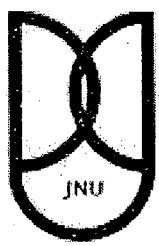
# DISCLOSURE OF GENETIC INFORMATION AND HUMAN RIGHTS VIOLATIONS

*Dissertation Submitted to Jawaharlal Nehru University*
*in Partial Fulfilment of the Requirements*
*for award of the Degree of*

**MASTER OF PHILOSOPHY**

**Cyril V.V.**

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## DECLARATION

I declare that the dissertation entitled **"DISCLOSURE OF GENETIC INFORMATION AND HUMAN RIGHTS VIOLATION"** submitted by me in partial fulfillment of the requirements for the award of the degree of **MASTER OF PHILOSOPHY** of Jawaharlal Nehru University is my own work. The dissertation has not been submitted for any other degree of this University or any other university

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## CERTIFICATE

We recommend that dissertation may be placed before the examiners for evaluation.

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## *Acknowledgment*

*I have great satisfaction in bringing out this dissertation titled "Disclosure of Genetic Information and Human Rights Violation". This is submitted to Jawaharlal Nehru University in partial fulfillment of the requirements for award of the degree of Master of Philosophy. The study is based on the human rights violation resulting from the disclosure of genetic information as well as from the advancement in human genetic and associated technologies and its applications, particularly in insurance and employment settings. I am greatly indebted and highly obliged to my supervisor Prof. Yogesh K. Tyagi, who inspired me constantly, for his valuable guidance, constructive suggestions and moral support he extended to me throughout the completion of this work.*

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*All above I am ever conscious of the fact that what so ever success that I have met with is due to the blessings of my parents and god almighty.*

*Cyril V.V.*

## List of Abbreviations

| | |
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| ADA | : Americans with Disabilities Act |
| AMA | : American Medical Association |
| CIOMS | : Council for International Organizations of Medical Sciences |
| DBT | : Department of Biotechnology |
| DNA | : Deoxyribonucleic acid |
| ECOSOC | : Economic, Social and Cultural Organization |
| EEOC | : Equal Employment Opportunity Commission |
| EU | : European Union |
| GINA | : Genetic Information Nondiscrimination Act |
| HGC | : Human Genetic Commission |
| HIPAA | : Health Insurance Portability and Accountability Act |
| HUGO | : Human Genome Project Information |
| ICMR | : Indian Council for Medical Research |
| ILO | : International Labour Organization |
| NBC | : National Bioethics Committee |
| NHGRI | : National Human Genome Research Institute |
| OECD | : Organization for Economic Cooperation and Development |
| RNA | : Ribonucleic Acid |
| UNESCO | : United Nations Education, Scientific and Cultural Organization |
| WHO | : World Health Organization |
| WMA | : World Medical Association |

*Chapter 1*

# *Introduction*

# Introduction

The ever increasing pace of scientific and technological advances has always been a matter of concern of law for its potential repercussion over human rights as well as other legal rights. Advances in human genetics and related technologies are not an exception to this preposition and have raised a lot of legal as well as social and ethical concerns. The human genome project, which was concluded in 2003, opened up tremendous prospects for mankind as a whole by revolutionizing the healthcare system. Genetic testing and screening increasingly are becoming part of public healthcare in many countries, which may help in improving the public health, but simultaneously raises significant legal, ethical and social concerns. One of the most frequently expressed concerns about this is the disclosure of genetic information, its misuse and its impact on human rights and dignity such as privacy violations, discrimination in insurance and employment settings, social stigmatizations and informational abuses.

## 1.1 *Objectives*

The present study titled "*Disclosure of Genetic Information and Human Rights Violations*" is an attempt to throw light on the emerging manifestations of human rights violations resulting from the disclosure of genetic information as well as the application of new human genetics and related technologies. The main objective of the study is to analyse the legal issues arising out of the disclosure of personal genetic information, to makes a critical review of the international legal responses as well as selected regional and municipal legal responses to these new forms of human rights violations, to address the definitional dilemmas regarding certain terms like personal genetic information, genetic testing and genetic screening, to identify the challenges in regulating the personal genetic information and genetic discrimination and in protecting the privacy and confidentiality of genetic information.

## 1.2 *Hypothesis*

- The jurisprudence on the protection of the privacy and confidentiality of personal genetic information is still in its infancy.

- The definition of personal genetic information and genetic testing is not yet adequately conceptualized under international or regional legal regimes, which will determine the nature of protection.

- Genetic screening, genetic discrimination, differential treatment, etc based on genetic characteristic should not be allowed. However where there involve high risk to life or where genetic screening is highly beneficial and can be efficaciously carried out without harming the privacy, dignity and integrity of individuals it can be allowed.

### 1.3 *Research Questions*

The present study is an attempt to get an answer to the following questions:

- What is the significance of genetic information, its pros and cons and how the genetic information has been misused or posed a threat to human rights?

- How genetic information has been conceptualized under international and regional legal instruments and the nature and extent of protection these instrument is offering for the privacy and confidentiality of genetic information

- What all are the legal principles laid down by these international as well as regional instruments in protecting the human rights and dignity from the potential harmful effects of the new developments in human genetics and related technologies?

- What all are the legal response to the new development in human genetics and associated technologies in US and in India and how far these instruments are effective in maintaining a sticking balance between individual interest as well as third party interest?

### 1.4 *Chapterisation*

Since it is important to be clear about the scientific terms that are frequently used in this work, chapter two titled '*Disclosure of Genetic Information: An Interface*

*between Science, Ethics and Human Rights'* opens with a brief description of the terms like DNA, gene and genetic information. The chapter further proceeds to bring out a clear picture of the significance of the genetic information and the pros and cons of genetic information in the context of new developments in the field of human genetic and biomedicine. Biomedicine and human genetics are advancing at a tremendous pace and mankind is perplexed with the emerging socio- ethical and legal dilemmas and biomedical challenges that are surfacing day by day. In this context the chapter makes a genuine attempt to illuminate some of the most controversial aspects of the new developments in human genetics and technology and draws a comprehensive picture of human rights violations and informational abuses resulting from genetic testing, genetic screening and disclosure of genetic information and moves on to analyze the divergent views maintained by various scholars on some of the relevant issues in this context. The questions debated here are the exceptional nature of genetic information as opposed to conventional medical records, the impact of genetic specific legislations, commercialization of genetic information, etc.

Third chapter titled '*Genetic Information and International Law: Some Basic Issues*', as its title implicates aims to provide a comprehensive review of the international law and regulations concerning the protections and privacy of genetic information in a wide range of context. It attempts to make a critical analysis of the general principles laid down by these international instruments in dealing with the misuse of genetic information and informational abuse resulting from the disclosure of genetic information and the practical difficulties operationalize these principles. It further examines the policy statements, guidelines and other initiatives adopted by relevant international organizations endeavouring in this field. The chapter outlines the definitional dilemmas confronted by the international instruments in this field and throws light on the definitional inadequacies, problems in framing and adopting comprehensive definitions.

Commercialization of genetic knowledge paved the way for the emergence of a number of practices in the past few years, which can result in the unfavourable treatment of individuals because of a perceived genetic risk. Instances of such practices are more often in the industrialized world like Europe and America. Therefore chapter four, which deals with regional legal regulations, look at the

European regional legal responses to advances in genetics and related technologies and its applications. The chapter mainly focuses on the European Convention on Human Rights and Biomedicine and other legal provisions which deals with genetic discrimination and privacy of genetic information. The chapter further discusses domestic legal regulations, in which federal legislations like The Americans with Disabilities Act, The Health Insurance Portability and Accountability Act, and the Genetic Information Nondiscrimination Act of United States of America is been critically analyzed. The chapter also looks into some of the cases decided by the US courts and Equal Employment opportunity Commission.

Municipal legal responses to developments in human genetics and related technologies in India are considered in chapter five titled '*India and Genetic Information*'. The 'Ethical Policies on the Human Genome, Genetic Research and Services' formulated by National Bioethics Committee, the 'Statement of Specific Principles for Human Genetics and Genomics Research', framed by the Indian Council for Medical Research, the 'Draft DNA Profiling Bill' steered by the Department of Biotechnology and National Academy of Legal Studies and Research, Hyderabad and the 'The Personal Data Protection Bill', which now pending the Rajya Sabha are also examined in this chapter.

*Chapter 2*

# *Disclosure of Genetic Information: An Interface between Science, Ethics and Human Rights*

# Disclosure of Genetic Information: An Interface between Science, Ethics and Human Rights

## 2.1 *Introduction*

The discovery of the double helical structure of deoxyribonucleic acid (DNA) has proven to be a milestone in the development of molecular biology and modern biotechnology[1]. Despite of the fact that DNA carries genetic information from one generation to the next, the structure of DNA[2] and the mechanism by which genetic information is passed on to the next generation remained as an unanswered question in biology until 1953. The double helical structure of DNA was discovered by James Watson and Francis Crick.

Prior to the efforts of Watson and Crick, an Austrian priest and scientist, Gregor Johann Mendel (1822 – 1884) known as the father of modern genetics, showed the world through his experiments in pea plant, how genetic traits are inherited from one generation to another, which laid the foundation of modern genetics. Today genetics has developed leaps and bounds and now lots of

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[1] Published in their paper entitled "A Structure for Deoxyribose Nucleic Acid" and they were awarded with Nobel Prize in Physiology or Medicine in 1962 for the same.

[2] DNA in human beings is arranged into 23 distinct pairs (together constitute the human genome) of chromosomes, which are a highly coiled, double helical structure made up of subunits called nucleotides. Each nucleotide is in turn made of a sugar, a phosphate and a base. There are four different bases in a DNA molecule namely, adenine, cytosine, guanine and thymine (Kingston 2002: 78). Adenine and guanine are called purines, and cytosine and thymine are called pryrimidine. Purines always pair with pryrimidine i.e., Adenine always pairs with thymine and vice versa and guanine always pairs with cytosine and vice versa to form a double helix (*ibid.*). Each chromosome contains many genes, which are small piece or segments of DNA sequence that are involved in the synthesis of particular protein, which plays a vital role in the structure and function of our body and are called the basic and functional units of heredity. Each cell contains the same sets of chromosomes and when a new cell is formed a carbon copy of these DNA will go to the new cell. Only a small portion of the DNA(about 2% of the human genome) constitute genes, which actively take part in the production of the protein and the rest of the DNA remains in a dormant condition and are called junk DNA (*Ibid*: 81). The function of these junk DNA is not currently understood. Some authors are of the view that its function may include providing chromosomal structural integrity and regulating where, when, and in what quantity proteins are made. Each gene consists of certain triplet codes, which codes for a particular protein that gives the organism the characteristic features like eye colour, hair colour, skin colour, height, etc. Genetic information is the information about the genetic material (DNA), or the genetic makeup of an individual, which includes the information about genes, personal genetic characteristics, information about private matters, his/her genetic vulnerability or susceptibility to certain diseases, existing genetic disorders, how he/she is related to family members, information regarding his/her race or ethnicity, etc.

developments are taking place in the area of human genome. The decoding of human genome in 2000 marked another colossal milestone in the progress of genetic science.

The significance of genetic information is manifold and a number of arguments are often made for treating genetic information different from traditional forms of clinical data. The first and the foremost is that it is predictive in nature and reveals the genetic vulnerabilities/ susceptibilities and future health status of an individual. In cases of late onset of genetic disease the person may not show any symptoms of the disease or illness in his/her early stage of life, but genetic tests can predict the probability of such person to contract a genetic disease. Genetic information also predicts the probability of genetic diseases to be inherited to next generation leaving implications for reproductive choices of prospective parents and characteristic features of future generations (Rothstein 2005:30). Secondly no two persons except for identical twins can have the exactly similar genetic sequence. This unique quality of the genetic material enables certain identification of the individual and the information that can be gathered from genetic material is vast. Thirdly individuals share certain genetic characteristic with their families, communities and ethnic and racial population. So they posses certain common material and this enables the generalization of the genetic information obtained from an individual to their families, communities, ethnic and racial population, the misuse of which can lead to discrimination, stigmatization, eugenics, racism and genocide. So the impact of genetic information is not just on the individual but on their families, genetically related communities and racial or ethnic groups as well.

### 2.2 *Pros and Cons of Genetic Information*

The Human Genome Project (HGP), which began in 1990 with the coordinated efforts of U.S. Department of Energy and National Institute of Health, identified that there are approximately 20,000 – 25,000 genes in human DNA and also determined the sequence of 3 million base pairs that make up human DNA. The knowledge generated as a result of the Human Genome Project, regarding the structure and function of gene and the effect of genetic variation in human being have revolutionized the genetic research and health care, in particular and other fields, in general. The researchers are now enabled to pinpoint the minute error in a gene that

contribute to the disease and design the drug accordingly to target specific sites, which have fewer side effects than many of the present day medicines (HGPI 2008). The advantage of this information is that it enables the researchers to develop new ways of treatment, prevention and even curing many diseases that may affect human beings in future.

The use of genetic testing or genetic screening as a device for crime regulation in forensic field have been the most discussed use of genetic information in the context of criminal investigation, in which the DNA fingerprint of the suspect is cross matched with that of the biological specimen/remnants left at the site of offence. This technique is also useful in determining parentage, exonerating persons wrongly accused of crimes, tracing out family relationship, etc.

The value of genetic information led to the creation of DNA or genetic database of criminals in certain countries like U.S. and U.K. This database is used for investigating crimes (Greely 1998: 477). Genetic database are created with the inputs of genetic materials from donors and in certain cases there involved an element of coercion in obtaining the samples of DNA to match with the DNA fingerprint of the offender because failure to participate in such screening programme could reasonably draw the attention of police[3]. So it is interesting to analyze, how voluntary is the participation in such screening programme, as it is claimed. Further once a sample is obtained for forensic purpose it will also be used for screening his/her close relatives also for similarity. This is based on the scientific fact that if the DNA fingerprint of a crime scene specimen is similar but not exactly the same as that of a known criminal/ lawbreaker, then that DNA may belong to a close relative of that known criminal. This crime- control strategy, which is in force in many countries, is based on the assumption that close relatives of criminals are more likely than others to break law and is accompanied with lot of criticism and controversy as many claim that this way

[3] In 2000, an elderly woman in Wee Waa, NSW, Australia, was sexually assaulted and in order to identify the offender, the police asked the township's approximately 500 male residents between the ages of 18 and 45 to volunteer a DNA sample analysis and 2 years later another screening program took place where around 2,500 men and boys living in Bundaberg, Queensland were asked to provide DNA samples to identify the person responsible for the death of a female British backpacker, who was robbed and believed to have fallen or have been pushed from a bridge (Gesche 2006: 86). In both the cases, considerable pressure was put on the male population to submit to genetic testing and involved element of coercion.

of thinking or attributing human behavior mainly or entirely to genetic makeup or markers as genetic reductionism (Hil & Hindmarsh 2006). This has raised concerns about human dignity, individual autonomy and self determination, invasion of privacy, discrimination and social stigmatization.

The role of genetic information in criminal justice has also been widely discussed, for its application in paternity tests, tracing out individual ancestry and identifying human remains. Genetic information has been used to reunite children of victims of the Argentinean Junta[4] with their grandparents. In such cases if the genetic information is used without the consent of the persons involved, it is having serious repercussions for their privacy, family relations and even for their lives. Genetic counselors have often encountered with this problem, while conducting tests for familial disorder or to trace out family relationship, that the presumed father was not in fact the genetic father (Greely 1998: 485). In such circumstances, whether they have the duty to reveal the true parentage remains an unclear question. This is the case in paternity disputes and use of genetic tests in such instances violate the privacy of the non consenting parent, and will have serious implications for family relationship. Not only genetic tests are used to trace out family relationship, with enough data, population geneticists can estimate how closely different populations of humans are related to each other. This information is also helpful in anthropological, archeological and historical studies to trace the history of human migration across the globe.

Genetic studies have provided another important breakthrough in studying more about the historical figures by analyzing DNA of such persons, who have died. Genetic tests on the dead remains can be used to determine whose remains they really are. This test can be used to determine whether such persons had suffered from any genetic disorder, etc.

Advances in genetic studies have also provided us with a new method of treatment for genetic disease- gene therapy, which is now in the experimental stage. Gene therapy is a technique, in which the defective gene, which is responsible for the

[4] On March 24, 1976, a military Junta (military Junta- government by a committee of military leaders) lead by Gen. Jorge Rafael Videla took control of Argentina, eliminating all due process of law. This military regime committed massive human rights violations, nearly 20,000 men, women and children were disappeared, abducted, raped and murdered leaving behind no information on their whereabouts.

disease is removed and a proper gene is inserted into the relevant cells of the person with genetic disease, so that the gene will produce necessary protein for the health. This type of genetic interventions will have an effect on the concerned person only and will not be inherited to the next generation unless the genetic variation is made on the germinal cells, from which the gametes are formed. These kinds of genetic interventions are also made on the germinal cells and even on the gametes to prevent the genetic diseases to be passed on to the descendants, which are also called gene manipulation or eugenics. Such kind of genetic interventions, however, is now greatly criticized by many scholars on the ground that such interventions have the potential to transform the natural order, the concerns of safety for fetus, complexities in the technology, will lead to the creation of a genetically superior and under privileged class (Greely 1998: 480; Diver and Cohen 2001: 1447), etc.

Discrimination among individuals in the employment sector has long been accepted legally, ethically and socially, based on certain criteria such as their past experience or their educational qualifications. But selecting employees on the basis of specific group, like sex, race, ethnicity, colour and place of birth is not allowed. With the development in human genetic studies, employers have a wide range of reasons to expand the list of criteria so as to include genetic information, based on which they can hire prospective employees and such information can also be used in promotion decisions. Employers may be interested in the revelatory quality of the genetic information, which is more often than conventional medical information will give insight into the genetic predispositions of the applicants, his/her susceptibility to diseases or occupational illness due to exposure to workplace toxins, etc. On the basis of this information the employer can screen the applicants so as to reduce the coast of compensation for occupational illness, avoid applicants who may be likely to take more sick leave or who may likely to terminate the employment due to illness thereby also can reduce recruitment and training costs.

Insurance companies may also use genetic test results so as to deny health insurance or life insurance to those who have a flawed genetic makeup or to decide about the coverage, enrollment and premium to avoid financial risk and to maximize profit (Baram 1997: 488).This could lead to a situation, where genetic information will expose individuals to a broad range of informational abuses resulting in the creation of a fear among general public regarding the abuses of genetic information

and they will not undergo genetic test despite of its diagnostic, therapeutic and health benefits.

### 2.3 *Emerging Manifestations of Human Rights Violations*

With the advancement in human genetics and its applications to detect, prevent and cure health disorders, its potentials for misuse have also been diversified. Following are the key human rights issues that are associated with the misuse of these scientific advancements and its applications:

#### *2.3.1 Privacy violation*

Genetic testing and genetic screening are serious invasion into the privacy of an individual. This is because genetic testing is the analysis of the genetic material of an individual and the information obtained as a result of such test is private/personal information. In the words of Annas, Glantz and Roche, 'genetic information is uniquely powerful and uniquely personal, and thus merits unique privacy protection' (quoted in Weisbrot 2006: 97). Genetic tests disclosing such personal and sensitive information leads to violation of privacy of individuals. The degree of intrusion into privacy varies depending on the fact that whether the test has been conducted with the consent of the individual or not (Kupfer 1993: 21) and for what kind of information such test is conducted. Since genes are inherited from parents; family members and blood relatives also share some genetic characteristics and a genetic test could invade the privacy of family members and blood relatives as well. The rapid developments in this field coupled with growing availability and decreasing cost of genetic testing will also increase the potentials for violating individual privacy.

Apart from genetic testing and screening, creation of genetic databases is also having the potential for violating individual privacy. Human genetic database is a collection of human genetic samples, data and associated information from which genetic inference can be obtained (Gesche 2006: 71). These genetic databases contain highly sensitive, personal information, if misused could lead to breaches of individual privacy and irreparable harm to the donor. Nonconsensual disclosure or use of genetic information stored in such genetic databases may compromise a person's individual autonomy and self determination. It also has the potential for commercial

exploitation, when companies or firms use such information without equitable compensation and this can also lead to discrimination or stigmatization of individual or a group of individuals.

### *2.3.2 Genetic Discrimination*

Discrimination means difference in the treatment of two or more persons or subjects on immoral or irrelevant grounds. Genetic discrimination means discrimination on the basis of one's genetic characteristics or discrimination against an individual or against a family member of that individual solely because of real or perceived difference from the normal genome of that individual or his or family member. However, some scholars are of the view that the harm caused by the disclosure of genetic information cannot be described by the term genetic discrimination and should be viewed in a broader sense as genetic knowledge is used to privilege some individuals and to subordinate others, which they call it as geneticism (Wolf 1995: 348). Genetic information is only used for predicting the future health status of an individual, but can also be used by others such as prospective employers, insurance companies and governmental agencies for discriminatory practices or differential treatments. On the other hand insurance companies maintains that, if they were forced by law to ignore genetic information of an applicant, then that might lead to unfair discrimination among the insured (i.e., treating low risk persons on par with persons known to have more risk) and may also lead to an increase in premium levels (Betta 2006: 42-44) and it is also possible that if the applicant knows that they are at risk and can hide such information, then there will be a systematic increase in insured high risk individuals and the insurers have to pay out more and more claims resulting in the collapse of the industry. Use of genetic information by employers and resulting discriminatory practices or differential treatment in appointment or promotion in employment is a violation of human rights that entails a waste of human talents, with detrimental effects on productivity and economic growth, and generates socioeconomic inequalities that undermine social cohesion and solidarity and act as a impediment in the reduction of poverty (ILO 2007: 7).

One has no control over his/her genetic makeup, which is inherited, fixed, unchangeable and unchosen and the individual who is having a flawed genetic sequence is not responsible for the same. So to penalize one or to discriminate or deny employment, insurance, education, etc. on the basis of a characteristic on which he/she is having no control and is not responsible is a serious attribution of injustice. Sometimes an individual, who may not be at the risk of developing a disease because of his /her unaffected carrier status[5], may also be discriminated against for having a faulty gene. This sort of discrimination is called *perceived discrimination* because 'carrier' has a definite biological definition but the societal connotation of the 'carrier' may be in a different way rather than its biological definition.

Genetic discrimination has an impact on public health. Millions of people could benefit from undergoing a genetic testing and knowing their genetic susceptibilities so that they can change their way of life or submit to early preventive and therapeutic treatment so as to reduce the risk. However advances in predictive genetic testing have aroused fears of potential genetic discrimination (National Partnership for Women & Families 2004:7; Greely 2001: 1484; Hudson 1995: 391; Rothenberg 1997: 1755), differential treatment, exclusion and inequality because of its power to predict the future health status and health risks as well, which will prevent people from taking advantage of this scientific and technological advancement, thereby increasing the financial and physical burden of the public health care sector. Yet another undesirable effect of fears of genetic discrimination is that people may not be willing to participate in genetic research or share information about their genetic status with health care providers or family members, which will also limit or nullify the anticipated benefits of genetic research.

### *2.3.3 Racial/ Ethnic Discrimination (Scientific Racism)*

Genetic tests and screening may not only discriminate individuals or families, but sometimes it also disproportionately discriminate a race or ethnic group of people. Since genetic material and genetic characteristics are inherited along the racial and

[5] Genes appear in pair in both allele of a chromosome pair and if a gene, which is a faulty one or which is responsible for a disease appear only in one allele of a pair and the other remains normal, then that faulty gene remain as recessive and disease will not be expressed in that individual. Such individuals are called 'carriers' because they carry a gene which is not expressed in his/her phenotype.

ethical lines (Murray 1983: 6), they share certain similar genetic material and genetic characteristic and the probability of recurrence of a flawed gene or a genetic variant will be high in a racial or ethical group or in other words certain allelic variants are more common in certain population and less in others and genetic studies or researches based on a particular population or race can lead to a racial or ethnic discrimination - scientific racism (Lee 2003: 993- 995).

Population based DNA sampling or race based genetic research and its potential harmful consequences of stigmatization and discrimination may affect those, who are not direct participants of such studies but are implicated by their identification with that population or race. There are instances of such studies resulted in stigmatization of population, for instance multiplex genetic test studies focused on Ashkenazi Jewish population concluded that the rate of risk for *Tay- Sachs disease*, *Cystic Fibrosis* and *Type I Gaucher Disease* are high in that population and tests coupling *Sickle cell anemia* and *Prostate cancer* found its frequency of occurrence is high in African American males (Council on Ethical and Judicial Affairs, AMA 1998: 19; WHO 2006: 54; Hodge 2003: 1017). This has resulted in the denial and charging higher premium of insurance coverage and other discriminatory acts by governments, insurers, employers against African American Males as early as 1970s (Hudson 1995: 391; Epps 2003: 957).

Genetic test results show only the genetic predisposition or the presence of a lethal gene in an individual, which may cause a genetic disease or illness in that individual's future life. The result gives only a probability and not a conclusive proof for the inevitable onset/ manifestation of disease or illness in a vast majority of cases and even in cases where it can be predicted, its severity cannot be predicted. It undermines the fact that environmental factors have an important role in the manifestation of a genetic disease, and life style as well as food also plays a vital role in the expression of a gene linked disease. Genetic tests do not measure the complex interactions between genes and environment that contribute to the onset of majority of diseases (Hodge 2003:1017). Clinical variability must also be taken into consideration because individuals who possess a genetic variant for a disease may not show the same level of severity of disease or impairment (Billings and *et al* 1992, quoted in Barclay & Markel 2007: 962). Apart from this, on the basis of the information

obtained from the test result, individuals undergoing such tests are having a better choice to take preventive steps such as medication, regular medical monitoring, preventative treatment, changing life style or environmental modifications that may be wholly or partially effective at preventing or even eliminating the onset of disease, illness or disability. Without taking into account these factors, denying employment, insurance, education or an equal opportunity to a person, who do not show any somatic symptoms of disease or disability, merely relying on a genetic test result, which gives only a probability assurance, is a gross violation of human rights and human dignity and integrity and also poses serious ethical issues.

### *2.3.4 Social Stigmatization*

Stigmatize means to mark anyone as disgraceful or dishonourable. Stigmatization involves an attribute or state that can lead to a feeling of devaluation and is a result of the co occurrence of labeling, stereotyping, separation, status loss and discrimination, which in turn results in self imposed limitation in choice and life directions (Barclay & Markel 2007: 956).

Genetic tests and screening may lead to social stigmatization of individuals as well as their families (Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice 1998) and sometimes a group of individuals or a population as having a flawed or substandard or uninsurable genetic profile, etc. or as genetically weak, which in turn leads to obvious denial of employment, insurance and other opportunities by other organizations. Publicity of a particular genetic condition as flawed one or undesirable one aimed at preventing the spread of genetically linked disease itself is an extreme form of stigmatization and the societal pressure to be genetically tested for preventing the spread of genetic disease will not only expose individuals to possible stigmatization but also pressurize individuals to avoid a pregnancy that has been identified as having a flawed genetic makeup.

Social stigmatization of individuals and their families may result in the social stratification of the society into individuals with a superior genetic makeup and others with an inferior genetic profile (Baram 1997: 489), which is contrary to public interest.

### *2.3.5 Genetic Determinism*

Genetic determinism is the fatalistic belief that behavioural and personality characteristics are mostly a function of genes and this leads to misuse of genetic testing, prenatal screening and pre-implantation genetic diagnosis. In fact such techniques are now widely being used for sex selection, selection of desired traits, etc. rather than disease control. Social engineering or selection of desired traits like increased stamina, athleticism, IQ, beauty, size, etc. is very much similar to the concept of Eugenic and the method applied by Nazi Germans in World War II[6]. In the twentieth century many legislation were passed in several countries like US, Canada, Australia, etc., which aimed at forcible sterilization of individuals, whom the state felt physically and mentally unfit so as not to inherit such traits to the next generation. Justice Oliver Wendell Holmes, Jr. of the US Supreme Court in a landmark judgment upheld the constitutional validity of such state action of forcible sterilization (Buck v. Bell 1927). With the advance of new genetic technology, it is now possible to abort a fetus with undesirable traits or bringing in desirable traits in the genetically selected babies- often called as designer babies (Spriggs 2002: 290), which can be viewed as a new version of eugenic in the genomic era and are severely been criticized on the ground of meddling with nature. These developments in the field of human genetics and associated technologies, can lead to social stratification i.e. creation of a class with a superior genetic makeup and another class of people with an inferior genetic makeup.

## 2.4 *Disclosure of Personal Genetic Information: Frontiers of Conflict*

Advances in new genetics stirred up a lot of social, ethical and legal issues regarding genetic testing and genetic information. One among such issues is the debates over the exceptional nature of genetic information. There are diverse views regarding genetic testing, nature and disclosure of genetic information as well as the regulation of genetic information. Even though there are diverse views regarding different aspects of genetic information, many people now agree on the fact that it is

[6] The Nazi regime in the wake of attaining a pure German race performed a serious of eugenic programs, in which hundreds of thousands of people were forcibly sterilized during the period 1930's and 1940's, whom they considered as mentally or physically ill. They went further by killing tens of thousands disabled through compulsory euthanasia program.

distinct from other types of conventional medical information or health information because it provides information about an individual's predispositions to future disease and can provide clues to the future health risks for an individual's family members as well (Hudson *et al.* 1995: 392). A lot of arguments are also put forward by proponents to substantiate the exceptional nature of the genetic information. Some of them are:-

(1) Decoding of DNA divulges vast amount of information, which is very sensitive and the disclosure of which to third party can raise concerns on privacy and confidentiality of genetic information, genetic discrimination, etc. The existence of such decodable information will also compel people to consider issues of privacy and confidentiality more seriously;

(2) Genetic information is predictive in nature (Everett 2005: 288). Like race, colour, sex, origin of individuals, genetic predispositions are also neither voluntarily chosen by the bearer nor can it be readily changeable. Therefore, the increased predictive efficiency of new genetic tests, having the potential to reveal the genetic predispositions of individuals and their genetic vulnerabilities to certain diseases and the future health status of such persons as well as their health risks, leads to discrimination, oppression, stigmatization and violation of privacy, which ostensibly calls for special protection;

(3) Genetic information may not always amount to health information because in many a case the information may not be about health, disability or provision of health service (Weisbrot 2006: 109). For instance in the case of paternity testing or forensic testing the focus is not on health but on the identity of the person. Again in carrier testing the focus is not on the health of the person undergoing genetic testing but the health of children of that person or future generation.

(4) Genetic information has implications for individuals as well as for their parents, siblings, children, and other immediate relatives, since genetically related family members share a portion of a common genetic material. This means the abnormalities found in an individual's genetic makeup may also be present in his/ her close relatives. It is also possible that individuals having a flawed genetic makeup may wish to keep it secret from other family members and can affect how family members perceive and relate to one another. Proponents of genetic exceptionalism are also

concerned about the psychological effect of learning one's predisposition to a deadly disease for which there is no effective treatment. This will not only be detrimental to the psyche of individuals and their families, but also lead to a kind of stigmatization and societal discrimination;

(5) Genetic information provides information about the reproductive and other characteristic features of next generation and can have implication for the child bearing decisions of parents. This power to foresee the genetic characteristic feature of coming generation and the idea of genetic defects or genetic variants will lead to a new eugenic civilization in which the society will be able to reengineer the human species to suit their own whims and fancies;

(6) Genetic material largely remains stable throughout life;

(7) Genetic information often carries stigma and the misuse of genetic information can lead to violation of privacy and confidentiality of genetic information, genetic discrimination, differential treatment, social stigmatization and eugenics,;

(8) Genetic information may even point towards certain behavioral traits, such as intelligence, sexual orientation, anxiety, or aggression (Gesche2006: 75), which may also lead to stigmatization and discrimination;

(9) Finally information relating to certain serious diseases like mental illness and HIV/AIDS are treated separately and special protection is provided to such information. Since genetic information is also analogous to such information it also requires special protection.

James Watson, the former director of the Human Genome project once declared "*We used to think our fate is in the stars. Now we know, in large measure, our fate is in our genes*" (quoted in Everett 2005: 288). Many scholars have expressed concerns over such view that undermines the economic, social and environmental factors involved in the disease. Every disease or disorder is having a genetic, socioeconomic and environmental factor and the causal role of each factor may be different. The view that emphasizes more on the genetic cause of the disease is what a number scholars like Thomas Murray and Isaac Rabino call it 'genetic exceptionalism' (Rothstein 2005: 27). Still some others call the exaggerated emphasis

on the importance of genes and genetic explanations of disease or behavior as "geneticization" of society, geneocentrism, genetic essentialism (Rabino 2003: 383), genetic reductionism (quoted in Rabino 2003: 383) and are willing to challenge the arguments for such views. This view can change the way in which illness is being perceived. One who is found asymptomatic and healthy can still be labeled as genetically ill. This is because of the shift in the criteria that constitute illness from the symptoms that are experienced by an individual patient to whatever is recorded in his / her DNA sequences.

There are drawbacks in strictly adhering to the view that genetic information is unique or different from conventional medical information and require special treatment. For instance special treatment of genetic information requires an increased level of confidentiality and privacy for genetic information, which will ultimately lead to strict provisions of individual privacy and individual autonomy that may impede the establishment of communal good and public health. According to Rothstein genetic information does not require any special treatment and the so called unique features of genetic information, which has led to its special treatment, is not unique to genetic information (Rothstein 2005: 30). He also believes that while concerns of genetic privacy and genetic discrimination could have been addressed effectively through public education and broad laws protecting the privacy of health information and prohibiting health discrimination, genetic exceptionalism has led to the enactment of several genetic specific laws, which intended to prohibit genetic discrimination and regulate third party access to genetic information. However, these genetic specific laws help only to reinforce discrimination and stigmatization by treating genetic disorder differently from nongenetic conditions (Rothstein 2005: 30). Further it is practically very difficult to identify and separate genetic information and non genetic information from a health record and then to provide access only to non genetic information to third parties leaving difficulties in regulating genetic information. A similar view is also maintained by Thomas H. Murray and he argues that genetic information is special because we are treating it as mysterious and having predictive potentials and significant from other sort of medical information because of the possibility that others may know information about an individual, which he/she himself/herself is unaware and the way in which it connects individuals to his/her immediate family members and more distant kin (Murray 1983: 6). In short opponents

of genetic exceptionalism are of the view that genetic specific laws are largely ineffective and may also be counterproductive or may result in unintended consequences.

Advances in human genetics and associated technologies boosted the commercialization of health care system, particularly because of the increased role of private parties and the collaboration between physicians, research scientists, medical industrial corporations, drug firms, etc. It is also an undisputable fact that biotechnology and human genetics is becoming a multibillion dollar industry and the recent commercial interest in this field revolves around 1) the discovery and sequencing of gene related to disease; 2) identification of biochemical markers; 3) ascertainment of the role and functions proteins; 4) development of individualized drug therapies; and 5) provision for genetic testing and this will lead to a situation as many feared, a reductionist approach of viewing genetic material as merely a profitable raw material (Betta 2006: 35- 44). Concerns of privacy, human dignity and protection of genetic information emerges directly from this growing demand for commercialization of the genetic information because the unique feature of genetic information makes it potentially valuable to employers, insurance companies, researchers, pharmaceuticals, etc. (Everett 2005: 288). Therefore, some scholars maintains the view that creation of a property right to one's genetic material is essential for the protection of the privacy and confidentiality of genetic information and preventing genetic discrimination. On the other hand still some others gives more stress to prior informed consent rather than the creation of property right to ones' genetic material because the nondisclosure norms are practically enforceable and morally sound more over one cannot base discrimination on a person's genetic information unless and until he has access to such information (Baram 1997: 491; Diver & Cohen 2001: 1445).

Apart from the ethical and privacy concerns, some libertarians argue that genetic testing will generate vast amount of information, which will provide people more knowledge, which in turn will help individuals in exercising the autonomy of choices regarding treatments or health care (Andorno 2004: 436). It can be exercised only when the patient is provided with all relevant information regarding his/her genetic status, and to know one's genetic destiny is his/her unalienable right. On the

other hand opponents to this argument say that information regarding a genetic disease for which there is no treatment will be a burden for the patient. It will lead to severe psychological impact on the patient and will also have a negative effect on his/her family life as well as on his/her social relationship in general. There is a counter argument for the above argument that if information is obtained about an untreatable genetic condition then it may enable the patient or the parents of the newborn to avoid recurrence or to facilitate early health care and financial planning for the affected (Natowicz and Alper 1991: 477).

### 2.5 *Summary*

Past few decades witnessed rapid developments in human genetics and its applications revolutionized the health care system. On the other hand it has also raised a lot of legal, ethical and social concerns and resulted in new forms of human rights violations like genetic discrimination, violation of privacy due to the disclosure of genetic information, scientific racism, genetic determinism and social stigmatization. This ambivalent nature of these developments has created many problems in regulating the genetic information and protecting the privacy and confidentiality of genetic information. It has also created disagreement on a wide range of issues relating to human genetics and its applications among scholars as well.

*Chapter 3*

# *Genetic Information and International Law: Some Basic Issues*

# Genetic Information and International Law: Some Basic Issues

## 3.1 *Introduction*

Rapid development in genetics and related new technologies presents a wide range of complex ethical and human rights issues in the field of medicine, especially in genetics, which apparently calls for legal responses to avoid misuse of these advanced technologies and informational abuses. The challenges presented by these advanced technologies are so alarming and far reaching that individual country alone cannot satisfactorily address these issues because of the increasing globalization of science and the easiness in evading municipal regulations by crossing the border. On the other hand, international legal consensus can ensure legal uniformity and consistency throughout the globe and avoid unwarranted restraints on medical research and interstate commerce with a jumble of inconsistent laws and can also lay down uniform legal standards to protect individual interests. That is why international cooperation is required to harmonize legal standards or to establish common standards and to bring into existence a mechanism to monitor whether such standards are being followed by nations. To reach a global consensus for establishing universal principles for the new emerging biomedical dilemmas is not an easy task because of the diversity in cultural, economic, social and religious factors but it is not impossible because international organizations can provide a stage for some constructive dialogue between these diversities. Viewing the urgency of the situation, notwithstanding the difficultness in obtaining international consensus over such a sensitive issue, certain international organizations have made significant efforts in this field over the last few years. Some of the international bodies which have taken initiative and come up with certain international instruments in this field are United Nations Education, Scientific and Cultural Organization (UNESCO), Economic and Social Council (ECOSOC), Commission on Human Rights, World Health Organization (WHO), World Medical Association (WMA), Council for International Organizations of Medical Sciences (CIOMS), Human Genome Organization (HUGO), International Huntington Association (IHA) and Organization for Economic Co-operation and Development (OECD).

There are three major international instruments dealing with biomedicine and human rights: Universal Declaration on Human Genome and Human Rights

(UNESCO 1997), International Declaration on Human Genetic Data (UNESCO 2003) and Universal Declaration on Bioethics and Human Rights (UNESCO 2005). Apart from these three instruments, the recent regulatory initiatives in human rights and biomedicine by various international bodies are Commission on Human Rights resolution "Human Rights and Bioethics" (ECOSOC 2003), Genetic Privacy and Non- Discrimination (ECOSOC 2004), Declaration on the Human Genome Project (WMA 1992), Human Genome Mapping, Genetic Screening and Gene Therapy (Declaration of Inuyama) (CIOMS 1990), International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002), Guidelines for the Molecular Genetics Predictive Test in HD (IHA 1994), Proposed International Guideline on Ethical Issues in Medical Genetics and Genetic Services (WHO 1998), Review of Ethical Issues in Medical Genetics ( WHO 2003), Statement on Benefit-Sharing (HUGO 2000), Statement on DNA Sampling: Control and Access (HUGO 1998), Genetic Testing - Policy Issues for the New Millennium (OECD 2000), etc.

### 3.2 *General Principles*

One of the distinctive features of these international instruments relating to human rights and biomedicine is its emphasis on respecting the human dignity and integrity. This principle has been affirmed under the Charter of the United Nations (UN 1945: Preamble), Universal Declaration of Human Rights (UN 1948: Preamble, Art.1), International Covenant on Economic, Social and Culture Rights (UN 1976a: Preamble), International Covenant on Civil and Political Rights (UN 1976: Preamble) and also under various other human rights instruments. However in international instruments relating to biomedicine and human rights respect for human dignity primarily aims to condemn the reductionist approach of reducing human identity to the genetic characteristic and requires respect for the uniqueness and diversity of genetic material. This has been specifically mentioned under the Universal Declaration on the Human Genome and Human Rights (UNESCO 1997: Art.2) as well as in the International Declaration on Human Genetic Data (UNESCO 2003: Art.1). Instruments relating to human rights and biomedicine are also special in their commonality of some of the general principles laid down by these instruments. They are:

- The principle of privacy.

- The principle of confidentiality.
- The principle of non – discrimination.
- The principle of prior informed consent.
- The right not to know.

### 3.2.1 *Principle of Privacy*

Rapid developments in science and technology particularly in biomedicine and human genetics have enhanced the capacity for collecting and storing personal information, especially personal genetic information, which has raised concerns on protection from unwarranted collection of personal genetic information and their disclosure. These are areas where privacy is at stake and the increased demands for the protection of privacy have produced a collection of international legal responses in the field of biomedicine and human rights like International Declaration on Human Genetic Data (UNESCO 2003: Art.14) and Universal Declaration on Bioethics and Human Rights (UNESCO 2005: Art.9), which protects the privacy of persons with respect to their genetic status. The right to privacy has also been protected under general human rights instruments like Universal Declaration of Human Rights (UN 1948: Art.12), International Covenant on Civil and Political rights (UN 1976: Art.17), etc.

The term "genetic privacy" has gained much attention in recent years in general public sphere as well as in legal parlor in the context of new predictive genetic testing because of the sensitive nature of information it divulges and its implications for the patient himself/herself, his/her relatives, future reproductive choices and subsequent generations (HGC 2002: 31). However all genetic information cannot be treated as personal or outside public domain and can claim privacy rights over it. For instance, information relating to one's hair colour, eye colour, which is also genetic information, strictly speaking, can be obtained by basic observation of a person, for which one cannot claim privacy right. Other personal genetic information, which is having more predictive nature and not readily visible, should be protected by the principle of genetic privacy.

None of the instruments relating to biomedicine and human rights, however, attempts to define the term "privacy". The term "privacy" has a range of meanings; in a lot of debates are going on the definitional aspects of the term privacy and how the privacy rights can be balanced against the rights and interests of others. There are two conceptual approaches in this context: one is the anti – reductionist approach and the other is reductionist approach. Both these views agree on the fact that the concept of privacy highly rely on the notion of free from intrusion or invasion, but they disagree on what ought to be protected from intrusion. Anti – reductionists are inclined to expand the meaning and scope of the term privacy so as to include a diverse set of things like personal information, secrecy, peace of mind, bodily integrity, anonymity, seclusion, intimacy and decisional autonomy, the invasion of which will constitute violation of privacy. On the other hand, reductionists claim that more liberal construction of privacy will lead to ambiguity, vagueness or indeterminateness and if the concept lacks clarity the appeal to privacy may not advance resolution of normative disagreements (Powers 1996: 370- 372).

Many scholars have defined the term "privacy" in terms of information. Some scholars maintain argues that privacy is related to the amount information known about an individual (Gavison 1980: 429). Prof. Alan Westin is of the view that it is a claim of individuals, groups or institutions to determine for themselves when, how, and to what extent information about them is communicated to others (quoted in Gavison 1980: 426). For some others it is a right to conceal from others some parts of our conducts, thoughts and emotions (Etzioni 2002: 255) or the right to be let alone (DeCew, Judith Wagner 1986: 150). So confusion surrounding the term privacy still persists and the possibility of achieving greater precision for the term is practically difficult.

### 3.2.2 *Principle of Confidentiality*

It has long been accepted that the principle of medical confidentiality is one of the most fundamental ethical principles that exists between the patient and doctor (Lesser and Pickup 1990: 18). This principle is at the heart of medical practice and procedure and preservation of the confidentiality of sensitive personal health information is the obligation of health care provider and is enforced by the rules of code of ethics that govern the medical profession. This is also essential for

maintaining the trust and integrity of patient- physician relationship. Any information that is disclosed by the patient or which emerges in the context of medical care is protected by the principle of confidentiality (HGC 2002: 55) and the physician is under a duty to keep such information confidential even after the death of the patient (WMA 1981: Principle 8; WMA 2002: Para. 2, 12; WMA 2006; WMA 2004: Para. 21). But the stark reality is that medical records are now increasingly being stored in electronic media from which it can be accessed by a number of persons in the hospital and can be communicated to a number of persons involved in the patient's care. However these disclosures are not disclosures to which the patient has expressly consented to but has now become part and parcel of modern medicine. Genetic information being a part of a person's health record can expect a similar degree of confidentiality only in the present day context.

Taking into account these practical realities, majority of the literature relating to biomedicine and human rights strongly focused and highlighted the special status of genetic data on account of its sensitive nature, power of predictability and its significant impact on family, coming generations and the reproductive choices of the parents and emphasized the need to treat it with high degree of confidentiality. The power of predictability of genetic information and its implications for people other than the patient himself/ herself makes the unwarranted disclosure of genetic information more serious than that of other confidential medical information. Disclosure of genetic information in cases of presymptomatic genetic testing has other implications for the person undergone such test, such as, his/her eligibility to health insurance or life insurance; his/her employment opportunities and prospects of promotion, etc. This overwhelming claim for confidentiality has been endorsed by Universal Declaration on the Human Genome and Human Rights (UNESCO 1997: Art.7), International Declaration on Human Genetic Data (UNESCO 2003: Art. 14), Universal Declaration on Bioethics and Human Rights (UNESCO 2005: Art. 9), etc. Apart from endorsing confidentiality to genetic information instruments relating to biomedicine and human rights also confer special status to genetic information. However the obligation to maintain confidentiality of medical records and genetic information obtained in medical settings is not an absolute one and can be breached, when there is adequate justification. The exception from confidentiality may be invoked only if there is extenuating or overriding personal harm to third parties. This

is particularly important when genetic information of an individual demonstrates the presence of an inherited disease or disorder because this knowledge can have serious implications for genetically related members of his/her family and this is the most compelling reason for limitations to the principle of confidentiality of genetic information besides those instances, where it is required by law. The international instruments mentioned above has restricted the third party access to genetic information, particularly disclosure to employers, insurance companies, educational institutions, other family members, etc, and allowed limitations to the principle of confidentiality for compelling reasons (UNESCO 1997: Art. 9; UNESCO 2003: Art. 14. b). According to the provisions of these instruments genetic information of a subject can be disclosed or communicated to employers, insurance companies, educational institutions, family members, etc only with the free and express consent of the subject. Ethically these limitations are crystallized in the form of a duty or obligation on the part of the health care provider to warn, when there is a clear and imminent danger to third parties (Murray 1995: 950). However the duty or obligation on the part of the health care provider to warn, when there is an imminent danger does not adequately justify in cases where the condition, demonstrated by the genetic information, is not treatable. In such cases there is no usefulness in passing such information to third parties and there is no evidence of harm as well, but in cases where there is treatment or methods of preventing or mitigating the severity of the disease, failure to communicate or failure to warn would result in harm to third party.

### 3.2.3 *Principle of Non – Discrimination*

Differential treatment among individuals has long been accepted legally, ethically and socially, but differential treatment among individuals based on certain irrelevant or immoral grounds such as race, colour, sex, religion, place of birth, political opinion, social origin, etc is considered as discrimination and is prohibited under almost all legal systems. Discrimination (Employment and Occupation) Convention of the ILO has provided an inclusive definition for the term discrimination, which states that discrimination includes any distinction, exclusion or preference made on the basis of colour, sex, religion, political opinion, national extraction or social origin, which has the effect of nullifying or impairing equality of opportunity or treatment (ILO 1958: Art. 1). The principle of non discrimination is

now a universal principle (ILO 2007: 7) and is recognized by many international instruments such as the Universal Declaration on Human Rights (UN 1948: Art. 7, 23(2)), International Covenant on Civil and Political Rights (UN 1976: Art. 24, 26), International Covenant on Economic, Social and Cultural Rights (UN 1976a: Art. 7), Convention on the Elimination of All Forms of Discrimination against Women, etc and under Discrimination (Employment and Occupation) Convention (ILO 1958: Art. 2) and Equal Remuneration Convention (ILO 1951) state parties are committed to eliminate all forms of discrimination in employment and occupation.

Rapid developments in human genetics and related technologies have set the stage for a new manifestation of discrimination- discrimination based on ones' genetic predispositions to certain genetic diseases or vulnerabilities to certain diseases, illness, work place toxins, etc. Some scholars call it as geneticism i.e., the use of genetic information to benefit some individuals and to disadvantage others (Wolf 1995: 348). Discriminatory practices based on ones' genetic predispositions or on ones' vulnerability to certain genetic disease, illness or disability are most common in employment sector as well as in insurance field. In the past few years, instances of such type of discriminatory practices are increasingly been reported in the industrialized states (ILO 2007: 48). These practices have aroused fears in the mind of employees that the employer may use their genetic information to lower their insurance and sick leave cost by weeding out employees with genes responsible for a genetic disease, illness or disability or for vulnerability to certain work place toxins and this has also created a similar mentality in individuals who seeks insurance services. Fears of genetic discrimination prevent many people from taking advantage of this scientific advancement resulting in the violation of human right protected under Universal Declaration of Human Rights (UN 1948: Art. 27), International Covenant on Economic, Social and Cultural Rights (UN 1976a: Art. 15), Declaration on the Use of Scientific and Technological Progress in the Interest of Peace and for the Benefit of Mankind (UN 1975: Para. 2, 6), etc.

The International Labour Organization in its latest report considered genetic discrimination as an emerging form of discrimination and expressed the view that since lack of clarity persists in the objective reason and circumstances justifying less favourable treatment of individuals based on their genetic predispositions, such

practices must be reasonable, appropriate and proportionate (ILO 2007: 48- 49). However the misuse of genetic information/data or human proteomic data leading to discrimination or stigmatization of individual has been strongly condemned under Universal Declaration on the Human Genome and Human Rights (UNESCO 1997: Art. 6), International Declaration on Human Genetic Data (UNESCO 2003: Art.7), Universal Declaration on Bioethics and Human Rights (UNESCO 2005: Art.11), Genetic Privacy and Non- Discrimination (ECOSOC 2001: Para.3, 5), Human Rights and Bioethics (CHR 2003: Para. 6), etc. States are also required to address the issues of genetic discrimination and stigmatization by taking specific measures including municipal regulations.

### 3.2.4 *Principle of Prior Informed Consent*

Prior informed consent is a central principle in biomedical laws, especially in laws regulating biomedical researches involving human participants, and also plays a significant role in medical treatment and procedures. The principle of consent in this context means that a person shall be subject to a medical examination/ treatment only with his/her free and full consent, obtained after communicating to him/her the relevant details of the examination and treatment. This principle not only applies in the examination or treatment but also in the obtaining, handling and storage of medical records. The emphasis on informed consent is based on the respect for human dignity and respect for individual choices or individual autonomy. This principle is also a rejection of the paternalistic approach, which was earlier prevalent in medical practices (HGC 2002: 42).

The principles of prior informed consent in the context of biomedicine and genetics are upheld by many human rights instruments like International Covenant on Civil and Political Rights (UN 1976: Art.7), Universal Declaration on the Human Genome and Human Rights (UNESCO 1997: Art.5b), International Declaration on Human Genetic Data (UNESCO 2003: Art.8a), Universal Declaration on Bioethics and Human Rights (UNESCO 2005: Art.6), Declaration of Helsinki (WMA 2004: Principle 9, 10), Genetic Privacy and Non Discrimination (ECOSOC 2001: Para. 4), etc. The principle of informed consent laid down in these instruments prescribes that prior, free, informed and express consent of the subject should be obtained for the collection of human genetic data, proteomic data or biological samples and for their

subsequent processing, use and storage. Consent is also required for any sort of preventive, therapeutic and diagnostic intervention and the subject/ patient reserves the right to withdraw the consent at any point of time without any disadvantage or prejudice and in such circumstances the data and biological samples obtained from the patient should irretrievably be unlinked or destroyed (UNESCO 2003: Art.9; UNESCO 2005: Art. 6(1), 6(2)). These instruments also direct state parties to lay down limitations on these requirements only for compelling reasons consistent with international law and human rights (UNESCO 1997: Art.9; UNESCO 2003: Art. 8a; UNESCO 2005: Art.6 (2); ECOSOC 2001: Para.4), such as forensic purposes, legal proceedings, etc. and to provide protection for persons, who are incapable of giving consent because of unsoundness of mind, infancy, etc. In such cases authorization is required to be obtained from the legal representative, who is having regards to the best interest of the concerned person, in accordance with domestic law (UNESCO 1997: Art.5e; UNESCO 2003: Art.8b; UNESCO 2005: Art.7; WMA 2004: Principle 11).

Prior informed consent is an indispensible requirement in genetic testing and genetic screening to ensure individual privacy and confidentiality as well as to promote individual autonomy in medical decision making. Receiving prior informed consent implies that the person concerned understands the relevant information relating to genetic testing/ screening and its socio-legal aspects and its implication for him/her and for his/her family members. It also implies that the decision arrived at by the person concerned to undergo medical intervention is voluntary. This being the fact obtaining prior, free and informed consent is not an easy task, it involves a lot of challenges. First and the foremost is the fact that to be fully informed of the relevant information about genetic screening / testing and its implications for the individual concerned and for his/ her family requires a basic understanding of genetics. This being a highly scientific and technical matter even highly qualified persons in a different discipline find it difficult to understand the intricacies behind this issue. So it is least expected from a lay person.

Secondly the nature of genetic information presents a lot of challenges to the requirement of prior informed consent. A physician is required, under this principle, to disclose all relevant information to the patient, without which he is not reasonably

expected to make a decision based on the clear analysis of available options and possible outcomes (The Council on Ethical and Judicial Affairs, AMA 1998: 17). However communicating the sensitivity[1], predictive value and the interpretations of the test results to the patient is a complex task. This is because since genetic tests are being conducted at an ultra molecular level there is always a possibility for errors to creep into test results so as to give a false positive or a false negative result. Further even if the test result registers a true positive result, it is not a conclusive proof of an inevitable onset of a genetic disease, disorder or disability. This is only a near certain prediction of a disease, illness or susceptibility to certain disease or illness and the predictive value changes from case to case. But the patient may sometimes believe it to be conclusive by its very nature. So there are problems in predicting the onset of a disease on the basis of the test result as well as in interpreting the test result.

The third major challenge in obtaining the prior informed consent lies in the fact that there are instances in which the results can provide insight into actual onset of a disease/ disorder in the later period of an individual's life but there is no effective treatment (The Council on Ethical and Judicial Affairs, AMA 1998: 17). In such cases if there is no preventive measure or effective treatment to mitigate the severity of the inevitable condition or to save the life of the patient, then whether the physician has the duty to disclose such information to the patient is a disputed matter, which needs further consideration. However, some thinkers maintains the view that the problems in communicating the complex scientific details to lay persons and the uncertainties in interpreting the test results and predicting the onset of genetic diseases or susceptibilities to certain diseases can be overcome by providing genetic counseling to patient by physician. To accept this view means taking it for granted that there is hardly anything, which the patient cannot understand and consider. Moreover even if a physician or a health care provider needs to give genetic counseling to patient, he should be well versed in human genetics and trained in genetic counseling and interpreting genetic tests. However, the stark reality is that there is a scarcity of physicians, who are well versed in human genetics (WHO 2006: 72; The Council on Ethical and Judicial Affairs, AMA 1998: 17), which ostensibly calls for shifting the

[1] Here in this context sensitivity of a genetic test means the ability of the test to register true positive results.

burden of conveying the relevant information to the patient or giving genetic counseling to the patient to non- physicians. The problem does not come to an end here because the process of genetic counseling involve the consideration of clinical implications also, which can be conveyed only by physicians. This also creates problem because it consumes a lot of time and the increasing demand on physicians to see more and more patients presents practical difficulties in implementing the counseling requirements. In short the requirement of prior, free and informed consent is practically difficult to implement and administer in clinical settings so far as genetic testing and screening is concerned.

### 3.2.5 *The right not to know*

Over the last few decades patient's right to be fully informed of the risk and benefit of a medical diagnosis/ intervention is considered as a fundamental legal and ethical principle in biomedical laws and is inculcated under the right to know. Now there is a hue and cry for an apparently opposite right- right not to know. This right has been referred particularly in the context of genetics and biomedicine. The international bioethical law considers this right as an emerging form of human right and is recognized under article 5(c) of the Universal Declaration on Human Genome and Human Rights (UNESCO 1997), article 10 of the International Declaration on Human Genetic Data (UNESCO 2003), principle 7(d) of the World Medical Association Declaration on the Rights of the Patient (WMA 1981), International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (WHO 1997: Table 7), etc. The right recognized under these instruments is that the person who is undergoing genetic testing or medical treatment is having the right not to be informed of the results of genetic testing or genetic status or information recorded in the medical records.

The international recognition of a right not to know by many human rights as well as biomedical legal instruments has been subject to severe criticism from the proponents of Enlightenment, who consider knowledge enables and gives the courage to use one's understanding without the guidance of another (Kant 1784: 1). This school of thought goes parallel to the principle of individual autonomy and individual self determination. For them knowledge is always good in itself and therefore right to remain in ignorance is in direct contradiction and opposed to patients autonomy

because it deprives the patient of relevant information leading to inaccurate self assessment or leaving the patient in a position unable to give consent based on his or her understanding (Chadwick 2004: 299-300). Therefore the right not to know is incompatible with the notion of right and human rights philosophy. Moreover they also argue that the right not to know is contrary to the doctor's duty to disclose risk to the patient and this will reinstate the paternalistic attitude in medical practice and leave patients in a state of ignorance, depriving them of choices.

However, those who argue for the right not to know claims that this right is not contrary to individual autonomy, but is based on individual's self determination because the choice not to know the results of genetic test is taken by the patient itself and respect for individual choices is an enhancement of individual autonomy (Andorno 2004: 436- 437). Further they also clarify that the argument that the right not to know will deprive the individual from relevant information leaving him in a position unable to give prior informed consent is a misapprehension because here the choice to remain in ignorance is taken by the patient himself or herself thereby relinquished/ waived the right to be informed of the genetic test results only and not the right to informed consent (*Ibid*: 437). The right to prior informed consent exists there because the patient knows that he/she will be subjected to genetic tests, which may reveal the susceptibility to a genetic disease or illness or he/she is having a gene responsible for a genetic disease or illness.

In the context of medical treatment or genetic testing, if a person is exposed to information that he/ she is at risk of a fatal disease for which there is no effective treatment or preventive measure even to mitigate its severity, then that knowledge will be a burden for the patient and the disclosure may harm the patient physically, psychologically and emotionally having a negative effect on his/ her family life and social life (Murray, 1995: 950). In such a circumstance it is justifiable to permit individual to opt not to receive such potentially harmful information which they don't want and is consistent with one of the oldest principle of medical ethics "non - maleficence", which certainly include not to harm the patient emotionally and psychologically.

The right not to know, however, is not an absolute right so far as genetic testing is concerned. This is because genetic testing not only divulges information about a person, but also reveals genetic information about family members as well. In such a circumstance a genetic test result may reveal serious risk to a family member, giving such person an opportunity to take preventive measures or treatment or to change the life style so as to avoid the risk or sometime completely curing the disease. So patient's choice to remain in ignorance about his/her genetic status may in some case necessitate the physician to disclose such information to his/her relatives. Even though this exception is not expressly mentioned in instruments relating to biomedicine and human rights it can be inferred from the lines which allow limitations on privacy and confidentiality of genetic information for compelling reasons as well as for important public interest reasons (UNESCO 2003: Art.14b; WMA 1981: Principle 7e, 8a). Further, there also arises a question whether the right not to know can be presumed or should it be explicitly claimed? Both, right to know and right not to know, are competing rights and which one will prevail over the other is a matter of dispute since legal instruments are silent in this regard. Physicians have a duty to disclose any risk to the patient, which form part of their professional ethics together with respect for individual self determination demands to treat right to know as a rule, at least as regards competent persons are concerned (WMA 2006) and to treat right not to know as exception, invoked only at the express choice of the patient.

### 3.3 *Definitional Dilemmas*

Apart from the principles lay down by international biomedical instruments, the factor, which determines the degree of protection these instruments offer or the effectiveness of these instruments, lies in the definitional aspects. So it will be important to critically analyze some of the fundamental definitions adopted by these international instruments like the definition of terms genetic information, genetic testing, etc.

#### 3.3.1 *Genetic Information*

Personal genetic information can be broadly defined as any information concerning the genetic makeup of an individual, which includes personal genetic characteristics, information about private matters, his/her genetic vulnerability or

susceptibility to certain diseases, existing genetic disorders, how he/she is related to his/her family members, information regarding his/her race, ethnicity, etc.

For the purpose of regulating genetic information and the human rights violations resulting from the disclosure of genetic information, two possible approaches can be adopted for defining genetic information. One is to define it in a narrow way and the other is to define it in much broader way, both have its own advantages as well as disadvantages. The advantage of a narrow definition is that it will be relatively clear but its disadvantage is that it will be easy to circumvent such definition (Greely 2001: 1495). A definition which simply defines genetic information as information obtained from DNA as a result of genetic testing can be considered as a narrow definition. This is because information about eye colour, hair colour, etc is also genetic information, which can be readily available by mere observation without any DNA test. A family doctor, on seeing a twenty five year old patient with an increased cholesterol level can reasonably suspect the genetic disorder, familial hypercholesteremia. Similarly family history, which forms part of medical record, also reveals some probabilistic genetic information (Rothstein 2005: 29) and a definition which does not include family histories will not provide protection to persons, who are known to have fifty percent chances of inheriting a genetic disease. Further genetic information can be obtained not only from DNA but it can be obtained also from proteins, RNA, other gene products, etc. Tests to determine diseases like Tay – Sachs and Sickle cell anemia are routinely done on proteins not on DNA[2]. So a definition, which does not take into account these aspects are considered as a narrow definition, which is insufficient to protect the privacy and confidentiality of genetic information and to regulate genetic discrimination.

On the other hand, a wider definition is also not free from shortcomings. For if family histories are included within the purview of the term genetic information, then much of the traditional medical under- writings would become illegal (Rothstein 2005: 29), physicians cannot inquire the patient about his/ her parents health status, which is now being considered as and forms part of medical record. Genetic information can be classified into four categories namely, observable (such as eye

[2] The variant genetic material involved in such genetic conditions will produce different protein in the body, which can be separated from other proteins and can be tested for the disease without dealing with DNA.

colour, hair colour, etc.), non- observable (such unaffected carrier status for a genetic disease), sensitive and non- sensitive genetic information (HGC 2002: 25- 29). Whether all these forms of genetic information are to be included within the purview of a broader definition of the term genetic information is an unsettled question. Experts, interest groups, institutions in this field have different opinion and majority are of the view that it should be defined in a broader way rather than be centered on DNA testing. However some are of the view that rather than emphasizing the method by which genetic information is obtained, emphasis should be placed on the content and implication of that information and the uses that can be made of it (HGC 2002: 29).

International instruments relating to biomedicine and human rights do not define the term genetic information except International Declaration of Human Genetic Data. In fact International Declaration of Human Genetic Data uses two terms "human genetic data" and "human proteomic data". It defines the term human genetic data as "information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis" (UNESCO 2003: Art.2 (i)) and it defines the term human proteomic data as "information pertaining to an individual's proteins including their expression, modification and interaction" (*Ibid*: Art.2 (ii)). The definition of human genetic data given by International Declaration of Human Genetic Data emphasized on two aspects that it should be about heritable characteristics and obtained as result of analysis of nucleic acid or any other scientific analysis. This instrument also defines the term proteomic data, considering the fact that information about genetic disease can be obtained not only by the analysis of DNA but also by the analysis of proteins. Mutations may also results in genetic disease or disorder and are not heritable unless and until it is on the germline or germ cells. This definition of human genetic data does not offer protection to persons having a genetic disease or vulnerabilities as a result of genetic mutation unless and until it is heritable. However whether it will come within the purview of the term human proteomic data is not clear.

### 3.3.2 *Genetic Testing and Screening*

Genetic screening and genetic testing are often used interchangeably but they are two different concepts. The term "genetic testing" comprises a range of procedure

including analysis of human DNA, RNA or protein. Genetic testing refers to medical procedure that determines the presence or absence of a genetic disease, condition, or marker in individual patients and involves an examination of chromosomes, DNA molecules, or gene products such as protein to find evidence of certain mutated sequences (Hodge 2003: 1016). While genetic screening is done to identify persons with a genetic disease or with a genetic variation in a population using genetic test and such screening programs are used to identify the rates of genetic disease in a given population, which may also uncover previously unknown or unrecognized genetic condition. Genetic tests are used to identify variant genes responsible for a specific genetic disease or disorder in clinical settings and for paternity testing, personal identifications, etc. in non- clinical purposes. In clinical settings, genetic testing is performed mainly for four purposes. Firstly it is performed on healthy persons without any symptoms to provide information about future health status. Such test may reveal the presence of a flawed genetic makeup/ gene that will lead to inevitable onset of a genetic disease/ disorder in future life of individuals, their vulnerabilities to certain disease (HGC 2000: 10) or workplace toxins, etc. In other words it gives information regarding the heightened risk of a patient to the onset of a particular disease or disorder and this test is often referred to as presymptomatic genetic testing. Secondly genetic test is carried out in patients with symptoms in order to assist him/her in the diagnosis and treatment of the disease and this type of testing is called diagnostic genetic testing. Thirdly genetic tests can be used to detect the carrier status of an individual for a genetic disease, which is not expressed in his/her phenotype but may pass on to next generation leaving them at risk and this type of testing is referred to as carrier testing. And finally genetic test is also performed to screen fetuses, newborns or embryos used in in-vitro fertilization for genetic defects.

With the genetic technological advances in the past decade, mainly two types of genetic tests are available, namely pathologic genetic testing and nutrigenetic testing. In the former type of testing patient approaches a doctor and the doctor prescribes a genetic test to determine a specific genetic variant. After that the doctor receives the report and will explain the findings of the test and the risk based on the information. However in nutrigenetic testing there is a radical shift in the context because these tests looks for a large number of genetic variants that appear in the human genome and these tests are now increasingly being marketed directly to the

consumers (Kohlmeier 2007: 9- 10) raising lot of socio- ethical and legal concerns. First of all since nutrigenetic tests look for large number of genetic variations in the human genome, there is always concern about the accuracy of the result or regarding the sensitivity and specificity of the result (The Council on Ethical and Judicial Affairs, AMA 1998: 16). Secondly these tests are increasingly been offered by private entities, which are motivated and driven by prospects of profit, the probability to offer questionable or inaccurate information is high (NHGRI 2004). Thirdly there is concern over the value of the voluminous information passed on to the consumer by these testing services, due to lack of scientific validation supporting their health claims and finally there is always possibility for misinterpretation of such information by the service providers, patient himself/herself, or the institutions or organization to which these information are disclosed.

Article 2 (xii) of the International Declaration on Human Genetic Data defines the term genetic testing as "a procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change". However, the declaration fails to lay down any specific provision for regulating the commercialization of genetic testing, marketing of genetic tests including online marketing, disclosure of unwanted or harmful information or releasing the test results to lay consumers, etc. There are insufficient restrictions and guidelines regarding the interpretation of test results by private service providers, to ensure the accuracy and reliability of the tests carried out by service providers, etc.

### 3.4 *Nature of International Legal Responses*

The recent international legal responses to the legal, ethical and social issues posed by the developments in human genetics and its applications can be generally be described as soft laws viewing the softness in its binding nature, lack of persuasiveness and declaratory nature of certain principles. Soft laws are those laws, which are having a soft means of enforcement (Chinkin 1989: 862) and are non-binding. Apart from that soft laws involve generally stated norms or principles and instruments, which lack specific commitments (Boyle 1999: 901). Principles like human dignity, privacy and individual autonomy mentioned in the Universal

Declaration on Human Genome and Human Rights, International Declaration on Human Genetic Data and Universal Declaration on Bioethics and Human Rights are merely declaratory in nature in the absence of precise definitions to terms privacy, dignity and autonomy and the inherent vagueness associated with these terms. In spite of this declaratory or soft nature of these instruments, it meets a genuine and growing need for international ethical standards in this area and the choice of soft nature of these instruments might have helped the framers in reaching an international consensus, which resulted in the unanimous adoption of the Universal Declaration on Human Genome and Human Rights and International Declaration on Human Genetic Data by the General Conference of the UNESCO. This is because it is easier to reach consensus when the form is non- binding, since the state parties can avoid the domestic treaty ratification and escape democratic accountability (*Ibid.* 1999: 902-903). The Universal Declaration on Human Genome and Human Rights, International Declaration on Human Genetic Data and Universal Declaration on Bioethics and Human Rights represents only a first step towards genetic specific international law and can play significant role in generating widespread and consistent state practice, which eventually can develop into a multilateral treaty, which is legally binding and enforceable.

### 3.5 *Summary*

The alarming and far reaching consequences presented by the new developments in human genetics and its applications prompted many international organizations to take initiatives to tackle such challenges. UNESCO, WHO, WMA, CIOMS, CHR, HUGO, etc are some of the major international organizations, which have made significant contribution in this field. The Universal Declaration on Human Genome and Human Rights (UNESCO 1997), the International Declaration on Human Genetic Data (UNESCO2003) and the Universal Declaration on Bioethics and Human Rights (UNESCO 2005) are the three major international instruments dealing with human genetics and its applications. These international instruments lay down some general principles in regulating the genetic information. They are respect for human dignity, privacy, and individual autonomy, principle of confidentiality, principle of non- discrimination, principle of prior informed consent and right not to know. However the term human dignity, genetic privacy and individual autonomy is

not defined in the instrument making it only a declaratory right and the inherent ambiguities associated with these terms makes it difficult to ascertain the commitment of the state parties. Further the term genetic information is defined only in International Declaration on Human Genetic Data, leaving behind ambiguities as to whether it offers protection to persons with a genetic variation as a result of mutation. All the three instruments mentioned above are only declaration having no binding force and also fails to incorporate provisions regarding commercialization of genetic information, online marketing of genetic tests, etc. However these instruments being an initial effort towards international consensus on some of the basic rules in human genetics and its applications and viewing the difficulties in obtaining a global consensus due to the economic, social and cultural diversity, these efforts are commendable.

*Chapter 4*

# *Disclosure of Genetic Information: Regional and Domestic Legal Perspectives*

# Disclosure of Genetic Information: Regional and Domestic Legal Perspectives

Scientists behind all scientific advancements and achievements may have a worthy aim but these developments and achievements may take a dangerous turn when these are used to benefit someone and to disadvantage some other or are utilized commercially for the purpose of profits only. Developments in human genetics and related technologies and their applications are not an exception to this preposition and have raised a lot of legal, ethical and social issues, which we have seen in the preceding chapters. Developments in genetics and biomedicine and the subsequent commercialization of their applications have resulted in enormous misuse of these technologies, resulting in a large number of human rights violations, particularly in industrialized world. So it would be pertinent to analyze, in this chapter, the regional regulations in the European Union (EU) and municipal regulations in the United States (US) in this context.

## 4.1 *Regional Regulations in EU*

Advances in the field of biomedicine and human genetics and related technologies in recent decade have made the protection of human rights and fundamental freedoms in this field increasingly important. Recognizing the urgency to protect human rights and fundamental freedoms in the field of biomedicine, and the need for international guidance and consistency in this field, representatives of twenty one member countries[1] of the Council of Europe signed the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Council of Europe 1997) in April 1997 at Oviedo, Spain, popularly known as Convention on Human Rights and Biomedicine or Convention of Oviedo, which came into force in 1999. The council has adopted three additional protocols to the convention on human rights and bioethics, which addresses in greater detail the issues of organ transplantation and the use of substances of human

[1]Denmark, Estonia, Finland, France, Greece, Iceland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Macedonia and Turkey.

origin[2], biomedical research in human beings[3], human cloning[4], etc. The European Convention on Human Rights and Biomedicine adopted by the Council of Europe is the first international treaty focused on human rights and fundamental freedoms in the field of biomedicine and its applications (Dommel and Alexander 1997: 259).

Rapid changes occurred consequent to the decoding of human genome and biotechnological development brought about adverse impact on a whole range of human right principles, such as respect for human dignity, personal autonomy, personal self determination, non- discrimination, privacy, equality, etc. European regional legal response to such controversial issues can be studied under the following headings.

### 4.1.1 *Human Dignity*

According to Immanuel Kant humanity itself is a dignity; for a human being cannot be used merely as a means by any human being "... but must always be used at the same time as an end and it is just in this that dignity of a human being consists, by which he raises himself above all other beings in the world that are not human beings..." (Kant 1996: 209). There is also another version of interpretations to the principle of respect for human dignity based on the duty of the individual, i.e., while every person is having a legitimate interest that his/ her dignity and individuality be respected by his/her fellow human being, in turn is bound to respect the dignity and individuality of other human beings (Beyleveld and Brownsword 1998: 666). Respect for human dignity is one of the fundamental principles of human rights and is recognized by most of the human rights instruments. Under the European Convention on Human Rights and Biomedicine, state parties to the convention were convinced and undertake to ensure respect for human dignity of individuals with regard to the application of biology and medicine (Council of Europe 1997: Preamble). Under the convention states parties also undertake to take necessary measures, including enacting internal laws to protect human dignity (*Ibid*: Art.1). The Charter of

[2]Additional protocol to the European Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin adopted in 2002 and came in to force in May 2006, ETS No. 186.

[3]Additional protocol to the European Convention on Human Rights and Biomedicine, Concerning Biomedical Research adopted in 2005 and came in to force in September 2007, ETS No. 195.

[4]Additional protocol to the European Convention on Human Rights and Biomedicine, on Prohibition of Human Cloning adopted in 1998 and came in to force in March 2001, ETS No. 168.

Fundamental Rights of the European Union recognizes respect for human dignity as an inviolable right (Council of Europe 2000: Art.1), and this principle has been incorporated under part II of the Treaty Establishing a Constitution for Europe (Council of Europe 2004: Art. II-61). The Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine also enumerates it as essential value to be upheld and is the basis of most of the values emphasized in the convention and also requires to interpret the provisions of the convention as broadly as possible so as to inculcate the principle of respect for human dignity within its ambit (Council of Europe 1997a). The report also pinpoints that article 1 of the convention on human rights and biomedicine purports to protect human rights of embryos and fetuses because it is well accepted principle that human dignity and identity of the human being have to be respected as soon as life began (*Ibid*). However, it is difficult to interpret these commitments of the state parties because of the inherent ambiguity or vagueness associated with the term "human dignity". This has been aptly stated by Mohammed Bedjaoui:

> 'A legal framework for potential new practices ...., which concern the human body is absolutely essential in that it protects man in his freedom and dignity. But it is by no means an easy task.... 'human dignity' is an expression which seems simple: one immediately apprehends its prospective import, if not its exact meaning. But, paradoxically, it is also an expression full of fragility, for in the name of the same argument of 'human dignity' some refute [sic] the legitimacy of euthanasia, whilst others claim it as the ultimate right of those who wish to 'die in dignity' (quoted in Beyleveld and Brownsword 1998: 661).

Albeit the Convention on Human Rights and Biomedicine reiterated the importance of the principle of respect for human dignity in the preamble and declares its purpose and object as preservation of dignity of all human beings without any discrimination under article 1, it is largely declaratory in nature and does not define the term human dignity like many other human rights instruments.

### 4.1.2 *Genetic Privacy*

Respect for privacy is an important legal principle in human rights as well as in the field of biomedicine and is recognized by several human rights instruments.

Right to genetic privacy logically mean that one has no duty to reveal his/her personal genetic information to another and/ or one has no right to reveal others personal genetic information to another (Hayry and Takala 2001: 405- 406). Privacy of health information, which includes personal genetic information, is protected under the European Convention on Human Rights and Biomedicine (Council of Europe 1997: Art.10). The Charter of Fundamental Rights of the European Union confers everyone the right to protect ones personal data concerning him/ her (Council of Europe 2000: Art.8), which can be interpreted so as to include the protection of personal genetic information also. This right has also been incorporated under the Treaty Establishing a Constitution for Europe (Council of Europe 2004: Art. II-68). However, right to genetic privacy is not an absolute right. It is subject to limitations laid down by competent law making body in exceptional circumstances. Such limitations are recognized by the Convention on Human Rights and Biomedicine, Charter of Fundamental Rights of the European Union and the Treaty Establishing a Constitution for Europe. Since genetic information of a person also reveals information regarding his family members and it may sometimes happen that one's genetic information reveal certain genetic disorder of his/her family member. In such circumstances it may be necessary to disclosure such information to that family member, which may be helpful for him or her to avoid, prevent or cure the disease or it may be helpful for diagnostic purpose. It may also happen that in legal proceeding a duty may be imposed on a person to disclose his/her genetic status. It can also happen that the patient may not be in a position to disclose his/ her genetic information and informed consent is required to proceed with the treatment. In such cases limitations on genetic privacy and confidentiality can be laid down.

### 4.1.3 *Confidentiality*

The principle of preservation of confidentiality of health information is at the heart of clinical practice and procedure and physicians has a duty to keep sensitive personal health information of the patients confidential even after the death of the patient. Since personal genetic information forms the part of health information physicians have the duty to keep personal genetic information confidential. The right to confidentiality of health information is not expressly mentioned under the European Convention on Human Rights and Biomedicine but it is implicit in Article

10(1) of the convention, which states that everyone has the right to respect for private life in relation to information about his/her health (Council of Europe 1997: Art.10(1)). The Charter of Fundamental Rights of the European Union also recognizes the right of individuals to protect their personal data, which include personal genetic data also (Council of Europe 2000: Art.8). The principle of confidentiality of health information has also been incorporated under part II of the Treaty Establishing a Constitution for Europe (Council of Europe 2004: Art. II-68) and European Convention on Human Rights and reiterated in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe 1981: Art.6).

The physician's duty to keep patient's sensitive health information confidential, however, is by no means an absolute one under medical law or ethics (Hayry and Takala 2001: 408). Limitations on the principle of confidentiality of health information and reservations to the obligations of physician are made on various grounds. In the context of confidentiality of personal genetic information, the rationality for laying down limitations on the principle is particularly because of the fact that it divulges information not only of the subject but also of his/ her family members as well, which may sometimes lead to the discovery of certain genetic risks to such family member. In such situations it becomes necessary to provide such information to the family member, failing of which may lead to serious health risk to such family member.

### 4.1.4 *Non-discrimination*

The issue central to debates concerning genetic testing and genetic screening is discrimination against people with genetic disorder and carriers of recessive genetic diseases / disorders. These debates particularly focused on the discriminatory practices followed in the insurance and employment field. The European Convention on Human Rights and Biomedicine prohibits such kind of discriminatory practices based on one's genetic heritage under chapter IV titled "Human Genome" (Council of Europe 1997: Art.11). The provisions of the said chapter permit predictive genetic testing, carrier genetic testing, susceptibility genetic testing, presymptomatic genetic testing, etc. only for health purposes or for scientific research linked to health purpose, subject to appropriate genetic counseling (*Ibid*: Art. 12). This implies that

these provisions purport to restrict pre- employment genetic screening and genetic testing for insurance underwriting.

The principle of non- discrimination recognized under the Charter of Fundamental Rights of the European Union also prohibits discrimination based on one's genetic features (Council of Europe 2000: Art.21). This principle has also been incorporated under part II of the Treaty Establishing a Constitution for Europe (Council of Europe 2004: Art. II- 81). However, Part III, Title II, which empowers the Union to lay down European Law or framework law to combat discrimination does not recognize genetic feature as a discriminatory ground (Ibid: Art.III-124), which may have an effect of delaying the harmonization of legal standards at national level with respect to the principle of non- discrimination.

### 4.1.5 *Prior Informed Consent*

The principle of prior informed consent requires the health professionals to disclose before the patient all relevant information before any diagnostic or therapeutic procedure (which is having a potential harm or benefit to the patient) is administered on the patient in order to obtain a free informed consent. The rationale for prior informed consent is respect for one's individual autonomy and self determination i.e., the patients right to know relevant information about his/her health status and on the basis of his/her understanding and reasoning to decide by his/her on choice, how to proceed. This concept of prior informed consent has been emphasized under many legal instruments of European Union like chapter two titled "consent" of the Convention on Human Rights and Biomedicine (Council of Europe 1997: Art. 5) and the Charter of Fundamental Rights of the European Union (Council of Europe 2000: Art.3) and this principle has also been incorporated under part II of the Treaty Establishing a Constitution for Europe (Council of Europe 2004: Art.II-63). The Convention on Human Rights and Biomedicine also makes detailed provision for obtaining consent of persons, who are incapable of giving a valid consent because of unsoundness of mind or because of infancy. In such cases the convention requires an authorization from a legal representative or an authority or person or body provided for by law to carry out any medical or therapeutic intervention (Council of Europe 1997: Art.6, 7). The Convention legitimizes the medical intervention carried out without the consent of the patient in cases of an emergency situation, where consent

cannot be obtained and such medical intervention was necessary for the benefit of the health of the patient concerned (*Ibid*: Art. 8) and also requires to take into account the previously expressed wishes of the patient regarding medical intervention, if the patient at the time of such intervention is not in a state to express his/her wishes (*Ibid*: Art.9).

The demand that patient's consent should always be obtained after fully informed of the risks and benefits of the medical intervention can be problematic in the case of genetic testing because there are cases, where the physician cannot fully explain the benefits or risks because of the inherent uncertainty related with genetic test result. It is also possible that a genetic test may reveal a different health risk than that for which the test was conducted and because of the highly scientific nature of the issue and the difference in the degree of understanding of patients the physician may find it difficult to covey it properly.

### 4.1.6 *Right Not to Know*

Everyone has the right to know information concerning him/her and this right has been recognized under various human rights instruments (Council of Europe 2000: Art.8 (2); Council of Europe 2004: Art.II-68 (2); Council of Europe 1981: Art.8 (b)). The right to access to one's health information has now become the part and parcel of biomedical law and is inculcated under chapter III of the European Convention on Human Rights and Biomedicine (Council of Europe 1997: Art.10). The European Convention on Human Rights and Biomedicine also respects the wishes of the patient to remain in ignorance (*Ibid*: Art.10 (2)), conferring a right not to know certain facts about their health status.

The right not to know has been subject to severe criticism based on the argument that it is in direct negation of patient's autonomy because it deprives the patient of relevant information leading to inaccurate self assessment or leaving the patient in a position unable to give consent based on his or her understanding. However, the Explanatory Report to the Convention on Human Rights and Biomedicine holds the view that the right of the patient not to know information about his/her health status goes hand in hand with the right to know and such exercise of the right by the patient is not regarded as an impediment to the validity of the consent to

medical intervention (Council of Europe, Directorate of Legal Affairs 1997). The right to know and the right not to know relevant information about one's health or genetic predispositions are not an absolute right. Limitations can be placed by law on these rights in exceptional circumstances (Council of Europe 1997: 10 (3)). In some cases physicians' duty to disclose relevant information to the patient may conflict with the interest of the patient's health and still in some other cases it may be important for the patient to know certain facts about their health even though they have expressed their wishes not to know them. In such cases it will be appropriate for the domestic law to make regulations to resolve the conflict taking into account the social and cultural background.

### 4.2 *Domestic Legal Regulations*

The human rights violations resulting from the advancement in new human genetics as well as in related technologies are one of the most discussed issues and attracted the attention of many national legislators and policy makers, particularly in the industrialized world, where such incidences are more often than in the developing and least developed countries. Genetic discrimination in employment and insurance sector, loss of privacy, social stigmatization are some of the emerging manifestations of human rights violations consequent to the application of these new genetic technologies. Many states have enacted legislations and many are in the process of making legislative framework to tackle these issues. This section considers the existing laws and regulations in the United States as well as in India concerning the protection of genetic information.

#### 4.2.1 *United States of America*

In the U.S there was no comprehensive federal legislation, which exclusively dealt with the genetic discrimination in insurance and employment field till 2008. Issues of genetic discrimination in employment and insurance field were addressed mainly by the provisions of the Americans with Disabilities Act 1990 and The Health Insurance Portability and Accountability Act 1996 respectively even though these legislations were not specifically drafted to address the issue of genetic discrimination in employment and insurance.

### *A. Health Insurance Portability and Accountability Act of 1996*

The most significant federal legislation that addressed the issue of genetic discrimination in insurance, till 2008 was the Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act (HIPAA) covers only employer based and commercially issued group health insurance plans. HIPAA prohibits group health plan and a health insurance issuer offering health insurance coverage in connection with a group health plan from using any health status- related factors, including genetic information (HIPAA 1996: S. 702 (a) (1) (F)) for establishing rules of eligibility (*Ibid*: S. 702 (a) (1)), for denying coverage, for requiring a higher premium or contribution amount (*Ibid*: S. 702 (b) (1)). It also puts limitations on preexisting condition exclusion by requiring that such exclusion may be imposed only in relation to a condition for which medical advice, diagnosis, care or treatment was recommended or received within a period of six months ending on the enrollmcnt date (*Ibid*: S. 701 (a) (1)). The HIPAA expressly prohibits the use of genetic information as a preexisting condition in the absence of a diagnosis of the condition related to such information (*Ibid*: S. 701(b) (1) (B)).

The HIPAA, however, does not prohibit insurer from requiring genetic tests or collecting or disclosing genetic information by the insurers. Nor it restricts the insurers from using genetic information for denying coverage, or requiring higher premium or contribution amount from individuals seeking health insurance in the individual market.

### *B. Americans with Disabilities Act 1990*

The Americans with Disabilities Act 1990 defines the term disability as (a) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (b) a record of such an impairment; (c) being regarded as having such impairment (ADA 1990: S. 3(2)). However, this definition does not expressly include genetic disease or disorder within the purview of the term disability and the definition is also not sufficient enough to provide protection to presymptomatic genetic condition as well as persons with carrier status for a genetic risk. This is because the definition of disability under Americans with Disabilities Act (ADA) provides protection only to persons with a manifested disability (Gin 1997:

1415; Diver & Cohen 2001: 1450). However in March 1995, the Equal Employment Opportunity Commission, an agency of the United States Government that enforces the federal employment discrimination laws, released a controversial guideline stating that individuals who are subjected to genetic discrimination may fall under ADA's definition of disability as persons regarded as having disability and in order to get the benefit of the guideline a plaintiff must prove that he/she was regarded as having genetic defect by the employer and the employer acted on that basis (quoted in Gin 1997: 1418). The Equal Employment Opportunity Commission guidelines are not binding on the judiciary.

In April 2001, however, the Equal Employment Opportunity Commission (EEOC) settled its first court action challenging the use of workplace genetic testing under the Americans with Disabilities Act of 1990. In EEOC v. Burlington N. & Santa Fe Railway Company (2005), the commission had sought a Preliminary Injunction against Burlington Northern Santa Fe Railway to end genetic testing of employees. In this case the EEOC alleged that the Burlington Northern Santa Fe Railway Company secretly subjected its employees to genetic testing without their knowledge or consent for screening employees with gene responsible for carpal tunnel syndrome. The EEOC acted quickly and sought an injection in federal court claiming that basing employment decisions on genetic testing is barred under the ADA's as stated in EEOC's 1995 policy guidance on the definition of the term "disability" and genetic testing, as conducted in this case, also violates the ADA as an unlawful medical examination.

### *C. Fourth Amendment Privacy Rights*

Genetic testing and the disclosure of genetic information have also raised concerns of individual privacy. The fourth amendment of the US Constitution represents the most interesting provision in relation to individual privacy. The Fourth Amendment (US Constitution) states that:

> 'The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and

particularly describing the place to be searched, and the persons or things to be seized'(The Constitution of the USA 2000).

The fourth amendment confers a right against unreasonable search and seizures. A plain reading of the provision gives an impression that non-consensual genetic testing as well as forcible genetic testing can well implicit the broadly conceived reach of search and seizure and privacy rights under the said amendment. The fourth amendment aim to prevent unreasonable search and seizure and incursions into privacy for reasonable cause is allowed under the provision.

The US courts in several occasions had the opportunity to consider the issue of privacy of employees in workplace and interpreted the fourth amendment privacy right of employees by balancing employees' legitimate claim of privacy in workplace and employers interest in surveillance, control and efficient operation of the work place. In doing so courts had laid down many tests for permitting intrusions into privacy of employees. In certain circumstances expatiation of privacy at workplace is not feasible due to practical work realities. So in order to invoke fourth amendment privacy right, the employee should first establish that he/she had a reasonable expatiation of privacy in such circumstance (O'Connor v. Ortega, 1987: 710; Richard Neal Schowengerdt v. General Dynamics Corporation, 1987: 1335). Once this is established then in order to legitimize the intrusion into employees privacy the employers have to establish that their activity, which is claimed to be violated the employees privacy was reasonable in such circumstance (O'Connor v. Ortega, 1987: 728; United States v. Nasser, 1973: 1123), the incursion into privacy is job related (O'Connor v. Ortega 1987: 722; Gillard v. Schmidt, 1978: 829) and the employer had a compelling interest in conducting such activity (United States v. Blok, 1951: 1022). Once this can be established that the alleged activity which violated the privacy of the employee is reasonable, work related and conducted due to compelling reasons then the search or seizure could obviate the warrant requirement.

So far as violation of individual privacy as a result of genetic testing and disclosure of genetic information is concerned, courts have a proactive role to play in maintaining the balance between individual interest and third party interest and this has been emphasized by courts by stating that under the Fourth Amendment, the

government's interest in conducting particular tests had to be balanced against the employees' expectation of privacy (Norman Bloodsaw v. Lawrence 1998: 1153). In this case a group of employees filed a lawsuit against their employer, Lawrence Berkeley Laboratory, for conducting medical tests for highly sensitive medical and genetic information relating to syphilis, sickle cell trait, and pregnancy. The plaintiffs brought charges against the employer based on violations of the ADA, and their right to privacy as guaranteed by both the United States and the State of California Constitutions. The district court dismissed the suit on the ground that the employees had (1) consented to the tests as part of a comprehensive medical examination; and (2) were put on notice by the questionnaire that their blood and urine would be tested for syphilis, sickle-cell traits, and pregnancy (*Ibid*: 1153). The employees appealed and the ninth circuit affirmed the district court's decision on the ground that the ADA does not limit the scope of such examinations to job-relatedness or business purposes necessity. The court further went on to say that an employment entrance examination need not be concerned solely with individual's capability to perform job related functions nor must it be related to job or consistent with business necessity. The ADA imposes no restriction on the scope of entrance examination but only guarantees the confidentiality of the information gathered and restricts the employer from using such information for discriminatory purposes (*Ibid*: 1177). However the court held that the district court errored in dismissing the privacy claim holding that it was de minimis. The court stated that the constitution prohibits unregulated, unrestricted employers inquires into personal sexual matters that have no bearing on job performance. Whether one is pregnant or has syphilis is intensely private and sexual matter and one is carrying a sickle trait or not can pertain to sensitive family medical information and reproductive decision making and nonconsensual intrusion into such matter is an invasion of a right that is of great importance. The court also added that one has consented to general medical examination does not abolish one's privacy right not to be tested for such private and sensitive matters and therefore it is not de minimis (*Ibid:* 1154). This decision underscores the need for a comprehensive legislation that protects employees against workplace genetic testing and is not limited to guaranteeing proper use of any information collected through such testing.

### *D. Genetic Information Nondiscrimination Act 2008*

In May 2008, George W. Bush, President of the United States of America signed into law the Genetic Information Nondiscrimination Act 2008, setting aside much of the disputes regarding the definitional dilemmas and limited protection offered by the ADA. The said act is the first federal legislation of the kind, which exclusively deals with the discrimination based on genetic information in insurance and employment and also deals with the privacy and confidentiality of genetic information. Originally the Bill was introduced in the House in 1995 and subsequent to it several versions of Genetic Information Nondiscrimination Act (GINA) were passed by large majorities in either the House or U.S. Senate but never fulfilled the congressional approval.

As its name implies, the GINA is designed to protect Americans from discrimination based on genetic information in employment and insurance as well as to regulate the disclosure of genetic information by employer and insurers and prescribes penalties for the violation of the provisions.

#### *(a) Prohibiting Genetic Discrimination in Insurance*

Title I of the GINA amends the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, the Public Health Service Act and title XVIII of the Social Security Act relating to medigap to regulate genetic discrimination in health insurance and prohibits:

- Collection and purchase of genetic information by insurers for underwriting purposes (GINA 2008: Ss. 101(b), 102(a) (2), 102(b) (1)) and imposition of any preexisting condition exclusion on the basis of genetic information (*Ibid*: S. 102(b));

- Requisition by the insurers to undergo genetic tests (*Ibid*: Ss. 101(b), 102 (a)(2)) and the computation of premium or contribution amount on the basis of genetic information (*Ibid*: Ss. 101(a), 102 (a)(1), 102(b)(1));

- Establishment of rules for eligibility of any individual to enroll in individual health insurance coverage based on genetic information (*Ibid*: Ss. 102 (b) (1)).

Title I of the GINA also amends Part C of title XI of the Social Security Act by adding provisions, which require treatment of genetic information as health information and prohibits the use or disclosure of genetic information by the covered entities (*Ibid.* S. 105(a)).

***(b) Prohibiting Genetic Discrimination in Employment***

Title II of the GINA deals with discrimination in employment based on genetic information. The said title makes genetic discrimination on the part of an employer, employment agency, labour organization or joint labour management committee as an unlawful employment practice and prohibits;

- Refusal to hire an employee for an employment or discharging an employee from an employment on the basis of genetic information or otherwise discriminating against him/her with respect to the compensation, terms, conditions, or privileges of employment;
- Failing /refusing to refer an individual for employment by an employment agency or excluding /expelling a member from the organization by a labor organization on the basis of genetic information;
- Requesting, requiring, purchasing or collecting of genetic information of employees by employer through workplace testing or other means.

Title II of the GINA also lays down provision for confidentiality of genetic information, which requires the employer, employment agency, labour organization, or joint labour-management committee possessing genetic information of an employee or member, to maintain it in separate forms and in separate medical files and to treat it as confidential medical record (*Ibid.* S. 206(a)) and imposes restrictions on its disclosure with few exceptions (*Ibid.* S. 206(b)). The GINA also penalizes obtaining of genetic information by employers and insurers for underwriting purposes or for discriminatory practices and prescribes penalty for the violation of the provisions of the act. Obtaining genetic information by employers as such, for maintaining employee health or for non discriminatory use, is not sanctioned under the act.

Even though the GINA 2008 is widely hailed as a major civil rights legislation in the genomic era, the act is not free from legal lacunae. One is that it will not provide legal protection to those who are applying for life insurance or long term care. Another important shortcoming, more precisely, impact of the act is that now there may be a greater demand for personal genetic testing by the individuals and the probability of institutional misuse of genetic information is high, which is not addressed by the act.

4.3 ***Summary***

The European Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine (Council of Europe 1997), popularly known as Convention on Human Rights and Biomedicine is the major regional instrument dealing with human genome in European Union. Convention on Human Rights and Biomedicine focuses on the human rights in the field of biomedicine generally. Chapter IV of the said Convention deals with human genome, which incorporated the principle of non- discrimination and prevents genetic interventions for non-therapeutic or non-diagnostic purposes. It also emphasizes on the principle of human dignity, individual autonomy, privacy, etc with regard to the application of biology and medicine. Apart from the Biomedicine convention, the Charter of Fundamental Rights of the European Union and the Treaty Establishing a Constitution for Europe also prohibits discrimination based on the genetic characteristic of an individual and incorporates provision for the privacy of personal information of an individual including health information. The convention on Human Rights and Biomedicine also lays down detailed provision for obtaining informed consent. However these instruments are applicable only within the European Union only.

In United States there were no comprehensive federal legislation, which dealt with employment and insurance discrimination based on one's genetic characteristic till 2008. In May 2008 the Genetic Information Nondiscrimination Act came into force, which addresses the issue of genetic discrimination in employment and insurance settings. Prior to this, genetic discrimination in employment were addressed by the Americans with Disabilities Act 1990 and genetic Discriminations in Insurance

were addressed by the Health Insurance Portability and Accountability Act 1996. However neither ADA nor HIPAA provided full protection from discrimination for persons with genetic disease. Judiciary in US also played a proactive role in maintaining a balance between the individual interests and third party interests so far as individual privacy is concerned.

*Chapter 5*

# *India and Genetic Information*

# India and Genetic Information

## 5.1 *Introduction*

Most of the literature and reports dealing with the legal, ethical and social concerns posed by the new developments in human genetics and its applications has focused particularly on its impact in developed and industrialized nation. This has resulted in a misconception that there is no real or potential threat raised by these scientific advancements in developing countries like India (WHO 2006). However the fact of the matter is that other spates like poverty, malnutrition, poor health care system and other infectious diseases have made the impact of genetic diseases or disorder somewhat blurred (*Ibid*: 21). This does not mean that we should neglect the severity of the manifestation of genetic disorder and the concerns raised by new genetic services and methods of treatment. In a developing country like India, where culture, religion, traditions and other social practices are deep rooted in the society, the new genetic services and methods of treatment can have an extended impact. For instance in India arranged marriages are more common and endogamous[1] and consanguineous marriages[2] are practiced in many communities for cultural, religious and customary reasons. Many people carry recessive gene for certain diseases and usually they will not manifest in their phenotype or in the phenotype of next generation because this gene are rare in general population. Since closely related family and members of a specific ethnic or racial group share certain common genetic material, there is higher possibility that, when people from same family or specific group, with recessive gene for similar trait or disease, mate the child will be inherited homozygously[3] for that trait or disease. Population based genetic studies and genetic research in such communities can stigmatize such population.

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[1] Endogamous marriage refers to marriage within a specific group, such as a tribe or clan, as required by custom. This sort of marriages is more prevalent in India, Pakistan and Bangladesh.

[2] Consanguineous means blood relative or one descended from the same ancestor. A consanguineous marriage is a marriage between a couple related as second cousin or closer.

[3] Genes appear in pair in both allele of a chromosome pair and if a gene, which is a faulty one or which is responsible for a disease, appear only in one allele of a pair and the other remains normal, then that faulty gene remain as recessive and disease will not be expressed in that individual and such individuals are carrier for that disease. However if both the parents are carriers for a disease, the probability for inheriting the gene responsible for the disease to the next generation is very high. If the faulty allele of both the parents is inherited to children, then the children will homozygous (i.e., will be present in both the allele of a chromosome pair) for that genetic disease or disorder and the disease will be expressed in his/her phenotype.

Further in communities where marriages are traditionally arranged and where men and women are not treated equally, the possibility of stigmatization of women, who are carriers of a genetic disease, is more (*Ibid*: 50) and where there is preference for male child, the possibility for misuse of these genetic services is also high. Another important matter of concern is shortage of qualified genetic counsellors in developing countries like India (*Ibid*: 61), which will create problems in obtaining valid informed consent of persons undergoing genetic testing and screening. The economic, social and educational disadvantageous position of the vast amount of population in India will also add to the challenges raised by the new developments in human genetics.

In India apart from the constitutional provision and various statutory provisions that outlaw discrimination generally, there is no specific legislation or legal provision, which addresses the issue of discrimination arising out of the disclosure of genetic information nor there any legislation, which deals with the matters of privacy and confidentiality of genetic information in employment, insurance or medical settings, genetic screening, storage, use and processing of genetic material, etc. The protection of the privacy and confidentiality of genetic information is not only a legal matter but it is equally important from an ethical point of view. In the biomedical field ethical guidance is provided by non legislative means such as policies, guidelines, principles, etc made by institutions like the Indian Council for Medical Research (ICMR) and the National Bioethics Committee (NBC). Two instruments, which are particularly important in this context and, which requires a detailed assessment are the '*Ethical Policies on the Human Genome, Genetic Research and Services*, 2000' and the '*Statement of Specific Principles for Human Genetics and Genomic Research*'.

### 5.2 *Ethical Policies on the Human Genome, Genetic Research and Services, 2000*

The *Ethical Policies on the Human Genome, Genetic Research and Services*, 2000 have been formulated by NBC, which was constituted with the approval of the Ministry of Science & Technology, Government of India, in November 1999. The policy is the result of deliberations by the NBC on various issues concerning human genome. This policy is formulated in line with internationally accepted principles and guidelines and:

- Recognizes the principle of autonomy, privacy, justice and equity in genetic research and services;
- Prohibits discrimination based on genetic characteristics or information of an individual;
- Requires that laboratories, institutions or individuals providing genetic testing services should be licensed or registered by appropriate governmental authority and should operate in accordance with nationally accepted standards for scientific accuracy, confidentiality and privacy;
- Strictly insist to provide genetic counseling, prior to the disclosure of genetic test results to concerned individuals;
- It condemns commercialization of genetic material;
- It requires informed consent of the donor for DNA banking and the written benefit sharing agreement, signed by the donor, sample collector and the repository for any commercial use of such stored samples;
- Regulates the transboundary movement of DNA sample.

### 5.3 *Statement of Specific Principles for Human Genetics and Genomics Research*

The *Statement of Specific Principles for Human Genetics and Genomic Research* is included in Chapter VI of the *Ethical Guidelines for Biomedical Research on Human Participants*, 2006 and was brought about by the ICMR. It lays down guidelines on genetic screening, therapeutic trials, DNA banking and diagnosis, etc. In this statement of principles, ICMR explicitly expresses its concern over the potential psychological harm, social stigmatization, discrimination in schooling, employment, health and general insurance as a result of the genetic research and the application of new genetic related developments and technologies. It points out the implications of using genetic information to individuals and their families, the issue of interpretation of genetic test results, DNA storage and access to genetic information, access to counseling services, etc. and requires the scientific community to address these issues before applying the knowledge generated by the Human Genome Project. The ethical principle recognizes that the ethical issues involved in the handling of genetic information is significantly different from medical records and lays down detailed guidelines on informed consent, confidentiality of genetic test results, and

requires mandatory genetic counseling for persons subjected for genetic testing and screening.

In India, the apex court has confronted with the question, whether undergoing DNA testing is a violation of individual privacy, in a number of cases relating to family matters. In R. *Rajagopal v. State of Tamil Nadu*, the Supreme Court outlined the concept of privacy as a right, which encompasses and protects personal intimacies of the home, the family, marriage, motherhood, etc. In spite of this the court allowed, in most part of cases, to conduct DNA testing by stating that no right to privacy is specifically conferred under Article 21 of the Constitution of India and the personal liberty under Article 21 cannot be held as an absolute right and must be subject to restrictions on the basis of compelling interest of the public (Sharada v. Dharmpal 2003; Govind v. State of M.P. 1975).

### 5.4 *Draft DNA Profiling Bill*

The above decision and the emerging new social, ethical and legal issues as a result of new developments in human genetics and related technologies clearly stress the need for a comprehensive legislation to address such issues in this genomic era. Hopefully the Department of Biotechnology (DBT) has piloted a *Draft DNA Profiling Bill* drafted by the Centre for DNA Fingerprinting and Diagnostics (CDFD) in association with National Academy of Legal Studies and Research (NALSAR), Hyderabad. The Ministry of Science and Technology, Government of India is now planning to introduce the bill in the Parliament after it has been approved by the cabinet and if the Parliament approves, it will be known as DNA Profiling Act, which will greatly help judicial and investigative process, and act as a tool to control crime.

The Draft Bill proposes to establish a DNA Profiling Board, which will make recommendations in the areas for maximizing the use of DNA techniques and technology in the administration of justice, privacy protection statutes, regulations and practices relating to the collection, storage, access to, processing and use of the DNA samples. The Board will make specific recommendations to ensure the appropriate use and dissemination of DNA information, accuracy, security and confidentiality of DNA information and to take necessary steps to protect privacy. It will advise the

concerned ministries and departments of central and state governments for the establishment and management of DNA laboratories and lay down standards of procedure for the establishment and functioning of DNA Banks. It shall also be the duty of the Board to deliberate and advice on the social, ethical and legal issues arising out of DNA profiling. The Bill also proposes to create and maintain DNA database of suspects, convicts and under trials for detection of crime. Even though the Draft Bill is backed with lot of expectation, there is a lot more to be addressed, particularly there is no provision in the Draft Bill which deals with the genetic discrimination, use of genetic information by employers, insurers and other governmental and nongovernmental agencies for discriminatory practices, genetic screening, etc.

### 5.5 *The Personal Data Protection Bill*

The Personal Data Protection Bill introduced in the Rajya Sabha on the 8th December, 2006 and is still pending before the Sabha. It intends to provide protection for personal data or information of individuals by preventing its use by others for commercial and other purposes and by enabling individuals to claim compensation for non consensual disclosure of personal data or information. The bill also penalizes acts, which contravenes the provisions of the bill. Section 2 (c) of the Personal Data Protection Bill as it is introduced in the Rajya Sabha defines the term "personal data" as;

> 'information or data which relate to a living individual, who can be identified from that information or data whether collected by any Government or any private organization or agency' (The Personal Data Protection Bill 2006).

The definition of the term personal data adopted in this bill also include genetic information since it is personal as well as reveals the identity of the person or the identity of the persons can be well inferred from genetic information. The bill prohibits the recording or holding or carrying out any operation including alteration, disclosure, transmission, dissemination and alteration on the personal data or information of an individual without the consent of the concerned individual and also prohibits the nonconsensual direct marketing or disclosure for commercial gain of

personal data or information. When this bill becomes law, it has a lot to offer to strengthen the protection of genetic information in India.

## 5.6 *Summary*

Advances in human genetics and its applications raised serious implications for developing countries like India particularly because of the socio-economic, cultural and traditional factors. However there is no constitutional or other statutory provision, which specifically deals with genetic discrimination or genetic privacy and confidentiality. But there is ethical guidelines and principle which deals with genetic testing and genetic research. Even though India achieved many advances in the field of biotechnology, we still lack a comprehensive legislation for preventing the potential harmful effects of these new developments in human genetics and its applications.

# *Chapter 6*

# *Conclusion*

# Conclusion

The rapidly evolving field of human genetics and biotechnology opened tremendous prospects for mankind as a whole. It has revolutionized the healthcare field by new methods of diagnosis, treatment with improved efficiency and earlier detection of diseases. The knowledge gathered as a result of researches in this field enables the researcher now to pinpoint minute errors in a gene that contribute to a disease/ disorder and design drugs, which are site specific with very few side effects than many of the present day medicine. The developments in this field have also significant impact on forensic science and criminal justice. Genetic test result is used in paternity disputes, to convict criminals and also to acquit persons. Identification of criminals has now become much easier by the DNA test of the biological remnants left out at the crime scene by the criminal. Many countries are now increasingly setting up DNA database of the criminals and convicted persons for utilizing it for investigation of crimes. The developments in human genetics are also utilized in population studies, anthropological studies, historical studies, etc.

Scientific advancement has always been misused because of human greed and ruthless commercial interest. Advancement in human genetics is not an exception to this and misuse of genetic testing and genetic information has brought adverse impact on a whole range of human rights principles. Genetic testing conducted for diagnostic purposes reveals one's predispositions to a genetic disease or disorder. It is also helpful for identifying one's genetic vulnerability to certain genetic disease or disorder or for workplace toxins. This revelatory nature of the genetic information is widely exploited by employers, insurers for wide range of discriminatory practices, particularly in the industrialized nations. An employer can deny employment to a person having a flawed genetic makeup so also an insurer can deny insurance to persons with a genetic risk leading to genetic discrimination. Once a person is denied employment because of having a flawed genetic makeup, he/she may find it difficult to get another job.

Since genetic testing can be carried out from a very small sample of biological material, which can be obtained even without the knowledge of the subject, like hair, blood sample, urine, inner cheek cells, etc., it is always having the potential for

violating the privacy of individual. Nonconsensual genetic testing or disclosure of genetic information amounts to violation of privacy of individual. It not only violates the privacy of the individual but also invades the privacy of his/her family members, since genetic test results reveals information about the person concerned and also reveal genetic information about his/her family member and have a bearing on the reproductive decision making. It is also having a potential to stigmatize individuals as having flawed or inferior genetic makeup or as genetically weak, which can lead to social stratification based on one's genetic makeup resulting in the creation of two classes; one with a superior genetic makeup and other with inferior genetic makeup. The over emphasis on the genetic cause of a disease or attributing genetic link to personality and behavioural traits or treating genetic information as exceptional than conventional medical record, (which many scholars call it as genetic exceptionalism) leads to genetic determinism; and more and more people may opt social engineering for desired traits, which may open up newer versions of eugenic in the genomic era.

Recognizing the alarming and far reaching effect of the new developments in human genetics and its applications and the urgency for international cooperation to address these issues, many international organizations have already initiated legal responses in this field. Some of the prominent organizations at the international as well as regional level are UNESCO, WHO, ECOSOC, WMA and EU. The major international instruments, which deal with the human rights issues arising out of these developments, are Universal Declaration on Human Genome and Human Rights (UNESCO 1997), International Declaration on Human Genetic Data (UNESCO 2003), Universal Declaration on Bioethics and Human Rights (UNESCO 2005) and European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine ( European Convention on Human Rights and Biomedicine)(EU 1997, ETS No. 164).

The Universal Declaration on Human Genome and Human Rights as well as International Declaration on Human Genetic Data deal exclusively with human genetic data and provide detailed provisions for ensuring protection of human dignity, human rights and fundamental freedoms in the collection, processing, use, and storage of human genetic data. These instruments lay down certain principles like respect for human dignity, genetic privacy and confidentiality, nondiscrimination on the ground

of genetic characteristic, prior informed consent and right not to know. The Universal Declaration on Bioethics and Human Rights and European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine address the ethical and human rights aspects involved in the field of biomedicine, biology and related technologies applied to human being as a whole.

It is a commendable step taken by these instruments in stressing on respect for human dignity, fundamental freedoms and privacy, which are basic principles in human rights, and emphasizing the need for observance of these principles in genetic research as well as in the collection, processing, use and storage of genetic information. However, it undermines the practical difficulties in operationalizing these principles because of the inherent ambiguity, vagueness, and indeterminateness associated with these terms. Further the terms privacy, dignity, autonomy, etc are not defined in the above mentioned instruments, which will make it difficult to ascertain the commitment of the state parties and there for these rights are declaratory in nature in these instruments.

The Universal Declaration on Human Genome and Human Rights, International Declaration on Human Genetic Data and European Convention on Human Rights and Biomedicine recognize a new right, namely the right to nondiscrimination based on one's genetic characteristics. These instruments prohibit the discrimination based on genetic characteristics of an individual and the use of genetic information for any purpose that may lead to stigmatization of the individual, family, group or community. They also prohibit the use of genetic information for financial gain. These instruments also recognize the right of patient not to know about health status or right of the patient to remain in ignorance with respect to genetic test results or health information. This has set fire to a lot of controversies and debates as it is directly opposed to the right to information and, as many claim, opposed to individual autonomy. The right not to know recognized under many international instruments is subjected to severe criticism that without access to relevant health information one cannot give valid informed consent and it is opposed to individual autonomy, and as it violates individual autonomy it is also a negation of respect for human dignity. However, the right not to know or the right to remain ignorant cannot

be defended only in the name of individual autonomy, and the debates and controversies associated with it are not yet been settled.

Prior informed consent is yet another principle laid down by Universal Declaration on Human Genome and Human Rights, International Declaration on Human Genetic Data and European Convention on Human Rights and Biomedicine. It is an indispensible principle so far as genetic testing, genetic screening, genetic intervention and genetic researches are concerned. However, it is not easy to obtain prior informed consent in the same sense as it is mentioned in the principle. To obtain a prior informed consent, the patient must be fully informed of the implications of genetic testing or genetic screening to himself/ herself as well as to his/her family. This requires a basic understanding of genetic, for it involves highly scientific and technical matters. So that necessitates a genetic counseling by a qualified counselor, which involves clinical implications also, that can be conveyed only by the physician. The increasing demand on physicians to see more and more patients will conflict with the counseling requirements and will present practical difficulties in its implementation.

International instruments relating to biomedicine and human rights do not define the term genetic information or genetic data except International Declaration on Human Genetic Data. And the International Declaration on Human Genetic Data defines human genetic data as well as human proteomic but still there are ambiguities as to whether it offers protection to persons with a genetic variation as a result of genetic mutation. Further, International Declaration of Human Genetic Data and Universal Declaration on Human Genome and Human Rights, which exclusively deals with human genetic data, are not binding instruments and the European Convention on Human Rights and Biomedicine, which deals with more general issues in the field of biomedicine, is applicable only to European countries that have ratified it. But these international instruments are evidence for a growing international concern and a general approach of international community in this area, which may, in future, bring international consensus regarding many legal principles dealing with human genetics and biomedicine.

The recent international legal responses to the legal, ethical and social issues posed by the developments in human genetics and associated technologies seems to be appropriate from a global perspective being it an initiative towards an international genetic specific law. It is also true that to reach a global consensus in this area is an onerous task owing to the differences in social, economic, cultural and religious backgrounds of countries. Fortunately many international institutions have taken initiatives, notwithstanding the difficulties in attaining global consensus, towards harmonizing some of the basic rules in human genomics and come up with framework instruments in this field. It is also encouraging to note that many states have enacted domestic legislations in tune with these instruments with particular focus on the employment and insurance sector, like the Genetic Information Nondiscrimination Act 2008 of USA, and in many other countries similar legislations are under consideration. However many developing countries like India is still lagging far behind in framing legal provisions to address the issues posed by the developments in human genetics and its applications. India should atleast amend the constitutional as well as other legal provisions, which deals with discrimination, so as to include 'genetic features/ characteristics' along with other objectionable grounds for discrimination like sex, race, colour, place of birth, etc.

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