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The International Legal Framework Governing Biotechnological Applications on the Human Body

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Abstract

This study explores the international legal dimensions of biotechnological applications involving the human body. We analyze a range of critical issues, beginning with the legislation governing stem cell research and the methods for obtaining stem cells. This includes an examination of how various countries regulate these advanced biomedical procedures. Next, we review the declarations and frameworks established by international legal systems to set ethical boundaries for biotechnological research, ensuring alignment with global ethical standards. We then focus on assisted reproductive technologies, such as in vitro fertilization, highlighting the ethical and legal challenges they present, including the implications of utilizing these technologies. Furthermore, we address the potential impacts of genetic interventions on a child's future, particularly in the context of preimplantation genetic diagnosis. Finally, we investigate the contentious issue of human cloning, examining the diverse legal and ethical concerns it raises across different jurisdictions. This research employs a theoretical approach, utilizing a descriptive-analytical method to provide a comprehensive overview of these complex topics. By synthesizing existing legal frameworks and ethical considerations, this study aims to contribute to the ongoing discourse on the regulation of biotechnological practices and their implications for human rights and dignity. Through this examination, we seek to highlight the necessity for a cohesive international legal framework that addresses the rapid advancements in biotechnology and their application to the human body.

Key words: Biotechnology, Genetic interventions, Legal protections, Stem cell, Embryo.

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Introduction

Biotechnology, like other technological fields, is advancing at an unprecedented pace and is rapidly emerging as one of the most significant domains of modern science. However, this raises a critical question: Are existing legal frameworks adequately equipped to address the vast "ocean of possibilities" offered by biotechnology and genetic technologies, which often stretch the limits of our imagination? Furthermore, can the current requirements for informed consent and counseling for genetic testing effectively resolve the ethical and legal dilemmas associated with these advancements? This study seeks to explore these questions by examining the methods and applications of genetic technology.

Since Francis Bacon proclaimed that "Man is the master and interpreter of nature," humanity has been engaged in a relentless pursuit to reshape nature for its benefit and to enhance living standards. Genetic technology, as this study demonstrates, is not inherently destructive or malevolent. Yet, it possesses the potential to transform into a leviathan within its sphere, raising profound ethical and legal challenges. Whether this transformation is an intrinsic feature of genetic technology or a consequence of human ambition remains a matter of debate.

What is evident, however, is that the initial pursuit of healthier and more comfortable lives has evolved into an obsession with predetermining every facet of future generations, from their physical appearance to their expected lifespan. This research critically examines these developments, aiming to provide insights into the balance between scientific progress and the preservation of ethical and legal norms.

Materials and Methods

Stem Cells

Stem cells are theoretically capable of infinite division and possess the ability to differentiate into various cell types because they have not yet specialized in a specific function. This unique potential to become any type of cell is what makes them so versatile, often referred to as "pluripotent" cells. Depending on their source, stem cells can vary in their differentiation capabilities, a property known as "plasticity." Cells with the highest level of plasticity are fertilized egg cells, known as "totipotent" cells. Totipotent cells can differentiate into all cell types in the body, including those that form the placenta. As these totipotent cells change, they become "pluripotent" cells. Pluripotent cells, also known as embryonic stem cells, can develop into almost any of the 210 different cell types in the body, except those that form the placenta. Embryonic Stem Cells: Embryonic stem cells are derived from the inner cell mass of a structure called the "blastocyst," which forms about four days after the fertilization of an egg when fluid begins to fill the embryonic cavity. These stem cells, while no longer capable of developing into a full human organism, retain the ability to differentiate into many types of body tissues.

One method of obtaining pluripotent stem cells is by transferring the nucleus of a donor's somatic cell into an egg cell from which the nucleus has been removed. This process is known as somatic cell nuclear transfer (SCNT). The tissues and organs derived from stem cells produced through SCNT carry the genetic material of the donor, which means they can be transplanted without causing immune rejection issues. Another way to derive embryonic stem cells is by using embryos that have ceased cell division and are considered deceased organisms. In this context, it could be proposed that the tissues of deceased individuals be donated and frozen for future research use or that living individuals request the freezing of their tissues or cells for potential future use. Although this method may raise ethical concerns and resistance from some quarters, it is viewed as an optimal approach for ensuring the diversity of the genetic pool.

A further source of embryonic stem cells comes from embryos developed from eggs donated to in vitro fertilization (IVF) clinics. These stem cells can be maintained in an undifferentiated state in the laboratory for about six months. At this point, issues may arise if the pluripotent stem cells obtained are used for purposes other than those intended by the donor. If we consider these cells as integral parts of the individual, any use beyond the original intent of the donation could

be seen as infringing upon the personal rights of the donor over these parts of their body. Fetal Stem Cells: Fetal stem cells can be extracted from fetal tissue obtained when a pregnancy is terminated, either voluntarily or involuntarily. Additionally, stem cells can be harvested from umbilical cord blood. Compared to other sources such as bone marrow and peripheral blood, cord blood contains stem cells that require fewer growth factors and have not fully developed their immune characteristics, making them more adaptable for transplantation into another individual. One significant advantage of using cord blood is that its collection poses no risk or burden to the donor. When a suitable donor is found, cord blood can be used immediately, offering a convenient and prompt treatment option. Furthermore, cord blood can be cryopreserved and stored for many years. The establishment of the New York Blood Center marked the beginning of cord blood banking, a practice that has since spread across Europe, notably in cities such as Paris, Milan, and Dusseldorf. To facilitate cord blood transplants between unrelated individuals, a network known as "Netcord" was created in 1998, aiming to organize and standardize these transplants internationally. (Plomer, Torremans, 2009).

Adult Stem Cells: After the eighth week of embryonic development, adult stem cells begin to emerge. These cells can be used for transplantation purposes. Today, embryonic stem cells are being harnessed in various medical fields. For instance, they are used to derive cardiovascular progenitor cells and to generate nerve cells that might treat conditions such as Alzheimer's or Parkinson's disease. Efforts are also underway to produce striated muscle cells to address muscular dystrophy, and to develop insulin-producing beta-islet cells for pancreatic functions. Additionally, they are used to generate blood cells for treating leukemia patients. (ISSCR, 2002).

Points to be Observed When Conducting Research on Humans

Confidentiality of Information

With the increasing applicability of genetic analyses and therapies on humans, one of the challenges that arises is the protection of personal data. Genetic information constitutes personal data, which can extend beyond an individual to encompass their entire family. One difficulty posed by this situation is identifying the person who can make decisions about personal information, thus requiring their consent. The Universal Declaration on Bioethics and Human Rights by UNESCO emphasizes the need for meticulous preservation of personal data. Examining other relevant regulations reveals that some countries' domestic laws specifically address the confidentiality of information. For instance, Article 19 of the Swiss Federal Constitution stipulates that a person's genetic information can only be disclosed to the public with their written consent.

In Switzerland, the Law on Genetic Investigations on Humans specifies that genetic examinations conducted for lineage determination can only proceed with "written consent of the interested party" or "court order" due to the potential invasion of personal data during DNA comparisons revealing information about the mother's sexual life that should remain confidential. According to Article 32 paragraph 3 of the German Genetic Engineering Act, information that needs to be kept confidential due to overriding interests of the operation or a third party shall not be disclosed. Article 21 of the Helsinki Declaration emphasizes the essential respect for the confidentiality of information concerning patients.

he United Nations Convention on the Rights of the Child, in Articles 7 and 9, acknowledges the child's right to know their ancestry and genetic parents. In cases of birth through sperm donation, the child may request the donor's identity information from the clinic based on these rights. The prevailing view in doctrine suggests that clinics should withhold donor identity information until the child attempts to reject their lineage and preserve family relationships. The convention provision is clear, and the child's natural desire to recognize their biological father should be supported. The clinic must provide the donor's identity information to the child upon direct request. Apart from this exception, access to archives containing patient information should be limited to a small number of officials and a

restricted period to prevent misuse. Even in studies conducted using patient information, explicit written consent from patients should be obtained, or data should be shared in encrypted form to ensure anonymity, including photographs. Genetic information should not be disclosed to family members unless necessary, as individuals identified as carriers of a disease or predisposed to it may face difficulties in marriage, employment, or insurance. (Isasi, 2006)

Autonomy

Addressed in Article 8 of the Helsinki Declaration, as well as in the Nuremberg Code and the Belmont Report, the concept of autonomy refers to respecting individuals' decisions about themselves as long as they possess the mental capacity to make those decisions. This includes the right to make decisions independently. According to Article 5 of Part II of the European Convention on Human Rights and Biomedicine, individuals are permitted to freely give their informed consent to interventions on their bodies. A person should autonomously decide whether to participate in research, refrain from participation, or withdraw from ongoing research. When patients are unfamiliar with medical science and language or are in emotional states such as fear or pain that may hinder reaching "rational" and "correct" decisions, paternalistic attitudes displayed by doctors contradict the principle of autonomy. According to Article 17 of the Council of Europe's Convention on Human Rights and Biomedicine, research involving children as subjects must present a strong likelihood of providing direct and concrete benefits to their health. The sole exception is research that is highly likely to benefit other children with the same disease and achieve conclusive results. Therefore, it is concluded that experiments cannot be conducted on healthy children, as this exception is likely only applicable to children who are already ill. (Sherlock, Morrey, 2002)

Prohibition of Commercial Gain

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine addresses that the human body and its parts shall not be used for commercial gain. At this point, the duration for which biological material obtained from the human body can be considered as part of it should be discussed. The classical view that accepts the human body as a whole within its natural limits considers all natural or artificial organs or parts closely connected to the body as integral to bodily integrity. Artificial organs and parts not closely connected to the body are considered as objects. In contrast, the newer view protects organs, tissues, and parts separated from the body under personal rights rather than property rights. This approach ensures that biological material obtained from humans is not treated as an object and cannot be subject to commerce.

From this perspective, medical interventions involving human cells and tissues in some cases may reduce humans to commodities or commercial goods, raising concerns that human dignity cannot be measured in monetary terms. For instance, when a "surrogate motherhood contract" is made between couples seeking to have a child and the surrogate mother, the uterus of the surrogate mother and the child are reduced to the status of goods. The child is delivered to the couple according to the contract terms. In this scenario, the child is commodified and effectively transferred as property. Building on this example, it can be argued that if parts separated from the human body - as we discussed earlier, those who claim property rights over these parts and those advocating personal rights could also consider them as commercial goods. the situation would clearly contradict human dignity. (Dinwiddie, Hoop, Gershon, 2004)

Justice

The principle of justice is primarily outlined in the Belmont Report and the Helsinki Declaration. This principle entails that everyone included in the study should benefit from the same treatment; if there is any deviation in treatment, they must be informed beforehand. Additionally, this principle prohibits excluding anyone from research without valid legal or medical reasons and ensures that no discrimination occurs during subject selection. Particularly in the context of high-risk research or studies with difficult access,

targeting only specific segments such as severely ill or lower-income patients for certain diseases with high potential benefits is also prevented. (Hawkins, 2001)

Use of Obtained Material within Permitted Scope

Given the recognition of an individual's bodily integrity, it is essential to honor the right of the person to determine the fate of their body parts. Whatever purpose the individual has consented to when donating their body part must be respected. If someone donates a body part for a specific purpose, their intention should be honored, and the use of the material should be strictly confined to that agreed-upon purpose. (Sherlock, Morrey, 2002)

Requirement of Informed Consent

Physicians are obligated to prioritize proven methods to heal patients. When these conventional methods are ineffective, they may resort to experimental treatments. For individuals subjected to these treatments, whose effects are not fully known, it is essential to provide accurate and comprehensive information about the interventions on their bodies and obtain their consent afterward. Without informed consent, no intervention can be performed on a patient's body or mental health. The decision of the informed person must be respected. Any intervention on a person's bodily integrity is fundamentally unlawful unless the patient's consent is obtained. Individuals have the right to know the purpose of the research they are being included in, the method of its application, its side effects, potential complications, the measures taken to prevent these complications or minimize their harm, and the duration of the procedures.

Ulus (2007) notes that the first documented instance of obtaining informed consent occurred during Walter Reed's yellow fever experiments in Cuba in the 1900s, where the American military physician prepared consent forms and had participants sign them. The obligation to obtain informed consent and provide information has been enshrined in legal frameworks as well. The Nuremberg Code, in its first article, emphasizes the need for adequate information and voluntariness in human subjects. Article 20 of the Helsinki Declaration discusses the importance of voluntariness and sufficient information, detailing what informed consent should entail. Article 12 of the Council of Europe's Convention on Human Rights and Biomedicine stresses not only the necessity of informed consent and information but also the requirement for genetic counseling. In Switzerland, the Law on Genetic Investigations on Humans requires the consent of the individual before conducting analyses for lineage determination. According to Article 6 of the Human Rights and Biomedicine Convention, for medical interventions involving those who can't give autonomous consent, approval must be obtained from a legal representative along with the subject's assent. Article 8 of the Helsinki Declaration calls for special protection for this disadvantaged group in research. (Salako, 2010)

International Foundations in the Field of Biotechnology

UNESCO Universal Declaration on Bioethics and Human Rights

Another significant international legal text is the Universal Declaration on Bioethics and Human Rights adopted at the UNESCO General Conference on October 19, 2005. Article 6, paragraph 2 of the Declaration emphasizes respect for subjects' autonomy in decision-making and the requirement for individuals' informed consent: "Scientific research should only be carried out with the prior, free, express, and informed consent of the person concerned. The information should be adequate, understandable, and presented in an accessible manner, and should include possibilities for withdrawal of consent without disadvantage or prejudice." Article 2 of the Declaration highlights that the welfare of individuals takes precedence over scientific research. Article 9 underscores respect for individuals' privacy and confidentiality of personal information, emphasizing that subjects' information should be collected by international human rights law, not used or disclosed beyond the purpose of consent. One of the most notable points of the Declaration is found in Article 16, which calls for the preservation of the genetic heritage

of future generations and stresses the necessity of carefully planning the effects of scientific research on future generations. The Declaration affirms the respect for human dignity and human rights, ensuring that the benefits to patients from research are maximized while minimizing harms and that everyone benefits equally from research. (Mousavi, 2017)

Nuremberg Code

The Nuremberg Code, which is the first international text to establish rules regarding experiments on humans, was created by the Nuremberg American Military Tribunal that judged the inhumane research conducted on humans in Nazi camps after World War II. During the trials, in response to defense arguments stating there was no justification for conducting experiments on humans, the tribunal formulated a 10-point code. Article 1 emphasizes voluntary participation in research; Article 2 mandates that experiments be conducted with societal benefit and scientific validity; Article 4 prohibits unnecessary and arbitrary physical/mental harm; Article 5 prevents experiments that pose risks of death or injury to subjects; Article 6 requires that harm to subjects be minimized while benefits are maximized; and Article 9 asserts the principle of autonomy, allowing subjects to withdraw from the research at any stage. (Schmidt, 2007)

The Helsinki Declaration

The Helsinki Declaration, first published in 1964 in Helsinki, Finland, and subsequently updated at various times, establishes ethical principles for medical research involving human subjects, as stated in its first article: "The Declaration of Helsinki was developed as a set of ethical principles for medical research involving human subjects, including research on identifiable human material and data." In the latest revision in 2008, the third article discusses general principles, emphasizing that the Medical Ethics Code dictates that a physician should act solely in the patient's best interest.

In Article 7, the Declaration emphasizes respect for the autonomy and rights of research participants. Article 8 states, "While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects," thereby firmly establishing the boundaries of autonomy within medical research. Article 9 assigns the duty to protect the life, health, dignity, bodily integrity, self-determination, privacy, and confidentiality of personal information of volunteers to the physician conducting the research. These elements form the basis upon which the professional responsibilities of physicians are evaluated.

Article 25 mandates that informed consent must be obtained directly from the subjects if they possess the capacity to give such consent. Article 26, paragraph 2, specifies the key considerations regarding the form of informed consent: "After ensuring that the prospective subject understands the information, the physician or another appropriately qualified individual should then seek the potential subject's freely given informed consent, preferably in writing. If consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed."

Article 28 requires the consent of a legal representative for individuals with limited or no capacity to consent. However, Article 29 further stipulates that if an individual with limited capacity can comprehend and provide informed consent, their consent should be sought alongside that of their legal representative. If the individual expresses a desire not to participate, they should not be included in the research.

These principles underscore the importance of respecting and protecting the rights and welfare of research subjects in the context of medical research and highlight the critical role of informed consent and autonomy.

Article 32 of the declaration underscores the application of autonomy not only to an individual's body but also to its constituent parts. It specifies that in any medical research involving identifiable materials or data, such as those stored in bio banks or similar repositories, physicians must obtain consent regarding the collection, storage, and/or reuse of these materials or data. Article 33 mandates that the benefits derived from research must be disseminated to all. Given the cumulative nature of science, everyone has the right to

benefit from it and to build upon prior research. Article 19 requires that all information about research be documented before its commencement, facilitating oversight by ethical committees. Article 17 outlines that biotechnological research on individuals or groups must offer significant benefits to humans, with a strong expectation of tangible benefits for the subjects. Upholding the principle of no maleficence ("do no harm") is essential. (Schmidt, 2007) The principle of beneficence is addressed in Articles 4 and 7 of the Declaration of Helsinki and in the Belmont Report. Article 2 of the Nuremberg Code stipulates that experiments must benefit society, while Article 4 prohibits unnecessary, arbitrary, and painful interventions by researchers. (Johnkennedy, 2024)

Belmont Report

On April 18, 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in the United States. This commission prepared a guide known as the "Belmont Report," outlining principles to be followed when researching on subjects. The Belmont Report defines three fundamental principles: respect for persons, beneficence, and justice. It emphasizes the necessity of providing subjects with adequate information, especially for autonomy in making decisions about their participation. The report also highlights that scientific research often significantly impacts individuals' social lives, underscoring the researchers' obligation to maximize benefits and minimize potential harms through careful long-term risk-benefit assessments.

Assisted Reproductive Technologies and Genetic Interventions on Embryos

Currently, four distinct assisted reproductive technologies (ART) are being utilized: artificial insemination (in vivo fertilization), Gamete Intrafallopian Transfer (GIFT), in vitro fertilization (IVF), and in vivo fertilization with embryo transfer.

In the in vitro fertilization method, ovulation induction is primarily used to stimulate the female's ovulation. Eggs are surgically retrieved from the female, and sperm obtained from a donor male are injected into these eggs to achieve fertilization in a laboratory setting. The embryos are then cultivated in an incubator. After 3 to 5 days, the embryos are evaluated using specialized techniques, and the ones deemed suitable are transferred into a uterus that has been prepared with hormone treatment.

In assisted reproductive technologies, the eggs and sperm used can come from various sources:

Homologous Insemination: This involves the use of eggs and sperm from the married couple. It is typically used when the male partner has low sperm count or quality, or when the sperm cannot reach or penetrate the egg.

Heterologous Insemination: In this case, the reproductive cells come from someone outside the marriage. For example, an egg from a woman without fertility issues can be donated to another woman. This process involves egg donation to a married couple.

If the eggs from a married woman are fertilized in the lab using sperm from a third party (not her husband), it is referred to as sperm donation. (Shaban, 2022)

Embryo Donation: When both partners in a couple are infertile, eggs and sperm from donors are used. This process is called embryo donation.

Embryo Transfer: Fertilization occurs within another woman's body. After artificial insemination, a biopsy is performed on the embryo, usually when it has between 6 to 10 cells, around 3 to 5 days after fertilization. Cells are taken from the embryo and examined under a laser microscope. This technique can diagnose chromosomal anomalies or single-gene disorders through a method called preimplantation genetic diagnosis (PGD).

PGD: Preimplantation genetic diagnosis helps prevent potential abortions by allowing the selection of healthy embryos before pregnancy. This reduces the number of pregnancies needed to have a healthy child. However, it raises ethical concerns as embryos predicted to be born with disabilities are often discarded. Embryos not meeting certain desired traits are not given a chance to live, which is a form of genetic selection. The widespread use of genetic selection could lead to increasingly strict selection criteria and eventually result in a population with high-

ly standardized phenotypes. (Plomer, Torremans, 2009)

According to Emine E. Vaatanoğlu Lutz, the first application of assisted reproductive technologies was performed by Dr. Robert Edwards. In 1978, the world's first "test-tube baby," Louise Brown, was born in Manchester, England. Similarly, the first baby born through in vitro fertilization (IVF) in France was Amandine, also born in 1978.

With the advent of research on embryos, the issue of creating embryos specifically for stem cell production has emerged. Article 18 of the European Convention on Human Rights and Biomedicine, commonly referred to as the Oviedo Convention, explicitly prohibits the creation of human embryos solely for research purposes. This prohibition does not extend to the creation of embryos for therapeutic purposes, such as in vitro fertilization (IVF), which is explicitly allowed.

Interpreting the Oviedo Convention broadly could inadvertently encourage "in vitro tourism," where couples from member countries seek IVF treatments in non-member states to circumvent restrictions. Such an outcome would conflict with the convention's intent.

Regarding the source of embryos for research, L.M. Guenin from Harvard Medical School advocates for the use of surplus embryos obtained from laboratories or clinics. These are embryos that are not intended to be implanted and allowed to develop into humans. For example, aneuploid embryos, which have chromosomal abnormalities and thus will not be transferred to the mother, can be utilized for research purposes. Similarly, women undergoing IVF could be asked to donate one or two additional eggs for research during the process.

In research involving embryos or pre-embryos, there can be scenarios where the embryos are destroyed or their development is terminated. This raises significant ethical debates about when an embryo should be considered "human" and thus protected under the notion of "human dignity." (Shaban, 2022)

One primary perspective is that the status of being human begins at fertilization, the moment when the gametes merge. Since the zygote possesses all the genetic information necessary for human development, it is attributed to human dignity from this point. This view emphasizes the species criterion, arguing that once an embryo enters the human species, it should be afforded protection specific to that species. This position is reinforced by Germany's Embryo Protection Act of 1990 and the Stem Cell Act of 2001, which both support the idea that human dignity begins at fertilization.

We believe this view is the most appropriate. However, there are also other perspectives that suggest the quality of being human starts either at implantation in the uterus or at the formation of the primitive streak (a structure that appears around the 14th day of development).

Legal Protections for Embryos

French Law

In French law, embryos cannot be used for the benefit of others without written consent from the genetic parents. Research and experimentation on embryos are permitted within the first 7 days after fertilization if the embryo directly benefits from the research or if it is conducted to obtain scientific data.

To regulate biotechnology, France enacted Law No. 94-654 in 1994, which governs the treatment of the human body, its parts, products derived from it, and the fate of assisted reproductive technologies. This law established foundational principles for managing biotechnological and medical practices.

The 2004 Bioethics Law further delineates the legal status of genetic treatments and genetic products. The National Consultative Ethics Committee for Life Sciences and Health (CCNE) in France has been divided on whether to permit therapeutic cloning. However, the majority opinion within the committee favors allowing it under strict regulation.

According to the CCNE, research involving embryonic stem cells is restricted to the use of:

- Embryos from spontaneous abortions (miscarriages),

- Surplus embryos produced during IVF that are not intended for implantation,

- Embryos that have had their cell nuclei removed.

The committee acknowledges that human embryos deserve respect and dignity. Consequently, creating embryos solely for research purposes is prohibited. However, there is an exception for the advancement of medical research through the use of embryos obtained via assisted reproductive technologies.

In 1998, France established the French Agency for the Safety of Health Products (AFSSAPS) to oversee genetic therapy research. This agency collaborates with the Biomedicine Agency and has the authority to regulate the preparation, transformation, and use of human tissues and organs in genetic therapies.

Under French law, only authorized entities can produce, store, distribute, or trade genetic therapy products. Unauthorized production, storage, distribution, commercial use, or the import and export of these products are strictly prohibited. This regulatory framework ensures that genetic therapies and associated products are handled with care and accountability. (Sirota, 2010)

Irish Law

The Constitution of the Republic of Ireland represents one of the most extreme examples of legal protection for embryos, as it safeguards embryos in the same way as it does individuals. (Sezen, 2015)

German Law

In the Embryo Protection Act of 1990, a human embryo is defined as a fertilized egg that, over time, can complete the fusion of nuclei. Additionally, it includes any totipotent cell derived from the embryo that has the ability to divide and develop into specific parts of a human being under necessary conditions. Interventions that do not benefit the human embryo are prohibited. Artificial fertilization is permitted solely for the purpose of initiating a pregnancy. (BEKSAÇ, 2004)

English Law

Under the Human Fertilisation and Embryology Act of 1990, an embryo at the moment of fertilization is defined as a living human embryo. From that point onward, any scientific research conducted on the embryo requires a license or special permit. To obtain this permit, research must aim to improve assisted reproductive techniques, enhance knowledge about defective births or genetic diseases, or similar objectives, and it must be conducted within 14 days of fertilization. Additionally, the written consent of the genetic parents is required for such research to be carried out. (Pourebrahim, 2021)

Swiss Law

The Swiss Federal Constitution addresses the protection of embryos and the regulation of genetic technologies in Article 119. According to paragraph 1, it is necessary to protect human reproductive health and prevent the misuse of genetic technology. Paragraph 2 further specifies that genetic material and reproductive cells cannot be used unlawfully. It explicitly prohibits the combination of human reproductive cells or genetic material with non-human reproductive cells or genetic materials in experiments. Additionally, gene transfer is only permissible under medical necessity, and the implantation of a non-human egg into a woman is strictly forbidden.

Article 120 extends these protections by stating that both humans and their environment must be safeguarded against the misuse of genetic technologies. This comprehensive legal framework ensures that human genetic material and reproductive processes are stringently regulated to prevent unethical practices and protect human dignity. (Sezen, 2015)

American Law

In August 2001, U.S. President George W. Bush announced a policy restricting stem cell research. According to this directive, embryonic stem cell techniques could only be used for in vitro fertilization purposes, and healthy fetuses could not be used to obtain embryonic stem cells. The policy also stated that research on donated embryos would not receive government funding. The directive did not include regulations for situations such as the sale of dead embryos or fetuses. For government-supported research involving embryos, it was required that the donor have a surplus of embryos and provide informed consent.

In contrast, the European Union's Life Sciences High-Level Group recommended in a December 2001 evaluation that the EU continue to support all stem cell research. The EU accepted the use of surplus embryos for the extraction of stem cells. (Andorno, 2005)

Results

Ethical and Legal Implications of Genetic Intervention and Human Cloning

Genetic engineering is progressing at an unstoppable pace. The concept of "reprogenetics," first introduced by Silver, involves imparting desired traits to early embryos and allowing these "selected" embryos to develop. This raises concerns that parents might eventually have the power to pre-determine the life paths of their children. Parents could potentially decide their child's mental, physical, or even sexual characteristics beforehand. Consequently, children born with specific traits enhanced through genetic modification would have advantages over their peers.

Families who choose to support their child's natural development might face accusations of failing in their parental duty to select the best possible options for their child if they reject genetic enhancement. If one parent opposes genetic enhancement while the other supports it, this disagreement could lead to accusations within the marriage, potentially causing marital discord and even leading to divorce being cited as a specific reason.

Children from families who cannot afford reprogenetic interventions may risk being treated as second-class citizens by their generation. All these possibilities would starkly violate Article 1 of the Universal Declaration of Human Rights, which asserts that all humans are born free and equal in dignity and rights.

Another controversial practice observed in some East Asian countries involves selecting the gender of the child due to social factors. (Goodwin, Mehlman, 2007)

The practice of having "custom-designed children" is emerging, where "clients" who choose this route typically prefer male children. This trend poses a significant threat to gender balance. Another contentious practice involves using Preimplantation Genetic Testing (PGT) to select embryos with compatible tissue types to create a suitable donor sibling. This is done to obtain stem cells from the umbilical cord blood or bone marrow of the newly born sibling to treat an older sibling with a genetic disorder. A notable example is Molly Nash, diagnosed with Fanconi anemia, whose parents used PGD and IVF to conceive Adam Nash, born in August 2000 as a healthy donor baby. (Petersen, 2023)

The ethical dilemma arises when a person is born primarily to serve as a tissue donor for another individual, reducing the donor child to a means to an end. This situation challenges the dignity of the child conceived to provide tissue, as they are subjected to bodily interventions before reaching an age where they can consent. Even if the argument of the greater good or necessity for the sick sibling is invoked, the dignity of the child from whom tissue is harvested and the potential abuse of parental authority to consent to invasive procedures on the child's body cannot be overlooked. Once alternative methods for stem cell harvesting that achieve similar results without creating donor siblings become available, it is clear that the practice of producing donor children should be discontinued. (Mayall, 2013)

One controversial issue arising from IVF is multiple pregnancies. To increase the chances of conception, doctors often implant three or four embryos at once. This practice not only poses risks to the mother's health but also endangers the fetus with complications such as miscarriage and premature birth. In cases where multiple pregnancies are seen as unsuccessful in IVF treatments, gynecologists may opt for interventions. One approach is embryo reduction, where a few fetuses are selectively terminated and removed from the placenta. The most common method of reduction involves using ultrasound-guided needle insertion to inject potassium chloride into the fetus's heart. Embryo reduction is ethically contentious due to concerns that it could lead to the loss of the entire pregnancy and negatively affect the development of the remaining fetuses left intact. (Stasi, 2023)

The increasing importance of genetic research and analysis, driven by the necessity to conduct these studies, has elevated the significance of gene sequences. This has led to the commencement of patenting gene sequences themselves, mutations of these genes, or therapeutic methods developed using human genetic material. However, reducing human genetic heritage, represented by gene sequences, to mere commodities owned by specific individuals or groups is ethically unacceptable.

Groups holding gene patents would wield monopolistic power over treatments that could be essential for the majority. While Article 29 of the European Patent Convention prohibits the granting of patents on the human body, substances isolated from the human body that can be produced without needing the human body itself, including gene sequences, are eligible for patenting. Genetic Copying of Human Cells – Cloning: Cloning technology raises possibilities for infertile couples to have children, for individuals grieving the loss of loved ones to potentially bring them back, for those seeking to overcome death by creating successive clones, or for patients needing donor tissues to create replicas of themselves. Critics who oppose applying cloning technology to humans argue that a cloned individual would be reduced to a mere "tool" for providing organs to its genetic donor, lacking uniqueness and violating human autonomy. They also argue that inevitable dominance over the clone by its genetic donor would undermine equality among humans. Another basis of anti-cloning views is the concern that individuals cloned from adult body cells would be identical down to their fingerprints. Even if surveillance responsibility over clones were regulated, modern criminal justice systems, focused on rehabilitating individuals with minimal possible harm, would not accept convicting someone whose status as the true perpetrator cannot be established. The prohibition of human reproductive cloning is a widely debated and accepted concept in international law. The European Convention on Human Rights and Biomedicine, in Article 18, prohibits the production of in vitro embryos and, in Article 13, prohibits altering the genetic structure of future generations. The first article of the Convention safeguards human dignity.

The Additional Protocol to the Convention on Human Cloning, Article 1, explicitly prohibits the creation of genetically identical human beings, whether living or deceased. The High-Level Group on Life Sciences established by the European Commission emphasized in its assessment published in December 2001 that reproductive cloning should be banned in stem cell research. The American Medical Association, in its statement H-460.915 published between 2000-2001, supported therapeutic cloning but opposed the use of somatic cell nuclear transfer for reproductive cloning. On April 25, 2002, the American Society of Hematology (ASH) called for the facilitation of therapeutic cloning research.

Regarding the implications for cloned individuals, there are divergent views. Critics argue that a clone would be unable to establish a unique life because it would be constrained to follow the donor's life trajectory, thereby severely compromising the clone's autonomy. On the other hand, proponents argue against solely attributing the determination of human life to genes, emphasizing the influence of the environment and pointing to the existence of identical twins who, despite sharing the same genetic makeup, develop distinct personalities. One significant concern is the unknown consequences leading to potential deaths or disabilities of "potential humans" until human cloning achieves success. (Goodwin, Mehlman, 2007)

Legal Issues Arising from Human Cloning Practices in Family and Inheritance Law

Between a child and its parents, there traditionally existed two types of parentage: biological-genetic, known as "real parentage," and non-biological, which is established by the court decision, known as "artificial parentage." With advancements in genetic technology today, the parentage of children born through artificial insemination can be disputed depending on the variability of donors. Adding to this complexity is the situation of cloned individuals.

In reproductive cloning, sperm is not required.

The nucleus extracted from a body cell is inserted into an egg cell whose nucleus has been removed. The fertilized cell is then transferred to the uterus, resulting in a child who is a genetic copy of the person whose body cell nucleus was used. Due to the technique of cloning, traditional family structures are inevitably disrupted. Will the cloned individual be considered the child of the person whose cell nucleus was taken, or in cases where cloning was used to create a donor, will they be considered a sibling? The implications of a sibling also being a "parent" or the potential for a genetic copy of a person's mother to feel a sexual closeness to the genetic donor need to be discussed. The inability to determine the parentage status between a cloned individual and the donor will complicate the calculation of inheritance shares. (Stasi, 2023)

Discussion

The rapid advancements in biotechnological applications on the human body have created unprecedented opportunities to enhance human health and quality of life. However, they also pose profound ethical, legal, and societal challenges. Fundamental human rights, such as dignity, autonomy, and bodily integrity, must remain the guiding principles in navigating these developments. the central challenge of biotechnological applications on humans lies in the potential violation of fundamental rights, particularly human dignity and bodily integrity, which individuals inherently possess from birth—and, as emphasized, even before birth. At the core of this issue is the difficulty of ethically justifying such violations, making informed consent a cornerstone of biotechnological practices. Despite concerns that embryo research might lead to eugenics or destabilize traditional family structures, advancements in this field continue to accelerate. The lack of a unified international response or consistent prohibitions has allowed researchers to pursue their work in countries with more permissive legal frameworks, driving progress in areas such as stem cell research, reprogenetics, preimplantation genetic diagnosis (PGD), and cloning technologies. Meanwhile, researchers in stricter jurisdictions often fall behind. These innovations have undeniably contributed to enhancing human health and quality of life but have also highlighted significant ethical and regulatory dilemmas. For instance, while speculative, the idea that cloned individuals could one day become cherished slaves of modern society raises profound moral and legal concerns. To prevent such dystopian outcomes, it is crucial to establish a balanced framework that supports the advancement of genetic research while firmly upholding fundamental human rights. Without such safeguards, the risks of harmful scenarios becoming reality remain high. This underscores the urgent need for international collaboration to harmonize ethical and legal standards in biotechnology.

References

Andorno, R. (2005). The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law. Journal of International Biotechnology Law, 2(4), 133-143.

Dinwiddie, S. H., Hoop, J., & Gershon, E. S. (2004). Ethical issues in the use of genetic information. International Review of Psychiatry, 16(4), 320–328.

Goodwin, M., & Mehlman, M. J. (2007). Biotechnology, Bioethics, and the Law. LexisNexis.

Hawkins, A. (2001), Protecting Human Dignity and Individuality: The Need for Uniformity in International Cloning Legislation, The Transnational Lawyer, v. 14, 2001, pp. 246-267.

Isasi, R., & Knoppers, B. M. (2006). Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries. European Journal of Health Law, 13(1), 9-26.

Johnkennedy, N. (2024). Biotechnology and its Applications, Biomedical Studies and Clinical Evaluations (BSCE) 1 (1).

Mayall, B. (2013), A History of the Sociology of Childhood, Institute of Education Press, London.

Mousavi, S. F. and Mirmohammadi, M. (2017). International Legal Regime Governing Human and Non-Human Genetic Resources. International Law Review, 34(56), 61-86.

Petersen, A. (2023). Patenting Human Biological Materials and Data. Journal of Intellectual Property Law & Practice, 18(7), 546-556.

Plomer, A., & Torremans, P. (Eds.). (2009). Embryonic Stem Cell Patents: European Law and Ethics. Oxford University Press.

Pourebrahim, A. (2021). A Comparative Study of

Criminal Laws and Regulations Regarding Stem Cell Technology in the British Legal System and Iranian Law; Challenges and Solutions. Journal of Comparative Law, 8(2), 75-94.

Salako, S E. (2010). "Informed Consent under the European Convention on Biomedicine and the UNESCO Declaration on Bioethics", Medicine and Law, 30(1).

Schmidt, H. (2007). "Whose Dignity? Resolving Ambigui- ties in the Scope of 'Human Dignity' in the Univer- sal Decleration on Bioethics and Human Rights" Jmed Ethics, 33(10).

Sezen, O. (2015). International Legal Dimension of Biotechnologic Practises on Human Body, Anadolu University Faculty of Law Journal, 1(1), 82-107.

Shaban, M. (2022). New Reproductive-Biological Technologies and Child Rights: An Introduction to the Future of Childhood in Iran. Fares Law Research, 5(10), 283-314.

Sherlock, R., & Morrey, J. D. (2002). Ethical Issues in Biotechnology. Rowman & Littlefield Publishers.

Sirota, R. (2010), French Childhood Sociology: An Unusual, Minor Topic or Well- Defined Field? Current Sociology 58 (2): 250-271.

Stasi, A. (2023). Biotechnology Law and Policy: Emerging Legal Issues, Cases and Materials. Springer.

The international society for stem cell research (ISSCR). Guideline for the clinical of nslationtra stem cell. 2002.