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Legal Scope of Human Cloning: Comparative Analysis Between the United Kingdom and France

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Abstract

“Reproductive” cloning and “therapeutic” or “research” cloning are both deliberate attempts to create humans that are genetically identical. Human reproductive cloning in general is prohibited by a number of international and regional agreements, including the Charter of Fukushima, the Additional Protocol of the Council of Europe to the Convention on Human Rights and Biomedicine, the World Health Organization resolutions on the implications of cloning for human health, and the Universal Declaration on the Human Genome and Human Rights. However, there are some countries that want to explore therapeutic cloning and cannot, therefore, support a general ban on cloning. This paper aims to review the legal position of human cloning in the UK and France and further compares the issue between the two countries. The legal position of human cloning in the UK and France, it is clear that both countries were initially against the idea and concept of human cloning in general. Human cloning is a much-needed technology, especially in these modern times. Every day we encounter new diseases and illnesses, so human cloning is essential to help us be better prepared for the future.

Keywords: Human Cloning; Comparative Analysis; UK; France.

Introduction

The intentional creation of genetically identical people is known as human cloning. There are two types of cloning: “reproductive” and “therapeutic” or “research” cloning.¹ In reproductive cloning, the embryo is transplanted into a female for gestation.² In July 1996, Dolly the Sheep became the first mammal cloned using this technique. In therapeutic cloning, a cloned embryo creates embryonic stem

¹ Shaun D Pattinson, ‘Reproductive Cloning: Can Cloning Harm the Clone’ (2002) 10 Med. L. Rev. [295].

² Finn Bowring, ‘Therapeutic and Reproductive Cloning: A Critique’ (2004) 58 Social science & medicine. [401].

cells with the same DNA as the donor cell.³ These stem cells can be used in research to better understand diseases and create new treatments.⁴ Every new creation is a perfect replica of the pioneer excellent.⁵ Monozygotic twins, commonly referred to as identical twins, are organic clones.⁶ A clone's body is made up of cells. Each cell has a nucleus, which contains the chromosomes.⁷ Each clone contains an identical collection of genetic material inside each cell nucleus. Consequently, the DNA and genes in the nuclei of cells generated from two clones are identical.⁸ The "factories" that produce energy are called mitochondria and are present in all cells, including eggs. These mitochondria also contain some DNA.⁹ These structures can be found in the cytoplasm, which is the part of the cell that is not the nucleus. Each of the mitochondria has its copy of DNA and can multiply independently.¹⁰ Although the word "clone" can also refer to individuals with the same DNA in their nuclei but a different DNA sequence in their mitochondria, true clones have the same DNA in both their nuclei and mitochondria. The creation of these nuclear transfer autologous embryonic stem cells (ntESCs), used in therapeutic cloning, has significant potential for reproductive and regenerative medicine and gene therapy as a gene delivery system. For example, therapeutic cloning and gene therapy can greatly enhance a patient-specific rescue of a loss-of-function type gene mutation that results in the decreased or deleted activity of a specific protein. In cell replacement therapy,

³ Xiangzhong Yang and others, 'Nuclear Reprogramming of Cloned Embryos and Its Implications for Therapeutic Cloning' (2007) 39 *Nature genetics*. [295].

⁴ Duane Nash, 'Recommended Response for Human Cloning Patent Applications' (2002) 42 *IDEA*. [279].

⁵ Khan Rumana Amanullah, 'Cloning And Genetic Engineering' *Advances in Animal Science* Volume II. [43].

⁶ Martina Fejtkova and others, 'TLR8/TLR7 Dysregulation Due to a Novel TLR8 Mutation Causes Severe Autoimmune Hemolytic Anemia and Autoinflammation in Identical Twins' (2022) 97 *American journal of hematology*. [338].

⁷ Alfredo de Bustos and others, 'The 5S rRNA Genes in *Alexandrium*: Their Use as a FISH Chromosomal Marker in Studies of the Diversity, Cell Cycle and Sexuality of Dinoflagellates' (2020) 98 *Harmful algae*. [101903].

⁸ Zhen Liu and others, 'Cloning of a Gene-Edited Macaque Monkey by Somatic Cell Nuclear Transfer' (2019) 6 *National Science Review*. [101].

⁹ Roberta Filograna and others, 'Mitochondrial DNA Copy Number in Human Disease: The More the Better?' (2021) 595 *FEBS letters*. [976].

¹⁰ Hans-Ulrich Klein and others, 'Characterization of Mitochondrial DNA Quantity and Quality in the Human Aged and Alzheimer's Disease Brain' (2021) 16 *Molecular neurodegeneration*. [1].

therapeutic cloning can produce various tissue types, such as osteoblasts, to combat osteoporosis and promote spinal cord regeneration following trauma.¹¹

Mammals can be cloned from live birth using one of two methods. Implanting an embryo inside a woman's uterus is a prerequisite for both procedures, which is then followed by the standard gestation and delivery times. However, the use of genetically identical embryos fit for implantation does not define the reproductive cloning of people or animals. This holds true whether human or animal cloning takes place. Even though these procedures have not yet been proven or documented, they would be regarded as cloning if they resulted in genetically identical persons, at least one of which would be an embryo that could be implanted and give birth. Embryo cloning for reproductive purposes can be done via two methods. The first approach is known as cloning through somatic cell nuclear transfer (SCNT). First, an egg's chromosomes are removed to convert the egg into an enucleated state prior to the operation. When a human being or embryo is cloned, the chromosomes are removed and replaced with a nucleus obtained from a somatic cell of the individual or embryo. This cell can be taken directly from the individual, cultured or frozen tissue. All of these options are viable. The egg is excited and will sometimes begin dividing after being stimulated. If this occurs, a procession of successive cell divisions will produce a blastocyst, also known as a pre-implantation embryo. After this step, the blastocyst is implanted into an animal's uterus, following which it can undergo further development, eventually leading to the birth of an animal. This will be a clone of the person who donated their nucleus for use in the cloning process. Only a genetic parent can contribute to someone's nuclear DNA. The only theoretical constraints on how many times a particular individual can be cloned are the number of oocytes obtained to accept somatic cell nuclei and the number of females available to receive developing embryos. Suppose the egg utilised in the process was donated by the same person who provided the transplanted somatic nucleus. If so, the surgery will result in an embryo which obtained both its nuclear and mitochondrial genetic material

¹¹ Charlotte Kfoury, 'Therapeutic Cloning: Promises and Issues.' (2007) 10 McGill journal of medicine : MJM : an international forum for the advancement of medical sciences by students.[112].

from a single person, because the same person provided the egg used in this process. This will likewise be the case if the egg comes from the mother of the nucleus donor because mitochondria are passed down through the maternal line. The creation of several clones is also possible when identical nuclei are inserted into a single donor egg. The clones produced if the somatic cell nucleus and egg cell are from different individuals will not be identical to the nuclear donor. This is because the mitochondrial DNA of each clone will be unique.

The second approach involves splitting an embryo during the cloning process. In vitro fertilisation, normally known as IVF, creates a zygote by combining sperm and an egg in a laboratory rather than inside a woman's body. The zygote is now called an embryo and will divide first into two and then into four identical cells.¹² At this point, the cells can divide and develop into separate but identical blastocysts, which can subsequently be placed in a uterus once the process is complete.¹³ Due to the limited growth capacity of the cells, the technique cannot be repeated; consequently, the embryo splitting may produce at most only two identical mice and possibly up to four identical humans. The DNA used to divide the embryo come from the germ cells of two people: the egg donated by the mother and the sperm provided by the father. Therefore, embryos, such as those created spontaneously or through IVF procedures considered conventional, have two parents. They share an identical copy of their mitochondrial DNA. This method of cloning requires covering in detail in this study as it is equivalent to the natural process which leads to monozygotic twins and, under very unusual circumstances, even quadruplets.

DNA is not the only factor that determines a person's appearance or personality; therefore, clones cannot be replicas of each other in terms of physical or behavioural qualities even if they are genetically identical.¹⁴ It is reasonable to predict that a clone

¹² Cerys E Currie and others, 'The First Mitotic Division of Human Embryos Is Highly Error Prone' (2022) 13 Nature Communications.[6755].

¹³ Marino Maemura and others, 'Totipotency of Mouse Zygotes Extends to Single Blastomeres of Embryos at the Four-Cell Stage' (2021) 11 Scientific reports.[11167].

¹⁴ Eman A Hussien and others, 'Reproductive Cloning' (2022) 5 Advances in Assisted Reproduction Technologies.[218].

pair will be subject to different inputs throughout their development, including from the parents, society and experiences they have in life. This is because the clones will have been exposed to different environments and received different amounts of nutrients while still in the womb. The environmental and dietary differences are likely to be more pronounced than in the case of the monozygotic (identical twins) clones derived from identical nuclear donors and identical mitochondrial donors if they are born at different times, as in the case where an adult is the somatic cell nucleus donor. This is because clones produced by identical nuclear donors and identical mitochondrial donors are themselves identical. Monozygotic twins are also not completely genetically or epigenetically identical because each twin receives unique contributions from mutations, stochastic developmental variances and numerous imprinting effects. Imprints are chemical DNA markers specific to one's parents. Clones that do not have identical mitochondria may have other distinguishing characteristics. These clones can be produced when one person provides the nucleus, and another provides the egg, or when a single person's nuclei are transferred to multiple donor eggs. The changes can manifest in regions of the body with high energy needs, such as the muscles, heart, eyes and brain, or in body systems that rely on the mitochondrial control of cell death to determine cell numbers in the body.

The Legal Status of Human Cloning in the UK

By supporting the ban on human reproductive cloning, the UK government is demonstrating its commitment to the position that such an act violates fundamental moral principles. However, a new advisory committee of experts has been created to evaluate the possible advantages of using cloning for therapeutic purposes.¹⁵ The Human Fertilization and Embryology Authority (HFEA) and the Human Genetics Advisory Commission have recently produced a report on cloning which the

¹⁵ Agus Suhariono and others, 'Sistem Publikasi Pendaftaran Tanah (Kajian Sistem Publikasi Negatif Bertendensi Positif)' (2022) 5 Notaire.[17].

government is responding to.¹⁶ The report recommended the cloning of embryos to create cells and tissues for therapeutic purposes. The research concluded that cell nuclear replacement procedures – also known as cloning methods – should be legal.¹⁷ However, the Commission disagreed with using cloning for human reproduction.¹⁸ Public Health Minister Tessa Jowell explained the government's response by noting that the government believes that human reproductive cloning is ethically wrong and cannot be done in this country. However, the UK recognises that the rules governing the conduct of therapeutic research must be approached carefully.¹⁹

The chief medical officer, Liam Donaldson, was asked to form an impartial expert advisory panel. To provide the government with a more realistic picture of the possible advantages of therapeutic cloning procedures, this group will seek the opinions of a broad spectrum of specialists from the UK and elsewhere. This group is explicitly invited to consider using human embryos in research to create cures for diseases, including mitochondrial disease and damaged or harmed organs or tissues. The advisory board members concur with the government's determination that additional thought is necessary on this subject. In addition, Christine Gosden, a group participant and professor of medical genetics at the University of Liverpool, noted that research into stem cells and human cloning is still in its early stages. There is still considerable animal study to be done before working with human eggs.

However, the HFEA has issued its first license for the therapeutic cloning of human cells. This comes three years after the UK became the first nation in the world to pass technology regulation. The Human Fertilization and Embryology Act of 1990 established the HFEA in August 1991.²⁰ Its main duties include licensing and monitoring facilities that perform donor insemination, IVF and human embryo

¹⁶ Paul A Martin and Ilke Turkmendag, 'Thinking the Unthinkable: How Did Human Germline Genome Editing Become Ethically Acceptable?' (2021) 40 *New Genetics and Society*. [384].

¹⁷ Defid Tri Rizky and Mochamad Kevin Romadhona, 'Prinsip Pembuktian Perkara Tindak Pidana Pencucian Yang Berdiri Sendiri (Stand Alone Money Laundering)' (2022) 5 *Media Iuris*. [381].

¹⁸ S Mayor, 'UK Government Confirms Ban on Human Reproductive Cloning' (July 1999). [8].

¹⁹ Dina Sunyowati and others, 'Can Big Data Achieve Environmental Justice?' (2022) 19 *Indonesian Journal of International Law*. [6].

²⁰ 'Human Cloning Licensed in UK' *Pinsent Masons* (2004) <<https://www.pinsentmasons.com/out-law/news/human-cloning-licensed-in-uk>>.

research. The HFEA also controls the preservation of embryos in addition to the conservation of gametes (eggs and sperm). The Newcastle Center for Life has been given a one-year license to do nuclear cell replacement, one of the processes that can be utilised to produce human embryonic stem cells. To replace a cell's nucleus, the nucleus of a human egg cell is removed and replaced with the nucleus of a human body cell, such as a skin cell. Consequently, a fresh human egg is produced. The egg then undergoes a phase of artificial stimulation. Due to this, the egg begins to split and takes on the characteristics of a typical embryo that has been fertilised by sperm. The stem cells, which can grow into more than 300 different types of cells found in the human body, will then be extracted from the tiny embryo. Stem cells can become any other form of cell in the body. Diabetes and Alzheimer's disease are just two examples of conditions that may improve in the future due to this. Cloned embryos will only be able to develop for fourteen days, after which the nervous system begins to take shape. The stem cells produced under the license will only be used for scientific purposes. Suzi Leather, chair of the HFEA in the UK, has stated that human embryo research is only licensed for use in limited circumstances. This study aims to expand the existing information on the stages of embryonic development and enable the use of this knowledge to create therapies for life-threatening diseases. The study is preliminary and does not focus on any particular disease; instead, it sets the stage for further advances in treating critical illnesses.

Legal Status of Human Cloning in France

The cloning of human embryos for reproduction is illegal in France, which calls the practice a "crime against the human species". This practice is punishable by 30 years in prison and a fine of 7.5 million euros (5 million British pounds; \$9.3 million), ending a two-and-a-half-year debate in the French parliament and modernising the country's bioethics standards, first approved in 1994.²¹ Furthermore, France has criminalised therapeutic cloning, or the process of creating stem cells to replace

²¹ Brad Spurgeon, 'France Bans Reproductive and Therapeutic Cloning' (2004) 329 BMJ. [130].

damaged organs and tissues, punishable by seven years imprisonment and a fine of one hundred thousand euros. However, in a controversial twist, the government has decided to suspend a five-year ban on human embryonic stem cell research. This was done to give the government time to study the ethical and medical ramifications of such research, which could lead to treatments for a variety of diseases, including Alzheimer's disease, diabetes and heart disease. Philippe Douste-Blazy, then French Minister of Health, explained that the work carried out gave birth to a law that seeks to find a path between the hopes of some and the concerns of others. However, the law passed included a provision that a national biomedical agency should be established on 1 January, 2005. The purpose of this agency is to conduct further research into the topic of therapeutic cloning and to monitor progress in this area elsewhere in the world. In addition, the agency will authorise genetics, prenatal diagnosis and embryology research. According to Mr Douste-Blazy, embryo protection is a very explicit purpose of the civil code. For this reason, the country has remained steadfast in preventing scientists from cultivating embryos in vitro to conduct studies on the subject. The parliamentary debate began in January 2002 under the socialist government of Lionel Jospin. Right-wing politicians across the political spectrum voted for the measure, whereas left-wing politicians voted against it. The Left wanted it to be part of much broader bioethics legislation, which would have covered issues such as legalising a widow to conceive an embryo. At the same time, his spouse is still alive and implanted in his body so that he can have a child. The law also includes exclusions for particular advances, such as "medicine babies" or "double hope" babies, as they are known in French. To choose an embryo that will not be impacted by the genetic condition and is compatible with the child with the disease, the mother of a child with an incurable genetic disorder may have an embryo analysed before implantation. The first child's umbilical cord is used to remove the future child's blood cells, which are then used to treat the illness.

According to Mr Douste-Blazy, the regulation on embryo research strikes a balance between the need to carry out beneficial research and the need to show respect for the embryo. However, Alain Claeys, a Socialist MP, stated that the

Socialist party would challenge the bill in France's Constitutional Council, which is the country's highest administrative authority. In addition to his other concerns, he opposed granting patents for items that incorporate a component of the human body, arguing that doing so creates a dependency on the patent holder for all inventors who then find another application for the same gene. Furthermore, research on embryos and human embryonic stem cells is regulated by decree 2006-121 in France. This law came into force in 2006.²² Embryos suitable for use in research are supernumerary embryos, which are no longer part of a parental project, or embryos that cannot be transferred. Before the embryo study can begin after the parenting plan has been completed, exclusive information prior to authorisation must be obtained for embryo research. After the couple are informed of the other options, which are to destroy the embryo or make it accessible for transfer to another couple, written approval from the couple (or the surviving member) is required before the procedure can proceed. Embryos unsuitable for intrauterine transfer due to their quality (developmental defects) and those rejected after preimplantation diagnosis when an anomaly is detected can be used for research purposes. Consent can be revoked at any time and under any circumstances.

The Biomedicine Agency grants institutions with a conservation license permission to conduct research with embryos and embryonic stem cells for five years, during which period the permit can be renewed. The Biomedical Agency investigates whether or not the protocol can be successfully performed, as well as the long-term viability of the research organisation and team, the condition of the facilities and equipment, and the methods used to ensure the quality, safety and traceability of embryonic cells. The agency maintains a national registry of embryos and (coded) cell lines. The Penal Code contains provisions for the imposition of severe consequences in cases where research with embryos or embryonic stem cells violates the law. The penalty for cloning is a fine of seven and a half million euros plus five years' imprisonment (article 214-2 of the Penal Code). No matter

²² Anne-Marie Duguet and others, 'Ethical and Legal Frameworks for Embryonic Stem-Cell Based Research in France and in Europe: A Challenge for Biotechnology' (2018).

where they are, anyone can be prosecuted for gamete donation for cloning under Article 511-1 of the Criminal Code. In the case of embryo research, Article 511-19 of the Penal Code states that an individual conducting research without consent and authorisation is subject to a seven-year prison sentence. The criminal courts have yet to establish any jurisprudence for breaking the law. Despite this, a decision was made against granting the authorisation to import stem cells. An association that supports the “Right to Life” presented a petition to the “Tribunal Administratif” in Paris in 2003, asking for the authorisation to import stem cells to be revoked. The group argued that stem cell research is a form of killing embryos. The Court concluded that these stem cells could not be considered embryos for any reason. Having heard the appeal, the Administrative Court upheld the original sentence.

Comparative Analysis

Referring to the legal position of human cloning in the UK and France, it is clear that both countries were initially against the idea and concept of human cloning in general. However, the existence of two forms of human cloning – reproductive and therapeutic – has changed the mentality of both countries towards human cloning. As far as the UK is concerned, human cloning, particularly therapeutic cloning, is believed to do more good than harm. This is evidenced by the UK issuing its first license for the therapeutic cloning of human cells. Meanwhile, France has realised the importance of human cloning, too especially the therapeutic kind, as demonstrated by the suspension on the ban on human embryonic stem cell research for five years to give the government time to study the ethical and medical implications of such research. Indeed, the only difference between France and the UK is that France has yet to pass legislation to legalise therapeutic cloning whereas the UK has already passed legislation on the matter.

Conclusion

Every country has its own perspective regarding human cloning. Some countries only ban reproductive cloning and allow therapeutic cloning, whereas

others ban outright all forms of human cloning. Despite this, most countries are starting to realise the importance of human cloning and its potential contribution to the field of medicine, which has made certain governments question the initial decision to ban human cloning. These countries are beginning to accept the concept of human cloning, especially therapeutic cloning, because of its purpose and benefits for humankind in the future. Furthermore, human cloning is a much-needed technology, especially in these modern times. Every day we encounter new diseases and illnesses, so human cloning is essential to help us be better prepared for the future. However, it must be conceded that human cloning is extremely complex and has no guaranteed results, and requires further research to demonstrate its benefits. Because therapeutic cloning has value and benefits for the medical community regarding its potential future contribution, it must be embraced and permitted. This is evident in the advantages of therapeutic cloning. The creation of the ntESCs used in therapeutic cloning has significant potential for reproductive and regenerative medicine as well as gene therapy as a delivery system for genes. A patient-specific rescue of a loss-of-function type gene mutation that results in the decreased or deleted activity of a specific protein is greatly enhanced by the combination of therapeutic cloning and gene therapy. In cell replacement therapy, therapeutic cloning offers the ability to produce different tissue types, such as osteoblasts, to combat spinal cord and osteoporosis regrowth following injury. This is consistent with modern times, where technology like this is required to combat all the ailments or diseases that have yet to be identified and studied.

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