CHAPTER: VI

CONCLUSION AND SUBMISSIONS

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The developments relating to Human Genome are affecting every aspect of human life. These technological advances have potential to infringe the basis human rights and destabilize the settled social norms. The intensity and magnitude of the problems generated by Human Genome cannot be adequately dealt with ethical guidelines. Biotechnological advances have opened up a new profitable financial market, so the greed of the sellers have made it necessary to have a strong legal mechanism.

Genetic information requires special protection due to its unique character. The level and standard of ethics is quite high for the health professionals in Genetic Counseling. The issue of informed consent is quite challenging due to the complexities of the modern biotechnologies. The problematic aspect of genetic counseling is that doctor-patient relationship is also influenced by the materialistic and commercialized people. So, leaving a patient on the ethical conduct of the doctor without a strong legal regulation seems unsatisfactory. Although self-restraint is the best regulation but taking into consideration the intensity of genetic information it is essential to have a legal mechanism to regulate it.

Insurers and Employers are claiming to have a access to the genetic information of the insuree and employee and they treat it ‘business as usual’. Depriving a person from his job or negating the insurance on the basis of these premature testing is not justifiable. Here the task before law is to create a balance between the interests of insurers and employers and that of insurees and employees.

Patenting of human genome has widened the gap between rich and poor and developed and developing countries. Although United Nations Educational, Scientific and Cultural Organization (UNESCO) has declared the human
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genome as a common heritage to the mankind but a large number of patents are being granted in the United States. In the United State the patent law is too weak which allows the patenting of gene fragments, the function of which are not yet fully known. It has impeded the research, crucial to the human life.

The conclusions related to patent in my opinion are that as long as a patent system persists (and we are not suggesting that it be abolished), developing sophisticated patenting and licensing practices that are sensitive to potential access problems, particularly if resolving those problems could greatly improve the lives of the world’s poor and sick, is key to improving the biomedical research and treatment systems.

Developing countries are exploited due to their diverse gene pool and poor people are always at stake. Benefit sharing has not become practicable. All these concerns demand an international regulatory mechanism defining the role of the parties involved. There is a need to take into consideration the interest of all the countries and provide safeguards in that direction. Economic and ethical relativity should be considered in patent laws. It also requires a balanced approach, striking a balance between the interest of patent holders and interest of the society by law.

Artificial reproductive technologies have posed a variety of complex problems relating to family law. In western countries these technologies are gaining popularity because the adoption laws are quite ambiguous. But there are many issues yet to be settled. For example, there is no consensus on the anonymity and non-anonymity of donors in artificial insemination. Countries which are backed by strong religious commitments are not allowing it and treat it as unsacred job. In India there is no specific legislation dealing with these modern technologies. But situation demands a specific legislation, controlling the misuse of these technologies. However, artificial insemination should be
allowed only in the case of married women with the written consent of the husband and the interest of the child must be given paramount importance.

Right to procreate children and to have a family is considered as a human right. According to Art. 16(1) of the *Universal Declaration of Human Rights, 1948* “Men and women of full age, without any limitation due to race, nationality or religion have the right to marry, and to found a family”. In India though right to procreation is not yet declared as a fundamental right but courts may declare it as a fundamental right as a part of right to life under Article 21 of the Constitution.

New technologies developed in the field of medicine have made it possible for infertile couples to bear children who are genetically related to them. Technological developments in the field of Artificial Reproductive Technology (ART) and related biotechnologies have evolved many ways to protect the right of this procreation. These ways provide cure for infertility. In-vitro Fertilization (IVF) is one of them. By using this technology couples who cannot procreate due to infertility they may bear children. If the couple cannot have children due to inability of female partner they may have children by using In-vitro Fertilization (IVF) with the help of gestational surrogacy. In case there is danger of miscarriage or any genetic deformity or disease to the child due to genetic reasons, couples may approach In-vitro Fertilization (IVF) to screen and detect genetic deformity. These technological advances are raising many legal and ethical questions which are posing challenge to present legal system. In absence of any legislative safeguards, there are chances of misuse of these technologies and violation of societal norms. They have capability to alter the social order and even to challenge the ethics of medical profession.

Originally these techniques were developed to treat infertile couples. But with the increased commercialization and widespread use of these technologies, now single (i.e. unmarried) and lesbians are also approaching to In-vitro
Fertilization (IVF) clinics for becoming parent of genetically related babies. Single male is also approaching In-vitro Fertilization (IVF) clinics to have their own children. This easy accessibility of In-vitro Fertilization (IVF) process may lead to many legal issues such as; Who are eligible to get treatment of In-vitro Fertilization (IVF) process? Whether a single male or female be allowed to use In-vitro Fertilization (IVF), or only married couples should be allowed?

In India we do not have any statutory mechanism to regulate it and to monitor its use and development. Because of these reasons it is imperative to respond such developments with suitable legislations. In India lack of any statutory guidance has made every one free to access In-vitro Fertilization (IVF). The Indian Council for Medical Research (ICMR) guidelines are only advisory and they do not have any statutory force. The law in developed countries generally allows only married couples to access Assisted Reproduction Technology (ART).

These technologies have shaken the corner stone’s of traditional concept of father and mother. Now parents may be divided as biological parents, social parents and gestational mother. Issue of parentage is not only important for the purpose of determining the child's succession rights but to determine the custody of child, who has to rare the child and shape his/her future. So the parentage issue of In-vitro Fertilization (IVF) child must be determined by the law.

Article 8 of the Child Right Convention, 1989 declares that child’s right to preserve his/her identity must be respected. With the development of technologies and knowledge of these technologies child may want to know its genetic identity, his/her genetic parents. So, this right of child must be protected by the law. Childs right to know his genetic parents may be in some cases clash with the interests of gamete donor. So, there is a need to maintain a balance
between children’s right to know his/her genetic parents and donors right to anonymity.

Eligibility to access gestational surrogacy is also one of the important issues which are posing challenges before our legal community. In developed countries gestational surrogacy is allowed only for those women who are not capable of bearing children. It is not allowed for avoiding pain of labour by a woman. This prohibition protects the exploitation of female body by persons of economically sound background. In almost all countries, if the surrogate is married then consent of husband of surrogate is must for allowing her to become a surrogate mother. Commercial surrogacy is prohibited in all developed countries, but generally some sort of compensation in lieu of loss of wages, medical expenses are allowed to be paid. In some states of the US, any type of payment is prohibited, and agreement having provisions of payment to surrogate are null, void and unenforceable. Similar is the position in Australia. But in UK, reasonable sum is allowed to be paid. But still we are not having any strict legislation to tackle the above mentioned concerns. Surrogacy in particular requires strict regulation in India and should not be allowed on the contract basis which jeopardized the basic human rights of the surrogate mother and leads to commercial exploitation.

As there is no legislation in India governing surrogacy arrangements, these contracts may be challenged on the ground that they are against the public policy, because the term ‘public policy’ has a very wide connotation and has ever changing meaning. So, it would be on the court to decide that particular surrogacy contract is in accordance with the public policy or not.

The issue of parentage of child born through gestational surrogacy is one of the important legal issues. This is because gestational surrogate is not genetically related to the child. In surrogacy arrangements while deciding the parentage issue, the court must keep in the mind the best interest of child. In all
developed countries, law generally favours the surrogate, though she is not genetically related to him. In case the surrogate can opt to keep the child, she must be allowed to do so irrespective of the contract. But generally determination of parentage is left with the courts.

In the words of Dr. Justice Jitendra N. Bhatt, “Mankind’s newly acquired ability such as In-Vitro Fertilization (IVF), semen-banking and artificial insemination, sex choice techniques, cloning or sexual reproduction and the like, have philosophical and political question that can no longer be left to be answered by the physicians or the scientists alone”.¹

These biotechnological development in the field of Assisted Reproduction Technology (ART), stem cell research and cloning, require a comprehensive legislation which is not only potent to govern present technological advancements but also to the future technologies, in accordance with the need of the society.

The most amazing example of the modern biotechnology is ‘human cloning’. Human reproductive cloning is not yet feasible. If feasible it will pose various challenges regarding individuality, identity, personal autonomy, family lineage etc. It needs a strong International legal mechanism to regulate the misuse of cloning technology and there should be penal provisions for it. But again any legislation regarding the cloning should not be made in hurry rather taking into consideration the whole nature of the issue.

Therapeutic cloning and stem cell research are providing various benefits to the mankind, opening new vistas in health care. But the claims need to be scrutinized because it is still in evolving phase and any wrongful claim may be disastrous for the life of an individual. Commercialization of embryos is another issue which requires great concern. Embryo trade is prevalent in India

also, where there is no statutory mechanism. There are some countries which although prohibit the embryo research but allowed transportation of embryos to other countries which ultimately facilitate the embryo trading. So, it becomes pertinent to regulate these transactions at international level through legally binding treaties and instruments. Mere declaration cannot do a lot on this issue.

So, conclusively it can be said that the intensity and the nature of biotechnological advances relating to human genome require strict regulation. The role of law has becomes very crucial but the main problem with the regulation is that the lawyers are not fully acquainted with the implication of these technologies. It is not easy to predict the emerging legal issues in this field. So this requires an interaction between legal and scientific communities.

On the International level there is a declaration of United Nations Educational, Scientific and Cultural Organization (UNESCO), Universal Declaration of Human Genome and Human Rights, which directly addresses the various issues regarding the Human Genome but mere declaration is not sufficient. It is submitted that the nature of the Human Genome requires, some stringent regulations which can be done only by adopting a legally binding instrument at the national and international level.

**SUGGESTIONS:**

In this regard following suggestions are made by the researcher, as under:

1. To understand the problems arising out of human genetics the interaction between legal experts and scientists is very necessary. An integrated approach is required in regulating the biotechnological developments relating to Human Genome. The interaction between all the disciplines enables one to have a complete look over the problem.

2. Human genetics is highly advanced and complicated study. Therefore, without its proper knowledge one can never identify the legal issues.
There should be legal experts who have expertise to deal with such type of advance issues. So, efforts should be made to have a distinct legal education system like Biotech LL.B. which may provide lawyers better understanding with the genetic knowledge.

3. Human Rights instruments should be redefined and enriched in the context of Human Genome. There should not be only declarations but legally binding treaties to ensure the protection of human rights of all consenting parties.

4. Specific legislations dealing with genetic information should be enacted keeping in view the interest of all the concerned individuals. The existing civil and penal laws should be reviewed in the present context because they are quite inadequate to comprehend the problems.

5. Patenting of human genome should be strictly regulated and in the evolutionary stage of human genome studies, wide patents in this regard should not be granted. Here the law should play a role to strike a balance between individual interest and social good. International patent system should be revised in the context of human genome.

6. Equitable benefit sharing should be given paramount importance and developing countries including India should make their position clear in this regard. The present situation requires thinking in advance.

7. Family laws should be revised accordingly to accommodate the issues of Assisted Reproductive Technologies (ART). Surrogacy arrangements should be strictly regulated through civil and penal laws.

8. Human cloning and embryo trade require a strong legally binding mechanism at international level. So efforts should be made to arrive at an international consensus through discussions and debates in this regard.
At the national level embryo trading should be regulated through specific legislation.

9. There must be a permanent statutory body on the model of Human Fertilization and Embryology Authority (HFEA) of UK, to regulate Assisted Reproductive Technologies (ART) clinics and research institutes in India, where In-Vitro Fertilization (IVF), surrogacy and cloning may take place. Such Authority must have members who are familiar with those technologies, e.g. scientists, doctors and most importantly legal experts.

10. Single or married female who is not infertile and capable of bearing children should not be allowed to access surrogacy arrangements only for the sake of avoiding labour pain, as it would be against the human dignity. Otherwise it would be a source of exploitation and corruption.

11. There should be a balance between child’s right to know genetic parents and donor’s right of anonymity. Information about donor should only be released to the child when donor consents for it or when justice demands to do so.

12. Commercialization of surrogacy arrangements should be prohibited as it would be against the human dignity. But reasonable compensation for loss of wages, medical expenses, and other related expenses should be allowed. Courts should also be empowered to grant surrogates the amount as compensation for her services to infertile couple.

13. There should be a mandatory arrangement of insurance of surrogates life, disabilities and related diseases. There should be statutory provisions to protect the interests of the surrogate.
14. In case of any conflict of interest between the surrogate mother and child in womb or commissioning couple, the interests of the surrogate mother should be protected, and given prominence.

15. For determining the parentage of child born through the gestational surrogacy, surrogate must be given an option to keep the child with the consent of her husband. This option must be exercised within a fixed period in the best interest of the child.

16. Although many countries have banned the reproductive human cloning, there are countries like India which do not currently have any strict legislation relating to cloning which provides ample opportunities for the misuse of cloning technology.

17. Human reproductive cloning should be strictly prohibited.

18. The Constitution of India does not guarantee the right to privacy as a fundamental right. The sole credit goes to the Indian judiciary for recognizing the concept of right to privacy because neither the Constitution nor any other legislation has defined the concept. So it is suggested that for the recognition and protection of right to privacy the legislature should enact law in India.

19. As United Nations Educational, Scientific and Cultural Organization (UNESCO) has declared Human Genome a "common heritage" to the mankind, there requires an international legal framework to regulate the patenting of human genome taking into consideration the interest of individual as well as the interests of developing countries.

20. It is suggested that right to surrogacy is necessary and is a boon to humanity, on the condition that the legislation regulates this technology. A statutory authority needs to be set up to adjudicate all matters in
relation to surrogacy. This authority can also be the adjudicating authority to determine disputes and to decide offences.

I wonder why the option of ‘Adoption’ is not considered by the infertile couples. There are many children who will never know love of parents in the orphanages but some couples are choosing unnatural way to have a baby surrogacy. They want to be genetically linked to their child. People will have to realize that children are not products to be made. It’s time for some more serious corrective thinking.

There are different personal laws based on religions in India. These personal laws prohibit marriage in certain relations. These relations are incestuous relations and donation of gamete to a couple with whom a person cannot marry, raises a controversial issue before our law framers, which must be answered and the only way is the need of legislation or by amendments in old personal laws should be made to cope with this concern.

Last but not the least, the law must be synchronized and developed in order to overcome the challenges posed by these biological advancements. Law and legal experts should play an important role to balance the conflicting interests and promote the social interest. Scientific developments are essential for the development of society and the law should act as a regulator as well as a facilitator in this context.

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