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Bioethics, Human Rights and Legal Accountability in Biotechnology Research

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A Critical Study of Confidentiality Obligations and Insider Trading Risks in Mergers and Acquisitions Transactions in India

ABSTRACT

In modern society, biotechnological studies have brought a revolution in the area of health care, agriculture, and environment management. As a result of the process, a great number of ethical and legal dilemmas arise connected to the protection of human rights in biotechnology. Gene editing, stem cell treatment, and synthetic biology give inexhaustible opportunities; however, they create many questions for existing legal principles and bioethics principles. The aim of the current research is to analyse ethical and legal problems in biotechnology and consider the dilemmas linked to bioethics and human rights. The issues related to autonomy, informed consent, beneficence, and justice will be considered within the framework of the existence of ethical and legal norms in national and international legislation in relation to science and technologies. In particular, genetic privacy, fair distribution of benefits obtained from biotechnological studies, and potential risks connected to the use of biotechnology and vulnerability of people will be considered. In accordance with the text, it is vital for legal accountability measures to be improved while maintaining scientific flexibility so as to ensure human dignity and promote good science practices. In other words, there needs to be a combined measure of ethics and law that should be enforced for the good of the society. Moreover, the comparisons made between the different sets of regulations present globally demonstrate the necessity of harmonizing bioethics principles in order to address the issue of cooperation across international boundaries.

KEYWORDS

Biotechnology, Bioethics, Human Rights, Legal Accountability, Genetic Privacy

1. INTRODUCTION

Biotechnology is currently recognized as the most important field of science in the 21st century. Significant developments in the field of gene editing, stem cell treatment, and synthetic biology have brought about a revolution in medical practices, agricultural procedures, and environmental policies. Biotechnological discoveries may result in the

cure of many illnesses, the enhancement of the safety of food supplies, and the resolution of ecological problems.[1]Nevertheless, biotechnological breakthroughs have posed considerable ethical and legal problems to be considered. Gene manipulation, the creation of new forms of life, the ability to modify human embryos, and other achievements give rise to concerns related to the dignity of humans, their freedom of choice, and equal opportunities.[2]The present essay will focus on the claim that the development of biotechnology has outstripped bioethics and legislation and, therefore, resulted in legal responsibility gaps in this sphere. In addition, the essay will support the claim that bioethics and human rights should be strictly regulated.[3]

2. EVOLUTION OF BIOTECHNOLOGY AND EMERGING ETHICAL CONCERNS

There was a spectacular transformation of biotechnology from traditional techniques such as selective breeding and fermentation to advanced genetic engineering. This transition represents the transition from understanding the laws of life to their conscious regulation.[4]

2.1 Key Technologies Developed

Modern biotechnology is distinguished by the following innovations:

Gene Editing Technologies (CRISPR-Cas9 Technologies): The possibility of editing the genome with high accuracy makes it possible to cure diseases caused by genetic mutations. Nevertheless, there is a danger that these technologies may be applied improperly.[5] Stem Cell Research: While stem cell research has led to groundbreaking medical treatments, ethical concerns regarding the utilization of human embryos for experimental purposes need to be considered.[6] Synthetic Biology: Synthetic biology involves the creation of artificial living beings that do not occur naturally, which creates a gray area between natural and artificial entities.[7]Genetic Databases/Biobanks: Genetic databases pose significant challenges regarding privacy and consent when utilizing patient data.[8]

2.2 New Challenges Arisen

[1] Henry T. Greely, *CRISPR'd Babies*, 122 JAMA 1 (2019).
[2] UNESCO, *Report on the Human Genome and Human Rights* (2015).
[3] UNESCO, *Universal Declaration on Bioethics and Human Rights* (2005).
[4] Sheila Jasanoff, *Designs on Nature* 25 (2005).
[5] Henry T. Greely, supra note 1.
[6] World Med. Ass'n, *Declaration of Helsinki* (2013).
[7] World Health Organization, *Human Genome Editing* (2021).
[8] Bartha Knoppers, Framework for Genomic Data Sharing, 3 HUGO J. 1 (2014).

The development of biotechnology introduced numerous ethical questions:

1. Does man have the right to alter genetic information?[9]
2. How far can his rights extend to genetic data?[10]
3. Is he entitled to intellectual property on his biological inventions?[11]

3. CORE PRINCIPLES OF BIOETHICS IN BIOTECHNOLOGY

Bioethics serves as a tool for evaluating the appropriateness of scientific investigation. On the contrary, the contemporary progress in biotechnology questions the traditional ethical norms.

3.1 Autonomy

Autonomy relates to the liberty of making decisions regarding one's body and personal information. The issue is that the biotechnological treatment itself is rather complicated from a scientific perspective, not to mention its possible outcomes that may affect the future generations.[12]

3.2 Informed Consent

Informed consent is crucial for an ethical scientific procedure. In the meantime, biotechnology raises the concern about the possibility of using genetic information without consent in the future.[13]This issue has led to the emergence of innovative dynamic consent concepts.

3.3 Beneficence and Non-maleficence

Beneficence and non-maleficence imply providing advantages for people through eliminating illnesses and similar measures. On the other hand, biotechnological treatments are associated with numerous risks such as off-target effects of genetic editing.[14]

3.4 Justice

Justice calls for a fair distribution of the benefits of scientific progress among all individuals. On the contrary, biotechnology is rather costly; therefore, it generates an inequality between privileged patients and

[9] Nuffield Council on Bioethics, *Genome Editing* (2018).
[10] Knoppers, supra note 8.
[11] *Moore v. Regents*, 793 P.2d 479 (Cal. 1990).
[12] Beauchamp & Childress, *Principles of Biomedical Ethics* (2013).
[13] UNESCO, *Report on Consent* (2008).
[14] Alta Charo & Henry Greely, 372 NEJM 967 (2015).

others.[15]

4. HUMAN RIGHTS IMPLICATIONS IN BIOTECHNOLOGY

Human rights are taken into account in biotechnology in relation to privacy, equality, and human dignity.

4.1 Genetic Privacy

Genetic information is highly private because it discloses a person's genetic background. Its illegal usage can lead to discrimination in employment, insurance, or social settings.[16]

4.2 Equality and Non discrimination

Due to the development of gene-enhancement technologies, there appears the problem of inequality among the population. This inequality occurs due to the fact that only rich people have access to such technologies.[17]

4.3 Human Dignity

Modification of human genes and embryos presents an ethical problem connected with the natural value of humanity. The modification of the human being brings to the commodification of humankind itself.[18]

5. LEGAL FRAMEWORKS AND REGULATORY CHALLENGES

5.1 International Legal Instruments

International instruments provide guidelines for ethics but are non-binding. For instance, the Universal Declaration on Bioethics and Human Rights underscores the significance of dignity, consent, and justice but plays an advisory role.[19]

5.2 National Regulatory Frameworks

There is variation in national regulatory frameworks. While some countries Favor innovation-oriented regulatory regimes, others adopt caution-based regulatory regimes with strict measures. These differences lead to fragmented regulations and encourage international

[15] Cary Fowler et al., 34 Dev. Pol'y Rev. 1 (2016).
[16] GDPR, Regulation (EU) 2016/679.
[17] *K.S. Puttaswamy v. Union of India*, (2017) 10 SCC 1.
[18] UNESCO, supra note 3.
[19] UNESCO, supra note 3.

exploitation.[20]

5.3 Judicial Decisions and Case Laws

Significant contributions have been made by judicial bodies towards bioethical debate:

- *Samira Kohli v. Dr. Prabha Manchanda*: The Indian Supreme Court stressed the importance of securing consent before carrying out any procedure in clinical settings.[21]
- *Mr. X v. Hospital Z*: The court examined the conflict between maintaining medical confidentiality and protecting public interests.[22]
- *K.S. Puttaswamy v. Union of India*: The Indian Supreme Court recognized privacy as a fundamental right in India.[23]
- *Association for Molecular Pathology v. Myriad Genetics, Inc.:* The Supreme Court held that naturally occurring DNA could not be patented.[24]

5.4 Regulatory Deficiencies

Some shortcomings remain in the current legal instruments:

1. No binding international laws[25]
2. Weak enforcement procedures[26]
3. Limited monitoring of private parties[27]
4. Cross-border regulation[28]

6. CASE STUDIES: ETHICAL AND LEGAL DILEMMAS

6.1 Gene Editing in Humans

There is an opportunity to use gene editing to remove the genes that cause inherited conditions; however, there is concern about the possible negative consequences of permanent modifications.[29]

6.2 Stem Cell Tourism

[20] CIOMS Guidelines (2016).
[21] *Samira Kohli v. Dr. Prabha*, (2008) 2 SCC 1.
[22] *Mr. X v. Hospital Z*, (1998) 8 SCC 296.
[23] *K.S. Puttaswamy*, supra note 17.
[24] *Myriad Genetics*, 569 U.S. 576 (2013).
[25] WHO, supra note 7.
[26] CIOMS, supra note 20.
[27] Jasanoff, supra note 4.
[28] Fowler, supra note 15.
[29] Greely, supra note 1.

Individuals seek medical treatment in areas that do not have strict laws concerning the procedure, thus putting themselves at risk and ignoring ethical guidelines.[30]

6.3 Synthetic Biology and Biosecurity

The fact that it is possible to create life forms artificially poses threats of misuse; therefore, regulations find it difficult to handle this issue.[31]

7. LEGAL ACCOUNTABILITY IN BIOTECHNOLOGY

Accountability plays an important role in ensuring biotechnology development is carried out appropriately.

7.1 Strengthening Regulatory Frameworks

There needs to be a legally binding framework at the global level, including universal ethical standards and accountability measures.[32]

7.2 The Need for Corporate Accountability

Businesses developing new technologies based on biotechnology need to adhere to principles of transparency, data security, and ethics in their operations.[33]

7.3 Public Engagement

Public engagement enhances legitimacy and accountability, contributing to alignment between technological advances and societal norms.[34]

8. TOWARDS AN INTEGRATED FRAMEWORK: BIOETHICS IMPACT ASSESSMENT

For tackling the mentioned gaps, a suggestion is made for applying Bioethics Impact Assessment (BIA).

8.1 Characteristics of BIA

- Mandatory ethical assessment prior to project approval[35]
- Human rights consequences assessment[36]
- Public participation[37]

[30] ICMR Guidelines (2017).
[31] WHO, supra note 7.
[32] WHO, supra note 7.
[33] Knoppers, supra note 8.
[34] Jasanoff, supra note 4.
[35] CIOMS, supra note 20.
[36] UNESCO, supra note 3.
[37] CIOMS, supra note 20.

- Regular monitoring

8.2 Importance

This approach emphasizes pre-emptive regulation, meaning that ethical concerns will be considered from the early stages of research development.

9. FUTURE CHALLENGES AND OPPORTUNITIES

9.1 Dilemmas

- Fast technology progress[38]
- Absence of international agreement[39]
- Differences among cultures regarding ethics[40]

9.2 Possibilities

- Personalized medicine treatment[41]
- Genetic disease eradication[42]
- Sustainable agriculture development[43]

Finding an appropriate balance between the above possibilities and ethics is a challenge.

10. CONCLUSION

There are numerous opportunities as well as ethical issues associated with biotechnology. While biotechnology provides means of dealing with the major problems the world faces today, there are also several ethical concerns associated with biotechnology and which put human rights and laws at stake. It is evident that the current legislative system is not equipped enough to deal with all sorts of challenges posed by biotechnology. The lack of sufficient legislative and regulatory mechanisms may allow biotechnology to become the source of unethical behaviour. In the present paper, it is emphasized that it is important to marry the notion of bioethics with legislation power. This explains why we introduce such an innovative concept as Bioethics Impact Assessment which is expected to address this problem.[44]

[38] Greely, supra note 1.
[39] WHO, supra note 7.
[40] Jasanoff, supra note 4.
[41] WHO, supra note 7.
[42] Greely, supra note 1.
[43] Fowler, supra note 15.
[44] UNESCO, supra note 3.