

## Regulating advanced biomedical technologies: A modern criminal law perspective

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**Abstract:** This study explores the urgent need for criminal law to address the advancements in biomedical technologies, particularly focusing on cloning. It highlights the dichotomy between the potential therapeutic benefits of cloning technologies, such as combating hereditary diseases, and their possible misuse. The paper discusses international legal frameworks and declarations, such as the United Nations Declaration on Human Cloning and the Council of Europe Convention on Human Rights and Biomedicine, which seek to navigate the ethical and legal challenges of cloning. The distinction between therapeutic and reproductive cloning is emphasized, with therapeutic cloning offering significant medical advancements raising profound ethical concerns, particularly regarding the moral status of the embryo. The paper critiques the current legislative landscape in the Republic of Armenia, which it finds insufficient in addressing the complexities introduced by these technologies, suggesting a need for comprehensive legal reform to safeguard human dignity and genetic integrity within the context of modern medicine.

**Keywords:** *Biomedical technologies, Bioprinting, Cloning, Criminal law, Genetic manipulation.*

### 1. Introduction

In the field of contemporary medicine, the rapid evolution of biomedical technologies is transforming treatment options and challenging existing legal norms. Technologies such as genetic editing and cloning offer unprecedented opportunities to treat diseases previously deemed untreatable, including genetic disorders. However, these advances also raise significant ethical and legal concerns, particularly regarding their potential misuse that could endanger individuals or society. This text underscores the critical need for a comprehensive legal framework that effectively balances these technologies' potential benefits and risks. It particularly examines the adequacy of criminal laws in the Republic of Armenia in light of international standards, exploring how these laws might be adapted to safeguard society while promoting scientific progress. By comparing international legal principles with national legislation, this analysis identifies essential disparities and suggests required reforms to ensure the ethical development and legal safeguarding of biomedical technologies.

### 2. Human Cloning as an Advanced Biomedical Technology

With the advancement of medical technologies and the introduction of cutting-edge biomedical innovations, there is an increasing need for criminal law to protect related social interests and to criminalize new behaviors. Modern biomedical technologies are crucial for treating diseases previously considered incurable, such as hereditary conditions. However, there are risks associated with their illegal use for criminal purposes. Notably, cloning has shown significant potential in addressing diseases like Alzheimer's and Parkinson's. Furthermore, substances derived from embryonic and fetal cells are

garnering attention for their potential in developing new therapeutic agents. [1] One area where the latest biomedical technologies could be applied is human cloning, which presents significant public and scientific risks and lacks consensus within the global community. In light of this, it is crucial to establish proper criminal law regulations for offenses involving these advanced technologies. Currently, Armenian criminal legislation falls short of keeping up with the rapid advancements in biomedical technologies, unlike the laws in some foreign countries, which thoroughly address criminal liability for cloning, assaults on human embryos, and criminal genome manipulations.

Given the global significance of the issue, several international legal instruments have been adopted concerning the regulation of the latest biomedical technologies, particularly the prohibition of cloning. Notably, the United Nations Declaration on Human Cloning urges member states to ban all forms of human cloning that conflict with human dignity and the protection of human life. [2] Additionally, the Council of Europe's Additional Protocol to the Convention on Human Rights and Biomedicine, dated January 12, 1998, emphasizes that intentional human cloning threatens individuality by allowing genetic predetermination by third parties. This protocol remains neutral on the cloning of cells and tissues for research and medical use, indicating that cloning serves as a valuable tool in medical advancement and the development of new treatments. Furthermore, Article 3 of the Charter of Fundamental Rights of the European Union enshrines the right to personal integrity, underpinning this right with a ban on reproductive cloning while distinguishing between reproductive and therapeutic cloning.

### 3. Types of Cloning and their Ethical Considerations

Cloning can be categorized based on its intended purposes. There are primarily two types: reproductive cloning, which aims to create a human being as a means of reproduction, and therapeutic cloning, intended for medical purposes such as organ regeneration for the individual from whom the cells were sourced. Supporters of therapeutic cloning advocate for its use on humanitarian grounds, emphasizing the importance of preserving and saving human lives. [3]

In addressing the legislative regulation of cloning in the Republic of Armenia, it's notable that Article 186 of the Criminal Code specifically criminalizes reproductive cloning but does not extend criminal liability to therapeutic cloning. Cloning represents a complex intersection between law and morality. The current criminal legislation in Armenia does not adequately cover the ethical and moral implications associated with cloning. While therapeutic cloning has potential benefits, particularly in expanding transplantation options amidst a donor organ shortage, it also raises significant ethical concerns. Cloning, in principle, challenges the inherent dignity of human beings, considered an inviolable value that demands stringent legal safeguards. The deliberate cloning of humans threatens individual uniqueness by allowing genetic determination by third parties, thus contravening the core principle of protecting a person's genetic autonomy. [4]

The principle of protecting human dignity is universally recognized at the international level and is a core aspect of criminal law protection. As an inalienable right and a special value that transcends monetary equivalence, human dignity is undoubtedly safeguarded under criminal law. This protection covers various dimensions of human rights and ethical considerations, ensuring that the intrinsic worth and respect of every individual are legally upheld. [5] The social conditioning of the criminalization of acts related to the infringement of genetic dignity is evident against the background of the rapid development of genetic research not only in Russia but also abroad. [6]

In the context of therapeutic cloning, research involves developing an embryo for up to 14 days before halting its growth; this embryo is not implanted into a uterine cavity. The primary objective of therapeutic cloning is to harvest embryonic stem cells to grow new organs. A key area of scientific inquiry is whether human embryonic stem cells—as opposed to stem cells derived from adult tissues—represent the most promising treatment option. Further, research is ongoing to determine whether creating cloned embryos specifically as a source of stem cells offers superior therapeutic benefits. This

exploration highlights the complex ethical and scientific considerations involved in the use of therapeutic cloning. [7].

#### 4. Legislative Response in Armenia

The use of embryonic stem cells in biomedicine inherently involves the destruction of the embryo, raising significant moral and legal questions regarding the embryo's status. [8]. In the Republic of Armenia, criminal legislation attempts to provide some level of protection for the embryo. For instance, there are provisions for criminal liability related to the non-performance or improper performance of medical duties resulting in harm to the embryo or fetus, as well as for the illegal trafficking of human embryos.

However, the absence of criminal responsibility specifically for therapeutic cloning indicates a gap in the legal recognition and protection of the human embryo at all developmental stages. Internationally, some national constitutions, such as those of the Slovak Republic and the Czech Republic, explicitly mandate the protection of human life from conception, emphasizing that "human life is worthy of protection even before birth." [9].

Furthermore, the European Court of Human Rights has ruled that therapeutic procedures using embryonic stem cells cannot be patented because the destruction of embryos for stem cell procurement contradicts the principle of protecting human dignity. In countries like Germany and Switzerland, national laws prohibit the harvesting of embryonic stem cells, recognizing that human life begins at fertilization. However, scientists in these countries are permitted to work with cells imported from other countries, as well as with animal cells and adult human tissue stem cells. This complex legal landscape reflects varied approaches to balancing the potential benefits of biomedical research with ethical considerations and the protection of human dignity. [10]. In addition to the ethical objection to "therapeutic cloning"—the creation of embryos specifically for research, thereby reducing them to mere tools for external objectives—there is also a significant concern that it could pave the way for "reproductive cloning," or cloning to produce babies. This fear stems from the notion that normalizing the use of embryos in therapeutic cloning might lower societal and ethical barriers, making reproductive cloning seem more acceptable or feasible. These ethical challenges highlight the need for rigorous debate and careful regulation to balance scientific advancement with respect for human dignity and ethical standards." [11] Indeed, while the medical benefits of therapeutic cloning and the resulting stem cells are significant, they must be balanced against the imperative of human dignity. Therapeutic cloning involves artificially creating an embryo, which is then deliberately destroyed, posing profound ethical and legal dilemmas about the embryo's status. This process raises the question: Is it ethically or legally justifiable to destroy an embryo to potentially save another person's life?

The moral controversy is further heightened by views from the clergy, who often view the cloning and subsequent destruction of human embryos as akin to abortion, underscoring the moral complexity of treating human embryos as a means to an end.

Internationally, approaches vary. For example, India's stance on cloning is guided by a prohibition on reproductive cloning as decreed by the Indian Council of Medical Research. [12]. However, therapeutic cloning remains a possibility but is strictly regulated, requiring case-by-case approval from the National Bioethics Committee. This method of regulation reflects an attempt to navigate the ethical intricacies of therapeutic cloning while considering the potential medical benefits under stringent ethical oversight. [13].

The stance of the National Episcopal Conference of Canada highlights a deeply rooted ethical perspective on the status of embryos, particularly in the context of discussions around reproductive health and cloning. The leadership unequivocally asserts that an embryo should be regarded as a person, emphasizing a philosophical rather than purely biological view of what constitutes a "human being." This viewpoint stresses that all individuals were once embryos and that human life should be seen as a continuous journey, suggesting that embryos share the same fundamental human rights as fully developed humans. This perspective is anchored both in reason and faith, reinforcing the Catholic

doctrine that a human being deserves respect and should be recognized as a person from the very beginning. [14]. This position influences their ethical considerations and legislative recommendations concerning cloning and reproductive health.

In Poland, the emphasis on the primary protection of the human embryo has led to a total ban on abortions prompted by embryonic pathology, underscoring the country's strict stance on embryo rights.

Given the profound social and ethical implications of cloning, it is proposed that the Republic of Armenia amend its criminal legislation to include criminal liability for therapeutic cloning as well. This recommendation reflects a concern over the increasing dominance of scientific and technological advances potentially overshadowing ethical and moral considerations. Introducing such legal measures could align Armenia's policies with a broader ethical framework that seeks to balance technological progress with fundamental moral principles.

Indeed, bioprinting offers a promising alternative to therapeutic cloning for expanding the possibilities of organ and tissue transplantation. While still in its early stages, bioprinting has the potential to revolutionize the medical field by enabling the production of human organs that are tailored to the specific structural, size, and complexity requirements of individual patients. This technology could significantly reduce the reliance on donor organs and circumvent some of the ethical concerns associated with cloning, such as the destruction of embryos. As bioprinting technology matures, it could provide a more ethically acceptable and potentially more effective solution for addressing organ shortages and enhancing transplantation outcomes. To this point, there have been significant developments in cartilage, bone, and skin tissue bioprinting [15]. a human ear [16]. and a miniature human heart [17]. have also been successfully bioprinted by researchers, and significant progress has been made toward the ultimate objective of supplying larger human organs with blood vessels and capillaries [18].

## 5. Alternative Technologies and Future Directions

Bioprinting is described in specialized literature as a high-precision, additive manufacturing technology that constructs three-dimensional tissues and organs layer by layer. This process utilizes a digital model to specify the external and internal architecture of the constructs, with living cells serving as the printing material. This innovative approach allows for the creation of complex biological structures that closely mimic natural tissues, potentially revolutionizing medical treatments and transplantation. [19]. This innovative development in bioprinting aims to address the critical shortage of donor organs. By eliminating the need to extract organs or tissues from living donors or cadavers, bioprinting uses the patient's living cells as the material for creating custom organs. This approach not only reduces the reliance on donor organs but also significantly lowers the risks of immune rejection, as the organs are created from the recipient's cells. Thus, bioprinting holds the potential to revolutionize transplant medicine by providing safer, more accessible, and personalized treatment options. [20].

Armenian researchers have played a pivotal role in advancing the practical application of bioprinting technology. The Armenian startup Foldink has made significant strides by developing biological materials for organ and tissue printing. This new technology, which is gaining attention worldwide, enables the creation of organs or skin using specialized 3D printers that utilize biological "inks." These inks are designed to closely mimic the extracellular matrix of living tissues—the substance that binds cells together within the body.

The benefits of this technology are manifold. Firstly, it eliminates the need for donor organs, addressing both the shortage of available organs and the logistical and ethical challenges associated with organ donation. Secondly, since the organs are biofabricated from cells derived from the recipient, the risk of immune rejection is drastically reduced. This obviates the need for lifelong immunosuppressive drugs, which are currently required to prevent rejection after traditional transplants. These advancements not only promise to transform the landscape of transplantation but also enhance the quality of life for recipients. [21]. While bioprinting of organs offers revolutionary potential in medicine, it also presents ethical challenges, particularly regarding the use of embryonic

stem cells. As noted by V. A. Mironov, the raw materials for "bio-inks" include stem cells derived from three sources, one of which involves embryonic stem cells. This method poses significant ethical issues as it involves the destruction of human embryos to extract stem cells, raising concerns about the protection of the embryo's rights." [22]. The latter method of creating bio-inks carries a direct threat to the proper protection of the human embryo, as it inevitably entails their destruction for the subsequent extraction of embryonic stem cells.

Given the rapid advancements in bioprinting and other innovative medical technologies, there is an urgent need to enhance the legal framework to address these developments adequately. First of all, it is necessary to determine the legal status of the embryo and provide proper criminal law protection of the embryo and, as a consequence, establish criminal responsibility for the use of embryonic stem cells for creating bio-inks. In addition to the noted, it is advisable to establish criminal responsibility for other encroachments in the field of bioprinting, in particular, the theft of organs created from bio-inks, etc.

Thus, the scientific developments in the field of bioprinting procedure and the possibility of creating bio-inks for printing organs from embryonic/embryonic tissues actualize the question of proper criminal law protection of human life from the moment of conception (protection of the proembryo, embryo). Bioprinting of human organs, as well as all types of cloning, violates several fundamental and inalienable human rights, including the right to life, the right to dignity, including the genetic dignity of a person.

The issue of the placement of cloning in the Special Part of the Criminal Code of foreign countries is resolved differently, however, it should be noted that several countries consider it as a special category of crimes against the personality of cloning in the Special Part, this act is usually referred to a special category of crimes against the person (Hungary, Colombia, Romania, El Salvador, Estonia). Thus, in the Criminal Code of Colombia, within the section on crimes against the person, it is included in the chapter "On genetic manipulations," in the Criminal Code of Romania - "Crimes related to genetic manipulation," in the Criminal Code of Estonia - "Illegal handling of a human embryo." [23].

The proposal to categorize crimes related to the latest biomedical technologies as iatrogenic crimes—specifically, non-traditional iatrogenic crimes—underscores a nuanced approach to evolving medical practices and technologies. Given the theoretical groundwork already laid regarding the classification and systematization of iatrogenic crimes, integrating an independent chapter into the criminal legislation of the Republic of Armenia dedicated to these crimes is a strategic move. This would serve several purposes:

1. Clarification and Specificity: By clearly defining these crimes within their section, the legislation would offer more precise legal language tailored to the unique complexities of biomedical technology. This can help avoid ambiguities that might arise from broader legal terms.

2. Enhanced Legal Framework: This dedicated chapter would create a structured framework that could more effectively regulate the rapidly advancing field of biomedical technologies, ensuring that the law keeps pace with technological innovations.

3. Focused Enforcement and Education: With specific laws in place, law enforcement and judiciary systems can be better trained and equipped to handle these types of crimes. Additionally, individuals and organizations involved in biomedical technologies would have clearer guidelines, which could help prevent unintentional legal violations.

4. Ethical Safeguards: A specific chapter on these technologies would reflect and enforce ethical standards within the field, addressing both public concerns and professional responsibilities.

5. International Alignment: This move could also align Armenia's legislation with global trends where similar legal structures are adopted to handle complex issues arising from new technologies in healthcare and medicine.

Incorporating these changes into Armenia's criminal legislation would not only strengthen the legal response to potential abuses but also support the responsible development of biomedical technologies.



## 6. Conclusion

In conclusion, as biomedical technologies rapidly advance, particularly in the realms of cloning and genetic manipulation, it is imperative that criminal law keeps pace to address emerging ethical and legal challenges. This text highlights the critical need for the Republic of Armenia, like other countries, to reevaluate and enhance its legal frameworks to effectively govern these technologies. By aligning national legislation with international standards, particularly those concerning human dignity and the prohibition of cloning, Armenia can better protect its citizens while still embracing the benefits of medical innovations.

Furthermore, exploring alternatives such as bioprinting presents a viable path forward that balances ethical considerations with scientific advancement. Ultimately, updating and refining criminal laws to cover new biomedical technologies will not only safeguard individual rights but also foster a legal environment that nurtures innovation in a morally and ethically responsible manner.

Thus, to address the advancements in biomedical technologies, particularly in the areas of cloning and genetic manipulation, it is necessary to implement the following recommendations:

1. It is essential that Armenian criminal law is revised to include comprehensive regulations on new biomedical technologies. This includes clearly defining and differentiating between therapeutic and reproductive cloning, and establishing criminal responsibility for unethical practices.
2. Republic of Armenia should align its legal standards with international frameworks, such as the United Nations Declaration on Human Cloning and the Council of Europe Convention on Human Rights and Biomedicine. This alignment will help ensure that Armenian laws reflect global ethical norms and legal practices regarding biomedical technologies.
3. The legal status of embryos, particularly in the context of therapeutic cloning and bioprinting, needs a clear definition. Criminal liability should be established for activities that harm the embryo, aligning with the ethical stance that human life deserves protection from conception.
4. As bioprinting emerges as a promising alternative to therapeutic cloning, specific regulations should be developed to manage this technology. This includes the ethical sourcing of biological materials, especially when involving embryonic stem cells, to prevent the destruction of embryos.
5. Given the unique nature of crimes involving biomedical technologies, a specialized chapter in the Criminal Code should be dedicated to these issues. This would clarify legal positions and facilitate the enforcement of laws specific to biomedical advancements.
6. Encourage the development and use of medical technologies like bioprinting that minimize ethical controversies, such as those surrounding donor organ shortages and embryo use.

By implementing these recommendations, Armenia can better navigate the complex interplay between law, ethics, and biomedical technology, ensuring both the advancement of medical science and the protection of fundamental human rights.

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