreme Court).
[68] *Oliver Brüstle v Greenpeace eV* (2011) ECLI:EU:C:2011:669 (European Court of Justice).

concerning the legal protection of biotechnological inventions. The central issue revolved around the patentability of neural precursor cells obtained from human embryonic stem cells. The ECJ clarified that any human ovum after fertilization, non-fertilized ova manipulated to commence development and stem cells from human embryos might be considered "human embryos" under the Directive. The court held that the exclusion from patentability applied not only to industrial or commercial uses but also encompassed scientific research involving human embryos. Importantly, the ECJ determined that inventions necessitating the destruction of human embryos, even if the patent claims did not explicitly focus on such use, were excluded from patentability. Despite the different legislations in this matter at the European level, to protect the EU Internal Market concerning biotechnological inventions, this decision considered the human embryo any cell that can develop in a future human being (regardless of the fact it results from natural reproduction, therapeutic cloning, parthenogenesis or any other technique). This decision reflects a cautious approach, aligning with the Directive's objective to protect human dignity. In essence, the Court affirmed that a human embryo although does not possess the fundamental right of human dignity (it is not a person as such) cannot be compared to a "thing" due to its human origin.

The multifaceted nature of the concept of human dignity, lacking a concrete context or universal meaning, has led to varied interpretations in legal contexts. Its application in decisions by national and EU courts has showcased its adaptability to different worldviews, resulting in diverse outcomes. The notion of human dignity, while foundational to EU principles, remains elusive in providing a standardized criterion for legal decisions[69]. The central question, therefore, arises as to whether the foetus falls under the right to life as articulated in Article 2 of the Charter. In the case of *H. v. Norway*[70], the European Commission offered a nuanced response, refraining from definitively determining whether the foetus merits protection under Article 2. The Commission acknowledged the considerable divergence of views within member states on the protection of unborn life, leaving the question open-ended.

In light of the EU's approach, where the foetus is situated within the mother's right to bodily integrity, coupled with legal precedents like *Oliver Brüstle v. Greenpeace eV.* and *H. v. Norway*, it becomes apparent that the EU lacks a straightforward answer regarding the foetus's legal status. This legal status, however, is intimately connected

[69] van den Driest, N.H. (February 2021). "Ectogenesis: a blessing with legal implications?" LL.M. Law and Technology, Tilburg Institute for Law, Technology and Society, Tilburg University.
[70] *H v Norway* (1992) ECLI:CE: ECHR:1992:0519DEC001700490 (European Court of Human Rights).

with the concept of viability. In addition to the consideration of the capability to feel pain, it is proposed that viability, marking the stage at which the unborn becomes capable of surviving outside the womb, either independently or with medical assistance, is the decisive factor for personhood. There is an intense ethical debate among scholars in this sense, considering that the concept of viability can be interpreted narrowly or broadly.

A narrow interpretation defines viability as the point at which the unborn can independently survive outside the womb, considering the integration of the functions of the human organism at this stage. However, others declare that the key requirement for qualifying for special legal and ethical protection is an integrative function governed by the brain, requiring sufficiently developed lungs. In contrast, a broader definition of viability considers a foetus viable if technological means to sustain it outside the womb are theoretically available somewhere, even if not for the specific foetus in question. The last one, however, presents practical challenges taking into account that it can seem absurd to shift boundaries due to improvements in medical facilities[71].

The legal significance of viability in the realm of the right to life protection has found reflection in certain common law jurisdictions. In general, in the United States, viability serves as the decisive criterion for initiating right-to-life protection. The *Colautti v. Franklin*[72] case saw the U.S. Supreme Court defining 'viable' as the capability of sustained life outside the mother's womb, with or without artificial support. The fetal viability standard underwent re-evaluation in the *Stenehjem*[73] case, with the court deeming it unsatisfactory for giving inadequate consideration to the substantial state interest in potential life throughout pregnancy. This approach neglects the states' capacity to incorporate advances in medical and scientific technology into the understanding of prenatal life, aligning with the technical possibility of viability from the moment of syngamy.

In various European national legislations, abortion is temporally limited to the child's viability, as seen in Norway, Portugal, and Sweden. While viability serves as an abortion limit in Denmark and the Netherlands, it is not preclusive. Unlike the European region's case law, where personhood is separated from the right-to-life protection, the

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[71] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

[72] *Colautti v Franklin*, 439 U.S. 379, 388 (1979)

[73] *MKB Management Corp. v Stenehjem*, 795 F.3d 768 (8th Cir. 2015), cert. denied, 2016 WL 280836 (U.S. Jan. 25, 2016)

Supreme Court of Canada conditions the right-to-life protection of the unborn on the presence of personhood. Moreover, personhood in Canada is not attributed based on a singular criterion. In addition to viability, two supplementary requirements of common law must be collectively satisfied. Thus, personhood in Canada is established through the 'born, alive, and viable' rule[74].

This rule was crystallized through case law addressing intricate circumstances. In *R. V. Sullivan*[75], the Supreme Court of Canada grappled with the legal status of a fetus during childbirth. The case originally involved midwives facing criminal liability for causing harm to a pregnant mother and the death of the child during delivery. Despite the child's viability, it did not meet the 'born, alive, and viable' criteria, rendering it ineligible for personhood and the associated legal protection. The absence of personhood in the relevant case law diverged from European jurisprudence, as it did not reference the 'public interest' when balancing the responsibilities of an established person and the eventual need for prenatal life protection. The mother cannot be held accountable for causing harm to the child before it attains personhood, as insisting on a duty of care would intrude extensively and unacceptably into the bodily integrity, privacy, and autonomy rights of women. This holds true even if the established person was not competent and exhibited addiction proven to be hazardous to prenatal life[76].

Here, the divergent nature of these two legal frameworks becomes evident, illustrating how the advent of ectogenesis will uniquely impact each. When examining the realm of reproductive choice, discussions within the European regional frameworks primarily revolve around achieving a fair balance between the imperative to protect unborn life and the conflicting rights and interests of others. Through abortion case law, the institutions of the European Convention on Human Rights aimed to delineate what could be deemed a fair equilibrium between a woman's interests and 'the need to ensure the protection of the unborn child' under the Convention.

A crucial determinant influencing the judicial interpretation of fairness in this conflict stems from the woman's irreplaceable role in reproduction, particularly her capacity to gestate. The unique gestational connection between the woman and the unborn grants her greater control over reproduction compared to men, as she is the individual 'primarily concerned by the pregnancy and its continuation or termination.'

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[74] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

[75] *R. v. Sullivan*, [1991] 1 S.C.R. 489 (Can.).

[76] Dakic, D., op cite.

This connection makes it impossible to isolate the life of the unborn from that of the mother. The Convention's institutions acknowledged that this gestational connection imposes limitations on the protection of unborn life when in conflict with the mother's interests. Within this framework, it seems reasonable to posit that, according to European case law, the scope of reproductive choice would be significantly impacted if the conflict between the mother's and the unborn's rights could be eliminated. The situation in Canada contrasts markedly. A human pre-person lacks legal status and is entirely devoid of legal protection. The Canadian Supreme Court's jurisprudence provides no grounds to consider the interests of prenatal human life under any scope[77].

Expanding on the considerations above, given that the end result of this process is the presence of genetic offspring in the world, it is imperative, in line with European case law, to scrutinize this development through the lens of Article 8 of the Convention, safeguarding the right to respect for private and family life. The concept of private life within Article 8 encompasses a broad spectrum, including personal autonomy and the right to psychological integrity. While personal autonomy, concerning physical-bodily integrity, lacks clear infringement without gestational interconnection, in the case of full ectogestation, the existence of offspring in the world could potentially disturb progenitors, infringing upon their psychological integrity.

Psychosocial indications, widely accepted grounds for abortion in Europe, extend beyond specific illnesses, covering circumstances like living conditions, marital status, employment, and education. The broad understanding of private life and psycho-indications suggests that the inability to request the cessation of the ectogenetic agent's existence may interfere with the progenitors' right to respect private life. Despite the preclusion of biological conflicts, social conflicts inherent in parenting obligations persist. The European Court of Human Rights requires a fair balance between the progenitors' decision not to have a child and the public interest in protecting the unborn/ectogenetic agent. State interference must align with the law, pursue legitimate aims, and be necessary in a democratic society. Fair balancing is essential, considering the progenitors' right to decide against parenthood and the profound moral values related to the nature of life. The Canadian context, contrasting European frameworks, emphasizes reproductive autonomy, prioritizing a woman's decision in the realm of reproduction. Public interest considerations in Canadian

[77] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

policies and Supreme Court rulings align with an expanded reproductive autonomy, marking a departure from past conservative policies[78].

Moreover, in these cases, the assertion of autonomy can be made on behalf of both progenitors, pertaining to their reproductive sphere, and unborn/ectogenetic agents, emphasizing their autonomous existence. Regarding progenitors, the interpretation of autonomy in the reproductive sphere has been aligned with the right to control their bodies, encompassing abortion as a means to exercise this right. Acknowledging reproductive autonomy through Article 8 implies respecting decisions related to both becoming and not becoming parents. However, the expansive interpretation of reproductive autonomy, seemingly granting unlimited control over parenthood, raises questions about its legitimacy, especially concerning human pre-persons. Some scholars highlight the growing legal significance of this issue, particularly with the emergence of artificial wombs, distinguishing between abortion as a right of evacuation ("the right not to be pregnant") or termination ("the right not to procreate"). The debate revolves around defining the purpose of abortion and the scope of reproductive choice.

Scholarly perspectives differ, with some endorsing the "only own body control" approach, limiting a woman's control to denying assistance to the developing fetus, while others favour the "motherhood control" approach, allowing termination of both pregnancy and the fetus. The latter perspective contends that abortion is not merely about severing the physical connection but preventing motherhood. However, European legislation introduces temporal limits on abortion, even for well-being reasons, reflecting societal interest in the fetus, particularly after viability. Examining autonomy from the standpoint of unborn/ectogenetic agents, who possess separate existence, reveals a distinction from unborn fetuses physically connected to mothers. Unlike prenatal life, an unborn/ectogenetic agent is not inseparably tied to the progenitor's interests. Some argue that once removed and in an ectogenic chamber, the fetus acquires an independent legal personality. Consequently, the ultimate request of progenitors, seeking the death of the ectogenetic agent, cannot be justified under the Convention, while the ectogenetic agent's right to life is undeniable[79].

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[78] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

[79] Ibid.

The global academic discourse and European judicial reasoning on the conflict between the right to life protection and competing rights delve into various theories proposed to achieve a fair resolution. In Europe, the judicial response can be distilled into the nuanced differentiation between the graded right to life protection and the legal status recognition concerning pre-persons. A pivotal factor in the European judicial interpretation of fairness in addressing this conflict stems from the unique role of women in reproduction, specifically their ability to gestate. This irreplaceable role grants women greater control over reproduction compared to men. Despite the gestational connection subrogating the interests of the unborn to those of the mother, recognizing the interests of the unborn remains a significant aspect of the European discourse.

Considering the institutional introduction of the weighing of women's competing rights against those of the unborn under the ECHR and the judicial recognition of "public interest" as a legitimate ground for intervening in women's private spheres, the advent of technological innovation capable of eliminating conflicts between rights and relativizing viability boundaries could potentially undermine the foundational principles of reproductive autonomy in Europe. Viability serves as the threshold for abortion constraints in national statutes across Europe. Once viability is reached, the rights and interests of the unborn receive stricter protection, limiting the justifiable grounds for infringement. If technology eradicates conflicts between comparable rights, it becomes challenging to advocate for a broad interpretation of reproductive choice based on established European legal standards[80].

Viability and conflict exclusion afford a substantial margin of appreciation to the State when imposing constraints on reproductive choice in the name of the "public interest." However, this margin of appreciation is always under scrutiny by the Strasbourg Court concerning the proportionality test, evaluating the balance between ends and means, which is particularly stringent. In cases where the right to respect for private and family life, including autonomy in the biomedical realm, is excessively sacrificed, the Court typically recognizes a violation, for example in the Open Door and Dublin Well Woman v. Ireland case. Simultaneously, conflict exclusion severs the ultimate demands of progenitors from the purview of the Convention, but it confers the right to life on the ectogenetic agent, introducing another restriction to the scope of

[80] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

reproductive choice. In contrast, the Supreme Court of Canada's case law firmly establishes that protection cannot be granted before meeting the cumulative requirements of the "born, alive, and viable" rule. This unequivocally excludes both the interests of the unborn and the public interest from encroaching on women's private spheres. Consequently, neither technologically induced viability nor artificial conflict exclusion would impede the scope of reproductive choice in Canada, allowing progenitors the freedom to demand the interruption of the process to avoid parenthood[81]. Hence, it is evident that the role of ectogenesis could significantly bolster the legal status of the foetus, prompting necessary adjustments in the legal frameworks, especially of the EU and its Member States.

The analysis above focused on how the advent of artificial wombs may yield disparate effects within varied democratic jurisdictions, comparing and interpreting the rights under the European Convention on Human Rights and Canadian constitutional standards. However, this technology might also affect the legal framework of England and Wales, as following demonstrated by Romanis[82]. Here, dialoguing specifically in the context of the arrival of partial ectogenesis, the author brings to attention the need for a legislative restructuring of the Offences Against the Person Act (OAPA) 1861 and the Abortion Act (AA) 1967, considering that the prospect of terminating a pregnancy before its natural conclusion - without necessarily leading to the death of the fetus - was not foreseen at the inception of these pieces of legislation.

The Acts of Parliament that introduced and modified defences to the offence of procuring miscarriage (AA 1967, Human Fertilization and Embryology Act 1990) were framed under the assumption that termination of pregnancy typically results in fetal death and that instances of termination later in pregnancy to safeguard a pregnant woman's life, referred to as 'premature deliveries,' were traditionally envisioned to occur in later stages of pregnancy and under circumstances covered by the AA 1967.

The AA 1967 specifies that the legal provisions pertaining to termination are outlined in sections 58 and 59 of the OAPA 1861 which specifies that the *actus reus* for unlawfully procuring miscarriage occurs when an individual takes illegal actions to induce miscarriage through any means - the necessary *mens rea* involves the intention

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[81] Dakic, D. (2017). "The Scope of Reproductive Choice and Ectogenesis: A Comparison of European Regional Frameworks and Canadian Constitutional Standards." Elte Law Journal, 2, 127. Retrieved from https://www.researchgate.net/publication/330712658_Full_text_The_Scope_of_Reproductive_Choice_and_Ectogenesis_a_Comparison_of_European_Regional_Frameworks_and_Canadian_Constitutional_Standards.

[82] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

of the individual to bring about miscarriage. This offence, therefore, can only occur in the absence of a defence, which is explicitly outlined in the AA 1967. The formulation of the offence of unlawfully procuring miscarriage was intentionally comprehensive, reflecting the limited understanding of pregnancy and fetal development in 1861. Its aim was to encompass a wide range of methods employed by back-street abortionists. However, as mentioned above, with the emergence of technologies like AWs, capable of prematurely ending a pregnancy without causing fetal death, certain aspects of the law are now inadequately addressed[83].

This demonstrates the need to analyse these uncertainties from their connection with the definition of miscarriage and the subsequent interpretation of an 'unlawful miscarriage,' which hinges on the definition of miscarriage itself. The term 'abortion' was initially used in Lord Ellenborough's Act of 1803, the first British statute regulating terminations. However, it became obsolete in subsequent statutes until the introduction of the AA 1967. The phrase 'termination of pregnancy' made its legal debut through the AA 1967, yet no amendments were implemented to modify, clarify, or replace the terminology associated with miscarriage in the OAPA 1861[84].

In the author's opinion, in the context of current and future medical advancements, the ambiguity surrounding the definition of 'miscarriage' becomes more pertinent, particularly considering the potential for ending a pregnancy in favour of ex-utero gestation if AWs replace conventional NIC. When the OAPA 1861 was formulated, there was no anticipation that terminating a pregnancy without causing fetal death might be a conceivable and intentional aspect of the process. Common perceptions, along with some medical definitions, framed miscarriage as inherently linked to fetal demise. Therefore, the interpretation of miscarriage entails concluding an established pregnancy with the resulting death of the fetus, denoted as 'miscarriage as fetal death.' But with AWT there is a crucial distinction, that lies in one interpretation being focused on the fetus's condition, while the other is not.

The *actus reus* and *mens rea* of the offence vary significantly based on the chosen interpretation. If miscarriage encompasses any purposeful cessation of pregnancy (absent a defence), opting for ex-utero gestation by ending a pregnancy would fall within the realm of unlawfully procuring a miscarriage. Consequently, a doctor would need to establish the lawfulness either under common law or within the

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[83] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

[84] Ibid.

AA 1967. However, if miscarriage inherently involves only terminations leading to fetal death, concluding a pregnancy to favour ex-utero gestation would not constitute a criminal matter, provided the intention is for the fetus to survive the pregnancy's termination. Advancements in medical technologies, including AWs, in accordance with the writer, contribute to the growing ambiguity between events labelled as 'medical premature deliveries' and the intentional, unlawful termination of pregnancy. This evolving landscape raises the likelihood of challenging the boundaries of unlawfully procuring miscarriage within obstetric practice.

In the exploration of the term 'miscarriage' and its legal implications in the OAPA 1861, the main question that arises is whether intentional pregnancy terminations should be universally regarded as criminal or if 'miscarriage' should specifically cover instances resulting in fetal death. In examining the potential presumption of criminality for all intentional pregnancy terminations, an analysis of related statutes, particularly the Infant Life (Preservation) Act 1929 (ILPA 1929), unveils overlapping offences with the OAPA 1861. The distinction between the two statutes lies in the ILPA 1929 explicitly tying the actus reus of child destruction to the resulting fetal death, while the OAPA 1861 remains vague in this regard. Scholars argue that the construction of the OAPA 1861 suggests an intrinsic connection between ending pregnancy and causing fetal death. Notably, the offence was initially conceived as a violation against the pregnant woman's body, emphasizing the absence of legal personhood for the fetus[85].

Furthermore, the presence of defences in the Abortion Act 1967 (AA 1967) specifically addressing cases resembling 'premature deliveries' implies the acknowledgement that terminations later in pregnancy, even with an attempt to save the fetus, fall within the criminal ambit. This explicit legal authorization for certain actions highlights the ongoing criminal relevance of ending pregnancies, reinforcing the need for comprehensive law reform, particularly in the context of evolving medical technologies and contemporary obstetric practices. The intricate nuances of defining 'miscarriage' necessitate a more precise legal framework to align with ethical considerations.

The interpretation of the term "miscarriage" within the framework of the OAPA 1861, for Romanis[86], presents a pivotal question, and competing perspectives provide nuanced insights into its legal ramifications. There are compelling arguments

[85] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[86] Ibid.

suggesting that the interpretation of miscarriage should be more restrictive since criminal statutes are typically construed narrowly in favour of the accused, following the principle of fair warning. Therefore, it seems improbable that, at the time of its initial drafting, Parliament intended the offence to encompass situations where individuals had not tried to terminate a pregnancy, resulting in fetal death (regardless of the outcome). This is because induced premature delivery was nonexistent in 1861, and understanding of obstetric complications was limited. Chemical induction of deliveries was not feasible, and although Caesarean sections were possible, they were not yet widely available or safe, with high mortality rates. Moreover, there was no NIC to support premature babies, and premature labourers were spontaneous events considered perilous for both the pregnant woman and the fetus. Taken together, these factors meant that doctors had no incentives to attempt premature deliveries. Consequently, one could argue that since Parliament likely did not intend to subject these circumstances to criminal law, miscarriage should not be interpreted to have such an effect.

The author follows declaring that there are indications within the language of the offence that may support the argument that only conduct intended to cause fetal death should be deemed criminal. It is noteworthy that Parliament specifically employed the term 'violence' in defining the offence. The absence of explicit exclusion of non-violent methods for terminating a pregnancy does not necessarily imply an intention to encompass such situations within the offence. The non-exclusion of 'non-violent' means of termination might have been intended to address scenarios where the fetus, removed unharmed from the uterus before the end of gestation, did not survive due to natural causes ex-utero. However, to the scholar, these arguments may lack persuasiveness without innovative judicial interpretation.

Principles of statutory interpretation may lead to the conclusion that the term 'miscarriage' only encompasses the intentional termination of pregnancy with the aim of causing fetal death. For example, the *Smeaton case* presented a situation where the law confronted an unexpected medical development. In 1861, the idea of contraception as effective as the morning-after pill was as inconceivable as partial ectogenesis. When legislating on abortion, Parliament did not intend to prohibit contraception but rather sought to penalize abortion. Similar reasoning applies here; Parliament did not aim to outlaw 'premature deliveries' but was establishing regulations on abortion[87].

[87] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

The interpretation of a term conceived in ignorance of future medical advancements poses a challenge, being necessary to address this issue through the principle of updating construction. The significance of Parliament leaving the word 'miscarriage' undefined despite subsequent opportunities for legislative intervention, means that 'miscarriage' should be interpreted in light of current understanding and the best scientific and medical knowledge available to the court. Consequently, the judiciary is likely and entitled to utilize medical evidence and definitions as external aids in interpreting the OAPA 1861.

The judiciary has consistently shown deference to medical opinion in the realm of abortion law. Various medical definitions of miscarriage exist, with no uniformity explicitly specifying fetal death. Medical dictionaries often define miscarriage as 'the spontaneous loss of pregnancy before 24 weeks,' causing confusion by focusing on pregnancy loss rather than deliberate termination. Nevertheless, these definitions underscore that the term 'miscarriage' is commonly associated with situations involving fetal death or its inevitability[88].

Moreover, beyond a literal examination of language, the judiciary is empowered to interpret terms in light of the intended purpose of the provision. The OAPA 1861 aimed primarily to limit abortion and protect women from the dangers of termination, especially back-street abortion, which was unsafe even when performed by doctors in 1861. Presently, the danger associated with premature pregnancy endings in medical settings is minimal, and the concern about back-street abortion has largely been eliminated, with no reported deaths since 1982 in England and Wales. While the OAPA 1861 serves to enforce some protection for fetuses by placing limitations on access, it prompts the important question of the extent to which this protection was intended to apply[89].

A similar question arises concerning the substantive protection afforded to the fetus when ending a pregnancy to facilitate gestation ex utero and how late in pregnancy this protection extends. From the arguments presented above, Romanis then argues that unlawful procurement of miscarriages should be interpreted as referring exclusively to incidents intending to cause fetal death even though this interpretation is not yet firmly established in the law (as it can be equally interpreted that the current legal framework requires miscarriage to encompass any deliberate

[88] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[89] Ibid.

cessation of pregnancy). The author even claims for clarity and reform of the law, assuming decriminalization is not feasible. Therefore, if the legal definition of 'miscarriage' were to include fetal death, it would ethically optimize the operation of the law (assuming criminalization is appropriate) and would spare doctors, acting on behalf of women, from the need to justify ending a pregnancy in favour of ex utero gestation[90].

Accepting the legitimacy of a criminal and medical model of termination provision, there is a meaningful distinction between later-term miscarriages, which might be considered criminal and require justification, and other pregnancy endings that need no such explanation. This distinction centres on the doctor's intention in concluding the pregnancy. When deciding to terminate a later-term pregnancy, efforts to preserve the fetus are influenced by viability, determined by the approach, and subsequent actions taken by attending medical professionals. Ending a pregnancy with the intention of preserving a woman's life and health, while respecting her desire to protect the fetus, is less likely to be criticized as unethical. The term 'premature delivery' implies an intention to birth the developing human entity into the world, focusing on promoting the fetus's survival. Conversely, 'miscarriage' implies failure or intentional prevention of the usual outcome of pregnancy (a baby). If decisions regarding ending pregnancy lack intention toward fetal survival or actively seek fetal death, this type of miscarriage seems intuitively to be the subject of regulation by criminal law[91].

In accordance with the author, this distinction is not based solely on when an attempt is made to end pregnancy or assumptions about likely outcomes but rather on a combination of why, how, and when deliberate intervention into pregnancy occurs. Defining miscarriage as the termination of pregnancy resulting in fetal death, requiring a *mens rea* of intent to cause fetal death, or excluding instances without fetal death from the term 'unlawful' in section 58 would provide a consistent approach to determining which pregnancy endings require justification, aligning with common intuitions about the purpose of criminal law. Considering intention is future-proof, allowing for continued regulation even with the introduction of technologies like AWT. It is possible that Parliament's concern in legislating to prohibit miscarriage procurement was overestimated in terms of protecting fetal welfare and may have been broadly intended to reinforce heteronormative regulation of female bodies. Broadly interpreting

[90] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[91] Ibid.

miscarriage as any unlawful deliberate cessation of pregnancy prioritizes fetal protection over women's interests, burdening women to provide legal justification for choosing artificial gestation. Criminalizing opting for ex-utero gestation, even if prima facie defensible, has significant negative consequences for women, carrying emotional and moralistic connotations.

Moreover, to Romanis[92], if all pregnancy endings were unlawful outside applicable defences in the AA 1967, this could impose a legal obligation on women to remain pregnant, replacing alternative forms of gestation, even when not facing an immediate serious risk to health or any risk to life. This raises the question of whether the Act intended to impose such an onerous requirement on women and entirely subjugate their right to bodily autonomy and integrity to privileged fetuses. The impact of an all-encompassing definition of termination on women's rights should be considered, and bodily autonomy, afforded the highest respect in law, should not be overridden without justifiable reasons.

The term 'unlawful' is prominently in section 58 of the 1861 Act suggesting its centrality to the actus reus of 'unlawful miscarriage.' However, every miscarriage brought on by a physician is not necessarily unlawful, especially when necessary to preserve a woman's life, for example, foetal extraction with the intent of completing gestation might not be considered unlawful, removing the need to consider defences. Saving the life of or preserving the mental health of the pregnant woman, for instance, can be deemed unlawful under section 58, therefore could also be conceivable that ending a pregnancy while preserving the fetus could also be considered a 'lawful miscarriage.'

To the scholar, for a comprehensive analysis, it is crucial to examine the circumstances in which a defence to unlawfully procuring miscarriage would apply if all deliberate pregnancy endings (including instances intending to continue gestation ex utero for medical or social reasons) were prima facie criminal. If a successful defence can be raised when a doctor terminates a pregnancy with the intention of the fetus continuing gestation ex-utero, their conduct would not be deemed unlawful.

This then leads to the question if there are available defences to unlawfully procuring miscarriages. The scholar states that for terminations occurring before 24 weeks gestation, medical practitioners indeed have a defence under the AA 1967. Access to conventional terminations is relatively unrestricted before 24 weeks, as

[92] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037..

section 1(1)(a) of the AA 1967, the primary defence for the majority of abortions, is broad, allowing for the legal termination of pregnancies within the first 24 weeks. Practically, doctors usually do not need to justify terminations before 24 weeks on clinical grounds. However, the legality of providing terminations, including those for ex utero gestation, before 24 weeks for non-medical or social reasons is not assured[93].

The "social ground" defence is framed in medical terms, allowing termination before 24 weeks if the risk of continuing the pregnancy is greater than the risk of ending it. Conventional abortion methods have advanced to the point where statistically, performing an abortion within the requested timeframe is generally less risky than continuing the pregnancy. It remains doubtful that the fetal extraction procedure required for transfer to an artificial womb (AW) would be less risky for a pregnant woman than maintaining the pregnancy or having a conventional termination in most cases. The AA 1967, however, does not grant all women an automatic legal entitlement to terminate a pregnancy, irrespective of the method or outcome. Instead, it has transferred the right to self-determination from women to the medical profession. Women must persuade a doctor that their circumstances warrant intervention in their pregnancy based on the medical model. Even when lawful, doctors are not obligated to perform interventions unless it is an emergency, and patients cannot demand specific treatments[94].

For women facing high-risk or dangerous pregnancies, it could potentially be legal for them to terminate their pregnancies in favour of ex-utero gestation before 24 weeks. Beyond 24 weeks, establishing a lawful defence for deliberately ending a pregnancy becomes more challenging. The relevant grounds under the AA 1967 for potentially dangerous or high-risk pregnancies include risk to the pregnant woman's life and risk of grave, permanent injury to her physical or mental health. These defences require the consensus of two medical practitioners in good faith, with no time limit imposed. However, they demand clear proof of the specified serious dangers. The separation of these two grounds (risk to life and risk to health) in the statute aims to distinguish that the risk to health requires more substantial proof than the risk to life[95].

In accordance with the author, regarding risk to life, it is understandable that physicians are not required to wait until a pregnant woman is in immediate peril of death to terminate a pregnancy, as there is a defence against unlawfully procuring

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[93] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

[94] Ibid.

[95] Ibid.

miscarriage when the pregnancy poses a risk to the woman's life greater than the risk of termination. The assessment involves weighing the risks of continuing the pregnancy against the risks associated with termination. Many premature deliveries are currently performed due to specific life-threatening risks associated with the pregnancy. The method chosen to end the pregnancy often carries similar risks to the delivery at the end of the normal gestational period when managing a pregnancy becomes necessary. This defence aligns with the decision-making process commonly employed in obstetric practice.

However, the advent of artificial wombs (AWs) may alter perceptions of which pregnancies are deemed risky, prompting a reconsideration of the interpretation of 'risk to life.' The explicit balancing exercise required by the defence implies that a lower threshold of risk to life cannot be easily incorporated into the provision. Even if a doctor believes that a lower level of risk earlier in a pregnancy justifies termination, it does not necessarily mean they can, in good faith, form the opinion that terminating the pregnancy carries a lower risk to life than continuing it. Conditions that currently warrant termination for life-threatening reasons may fit within the defence in milder forms and potentially at earlier stages. AWs, however, might lead pregnant women with a broader range of medical complications, even of lesser severity, to seek termination since there is a reduced risk of fetal loss[96].

Consider a pregnant woman struggling with severe nausea, which may not overtly threaten life and certainly would not be considered more life-threatening than complications arising from medically induced termination, especially in cases where a routine vaginal birth is anticipated. The critical question revolves around whether a doctor could, in good faith, conclude that the patient's circumstances fall within the scope of the defence. It is challenging to prove that a doctor did not form their opinion in good faith. However, there could be room for questioning a doctor's opinion if they perceive conditions like sickness, swelling limbs, or limited mobility during pregnancy as life-threatening or a greater threat than induction or caesarean. The prospect of 'foetal extraction' for ex utero gestation in an AW before the usual gestational period's end would likely be lawful under section 1(1)(c) of the AA 1967, but primarily in

[96] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

circumstances where the threat to the woman's life is readily observable and falls outside conventionally serious scenarios[97].

Likewise, following Romanis, to invoke the defence related to preventing grave and permanent injury to a pregnant woman's physical or mental health, a doctor must genuinely believe that termination is necessary to prevent the injury, although it doesn't necessarily have to be an immediate necessity. The doctor can take action when a permanent and severe injury is anticipated. The statute does not provide explicit guidance on the definitions of 'grave' and 'permanent,' leaving it to the interpretation of doctors forming their opinions in good faith. However, it is evident that only serious and long-term illnesses directly resulting from the continuation of pregnancy would qualify. Unlike the previous defence, there is no balancing exercise involved; it is not a matter of weighing the risk of injury from remaining pregnant against the risks associated with early termination. The doctor must hold the opinion that grave, permanent injury is reasonably certain to occur if the pregnancy continues, emphasizing that the defence is intended for cases of serious injury.

Examples of injuries deemed sufficiently serious included conditions like severe hypertension potentially leading to permanent kidney, brain, or heart damage. Additional examples suggested by experts encompass mild preeclampsia, breast or cervical cancer, uncontrolled diabetes, and conditions that might fluctuate during pregnancy, such as asthma or epilepsy. Notably, the debate predominantly focused on physical health rather than mental health and it was designed to accommodate decisions aligning with current medical practices[98].

The defence was crafted with the notion of 'premature deliveries' in mind, rather than terminations resulting in fetal death considering the bond between a woman and fetus during pregnancy, anticipating that terminations resulting in fetal death would typically be performed only when it was the sole method to end the pregnancy, sparing or significantly reducing the likelihood of injury to the pregnant woman, such as in cases involving a birth canal obstruction requiring cranial crushing for extraction. However, the AA 1967 still provides a defence against unlawfully procuring miscarriage when the pregnancy poses a threat of serious injury, even if a miscarriage resulting in fetal death is chosen for any reason. In most cases where pregnancies are terminated early through intervention, the pregnant woman typically desires the best chance for

[97] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[98] Ibid.

the fetus to survive, and decisions regarding timing and method are made accordingly. If the decision-making calculus shifts due to the introduction of artificial wombs, there might be instances where ending a pregnancy is medically advantageous (given the reliable alternative form of gestation) without necessarily posing a 'grave permanent injury' threat to the woman's health, as is often the case with current serious medical conditions warranting intervention to end the pregnancy[99].

Compelling arguments exist that all pregnancies entail grave and permanent injury to women's bodies. However, the defence is constructed to legally preclude entertaining such an argument. Many women, despite experiencing comparatively milder complications or 'side effects' during gestation, find their pregnancies challenging. While some women might consider it better for their physical and mental health not to endure these symptoms, such side effects are unlikely to be deemed 'grave' or pose a threat to long-term health, causing serious and/or lasting damage. Symptoms like morning sickness, limited mobility, and swollen limbs are temporary health hindrances that cease with the pregnancy, making them unsuitable descriptors for long-term injuries. The perception of how severe these symptoms are to endure will vary significantly. Many women who choose to persist with pregnancy despite these side effects do so because they desire a future child, not necessarily deriving enjoyment from the pregnancy experience. If artificial wombs were a reliable alternative to pregnancy, offering a better guarantee of the desired outcome, it is conceivable that some women would prefer to terminate their pregnancies, opting for artificial wombs. Continuing a pregnancy encompassing challenging symptoms that hinder short-term health or quality of life may not be in the best interests of these women. However, the AA 1967 does not explicitly permit a doctor to procure the termination of a pregnancy to improve a woman's short-term health or perceived quality of life after 24 weeks[100].

Interestingly, this ground of the AA 1967 also provides a defence if a doctor believes that termination would prevent grave and permanent injury to a woman's mental health. In one case, the judges emphasized that termination would be lawful if a doctor reasonably believed that the probable consequence of continuing the pregnancy would render the woman a physical or mental wreck. The judgment acknowledged the emotional and psychological trauma inherent in forcing a young girl to carry a fetus

[99] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[100] Ibid.

conceived through violent rape. However, the legal standards for what other circumstances might be considered sufficient under the AA 1967 remain uncertain[101].

In essence, to Romanis, without an amendment to the AA 1967, there exists a misalignment between the law and the decision-making calculus, driven by artificial wombs, those obstetricians might wish to employ in women's interests. The current statutory provisions potentially compel women to sustain their fetuses by remaining pregnant instead of opting for artificial gestation. This framing of the law, even if merely symbolic, seems to subordinate the female body for the purposes of reproduction, presenting an ethical issue that warrants more attention in the legal discourse surrounding artificial wombs.

It is also important to mention that the interpretations of the defences in the AA 1967 are broad, with the legality of pregnancy termination dependent on whether doctors, in good faith, perceive that a pregnant woman's circumstances align with the grounds specified in the AA 1967 rather than the actual circumstances. Furthermore, these defences were not the initial ones available to doctors procuring miscarriage, as common law implicitly granted a defence long before 1967. The term 'unlawful' in the offence of procuring miscarriage provides considerable judicial discretion in determining what constitutes an 'unlawful' procurement[102].

Several factors suggest that the authority to determine the legality of procuring miscarriages has been firmly placed in the hands of the medical profession. It is unlikely that any decision-making process regarding ending pregnancy, not intended to harm the pregnant woman or the fetus, would be treated as criminal. Judges are likely to guide juries in a way that encourages acquittal on charges of procurement of miscarriage, emphasizing the difference between medicalized pregnancy endings and illegal actions of 'backstreet abortionists.' Juries are unlikely to convict a doctor unless there is evidence of blatant disregard for the law's purpose. Judges may quash convictions they feel are unsafe, particularly if there is clear bad faith or an obvious attempt to perpetrate a criminal offence[103].

Even before the advent of artificial wombs, the judiciary has been hesitant to question doctors' decision-making in pregnancy termination. Legal uncertainty, as explored, is problematic, violating human rights and potentially limiting the use of future medical technologies. While the AA 1967 placed decisions about ending pregnancies

[101] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037..
[102] Ibid.
[103] Ibid.

within the medical profession's ambit, the increasing choices available to women warrant a re-examination of the degree of medical control over those choices. The current level of medical control over women's decisions to opt for ex-utero gestation is not justifiable based on the termination jurisprudence thus far[104].

However, to the author, the focus on the 'state interest' in preserving a fetus's right to be gestated does not apply in these circumstances, and women should be allowed to decide the duration of their pregnancies and their termination regardless of their intended outcome. The medicalization of termination decisions in the AA 1967 has limitations in defending and furthering women's reproductive rights.

Within the same legal sphere, but examining different facets of diverse potential concerns that may arise with AWT, Hammond-Browning[105] highlights the importance of discussing topics such as the well-being and best interests of future children born from an artificial uterus under the pre-conception welfare principle in section 13 of the Human Fertilisation and Embryology Act 1990 (as amended). Section 13 states that a woman should not receive treatment services unless the welfare of any potential child resulting from the treatment and any other child affected by the birth has been considered. The Human Fertilisation and Embryology Authority's Code of Practice provides additional guidance, requiring fertility centres to assess each patient and their partner before treatment to determine any risk of significant harm or neglect to a child. However, the factors assessed pertain to the history and behaviour of the intended parent(s) and their significance for the future child, rather than assessing how reproductive technology may impact the future child. This approach is understandable given the safety of current assisted reproduction methods, such as IVF.

Here, it is essential to note that studies highlight the importance of openness with children about their origins for their well-being, a consideration equally applicable to future children born from an artificial uterus. To apply the pre-conception welfare principle to future children born from AWT, a new approach is necessary, expanding its application from pre-conception to include the pre-birth phase. This allows for the assessment of the welfare of the *in-utero* fetus, whether natural or artificial and the potential risk of significant harm. The factors for assessment, as outlined in the Code of Practice, will also need expansion. However, this reinterpretation and application of the welfare principle must not impede access to pregnancy termination, considering both

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[104] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

[105] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.

women's health and fetal interests. It is preferable to limit its application to *ecto-fetuses*. Proactive regulation in this area is essential considering that without such regulation, existing legislative provisions will be applied, making exploration of their implications necessary[106].

While scientific and medical advancements that enhance survival rates and reduce morbidity for very premature babies are commendable, the pursuit of research that may inflict pain and suffering during its development raises ethical concerns. It is extremely necessary to assess the potential risk of fetal pain in ectogenetic research, emphasizing the importance of excluding such possibilities in the research design. Therefore, when granting ethical approval for partial ectogenesis, careful consideration must be given to the potential pain, distress, and suffering that may arise from the transfer from a female uterus to an artificial uterus and the subsequent period of artificial gestation. Uncertainties about the degree of pain felt by fetuses in utero add complexity to these considerations. The ethical dilemma here lies in weighing the potential for suffering against the opportunity for survival, as some may argue that any chance of survival justifies the potential pain[107].

To address these concerns, the author recommends the inclusion of physical harm and suffering as factors in the Human Fertilisation and Embryology Authority (HFEA) Code of Practice for assessing the risk of significant harm to the future child. Although this may pose challenges in accessing partial ectogenetic services and complex artificial uteruses, the potential risk of harm might diminish with an increased gestation period, enhancing viability. Moreover, legally requiring a minimum female gestational period before permitting transfer to an artificial uterus has been suggested by some specialists as a means to mitigate the risk of harm since their perspective on pregnancy is to view it as a dynamic and responsive exchange that supports the idea that as fetal development progresses, the potential for viability increases, providing grounds for a legal minimum gestation period[108].

This is particularly significant in cases of potential disputes over the use of an artificial uterus for a very premature baby. The court would then face a significant balancing act considering that emergency situations necessitate swift decisions, and without clear guidance, the court would need to balance the risk of suffering during

[106] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.
[107] Ibid.
[108] Ibid.

transfer, the risk of death and morbidities, and the potential for survival. While there is a strong presumption to prolong life, this presumption can be rebutted.

The next subject worth exploring in accordance with the scholar is legal parenthood and the necessity of it becoming imperative at a legislative level before commencing either research trials or treatment involving complete ectogenesis. The current acknowledgement that it is a fundamental right of children to identify their legal parents, with corresponding rights and responsibilities for the legal parents, underscores the ongoing importance of legal parenthood. This is important when considering AWT as a reproductive treatment and it is equally crucial during research trials and reproductive treatments involving complete ectogenesis. For the insurance of the welfare of future children born from AWT, the determination of legal parenthood aims to facilitate decision-making on their behalf, safeguard their best interests, and provide stability upon birth and failure to do so would burden the court with unnecessary responsibilities[109].

It is proposed that legal parenthood may differ between research trials and reproductive treatments. Currently, legal motherhood often relies on gestation, designating the birth mother as the legal mother. However, the absence of a birth mother in complete ectogenesis shifts the focus to other aspects of parenthood, including social, psychological, and genetic roles. Legal parenthood is integral to defining responsibilities for a child after birth and ensuring the child's security. In complete ectogenetic research, involving donated gametes and embryos, clarity is needed on who assumes legal parenthood and responsibility for surviving ectofoetuses. Unlike natural pregnancies, where gestation and intention to become parents guide parenthood provisions, these factors are not applicable in complete ectogenetic research. Therefore, a period of consultation and legislative debate must be recommended to establish legal parenthood, possibly involving an appointed guardian during research trials[110].

In contrast, complete ectogenetic reproductive treatment is proposed to follow an intended parenthood model. Those initiating ectogenetic services, whether single individuals or couples, should assume legal parenthood based on relevant criteria aligned with current arguments surrounding legal parenthood in surrogacy agreements. Legal parenthood, in this context, reflects the planned gestation initiated by the intended parent(s), akin to a surrogacy agreement. Lack of legal parent(s) poses

[109] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.
[110] Ibid.

significant risks to the future child born from AWT, including psychological harm. Furthermore, if donor gametes are used for reproductive treatment, the donors are relieved of legal responsibility for resulting children born from ectogenesis. Legal parenthood emerges as a crucial element providing security regarding the family situation, as consistently recognized by the courts. Without a consensus on legal parenthood for children born through ectogestation, they face risks of harm, and the state might unnecessarily intervene, burdening its resources.

The UK legislation on embryo regulation underscores the necessity for legislative reform or similar measures to address emerging challenges and ensure alignment with evolving societal values and technological advancements. This includes considerations surrounding termination and its implications for legal parenthood within the context of AWT. While termination has been previously addressed in this study, revisiting the topic is essential to provide context for this discussion. While legal rights are not attributed to embryos or fetuses until birth, the UK establishes a distinct status for the human embryo and fetus, thus emphasizing the complex interplay between legal frameworks and reproductive rights.The law protects in vitro embryos for up to 14 days of development, permitting research under specific regulations. Moreover, legal safeguards extend to embryos and fetuses in utero, with termination allowed only under specified circumstances. However, termination becomes increasingly restricted after 24 weeks gestation, coinciding with the recognition of viability. There exists a moral and legal distinction between an early embryo in vitro and one in utero. While in vitro embryo is protected to some extent, it attains greater respect once transferred to the female uterus. This transfer marks a significant moment, offering the embryo the chance to realize its potential within the environment conducive to development and eventual birth[111].

Legal termination is allowed under limited circumstances due to the potentiality and viability of the developing embryo/foetus in utero. This is balanced with considerations for the gestating woman's needs and respect for her bodily autonomy. A gestating woman typically has decision-making authority regarding the pregnancy, factoring in her health needs and interests. Despite her moral responsibility to the foetus, legal parenthood is not recognised until birth. Therefore, in the context of complete ectogenesis, where a gestating woman is absent, legal parenthood must be

[111] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.

acknowledged from conception to enable decision-making about ecto-gestation and the ecto-foetus[112].

Situations, when the risk of significant harm to the future child born from ectogenesis justifies termination, will probably arise. For example, the possibility of termination during research trials could be considered, especially if something goes wrong in the development of the ecto-foetus. Severe disabilities in the ecto-foetus may prompt considerations for termination to prevent a life of suffering. In the case of research trials, the appointment of a guardian could facilitate consent for termination if needed[113].

In fact, termination might occur frequently in the early stages of research trials to study the development of the ecto-embryo/foetus. Here, Hammond-Browning[114] suggests, as Romanis has done above - but tackling a different topic and coming from a diverse perspective - a legal reform of the Abortion Act of 1967 to permit termination on research grounds, extending beyond the therapeutic grounds currently allowed. Some authors even suggest the need for new legislation that allows the termination of ectogenetic gestation for research purposes, acknowledging the ethical complexity of such a proposition. Despite the topic of termination based on foetal disability being a divisive viewpoint, it is important to notice that it does align with existing legislation permitting the use and destruction of embryos for research purposes. Thus, this legal permissibility for terminating ecto-gestation could be justified in cases of malformed embryos or severely disabled foetuses to avoid significant harm.

However, it is crucial to mention that the British legislation concerning embryo regulation operates within the framework of the ECHR, necessitating compliance with its standards, which may lead to differing conclusions and potential condemnation of the UK. Notably, even after Brexit and the UK's withdrawal from the EU, these regulatory constraints are likely to persist, shaping the landscape of biomedical research and innovation within the UK.

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[112] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.
[113] Ibid.
[114] Ibid.

2.5 Exploring legal ramifications: a study of Ectogenesis and its influence on Employment Rights and other legal frameworks

After delving into many different legal aspects of England and Wales above, it becomes necessary to analyse another domain that the advent of partial ectogenesis may significantly impact the same legal context: employment rights. Here, Hooton and Romanis[115] recognise AWs potential to contribute to broader social benefits by addressing gender disparities in reproduction and childrearing and feel the need to expand this discussion to the employment sphere, where individuals undergoing pregnancies often face discrimination.

However, they point out the risk that this technology brings where individuals could start being deemed 'substandard' gestators, possibly coerced into opting for ectogestation. The notion of having an alternative to in-utero gestation may be misused to control the behaviour of the pregnant person and the introduction of ectogestation may exacerbate this issue. This becomes especially relevant in an employment context, where individuals may feel pressured to either give up work to ensure they are an 'optimal gestator' compared to a machine or opt for ectogestation to remain in or return to work. This pressure is likely to impact those in roles considered riskier during pregnancy, such as heavy lifting or exposure to toxic substances[116].

Additional concerns may arise about pregnant workers having genuinely autonomous choices about how to gestate. Large tech companies offering reproductive assistance benefits, like social egg freezing, may compromise maximal autonomy in decision-making. The motives behind offering such benefits vary, and the employer's interests may influence the information provided to employees. This practice has faced criticism for reinforcing harmful notions about female responsibility for negative employer attitudes. Nonetheless, in the end, the pressure to use these benefits persists in these environments, whether framed as a 'benefit' or a way to delay pregnancy.

In the UK, employers may lack cost incentives to encourage egg freezing due to statutory maternity leave. However, there could be a greater incentive in countries with statutory maternity leave to subsidize egg freezing, postponing pregnancy until the individual is no longer an employee. If AWs become capable of full-term gestation, employers may incentivize its use, particularly if it avoids making accommodations for pregnant employees. The design and function of AWs might, however, limit incentives,

[115] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[116] Ibid.

as it could require more leave and does not serve employers' goals in subsidizing assisted reproduction: delaying or preventing their employees from reproducing[117].

In addressing workplace equality, some argue that technology enabling complete gestation could eliminate discrimination against women, especially in the workplace. However, in the scholars' opinion, this should be viewed with caution, since framing it as such overlooks the actual problem of societal devaluation of care labour and the need for structural and social changes in employment rights. Claims that AWs can solve gender inequality by removing the association of pregnancy with women's bodies may not lead to progressive change. Even if gestation becomes machine-facilitated, broader social and legal reforms are necessary.

Thus, according to the authors, the focus should shift from the physical aspects of pregnancy to substantive reforms protecting those who have reproduced since AWT alone may not challenge deeply rooted associations of female bodies with specific roles in child-rearing. Uncoupling gestation from the body may not address other forms of socially *reproductive labour* or alter the gendered nature of labour markets. Discrimination against women in the workplace might persist, as hiring and promotion practices could still favour men due to preexisting perceptions about caregiving responsibilities. Nonetheless, the authors recognize that while AWT may not "solve" workplace inequality, it offers benefits by providing more choices for pregnant individuals. Supporting bodily autonomy, reproductive autonomy, and equal opportunities in the workplace requires adapting national and regional employment laws to accommodate gestation choices. AWT changed the landscape of birth and maternity, necessitating adjustments in employment laws to ensure the technology's benefits are accessible to all.

After raising these concerns, Hooton and Romanis[118] start analysing employment law rights at the EU level and the challenges associated with integrating the use of AWT into the existing framework, drawing on case law related to advancements in reproductive practices, such as in vitro fertilization (IVF) and surrogacy. While EU law has established a protective legal landscape for pregnant workers and new parents, it inadequately addresses the evolving landscape of reproduction and parenthood, particularly for non-traditional families. Past judgments by the Court of Justice of the European Union (CJEU) have not always extended the same protection to experiences like IVF and surrogacy as to "traditional" physiological

[117] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[118] Ibid.

conception and pregnancy. In the authors' opinion, the introduction of AWT could widen this gap and they propose interpretations that ensure AWT users receive the same protection under the EU maternity framework.

However, in the case of *Menneson v. France*[119], the European Court of Human Rights (ECtHR), for example, addressed the issue of surrogacy and the recognition of legal parentage in favour of the parents of a child brought to life through surrogacy. Ms. Menneson, a French national, and her husband had a child through surrogacy in the United States. Upon returning to France, they encountered difficulties in obtaining legal recognition as the child's parents. The ECtHR ruled that France's refusal to recognize their legal parentage violated Article 8 (right to respect for private and family life) of the European Convention on Human Rights (ECHR). The court held that this refusal amounted to an interference with the right to respect for family life and was not justified under the ECHR.

According to the scholars, EU law offers two main systems for maternity rights protection: regulations concerning the health and safety of pregnant workers and maternity leave (Pregnant Workers Directive) and a general prohibition of discrimination based on maternity or pregnancy (Recast Directive). Both systems complement each other but differ in objectives and rights afforded. The Pregnant Workers Directive establishes minimum standards for maternity leave, time off for antenatal examinations, and protection against dismissal during pregnancy and maternity. The Recast Directive prevents discrimination in various employment aspects, explicitly addressing any less favourable treatment related to pregnancy or maternity leave[120].

The interpretation of these provisions for AWs users is crucial, as it affects their protection from dismissal and pregnancy discrimination. The determination of when "birth" occurs and when maternity leave begins is paramount. The authors suggest that AW gestation should allow the worker to retain their "pregnant worker" status to ensure adequate protection and reach equality of outcome, recognizing technical reasons for potential adjustments, such as the lengthening of maternity leave for AWs cases. Striving for equality of outcome is viewed as essential to preserving AWT as a genuine choice without compromising substantial maternity and equality rights. The writers also affirm that despite potential counter-arguments, their analysis supports the application

[119] *Menneson v. France*, Application no. 65192/11, judgment of 26 June 2014, Reports of judgments and decisions 2014.
[120] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.

of the existing EU maternity framework to AWs users, advocating for equal rights in labour settings.

For example, Article 8 of the Pregnant Workers Directive stipulates that pregnant, postpartum, and breastfeeding workers are entitled to a 'continuous period of maternity leave lasting at least 14 weeks allocated before and/or after confinement in accordance with national legislation and/or practice'. The purpose of maternity leave is to facilitate physical recovery post-birth and promote bonding and caregiving between the worker and their newborn. However, for users of AWT, the Directive's timeline doesn't align. AWT involves an invasive procedure before gestation becomes a baby, making recovery and maternity care non-continuous. The Directive, designed for traditional conception-gestation-birth patterns, is inadequately suited for reproductive techniques like ectogestation or surrogacy, where 'confinement' and 'birth' may not occur conventionally. Concerns arise as interpretations of the Directive have been rigid, excluding those without birth or physiological gestation from maternity leave entitlement[121].

The CJEU's decisions on surrogacy and employment rights, particularly *CD v ST*[122] and *Z v A* Government Department[123], have highlighted the central role of maternity leave rights. These cases affirmed that EU law, as per Article 8 of the Pregnant Workers Directive, does not compel employers to provide maternity leave for commissioning parents, avoiding a breach of gender equality provisions. The court's focus on this issue led to conflicting opinions from Advocates General Kokott and Wahl. Kokott advocated for a flexible interpretation of maternity, accommodating surrogacy within the Directive and emphasizing the broader objectives beyond physiological vulnerability. She sought a modern approach to reproductive advancements in line with legislative intentions. However, the Court, in alignment with AG Wahl's perspective, excluded commissioning parents from the Directive's scope, emphasizing the protection of those physically undergoing pregnancy and childbirth. The Court prioritized biological conditions, referencing confinement in the Directive and overarching health and safety goals. Despite differing opinions, both AGs and the Court agreed that denying commissioning mothers maternity leave did not constitute direct

[121] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[122] *C.D. v S.T.*, Case C-167/12, ECLI:EU:C:2014:169 [2014], para. 34.
[123] *Z. v A* Government Department, The Board of management of a community school, Case C-363/12, ECLI:EU:C:2014:159 [2014].

sex discrimination, as commissioning fathers were treated similarly in the national framework[124].

In this context, in the authors' opinion, concerns arise regarding workers using AWT. Although unlikely to be excluded from the health and safety framework, given the temporary pregnancy period and caesarean-esque procedure, the issue of 'confinement' triggering maternity leave raises questions. The Court might consider AWs transplant as 'birth' to align with surrogacy cases, streamlining the pregnancy/maternity period administratively. However, this might impact the legal protection of the parent-child relationship, a crucial aspect for AWT users. While EU law acknowledges the special status of this time, it hasn't played a substantive role when pregnancy's physiological vulnerability is absent.

Suggesting that AWs-caesarean recovery, artificial gestation presence, and 'birth' being seen as part of 'pregnancy' could significantly lengthen the process for AWT users. For instance, a person undergoing extraction at 24 weeks might need a standard 6-week leave for recovery, extending maternity leave during a period when they could potentially work. Allowing this extension could provide individuals with the necessary privacy and time for involvement in the AWs process. The active involvement of AWT users in medical/technical decision-making and the emotional connection with the developing child necessitate thoughtful consideration in the design and interpretation of maternity leave.

In this scenario, the authors explicitly state their non-endorsement of a broad application of the leave approach, emphasizing that various justifiable reasons for absence may necessitate the provision of full-pay leave. Comparing this leave to sickness or compassionate leave is deemed inappropriate in their point of view, as reproductive processes like pregnancy and birth differ fundamentally from these situations. Their practical standpoint stems from potential benefits for both parents and employers. Extending maternity leave might prove advantageous for employers by avoiding the logistical challenge of securing cover for both the recovery and subsequent maternity periods, occurring in close succession. While covering maternity leave and possibly replacement costs could be incurred, it may be preferable to manage the complexities of finding two short-term employees for consecutive absences.

[124] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.

From a productivity standpoint, an employee recovering from major surgery and anticipating a newborn may not perform as efficiently. However, the core concern in the context of AWT lies in how to treat the formerly pregnant individual during the post-recovery period. The gestateling would not be delivered from the artificial placenta until 38 weeks, the average full gestation period. Traditional pregnancies might involve individuals working close to their due date, but AWT users undergo a caesarean recovery long before the due date. Legal frameworks must adapt to these changes in the gestation/maternity timeline if ectogenesis becomes widely available[125].

Contrary to some other scholars, Hooton and Romanis argue against considering AW transfer as equivalent to 'birth,' despite the need for a recovery period and the cessation of physiological pregnancy vulnerability. For them, treating it as 'birth' would grant recovery and visitation time but impede meaningful parent-child bonding or breastfeeding. While similar to the position of commissioning parents, the distinction for AWT users lies in their physiological pregnancy, bringing them under the Directive's scope. While advocating for an approach not solely based on physiology, they recognize that AWT can integrate into the Directive's framework and interpret its use as the continuation of 'pregnancy' (due to ongoing gestation) and considering the gestateling's removal from the AWs as 'birth' aligns with the Directive's envisioned timeline, ensuring meaningful maternity leave for those opting for machine-assisted gestation[126].

An alternative to extending maternity is using the right to antenatal examination, in the authors' perspective, permitting visitation of the gestateling. Article 9 of the Pregnant Workers Directive mandates Member States to grant pregnant workers time off for antenatal examinations without loss of pay. 'Antenatal' could encompass medical care before birth, benefiting AWT users despite the law's current uterine-centric focus. This interpretation strikes a balance by allowing AWT users informed involvement in their gestateling's development, maintaining equality with bodily gestators, and facilitating employer access before post-birth maternity leave. Other alternatives may not strike this balance effectively—elongating maternity leave might be unfavourable for employers while denying time off after caesarean recovery would deprive the pregnant person of involvement in their future child's development[127].

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[125] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[126] Ibid.
[127] Ibid.

In the event that the health and safety directive does not permit visitation of the gestateling, addressing this through discrimination claims may not be feasible. This is because situations related to post-transfer, involving both male and female parent(s) attending the hospital, may not fall under the framework of sex discrimination. Some bioethicists argue that AWT promotes equality between sexes in reproduction, allowing male genetic progenitors to take more 'care' or 'custody' of gestating entities before birth. However, many feminist scholars contest this interpretation. If the worker retains the status of a 'pregnant worker' during AW gestation, enjoying the same rights as those undergoing bodily gestation, the need to consider whether the sex discrimination framework allows time off for involvement in the ecto-gestation process would be eliminated. This would circumvent the challenges faced by surrogacy cases within the EU law framework.

Here, while the researchers advocate for a more favourable outcome for AWT users compared to commissioning parents, they oppose the stratification of rights based on reproductive or gestational choices. The argument is that the existing maternity leave framework inadequately addresses the realities of modern family structures and reproductive practices. Nevertheless, the optimal interpretation should recognize that the fetus's transfer to an AW machine does not constitute 'birth' but a continuation of pregnancy. Thus, 'confinement' occurs during the AW delivery, triggering the maternity leave timeline at the appropriate moment[128].

As a consequence, legal arguments may arise regarding whether maternity should cover the 8 weeks between recovery and AWT birth or if this period should involve work with access to an antenatal visitation of the gestateling. The paramount consideration is not to overlook the impact of early maternity on the parent(s)-child bond's development. In surrogacy cases, achieving one objective of the Directive (protecting caring and bonding time) becomes challenging due to the restrictive definitions of 'pregnant worker' and 'worker who has just given birth.' The authors propose a more flexible approach for workers who have been pregnant to align with the Directive's objectives in AWT use: if the goals of recovery and bonding can be realized, they should be[129].

This interpretation leaves the issue of accounting for recovery time after fetal extraction surgery for AW open. The preferable approach would be to establish a framework at the national and regional levels that divides maternity leave rather than

[128] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[129] Ibid.

maintaining it as a continuous period. In the absence of such an accommodating framework in the employment rights context for AW gestation, using sick leave may be the most viable option, as exemplified by the inclusion of some IVF processes under 'sick leave.'

However, the scholars acknowledge that a persistent focus on the physiological aspects of pregnancy might lead a court, despite metaphysical, ethical, and legal arguments to the contrary, to interpret AW transferal as equivalent to 'birth', which they do not agree with. The perspectives of national regulators and legislatures will also influence this, as reproductive choices are unfortunately a politicized matter for many Member States within the EU. Hooton and Romanis also mention understanding why some commentators agree with the legal outcomes of the surrogacy cases in CD and Z, considering the sensitivity of the EU framework's impact on national choices in a politically and socially charged area[130].

However, they remain unconvinced by the hyper-focus on the physiological state of pregnant workers and their physical vulnerability as the sole guiding forces for interpreting the Directive. They claim that there might be room to maintain the Directive's focus on vulnerability as a guiding factor without reducing 'vulnerability' to being synonymous with being 'physically pregnant'. The mental health of individuals in the early stages of bonding and caregiving could be worthy of protection under the Directive if a broader approach is taken by the Court of Justice of the European Union (CJEU). Article 10, which prohibits the dismissal of pregnant workers, already recognizes the need to protect the physical and mental state of those who are pregnant, have recently given birth, or are breastfeeding[131].

While the prevention of physical and mental distress from dismissal and the allocation of recovery time in maternity leave are distinct legal facets, it seems logical to protect mental well-being in both cases. Ensuring adequate maternity leave for those relying on non-traditional reproductive and gestational practices could fall under the Directive's scope, safeguarding the mental and physical well-being of those undertaking bonding and caregiving tasks anticipated during maternity leave.

The scholars[132] recognize that this approach may not be flawless, and arguments may persist that the Directive primarily aims to protect the physical health and safety of pregnant workers and those recovering from birth. The narrow focus on

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[130] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009..
[131] Ibid.
[132] Ibid.

protecting pregnant physiology, rather than pregnant people and new parents, renders the law increasingly inadequate for safeguarding critical bonding and caregiving time essential for newborns and their primary caregivers. If EU law genuinely aims to protect that bonding time, it may be necessary to reconsider its fitness for purpose. The legal gap between the rights of different child-rearing workers will continue to widen with ongoing medical advancements, potentially leading to social disparities and perceptions of certain forms of child-bearing or gestation as 'less than' and unworthy of protection.

Furthermore, the writers argue for granting 14 weeks of maternity leave to all primary caregivers potentially falling under the Directive's scope, given a broad enough interpretation and advocate for interpreting AWT as continued gestational labour, making an individual using it a 'pregnant worker' eligible for bonding and caregiving time after the AW delivery of their newborn. A similar approach, albeit rejected, by AG Kokott for surrogate mothers could broaden the Directive's scope. This approach has gender-related limitations, as the Directive is inherently gendered due to its focus on female physiology and perceived physical vulnerability.

They also do not foresee a commissioning father falling under the Directive's scope. Affirming that this doesn't diminish the importance of parental leave for bonding time; it underscores the inadequacy of a health and safety Directive focused on pregnant physiology when considering modern reproductive practices and parenting. Moreover, the polarized approaches in CD and Z reflected opposed conceptions of parenthood, which could influence subsequent litigation amid ongoing redefinitions of family structures and family law. Urgent attempts to update the law should distinguish critical parental leave for newborn bonding and caregiving from the protection of pregnant people's health. Absent such a change, Hooton and Romanis argue for interpreting the Directive to allow maternity leave when an individual assumes care of a newborn, not simply when they have just given birth[133].

This prevailing focus on pregnant physiology for employment law rights is problematic, in the eyes of the authors. In the context of existing structural violence and policing of female physiology, this is not just a matter of EU law hesitating to take a bold step forward with labour rights but an active step back. It solidifies the regulation of the female form, condoned by the CJEU. While this pertains to the legislature, a narrow reading of the Pregnant Workers Directive remains unhelpful, with potential

[133] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.

repercussions for equality in various family structures and situations involving surrogacy or adoption[134].

For instance, Article 10 of the Pregnant Workers Directive serves as a safeguard against the dismissal of individuals from the commencement of pregnancy until the conclusion of maternity, except in 'exceptional cases' where dismissal is unrelated to the pregnancy, birth, or maternity. The purpose of this provision is to protect pregnant individuals and new mothers from discrimination during dismissal proceedings. The Court recognizes that a dismissal during pregnancy or maternity leave could adversely affect the physical and mental well-being of the pregnant person, potentially influencing their decisions regarding the continuation of the pregnancy[135].

The efficacy of this provision in accommodating advances in reproductive practices and technology hinges on the circumstances surrounding pregnancy and birth. As previously discussed, unless a Member State legislates to grant maternity leave to commissioning parents, surrogacy cases fall outside the scope of this provision, as the intended parent will never have been pregnant or on maternity leave. In the case of AWT users, there is evident potential for the provision to apply, as the individual will be physically pregnant at some point. However, the ambiguity lies in determining when 'maternity leave' commences and concludes for AWT users, thereby influencing the duration of protection against dismissal[136].

Once more, the writers stress that interpreting AW transfer as equivalent to 'birth' would significantly expedite the timeline of protection against dismissal. The individual, previously pregnant, would utilize maternity leave for recovery from the caesarean, with little or no leave remaining for caring and bonding with their child upon delivery from the artificial placenta at 38 weeks. While Article 10 safeguards against dismissals during the early stages of pregnancy and throughout the recovery period labelled as 'maternity leave,' this protection would terminate either before the arrival of the newborn or very early in the bonding process[137].

Before being delivered from the artificial placenta, the gestateling does not require physical care to survive. Once the newborn arrives, the previously pregnant person will face demands for care and bonding. If maternity leave has already concluded, there is a risk that a new parent may require absences from work to attend to their child, and these absences would not be covered by the Directive's prohibition of

[134] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[135] Ibid.
[136] Ibid.
[137] Ibid.

dismissal. Disciplinary and dismissal policies related to absence would apply without the protection offered by the discrimination framework, as dismissals for these absences would not qualify as 'maternity' discrimination (as maternity leave would have ended) or sex discrimination (as parents of any gender may need time off for childcare).

Therefore, Article 10 of the Directive could provide substantial protection to AWT users, if it covers the period after the newborn has been delivered from the machine. Here, the scholars argue once more against considering the transfer into the AW machine as 'birth.' They affirm that to truly achieve the objective of ensuring the mental and physical well-being of pregnant individuals and those with newborns, AWT users should be granted meaningful maternity leave without concerns about the consequences of taking time off.

Similar to the authors' examination of maternity leave[138], they harbour scepticism regarding the adequacy of the existing framework for protection from dismissal concerning advancements in reproductive practices. As with maternity leave, the current protection against dismissal revolves around physiological events, namely the initiation of pregnancy and subsequent events leading to the conclusion of maternity. This framework poses challenges for most non-traditional reproductive practices. Surrogacy arrangements, falling beyond the scope of the Directive, face a lack of protection from dismissal coupled with the absence of maternity leave. AWT users face potential uncertainty, as the CJEU's potential classification of the caesarean as 'birth' could leave them without substantive maternity leave or protection against dismissal for absences related to caring for their newborn. This physiological focus becomes evident when considering the prohibition of dismissal in In Vitro Fertilization (IVF) cases.

In the *Mayr*[139] case, the Court grappled with the question of whether individuals in the early stages of IVF are protected from dismissal as pregnant workers. Although IVF and AWT differ – one involves assisted conception and the other assisted gestation – the IVF case provides insights into the protection afforded by EU law to individuals engaged in reproductive processes without a developing pregnancy. Ms. Mayr, undergoing IVF, was on 'sick' leave when dismissed. At the time of dismissal, her ova had been fertilized, and the embryos were set for transfer to her uterus three days later.

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[138] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009..

[139] *Sabine Mayr v Bäckerei und Konditorei Gerhard Flöckner OHG*, Case C-506/06, ECLI:EU:C:2008:119 [2008].

Disputing her dismissal, Ms. Mayr claimed protection under pregnancy status. However, her employer contested that there was no pregnancy until the embryos were transferred to the uterus, as a pregnancy independent of the female body was deemed 'unimaginable.'[140]

The CJEU was tasked with clarifying the definition of a 'pregnant worker' under the Pregnant Workers Directive, specifically whether pregnancy initiation occurs with the fertilization of ova, thereby extending protection from dismissal to those in early IVF stages. Advocate General Ruiz-Jarabo Colomer opined that Ms. Mayr was not 'pregnant' for Directive purposes, relying on a scientific definition associating pregnancy with the implantation of the conceptus in a woman. Since implantation had not transpired before Ms. Mayr's dismissal, she was not deemed 'pregnant.' The AG emphasized the 'usual' meaning of pregnancy as the development of a new human being in the woman's womb, which had not occurred when Ms Mayr was dismissed. The AG's stance was rooted in preserving legal certainty in dismissal protection administration. Considering the potential for frozen ova and postponed transfers, linking pregnancy initiation to fertilization would extend dismissal protection almost indefinitely, beyond or before the physiological vulnerability associated with pregnancy[141].

The AG's opinion, while aligning with a plausible intuition that no pregnancy exists when an embryo is ex-utero, also introduces the possibility of sex-based discrimination slipping through. Employers could terminate employment without being accused of discrimination against a person for being pregnant, even if the termination results from their intent to become pregnant or efforts in that direction. This underscores the vulnerability that individuals, particularly those presenting as female, may face in the workplace based on the potential to become pregnant. While the AG acknowledged the potential role of discrimination provisions in such disputes, it highlighted that IVF users, by showing that dismissal was related to their IVF, could potentially find protection under sex discrimination provisions. However, this protection may not extend as easily to other intended parents (surrogacy) or those beyond the physiological aspect of pregnancy (AWT users).[142]

The Court largely concurred with the Advocate General's findings in the Mayr case. The judgment clarified that fertilization of ova pre-transfer to the uterus could not

[140] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[141] Ibid.
[142] Ibid..

be deemed 'pregnancy' under the Directive, resulting in Ms Mayr not being classified as a 'pregnant worker,' thereby rendering her dismissal not unlawful under the Pregnant Workers Directive. However, if the dismissal was linked to her absence during in vitro fertilization, it could potentially be considered discriminatory on grounds of sex, especially given that only individuals with typically female physiology can undergo a follicular puncture.

While the outcome may be disheartening from a pregnancy and maternity protection perspective, it sheds light on the limitations of EU law in safeguarding those seeking medical assistance in reproduction. The Court, perhaps wisely, refrains from delving into the contentious debate on the commencement of life. Importantly, the Court's rationale allows for the future inclusion of AWT users within the definitions of 'pregnancy' and 'pregnant worker.' The fact that the ova had not reached the uterus was not deemed conclusive evidence of the beginning of pregnancy. Had it been, it could have significantly impacted the recognition of extra uterum gestation, such as AWT, as a continuation of pregnancy for Directive purposes.[143]

The Court's decision was more based on concerns about legal uncertainty, especially in cases where fertilized ova could be preserved for extended periods. This contrasts with AW gestation, which has a definite timeframe and concludes with the development of the fetus. Given the crucial distinction between AWT and the early stages of IVF, where there is already a developing fetus with a reasonably predictable timeframe, we remain confident that gestation outside the uterus does not preclude an individual from being a 'pregnant worker' under the Directive.

However, the IVF cases underscore a broader issue with the law. While the Court's reasoning focused on arguments surrounding legal certainty, Mayr's case heavily depended on the timing of the dismissal in the IVF procedure. This emphasis on the physiological experience of pregnancy, particularly the role of the uterus, in obtaining protection under the Directive may foreshadow potential challenges for AWT users under EU law. Those opting for machine-assisted gestation will be exempt from the physiological experience of later-term in-utero gestation. [144]

The reliance on traditional physiological experiences and biological vulnerability for protection might imply that AWT users could fall outside the scope of such protection. While an opinion from over 15 years ago may not perfectly reflect the current understanding of pregnancy or the perspectives of Advocates General and the

[143] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[144] Ibid.

Court, the law might not have evolved sufficiently to offer more inclusive protections for individuals leveraging technological and social advancements in reproduction by the advent of AWT. The central issue here is the physiological focus presenting a challenge for interpreting the law in the context of AWT, analogous to the issue of when pregnancy 'ends' being as critical for ectogestation as the start of pregnancy is for IVF. While one suggested approach is to consider AW gestation as a continuation of pregnancy, the broader problem of the law failing to adequately protect the rights of those embracing advancements in reproduction would benefit from comprehensive reform.

Moreover, Hooton and Romanis[145] emphasize and discuss the existence and the consequences of two fundamental equality-based rights related to employment for pregnant workers and individuals involved in the reproductive process. The first is the right not to face discrimination for being pregnant, and the second is a broader right not to be discriminated against based on their sex. Pregnancy and maternity hold a uniquely protected status, as proving discrimination on the basis of these characteristics does not require a comparator assessment, which is typically needed in discrimination cases. Discrimination usually necessitates showing that a person with a protected characteristic was treated less favourably than someone without that characteristic. Pregnancy and maternity are considered gendered issues, and discrimination based on pregnancy is deemed 'sex' discrimination, given that only individuals with typically female physiology can become pregnant.

However, this model poses challenges for genderqueer or transmasculine individuals whose physiology might be capable of pregnancy. Broadening the scope of pregnancy discrimination to include discrimination related to reproduction, rather than tying it strictly to sex discrimination, might be a more inclusive approach in the authors' opinion.

The pregnancy discrimination framework, including CJEU jurisprudence and the Recast Directive, potentially provides limited support for AWT users. Similar to the issues with maternity leave and the prohibition of dismissal under the Pregnant Workers Directive, the prohibition of discrimination based on pregnancy and maternity relies heavily on the definition of 'pregnancy.' If an individual opting for ectogestation is considered a pregnant worker throughout machine-assisted gestation, the discrimination framework will protect them from less favourable treatment by employers

[145] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.

in terms of promotion, training, employment opportunities, and dismissal, similar to 'traditional' pregnancies. However, if an individual is only considered pregnant until their fetus is transferred to the AWT, the pregnancy discrimination framework ceases to apply at the end of their (early) maternity leave. Any discrimination thereafter, such as refusal to provide training or promotion opportunities due to an individual working part-time to care for their newborn, would need to fall under the general sex discrimination framework, requiring a comparator assessment[146].

A sex discrimination claim hinges on whether a comparator of the opposite sex would be treated the same in the claimant's circumstances. If an AWT user attempts to use this framework, they may struggle to show that a comparator of the opposite sex would be treated any differently. While there is the possibility of practices indirectly discriminatory towards AWT users, as they may disproportionately affect women, the burden of proof for the ectogestation user is higher under the sex discrimination framework compared to being considered pregnant for the entirety of gestation. At that point, any less favourable treatment due to AWs use or maternity leave would be outright prohibited[147].

The discrimination framework, as it stands, may not fully accommodate advancements in reproductive technology and practices. AWT users are not expected to lose all their rights under the discrimination framework, as the situation is more comparable to IVF (Mayr decision) than surrogacy. The individual advocating for their rights will experience some physiological pregnancy and fetal development, making them protected from pregnancy discrimination during this time. Even if AWT transfer is not considered 'birth' or 'pregnancy continued,' less favourable treatment linked to ectogenesis use could still constitute direct discrimination on the grounds of sex because it involves typically female physiology, as in the Mayr case[148].

However, according to the authors, the effectiveness of discrimination laws in protecting workers opting for ectogenesis may be limited. Some scholars suggest that Mayr may not be a robust legal foundation for an equality claim, as conditions requiring IVF can exist only in men, involving both sexes in the reproductive process. The Court's emphasis on ovum extraction being linked to female physiology, rather than the necessity of IVF in general, suggests that the protection is specifically for those with typically female physiology undergoing the medical intervention necessary for IVF. In

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[146] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[147] Ibid.
[148] Ibid.

the case of AWT, the strain on the female form ends after recovery from the caesarean-esque procedure, and any 'less favourable treatment' after recovery depends on whether the employer would treat a typically male colleague similarly. If the employer can demonstrate that a (usually male) colleague would be treated the same way, the discrimination provisions offer no protection to the AWT user[149].

Regarding the rights in Articles 8 and 10 of the Pregnant Workers Directive, the argument here is that an individual opting for ectogenesis should be considered a 'pregnant worker' throughout machine gestation. This is crucial to maintaining a protective framework for childbearing workers similar to 'traditional' pregnancies. The assessment of discrimination rules leads to a similar outcome: if the individual is a 'pregnant worker' throughout machine gestation, and maternity leave starts at the appropriate time, the framework for protection from pregnancy and maternity discrimination will cover the AWT user. If AW transfer were considered 'birth,' the individual might face discrimination after their 'maternity' leave, which may or may not be prohibited, depending on a comparator assessment. Both protection frameworks (discrimination and health and safety) require a broad interpretation of 'pregnancy' to safeguard the employment law rights of those opting for ectogestation[150].

The discussions illustrate, according to the scholars, the inherent overlap between the frameworks and how they offer distinct protections. When (or if) maternity leave begins will influence the duration of the prohibition of pregnancy and maternity discrimination. On the other hand, the Recast Directive or discrimination provisions cannot guarantee enforceable rights to meaningful maternity leave for an AWT user; only falling under the provisions of the Pregnant Workers Directive can achieve this. The EU law's understanding and interpretation of pregnancy directly impact both streams of protection[151].

The introduction of ectogenesis as an alternative to traditional gestation will undoubtedly raise complex legal questions about interpreting existing rights within the pregnancy protection framework, in the opinion of the writers. If current forms of assisted reproduction cannot seamlessly fit into existing protection, the integration of AWT poses significant challenges. Several key issues and lessons emerge from the analysis of the rights framework and case law on assisted reproduction, shedding light on the critical problems arising from AWs use.

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[149] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009..
[150] Ibid.
[151] Ibid.

Firstly, EU law has entrenched traditional notions of pregnancy and motherhood, exemplified by the Latin maxim 'mater semper certa est'—the legal mother is someone who gestates and gives birth to a child. For EU law, a pregnant worker must be or have been engaged in the physical and physiological vulnerability of pregnancy. The hyper-focus on biology may not align with the social reality of child-rearing, potentially creating ambiguity in situations like AWT use. Questions may arise about whether the traditional notion of pregnancy and maternity can accommodate a scenario where a machine continues gestation, and whether an individual opting for ectogenesis has given birth or the machine has. The pivotal issue is determining when an individual opting for ectogestation would gain maternity rights and whether maternity leave would be meaningful. The definition of 'birth' will be subject to legal interpretation in the AWT context. The argument here subscribes to the view that birth only occurs when the gestateling is delivered from the artificial placenta. This ensures that existing employment law rights can effectively address AWT use[152].

Secondly, existing case law related to employment rights and advancements in reproductive practices demonstrates that the regulation of rights for parents opting for AWT will initially depend on the choices of national legislatures. Legal disputes, likely involving the CJEU, may arise if AWT and employment law conflicts occur within the EU, given the minimum harmonization of maternity leave rights under the Pregnant Workers Directive and the prohibition of discrimination on the grounds of pregnancy or sex. The legal questions facing the court will revolve around whether machine gestation is considered pregnancy and, more crucially, when confinement or 'birth' occurs in such instances. Rethinking the protection framework may be necessary, but in the absence of such reforms, AWT could be incorporated into the existing system more easily than surrogacy or IVF.[153]

Thirdly, the pregnancy protection framework, when viewed through the lens of advancements in reproductive practices, emphasizes a prevalent focus on pregnant physiology at the expense of other crucial aspects, such as the autonomy of the pregnant person. Interpretations that initiate the maternity process too early for AW users may be viewed as a form of punishment for their choices about gestation, potentially infringing on the autonomy of pregnant individuals. To ensure that AWT remains a genuine choice without adverse work-related consequences, a legal framework is essential to retain rights to maternity leave and prohibit dismissal for

[152] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009.
[153] Ibid.

those opting for non-traditional gestation. The suggestion that AWT is a form of continued pregnancy for legal purposes reduces the likelihood of employers pressuring employees or using the law to punish them for their choices[154].

Lastly, this exploration of ectogestation reveals potential legal challenges for the courts if the maternity and pregnancy discrimination framework is not adapted to accommodate this technological advancement. Similar to the legal questions raised by surrogacy and IVF, the CJEU may have to decide when pregnancy starts and who falls under the scope of a 'pregnant worker.' In the context of AW transfer, questions will arise about whether a person who previously experienced pregnancy and opted for machine gestation is still considered a 'pregnant worker.' Moreover, the court may face the politically and socially sensitive issue of determining when 'birth' occurs in an AWT scenario—whether it is the process of transferring from the uterus to the AW or the removal of the fully gestated baby from the AW. This complex legal scenario presents another challenging decision: when ruling on when 'birth' occurs, the court must also determine when 'confinement' and maternity leave start and end. Accommodating recovery from the surgery and time off to care for the newborn will be the most challenging aspect of AWT use under the framework of protection[155].

Moving forward with legal analysis and the impact of AWT in different legislations globally, Abecassis[156] reviews how the French and U.S. laws stand before current reproductive technology practises. Here, many insights can be drawn from cases such as *Cour de cassation No. 18-24.131*[157], for example. In this case, the French Supreme Court ruled on the legal parentage of a child born through surrogacy abroad, a decision with significant implications for the recognition of surrogacy arrangements in France. Similarly, *Johnson v. Calvert*[158], a landmark case in the United States, addressed the parental rights in surrogacy arrangements, establishing important legal precedents. This comparative analysis explores the existing legal frameworks in both jurisdictions and considers how they might be influenced or adapted in response to advancements like complete ectogenesis.

The author argues that France adopts a cautious stance towards the utilization of reproductive technologies, guided by prudence. This approach seeks to avoid

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[154] Hooton, V., & Romanis, E. C. (2022). Artificial womb technology, pregnancy, and EU employment rights. *Journal of law and the biosciences*, *9*(1), lsac009. https://doi.org/10.1093/jlb/lsac009..
[155] Ibid.
[156] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.
[157] *Cour de cassation* (French Supreme Court), 1st Civil Chamber, Judgment of May 6, 2020, No. 18-24.131.
[158] *Johnson v. Calvert,* 5 Cal.4th 84 (1993).

compromising ethical standards merely to fulfil the desire for parenthood, emphasizing a reluctance to play the "sorcerer's apprentice." Despite recognizing the societal benefits of reproductive technologies, particularly evident since the birth of the first French "test-tube baby" in 1982 under the supervision of Dr. Frydman, the French legislature imposes strict limitations on their availability. The French Code of Public Health explicitly dictates that assisted reproductive technology (ART) should only be employed to address medically diagnosed pathological infertility or prevent the transmission of severe disease to either the unborn child or the other partner in the couple. The last decade has witnessed legislative and regulatory expansion, outlining and circumscribing various bioethical practices, rather than outright prohibition.

The utilization of ART in France reflects the tension between a conservative legislative push restricting reproductive technology and the widespread, popular use of the technology. The French social security system covers all costs associated with in vitro fertilization (up to four attempts) for female residents up to the age of forty-three. With one of the highest fertility rates in Europe, France witnessed a significant proportion of babies born in 2012 conceived with the assistance of ART, in contrast to the United States. While France accepts ART, it strongly resists embracing more innovative reproductive technologies.

France's stance on surrogacy is less nuanced than its approach to in vitro fertilization. Since 1991, the French Supreme Court has deemed surrogacy contrary to the fundamental principle of the "non-commercialization of the human body." A provision in the French Civil Code further declares all agreements related to procreation or gestation for the benefit of another as null. Interestingly, the European Court of Human Rights recently criticized France for not acknowledging the establishment of a relationship between a father and his biological children born through surrogacy arrangements abroad[159]. The Court, in this instance, limits France's ability to disregard the effects of a foreign judicial decision on surrogacy issued in the United States. While not endorsing surrogacy agreements, the Court implies that the biological father-child relationship established in the United States should be recognized similarly in France[160].

On the other hand, the United States stands out for its notable absence of federal regulations concerning reproductive technologies. Oversight from the Centers

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[159] *Menneson v. France*, Application no. 65192/11, judgment of 26 June 2014, Reports of judgments and decisions 2014.

[160] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) is limited to ensuring the safety of technological devices used in assisted reproductive technology (ART) rather than governing the broader use of these devices. State-level regulation of medical activity, including treatments for infertility, is accomplished through the licensing of practitioners, allowing for the suspension or revocation of licenses in cases of malpractice. The medical profession, notably organizations like the American Society for Reproductive Medicine, engages in self-regulation and establishes standards for in vitro fertilization[161].

Compared to European counterparts, the U.S. adopts a highly permissive stance towards ART due to the influence of America's long tradition of individual liberty, free-market orientation, and broad autonomy granted to medical professionals. American social values, driven by economic principles, readily accept unregulated reproductive technologies and exhibit a general trust in the medical profession. In 2012, over 1% of all infants born in the U.S. resulted from assisted reproductive technologies. Surrogacy, categorized as a form of ART, is subject to varying laws across different states. Some states explicitly declare surrogacy contracts void and unenforceable (e.g., Louisiana), or even impose penalties on parties involved in a surrogate contract (e.g., New York). Other states distinguish between paid and unpaid surrogacy (e.g., Washington), while some permit and regulate surrogacy (e.g., Florida), and others remain silent on the matter (e.g., Colorado). Currently, the U.S. (alongside Canada) is a preferred destination for French couples seeking surrogacy. These disparities in legal frameworks, theoretical approaches, societal values, and practical implementations, both in the United States and France, in accordance with the author, underscore the necessity of establishing uniform regulations, especially if ectogenesis becomes a widely adopted practice in the future.

Abecassis[162] then views the necessity of the reevaluation of the legal status of the embryo due to the advent of (relatively) autonomous fetal existence through ectogenesis. This reexamination involves addressing two primary issues to the author: First, what types of harm should be protected against in the case of ectogenetic embryos? Second, is the attribution of personhood a satisfactory legal response? Given the physically independent nature of ectogenetic embryos from the woman's body, the law must safeguard them against physical harm without implicating the

[161] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.
[162] Ibid.

woman's bodily integrity. This holds particular significance under French law, where harm to an unborn child typically results in civil compensation or criminal sanctions in the name of the pregnant woman, despite subsequent legal effects triggered by the live birth.

In the United States, many states have fetal homicide laws considering the fetus a "person" for criminal proceedings involving harm to a pregnant woman that leads to the fetus's death. Both U.S. and French law currently position human embryos in an "interim category," acknowledging them as more than mere human tissue but less than full-fledged persons. The introduction of artificial wombs underscores the need for regulators to address the legal ambiguity surrounding gestating fetuses.

Moreover, ensuring the protection of embryos must be complemented by a comprehensive liability system. Questions arise, such as who should be held responsible in the event of a power outage affecting incubators and to what extent they should be accountable if ectogenetic fetuses perish. Distinctions must be drawn between embryos grown in ectogenetic incubators for parental projects and those subject to alterations for research purposes. This will necessitate regulators to contemplate the ethical implications of scientific research on growing embryos versus frozen embryos.

Another pressing issue involves determining the fate of ectogenetic fetuses if the initiating couple separates or no longer wishes to pursue their parental project. The courts (and potentially the Legislature) would need to establish strict regulations governing the right to terminate the gestation of ectogenetic fetuses. In contrast to the abortion of a fetus within the mother's womb, the termination of an ectogenetic fetus places both parents on equal footing in the decision-making process. Some propose drawing inspiration from existing laws governing frozen embryos. For example, in the United States, courts typically refer to any prior agreements between the parties involved. For instance, in *Davis v. Davis*[163], the Tennessee Supreme Court established a three-part test for resolving disagreements between couples over embryo disposition: (1) Preference of the progenitors, (2) Enforcement of any prior agreements in cases of disagreement between gamete donors, and (3) Balancing the relative interests of the parties in the absence of prior agreements. If interests are evenly balanced, courts tend to favour the party seeking to avoid procreation, provided the other party has alternative means to achieve parenthood. Similarly, in *Kass v. Kass*[164], the New York Court of Appeal presumed validity and enforced embryo agreements governing

[163] *842 S.W.2d 588* (Tenn.1992)
[164] *673 N.Y.S 2d 350* (N.Y 1988)

disposition. In England, however, prior agreements made between couples undergoing IVF treatment are not binding. The Human Fertilisation and Embryology Act 1990 grants both gamete progenitors the statutory right to withdraw or alter consent to embryo use until implantation[165]. Consequently, in *Evans v. Amicus*[166], the courts upheld the partner's decision to withdraw consent, despite the embryos being the former partner's last opportunity for genetic motherhood[167].

However, despite similarities with other reproductive techniques and the relation to frozen embryos, the uniqueness of ectogenetic fetuses, already implanted and engaged in parental projects, demands careful consideration of potential arbitrary decisions by parents regarding their fate. Respecting fetal life during the early stages of gestation requires determining a point of no return, addressing whether the couple's consent to pursue gestation until birth is irrevocable once the embryo is successfully placed in the artificial womb. The Legislature would need to define exceptions to this irrevocable consent, considering therapeutic or extreme familial situations.

The externalization of human gestation through ectogenesis will cast a fresh perspective on debates surrounding the commencement of human life and the attribution of personhood, in accordance to the author. While the notion of attributing personhood to a fetus from conception holds appeal, especially in the context of fetuses capable of growing outside the woman's body, it may not offer the most satisfactory solution for ensuring the protection of ectogenetic fetuses. The question of "the beginning of human life" is highly intricate and lacks a unanimous consensus.

From a biological standpoint, the union of human gametes creates a "being that is alive and is a member of the human species," as articulated in the U.S. Congressional Report of 1981. However, philosophically, human embryos lack the "conscious self-awareness" characteristic of the human species but carry the potential to become rational beings. Defining the beginning of human life becomes a matter of essence, existence, or potential existence.

Practical consequences linked to attributing personhood extend beyond theoretical debates about the onset of human life, in the scholar's opinion. Legal protection for the right to life, bodily integrity, and constitutional rights poses challenges if personhood is assigned to embryos from conception. This poses complexities for

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[165] Human Fertilisation and Embryology Act 1990, Schedule 3.
[166] *Evans v. Amicus Healthcare*, [2003] EWHC 2161 (Fam).
[167] Alghrani, A. (2007). The Legal and Ethical Ramifications of Ectogenesis. *Asian Journal of WTO & International Health Law and Policy*, 2(1), 189-212. Retrieved from SSRN: https://ssrn.com/abstract=1019760.

embryonic research, selection, and abortion. Treating each frozen embryo in a fertility clinic as an individual person would be impractical and procedurally burdensome.

The existing legal uncertainty surrounding the status of embryos in both France and the U.S., exacerbated by incidents involving gestating fetuses or frozen embryos reaching courts or legislatures, calls for a more coherent approach. The current case-by-case method, unsuitable for addressing the situation of ectogenetic embryos, should be replaced with the establishment of clear and innovative legal statuses specific to embryos, distinct from the categories of "persons" and "things."

These new statuses should accommodate flexibility for research and abortion/termination while ensuring adequate legal protection for embryos. Different factors should determine the extent of legal protection, leading to the creation of various statuses or subcategories. For instance, distinctions could be made between "pre-implantation" embryos (fertilized eggs, frozen embryos) and "post-implantation" embryos (successfully attached to a womb), further categorized into "intracorporeal" and "ectogenetic" embryos. This nuanced set of legal statuses aligns better with the unique place of embryos in the legal landscape, avoiding their reduction to an interim category and addressing the diverse and intricate situations involving embryos and fetuses[168].

Regarding the redefinition of the concept of parenthood, Abecassis makes a comparison between the use of artificial wombs and surrogacy. She believes that despite the concept of family being portrayed as archaic, reminiscent of a primitive societal model for some authors, the emergence of reproductive technologies possesses the potential to strengthen familial bonds.

In surrogacy arrangements, a surrogate or gestational carrier agrees to carry a child for a commissioning couple, also known as the intended parents. The child can be conceived using the gametes of the intended parents, donors' gametes, or a combination of one parent's gametes and one donor's gametes, including the surrogate's own egg in traditional surrogacy or gestational surrogacy where the surrogate is implanted with an embryo conceived through in vitro fertilization. Surrogacy agreements explicitly outline the terms between the involved parties, with the gestational carrier committing to diligently carry the intended parents' child in exchange for compensation. However, the enforceability of surrogacy agreements, even when legally deemed valid, is a subject of considerable controversy.

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[168] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

For Abecassis[169], drawing parallels between ectogenetic incubators and existing surrogacy agreements justifies the application of common principles. First, ectogenetic incubators can serve as an alternative to surrogacy, giving rise to similar parentage consequences. When surrogacy is successful, neither the surrogate nor the donors have a parenting role, with legal parentage recognized for the intended parents. Recognition can occur through legal means, including pre-birth orders. Second, the promise of artificial wombs presents advantages over traditional surrogacy. Ectogenetic incubators eliminate concerns about a gestational carrier withdrawing consent or deciding to continue or terminate the pregnancy against the intended parents' wishes.

Moreover, artificial wombs protect potential surrogate mothers from exploitation, removing them entirely from the process. By removing the need for a surrogate mother to carry the pregnancy to term in her own body, AWs eliminate the physical and emotional burdens often associated with surrogacy. This eradication of direct involvement mitigates the risk of coercion, manipulation, or pressure that surrogate mothers may face, whether from intended parents, agencies, or other parties involved in the surrogacy process, for example.

Despite these advantages, using ectogenesis in lieu of surrogacy poses constraints for intended parents. Their decisions regarding the ectogenetic child may face monitoring and challenges to protect the fetus, either through legal processes, medical team considerations, or market realities where artificial wombs become a lucrative business. Despite these constraints, final agreements between intended parents may not always be enforceable in court, similar to existing contracts determining the ownership of frozen embryos that are occasionally deemed unenforceable for policy reasons.

The author[170] also recognizes the capability of ectogenesis for changing the concept of motherhood, especially affecting French law and its filiation principles, affirming that AWT could relegate French family law to obsolescence.

In 2011, the Cour de Cassation reiterated that, under French law, the principle is that the mother is the one who gives birth. This concept aligns with the language of the French Civil Code. Article 332 allows contestation of maternity by proving that the alleged mother did not give birth. Notably, in French law, the process of pregnancy (biology) takes precedence over genetics in determining motherhood. For instance, a

[169] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.
[170] Ibid.

woman using an egg donor can be the legal mother if she gives birth, while a woman seeking surrogacy, even with her own egg, is not recognized as the legal mother.

The French approach to motherhood raises concerns on multiple fronts. Firstly, it introduces a gender-based inequality between women and men, for whom biology and genetics are naturally intertwined in procreation. This inequality is evident in cases where the genetic father of a child conceived through surrogacy abroad can be recognized as the legal father in France, whereas the intended mother faces barriers. This discrepancy may intensify with the use of artificial wombs, potentially making it easier for the biological father to gain legal parentage than the non-gestational mother, even if the child shares her genes. Secondly, the advent of artificial wombs presents a unique legal challenge, as a child gestated entirely in an incubator would technically be born to a "machine." Current French law, thus, leads to an absurd situation where the only potential "natural" mother is not a human being.

Despite certain philosophers arguing that artificial wombs could usher in a new era of women's social liberation by liberating them from the constraints of reproductive biology, from a parenting perspective, especially for women, artificial wombs might introduce new challenges. Considering the issues outlined earlier, the French Legislature needs to reconsider the fundamental concept of motherhood in light of artificial wombs, while the U.S. Legislature must build upon the changes spurred by surrogacy agreements.

One potential solution is to treat the ectogenetic incubator as an extension of the intended mother's uterus. However, this approach presents theoretical and practical challenges, as it denies men, who lack a uterus, the right to use the technology to fulfil their desire for parenthood. Another imperfect solution could be to offer intended parents the option to adopt their ectogenetic child upon birth. However, adoption processes are cumbersome, and it seems absurd for a couple providing genetic materials and initiating the child's conception to adopt them at birth[171].

A more fitting solution involves expanding the definition of parents and adopting a model akin to surrogacy agreements. The U.S. Citizenship and Immigration Services, in a policy alert from October 28, 2014, formally defined "natural mother" or "natural father" as a genetic or gestational parent. Ideally, regulations should go further by recognizing "intended" parents, irrespective of purely "genetic" or "gestational" connections, as potential legal parents. Establishing the legal category of "intended

[171] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

parents" requires robust safeguards against potential fraud. The definition of "intention" must be broad enough to accommodate the needs of the intended parents of an ectogenetic baby, regardless of genetic connections, while remaining strict to prevent opportunistic claims of parentage. The introduction of "pre-birth orders" could help secure the parent-child relationship and deter fraud or trafficking. These orders should adhere to stringent conditions to protect the ectogenetic child, drawing on concepts and procedures from both acknowledgement and adoption processes[172].

When regulating access to AWT, to the scholar, the challenge lies in navigating conflicting rights and addressing uncertain ethical concerns. Public decision-makers face a complex task, requiring a rational consideration of various elements to strike a fair balance. While this article assumes that hard law is the optimal tool for regulating access to artificial wombs, alternative avenues include medical deontology, private markets, or economic incentives.

In accordance with the author, U.S. and French regulators must define the likely users of this new reproductive technology, categorizing them into three main groups. The first comprises women with severe medical conditions that make pregnancy highly unlikely, impossible, or potentially life-threatening. The second group includes single men and homosexual male couples seeking alternative parenting options beyond adoption and surrogacy. Artificial wombs provide a valuable substitute for a female womb in this context. The third category consists of women who, for personal and/or professional reasons, choose not to undergo pregnancy. These reasons range from personal comfort to concerns about traditional pregnancy-associated constraints.

Ectogenetic regulations must balance government policy directives with the interests of the individuals it aims to protect. Scholars have highlighted the potential financial barrier, suggesting that only the wealthiest can afford this technology without additional financial aid. To address this inequity, one proposal involves compelling healthcare insurance to cover the costs associated with artificial wombs. Legislatures must also consider the ethical implications of access to artificial wombs, particularly concerning the welfare of the child. While ectogenetic incubators may offer a safer environment for embryos compared to a human womb, the potential legal implications are concerning. A scenario is imagined where a court might intervene if a mother's conduct during pregnancy jeopardizes the child's well-being, potentially ordering the fetus into an incubator in the child's best interest. This raises questions about the

[172] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

balance between protecting the child's welfare and the potential infringement on a mother's rights[173].

Concerns persist about the externalization of pregnancy and its impact on the mother-child relationship. Ethicists express reservations about the unknown consequences of artificial gestation on the psychological and physical well-being of ectogenetic children compared to naturally gestated children. There's also the fear of a society leaning towards a "manufacture of children" due to unregulated access to artificial wombs, potentially leading to the industrialization of human procreation. Public decision-makers must grapple with these "slippery slope" arguments and determine the extent to which they should influence regulatory decisions.

Drawing a useful parallel with the regulation of in vitro fertilization (IVF), which is now widely accepted globally with over five million successful conceptions, sheds light on potential parallels in the acceptance and regulation of artificial wombs. Ectogenetic technology, like IVF, has the potential to address a natural inequality, specifically between fertile and infertile couples. However, while IVF primarily focuses on fertilization, ectogenetic technology addresses both gestation and fertilization, tackling a distinct type of infertility referred to as "gestational infertility" – the inability to carry a pregnancy. The gestation period is considered crucial by prenatal specialists, acknowledging the significant bond formed between a woman and the developing child in her womb[174].

While IVF technology is often simplistically viewed as the union of sperm and egg in a laboratory, it involves additional elements such as freezing, destruction, and genetic testing of human embryos. Considering these complexities, the gap between artificial wombs and the current generation of assisted reproductive technology is smaller than expected. Consequently, access to artificial wombs should not significantly differ from access to IVF, with the main distinction lying in the type of infertility each technology aims to address.

In France, access to IVF is tightly circumscribed, limited to heterosexual couples of reproductive age seeking assistance for diagnosed pathological infertility or to prevent the transmission of a severe genetic disease. Mere difficulty in conceiving or early menopause does not automatically grant access. In the U.S., assisted reproduction is less regulated, and managed by the private market with discretion

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[173] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

[174] Ibid.

granted to healthcare professionals, while still subject to general rules of torts and contracts[175].

J.B.S. Haldane envisioned that France would be "the first country to adopt ectogenesis officially, and by 1968 [would be] producing 60,000 children annually by this method," anticipating stronger opposition in most other countries. However, the reality may be that France, compared to the U.S., will likely exhibit more reluctance in broadening access to ectogenetic technology, assuming it is permitted in the first place. The U.S., on the other hand, might not introduce specific legislation to restrict the use of artificial wombs.

The question arises: should unregulated access to artificial wombs raise more concerns than the unframed use of in vitro fertilization (IVF)? Can reliance solely on medical professionals ensure the "right" choices when significant public policy issues are at stake? Both French and U.S. regulators should intervene to define access to artificial wombs, but legal interventions may differ due to opposing legislative cultures and views on reproductive technologies.

In France, artificial wombs are likely to fall under the existing provisions of Title IV of the Code of Public Health, which regulates assisted reproductive technologies, unless they are considered an exceptionally invasive technology exceeding mere "assistance" to human reproduction. Consequently, access to artificial wombs would be limited to pathologically infertile couples, given that the absence of a uterus does not render a man "infertile" under French law. This article recommends that the French Legislature broaden the definition of "infertility" to encompass the physiological infertility of same-sex (male) couples, enabling them to access IVF and potentially artificial wombs for their parental projects if legalized.

In the U.S., the prospective introduction of ectogenetic technology necessitates federal regulation for uniform application. Potential risks associated with this technology, such as the possibility of "manufacturing" children and concerns for the well-being of ectogenetic infants, as well as the risk of profound inequity between wealthy and poor couples, emphasize the need for legal safeguards beyond existing regulations on reproductive technologies. Artificial wombs are likely to raise more profound concerns compared to the current use of IVF and surrogacy[176].

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[175] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.

[176] Ibid.

In this scenario, it is known that IVF and surrogacy rely on contracts as part of their regulation in many countries, but especially in the U.S. Schultz[177], then, making a parallel between these reproductive techniques and AWT, question whether these contracts concerning embryos in AWs could be enforceable, especially those related to the termination of the fetus. Despite this topic having already been debated exhaustively in this and other chapters of this work, here, however, the author proposes analyzing it from another angle: defining the rights of genetic parents over a fetus in an artificial womb utilizing contracts, akin to those employed by IVF clinics, for instance. A potential *contract* for artificial womb scenarios might grant either party the authority to terminate the "pregnancy" in the scholar's opinion.

To the author, depending on legal regulations regarding the permissible abortion period, the contract could specify the termination's timeframe, such as before a certain gestational age. However, even if a contract aligns with existing laws, uncertainties arise regarding whether courts would uphold these agreements or declare them contrary to public policy considering that the court's stance on the enforceability of contracts dictating the fate of unused frozen embryos remains divided. The lack of uniformity in judicial decisions on this matter raises questions about the applicability of similar contracts concerning embryos in artificial wombs since the court rulings do not appear to be grounded in minor factual distinctions but rather stem from the assertions made by the involved parties and the court's decision on whether to prioritize public policy considerations or concentrate solely on contractual principles such as unambiguous language and mutual consent.

Some argue for the consistent enforcement of contracts dictating the fate of frozen embryos in cases of divorce or the death of genetic parents, positing that this approach would establish a clear rule motivating parties to thoroughly contemplate their preferences for embryo disposition. Moreover, certain courts are already cautious about couples contracting, for instance, the destruction or donation of embryos in the event of divorce. These courts express concerns not only about parties adequately reflecting on their choices when signing the contract but also about the freedom to change such significant decisions regarding bringing a child into the world[178].

Here, it is important to mention the *Parrillo v. Italy*[179] case. Ms Adelina Parrillo challenged Italy's prohibition on donating embryos conceived through medically

[177] Schultz, J. H. (2009). Development of Ectogenesis: How Will Artificial Wombs Affect the Legal Status of a Fetus or Embryo. *Chicago-Kent Law Review*, 84, 877.
[178] Ibid..
[179] Parrillo v. Italy, Application no. 46470/11, Judgment of 27 August 2015, European Court of Human Rights.

assisted reproduction to scientific research, alleging violations of her rights to privacy, property, and freedom of expression under the ECHR. Specifically, she argued that the ban infringed upon her rights to respect for private life, peaceful enjoyment of possessions, and freedom of expression as guaranteed by Articles 8 ECHR, 1 of Protocol No. 1, and 10 of the Convention, respectively. The case was brought before the ECtHR, which ultimately ruled that Italy's ban on donating embryos for scientific research was not in violation of the Convention. Specifically addressing Article 1 of Protocol No. 1, which guarantees the right to property, the Court clarified that this right does not extend to embryos. The ruling emphasized that embryos cannot be categorized as "things" or objects of property. Therefore, they do not fall within the scope of property rights protected by the protocol. The case was declared inadmissible.

In the case of a fetus in an artificial womb, however, it has been implanted and is undergoing development, distinguishing it from a frozen embryo. Nevertheless, a fetus lacks the same legal status as a minor child, in the writer's opinion. Additionally, while courts handling frozen embryo cases must decide on the potential use of embryos, courts handling artificial womb cases would be tasked with deciding on an actively developing life[180].

Therefore, to the scholar, two conceivable types of *contracts* could be established regarding an artificial womb: one mandating the continuation of the pregnancy under any circumstances and another authorizing termination. The latter, involving a contract allowing termination, presents more challenges to the courts, as it requires the court to take action to terminate a developing life. If certain courts are hesitant to enforce contracts affecting potential life, it is likely that a larger number of courts would be uncomfortable enforcing contracts influencing an actively developing life instead of a potentially developing life that is currently static. The court's intervention in potential human life in the context of artificial wombs is more complex compared to its role in frozen embryo cases[181].

To Schultz, if a court chooses not to enforce an artificial womb contract, it is essentially allowing a potential life to continue its development. However, enforcing such a contract means actively preventing the ongoing development of a life. Moreover, the consequences of time delay and inaction differ in the context of an artificial womb contract. In cases involving frozen embryos, where one party wishes to use them and the other seeks to prevent it, the embryos remain unused when the court takes no

[180] Schultz, J. H. (2009). Development of Ectogenesis: How Will Artificial Wombs Affect the Legal Status of a Fetus or Embryo. *Chicago-Kent Law Review*, 84, 877.
[181] Ibid.

action. In contrast, in a potential artificial womb case where one party wishes to continue the "pregnancy" and the other aims to terminate it, the embryo or fetus continues to develop towards full gestation during the court proceedings. Not enforcing a contract that grants one party the option to terminate the pregnancy maintains the status quo, allowing the fetus to continue growing. Therefore, enforcing an artificial womb contract entails a more active role for the court compared to enforcing a frozen embryo contract.

To the author, there is also the possibility of a contract allowing parties to mutually consent to discontinue an artificial womb. In this scenario, where both parties share the objective of discontinuing the artificial womb, the contract would likely be assessed solely for its legality. If the law prohibits the termination of a fetus in an artificial womb once it is implanted, a contract stating that the parties can mutually consent to terminate the pregnancy would likely be deemed illegal and unenforceable. While artificial womb contracts involving mutual consent would depend on the legality of the action, contracts permitting unilateral termination of the embryo or fetus would probably be unenforceable. This aligns with the more stringent stance often taken in cases involving frozen embryos, where such contracts are frequently deemed unenforceable. Additionally, supporting a clear rule that renders both *unilateral and mutual consent termination contracts* unenforceable is grounded in practical and public policy considerations[182].

Here, it is crucial to consider the implications of current legislation and the rulings of the EU Courts concerning embryos and preterm babies. These legal frameworks and judicial decisions suggest that the right to terminate the fetus in an AW setting is legally untenable. As such, any contractual attempts to authorize such terminations would likely be invalidated and deemed illegal. Expanding on this, the concept of 'gestateling' introduced by Romanis prompts academic discourse on the intentional termination of the gestateling prior to 'birth', referred to as gestaticide[183]. Within this discourse, gestaticide is viewed as more ethically complex than abortion due to the gestateling's complete independence from its biological parents. Given the moral parallels drawn between gestaticide and infanticide, there emerges a significant ethical dilemma regarding its permissibility within the broader ethical discourse.

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[182] Schultz, J. H. (2009). Development of Ectogenesis: How Will Artificial Wombs Affect the Legal Status of a Fetus or Embryo. *Chicago-Kent Law Review*, 84, 877.

[183] Rodger, D., Colgrove, N., & Blackshaw, B. P. (2020). Gestaticide: killing the subject of the artificial womb. *Journal of medical ethics*, medethics-2020-106708. Advance online publication. https://doi.org/10.1136/medethics-2020-106708.

Chapter 3 - Ethical complexities and challenges in the realm of Artificial Womb Technology

3.1 Human trials in AWT: ethical boundaries and technological advancements

Although artificial wombs have undergone animal testing, human clinical trials have not been conducted to date. The FDA has yet to authorize this technology, although an advisory panel, as mentioned above, has extensively deliberated upon the existing scientific data, clinical risks, potential benefits, and ethical implications associated with conducting human trials for AWs.

When discussing ethical debates around the subject and human trials, many questions arise and one of them is regarding the legal personality of human beings and when it is acquired. In most secular states, legal personality for human beings is acquired at birth and it encompasses a delineation that has been clear and consistent. Before birth, a fetus is not recognized as possessing legal personality; however, after live birth, an individual is acknowledged as a legal person. However, the impact of emerging reproductive technologies, such as AWT, prompted a reevaluation of how legal personality is attributed according to the law. The advent of newer possibilities for human existence at earlier developmental stages, such as ex-utero stages, challenges the simplicity of the birth concept. Consequently, the legal elements of personality, particularly birth and being born alive, necessitate further elucidation and refinement.

The term "gestateling" was coined by Romanis, as previously mentioned in this work, as the right denomination for "a human being in the process of ex utero gestation exercising, whether or not it is capable of doing so, no independent capacity for life"[184]. The author views the necessity for creating a new terminology since describing entities in AWs as 'preterm' or 'fetus' misrepresents their behaviour and developmental stage. These labels, borrowed from intrauterine contexts, inadequately capture the distinct nature of entities gestating ex-utero.

Within existing legal frameworks, gestatelings might be considered legally birthed due to their ex-utero existence. However, they are unlikely to be regarded as legally born alive. Their status does not align with traditional legal notions of an active and independent life. Legal criteria for being considered born alive often centre on breathing, although there might be a shift toward acknowledging 'other signs of life.'

[184] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755. https://doi.org/10.1136/medethics-2018-104910.

Gestatelings, lacking independent breathing or the ability to manifest signs of life, continue a process akin to gestation, resembling the in-utero fetal stage. While dependent on the umbilical cord and placenta, they are not deceased; they retain the potential to demonstrate signs of life or breathe in the future. These technological advancements highlight the necessity of a deeper examination of what constitutes being alive within the scope of the law and what considerations should govern legal definitions of life[185]. In the following chapters, a more exhaustive examination and detailed exploration of this theme will be conducted to thoroughly scrutinise its complexities and ramifications considering that, despite its obvious influence in the considerations regarding human trials, its impact on legislation and reproductive health policy is even greater.

Thus, the new terminology - gestateling- comes not only as an empty definition but as a completely new definition for a subject, that may be acquiring legal personality soon, considering the prospective utilization of the biobag beyond the current viability threshold and its consequences. Regardless of the researcher's emphasis that the objective of the biobag and future usage of the technology is exclusively aimed at mitigating mortality and disability rates among 'just-viable' preterms -explicitly steering clear of extending the viability threshold-, should the biobag prove as effective for human preterms as observed in animal trials, it may inherently challenge prevailing notions of its viability. This mirrors the evolutionary trajectory witnessed in conventional NIC. Despite the internationally recognized viability threshold at 24 weeks gestation, medical attempts to rescue preterms as young as 22 weeks persist, buoyed by societal norms and parental advocacy. The successful implementation of AWs for older neonates could potentially prompt a natural inclination towards their application with younger preterms, mirroring historical trends observed in conventional NIC's gradual evolution toward the existing viability standard. The deliberate narrowing of their scope at this early experimental juncture by the researchers may, therefore, be mostly attributed to viability's entanglement within legalities regulating abortion access—a point often negotiated through a pragmatic compromise.

Considering that experimental treatments may soon make gestateling a medical reality, introducing complexities to ethical and legal discussions in obstetrics and neonatology, it is imperial then to answer the question of whether AWT is an innovative

[185] Romanis, E. C. (2020). Challenging the ‘Born Alive’ Threshold: Fetal Surgery, Artificial Wombs, and the English Approach to Legal Personhood. *Medical Law Review*, *28*(1), 93-123. https://doi.org/10.1093/medlaw/fwz014.

treatment or medical research. Romanis[186] advocates for distinctions between AWT and neonatal care, citing the uniqueness of 'gestatelings'. However, authors like Kingma and Finn[187] counter these arguments, asserting their insufficiency. This debate holds potential clinical implications, hinting that AWT might be presented more as an innovative technology than as an experimental research endeavour.

Many authors contended that AWT merely extends the scope of conventional NIC, suggesting inherent ethical compliance in experimental treatments, saying that ectogenesis is essentially an attempt to apply similar interventions to preterms born at an earlier stage. However, despite intentions, AWT is potentially the sole technology capable of challenging the existing viability threshold. Many experts posit that conventional NIC faces limitations impeding its ability to support younger preterms, contrasting the more radical approach of AWs due to their distinct innate features. The flawed assumption underlying the notion that partial ectogenesis is already a partial reality in these cases lies in the conflation of incubation and gestation as conceptually identical processes. This differentiation warrants consideration in future clinical applications, as disregarding conceptual disparities could lead to detrimental decision-making for involved parties. One critical distinction can be found in the nature of the support offered by AWT, wherein AWT provides more comprehensive assistance compared to conventional NIC[188].

It has been argued that incubation involves 'rescuing' a preterm by providing assistance for the preterm's life functions it is attempting or starting to manage independently. However, the process of gestation involves the creation of humans. The advent of AWT represents a significant shift in treating underdeveloped human preterms: from 'rescuing' them by assisting life functions necessary for independent living to facilitate the 'creation' of the subject by continuing the gestational process ex utero. Unlike conventional NIC, which relies on preterms using their lungs for oxygen, hindering further lung development, AWT devices are intentionally designed to bypass lung utilization. Gas exchange occurs through a catheter, mirroring in-utero placental gas exchange. The goal is to create an environment where the subject behaves more like a 'fetus' than a 'baby'[189].

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[186] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.
[187] Kingma, E., & Finn, S. (2020). Neonatal incubator or artificial womb? Distinguishing ectogestation and ectogenesis using the metaphysics of pregnancy. *Bioethics*, *34*(4), 354–363. https://doi.org/10.1111/bioe.12717.
[188] Romanis E. C. (2018). Artificial womb technology and the frontiers of human reproduction: conceptual differences and potential implications. *Journal of medical ethics*, *44*(11), 751–755.
[189] Romanis E. C. (2020)., op. cite.

AWT possesses the potential to completely supplant a human function by replicating biological processes, not merely attempting rescue measures. For example, if AWT malfunctions, an underdeveloped gestateling would perish, akin to a fetus during a severe placental abruption. Conversely, a premature neonate in an incubator might survive briefly after being turned off. Unlike ongoing human development, gestation, whether in or ex utero, is a distinct process focused on formation, crucial for the independent capacity for life. Another significant distinction lies in their environments—NIC is invasive yet allows some human interaction, whereas AWT is non-invasive, enclosing the gestateling with minimal disturbance.

Moreover, the crucial distinction raised here emphasizes that experimental AWT represents an advancement over NIC primarily in its conceptual superiority in process and potential outcomes. However, using AWT on preterms means entirely disregarding established and proven treatment methods for a vulnerable population to experiment with an approach whose short- and long-term consequences remain unknown, thereby subjecting the individual to risks. While conventional NIC is not without risks, we are familiar with these risks and can attempt to mitigate them, although their effectiveness might not be assured. Additionally, with conventional NIC, there's a reasonable expectation of preterm survival after 26 weeks. Experimental AWT could introduce unknown risks and possibly lead to worse outcomes for subjects compared to conventional treatments.

Nonetheless, innovative approaches often signify novel treatments that hold potential clinical benefits for patients. If there was a credible expectation of direct benefits from experimental AWT for individual preterms, it would not necessitate classification as research. For instance, if 'just viable' preterms were utilized for AWT trials, it could be argued that these preterms have survived with conventional treatment, justifying AWT use. However, the mere survival of this group with support does not guarantee or imply direct benefits from AWT. The theoretical concept of AWT (continuing gestation) is conceptually plausible, but its translation into practical application is uncertain. While animal studies hint at the possibility of ex-utero gestation, significant physiological differences limit the extrapolation of benefits to human subjects.[190] Typically, research progresses through animal trials before human trials to validate clinical expectations. The proposal to test on animals with physiologies more akin to humans has been made. However, this idea raises ethical controversy, particularly concerning the use of non-human primates. It requires extensive ethical

[190] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

evaluation to weigh the moral implications, including compromised animal welfare, against the potential moral benefits derived from ectogenesis research. In the end, the absence of clinical evidence supporting AWT in humans indicates that it should be regarded as research until proven otherwise.

In research endeavours, the main aim is to generate broad and applicable knowledge, whereas innovative treatment aims at benefiting individual patients. When seeking generalized knowledge, ensuring that health isn't compromised unduly due to experimental design becomes crucial. Both main researchers on AWT envision it as a potential new standard of care for extremely premature infants, stating their goals as to develop a new therapeutic option, replacing traditional ventilation methods, and aiming for improved preterm outcomes. The ultimate objective in AWT development is the potential replacement of conventional NIC, aiming to reduce mortality and morbidity rates in preterms if the devices prove as effective as anticipated. Establishing consistent evidence demonstrating superior outcomes through AWs becomes paramount. Thus, the primary objective of experimental AWT is to generate generalizable knowledge, indicating AWT's potential replacement for traditional technologies.

This primary objective doesn't eliminate the possibility that physician-investigators aim for potential benefits to individual recipients of the AWT, such as enhancing survival chances or reducing complications. However, this intent remains secondary to the overarching goal of producing generalizable knowledge. The initial translation of this technology into clinical practice will likely involve trial and error. If the aim were to provide the best treatment for a 'just viable' preterm (say, at 23–25 weeks), a logical approach would involve established therapies that have shown some success, rather than risking an uncertain device as an alternative. For instance, NIC survival rates at 25 weeks of gestation stand at around 81%. It might seem more justifiable to trial the technology on preterms at an earlier threshold, such as 22 weeks, where NIC is less reliable. However, experimental AWT carries significant uncertainties and risks. Thus, the primary motivation behind it isn't solely to aid individual preterms. Even if AWT demonstrated individual benefits in each case, it would still be regarded as research rather than treatment[191].

The significant risks undertaken by subjects in experimental AWT are unlikely to be justified solely based on individual benefit. In the realm of medical practice, including innovative treatments, some inherent risks are acceptable if the patient is

[191] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

expected to benefit. However, as research primarily aims at advancing knowledge rather than an individual's medical interest, justification typically takes a consequentialist stance. It argues that the risk endured in an experiment might be justified by the contribution to knowledge, leading to better outcomes for future patients. This distinction in justifying risks helps differentiate between innovative treatment and research. Experimental AWT poses substantial risks like circuit overload leading to cardiac failure, inadequate nutrient supply causing liver dysfunction, and the risk of brain injury. Circuit malfunction, particularly delicate in balancing flow, adds to these risks, with the subject's size impacting nutrition and flow dynamics. Initial use on human subjects might not immediately benefit them but holds potential for future preterm care. While lacking a reasonable expectation of immediate success and understanding the involved substantial risks, justifying AWT for an individual preterm's benefit may be unsound. However, it could be deemed justifiable due to its potential to revolutionize future preterm care.[192]

For all the reasons mentioned above, and in alliance with Romanis's viewpoint, it is evident that the implementation of AWT in clinical practice constitutes a form of research and with it comes the necessity of justifying experimental AWT. Research involving the development of human beings sparks controversy, particularly when the potential benefits are uncertain. Nevertheless, esteemed bodies such as the World Medical Association, British Medical Research Council, and U.S. Department for Health and Human Services recognize that non-therapeutic research in these circumstances can be justified if it aims to benefit future preterm infants and strictly adheres to identified populations. Some specialists argue that the potential of AWT to enhance premature baby care justifies ethically approved research. Despite this argument, the actual benefit of initial subjects in ectogenesis research remains debatable. If AWT is classified as research, it will imply formal protocols, robust study designs, and protective procedures for subjects' welfare and the creation of generalizable knowledge. Any such research would typically begin with a clinical trial, necessitating extensive clinical evidence before these devices can be used beyond controlled environments. Regulatory agencies like the FDA in the U.S. or the Therapeutic Goods Administration (TGA) in Australia, where this technology is under development, categorize AWT as a 'high-risk device.' This classification, akin to an implanted device, reflects its role as an advanced life-support system intimately linked to subjects. Given the uncertainties surrounding individual outcomes, potential adverse effects pose

[192] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

unreasonable risks. Consequently, high-risk devices need pre-market approval, demanding substantial evidence of safety and effectiveness from clinical investigations. Both IRBs and the FDA must approve studies with significant risks, with similar stringent classification systems existing in Australia and Europe.

In the scenario of a research trial with potential non-beneficial outcomes, both foetuses and preterms share substantial similarities in their treatment, as regulatory bodies typically prohibit exposing either to unnecessary risks. Requirements mandate researchers to maximise potential benefits and secure parental consent. The U.S. Office for Human Research Protections (OHRP) has established regulations under Subpart B[193], which offer additional safeguards for foetuses and neonates involved in research. According to §46.204, interventions involving foetuses must carry a prospect of direct benefit or minimal risk, focusing on generating essential biomedical knowledge that cannot be obtained otherwise. Obtaining informed consent from both parents is mandatory, or solely from the pregnant individual if the research is beneficial for them. In §46.205, the guidelines for research on neonates of uncertain viability (a probable category for AWT studies) necessitate enhancing survival prospects with minimal risk, aiming for critical biomedical knowledge without added risk. Seeking informed consent from either parent is necessary, except when the neonate is perceived as non-viable, in which case consent from both parents becomes essential (based on availability). Consequently, regardless of whether subjects are equated to foetuses or neonates in moral status, the practical considerations of IRBs reveal significant similarities in their treatment protocols[194].

Some may contend that AWT trials hold ethical validity due to the potential benefits for the subjects involved. The argument might suggest that any chance at life or a life free from significant medical complications is superior to no chance at all. However, as previously outlined, this justification is unlikely to suffice given the inherent uncertainties. Nonetheless, revisiting this argument emphasizes its reliance on identifying a specific category of research subjects. There could indeed exist a discernible population for whom the potential reward of 'some chance at life' outweighs the risk, particularly those with limited prospects in NIC. In such cases, AWT might be regarded as at least as safe as NIC, and possibly with comparable or improved outcomes. The critical inquiry then shifts towards assessing the potential suffering

[193] Protections, O. F. H. R. (2021, December 13). *Subpart B — Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research*. HHS.gov. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html.
[194] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

endured by the subject against the prospect of life and defining the degree of 'life' that constitutes a meaningful gain. For certain parents, even a small extension of time, such as a few extra days, might be viewed as a valuable benefit. However, this perspective becomes harder to justify if the subject is expected to bear substantial burdens during the study.

Arguably, it's challenging to support the assertion that more mature preterms (> 24 weeks) derive any discernible benefit from being exposed to experimental AWT. This claim hinges on the researchers effectively demonstrating that AWT is as safe as or capable of yielding superior outcomes compared to current NIC, a much higher standard given the > 50% survival rate in NIC for this group. Regardless of the identified clinical population, researchers will rely primarily on animal study outcomes to rationalize an initial trial. Nevertheless, findings from lamb studies lack the robustness needed to validate potential benefits in humans. Therefore, researchers may need to gather data through testing on more analogous animal models, such as primates, particularly if considering trials on subjects already deemed viable.

Having discussed the aforementioned points, it is now pertinent to consider who is going to be the subject of the clinical trials. Patient eligibility for the trials has been debated among many experts. For example, the group of researchers composed of Kukora SK, Mychaliska G and Weiss EM[195] advocate for its initial utilization in patients whose predicted mortality exceeds 80%. On the other hand, Flake AW, De Bie FR, Munson DA, and Feudtner C[196] argue that the 80% threshold confines their potential participant pool solely to growth-restricted male neonates at 22 weeks, without proposing an alternate starting criterion. Traditionally, new technologies have been historically employed in populations with graver prognoses and higher expected benefits, akin to the criteria set for the initial ECMO trials in neonates.

Kukora et al. propose utilizing The Extremely Preterm Birth Outcomes Tool[197] to establish initial eligibility for EXTEND. In general, they recommend that the initial phase of first-in-human trials should strategically balance the challenges surrounding potential harm, the limited target population, and the avoidance of therapeutic delays due to poor study design. In accordance with the authors, employing a sequential enrollment

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[195] Kukora, S. K., Mychaliska, G. B., & Weiss, E. M. (2023). Ethical challenges in first-in-human trials of the artificial placenta and artificial womb: not all technologies are created equally, ethically. *Journal of perinatology : official journal of the California Perinatal Association*, *43*(11), 1337–1342. https://doi.org/10.1038/s41372-023-01713-5.

[196] Flake, A. W., De Bie, F. R., Munson, D. A., & Feudtner, C. (2023). The artificial placenta and EXTEND technologies: one of these things is not like the other. *Journal of perinatology : official journal of the California Perinatal Association*, *43*(11), 1343–1348. https://doi.org/10.1038/s41372-023-01716-2.

[197] *Use the Tool*. (2020, March 2). https://www.nichd.nih.gov/. https://www.nichd.nih.gov/research/supported/EPBO/use.

strategy, researchers can cautiously admit infants, progressively identifying unforeseen risks while minimizing exposure and rigorously evaluating the treatment's feasibility and safety. Initially targeting a small cohort of infants with extremely poor prognoses (e.g., < 20% survival rate), the study will primarily assess feasibility measures such as successful cannulation and duration on the circuit. As the trial progresses, this enrollment can gradually expand, encompassing infants with more favourable prognoses (e.g., 20–50% survival rate). This phase, designed as a comparative trial against standard therapy, aims to evaluate outcomes like survival rates and long-term neurodevelopmental effects, serving as a critical step in understanding the treatment's effectiveness across varied prognostic spectrums. However, the specialists do highlight that the present results for neonates delivered at 23 weeks gestation or later might be excessively positive to justify the utilization of AW technology, considering that in recent studies conducted in the United States, approximately 50% of infants born at 23 weeks gestation have survived, with around one-third of them exhibiting either no or mild neurodevelopmental impairment by the age of 2[198].

On the other hand, Flake et al. argue that applying experimental interventions is justified due to the considerable mortality and morbidity experienced by infants born between 23 to 24 weeks. Their argument emphasizes the prevalence of bronchopulmonary dysplasia, which impacts around 85% of infants born at 23 weeks, representing a significant morbidity[199]. They underscore the potential of EXTEND to potentially mitigate this condition, suggesting its capacity to offer neuroprotection compared to current therapies, although this possibility is still evolving based on emerging data from lamb models. They base their assertion about reevaluating eligibility thresholds for Artificial Womb (AW) technology on the consideration of these outcomes and the potential improvements that the technology might offer.

Considering both papers mentioned above, on their own analysis Werner, K.M., Baker, A.C. & Mercurio, M.R attest that appears logical to contemplate the prospective decrease in both mortality and morbidity while establishing the eligibility criterion for implementing EXTEND and propose a series of questions that must be answered before the initiation of the clinical trials: "At what upper threshold are current outcomes “too good” to warrant eligibility for inclusion in clinical trials for EXTEND? Should this

[198] Bell, E. F., Hintz, S. R., Hansen, N. I., Bann, C. M., Wyckoff, M. H., DeMauro, S. B., Walsh, M. C., Vohr, B. R., Stoll, B. J., Carlo, W. A., Van Meurs, K. P., Rysavy, M. A., Patel, R. M., Merhar, S. L., Sánchez, P. J., Laptook, A. R., Hibbs, A. M., Cotten, C. M., D'Angio, C. T., Winter, S., … Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network (2022). Mortality, In-Hospital Morbidity, Care Practices, and 2-Year Outcomes for Extremely Preterm Infants in the US, 2013-2018. *JAMA*, *327*(3), 248–263. https://doi.org/10.1001/jama.2021.23580.

[199] Ibid.

threshold be based solely on predicted mortality or a combination of morbidity and mortality? Furthermore, survival outcomes for infants at 22 and 23 weeks have recently improved with conventional care at some centres practising active management, including antenatal corticosteroids (>60% survival at 22 weeks at a single U.S. centre], >80% at 22 weeks at a single centre in Japan]. In light of this, should the eligibility for EXTEND be based on current outcomes at the centres with the best results, the centre where the EXTEND is to be trialled, or on national means?"[200]. They conclude that before AW trials, mirroring successful protocols used elsewhere may be advisable. Initial EXTEND enrollment may prioritize patients with poor prognoses and outweigh risks by potential benefits. Establishing a threshold distinguishing overly favourable predicted outcomes from receiving experimental treatment versus standard care is crucial. This requires a deep understanding of current outcomes data for tailored patient selection criteria. Continuing attention to recent outcomes with standard care and ongoing discussions on an appropriate patient selection is crucial as technology advances toward clinical trials. However, the initial eligibility requirements should be based on ethical considerations of risk and benefit, rather than on the need to enrol a sufficient number of subjects. However, determining the precise threshold of a significantly poor prognosis to validate the inclusion of AW in early human trials is still a challenge.

Given that, Romanis[201] then proposes some observations on the most common ethical conundrums around human trials for AWT, for example, the consequentialist justification. This rationale claims that despite the high risks involved, an AWT trial holds the promise of significant rewards if the devices prove successful. Being the primary aim of these trials the improvement of the prospects of future generations and individuals navigating challenging pregnancies. While survival rates post-NIC have increased, the prevalence of long-term complications among survivors has plateaued due to the inherent limitations of current rescue technologies. AWT is envisioned not only as a potential lifeline for preterm infants but also as a solution for individuals facing dangerous yet desired pregnancies. Its success could profoundly benefit both future infants and parents, potentially reducing emotional distress.

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[200] Werner, K. M., Baker, A. C., & Mercurio, M. R. (2023). Unique ethical considerations of the artificial womb and placenta: the threshold for patient eligibility in clinical trials. *Journal of perinatology : official journal of the California Perinatal Association*, *43*(11), 1335–1336. https://doi.org/10.1038/s41372-023-01753-x.

[201] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

Failing to explore AWT research risks missing out on its substantial potential to address these challenges and facilitate positive outcomes. However, a purely consequentialist rationale implies that for the sake of maximizing future well-being, even at a considerable scale, subjecting research participants to significant risks with minimal potential gain may be acceptable. On the other hand, inflicting substantial suffering would contradict regulatory standards that aim to protect vulnerable populations from harm. Building on this line of reasoning, the author mentions U.S. regulations regarding potential trials, that permit non-beneficial research if it leads to critical biomedical knowledge unattainable by other means, provided it does not add risks to the developing human.

Nevertheless, if this consequentialist argument relies on meticulous research design without effectively addressing the research question through appropriate methods, the anticipated future benefits remain elusive. Therefore, Romanis proposes that "There are ethical issues embroiled in these methods that need to be addressed as part of any justification. Research subjects in any potential AWT trial would be vulnerable to exploitation because they are not participating in a wholly therapeutic arrangement. How can we ensure that a research trial is able to answer its research question? How do we mitigate concerns about coercion and parent(s) feeling pressured to consent to experimental procedures? How do we ensure that preterms are not exposed to unnecessary additional risk in the course of experimental procedures?"[202].

Following Romanis' opinion, conducting clinical investigations remains the sole path for experimental AWT to yield universally applicable insights. Some specialists stress the ethical necessity of methodological rigour in research, highlighting that without validity, research fails to generate intended knowledge, lacks justifiable benefits, and poses undue risks to subjects. Others mention observing doctors grappling with providing the latest technology to accommodate parental wishes 'not to give up,' irrespective of uncertain benefits and risks. Offering AWT in uncontrolled settings to preterms would inhibit the ability to draw generalizations about its effectiveness, impeding the collection of pertinent information and accounting for confounding variables. This absence of accumulating evidence would hinder establishing AWT as a viable alternative or replacement for conventional NIC.

Clinical trials, as recommended by the Council of International Organisations of Medical Sciences, uphold ethically sound research by mitigating risks for subjects.

[202] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

They stress pivotal research elements such as randomization, blinding, and controls, ensuring statistically significant data that potentially enhances treatment for preterms. Absent this data, the potential benefits of AWT remain uncertain, rendering it unethical to subject future subjects to associated risks[203].

Nevertheless, the author emphasizes ethical concerns that arise with specific research methods, notably randomization. In an AWT research trial comparing new and existing technologies, potential subjects would be randomly assigned to receive either NIC or AW care. Conducting this direct comparison under controlled conditions determines AWT's effectiveness. Randomization raises concerns about subject disadvantage, as some might receive an inferior treatment (either NIC or AWT) during the trial. Freedman[204] notes a consensus in clinical research ethics about commencing with an 'honest null hypothesis,' indicating genuine uncertainty regarding treatment comparisons for a given population. This uncertainty, termed clinical equipoise, occurs when expert clinicians disagree about the preferred treatment. Therefore, a viable way to alleviate discomfort about randomization, depending on the identified clinical population for an AWT trial, could be demonstrated by the use of clinical equipoise.

The uncertainties in animal studies and the inherent unknowns in human subjects during initial trials complicate its use, as clinical equipoise requires that the comparison treatment also be uncertain. However, for NIC, outcomes significantly improve with gestational age. Defining the threshold of uncertainty based on prediction models, likely concerning survival prospects, demands meticulous determination. The viability threshold, typically at 24 weeks, denotes a 50% chance of survival with NIC. Preterm infants below this point, with lower odds of survival, may lack sufficient evidence suggesting worse outcomes with AWT. As a result, determining the threshold for adequate uncertainty remains subjective. Determining when morbidity chances justify uncertainty in AWT over NIC is intricate. Additionally, gestational age remains crucial, given higher morbidity rates below the viability threshold. Hence, enrolling 'almost viable' rather than 'just viable' subjects seems more justifiable due to their lower potential risk exposure during the study in comparison to standard care. Therefore, the aim is to enhance the survival chances of entities of uncertain viability while minimizing associated risks. 'Almost viable' subjects could be inherently vulnerable due to the higher likelihood of futile treatment, potentially posing an ethical burden. Balancing the

[203] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.
[204] Freedman B. (1987). Equipoise and the ethics of clinical research. *The New England journal of medicine*, *317*(3), 141–145. https://doi.org/10.1056/NEJM198707163170304.

researchers' quest for valuable data against ethical considerations in burdensome treatment within both arms of the trial requires delicate navigation. Additionally, assessing the worth of survival opportunity against potential suffering during the process for subjects in both arms of an AWT trial is crucial[205].

Following this principle, Lantos[206] highlights that in NIC, standard care inherently carries serious risks of morbidity and mortality. Thus, evaluating the study shouldn't focus solely on risk but consider attributable risk—risks attributed to study participation rather than the subject's clinical condition or known risks of conventional treatments. However, subjects assigned to NIC in a potential AWT trial would face no attributable risk. Presumably, if parents consent to the study, they also consent to standard NIC care. The AWT group is potentially more significant, but considering the high risk in 'almost viable' subjects, the attributable risk is likely minimal.

In further elaboration, imperative to underscore the fact that the consideration of the consent process for AWT research is key. In neonatal or foetal research, obtaining informed consent from the subject's parent(s) is mandatory. Parents can only decide on trial participation if adequately informed about the research's purpose, potential risks, benefits, and alternatives. Laws across various jurisdictions necessitate higher risk disclosure for research compared to treatment, ensuring more rigorous consent procedures to prevent coercion. Investigators should clearly explain the standard care versus trial specifics to parents considering AWT trials, including the options of not enrolling and potential harms and benefits (including randomization).

Challenges arise regarding parents' ability to consent meaningfully due to the emotional strain inherent in decisions about providing their offspring a 'chance of life.' In instances where prospective parents provide their consent for such a trial with the expectation of potential benefits for the child, the critical consideration is whether this aligns with the best interests of the future child, acknowledging the potential trade-off between viability and the risk of severe disability. The application of AWT on preterm infants in an experimental context not only subjects research participants to uncharted short- and long-term risks but also raises questions about the validity of parental consent in emotionally taxing and distressing situations. Elements like randomization and conveying uncertainty can be distressing to grasp. Explaining that the trial may not directly benefit their child but could aid future preterms is a complex conversation for

[205] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.
[206] Lantos, J., & Meadow, W. L. (2006). *Neonatal bioethics: The moral challenges of medical innovation* (pp. 1–177). Retrieved from https://repository.library.georgetown.edu/handle/10822/975933.

researchers. Therefore, the emotional impact on parents needs to be carefully considered.

A significant issue in research is combating 'therapeutic misconception,' where participants perceive the experiment as medical treatment. Parents inclined towards experimental AWT often believe it offers the best chance or a complication-free life post-NIC for their preterm. While AWT may benefit initial preterm subjects, there's a risk of underestimating its potential failure or harm. In the context of a research trial, the perception shifts, emphasizing the trial's investigative nature and acknowledging the possibility of risks or receiving standard care due to randomization. The thoughtful design of the consent process should address therapeutic misconceptions effectively[207].

The moral concern for the future child's well-being remains paramount, even when it surpasses the 'wrongful life' standard, suggesting that the potential good of bringing someone into existence doesn't automatically outweigh the inherent harm associated with that action. There's an ongoing debate about where the bar for the future child's welfare should be set, with various guidelines in place. The 'reasonable welfare threshold,' for instance, asserts that medical professionals shouldn't provide technology if known risk factors indicate a high likelihood that the future child would experience a significantly diminished quality of life[208]. Furthermore, central to this innovation strategy is the imperative of long-term follow-up, necessitating ongoing consent from both parents and the maturing child. Given the potential complications in organ development and the regulation of vital parameters like oxygen and nutrition associated with AWT, a continuous follow-up is essential. This involves strict feedback mechanisms for addressing irregularities promptly. The impact on physical and mental health may only manifest after birth, emphasizing the importance of extended follow-up to mitigate risks for future children born via AWT[209]. However, the optimal duration for participant data collection post-ectogenetic birth remains presently unclear being the centre of numerous discussions not only by researchers and authors but also by many health regulatory bodies and organizations around the world.

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[207] Romanis E. C. (2020). Artificial womb technology and clinical translation: Innovative treatment or medical research?. *Bioethics*, *34*(4), 392–402. https://doi.org/10.1111/bioe.12701.

[208] ESHRE Task Force on Ethics and Law including, Pennings, G., de Wert, G., Shenfield, F., Cohen, J., Tarlatzis, B., & Devroey, P. (2007). ESHRE Task Force on Ethics and Law 13: the welfare of the child in medically assisted reproduction. *Human reproduction (Oxford, England)*, *22*(10), 2585–2588. https://doi.org/10.1093/humrep/dem237.

[209] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

Additionally, another topic for debate involves the utilization of fetuses in cases where a decision has been made to terminate the pregnancy. Key considerations arise regarding whether individuals seeking to terminate their pregnancy can provide authorization for the use of the fetus in ectogenesis research. Despite the significant risk of fetal death or injury, the primary aim of such research is the survival of the fetus. Although the chance of survival may currently be slim, if the fetus does survive, it will necessitate confronting the ethical question of whether, in that circumstance, it can be ethically terminated.

However, there are significant differences in aims between early and late ectogenesis research. Current experiments face legal restrictions and physical challenges, such as reimplanting embryos for ectogestation. Therefore, there is the need to consider ethical challenges in forward research, where embryos are implanted into artificial structures for gestation, with potential outcomes ranging from live neonates to gestatelings with developmental abnormalities. Since these ethical concerns arise from the risk of abnormal development or death in ectogenic trials researchers are posed with difficult choices: accepting such risks or reducing them by terminating gestatelings before a certain gestational stage.

In literature exploring the 'backwards' development of ectogenesis, some scholars argue that experimental interventions at the end of pregnancy, even with potential health risks, may be ethically justifiable if they are the only chance to save the fetus's life. However, when deciding to trial an ectogenic prototype using a human embryo, the usual ethical justifications, such as life-saving potential or benefits for existing patients, cannot be applied. Some suggest that despite assumed risks, such research might be justified by potential benefits for future patients. However, the key ethical question for 'forwards' ectogenic research is whether bringing new gestatelings into existence solely for research benefits is ethically justifiable[210].

Comparing ectogenic research to clinical trials involving pregnant women, who are often excluded to protect fetuses from unknown harm, raises ethical concerns. The exclusion aims to safeguard both the mother and the fetus. The argument against 'forwards' ectogenic research is extended to various areas of reproductive medicine and technology, where experimental interventions may pose risks to fetal development. Yet, historical examples like IVF trials show that such risks have been deemed justifiable for the advancement of medical knowledge. Ectogenic research that aims to gestate a healthy embryo, requires implantation as a prerequisite. However, unlike

[210] Baron T. (2021). Moving forwards: A problem for full ectogenesis. *Bioethics*, *35*(5), 407–413. https://doi.org/10.1111/bioe.12848.

other embryonic research, where failure can lead to non-implantation, ectogenic research may expose gestatelings to risks, potentially resulting in late gestateling outcomes (gestateling with no developmental abnormalities, that cannot/ does not survive removal from the gestational environment or gestateling that dies at some point between implantation and full term). Ethical consideration emerges concerning the possibility of terminating gestatelings with developmental abnormalities, questioning the moral permissibility or necessity of such actions in ectogenic research policy[211].

Even though countries like Spain, the UK and Australia do not acknowledge a legal entity in utero, forthcoming children hold moral importance and carry legal implications. The Offences Against the Person Act 1861 (UK) protects the fetus, with legal provisions allowing exceptions to the absolutist stance in the Act. This illustrates an overall approach that recognizes the gradual development of the embryo. The 14-day limit is the length of time that a human embryo can be developed in vitro for scientific research nowadays. Experts, however, have been requesting an extension of this limit for up to 28 days[212].

Assuming a case for extending current limits on embryonic research beyond 14 days, envisioning successful animal trials, and subsequent human subject trials using ectogenic prototypes, the possibility of terminating gestatelings after signs of adverse development is considered. Various rounds of trials are conducted, modifying the ectogenic environment based on observed outcomes. Eventually, healthy embryos develop into early gestatelings, allowing further gestation. The later gestateling, capable of experiencing pain and distress, poses ethical challenges if the ectogenic environment malfunctions or adverse outcomes occur. Balancing valuable data for technology improvement against the potential suffering and death of gestatelings becomes a critical consideration.

Another point of view that must be considered is the draw of analogies between gestatelings and foetal animals in research. Regulations under the Animals (Scientific Procedures) Act 1986 (ASPA) restrict the use of certain animals in scientific procedures beyond two-thirds of the gestational period if the procedure may cause suffering equivalent to hypodermic needle insertion. Considering the suffering of gestatelings, analogous restrictions could be proposed for ectogenic research, raising questions about ethical justifications for non-therapeutic technological development. It is

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[211] Baron T. (2021). Moving forwards: A problem for full ectogenesis. *Bioethics*, *35*(5), 407–413. https://doi.org/10.1111/bioe.12848.

[212] *The limit on how long scientists can culture embryos is decades old, but new recommendations suggest this should be extended*. (2023). https://www.focusonreproduction.eu/article/ESHRE-News-PETConference.

necessary, then, to weigh the potential outcomes of early ectogenic trials and the likelihood of each, acknowledging that the live neonate outcome is the least likely. Evaluating possible benefits to society against the suffering of gestatelings introduces a complex ethical dilemma. Comparing the use of gestatelings to foetal animals in scientific research, the question arises of how stringent restrictions on ectogenic research should be, considering possible outcomes and societal benefits[213].

The heart of the ethical dilemma lies in the decision-making process regarding gestatelings – whether to persist in maintaining them until full term in pursuit of technological improvement, potentially at the cost of their suffering or demise, or to opt for termination in response to abnormal development. This pivotal choice underscores the delicate balance between the advancement of technology and the ethical imperative to minimize harm and prioritize the well-being of gestatelings.

The exploration of human trials in AWT presents a complex landscape where ethical considerations intersect with the rapid pace of technological advancements. As AWT progresses toward human trials, the ethical challenges become increasingly pronounced, necessitating a thoughtful and comprehensive approach to address issues of consent, potential risks, and the overarching impact on individuals and society.

3.2 Beyond pregnancy: rethinking parenthood in contemporary discourse

Ectogenesis, a process involving the development of artificial wombs capable of sustaining fetuses to term without relying on women's bodies, emerges as a key solution when addressing the challenges of reproductive decisions. This method aims to alleviate the unjust pressure on women, allowing them more autonomy and choices in reproductive endeavours considering the need to shift societal expectations and provide technical alternatives to traditional gestation and childbirth. Rather than burdening women with the obligation to conform to external timelines, this approach acknowledges the unjust nature of expecting women to be the sole risk-takers in reproductive ventures. Ectogenesis addresses the inherent natural and physical injustices associated with unequal gender roles in reproduction. This combined

[213] Baron T. (2021). Moving forwards: A problem for full ectogenesis. *Bioethics*, *35*(5), 407–413. https://doi.org/10.1111/bioe.12848.

approach seeks to reshape the discourse around reproductive rights and responsibilities, promoting the welfare of both the future child and the woman involved.

Therefore, exploring the moral dimensions of partial ectogenesis reveals potential ethical justifications, particularly in scenarios where the well-being of the future child is imperilled within the maternal body. It offers a promising avenue for aiding fetal development without jeopardizing maternal health. However, such interventions must be conducted with the explicit consent of the women involved and with due consideration for the invasiveness of the procedure. Nonetheless, it is essential to recognize the robust protection afforded to maternal health within existing legal frameworks, notably enshrined in the European Convention on Human Rights (ECHR), specifically Article 8. This provision underscores the inseparable link between maternal well-being and fetal health, emphasizing that the interests of the unborn child cannot supersede those of the mother, who is legally recognized as an individual.

Thus, one of the strongest arguments for the advancement of AWT is to provide a novel solution for individuals desiring to conceive but facing health obstacles or risks associated with traditional pregnancy. Despite its associated risks, AWT comes with the prerogative of not only aiding preterms but also providing options for managing dangerous pregnancies, presenting an alternative to life-threatening scenarios. AWT introduces fetal transfer possibilities that were never available before, offering pregnant people choices beyond the dangerous pregnancy-abortion dilemma especially when the health of the pregnant person is at stake. It stands apart from rescue technologies as it allows the transfer of gestatelings that would otherwise never exist outside the uterus.

The decision to terminate a pregnancy and deliver a fetus prematurely (before 37 weeks) is a challenging yet not uncommon situation that women and obstetricians often confront when pregnancies face complications. This choice, involving the induction of an early conclusion to the pregnancy, arises in response to complications that pose a threat to the life or well-being of either the pregnant woman or her fetus. Instances where the premature termination of a pregnancy is deemed necessary to address risks may include scenarios such as placental abruption, severe traumatic injury, preeclampsia, chronic hypertension, diabetes, unmanaged uterine infection, significant fetal compromise, maternal cancer, and fetal growth restriction. These complications, when occurring during pregnancy, are relatively frequent, thereby

making the induced termination of a pregnancy to manage these issues a not uncommon occurrence.[214]

The determination of whether a pregnancy should be sustained or terminated, either through a termination likely resulting in fetal death or by 'premature delivery' with the intention of sustaining the delivered preterm with NIC, involves a careful balance of several factors. Critical considerations include the gestational age and maturity of the fetus, the severity and nature of complications, additional risks that escalate with the duration of pregnancy, the risk for the fetus in utero, and the risk to the fetus of being born prematurely, the wellbeing of the mother, her health, the risks related to pregnancy and, ultimately, legal considerations about the rights of the mother and the (legal) status of the embryo.

"Extracting the fetus" before complete gestation is precarious due to its underdeveloped state, usually rendering it unable to survive without support. Although NIC can enhance survival chances, there remains a significant risk of complications causing disability or death. As gestation progresses, the threshold of the risk of early delivery decreases because the likelihood of complications from premature birth diminishes with gestational age and maturity. In cases where the pregnant woman is stable and eager to preserve her fetus, termination is postponed until the latest possible time. The decision to end the pregnancy is viewed as a last resort since NIC does not guarantee the survival of a delivered preterm. Once the decision to terminate is made, and the timing is determined, the method of termination must be selected. The chosen mode of termination significantly influences the outcome. In what is considered 'attempted premature deliveries,' the fetus is either extracted from the uterus through caesarean (surgical opening of the abdomen and womb) or delivered vaginally with the use of drugs[215].

These methods of ending pregnancy come with inherent risks. The decision of when and how to end a pregnancy involves a delicate balance of risks affecting both the pregnant woman and the fetus, weighing the option of continuing the pregnancy versus terminating it. In cases where continuing the pregnancy poses dangers to both the pregnant woman and the fetus, opting for termination (along with NIC post-birth) may be a clear choice aimed at saving both. This decision becomes challenging when continuing the pregnancy is perilous for the pregnant woman but beneficial for the

[214] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[215] Ibid.

fetus, while termination poses greater risks to the latter. Assessing these risks can be complex for both doctors exercising clinical judgment and pregnant women concerned about their health, well-being, and the welfare of their fetuses. The introduction of AWs may potentially alleviate the complexity of this decision-making process.

Romanis[216] declares that AWs shall reframe perceptions of risk in pregnancy, opening a discussion about what level of risk the fetus transfers to an AW is justifiable on the grounds of the pregnant person's health. At present, the concerns about prematurity mean that only the most serious risks to the pregnant woman's health and life are considered medically sufficient grounds to end pregnancies prematurely. This often results in women making the choice to sacrifice their own health. With the advent of AWT, this threshold might be lowered to include less severe complications (such as the earlier stages of preeclampsia or less serious traumas) that are not thought sufficiently grave to justify risking a woman's wanted fetus being born premature but might be thought sufficient to justify ending a pregnancy in favour of artificially continued gestation.

The same goes for perceptions of viability and could, therefore, remove the importance placed on gestational maturity in obstetric decision-making. If fetuses are considered 'viable by virtue of technology' earlier in a pregnancy, this could diminish the emphasis placed on the timing of delivery in the decision-making process that obstetricians evoke when considering bringing a high-risk pregnancy to an end. With the concern about fetal viability increasingly removed from the equation, and because lower levels of risk that signal the need for intervention are likely to occur earlier in pregnancy, there could not only be an increase in premature endings to pregnancy, but these terminations could be more 'premature'.

A distinct possibility, in the case that AWs become a reliable alternative to pregnancy, a demand might emerge for endings to pregnancy (in favour of ex utero gestation) in less urgent or non-medical circumstances. Pregnant women whose pregnancies pose a lesser risk to health may request to opt for an alternative to their gestation. Unpleasant or uncomfortable, but not actively dangerous, experiences during pregnancy might encourage women to seek termination in favour of AWs. Unrelenting morning sickness, mobility issues and swollen limbs, migraines, insomnia, anxiety, fear of developing post-partum depression, and plenty of other side effects can

[216] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.

be difficult to endure for some women. According to Romanis[217], then, some women could seek early termination of their pregnancy in favour of an AW (as in fetal transfer) to evade social stigmas associated with pregnancy. For example, women concerned about the impact on their work and potential discrimination or women struggling with addiction.

Despite all that, Vera Brittain[218], nearly a century ago, rejected the concept of ectogenesis with the claim that natural gestation is essential for children, irrespective of its necessity for mothers. This apprehension has endured and continues to be prevalent for many scholars. The predominant concern centres around the psychological and emotional development of the child, although recent attention has also been directed towards understanding the potential psychological impact on the adult who lacks the sensory experience of pregnancy in the case of ectogenesis. These psychological concerns are mostly related to the development of relational psychology that pregnant women and the fetus create through activities such as talking or singing, triggered by physical interactions like kicks or turns. This relational psychology involves the stimulation of contractions and milk flow, linking physical and emotional sensations. While oxytocin levels in pregnant individuals are recognized to significantly promote maternal behaviour after birth, the physical sensation of gestation is also considered essential in the formation of the parent-child bond[219].

Moreover, pregnancy and breastfeeding are linked to reduced risks of breast, ovarian, and endometrial cancers for women. Furthermore, children born through full-term pregnancies experience significant long-term health benefits, including lower rates of hospital admissions and enhanced cognitive and motor development[220]. Also, increasing knowledge about the maternal-fetal bond and the effects of the maternal environment on the fetus prompts considerations of how gestation in an ectogenetic incubator might emotionally impact the child. Concerns include the absence of exposure to a mother's heartbeat and the resulting impact on the mother-child bond and how it might affect the child's motor functions, emotional well-being, and cognitive development, considering the historical evidence that infants deprived of human touch

[217] Romanis E. C. (2020). Artificial Womb Technology and the Choice to Gestate Ex Utero: Is Partial Ectogenesis the Business of the Criminal Law?. *Medical law review*, *28*(2), 342–374. https://doi.org/10.1093/medlaw/fwz037.
[218] Brittain, V. (1929). *Halycyon, or the future of monogamy*. London: Kegan Paul, Trench, and Trubner.
[219] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[220] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.

and bodily contact face challenges in developing the full range of human emotions or may experience adverse outcomes later in life[221].

Regarding the rights and welfare of prospective offspring, Smajdor[222] proposes analysing these concerns from two different perspectives. First, she points out that the mother-child bond does not rely entirely on the physical gestation of the child, highlighting the importance of noticing the deep love that step- and adoptive parents can have for their children. Secondly, she asserts that this perspective dismisses the possibility that fathers can love their children just as much as mothers. Moreover, the author also stresses that a mother's physical connection with her baby does not guarantee a secure and unconditional flow of motherly love, as many women fail to bond with their naturally born children considering that the traumatic processes of birth can contribute to postpartum depression, affecting around 13% of women who have given birth. This may lead to a mother rejecting her child or refusing to nurture it, negatively impacting the child's subsequent development.

Furthermore, the author also mentions that advancements in visualisation techniques during pregnancy, which allow couples to "see" the baby on a screen, are considered highly significant in the creation of the bonding between the fetus and the parents. As a consequence, she sees that physical gestation alone is neither necessary nor sufficient for the development of a loving parental bond.

Nevertheless, it is crucial to recognize that, up until now, all children have either been gestated by someone else or have had a partial gestational relationship with the person overseeing the gestation, a scenario much different from the process of complete ectogenesis. Therefore, many scholars suggest that research into AWs should strive to simulate various aspects of organic gestation beyond the basic physical components of nutrition and waste removal, to enhance interaction with the fetus before birth. According to Sergers, this scenario would even offer unique opportunities for parent-child bonding, particularly for the father[223].

However, while our understanding of the physical mechanics of pregnancy has significantly improved in recent decades - encompassing stages such as conception, implantation, pregnancy, and birth-, a comprehensive understanding of the entire

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[221] Alghrani, A. (2007). The Legal and Ethical Ramifications of Ectogenesis. *Asian Journal of WTO & International Health Law and Policy*, 2(1), 189-212. Retrieved from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1019760.

[222] Smajdor A. (2007). The moral imperative for ectogenesis. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *16*(3), 336–345. https://doi.org/10.1017/s0963180107070405.

[223] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

reproductive process from both a physical and psychological standpoint for both the future child and the gestating woman remains elusive. Thus, scholars have provided numerous recommendations for research on parental bonding, highlighting that the deficiency in research not only hinders the recreation of the uterine environment but also constrains opportunities for its enhancement.

In light of these circumstances, establishing legal parenthood becomes crucial for ensuring the security of future children born through AWT. This process will also determine the individual with legal responsibilities and decision-making authority during ecto-gestation. For most scholars, in the AWT context, the decision to terminate the life of the fetus is not an individual woman's right but rather a collective right of genetic parents that can only be exercised jointly. The separation of gestation from the female body raises the question of gender equality in decision-making regarding termination, advocating for equal status and balanced conflict resolution provisions. However, what actions should be taken concerning the fetus if the biological parents hold conflicting views on its future?

Many scholars believe that both parents would have an equal say in deciding to terminate the fetus (assuming the right of termination exists). This equalization stems from the elimination of the main difference between them—the gestational burden borne by the pregnant person. Moreover, crucial questions arise regarding whether either parent, based on negative reproductive rights, could opt for the termination of an ectogenetic fetus, whether one parent would require the consent of the other or the state for such a decision, and whether the act of 'switching off the machine' would be subject to abortion laws[224].

Räsänen[225] advocates that if there is disagreement between genetic parents regarding the fate of the fetus, the right cannot be invoked individually. She proposes the use of the "status quo" approach, suggesting the maintenance of the existing situation unless there is a compelling reason for change. For instance, if one parent desires the death of the fetus while the other opposes it, the suggested course of action is not to kill or abandon the fetus. Instead, it could be detached and placed in an artificial womb to continue its development (in the case where detaching the fetus alive is not more physically harmful to the woman than abortion). Moreover, in cases where the biological father cannot be found or is an anonymous sperm donor, the author

[224] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[225] Räsänen J. (2017). Ectogenesis, abortion and a right to the death of the fetus. *Bioethics*, *31*(9), 697–702. https://doi.org/10.1111/bioe.12404.

leans toward the idea that an anonymous sperm donor may have already relinquished any rights regarding the fate of the fetus, leaving the mother with sole decision-making authority.

Hammond-Browning[226] suggests that parenthood provisions or pre-conception contractual arrangements could be utilised, with legal enforcement if necessary. Anticipating potential legislative regulation suggests the need for careful consideration of the welfare of future children born through AWT. Examining termination's best interests for the ecto-fetus should extend beyond gestation, considering post-birth circumstances. If intended parents abandon children born through AWT, adoption or foster care emerges as potential options. However, limited social care resources and potential public distrust in the long-term effects of ecto-gestation may complicate finding suitable caregivers.

The "right of termination of the fetus", however, can be relativised in different circumstances, for example, in the case of full ecto-gestation. The discussion surrounding this right in this context diverges from the conventional discourse on bodily autonomy. Given its meticulous foundation and the considerable financial investment associated with its initial implementation, the act of withdrawing support, leading to the termination of the fetus, may be perceived as less readily acceptable. A counterargument may be raised concerning the right to abstain from biological parenthood. However, this contention could be challenged by the prior expression of the intent to become biological parents. Moreover, this introduces an additional layer of consideration: whether the termination procedure is ethically viable and if a predetermined threshold, analogous to the regulations governing conventional abortion in many countries, should be established for such circumstances.

Moreover - now making use of the IVF example - it is necessary to bring to attention considerations about the psychological impact on the first children born through ectogestation. Considering that they will undergo extensive long-term follow-up studies, it is reasonable to assert that they will attract heightened media attention and spark discussions on social platforms. This unprecedented status may expose them to potential psychological harm merely because they are the inaugural offspring born from an artificial uterus. Despite being born during an era devoid of the internet and social media, similar conditions were experimented on by the first IVF baby, Louise Brown throughout her entire life. This continuous scrutiny poses challenges related to privacy invasion, loss of confidentiality, and the risk of singling out and stigmatizing these

[226] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.

children. Recognizing the significance of psychological well-being, it is crucial to consider potential harm to the mental health of these children born through ectogestation. While initial media interest may diminish over time, the long-term studies to which first children born through AWT will be subjected serve societal and medical interests, providing insights that may benefit both the children and society. Thus, active participation in well-conducted long-term studies could become a platform to identify, address, and support any physical, mental, or social challenges faced by first children born through ectogestation, contributing to their overall well-being[227].

Partial ectogenesis, however, - despite all the arguments related to the mother-child relation to safety and health concerns - could also benefit fetuses diagnosed with complex health needs that can be treated in utero with the transfer to an artificial uterus. In cases where intricate surgery is required, potentially offering improved success rates and outcomes for the foetus, the medical best interests of the foetus may align with a transfer[228].

When addressing full ectogenesis, with the advancement of AWT, many believe that this innovation could benefit a diverse range of individuals, including those with a compromised uterus (e.g., due to cancer treatment), uterine abnormalities (e.g., congenital malformations), or the absence of a uterus (e.g., post-hysterectomy or uterine agenesis); transgender women; single men and gay male couples; and pregnant individuals dealing with health complications that prevent them from carrying the fetus to term.

Segers[229] proposes a comparison of the benefits and disadvantages of AWT concerning other forms of creating families nowadays, for example, adoption, surrogacy and uterine transplantation (UTx). The rationale for investing in ectogenesis to aid procreation in the mentioned groups primarily rests on the value of reproductive autonomy, encompassing the right to decide how, when, and with whom to have children. In the broader context of assisted reproduction, scholars argue that autonomy should guide a person's preferred path to parenthood, redirecting towards alternatives warranted by factors such as safety, cost-effectiveness, and equity considerations. Ectogenesis, when compared to alternatives like adoption, surrogacy and UTx, is often evaluated favourably under the light of reproductive autonomy. Surrogacy faces moral complexities and is prohibited in several countries due to concerns about coercion,

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[227] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.
[228] Ibid.
[229] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

liability, and child placement uncertainties. UTx presents safety risks for the fetus, recipient, and donor, with additional concerns about black market trade, donor organ availability, and societal pressures on women. Adoption, while not posing physical risks, is characterized by its onerous, costly, and emotionally burdensome nature. Some argue that adoption may be preferable to ectogenesis, emphasizing the social benefits of adoption and questioning whether the unproven and expensive nature of ectogenesis as an 'infertility' treatment justifies the preservation of the prospect of a genetically related child.

Here, it is important to explain in more detail how surrogacy and UTx work in comparison to AWT for a more equitable evaluation of their benefits and risks, and how or if AWT can be considered a viable replacement option. The first alternative to be briefly analysed is the services of a gestational surrogate. This practice, however, presents moral and legal complexities and encompasses significant considerations related to race, class, and culture. According to MacKay[230], on careful examination, it appears that gestational surrogacy may have adverse implications for the women involved since gestational surrogacy raises concerns for the women commissioning the "gestational work", as it aligns with and reinforces societal pressures to produce genetically related offspring. Simultaneously, it poses challenges for the women providing the "gestational work", with various authors highlighting instances of mental, physical, and structural hardships endured by surrogate labourers.

Complicating matters further is the illegality of paying women for gestational work in many countries, including Canada and Australia, and the increasing difficulty in creating paid international gestational surrogacy contracts. Nations that once permitted paid surrogacy, such as India, have implemented laws banning international or paid contracts to ostensibly 'protect vulnerable women' and avoid becoming destinations for reproductive tourism[231]. However, it's important to consider that some regulations may inadvertently perpetuate exploitation, especially when people from developing countries are involved, for instance. By restricting compensation, for example, these regulations may perpetuate a form of exploitation where a country effectively becomes a source of reproductive labour for another, potentially exacerbating economic disparities and reinforcing unequal power dynamics.

In accordance with MacKay, recently, other authors have proposed alternative moral solutions to the ethical dilemmas posed by gestational surrogacy. One

[230] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.
[231] Ibid.

proposition involves fully legalizing surrogacy, unionizing reproductive workers, and granting control of surrogate gestational labour to the gestators themselves. This approach advocates recognizing reproduction as labour and organizing reproductive workers to assert their rights. In this scenario, ectogenesis emerges as a viable alternative. Pregnancy is inherently risky and challenging work, and while women who choose to undergo pregnancy for personal procreative desires should have that option, they should not be compelled to undertake gestational work solely for others' procreative fulfilment. According to this position, the labour, dangers, restrictions on freedom, and mental and physical stresses associated with gestational surrogacy may not be justifiable when considering alternatives such as ectogenesis. For these scholars, currently, women may engage in gestational surrogacy due to economic considerations within unjust circumstances, as it remains the best available gestational option.

Uterine transplant (UTx) has also currently been used as an alternative to facilitate women in gestating offspring despite being a highly risky procedure. For example, in 2020, success rates for this procedure were notably low since the elective transplantation of a uterus carries inherent risks similar to other organ transplantations, necessitating the recipient to undergo potent immunosuppressant therapy. In the event of a successful pregnancy through IVF embryos, the fetus is also exposed to these drugs in utero, with potential effects that remain largely unknown. By that year (2020), only two live births have resulted from UTx involving deceased donors, and 39 transplants from live donors have been performed, resulting in 11 births since 2013[232].

Despite the transplanted uterus being connected to the woman's blood supply, it lacks enervation, leading to a lack of internal sensory communication between the mother and fetus, including the absence of sensations related to contractions. Following the conclusion of its use, the uterus must be promptly removed, as its continued presence poses a high risk of infection and disease. While some women seek this transplantation to 'experience' pregnancy, the precise nature of this experience and the ability of the transplanted uterus to fulfil this desire remain unclear. The procedural methods and the current success rates underscore the uncertainty and risks associated with using UTx as a method for gestating offspring[233].

With these scenarios in mind, and also considering the dangers of gestations in general, ectogenesis presents itself as a viable option in many contexts. Scholars even

[232] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.
[233] Ibid.

argue that extracorporeal gestation (ExCG) does not need to be flawless, considering that pregnancy itself is also imperfect. Pregnancy poses risks and trauma for both women and babies, resulting in injuries and even fatalities during childbirth. There are advantages to nonvaginal births, and similarly, there may be benefits to nonuterine gestation for both offspring and mothers. The uterine environment can be detrimental to fetal well-being, influenced by factors such as the mother's diet, exercise, and stress levels[234]. However, it is reasonable to assert that ectogenesis possesses a comparable advantage concerning the physical aspect of fetal well-being, not only for enhancing fetal therapy but also for optimizing the fetal environment through meticulous monitoring of factors such as nutrition, temperature, and oxygenation[235].

Both partial and full ectogenesis can also be seen as a viable solution when dealing with substance abuse during pregnancy. If the pregnant person regularly engages in excessive alcohol and/or harmful drug use, there may be grounds to consider offering her the option of an artificial uterus. The justification for foetal transfer lies in its potential benefits for the specific foetus involved and the enhancement of autonomy and choice for the pregnant woman. Removing the foetus from substance abuse, or avoiding it altogether, reduces the risk of significant harm to the future child, mitigating both short- and long-term consequences. Considering the welfare of the future child strongly supports the notion that foetal transfer to an artificial uterus is in the best interests of the foetus in such cases[236].

Additionally, the potential benefits extend to the pregnant woman as well, with the possibility of maximizing her well-being and presenting a resource advantage. Women opting for foetal transfer or the usage of AW from the beginning would have the opportunity to address their substance abuse problems, creating a more secure environment for their future children after birth from the artificial uterus. However, imperial to acknowledge that the availability of ectogenesis might inadvertently encourage continued substance abuse, difficulty in accessing services, or challenges in overcoming addiction. Yet, it remains crucial to emphasize that partial ectogenesis serves the best interests of the future child by eliminating exposure to harmful

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[234] Smajdor A. (2012). In defense of ectogenesis. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *21*(1), 90–103. https://doi.org/10.1017/S0963180111000521.

[235] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

[236] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.

substances. In this context, the potential welfare of the child(ren) could justify the use of an artificial uterus with the woman's consent[237].

The same goes for cases of treatment of serious conditions. For example, foetuses carried by women facing cancer treatment or similarly severe conditions could potentially benefit from foetal transfer or complete gestation ex-utero. In instances where pregnant women are diagnosed with cancer, they often face the challenging decision of either terminating their pregnancy to commence treatment or delaying treatment until after birth, compromising their own chances of survival. Current recommendations advise against standard cancer treatment during the first trimester due to potential risks to the foetus. AWs comes, in this instance, as a viable alternative for such situations, eliminating the risk of significant harm to the foetus from exposure to harmful drugs and radiation while optimizing the treatment for the pregnant woman. The opportunity for the foetus to start or continue its development within an artificial uterus, shielded from exposure to cancer drugs, also aligns with maximizing foetal welfare. Notably, ectogenesis offers benefits to women as well, allowing them to initiate cancer treatment promptly, thereby enhancing their chances of survival while still being able to have their child.[238]

Now, it is paramount, and again important to highlight that, in all the scenarios above regarding partial ectogenesis, the decision to transfer the embryo/foetus from within the woman's body to an artificial uterus remains at the woman's discretion, as her informed consent is a prerequisite for such a procedure. While the welfare of the foetus is a crucial factor in determining the appropriateness of foetal transfer to an artificial uterus, it cannot supersede the pregnant woman's interests in this scenario. Since the foetus resides within her body, she retains the final say on whether her body can undergo the necessary procedures to transfer the foetus to an artificial uterus.

This brings to attention another point of consideration: will ectogenesis become a viable choice for pregnant people, even in situations where it is not strictly necessary? Can be ethically justifiable for a woman to opt for ectogenesis, even when she can naturally and safely reproduce without fertility issues?

Tripodi[239] suggests, in order to assess the ethical acceptability of new reproductive technologies and, as a consequence, answer the question above, that ectogenesis provides an alternative for women who are capable of pregnancy or for

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[237] Hammond-Browning, N. (2018). A New Dawn: Ectogenesis, Future Children and Reproductive Choice. *Contemporary Issues in Law*, 14(4), 349-373.
[238] Ibid.
[239] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.

whom pregnancy is not risky, highlighting that this choice would not render motherhood obsolete, as the desire for a baby or to be a mother is distinct from the desire to be pregnant. Ectogenesis, if properly understood, is not a form of surrogacy for motherhood but rather for pregnancy. It may not undermine the specific roles of a woman intending to fulfil the social role of a mother, including the associated social and emotional responsibilities toward the child, such as the obligation to provide economic support, guidance, and education. Therefore, ectogenesis should be considered a morally permissible medical practice, available to both couples (heterosexual or same-sex) and singles (regardless of gender or sex) and it should be viewed as a legitimate path to "found a family" and "have children," accessible to both women with health problems and those without.

The ethical acceptability of ectogenesis as a choice for women, lies in the autonomy of women in making reproductive decisions. Furthermore, the absence of scientific evidence indicating harm to the child or others born through ectogenesis is considered a basis for its moral permissibility. Clinical and personal reasons, such as health concerns or career commitments, are both recognized as valid motivations for choosing ectogenesis. For the author, being a good parent does not hinge on physical involvement in conception or gestation, and the desire for parenthood, whether achieved through ectogenesis or traditional methods, is seen as a significant and morally permissible life project. Therefore, according to this position, ectogenesis can be positioned as a technology that broadens possibilities and challenges traditional paradigms, contributing to individual happiness while respecting ethical considerations. In this regard, women might have the freedom to opt for ectogenesis if they desire to have a child without undergoing pregnancy, considering that ectogenesis ultimately upholds women's reproductive rights.

Considering the enduring influence of gendered myths surrounding motherhood within the scientific community - many hingering on the notion that gestating genetic offspring is an intrinsic and essential aspect of a woman's life - founded on the belief that female reproductive function holds central significance to a woman's identity and value; as well as feminist perspectives recognizing pregnancy as a unique and vital experience for women, contributing significantly to their sense of self and worth, while acknowledging the distinctiveness of pregnancy in a woman's life; and among individuals who, notwithstanding all associated risks, remain genuinely committed to undergoing the experience of gestation and childbirth; it is reasonable to assert that a significant number of individuals may opt for natural gestation, even in the presence of

the artificial womb (AW) alternative. This preference highlights the enduring significance of personal choice in reproductive decisions. However, it is crucial to acknowledge that the assurance of a genuine and supported choice is not universally guaranteed by societal standards or expectations. The concept of choice in reproductive matters remains subject to various social, cultural, and ethical considerations, which may impact the autonomy individuals have in making decisions about their reproductive experiences[240].

According to this position, it would be important that women feel empowered to choose the use of these new technologies in their favour even when not necessary, especially considering that AWs can be seen as a method to emancipate all women from their "societal reproductive obligations", thereby effectively putting an end to pervasive gender injustices. Breaking the historical reliance on the female body for procreation opens the path for women to be emancipated not just from the challenges of pregnancy and childbirth but also from the ensuing disadvantages they traditionally face due to these processes.

In this view, following MacKay, AWT could shift the limits in the concept of parenthood, transcending the traditional boundaries associated with pregnancy. It could be perceived, in accordance to the author, as a form to put an end to the "dominance of cis-gendered-straight privilege", and geneticism commonly upheld through various social practices in our society. Adoptive, kinship, and same-sex parents challenge conventional views, and ectogenesis adds to this by challenging the notion that gestation, a crucial aspect of female reproductive function, must involve a woman[241].

AWT enables individuals or couples to experience parenthood without being bound by the conventional constraints of gestation in the human body. The scholar declares that this revolutionary technology would then, introduce a level of flexibility and inclusivity in defining parenthood, as it allows for a more equitable distribution of reproductive responsibilities. Consequently, the redefinition of parenthood through AWT would promote a more diverse and encompassing understanding of family structures. It has the potential to challenge established norms, fostering a society where the journey to parenthood is not solely determined by biological factors but is open to a wider array of individuals, fostering inclusivity and reshaping societal perceptions of what it means to be a parent.

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[240] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.

[241] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.

However, AWT has the potential, in the case of complete ectogenesis, to redefine not only fertility issues among people but also how humans reproduce as a whole. In 1931, the English writer Aldous Huxley vividly portrayed artificial wombs in his novel Brave New World[242], describing fetuses growing in the crimson darkness, nourished by blood surrogates and hormones. Initially, the fiction faced criticism and groups in the United States still advocate for its removal from circulation. In 2005, French biologist Henri Atlan delved into a pragmatic analysis of the potential consequences of introducing artificial wombs in his widely discussed book, L'Uterus Artficiel. His work sparked a lively debate among French scholars in the field of bioethics[243]. In 1999 the Matrix was released, a sci-fi blockbuster depicting a dystopian future where humanity exists within a simulated reality known as "the Matrix." In the movie, human bodies are immersed in pods, where their physical heat and electrical activity are harvested as energy to sustain technology "the Matrix." The film also casts a shadow over the idea of artificial wombs since it portrays "growing humans outside the body"[244].

Given how ectogenesis is often portrayed in mainstream media, it's easy to see why people might be afraid of it. Implementing ectogenesis raises fears because it's hard to tell where the line between futuristic fantasy and real science and society lies. AWT alone cannot achieve the type of future portrayed in the novels and movies, however, it represents the culmination of a long-standing transformation in human reproduction that has spanned several decades with the advent, for example, of IVF, mitochondrial replacement, cryo-conservation, sperm donation, and surrogacy.

This evolution could bring about a significant dissolution of boundaries in three key dimensions: spatial, social, and temporal. Spatial boundaries can be dissolved as ectogenesis transitions from parts of the reproductive process occurring outside the human body, such as in Petri dishes and laboratories, to the entire prenatal period unfolding entirely inside a machine. This shift could dissolve previous social boundaries by fundamentally altering the dynamics of reproduction and opening up new possibilities for social roles and relationships. Instead of the traditional model involving two heterosexual individuals assuming the roles of genetic, biological, and social parents, ectogenesis introduces a more diverse array of contributors. These contributors may include individuals who have never met, deceased individuals, or

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[242] Huxley, A. (1931). *Brave New World*.
[243] Abecassis, M. (2016). Artificial Wombs: The Third Era of Human Reproduction and the Likely Impact on French and U.S. Law. *Hastings Women's Law Journal, 27*(1), 3. Retrieved from https://repository.uchastings.edu/hwlj/vol27/iss1/1.
[244] *The Matrix* (Wachowski & Wachowski, 1999)

those connected in novel ways, all play a part in bringing a new life into existence. Furthermore, the necessity of having a biological mother would be eliminated, and temporal restrictions would be abolished, as artificial wombs can be activated whenever biomaterials become available, independent of a woman's fertility cycle, egg donor's menopause, or the death of biological or genetic parents[245]. In this case, the same could be said for an elderly person who may have therapeutic reasons for resorting to artificial womb technology, akin to those of a woman seeking reproductive assistance. The prospect of such scenarios prompts reflection on whether imposing age-related limits on access to artificial womb technology could be ethically justifiable, for example.

AWT when combined with other biotechnologies, has the potential for the creation of dystopian scenarios like the ones portrayed in the mainstream media. For example, ectogenesis has the potential to simplify genome editing in fetuses, addressing both disease-related and non-disease-related traits. Through genetic engineering, such as the use of restriction enzymes to cut DNA, polymerase chain reaction (PCR) to amplify DNA, and CRISPR-Cas9 gene editing to modify DNA, there is the potential creation of "enhanced" people, which would lead to the constitution of groups and subgroups of people. Within this transhumanist scenario, AWT would become the necessary means for reshaping humans and the whole society in eugenics terms.

In the European context, however, the legal framework governing Human Enhancement establishes a clear distinction: genetic modification for therapeutic purposes is generally permissible, while enhancement interventions must be voluntary, in line with the principles of individual autonomy and dignity upheld by various international agreements. This distinction aligns with the principles outlined in the UNESCO Universal Declaration on Bioethics and Human Rights, which underscores the importance of respecting individuals' autonomy in decision-making. Within the ECHR, Articles 8 (respect for private and family life) and 3 (prohibition of inhuman and degrading treatment) serve as the legal foundation for safeguarding individual autonomy in matters concerning bodily integrity and personal choices. The Oviedo Convention also reinforces the significance of individual autonomy by requiring free and informed consent for medical interventions, including those with enhancing purposes, such as certain forms of genetic enhancement.

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[245] Eichinger, J., & Eichinger, T. (2020). Procreation machines: Ectogenesis as reproductive enhancement, proper medicine or a step towards posthumanism?. *Bioethics*, *34*(4), 385–391. https://doi.org/10.1111/bioe.12708.

Thus, within the EU legal framework, any modifications targeting offspring - that cannot provide any type of consent - are strictly prohibited. This underscores the importance of upholding individual autonomy and preventing coerced enhancements, especially when shaping future generations. The prospect of AWT shaping human societies in eugenic terms, as mentioned above, underscores the need for robust ethical frameworks and regulatory measures to safeguard against unintended consequences and uphold human dignity and rights.

Research has also been developed with stem cells. For instance, a group of researchers aiming at studying the early stages of human development created embryo-like structures using stem cells in the lab. These structures mimic some aspects of real embryos, which assisted the researchers learn more about how embryos develop before and just after implantation[246]. A different group of scholars has been developing lab-grown embryo models that can mimic the development of real mouse embryos from day 5.0 to day 8.5, including the formation of advanced tissues like the heart and yolk sac. This study aims at building a complete model of a mouse embryo using mouse embryonic stem cells and induced embryonic stem cells[247].

Moreover, recent advancements in stem cell research have led to the development of techniques for generating reproductive cells, such as sperm and egg cells, in laboratory settings. This technique is known as in vitro generated gametes (IVG). Previously reliant on embryonic stem cells, these methods now utilize somatic cell reprogramming, enabling the creation of such cells from the somatic cells of individuals. This progression has sparked ethical deliberations regarding the utilization of these lab-grown reproductive cells, particularly in the context of addressing infertility and expanding options for genetic parenting[248].

In envisioning the societal landscape shaped by advanced biotechnologies, especially AWT, profound questions emerge regarding the nature of parenthood. The European Court of Justice in the Brustle[249] case classifies human embryos as encompassing not only fertilized human ova but also non-fertilized human ova into which the cell nucleus from a mature human cell has been transplanted, as well as

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[246] Pereira Daoud, A. M., Popovic, M., Dondorp, W. J., Trani Bustos, M., Bredenoord, A. L., Chuva de Sousa Lopes, S. M., van den Brink, S. C., Roelen, B. A. J., de Wert, G. M. W. R., & Heindryckx, B. (2020). Modelling human embryogenesis: embryo-like structures spark ethical and policy debate. *Human reproduction update*, *26*(6), 779–798. https://doi.org/10.1093/humupd/dmaa027.

[247] Lau, K. Y. C., Amadei, G., & Zernicka-Goetz, M. (2023). Assembly of complete mouse embryo models from embryonic and induced stem cell types in vitro. *Nature protocols*, *18*(12), 3662–3689. https://doi.org/10.1038/s41596-023-00891-y.

[248] Palacios Gonzalez, C., Harris, J., & Testa, G. (2014). Multiplex Parenting: IVG and the generations to come. *Journal of Medical Ethics*, *40*, 752-758. https://doi.org/10.1136/medethics-2013-101810.

[249] *Oliver Brüstle v Greenpeace eV* (2011) ECLI:EU:C:2011:669 (European Court of Justice).

non-fertilized human ova whose division and further development have been stimulated by parthenogenesis. This means that within the EU countries, it is to be considered a human embryo any cell that is able to develop into a human being regardless it is the result of fertilisation of human ova or therapeutic condition, partenogenesis or any other technique. What counts is only the capability of developing. This definition is intended to ensure a uniform interpretation and application of the law across the European Union regarding the patentability of biotechnological inventions involving human embryos.

However, the ECJ emphasized the need to interpret the concept of a human embryo in a wide sense, consistent with the overarching aim of the directive to promote investment in biotechnology while respecting fundamental principles safeguarding human dignity and integrity. This definition, however, raises fundamental questions about personhood and autonomy within the context of advanced reproductive technologies, for example, the complexity of embryonic development and the moral significance of autonomy. Moreover, the absence of explicit consideration for personality in the definition of a human embryo prompts reflection on the interplay between cellular capability and the emergence of individuality.

The advent of technologies enabling the creation of humans without the traditional involvement of human reproductive cells poses profound questions about the preservation of human dignity in the context of reproduction. While these advancements may offer unprecedented opportunities for individuals and couples facing infertility or genetic challenges, they also raise ethical concerns regarding the manipulation and commodification of human life. Respect for human dignity in this evolving landscape necessitates careful consideration of the implications of these technologies on individual autonomy, bodily integrity, and the intrinsic value of human beings. Moreover, as scientific progress continues to blur the boundaries of conventional reproduction, society must grapple with the redefinition of parenthood, family structures, and societal norms. Ensuring the ethical and respectful use of these technologies will be paramount in shaping a future where human dignity remains central to reproductive practices and the broader human experience.

However, a more refined inquiry emerges here, delving into the profound anthropological implications of a groundbreaking initiative like ectogenesis. This exploration seeks to comprehend the far-reaching effects of AWT in a comprehensive and rational manner, acknowledging that its repercussions may extend beyond issues such as gender equality and the redefinition of parenthood. It is conceivable that the

adoption of AWs could profoundly alter fundamental aspects of humanity, surpassing mere shifts in gender dynamics, for example. The concept of full ectogenesis, in particular, introduces the notion of eliminating not only the physical aspects of motherhood but also a fundamental aspect of human existence: the biological genesis of one individual from another. This consequence, often overlooked amidst discussions about relieving women of reproductive burdens, presents a stark reality of future children nurtured and born completely through mechanized processes, raising, from this viewpoint, several ethical concerns[250].

3.3 Feminist perspectives on Reproductive Rights, Women's Rights, and abortion in the era of AWT

A central debate within feminist ethics and bioethics, with a focus on artificial wombs, revolves around the question of whether AWT can contribute to women's liberation and emancipation or if it will act as an instrument of further oppression; and what are the repercussions of the advancement of this piece of technology, especially regarding abortion rights. This discussion delves into a genuine philosophical disagreement among feminists regarding the potential social benefits of AWT for women. Some feminists argue that artificial wombs have the capacity to liberate women from patriarchal models and the heavily gendered nature of the reproductive process. They contend that by relieving women of traditional reproductive duties, AWT could empower women to more fully pursue their individual interests and aspirations. In contrast, opposing feminist perspectives raise ethical concerns about the diminishing maternal-foetal relationship and question whether ectogenesis can effectively address broader socioeconomic inequalities between genders.

To understand this debate is important to dive a little bit deeper into the primary different categories into which the feminist theory can be divided: liberal, radical, and socialist. Many feminist perspectives often highlight reproduction as a focal point in explaining women's oppression. Therefore, most strands of feminist theory emphasize the significance of the social organization of reproduction, encompassing both social relations and biological aspects, in understanding women's experiences. Consequently,

[250] Eichinger, J., & Eichinger, T. (2020). Procreation machines: Ectogenesis as reproductive enhancement, proper medicine or a step towards posthumanism?. *Bioethics*, *34*(4), 385–391. https://doi.org/10.1111/bioe.12708.

feminists have scrutinized various aspects of reproduction, including the organization of childbirth, childrearing, abortion, and contraception[251].

The agenda of liberal feminism, aimed at achieving an egalitarian society, centres on integrating women into the social mainstream through progressive reform within the existing system. This perspective advocates for eliminating discriminatory laws, enacting anti-discrimination laws, redefining sex roles, and restructuring role socialization. Unlike the other two perspectives, liberal feminism does not perceive reproduction as the central sphere for women's oppression, viewing it as one among several areas where women's rights are violated. While supporting reproductive rights, liberal feminists assert that reproductive technologies provide women with enhanced opportunities to control their bodies and lives. According to this perspective, individuals should have the autonomy to choose which reproductive technologies to use and under what circumstances[252]. Therefore, feminists in this line of thought, advocate for the autonomy of infertile women in deciding whether to undergo the risks and costs of ART and other reproductive techniques including, more recently, AWT.

In the realm of surrogate motherhood, liberal feminism upholds the principle of individual choice, allowing a woman to use her body to produce a child for another, whether for compensation or not. In approaching surrogate motherhood, liberal feminists believe that, as long as it is freely chosen, it should not be subjected to stringent restrictions. However, they acknowledge the need for women to have access to education and alternative employment opportunities before making such choices. From a liberal feminist standpoint, reproductive technologies are neither inherently good nor bad, but to ensure women's equality and liberty, reforms are needed in their development and distribution. Liberal feminists argue for increased involvement of women in formulating and administering policies related to reproductive technologies, equal access for all individuals, including lesbians and economically disadvantaged people, and legislative measures to safeguard reproductive rights.

During the historical period of radical feminism, men were perceived as the root cause of women's oppression, prompting radical feminists to advocate for revolutionary measures. The overarching goal was to overthrow male dominance and patriarchy, with the belief that true liberation for women required creating a new society valuing women and their principles. Contemporary radical feminism encompasses various perspectives, ranging from those supporting societal restructuring for equal valuation of

[251] Rushing, B., & Onorato, S. (2003). Controlling the Means of Reproduction: Feminist Theories and Reproductive Technologies***. *Humanity & Society*. https://doi.org/10.1177/016059760302700321.
[252] Ibid.

both genders to those advocating a separatist female-centred society with minimal contact with men. Regardless of the specific stance, all strands of radical feminism maintain the view that men are responsible for women's oppression. Early radical feminists asserted that women would remain socially subordinate as long as biological (sex) differences imposed social (gender) restrictions on them. Reproductive technologies were initially seen optimistically as a potential key to women's liberation, offering the prospect of a limited role for women in the reproductive process. However, despite recognizing the potential benefits, most radical feminists acknowledged that cultural beliefs, male supremacy, and patriarchal institutions could hinder the liberating impact of technology[253].

Two distinct approaches within radical feminism emerged: one that glorifies biological differences and values women's capacities, emphasizing the importance of women understanding and gaining control over their bodies; and another that sees men's devaluation of the reproductive process as the source of enslavement. Both strands agree that men controlling reproductive technologies perpetuate oppression, with some radical feminists arguing that men have historically been envious of women's ability to bear children. The central tenet of radical feminism is the belief that reproduction is integral to explaining women's oppression, and the focus is on redefining reproduction as a positive experience while diminishing men's control. Advocating for a transformation of patriarchal society, radical feminists stress the need for a revolution in human consciousness. They call for the demystification of paternalistic ideology, consciousness-raising, and the elimination of sex-based social roles, rejecting the notion that motherhood should define womanhood. Reproductive technologies, according to radical feminists, risk further isolating women from the reproductive process, allowing men's intervention and potentially undermining women's traditional roles in a patriarchal society. Concerns are raised about the compartmentalization of women into separate roles in the mothering process, controlled by men and defined based on societal values and hierarchies[254].

Socialist feminism, as another strand, explains women's oppression by considering the interaction among semi-autonomous systems of human domination, such as class, race/ethnicity, and sex/gender. Unlike traditional Marxism or radical feminism, socialist feminism avoids a reductive approach and views social relations of production and reproduction as mutually supportive structures of domination and

[253] Rushing, B., & Onorato, S. (2003). Controlling the Means of Reproduction: Feminist Theories and Reproductive Technologies***. *Humanity & Society*. https://doi.org/10.1177/016059760302700321.
[254] Ibid.

exploitation. The analysis emphasizes the interconnectedness of class, race/ethnicity, and sex/gender relations in perpetuating women's oppression. Socialist feminists assert that women's identity is inseparable from social relationships, challenging the universalist and essentialist stance of radical feminism. They argue that women's oppression is not inherent but socially constructed, paving the way for transformative change. Unlike traditional Marxism, socialist feminism expands the concept of production to encompass both goods and services and the production of people. Historically, women were compelled to focus on reproductive labour, mirroring workers' exploitation under capitalist relations. The ultimate objective of socialist feminism is to transcend oppressive social formations, aiming to abolish class and gender[255].

Central to socialist feminism is the idea that reproductive freedom extends beyond bodily autonomy to include a transformation of the sexual division of labour and restructuring social structures organizing sexuality and procreation. The synthesis of feminist and socialist ideologies is seen as crucial for genuine reproductive freedom, recognizing the collective responsibility of society for the well-being and futures of children. The socialist feminist critique of new reproductive technologies revolves around three interconnected concerns. Firstly, these technologies contribute to women's alienation by separating them from the products of their "reproductive labour". Secondly, they are developed for profit under capitalism. Thirdly, men dominate the development and implementation of these technologies, a shared concern with liberal and radical feminists. The separation of fetus and woman by reproductive technologies creates distinct interests for women and fetuses, potentially allowing external authorities to overrule women's desires for the sake of fetal well-being. The commodification of reproductive processes is a primary worry for socialist feminists, as new reproductive technologies like surrogacy, can lead to the "commodification of children." This shift towards viewing children as luxury items subject to both quality and quantity control underscores concerns about the objectification of women's reproductive capacities. Moreover, the male dominance in the development of these technologies raises apprehensions among socialist feminists[256].

Based on the foregoing information, it is evident that concerning AWT, there's no consensus in the community. The feminist arguments for supporting AWT are based on the idea that gender-based oppression is intimately connected with female

[255] Rushing, B., & Onorato, S. (2003). Controlling the Means of Reproduction: Feminist Theories and Reproductive Technologies***. *Humanity & Society*. https://doi.org/10.1177/016059760302700321.
[256] Ibid.

biological functioning, as proposed by de Beauvoir[257] and Firestone[258] - where they both acknowledged, however, that biology alone does not account for the entire construction of oppressive structures. Yet, the concept of 'woman' is still intricately tied to female reproductive capability in today's culture. This capacity is often employed as a means of determining who falls within the category of 'woman' and establishing the value attributed to individuals in this category. Additional evidence supporting the argument that women's claims to identity and value are still closely tied to reproductive function can be found by examining the extent to which technology has advanced to aid gestation.

In this scenario, ectogenesis poses a challenge to the biological basis of women's oppression by disrupting the conventional understanding of gender categories. Specifically, separating women from the act of reproduction destabilizes the conceptualisation of 'woman' as the definiendum and fundamentally eliminates the basis for a functionalist argument that considers female reproductive capacity a crucial definition. The absence of the functionalist argument for 'woman' may undermine societal expectations surrounding 'motherhood' and necessitate a redefinition of 'parent' in a gender-neutral manner. Therefore, it presents intriguing possibilities for liberation in relation to these roles and expectations, as it severs the connection between 'mother' and female biological reproductive labour[259].

Considering that gender-based oppression serves as the groundwork for certain oppressive practices, beliefs, discussions about who qualifies as a woman, and the persistent myth of legitimacy in social institutions - shaping people's roles and choices -, it becomes very clear and self-evident with the division of labour that permeates heterosexual household's, particularly in the realms of child-bearing and child-rearing. This notion that women can only achieve freedom once liberated from biology is the enduring conceptual connection between female reproductive function, the identity category 'woman,' and the social role of 'mother"[260]. Some scholars claim that this represents a paradigm of human enhancement, rooted in the belief that the limitations imposed by biology, particularly those specific to women, must be surpassed and transcended. Thus, in their opinion, this viewpoint could be aligned with the ethos of transhumanism, advocating for the augmentation and evolution of human capabilities beyond natural constraints, for example.

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[257] De Beauvoir, S. (1997 [1949]). *The Second Sex*. (H. M. Parshley, Trans.). London, U.K.: Vintage Books.
[258] Firestone, S. (2015 [1970]). *The Dialectic of Sex* (p. 213). London, U.K.: Verso Books.
[259] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.
[260] Ibid.

However, according to Alison Stone[261], the oppression of women based on biology doesn't primarily stem from their biological capacity for childbearing. Instead, it occurs due to their social position as the presumed, and often actual, primary bearers and caregivers for children. The social positioning of the 'mother' role, although influenced by female reproductive functioning, is not solely a natural occurrence; it is profoundly conceptual. 'Mother' has become a symbol encompassing female biological features and various assumptions about gendered behaviours, attitudes, characteristics, and socio-political status, particularly within the family. This link is institutionalized in social expectations, practices, and even legal frameworks.

These gender identities, based on reproductive organs that ultimately define ‘woman’ and ‘man’, are further used to decide who among those can be categorized as ‘woman’ or as ‘mother’, or sometimes as ‘real mother’. Ectogenesis could be seen, in this scenario, as a form to promote the separation of female reproductive function from 'woman' and 'mother. Through the quality-promoting argument[262], it can enhance equality not only between men and women but also among women, addressing much more than physical, social, and financial burdens related to pregnancy and childbirth, thereby fostering greater equality between the sexes, but also offering an opportunity for other women/non-binary people currently unable to undergo gestation to have children in a similar manner to women who can.

Therefore, in accordance with MacKay[263], this technology could also be beneficial for trans-inclusionary radical feminist objectives, encompassing a broader range of genders and sexual orientations, contributing to a larger initiative of challenging dominant power relations rooted in familial structures. The theoretical possibility of removing female reproductive work from women's bodies undermines this basis for delineation. The utilization of female reproductive function as a criterion for 'who counts' evidently grants certain women privileges over others, both legally and in moral and political perspectives, as reflected in various regulations and socio-political behaviours.

Thus, the cis-gendered-straight privilege becomes disputable with the advent of ectogenesis since it introduces the notion that a crucial element of female reproductive function—gestation—may not necessarily involve a woman. If an infant could be conceived without being 'carried' or 'birthed' by a specific individual, the significance of

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[261] Stone, A. (2019). *Being Born: Birth and Philosophy* (p. 19). Oxford, U.K.: Oxford University Press.
[262] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[263] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.

carrying and birthing in defining womanhood or motherhood becomes undermined. By reimagining the role of 'mother,' women could be freed from the unequal status of being the primary bearer and caregiver for children. It possesses - in accordance with the feminist authors that defend the concept that ectogenesis has the power to liberate women - a disruptive potential on traditional patriarchal family structures, and consequently, other male-dominated realms like work, education, and cultural production[264].

However, despite these discussions around parenting, particularly in the context of full ectogenesis, often emphasizing its potential to 'equalize' reproductive opportunities for LGBTQ+ couples or single individuals, many see them as overly optimistic. When analysing the existing assisted reproductive technologies like IVF and surrogacy, it is noticeable that individuals outside heteronormative parenting norms consistently encounter challenges in accessing these technologies. Legal and social constraints across various jurisdictions have curtailed the liberating possibilities of such reproductive technologies, imposing restrictive rules on parenthood and surrogacy agreements. While it may be argued that the potential for enhancing parental equality through full ectogenesis is limited to heterosexual relationships, pursuing this benefit becomes crucial, particularly in the current socio-legal landscape that hampers access to non-heteronormative family formations[265].

Moreover, while ectogenesis does not eliminate the need for parental leave, for example, it has the potential to disrupt conventional notions of reproduction and parenting. This disruption could question the gendered expectations associated with child-rearing prevalent in workplaces. Employers and governments may find themselves compelled to justify the default assumption that female employees would predominantly take leave or handle the majority of child-rearing responsibilities, rather than considering equal parenting arrangements or a more involved role for the co-parent. By challenging these assumptions, ectogenesis may bring to light the connections between merit-based promotion criteria and factors like uninterrupted work life or a specific production rate over time[266].

When completely removing pregnancy from the body, an infant then is not born of a woman but instead 'decanted' from an artificial womb, the primary caregiving role

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[264] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.
[265] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.
[266] MacKay K. (2020)., op. cite.

cannot be automatically determined by the one who gave birth. This encourages the understanding of 'mother' and 'father' as social roles, not specifically tied to gender or biological identities. These roles are associated with certain caregiving functions and relations within a group, such as a family or community, and are adopted by those who take them up. According to this perspective, the potential of ectogenesis reveals that the concepts of 'mother' and 'father' are arbitrary and contingently linked to biology. If we envision similar contributions to reproduction from both females and males, with no gestational work involved, then the loaded meanings currently associated with 'mother' and 'father' must dissipate. Instead, in this way, what remains would be the notion of 'parent' that is indifferent to gender identity, in MacKay's opinion[267]. Thus, for the author, by disrupting the link between femininity and motherhood perpetuated by patriarchal societies, ectogenesis becomes a tool for fostering social equality among men and women in the realm of parenthood.

Furthermore, Smajdor[268] poses that ecto-gestation has the potential to liberate women from the unjust and physically burdensome aspects of pregnancy, offering an alternative for those at high risk or facing complications, and providing means for women in danger during pregnancy to avoid terminating fetal development. The author declares that the pregnancy's physical burdens can be seen even more clearly when considering that approximately 15% of pregnant individuals face potentially life-threatening complications; that during the years 2000–2002, the maternal mortality rate in the United Kingdom stood at 13.1 maternal deaths per 100,000 maternities; that pregnant individuals are susceptible to various health issues, such as back pain, fatigue, bowel problems, and urinary incontinence, persisting for at least six months post-delivery and beyond (notably, the prevalence of faecal incontinence after childbirth has only recently garnered recognition); that the systematic neglect of morbidity linked to childbirth has contributed to research findings indicating that first-time mothers often perceive the experience as more challenging than anticipated and that awareness of childbirth risks can intensify fear, potentially leading to an increased likelihood of opting for caesarean sections due to complications arising from tension and trauma during delivery.

Likewise, the scholar declares that the repercussions of childbirth and labour on women's health extend to their functioning as mothers and members of society.

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[267] MacKay K. (2020). The 'tyranny of reproduction': Could ectogenesis further women's liberation?. *Bioethics*, *34*(4), 346–353. https://doi.org/10.1111/bioe.12706.

[268] Smajdor A. (2007). The moral imperative for ectogenesis. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *16*(3), 336–345. https://doi.org/10.1017/s0963180107070405.

Experiencing challenging labour increases the likelihood of posttraumatic stress syndrome, while issues like incontinence and back pain can hinder women's ability to work or significantly limit their employment options, thereby affecting their financial well-being. Additionally, in Smajdor's viewpoint, the well-established reality is that expecting mothers often grapple with a substantial impact on their autonomy due to the responsibility of carrying another life within their bodies. Pregnant women routinely encounter societal expectations to prioritize the well-being of the fetus over their own appetites and desires. Furthermore, their decision-making abilities and rights regarding medical care may be jeopardized, potentially overridden in favour of the unborn child's interests.

Thus, as a reproductive technology, ectogenesis could also extend women's reproductive capacities, challenging the natural constraints of age-related fertility decline. This could enable women to postpone motherhood, plan pregnancies with more flexibility, and focus on various aspects of their lives without the pressure of a biological clock. Additionally, by eliminating the need for gestational surrogacy, ectogenesis addresses ethical concerns related to the commodification of the female body, providing a more equitable approach to parenthood for men and potentially reducing the reproductive burden traditionally borne by women[269]. However, these unconventional aspects of ectogenesis and its departure from conventional pregnancy may impede its social acceptance. Under Simonstein and Mashiach-Eizenberg's[270] research on public attitudes toward ectogenesis, it is revealed that the adoption of Artificial Womb Technology (AWT) is perceived as more acceptable when directed toward the survival of extremely preterm fetuses and facilitating motherhood in cases of absolute uterine factor infertility then when it is related to the relieve women from the burdens of pregnancy.

Those against AWT in the feminist community, on the other hand, divide their objections into three core arguments. First, medical technologies, often male-dominated, may lead to the commercialization of biological reproduction. They argue that ectogenesis could become a tool for male dominance, reinforcing the surveillance of motherhood and enabling male control over reproductive technologies. There is a concern that men aim to disconnect women from the experience of

[269] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.
[270] Simonstein, F., & Mashiach-Eizenberg, M. (2009). The artificial womb: a pilot study considering people's views on the artificial womb and ectogenesis in Israel. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *18*(1), 87–94. https://doi.org/10.1017/S0963180108090130.

gestation, disrupting a traditional ritual that historically bonded women through shared experiences. The fear is that, historically, reproductive technologies have been used to control rather than liberate women. Furthermore, some feminists argue that ectogenesis is unnatural and violates the natural link between reproduction and mothering, potentially disrupting the positive aspects of the female reproductive experience. The worry is that, if left unchecked, technological advancements like ectogenesis could exceed ethical limits and threaten the "sanctity of life"[271].

Second, they fear that these technologies might further subordinate women, viewing AWT as a devaluing tool of the female biological capacity. They also celebrate motherhood as a positive aspect - the experience of motherhood that according to them is completely different than forced motherhood imposed by the patriarchy - arguing that female reproductive capacity should not be considered a barrier to emancipation; instead, it should be embraced as a resource. This perspective (predominantly discussed in the radical feminist school of thought) highlights the importance of female sexuality, reproductive potential, and maternal roles in fostering positive values. For example, the subjectivities immersed in relationships of intimacy and dependence between mother and child. This type of subjectivity can be elucidated by understanding how a mother typically replicates her history of bodily connections with her own mother in her relationship with her child. This process gives rise to a maternal and cyclical form of lived time, that operates in the connection with the maternal body and the mother's bond with the child through signs and images that represent a pre-discursive phase, preceding the separation from the mother's body and the development of linguistic-symbolic communication[272].

Third, they raise concerns about the rights and well-being of future children, especially the first babies brought into existence through ectogenesis. Critics argue that, given the early stage of the technology, making precise predictions about its impact on the children involved is challenging. This is particularly true when considering the psychological effects of ectogenesis on a human fetus, as the significant epistemological challenges make it difficult to fully understand these effects solely based on data obtained from animal models[273]. Therefore, many questions arise about the potential adverse effects of severing the maternal-fetal bond during gestation

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[271] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.
[272] Ibid.
[273] *Sander-Staudt, M. (2006). Of Machine Born? A Feminist Assessment of Ectogenesis and Artificial Wombs. In S. Gelfand & J. R. Shook (Eds.), Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction (pp. 109-128). Amsterdam; New York: Editions Rodopi, B.V.*

and the child's long-term well-being. However, it seems unnecessary to delve extensively into this topic, as it was thoroughly addressed in the preceding sub-chapter.

Despite the conflicting arguments, the consequences of ectogenesis remain vast and uncertain. However, there is a consensus among many authors that AWT could potentially limit women's reproductive liberties and influence abortion debates. Some specialists believe that in the future, when ectogenesis becomes a safe and widely accessible practice, there may be pressure for women to opt for reproduction through artificial wombs, or it could even be considered a moral obligation for women not to undergo natural childbirth if it is deemed riskier. Consequently, these scholars argue that ectogenesis might constrain women's reproductive freedoms, and those desiring a natural pregnancy could face judgment for being perceived as irresponsible. Women facing a high risk of abortion or pregnancy complications due to health reasons might be dissuaded from choosing natural gestation[274].

Before delving into the discussion, however, it is crucial to address the legal status afforded to the gestational subject ex-utero or gestateling, as it holds significant implications. This legal standing has the potential to impact ongoing debates concerning the definition of stillbirth and abortion - and it has already been largely discussed in the preceding subchapter on human trials for partial ectogenesis. Nonetheless, revisiting this topic is essential because it has the capacity, alongside the extent of invasiveness associated with the procedure, to influence the moral landscape of artificial womb technology, reshaping the tone and intensity of the moral debacle around AWT. Consequently, it will not only frame the jurisprudence of abortion but also contribute to the legal discourse on embryo research, given the normative and political ramifications linked to the granting or withholding of specific rights and entitlements for the gestating human being.

Colgrove[275], for example, contends that subjects of partial ectogenesis can be regarded as a type of newborn, asserting that common definitions of 'live birth' appear to be applicable to these subjects. According to the argument, they share the same moral status and, therefore, deserve identical moral treatment as newborns. The argument extends to subjects of complete ectogenesis, contending that while they cannot be identified as newborns (as standard definitions of 'live birth' do not apply in this context), they do share the same moral status as newborns and, as a

[274] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.
[275] Colgrove N. (2019). Subjects of ectogenesis: are 'gestatelings' fetuses, newborns or neither?. *Journal of medical ethics*, *45*(11), 723–726. https://doi.org/10.1136/medethics-2019-105495.

consequence, whatever protections that are afforded to the latter should be extended to ectogenetic subjects.

Romanis, on the other hand, strongly disagrees with Colgrove's opinion since, in her point of view, labelling the expulsion of the fetus from the uterus to the artificial womb as 'being born' appears to overlook that the emergence of the entity from the gestation process is a crucial criterion for a definition of 'live birth' that is not fully met by such fetal transfer. Furthermore, she elucidates that assigning a moral status does not inherently dictate how entities should be treated, but the opposite: "Once the status is assigned, we must then make moral judgments about whether that status justifies certain treatment"[276].

Another pertinent subject for discussion preceding the assessment of the abortion debate, aimed at establishing its foundation, pertains to procedural details. For example, if the process of 'foetal extraction' for gestation outside the uterus is considerably more invasive than standard abortion procedures, whether induced by drugs or performed through vacuum/surgical methods, it is justified to assert that the pressure on pregnant people to engage with reproduction through artificial wombs will be considerably smaller than if the procedures for abortion and the "foetal extraction" pose the same risks or invasiveness. As mentioned in previous chapters of this work, many scholars believe that the surgery for the transfer of the fetus to the AW is going to be similar to a cesarean. If that is the case, it is safe to declare that it is significantly more dangerous than the abortion procedures commonly used nowadays.

The procedure that most closely resembles "fetal extraction" is related to women who currently deliver extremely preterm babies through caesarean. In these cases, they face many risks, including "haemorrhage, infection, and admission to the intensive care unit. A midline uterine incision or “classic” caesarean section, which has a higher chance of scar dehiscence in subsequent labours than lower segment caesarean section, is more frequently performed, and women are therefore advised against having future vaginal deliveries. Pregnancy-related conditions that are associated with extreme preterm birth are also associated with increased risks of disease in the mother. Women with pre-eclampsia are twice as likely to be diagnosed with cardiovascular disease or stroke as women with uncomplicated pregnancies, and

[276] Romanis E. C. (2019). Artificial womb technology and the significance of birth: why gestatelings are not newborns (or fetuses). *Journal of medical ethics*, *45*(11), 728–731. https://doi.org/10.1136/medethics-2019-105723.

approximately half of women with gestational diabetes mellitus develop type 2 diabetes within 10 years"[277].

Therefore, considering that this debate is based on a hypothetical transfer surgery, in the end, it will all depend on how invasive the "foetal extraction" is going be. For Cohen: "The more invasive, the stronger the constitutional claim that woman could not be forced to undergo it. Perhaps this claim would find support in the right to refuse treatment."[278]. However, important to mention that forced extraction, in all its manifestations, constitutes a grave violation of multiple legal frameworks, ranging from penal and constitutional law to international human rights standards. Within the realm of penal law, forced extraction stands as a criminal act, transgressing fundamental principles of personal liberty and health rights enshrined within constitutional provisions. Moreover, at the international level, forced extraction runs afoul of established human rights norms, notably contravening the principle of free and informed consent to medical treatment. This principle, integral to the right to health, safeguards individuals' autonomy in decisions concerning their own bodies. Furthermore, forced extraction could be deemed tantamount to torture under Article 3 of the European Convention on Human Rights, which unequivocally prohibits any form of inhuman or degrading treatment. Consequently, the practice of forced extraction not only violates legal statutes but also undermines the inherent dignity and autonomy of individuals, warranting robust legal and ethical condemnation and redress.

Here, it is important to notice that these discussions are very much based on theoretical grounds since it is unlikely that AWT will have the capacity to support embryonic products of conception in the near future, considering that the majority of women seeking conventional abortion typically do so before 13 weeks of gestation. Lastly, the assertion that AWT serves as an 'alternative' to abortion reflects a fundamental misunderstanding of why abortion is protected in liberal societies, including women's rights.

Within the feminist discourse advocating for the right to choose abortion, the main argument is that women have the autonomy to terminate a pregnancy and should not be compelled to carry a child against their will. However, when it comes to AWT, where the woman's body is not directly involved, questions arise. For example, would a woman still retain the right to abort in the case of an unwanted ectogenic pregnancy?

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[277] Morgan, A. S., Mendonça, M., Thiele, N., & David, A. L. (2022). Management and outcomes of extreme preterm birth. *BMJ (Clinical research ed.)*, *376*, e055924. https://doi.org/10.1136/bmj-2021-055924.
[278] Cohen I. G. (2017). Artificial Wombs and Abortion Rights. *The Hastings Center report*, *47*(4), . https://doi.org/10.1002/hast.730.

Does the fetus, in the context of AWT, belong to the woman's body? Individual freedom includes the right to control one's own body, and a pregnant woman traditionally has the right to decide not to continue with the pregnancy. However, according to Tripodi[279], AWT eliminates the necessity for women to physically bear children. With ectogenesis two presently intertwined events can be disentangled: a woman could, theoretically, terminate the pregnancy without ending the fetus's life.

This proposition, in the opinion of some scholars, could offer a potential resolution to reconcile both pro-life and pro-choice stances. The common belief is that if a fetus can be detached alive and gestated in an artificial womb there is no inherent right to its demise. Here, once more - and as already mentioned above -, it is important to underscore that forced extraction of a fetus constitutes a serious crime. When such actions are mandated by a state, for instance, it not only violates ethical principles but also amounts to an international crime, specifically categorized as torture. In accordance with established legal frameworks, including the jurisdiction of the International Penal Court, states engaging in such reprehensible practices would be subject to prosecution and condemnation on the grounds of committing grave violations of human rights.

In light of this, many believe that ectogenesis might complicate even more the debate around abortion in general societal views, considering that there are indications that women, regardless of their stance on the issue, may not consider ectogenesis as a viable "solution". For anti-abortion women, for example, a significant objection arises from the notion that being a 'good mother' involves assuming responsibility for the care of the fetus/child, a concept incongruent with having the child brought to term in an artificial womb and then put up for adoption. Pro-choice women similarly express concerns about maternal responsibility, suggesting that ectogenesis and adoption might leave them with a lingering sense of obligation to the future child, whereas abortion is viewed as a form of preventing motherhood[280].

This last argument is primarily based on the right not to become a biological parent, balancing the right to abortion and the presumed right to life of the fetus. The ongoing discourse is usually divided into three main arguments: the right not to become a biological parent (as mentioned above), the presumed right to genetic privacy and the presumed property right of genetic parents over the embryo/fetus. However, these

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[279] Tripodi, V. (2022, January 1). *The Right and Unfair Aspects of Artificial Womb Technology*. Springer eBooks. https://doi.org/10.1007/978-3-030-88793-3_5.
[280] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

latter two arguments cannot be deemed sufficiently robust to warrant the right to terminate the fetus; hence, they will be excluded from the discussion.

In contrast, the right not to become a biological parent does present a solid base for the death of the fetus, in the words of Overall[281]: "[W]omen who seek pregnancy termination are usually choosing that there be no being at all who is their genetic offspring. They are choosing not only not to be social mothers, but also not to be biological mothers. In other words, they are claiming a right not to reproduce. (…) When women obtain a termination of pregnancy, they are (…) acting upon their legitimate reproductive right not to become a biological parent". Therefore, it is unjust to remove from women the right to abortion even with the availability of transferring the fetus to the AW, as the right to abortion is not only intimately related to the bodily autonomy of pregnant individuals, but it also encompasses reproductive autonomy rights and the pursuit of sex/gender equality.

Building upon this thought, Räsänen[282], quoting Mackenzie[283], claims that "abortion is not a matter of wanting to kill this particular being, which is, after all, as yet indistinguishable from oneself. It is rather a matter of not wanting there to be a future child, so intimately related to oneself, for which one either has to take responsibility or give up to another". Räsänen then proposes three arguments for the Right Not to Become a Biological Parent. She expresses that becoming a biological parent causes harm to the couple because of parental obligations towards the child; that the couple has the interest to avoid the harm of parental obligations; and as a consequence, the couple has a right to the death of the fetus to avoid the harm of parental obligations. Thus, in the eyes of the author, to rebut the argument supporting the right not to become a biological parent, one must present a parental responsibility theory that absolves genetic parents entirely from their parental obligations or provide an alternative rationale for why the argument is flawed.

Thereby, the proposition that the emergence of ectogenesis could offer a potential "solution" to abortion, allowing pregnant individuals to terminate pregnancies without necessarily leading to fetal demise cannot be taken into account since such actions would constitute a crime, as they directly contravene the principle of free informed consent to the medical treatment outlined in Article 5 of the Oviedo Convention. Moreover, the enforcement of such practices would be deemed as torture

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[281] Overall, C. (2015). Rethinking abortion, ectogenesis, and fetal death. *Journal of Social Philosophy*, *46*, 126–140, p. 131.
[282] Räsänen, J. (2017). Ectogenesis, abortion and a right to the death of the fetus. *Bioethics*, *31*(9), 697-702. https://doi.org/10.1111/bioe.12404.
[283] Mackenzie, C. (1992). Abortion and embodiment. *Australasian Journal of Philosophy*, *70*, 136–155. p.

under Article 3 of the European Convention on Human Rights (ECHR). Thus, any attempt to coerce or compel individuals into undergoing procedures without their explicit consent not only violates fundamental ethical principles but also amounts to a gross infringement of human rights, warranting condemnation and legal action. Moreover, interpreting the use of this technology as a means to "end abortion" and "promote gender/sex equality," does not reflect the prevailing social conditions and can be seen as vastly disconnected from current societal realities. It can actually pose a contrary effect, limiting reproductive choices by making it more difficult for individuals to willingly engage in pregnancy experiences and may even lead to a deterioration in prenatal and birthing care.

Also, alongside ethical considerations, there has been contemplation on the potential impact of AW on abortion law since in numerous jurisdictions, abortion laws are structured around the concept of viability. These laws often dictate easier access to abortion before the fetus reaches "viability" and more stringent access afterwards. Viability is typically understood as the fetus's ability to survive outside the womb. Romanis[284] then, argues that if viability remains central in regulation, it needs a more precise definition, reflecting the purpose of the viability threshold as the ability to survive ex-gestation. Since ectogenesis might lower the limit of viability, there is a possibility that abortion could be deemed impermissible under laws that link abortion rights to the established standard of viability[285].

One potential scenario is the states restricting abortion outright only after the point of viability or mandating the transfer to an artificial womb instead of allowing abortion for women between eighteen weeks and viability. Another scenario involves the transformative impact of artificial wombs on our concept of viability. Even though an eighteen-week-old fetus may not traditionally be considered viable, the ability to transfer it to an artificial womb could redefine viability. Consequently, in accordance with Cohen[286], the state might have the authority to prohibit both the transfer to an artificial womb and abortion at eighteen weeks. A third possibility entails an expansion of post-viability pregnancy rights, compelling states that would have previously banned abortion after viability to at least permit women to opt for transferring the fetus to an artificial womb as an alternative. This underscores the necessity of considering the

[284] Romanis E. C. (2020). Is 'viability' viable? Abortion, conceptual confusion and the law in England and Wales and the United States. *Journal of law and the biosciences*, *7*(1), lsaa059. https://doi.org/10.1093/jlb/lsaa059.
[285] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.
[286] Cohen I. G. (2017). Artificial Wombs and Abortion Rights. *The Hastings Center report*, *47*(4), . https://doi.org/10.1002/hast.730.

human rights perspective and the right to safe abortions in this discourse. AWT could potentially, instead of empowering women's reproductive choices, serve as a counterproductive force in this regard.

In countries where abortion rights are intimately connected with the viability standard, this right can be perceived as a "moral problem." This is not merely a theoretical concern, as evidenced by recent developments such as the US Supreme Court's decision to no longer recognize abortion as an established part of the constitutional right to privacy, leading to anticipated abortion bans in numerous regions of the country. The threat to abortion rights is not confined to the United States, as many countries globally enforce stringent restrictions on abortion. Scholars argue that given this context, it is imperative to shift the narrative away from viewing "abortion as a problem" and, instead, focus explicitly on AW as a technology that has the potential to assist parents facing the risk of losing their desired offspring[287].

While some may argue that there is room for speculative literature examining the permissibility of abortion if AW-fetal transfer were comparable to traditional abortion, many scholars assert that responsible ethical assessments of the future implications of ectogenic technology should start by affirming contemporary (and future) abortion as essential healthcare. Some authors, going one step further, even suggest that AW strengthens the case for decriminalizing abortion, challenging the central role of viability in determining the legal permissibility of abortion[288]. Horn[289], however, contends that viability, when used in regulation, will inevitably restrict abortion access, regardless of the measure adopted, undermining the crucial reasons why abortion is essential for individuals.

These speculations about ectogestation potential impact on the "abortion debate," driven by evolving perspectives on viability range from predictions of an inevitable ban to suggestions that the procedure could still be protected through claims of bodily autonomy if fetal extraction were deemed invasive. Ethicists emphasizing the significance of challenges to the viability threshold in the abortion context often reference biobag and similar studies to support their arguments. This, however, in the point of view of Romanis and Horn[290] can be misleading without nuanced

[287] Segers, S., & Romanis, E. C. (2022). Ethical, Translational, and Legal Issues Surrounding the Novel Adoption of Ectogestative Technologies. *Risk management and healthcare policy*, *15*, 2207–2220. https://doi.org/10.2147/RMHP.S358553.
[288] Ibid.
[289] Horn, C. (2020, May 15). *Ectogenesis is for Feminists*. Catalyst. https://doi.org/10.28968/cftt.v6i1.33065.
[290] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.

considerations of the practical applications of the technology as they propose a different point of view in the matter.

The authors claim that these scholars, who are primarily concerned with abortion, focus on partial ectogenesis, as they are interested in pregnancies facilitated by a person. Consequently, their claims are often based on a technological future that, at present and in the foreseeable future, does not operate as their arguments assume considering the viability theshild addressed in the recent studies of the biobags and AWs mentioned previously in this work. Only a few scholars provide disclaimers about the speculative nature of their arguments, leading them to use a potential technological future in the present tense to raise doubts about the provision of abortion, both now and in the future.

Discussions in the literature concerning ectogenesis and abortion often portray abortion not as an essential healthcare resource but as a moral 'problem' that could potentially be surpassed by advances in reproductive technology. To Romanis and Horn, these arguments, while attempting to set up a thought experiment (though rarely explicitly acknowledging this), seek to question the justifiability of abortion when 'bodily autonomy issues' are temporarily set aside. However, such discussions inherently overlook abortion as a crucial reproductive freedom and shift the focus away from the pregnant person's body, rights, and health needs. Instead, they speculate about a future where these concerns become irrelevant. The authors use the example of the United Kingdom where these arguments do not align with the prevailing political discourse, which is progressively moving towards establishing abortion as an essential healthcare service rather than a procedure contingent on limited and paternalistically guarded private rights. They mention that despite the Abortion Act 1967 still requiring women to obtain approval from two physicians before undergoing an abortion, recent years have witnessed successful initiatives allowing individuals to take the second pill in a two-pill medical abortion procedure at home in England, Scotland, and Wales. The campaign to officially remove abortion from the criminal code continues to gain public support. Notably, considering the gatekeeping role assigned to doctors by the Abortion Act, the British Medical Association has actively supported decriminalization in the United Kingdom, emphasizing the importance of treating abortion as a protected medical procedure[291].

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[291] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.

However, abortion rights still face resistance in various jurisdictions, and despite advancements, anti-abortion sentiments persist in numerous parts of the United Kingdom. In the realm of ectogenesis scholarship, especially within jurisdictions where laws are progressing toward greater self-determination for women and pregnant individuals regarding abortion, it is politically crucial to approach the procedure not as a predicament to be solved but as an indispensable form of reproductive care. This assertion prompts the question of whether ethical-legal scholarship does or should have a political agenda. The assertion that 'the ethical' operates in an entirely different sphere from 'the political' is misguided. Determining what is considered an ethical issue involves a political choice, especially in the case of abortion, where labelling it an ethical problem inherently carries political implications. Ethical analysis cannot be separated from politics when addressing normative claims about real-life issues individuals face. Ethical analysis, which guides decisions under specific circumstances, inherently has a political end when aiming to determine what individuals should do. Therefore, it is fair to state that ethical commentary directly influences political opinions - especially because these academic ethical arguments are often wielded by advocacy groups to support political positions - particularly when attempting to persuade on moral concerns like abortion, leading to potential political interference[292].

In instances where scholars anticipate that the advent of ectogenesis could potentially lead to the prohibition of abortion or the compulsory use of AWs as the pregnant woman and fetus become separable, there is a concern about endorsing a discourse that historically undermines abortion rights. These claims often project into a future dominated by full ectogenesis, exhibiting a certain confidence in the development of such technology (which was earlier contested) and sidestepping the current, intricate, and inherently political reality where the pregnant person's body and the fetus are interconnected. Claims suggesting restrictions on abortion if AWs were available hinge on the premise that a fetus holds equal or even superior value and legal status compared to the pregnant person. Efforts to shape the envisioned future applications of AWs toward certain objectives extend beyond academic discourse. The rhetoric portraying a future where the fetus is completely distinct from the pregnant person, potentially justifying the banning of abortion, adds momentum to ongoing anti-abortion discussions. When engaging in a speculative exercise wherein the fetus is deemed viable and an autonomous legal entity before birth, these assertions

[292] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.

disturbingly mirror anti-abortion advocacy, asserting fetal personhood. The promotion of fetal personhood is a key element in the campaigns of international anti-abortion entities and, while the speculation about ectogenesis eliminating the rationale for abortion may seem contingent on a yet-to-arrive future, this same rhetoric has contributed to the criminalization of pregnant women in various jurisdictions for actions perceived as harmful to their fetuses[293].

The anti-abortion lobby has frequently employed scientifically unfounded claims to restrict access to services for women and pregnant individuals. In the United States, politicians have often wielded rhetoric and imagery related to so-called 'partial-birth abortions' in legislative efforts to limit abortion access. However, the term 'partial-birth abortion' is not a medical term, and late-term abortions are rarely performed. It is plausible that the anti-abortion lobby may increasingly use AWs to legitimize their stance. Therefore, it is necessary to reframe and align the discourse about abortion with present realities. It is crucial to recognize that claims suggesting full ectogenesis can 'ban' abortion by providing an alternative to gestation are legally flawed[294].

The legal construction of the viability threshold does not grant pregnant individuals the choice to end their pregnancy when it reaches viability. In fact, it is unlawful to induce labour at viability unless there are emergency circumstances. The viability threshold is designed to prevent pregnant individuals from opting out of pregnancy when the fetus is deemed viable, even when there are technical alternatives, except in emergencies. If the 'state interest' in a fetus allows the law to demand that a pregnant person continue pregnancy after viability, it would persist even with the existence of AWs, unless a legal argument demonstrates that AWs are significantly 'better' than natural gestation. Furthermore, the presence of neonatal incubators has not been deemed sufficient grounds to permit inducing labour when a fetus is presumed viable. Instead, incubators have been considered sufficient grounds to mandate continuing a pregnancy simply because the fetus could potentially be sustained by the incubator if born. Therefore, claims about full ectogenesis fail to establish that AWs can provide freedom from pregnancy while 'ending abortion.'[295]

Moreover, AWs should not be perceived as a substitute for abortion and cannot replace it. First, partial ectogenesis, despite its potential impact on viability perceptions, is not a viable 'alternative' to abortion. Extracting the fetus for ex-utero gestation is a

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[293] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.
[294] Ibid.
[295] Ibid.

more invasive termination method than conventional means, particularly in early pregnancy. The majority of women seek abortion within the first 13 weeks, and AWs may not sustain embryonic products for an extended period. Mandating termination methods for ex utero gestation would force women to endure a longer pregnancy until the fetus is adequately gestated for extraction, compelling them to undergo a medical procedure without consent. This approach regresses by treating pregnant individuals as gestational vessels for state use rather than autonomous decision-makers about their bodies. Thus, even if abortion is justified based on bodily autonomy alone, partial ectogenesis doesn't alter the harm caused by restricting abortion.

Furthermore, it is important to highlight that while bodily autonomy is crucial, it alone is insufficient. Considering the probable cost of developing and implementing artificial womb technology in the contemporary United States, mandating that pregnant individuals terminate unwanted pregnancies through fetal extraction would not only fail to safeguard reproductive freedom by preventing people from terminating unplanned pregnancies on their own terms but would also perpetuate the ongoing criminalization of many pregnant individuals, particularly low-income women of colour, who already lack legal access to reproductive care. Autonomy can only be effectively exercised within a relational framework that provides positive resources, enabling individuals to terminate or continue a pregnancy and offering support resources for either choice[296].

Second, scholars should be cognizant of the political context influencing their arguments. Recognizing the interconnection of ethics and politics, setting clear political boundaries—such as affirming abortion as an essential healthcare service—is crucial. Acknowledging contemporary abortion provision as a vital healthcare service helps avoid complicating these procedures. This stance should persist even if full ectogenesis develops because the termination of pregnancy remains a private matter. Feminist scholars assert that viewing ectogenesis as an 'alternative' to abortion misunderstands the reasons abortion is protected in progressive societies. They emphasize the diverse factors, individual, social, and structural, influencing a woman's decision to seek an abortion. The desire not to be a genetic parent, as mentioned above, can be seen as valid considering that gestational work has significant social implications, with women often facing judgment for abandoning child-rearing

[296] Horn, C. (2020, May 15). *Ectogenesis is for Feminists*. Catalyst. https://doi.org/10.28968/cftt.v6i1.33065.

responsibilities after gestation. Even with ex-utero gestation, emotional and social consequences and pressures would likely persist[297].

Furthermore, ectogestation could never be perceived as a proper alternative to abortion considering the following question: who will attend to the ectogenetic fetus and how this care will be financed, particularly in cases where both parents ultimately reject responsibility? In the case of an ectogenetic fetus unwanted by both parents after its "birth," many scholars argue that a possible solution is putting the baby up for adoption. However, this could potentially result in a surplus of ectogenetic babies in an already overloaded system[298].

Termination of pregnancy, therefore, offers closure, allowing pregnant individuals the opportunity to definitively reject biological parenthood and/or social motherhood, as the latter is strongly tied to biological parenthood for women in societal perceptions. This conclusive rejection is not achievable through other means. Pregnant individuals should retain the entitlement to decide against completing their reproduction due to the social costs associated with undertaking gestational work and the subsequent social experiences that follow. The validation of the moral worth of pregnant individuals and their entitlement to make choices regarding their health, body, and procreative status, rather than the disputed status of the fetus, leads to the assessment of the conception of abortion as essential healthcare. The establishment of a clear political boundary asserts that abortion rights must be considered a given as long as women face harm and criminalisation for seeking abortions in restrictive jurisdictions[299].

As a result, these arguments demonstrate the necessity for reform in abortion law. Horne's[300] arguments seek to counter the three recurring proposals for protecting abortion rights post-ectogenesis, namely: (i) redefining foetal viability to encompass an advanced gestational stage or the capacity to survive independently of both the pregnant person and the artificial womb, (ii) granting genetic progenitors a property right to the foetus, and (iii) allowing genetic progenitors a shared right to avoid genetic parenthood by terminating the foetus. She defends, as mentioned before (by her and Romanis), that abortion should be fully decriminalised - and it also should be free, safe,

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[297] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. *International Journal of Feminist Approaches to Bioethics, 13*(2), 174-194.

[298] Horn, C. (2020, May 15). *Ectogenesis is for Feminists*. Catalyst. https://doi.org/10.28968/cftt.v6i1.33065.

[299] Romanis, E. C., & Horn, C. (2020)., op. cite.

[300] Horn C. (2021). Abortion Rights after Artificial Wombs: Why Decriminalisation is Needed Ahead of Ectogenesis. *Medical law review*, *29*(1), 80–105. https://doi.org/10.1093/medlaw/fwaa042.

legal, and accessible - since it should be understood not as a moral problem to be challenged by new technology but as a medical procedure that will remain essential after ectogenesis.

Viewing abortion as healthcare implies that it is a procedure devoid of the need for ethical justification. The assumption is that someone seeking an abortion is morally obligated to transfer their fetus to an artificial womb if another person wishes to adopt it problematically characterises the fetus as a person. However, the authors making such arguments often neglect to address how legal frameworks recognising fetuses as persons continue to undermine the self-determination of pregnant individuals in many jurisdictions. Abortion must primarily be understood in the context of pregnant people's health and rights rather than the contested moral status of the fetus. Speculation about the impact of artificial wombs should remain grounded in the reality that in places where abortion is illegal or unavailable, individuals turn to unsafe and backstreet abortion practices. With the advent of ectogestation, concerns about the potential rise of people using these "backstreet" abortions or new criminalization for accessing a safe and ordinary medical procedure increase. Protecting reproductive freedom in relation to abortion, under the normative position that it is a vital medical care form implies that criminal law and moral philosophers should not interfere with a person's motivations for seeking the procedure[301].

Severing the link between abortion and criminal law in preparation for technologies like the artificial womb is extremely important. For example, in Canada, abortion is decriminalized throughout pregnancy, protected under the right to liberty and security of the person in the Canadian Charter of Rights and Freedoms. This approach, not framing abortion as a balance between bodily autonomy and foetal personhood, makes the potential impact of artificial womb technology less threatening to abortion rights. In the US, however, where abortion rights vary by state, artificial wombs might challenge these rights, particularly in states with strict anti-abortion sentiments. The UK, with legal restrictions post-24 weeks, could face legal challenges from artificial womb technology, but a supportive sociocultural context for abortion rights may mitigate this[302].

While strategies like redefining viability or basing abortion rights on property or genetic parenthood may be applicable in jurisdictions with restrictive abortion environments, a focus on decriminalization is urged where there's broad sociocultural

[301] Horn C. (2021). Abortion Rights after Artificial Wombs: Why Decriminalisation is Needed Ahead of Ectogenesis. *Medical law review*, *29*(1), 80–105. https://doi.org/10.1093/medlaw/fwaa042.
[302] Ibid.

support for abortion. Decriminalization, as seen in the Canadian example, allows artificial womb technology to lower viability thresholds without jeopardizing abortion rights. Criminalizing abortion, even with advancements like the artificial womb, is critiqued for paternalism and may hinder access to lifesaving medical interventions for pregnant individuals. Therefore, decriminalization emerges as a path to protect both abortion rights and access to care in the context of emerging reproductive technologies like ectogenesis[303].

Furthermore, the value of AWT can also be found in its political potential[304] for feminist causes. To reconceptualize the defences of ectogenesis in political terms, the interpretation of Silvia Federici[305] regarding the international feminist campaign "Wages for Housework" originated in Italy in the 1970s can be useful. This campaign advocated for the political recognition of the reproductive labour performed by women in their homes, such as housework and childcare. The demand for wages for housework aimed to challenge the devaluation of this labour and to render visible the structures and dynamics of labour markets, families, and society. It served as a provocation to unite and collectively demand the power to reshape society, constituting a crucial step in challenging existing labour and social arrangements.

Here, one can find valuable insights to be gleaned from these interpretations of the Wages for Housework campaign. To fully realize its potential for promoting equality and freedom, defences of ectogenesis must be framed within a broad political perspective. This perspective facilitates a critical examination of the risks and burdens associated with pregnancy and childbirth, as well as the unequal distribution of childrearing responsibilities between genders. It also allows for a critical evaluation of women's societal roles, their contribution to social reproduction, and the impact of these roles on their lives both at home and in the workplace, as already mentioned. By adopting this approach, the focus shifts away from women's roles and responsibilities in gestation and childrearing, towards the societal structures that hinder their attainment of equality and freedom[306].

Defending ectogenesis, therefore, should be seen as a call to action, demanding improved medical and social services for pregnant people, a reduction in the medical risks associated with pregnancy and childbirth, better working and living

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[303] Horn C. (2021). Abortion Rights after Artificial Wombs: Why Decriminalisation is Needed Ahead of Ectogenesis. *Medical law review*, *29*(1), 80–105. https://doi.org/10.1093/medlaw/fwaa042.
[304] Cavaliere G. (2020). Gestation, equality and freedom: ectogenesis as a political perspective. *Journal of medical ethics*, *46*(2), 76–82. https://doi.org/10.1136/medethics-2019-105691.
[305] Federici, S. (1975). Wages Against Housework. Power of Women Collective.
[306] Cavaliere G. (2020)., op. cite.

conditions for mothers, gestating mothers, pregnant individuals and women in general, as well as a genuine redistribution of the burdens and responsibilities of social reproduction. In essence, what is needed is a reproductive agenda centred around women's needs, particularly those of marginalized women, including poor women, women of colour and other minorities, as well as the LGBTQ2SIA+ community.

3.4 Exploring equitable access to Artificial Womb Technology: a comprehensive examination of marginalized demographics and implications for societal stratification

Context is key when analysing equitable access to AWT. For instance, it is crucial to examine the data on preterm birth with a little more depth. As mentioned above, in the year 2020, approximately 13.4 million live births were classified as preterm, the equivalent of 9.9% of all live births. The prevalence of preterm births, of course, exhibits many regional variations, with the highest rates found in Southern Asia, where 13.2% of babies were born prematurely in 2020. In contrast, regions such as Eastern Asia, SouthEastern Asia, Northern America, Europe, Australia, and New Zealand experienced preterm birth rates of fewer than 8%. At the global level, Bangladesh recorded the highest preterm birth rate (16.2%), followed by Malawi (14.5%) and Pakistan (14.4%). Notably, almost half (45%) of all preterm births in 2020 occurred in five countries: India, Pakistan, Nigeria, China, and Ethiopia. India alone accounted for the highest number of preterm births (3.02 million), representing over 23% of global preterm births[307]. These disparities in numbers show an obvious trend, the poorer and unequal the region or country, the higher the number of preterm babies.

Discrepancies in healthcare both between and within countries also contribute to substantial differences in survival rates for preterm babies. In well-resourced settings, babies born over 28 weeks' gestation generally experience nearly universal survival. In contrast, regions with limited access to healthcare often exhibit higher mortality rates, even for babies born up to 32 weeks gestation. Despite the existence of many reasons for this imbalance, it is important to notice how these people's lives are affected even more by conflict, for example. In 2022, the global count of individuals forcibly displaced due to war, violence, persecution, and human rights violations exceeded 100 million, with a disproportionate impact on women and children. Apart

[307] *Born too soon: decade of action on preterm birth*. (2023, May 9). https://www.who.int/publications/i/item/9789240073890.

from direct conflict-related fatalities, the indirect repercussions such as collapsing health systems and restricted access often result in an even greater toll. Among the 16 nations with the highest rates of newborn mortality, 11 have recently faced humanitarian crises[308].

Climate change and the displacement of people caused by it also presented huge health impacts. Air pollutants, for example, such as methane and black carbon, not only contribute to climate change but also pose health risks. In 2019, it was estimated that air pollution played a role in 6 million preterm births and almost 3 million cases of low birth weight. A global report in 2020 suggested that air pollution contributes to 20% of newborn deaths worldwide, primarily due to preterm birth and low birth weight. The escalating frequency and reach of extreme heat are increasingly linked to adverse birth outcomes, including preterm birth and stillbirth[309].

Moreover, as mentioned in the previous sub-chapter, in 2020, Around 287,000 women lost their lives in the course of pregnancy and post-childbirth and almost 95% of maternal deaths occurred in low and lower-middle-income countries, with Sub-Saharan Africa and Southern Asia accounting for around 87% (253,000) of the global total. Sub-Saharan Africa alone contributed to 70% of maternal deaths (202,000), while Southern Asia accounted for 16% (47,000)[310].

In regards to the number of infertile people, in 2022, approximately 17.5% of the adult population, which equates to roughly 1 in 6 individuals worldwide was affected by it[311]. These rates exhibit variations between developed and developing nations. A meta-analysis of population surveys since 1990 revealed infertility prevalence estimated at 3.5-16.7% in developed regions and 6.9-9.3% in developing nations. Notably, the Middle East, North Africa, and South Asia have witnessed a rising trend in both primary and secondary infertility rates. Factors contributing to higher infertility rates in these regions include secondary infertility experiences among couples who already have a child, a high prevalence of infectious diseases, and socio-cultural aspects. Developing countries show a higher increase in infertility rates, linked to factors such as dietary insufficiencies and exposure to environmental toxins[312].

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[308] *Born too soon: decade of action on preterm birth*. (2023, May 9). https://www.who.int/publications/i/item/9789240073890.
[309] Ibid.
[310] *Maternal mortality*. (2023, February 22). https://www.who.int/news-room/fact-sheets/detail/maternal-mortality.
[311] *1 in 6 people globally affected by infertility: WHO*. (2023, April 4). https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility.
[312] Borumandnia, N., Alavi Majd, H., Khadembashi, N., & Alaii, H. (2022). Worldwide trend analysis of primary and secondary infertility rates over past decades: A cross-sectional study. *International journal of reproductive biomedicine*, *20*(1), 37–46. https://doi.org/10.18502/ijrm.v20i1.10407.

Disparities between the developed and developing world are becoming evident lately due to variations in the availability of infertility care and distinct socio-cultural values regarding procreation and childlessness.

Ectogenesis comes as a solution for most reproductive and childbirth issues. Partial ectogestation would aid preterms and significantly lower the numbers of maternal mortality. Infertility, which has already benefited from ART could notice even bigger improvements with the combination with AWT (as in complete ectogenesis). However, it is fair to declare that these services will not be equally accessed and distributed to people around the world, following the same trend in which ART services and other fertility treatments are available and accessed by people. Just as an example, approximately only half of all infertile couples in both developed (56%) and developing countries (51%) pursue some form of infertility care, likely due to limited availability, unavailability, or high costs of services[313].

Moreover, despite the annual performance of over 3 million ART cycles worldwide, the estimated demand for ART exceeds 10 million cycles per year, with an overall need exceeding 20 million cycles. Most individuals who require ART services may not seek them due to limited fertility awareness, financial constraints, lack of reproductive autonomy, and societal misconceptions or restrictions. The primary obstacle to access is affordability, measured as the out-of-pocket cost relative to net disposable income. Unless third-party funding, such as government health plans, insurance, or employer support, is available, the cost of ART remains prohibitive for most individuals. While certain high-income countries are expanding insurance and government coverage, substantial financial barriers persist, hindering equitable access to care, particularly in lower- and middle-income countries[314].

In the case of IVF, the most notorious of the ART procedures, considering the absence of clinics in certain countries and the high expenses associated with the interventions in many others, forces many infertile couples to face substantial financial burdens to finance their IVF cycles or resort to cross-border reproductive care to access more affordable IVF services outside their home countries. Up until the year 2000, IVF services were accessible in only about one-quarter of the world's nations, representing 45 out of 191 WHO member states (24%). These were predominantly

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[313] Inhorn, M. C., & Patrizio, P. (2015). Infertility around the globe: new thinking on gender, reproductive technologies and global movements in the 21st century. *Human reproduction update*, *21*(4), 411–426. https://doi.org/10.1093/humupd/dmv016.

[314] Adamson, G. D., Zegers-Hochschild, F., & Dyer, S. (2023). Global fertility care with assisted reproductive technology. *Fertility and Sterility*, *120*(3), 473-482. https://doi.org/10.1016/j.fertnstert.2023.01.013.

affluent Western nations contributing to 91% of the world's gross domestic product. By 2005, the number had expanded to nearly one-third of the world's nations, accounting for 31% (59 out of 191). By 2010, there was substantial growth in IVF services in the developing world, particularly with over 500 clinics in India, signifying globalization of IVF[315].

By 2010, over half of the world's nations, comprising 105 or 55% had either developed or were in the process of establishing IVF services, with an estimated 4000 to 4500 IVF clinics in operation. However, the regional distribution of IVF clinics in 2010 revealed notable disparities, particularly in sub-Saharan Africa, where the prevalence of IVF clinics was considerably lower compared to regions such as Asia, the Middle East, and Latin America. Sub-Saharan Africa, characterized by high infertility rates, faced a relative dearth of IVF clinics, contrasting sharply with the IVF-rich regions of the Middle East and North Africa.

This issue, however, extends beyond the African continent and is observed as a 'global shadow' on the uneven world map of IVF clinic development. Several other regions were entirely missing, such as the large Central Asian countries, including Afghanistan, Kazakhstan, Kyrgyzstan, Mongolia, Tajikistan, Turkmenistan, and Uzbekistan. In 'successful' regions like the Middle East, these disparities arise due to political isolation and violence. Instances include Iraq and Syria, which were in the early stages of IVF development when wars erupted in 2003 and 2011, respectively. Within the Arab Gulf, disparities exist between central, resource-rich nations and peripheral, resource-poor ones, as seen in the contrasting IVF development timelines of Saudi Arabia, Oman, and Yemen[316].

Despite the economic and geographic disparities in accessing ART, the intersectional lived realities of race, gender, sexuality, and class also significantly influence reproductive experiences. Currently, the privatization of ART results in a highly stratified and stratifying access process since when certain groups have more accessibility to ART than others, it perpetuates existing structures of power and privilege. Black, Indigenous, people of colour (BIPOC) and LGBTQ2SIA+ individuals, belonging to more than one marginalized group, contend with compounded forms of oppression such as racism, homophobia, and heterosexism. Their experiences of reproduction, reproductive capacity, and decision-making are influenced by various

[315] Inhorn, M. C., & Patrizio, P. (2015). Infertility around the globe: new thinking on gender, reproductive technologies and global movements in the 21st century. *Human reproduction update*, *21*(4), 411–426. https://doi.org/10.1093/humupd/dmv016.
[316] Ibid.

regulatory structures, including racialization (ascribing hierarchical racial identity to a social group), heteronormativity (assigning power and normative status to heterosexuality, sexual behaviours, and family structures), and cisnormativity (assuming a person's gender identity aligns with their biological sex). These intersecting hierarchical power structures create cumulative barriers to ART access for these individuals[317].

Moreover, the emphasis of ART on infertility and low fertility in heterosexual couples has resulted in uneven access and research attention, neglecting to adequately address the reproductive needs of lesbian, gay, bisexual, transgender, queer, two-spirit, intersex, and asexual (LGBTQ2SIA +) individuals. Considering that current research on reproductive technologies and fertility clinics tends to focus predominantly on white, cisgender, heterosexual couples with socioeconomic privilege the access gap for these services widens even more. For example, the access to ART for the LGBTQ2SIA + community in Europe faces considerable obstacles, especially in regions where obtaining a job, being open about one's identity, getting married, or undergoing legal gender recognition is already challenging. Even in countries where reproductive assistance is legally available, individuals may encounter discrimination, harassment, or violence during the process, with trans and intersex people facing the most significant challenges[318].

Until 2011, for instance, trans individuals in Germany, and still in several European countries, were required to undergo sterilization for gender change. Some countries have laws preventing access to ART for those who have undergone gender recognition, creating a rights dilemma. It is evident, however, that individuals shouldn't have to choose between being who they are and fulfilling the dream and wish of parenting. While twenty countries recognize ART access for trans people, six do not, and in some, like Germany, it remains unregulated. In Italy, completing the transition is mandatory. Legislative changes in certain countries, such as Hungary, attempt to deny the existence of these issues, with legal gender recognition banned[319].

Despite the clear I attempts of society and the state to hinder LGBTQ2SIA + individuals from constituting families through parenting, studies suggest that

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[317] Tam, M.W. (2021). Queering reproductive access: reproductive justice in assisted reproductive technologies. Reprod Health, 18(1), 164. https://doi.org/10.1186/s12978-021-01214-8.

[318] *More than half of European countries prohibit access to assisted reproduction for lesbians and almost a third do so for single women - European Data Journalism Network - EDJNet*. (2023, July 26). European Data Journalism Network - EDJNet. https://www.europeandatajournalism.eu/cp_data_news/more-than-half-of-european-countries-prohibit-access-to-assisted-reproduction-for-lesbians-and-almost-a-third-do-so-for-single-women/.

[319] Ibid.

transgender adults, for example, exhibit diverse attitudes and wishes regarding biological parenthood, with approximately 18–54% of transgender adults and 24–36% of transgender youths expressing a desire for parenthood[320]. Therefore, LGBTQ2SIA + individuals facing discrimination in accessing ART usually resort to one of the following options: misrepresenting their identity, crossing borders to seek assistance in another country, or conceiving with friends or trusted individuals, even if there is no romantic attraction[321].

Moreover, studies exploring the experiences of LGBTQ2SIA+ individuals in reproductive access often involve primarily white, cisgender lesbian and bisexual women with relatively high levels of education and income[322]. This demonstrates how structural racism and white supremacy contribute to racial inequities that stem from differential access to resources and opportunities, ultimately shaping health outcomes. The fact is that BIPOC women have a prolonged history of experiencing both overmedicalization and neglect from reproductive endocrinologists and obstetric gynaecologists. Furthermore, over time, these women have endured many attempts by societal institutions to control their bodies, with systemic racism playing a significant role in this control through practices like eugenics and forced sterilizations. Fertility clinics and access to ART in general, could be seen, in this context, as a contemporary method of asserting control over the reproductive rights of Black women, adding to existing barriers to fertility and reproduction treatments.

The main challenges encountered by BIPOC women in accessing fertility methods are economic, educational, historical, and health-related barriers. Economic barriers encompass the expenses associated with fertility treatments and the connections between socioeconomic status and health outcomes. The exorbitant costs of ART treatments accentuate income disparities based on race and class. Such inequalities linked to socioeconomic status strongly predict health outcomes, placing those from lower socioeconomic classes at a disadvantage. Here, intersectionality comes into play, as overlapping identities of race and socioeconomic status contribute to overarching economic barriers to fertility treatment, reflecting historical cycles of poverty within BIPOC communities[323].

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[320] Kimberly, L. L., Sutter, M. E., & Quinn, G. P. (2020). Equitable access to ectogenesis for sexual and gender minorities. *Bioethics*, *34*(4), 338-345. https://doi.org/10.1111/bioe.12723.

[321] *More than half of European countries prohibit access to assisted reproduction for lesbians and almost a third do so for single women.,* op. cite.

[322] Tam, M.W. (2021). Queering reproductive access: reproductive justice in assisted reproductive technologies. Reprod Health, 18(1), 164. https://doi.org/10.1186/s12978-021-01214-8.

[323] Rosenberg, E. B. (2022). Racism and Reproductive Injustice in the Black, Indigenous, People of Color Community: A Look into the Barriers BIPOC Women Face with Accessing Fertility Methods. (Master's

Educational barriers underscore the restricted access to fertility education and the influence of limited education on career paths and subsequent health insurance coverage. It is unequivocally demonstrated that education plays a crucial role in shaping access to medical care, particularly fertility care, for BIPOC women since it empowers women across various socioeconomic backgrounds to access resources for making informed decisions about their health. Higher education has been shown to lead to better employment opportunities, increased income, and consequently, improved access to health care services. When examining the Obstetric theory in connection with the insufficient educational support related to fertility, it becomes evident that obstetric violence encompasses both gendered and racial violence. Even educated BIPOC women experience more severe health disparities than uneducated white women, highlighting the role of racism in shaping health outcomes. Education, coupled with health disparities and systemic racism, detrimentally affects the reproductive health and agency of BIPOC women as a holistic concern[324].

Historical barriers shed light on decades-long restrictions on reproductive rights, shaping the landscape of autonomy over reproductive choices. These barriers are rooted in events dating back to slavery and significantly contribute to the persisting challenges faced by BIPOC women in accessing fertility treatments today. During the era of slavery, Black women's bodies were dehumanized as part of a system that aimed to control their sexuality and reproduction. Instances of rape by white men were not just acts against women but were specifically targeted at Black women to assert racial dominance. These women were subjected to rape and forced to bear children to serve as a new generation of the workforce. Eugenics theory introduced a new form of reproductive control with the goal of preventing socially undesirable individuals from procreating. This led to the implementation of forced sterilizations, where the intersection of race, gender, and education played a crucial role. Sterilizations were not solely based on one identity; rather, it was the combination of being Black, female, and perceived as "feeble-minded" that created barriers to autonomy over reproductive rights. Moving forward, the birth control pill, initially providing autonomy to white women, took a troubling turn as it was marketed towards poor Black women with a covert emphasis on sterilization. While these pills aimed to prevent pregnancy, they also posed higher risks of hypertension and strokes, conditions that disproportionately affect Black communities. Given this historical context, BIPOC women usually express

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Thesis). San Francisco State University. Retrieved from http://hdl.handle.net/20.500.12680/p5547z534. doi: 10.46569/20.500.12680/p5547z534.

[324] Ibid.

a lack of trust in their healthcare providers, feeling that their reproductive concerns are not listened to or treated without prejudice.[325].

Health barriers emphasize statistical evidence and survey findings that recognize the impact of racism and bias within the medical field and on overall reproductive justice. A survey conducted among Black women in the U.S. revealed that 26% suspected their interactions with medical professionals were influenced by gender, race, and/or class discrimination. Black women reported extended wait times for referrals to fertility specialists compared to their white counterparts, waiting beyond the typical six-month period. Additionally, BIPOC women were more inclined to delay seeking fertility assistance, being 50% less likely to pursue aid upon discovering potential infertility. Intersectionality plays a significant role alongside unconscious bias and systemic racism, contributing to ongoing health inequities in interactions with individuals and populations[326].

In light of the extensive range of reproductive injustices encountered by BIPOC and LGBTQ2SIA + individuals, the existing rights-based reproductive movement proves inadequate in addressing how the state employs necropolitics against minorities. Operating within this system and prioritizing rights over freedoms inherently imposes restrictions on who can avail themselves of those rights. The mainstream reproductive movement's origins can be traced back to the rights framework of traditional white feminist movements, which underscores the rights of "individuals" and predominantly applies to a specific group of women. Therefore, this group excludes women and other individuals who do not align with the envisioned ordinary citizen and are thus considered undeserving of the protections that rights afford. The pro-choice stance does not inherently attribute rights to BIPOC women or members of the LGBTQ2SIA + community; instead, these people are seen as possessing reproductive choices if they can afford them or are deemed legitimate decision-makers. To counter necropolitics in this context in the realm of reproductive rights, a more intersectional approach is needed that distinguishes reproductive "rights" from reproductive "justice."[327]

For the reasons above, black feminist grassroots activists initiated the reproductive justice movement recognizing the shortcomings of conventional reproductive rights. It places a strong emphasis on positive rights, encompassing

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[325] Rosenberg, E. B. (2022). Racism and Reproductive Injustice in the Black, Indigenous, People of Color Community: A Look into the Barriers BIPOC Women Face with Accessing Fertility Methods. (Master's Thesis). San Francisco State University. Retrieved from http://hdl.handle.net/20.500.12680/p5547z534. doi: 10.46569/20.500.12680/p5547z534.

[326] Ibid.

[327] Kimberlin, H. (2016). Reproductive Rights as a Tactic of Necropolitics Under Neoimperialism. *Sprinkle: An Undergraduate Journal of Feminist and Queer Studies, 9.*

aspects such as healthcare access, support throughout pregnancy, and liberation from diverse forms of oppression. Within this framework, feminist legal theorists promote a thorough advocacy campaign, aiming for widespread access to safe and community-based reproductive care, while also opposing the criminalization of reproductive choices and challenging paternalistic assumptions[328].

Therefore, considering that the main barrier to access to ART procedures - and following the same trend, AWT - is economic (remembering that this issue crossover all instances of marginalised collectives) and taking into account the frameworks of reproductive justice, the necessary to increase the access to affordable, high-quality fertility care for those in need arises.

In this context (and as a possible "solution" or alternative to the financial issue), important to mention the appearance of an alternative social movement, called the LCIVF movement. The LCIVF movement emerged as a response to the Universal Declaration of Human Rights, and advocates for reproductive justice by addressing the needs of the world's infertile, particularly those in resource-poor settings. This movement is associated with The Walking Egg (WE) organization, introducing a low-cost in vitro fertilization (LCIVF) method. The LCIVF method aims to make IVF more affordable and accessible by simplifying embryo culture methods and eliminating the need for expensive equipment. The implementation of LCIVF, nevertheless, has been facing challenges such as the need for replication in different laboratories, assessment for safety issues, and training of embryologists in low-resource settings. Furthermore, considering that LCIVF may not address the high costs associated with intracytoplasmic sperm injection (ICSI), alternative initiatives like 'Friends of Low-cost IVF' (FLCIVF) have been established. FLCIVF focuses on providing simplified clinical IVF services at minimal costs, along with reproductive health education to prevent infertility[329].

It is important to highlight, once more, that the justifications for the necessity for a more fair and equitable access to fertility healthcare and ART can all also be applied to justify the same arguments for ectogenesis, considering that the procedure (both partial and complete) is very likely to be extremely expensive and it is probably going to mirror the same gaps in access as ART, if not more.

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[328] Horn, C. (2020). Ectogenesis is for Feminists: Reclaiming Artificial Wombs from Antiabortion Discourse. Catalyst: Feminism, Theory, Technoscience, 6. https://doi.org/10.28968/cftt.v6i1.33065.

[329] Inhorn, M. C., & Patrizio, P. (2015). Infertility around the globe: New thinking on gender, reproductive technologies and global movements in the 21st century. *Human Reproduction Update*, *21*(4), 411-426. https://doi.org/10.1093/humupd/dmv016.

With this scenario in mind, some authors defend that AWT should also be state-funded, considering that it is a form of addressing the natural or physical injustices inherent in the unequal gender roles of reproduction and as a means to mitigate the social injustices stemming from them. Smajdor[330] employs Burley's argument, which explores the idea of a right to fertility treatment, drawing inspiration from Dworkin's perspective on integrating healthcare into broader concepts of distributive justice, as justification for her reasoning.

According to Dworkin, natural inequalities may create a prima facie right to restitution, as seen in the case of compensating those born with disadvantages like blindness. Burley extends this notion to argue that the infertile might similarly seek compensation through state-funded fertility treatment. However, she acknowledges a potential challenge: the desire for children could be considered an expensive taste. According to Dworkin, tastes related to the "good life" may not warrant compensation. Burley notes that infertile individuals generally seek children themselves, not just the removal of the desire. From this, she concludes that state funding for fertility treatment may not be justified, if the desire for children is intricately linked to people's conception of the good life. However, she argues that infertility, unlike the choice to have children, is not part of one's ethical beliefs about a good life. Thus, compensating for the infertility-related deficit becomes a form of redistributive justice within Dworkin's framework, addressing a lack of personal resources resulting from factors beyond an individual's control. Despite establishing a prima facie entitlement, the allocation of resources for fertility treatments within the broader funding hierarchy remains a complex challenge, requiring considerations of limited resources and societal priorities. Dworkin's "veil of ignorance" approach, where individuals choose provisions without knowing their future conditions, is suggested as a solution for these conditions, highlighting the pervasive importance of reproduction in society and the potential consensus on compensating for infertility.

Smajdor then applies Burley's/Dworkin's Argument to "natural" fertility, asserting that natural inequalities, such as the requirement for women to gestate and give birth, constitute a prima facie injustice. These natural inequalities, which often lie beyond the current remedial capabilities, are challenged from the point of view that moral duties are not restricted by current feasibility when there is no logical impossibility. Technological advancements, particularly in ectogenesis, present possibilities for

[330] Smajdor A. (2007). The moral imperative for ectogenesis. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *16*(3), 336–345. https://doi.org/10.1017/s0963180107070405.

addressing these natural inequalities. Therefore, if a prima facie injustice exists in reproduction, there could be a moral duty to explore possibilities for alleviation. The author then focuses on the prima facie injustice that women must undergo gestation and childbirth while men do not, suggesting the need for the development of ectogenesis. With advancements in technology, the idea of gestating babies without relying on a woman's body through ectogenesis is becoming feasible and potential challenges in allocating resources and prioritizing different interventions must be recognized.

The right to compensation lies on the grounds that relieving women of the inherent inequalities associated with natural reproduction is the moral imperative for AWT and that it can be a form of reviewing the roles of parenthood with the advent of ectogestation: "Gestation is neither necessary nor sufficient to guarantee parental bonding and can actually impede mothers' ability to care for their children. Moreover, because children are not raised solely by gestational or genetic mothers, the value of pregnancy cannot be established simply by asserting that it prepares women for motherhood"[331].

From this standpoint and expanding it, it is extremely important to highlight that in order to fulfil the commitment to promote equality for all women and other people who wish to get pregnant accessing these services - and not only covering the gap between natural biological inequalities between women and men -, advocates for ectogenesis must also advocate for a comprehensive political perspective on the issues. This perspective should go beyond merely criticizing gender inequality and should also address concerns related to social disparities within the sexes. If the environment in which ectogenesis is developed and offered overlooks inequalities that create additional barriers for specific potential beneficiaries, such as individuals from ethnic minorities, those with disabilities, and those who are socioeconomically disadvantaged, ectogenesis might inadvertently contribute to the reinforcement of social inequalities[332].

Therefore, deliberations about the accessibility of ectogenesis for different demographic groups and varied reasons should be subject to democratic discourse grounded in robust argumentation from a holistic standpoint, taking into account

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[331]Smajdor A. (2012). In defense of ectogenesis. *Cambridge quarterly of healthcare ethics : CQ : the international journal of healthcare ethics committees*, *21*(1), 90–103. https://doi.org/10.1017/S0963180111000521.

[332] Segers, S. (2021). The path toward ectogenesis: looking beyond the technical challenges. *BMC Medical Ethics*, *22*(1), 59. Retrieved from: https://doi.org/10.1186/s12910-021-00630-6.

intersectionality, as well as impacts on the future child's well-being, societal inequalities, and, in the case of partial ectogenesis, the inherent risks associated with prematurely extracting a fetus for ex utero gestation.

Additionally, it is imperial to remember that the successful implementation of accessible infertility treatment (and AWT) in developing countries hinges on meeting sociocultural and economic prerequisites. It also requires persuading governments to endorse and support their introduction. Collaboration with relevant authorities is essential to engage in discussions about fortifying infertility services. At the heart of this enhancement is the integration of infertility, contraceptive, and maternal health services into public healthcare structures.

This, however, brings to attention another merit. Considering the limited resources that governments have, can be challenging to justify expensive fertility treatment in settings with scarce resources and more pressing issues to address. In many developing nations, the primary focus in reproductive health is on reducing maternal mortality and promoting contraception.

The promotion of contraception takes into account the overgrowing populational rates. The global population is anticipated to rise from 6.7 billion people in 2005 to 9.2 billion in 2050, as reported by the United Nations in 2007. By 2050, the developing world is projected to experience an annual addition of 35 million individuals, with the least developed countries absorbing 22 million of this increase. However, even if accessibility to infertility treatment were enhanced in developing countries, it would likely constitute less than 1% of all deliveries. Focusing on increased efforts in family planning and health education could easily outweigh this modest contribution to the fertility rate[333].

In financial terms, however, one argument in favour of making ART more attainable is that while fertility care often remains financially inaccessible for individuals, it proves to be economically feasible from a societal standpoint. Indeed, funding fertility care at a public level is highly cost-effective, as the positive returns on investment come in the form of the future economic contributions of infants born through treatment. Another perspective on the significance of fertility care involves evaluating the financial worth of human life, estimated at US$5.7 million, a value that surpasses the expenses associated with fertility treatments. Again, all these parallels with ART can be traced to the advent of Ectogenesis and AWs.

[333] Ombelet W. (2011). Global access to infertility care in developing countries: a case of human rights, equity and social justice. *Facts, views & vision in ObGyn*, *3*(4), 257–266.

In the context of different levels of accessibility and financial restrictions for the services of AWs, Romanis and Horn bring to attention an important scenario that may arise in the case of the creation of reproductive stratification for those reasons. In both the ectogestation experimental stages and as it becomes more widely available, concerns about equality in healthcare appear with the biobag exacerbating existing inequities. For example, if women from lower socio-economic backgrounds are more likely to need this technology, they may bear the risks and burdens of its development, including invasive and experimental surgeries[334].

This scenario, which must certainly be avoided, only demonstrates the importance of applying the reproductive justice approach both to access to ART and AWT. Recognizing and dismantling structures that control the reproductive capacities of marginalized communities, while promoting accessibility and challenging white supremacy and heteronormativity should be imperial for the arrival of this piece of technology. Incorporating reproductive justice into the accessibility of these services and their research/trials involves addressing questions such as who gets it, comprehending the existing and historical conditions that affect access, and scrutinizing the socio-political factors that influence reproductive accessibility. Reproductive justice extends beyond merely collecting socio-demographic data by considering the lived realities of reproductive capacity and decision-making among BIPOC and LGBTQ2SIA+ communities in research, clinical work, and policy development. It acknowledges the impact of integrative social locations, such as race, class, gender, sexuality, family structure, and access to healthcare, shaped by historical inequities, reproductive violence, and the regulation of bodies, sexuality, and population when assessing the availability and accessibility to ART and AWs services.

[334] Romanis, E. C., & Horn, C. (2020). Artificial Wombs and the Ectogenesis Conversation: A Misplaced Focus? Technology, Abortion, and Reproductive Freedom. International Journal of Feminist Approaches to Bioethics, 13(2), 174-194.

Conclusion

This master's thesis aimed to examine the ethical implications of the emergence of ectogenesis within the framework of human rights considering that recent advancements in research are bringing it closer to reality, albeit currently in the form of partial ectogenesis. AWT holds promise in enhancing neonatal intensive care, providing an alternative to surrogacy or uterus transplantation, advancing prenatal therapy, addressing gender inequities, and allowing for pregnancy termination without terminating fetal life. However, the advent of partial ectogenesis raises numerous ethical questions, particularly regarding human trials and the legal status of the fetus.

Critical research is imperative to determine whether and how experiments involving human subjects can be conducted within an acceptable risk threshold. This includes rigorous monitoring throughout pregnancy and post-birth, privacy protection, and obtaining informed consent. Concerns arise regarding unforeseen physical and psychological risks to research subjects and ethical considerations surrounding consent to experimental procedures. These discussions also intersect with debates on abortion rights, often tied to the concept of fetal viability.

Contrary to the doctrines of part of the academic community, despite the advancements offered by AWT in reproductive health, it fails to resolve the "abortion dilemma" since forced fetal extraction stands in direct violation of numerous legal and ethical frameworks, including constitutional laws safeguarding personal liberties and international statutes protecting human rights. Thus, while AWT introduces novel possibilities in reproductive medicine, it does not obviate the fundamental right to abortion. Irrespective of technological progress, the right to abortion must endure, grounded firmly in principles of bodily autonomy, reproductive rights, and the preservation of individual freedoms.

Moreover, despite advancements in reproductive technologies affecting various demographics, such as men and the LGBTQ2SIA+ community, people with the capacity for pregnancy remain disproportionately affected. Partial ectogenesis poses implications for the physical well-being and autonomy of pregnant individuals, particularly concerning the relocation of the fetus to an ectogenetic incubator. Therefore, any decision regarding AWs transfer should prioritize the pregnant person's autonomy and well-being. It should always be the pregnant person's choice whether to

pursue such a procedure, with comprehensive information and support provided to facilitate informed decision-making.

Likewise, considerations of safety, cost-effectiveness, and equitable access are crucial. Establishing uniform eligibility criteria poses a significant challenge in ensuring equitable access to AWT. Ectogenesis, however, may not inherently promote equality; instead, it could exacerbate gender disparities within society. The accessibility of ectogenesis services mirrors existing disparities seen in ART and other forms of reproduction assistance. Structural prejudices against marginalized communities, including LGBTQ2SIA+ and BIPOC communities, persist and may continue with the advent of ectogenesis, necessitating address.

This observation is pertinent to the current discourse because merely introducing a new reproductive technology or practice, even one as transformative as ectogenesis, does not determine how or whether such a technology or practice will shape existing arrangements, social values, and norms. The manner in which technologies influence established arrangements and norms appears to be more contingent on how they are designed, implemented, and regulated, as well as whose interests they serve, rather than the inherent attributes of the technologies themselves. Advocating for ectogenesis without contextual consideration may only advance the equality and freedom of select demographics, or may not improve equality and freedom at all and it might, in some cases, perpetuate the status quo or exacerbate existing inequalities.

Consequently, when regulating and legislating AWT, greater attention should be directed towards policies, practices, and values that hinder equal access to reproductive healthcare services and technologies. This includes addressing systemic inequalities in access to healthcare based on factors such as socioeconomic status, race, ethnicity, gender identity, sexual orientation, and geographical location. Discriminatory policies and practices, such as high costs, lack of insurance coverage, or geographic disparities in healthcare infrastructure, can create barriers to accessing AWT for marginalized populations. Additionally, legislative frameworks should prioritize promoting reproductive autonomy and bodily integrity for all individuals, regardless of their demographic characteristics. This involves ensuring that individuals have the right to make informed decisions about their reproductive health without coercion or discrimination. Legal protections should also extend to safeguarding individuals' privacy and confidentiality throughout the process of accessing and utilizing AWT.

Scholars speculate about the potential convergence of partial ectogenesis with advancements in embryonic research, possibly leading to the realization of full ectogenesis. This envisioned future prompts extensive ethical discussions, potentially reshaping societal perceptions of reproduction and giving rise to unforeseen physical, psychological, and sociological implications, including dystopian scenarios. The concept of full ectogenesis presents numerous ethical dilemmas, particularly concerning the commodification of reproduction, the sanctity of life, and the disruption of natural processes. The ethical discourse surrounding ectogenesis must grapple with these multifaceted considerations, ensuring that technological progress aligns with principles of justice, autonomy, and human dignity. Ultimately, exploring ectogenesis, whether partial or full, requires a nuanced approach that prioritizes the well-being, autonomy, and rights of all individuals involved.

Moreover, both partial and complete ectogenesis ultimately highlight how women's biological role in childbearing often shapes their predominant involvement in childrearing—a role that has been culturally reinforced and widely acknowledged across many societies. While it's true that attitudes and norms related to childrearing can evolve, the introduction of ectogenesis may impact these societal perceptions. However, it's worth noting that other assisted reproductive technologies have not only introduced new family structures and reshaped interpretations of social and biological connections but have also perpetuated prevailing beliefs regarding the importance of genetic ties and have not effectively challenged existing social norms and structures.

Yet, it is imperative to recognize that ectogenesis, whether partial or complete, should be regarded as a viable option for pregnant individuals and individuals seeking to become biological parents, whether for therapeutic or non-therapeutic reasons. Despite raising profound ethical and societal considerations, from a feminist perspective, ectogenesis has the potential to significantly impact women's rights and foster greater gender equity. By alleviating women of the exclusive burden of pregnancy and childbirth, full ectogenesis could mitigate systemic inequalities and empower women to pursue their aspirations unencumbered by traditional gender roles. Furthermore, the availability of full ectogenesis could enhance reproductive autonomy, providing individuals, irrespective of gender, with unprecedented control over their reproductive choices.

Ectogenesis, however, must not be allowed to divert attention from the pressing needs of individuals, nor should it misdirect focus away from the systemic issues embedded within societal structures and arrangements. Instead, it should serve as a

catalyst for addressing a broad spectrum of concerns, encompassing ethical, psychological, sociological, and legal dimensions. By confronting these multifaceted challenges head-on, AWT has the potential to foster meaningful progress towards equitable, just, and ethically sound reproductive practices.

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