Chapter 7

Human Genome Project: Indian Legislative and Judicial Response

It really is a gift to the world, and not just to the developed world but the developing world.

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Introduction

Biotechnology, globally recognized as a rapidly emerging and far-reaching area, is aptly described as the "technology of hope" for its promising of food, health and environmental sustainability. HGP constitutes an important milestone in the development of biotechnology revolution. This chapter analyzes whether the above observation regarding HGP holds any importance to India being a developing country. The chapter discusses the role of India in the HGP and analyzes the special ethical and legal concerns arising out of HGP for India. The chapter reviews the existing legal framework with an emphasis on whether it is sufficient to deal with the genetic revolution. It also discusses the Institutional responses with an emphasis on the Ethical Guidelines developed by Indian Council of Medical research (ICMR) and the document developed by the National Bio-ethics Committee of Department of Bio technology relating to human research. It explores the substance of both the guidelines in detail with its drawbacks. Finally, the chapter looks to future regarding what steps India can take to reap the benefit of genetic revolution. The chapter concludes that any policy response has to take into account the unique social dimensions prevailing in India.

India and Biotechnology Development

India is one of the first few countries, among the developing nations to have recognized the importance of biotechnology as a tool to advance the growth of agricultural and health sectors as early as in 1980s. India's sixth five year plan (1980-85) was the first policy document to cover biotechnology development in the country. The plan document proposed to strengthen and develop capabilities in areas such as immunology, genetics, communicable diseases etc. ²

As envisaged under the plan an apex official agency, National Biotechnology Board (NBTB) was set up in 1982, to spearhead the development of biotechnology. The NBTB was chaired by member, science of the Indian planning commission and had representation of almost all the science and technology agencies in the country.³ NBTB issued the "Long Term Plan in Biotechnology for India" in April 1983. This document spelt out priorities for biotechnology in India in view of the national objectives such as self sufficiency in food, clothing and housing, adequate health and hygiene. Later in 1986, NBTB graduated to a full-fledged government department called Department of Biotechnology.⁴

From the time of inception Indian biotechnology sector has advanced through a number of technical initiatives started by academic and industry.⁵ Presently India is being targeted as a hot destination for investment mainly due to its developed human resource potential and infrastructure. Indian genetic diversity also contributes to its popularity. For

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³ Ibid.
⁴ Ibid.
⁵ Viren Konde, "Bio-Technology in India Public and Private Partnerships", Journal of Commercial Biotechnology 14, at 43–55,(2008). Published online 27 November 2007. The Indian biotechnology sector crossed the US $2bn mark during 2006–2007. Although this accounts for only a little more than 1 per cent share of the global biotech market, the encouraging sign is that the sector is riding on a healthy growth rate of over 35 per cent annually over the last five years.
a country like India, biotechnology is a powerful enabling technology that
can revolutionize agriculture, healthcare, industrial processing and
environmental sustainability.⁶

In India, due to the concerted effort in research and development in
identified areas, modern biology and biotechnology have given rich
dividends. The proven technologies at the laboratory level have been
scaled up and demonstrated in field. Patenting of innovations, technology
transfer to industries and close interaction with them have given a new
direction to biotechnology research. Initiatives have been taken to promote
research in plants with emphasis on pest and disease resistance,
nutritional quality, molecular biology of human genetic disorders, brain
research, plant genome research, development, validation and
commercialization of diagnostic kits and vaccines for communicable
diseases, food biotechnology, biodiversity conservation and bio-
prospecting, etc.⁷ Special attention has been paid to rural areas, women
and for different States. Indian government has circulated the National
Bio-Technology Development strategy for public comments. The strategy
taking into account the past development focuses on various issues such
as human resource development, academic and industry interface,
infrastructure development, promotion of industry and trade,
biotechnology parks regulatory mechanisms, public education and
awareness building. This policy also aims to chalk out the path of progress
in sectors such as agriculture and food biotechnology, industrial
biotechnology, therapeutic and medical biotechnology, regenerative and
genomic medicine, diagnostic biotechnology, bio-engineering, nana-
bio-technology, bio-informatics and IT enabled biotechnology, clinical

⁶ Supra note 1 See Sachin
biotechnology, manufacturing & bio-processing, research services, bio-resources, environment and intellectual property & patent law.  

In spite of the spectacular progress registered by India in the field of biotechnology, some drawbacks and lacunas still needs to be tackled. 

For any research flow of funds constitute a major impetus and in India the flow of funds in bio technology seems to be limited mainly from Department of Bio-technology. Further like any other commercial venture much of the funding is limited to area with substantial commercial applications or returns on investment. For instance In India the emphasis seems to be on agriculture plants and medical resources.

Besides these there is concern of depletion of human resources due to brain drain. Though India can boast of highly skilled technical and scientific community they seems to be attracted by the better remuneration and potential of working conditions abroad. Roughly 100,000 Indian professionals per year are expected to take up work visas in the U.S.A., causing India a yearly loss of about US$2 billion. While much remains to be done in India, its spectacular advances in the biotechnology sector are emulative and appear to inspire emerging biotechnology program.

Human Genome Project: Indian Involvement

It is now well known that India is the only country in the world which had extensive scientific infrastructure and capabilities and was not a part of the

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8 Supra note 1, See Sachin.
9 Virander S. Chauhan & Devesh Bhardwaj, Current Status of Malaria Vaccine Development, in Biotechnology in India at 174, (2003) 10<http://dbtindia.nic.in/programmes/progmain.html> (Last visited on 10-2-2008) The Department during ninth plan period has invested to the tune of Rs.30 Crore to implementing the Human Genetics & Genome Analysis programme. In order to implement new projects, the Department has projected about Rs.300 Crore during its tenth plan.
international human genome sequencing project.\textsuperscript{12} Perhaps this decision was taken due to the belief that it requires huge infrastructure and financial requirements and such an endeavour may perhaps distract countries other pressing research priorities. India had set up in 1992, just around two years after the Human Genome Project (HGP) was initiated the Indian Genome Project (IGP), reportedly to work on diagnostic tools for neurological disorders, thalassemia and tuberculosis, population genetic diversity programme and gene therapy.\textsuperscript{13} But it seems that not much progress has been undertaken in this area.

Participation in the project would have given India, some significant headway. First of all scientists would have had the benefit of working in close association with the world's best in the area, and given the country an opportunity to be part of the global excitement. In addition, a degree of continuum for further utilizing the results of HGP would have automatically come India's way. If we were a part of the HGP the access to information that was not made available normally to the world when the final results were put in the public domain would have been easily accessible for our scientists. This kind of information often becomes crucial for optimal utilization of the result and for immediate future impetus in the research. Further it would have significantly aided the skills required to handle similar genome projects.

It is not that we have not taken any initiative; Dept of Biotechnology identifies human genetics and genome analysis as one of the priority area. The programme was initiated with the main objective to develop basic capabilities, strengthen existing institutions which have good expertise, to initiate work in molecular genetics and to support some

\textsuperscript{13} N.D Nair, “How Should India Exploit the Genome Bonanza”? \textit{The Hindu} Thursday, November 30, (2000).
application oriented projects so as to reduce the burden of genetic disorders in the country.\textsuperscript{14} Since its inception major programmes have been initiated in the area of functional genomics, human genome diversity, and gene therapy. India is one of the first countries to take up the project on "Human Genome Diversity". Till now the project has identified

- DNA typing of 25 autosomal markers in 40 ethnic groups (tribal, caste and religious communities) of India has been completed.
- This study also provided evidence of human migration from India to South-East Asia. It revealed that the expansion of the ethnic population took place about 50,000 years ago.
- The studies indicate that Austro-Asiatic speaking tribal populations in India were the original inhabitants.\textsuperscript{15}

But the need of the hour is to come up with an integrated genome research Project with substantial funding. The time has come for India to move expeditiously into converting its knowledge base for the industrial and economic growth of the country. One of the important mechanisms to bring about a major transformation in the quality of life of people is the application of genomic information not only of the humans but of all living organisms, for the detection, prevention and treatment of diseases ailing humanity.\textsuperscript{16}

**Human Genome Project: Implications for India.**

The Genetic revolution spearheaded by the HGP opens up new vistas and hopes for India in various medical areas especially in preventive medicine. In the preventive medicine the possibility of designer drugs brings new

\textsuperscript{14} Supra note 10.
\textsuperscript{15} Ibid.
\textsuperscript{16} Supra note 13, See N.D. Nair
expectation. Till now the medical practitioners and researchers used to experiment drugs on animals or volunteers for its effectiveness. This practice suffers from certain drawbacks as it can be very costly and time consuming especially in the case of its failure. But with the HGP this is expected to undergo rapid transformation. On the basis of genetic profiles gathered it is quite possible to determine and decide in advance which medicine and treatment should be given to each patient.

Further India due to its wide genetic diversity is positioned strongly to play a decisive part in understanding, diagnosis and cure of various categories of disease. The close knit social structure plays a major role in this. In India marriages generally take place among same caste and religion. This provides for the maintenance and continuance of unique genetic make up. Thus special genetic traits like intelligence, arts, creativity run along the families. This will help scientists to easily identify the gene responsible for these special traits and analyze how these genes are inherited. This may also aid the scientists in understanding diseases like Alzheimer's thalaseemia etc found to be concentrated in certain communities.

On the flip side there is a grave danger of personal information getting misused. The fear of such misuse is not very farfetched. Our society is already broken on the basis of caste, class etc and with genetic revolution another category may be added which is that of "gene". It is possible that certain castes may be identified with certain genetic predispositions to disease and can be discriminated. Thus the past caste discrimination may be revisited in the form of genetic discrimination. The genetic discrimination can occur in various fields like access to education, employment, adoption, Insurance etc. Further due to the functional creep which occurs in every field the possible band and area of discrimination may expand in the coming years. Further there is an underlying bias against certain people in the operation of any legal system. In this growing age of connecting genes with behavioural traits including anti social
characteristics, this may lead to atrocities and attaching stigma on certain communities. Legislators and society will have to bring forth enormous will to prevent discrimination of this kind.

**Existing Legislative Frame Work**

In contradistinction to what appears to characterize the International and western developed countries experience regarding genetic laws India has chosen not to recognize "genetic exceptionality," To date we have refrained from crafting any distinctive legislative mechanism to deal with genetic information, apart from certain provisions which generally deal with the use of DNA in criminal investigations and those relating strictly to reproductive technologies.\(^{17}\) Instead, most provisions relevant to genetic information are found in general norms drafted in the abstract of genetics, not taking genetics into account and often long before the so called genetic revolution. Chief amongst these is India's constitutional law, and other statutes.

**Relevant Constitutional Provisions: Genetic Discrimination and Privacy**

The articles relevant to discussion here relates to certain Fundamental Rights provisions, Directive principles and Fundamental Duties. The relevant fundamental rights which can be said to have some connection with the issues and legal questions arising out of genetic revolution in terms of discrimination and privacy are Article 14, 15 16 and 21. Regarding fundamental duties the principles of relevance is Article 51 (h) which provides for promoting scientific temper, humanism and spirit of enquiry.\(^{18}\) The relevant directive principle is contained under article 39(f)

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\(^{17}\) The Indian Evidence Act 1872 Section 45 deals with admissibility of DNA Evidence. Further The Pre conception and Pre-natal Diagnostic Techniques (Regulation and prevention of Misuse) Act, 1994 regulates the use of genetic technologies relating to procreative technology.

\(^{18}\) Constitution of India, 1950 Art 51.
which ensures certain rights on children\(^{19}\) and Article. 47 which imposes duty on the state to raise the level of nutrition and the standard of its people and the improvement of public health as among its primary duties\(^{20}\).

One of the areas of concern arising out of HGP relates to possible genetic discrimination possible in the fields of education, employment, insurance, adoption etc. Article 14 of the constitution guarantees equality before law and prohibit discrimination in general terms,\(^{21}\) where as Article 15 and 16 are specific application of Article 14. In case of genetic discrimination, it stands to reason that discrimination on the basis of genetic status could implicate the violation of Article 14, 15 and 16 of the constitution if we analyze the relevant constitutional provisions; Article 14 guarantees equality before law but allows for reasonable classification.\(^{22}\) But it is submitted that a classification based on genetic make up can never stand the test of reasonableness under the said article. The reason being such a classification will not have any nexus to the purpose sought to be achieved whether in relation to employment, insurance or education. Article 15 prohibits discrimination on the basis of religion, race, caste, sex, and place of birth or any of them for the purpose of admission to educational institutions.\(^{23}\) Article 16 prohibits discrimination in employment on grounds of religion, race, caste, sex, descent, place of birth, residence or any of them for the purpose of employment.\(^{24}\) The question arises

\(^{19}\) Id., at Art 39(f) provides that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.

\(^{20}\) Id., at Art 47.

\(^{21}\) Id., at Art 14 guarantees Equality before law.—The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.

\(^{22}\) Ibid.

\(^{23}\) Id., at Art 15. Prohibition of discrimination on grounds of religion, race, caste, sex or place of birth.—(1) The State shall not discriminate against any citizen on grounds only of religion, race, caste, sex, place of birth or any of them.

\(^{24}\) Id., Art 16 Equality of opportunity in matters of public employment.—(1) There shall be equality of opportunity for all citizens in matters relating to employment or appointment to any office under the State.
whether the grounds of non discrimination mentioned under these articles are satisfactory or wide enough to cover the genetic base discrimination. There are possibly two arguments to this. One argument takes the view that since Article 15 and 16 of the constitution mentions caste, race and religion as the grounds of non discrimination if there is an instance of genetic discrimination linking a particular race or caste, the grounds of prohibition mentioned under these articles will be enough to cover those cases. Problematically, however, that protection would only extend if the genetic status in question is deemed to be significantly connected to a particular race or ethnic group, which is rarely the case. The next argument relates to whether the grounds of prohibition mentioned under article are inclusive or exhaustive. If we go by the literal interpretation of the term used in the constitution, the article 15 reads “The state shall not discriminate against any citizen “only” on the basis of Religion……. Place of birth, meaning other grounds of discrimination are possible. This leaves open the possibility of genetic discrimination. The same argument can be advanced regarding article 16 also which bans or prohibits discrimination on the basis of religion, race, caste, sex, descent, place of birth, residence or any of them.

But the problem is that even if we argue that both these articles 15 and 16 touches upon genetic discrimination, constitutional protection is of limited application to this inquiry, as it generally applies exclusively to state action, whether in terms of education or employment and only a few namely government employees can practically avail themselves of its safeguards against employer intrusions in that context. That raises particular concern as most violations in the area of genomics are expected to be attributed to private actors. As Frances Raday warns,

(2) No citizen shall, on grounds only of religion, race, caste, sex, descent, place of birth, residence or any of them, be ineligible for, or discriminated against in respect of, any employment or office under the State.
In our day, the most grievous and most frequent abuses of civil liberties occur in the exercise of private power. The occasions for discriminatory state action are both comparatively few and subject to relatively formalized procedures for their exercise when contrasted with an employer's power to dismiss, a landlord's power to exclude the needy, or an entrepreneur's refusal to provide service. Further the globalization and liberalization of Indian economy has opened up more employment and insurance opportunities in private sectors. Hence existing constitutional provisions may be of very limited use.

This scenario arises due to the traditional human right and fundamental right concepts. Traditional human rights and fundamental right scenarios typecast the state as the human rights violator. They portray governments as awesome, centralized monsters that actively abuse their people. Conventional juristic opinions also depict the human rights and fundamental right victim as a living member of a defined group, one that is easily demarcated by a mental boundary. In most cases, members of this group are physically distinguishable by race or gender, or by a natural affiliation with an ethnic, national, linguistic or religious group. By adding new players and new issues to the human rights framework, genetic technology defies the concepts underlying the existing model and reveals the need for a revised language. Genetic technology privatizes human rights issues by placing the power to violate rights in the hands of private actors throughout society -- the biotech companies that develop the technology, the public and social authorities that demands it and use it for perpetuating genetic discrimination. Through their specialized and concentrated expertise, biotech companies and multinational companies, insurance companies develop a kind of power that is analogous to state

power. Accordingly, their conduct deserves scrutiny under international and national human rights standards.\textsuperscript{27}

But this, it is submitted is a minor problem which can be easily tackled by an amendment to the constitution as evident from the recent amendment to the constitution inserting Article 15 (5) allowing reservation even in private sectors.\textsuperscript{28} Further all fundamental rights have some human right basis and whenever human right violations take place on the basis of genetic make up, we can't take protection under the argument that since fundamental rights are available only against state actions the affected parties have no available remedy.

The only constitutional provision we can conclude safely will include genetic discrimination is Article 21 which guarantees "protection of life" as a fundamental right and reads: "No person shall be deprived of life or personal liberty except according to procedure established by law."\textsuperscript{29} The courts in India have always used this provision to emphasize the dignity of individual. The issue of genetic discrimination may be interpreted as violation of Article 21 in two ways. Firstly as against the basic human dignity and secondly as violation of privacy rights as most of the genetic discrimination occurs as a result of violation of privacy rights. If we take the case of Insurance sector and the use or misuse of genetic information in a manner that adversely impacts on a person's ability to access healthcare has a direct effect on the person's right to human dignity and

\textsuperscript{27} Ibid.
\textsuperscript{28} Supra note 18, Constitution of India 93rd amendment added clause 5 to Art 15. "(5) Nothing in this article or in sub-clause (g) of clause (1) of article 19 shall prevent the State from making any special provision, by law, for the advancement of any socially and educationally backward classes of citizens or for the Scheduled Castes or the Scheduled Tribes in so far as such special provisions relate to their admission to educational institutions including private educational institutions, whether aided or unaided by the State, other than the minority educational institutions referred to in clause (1) of article 30.
\textsuperscript{29} Id., Art 21.
In other words, people’s dignity is at stake when they do not have access to healthcare, and insurance roadblocks based on genetic considerations may just result in debased human beings. The same argument can be advanced in relation to access to employment and education since the denial of employment or education directly comes in the way of leading a dignified life. Besides this, genetic discrimination in case of employment can be interpreted to infringe the right to livelihood declared as a fundamental right under Article 21. But leaving the entire issue of genetic discrimination to the wider interpretation of Article 21 is highly inadequate. We need to seriously think of enacting legislation if India need to reap the potential economic and health benefits of advances in the field of human genome research.

Another area of possible genetic discrimination may occur in the area of adoption. In India the domestic adoptions are regulated by personal laws and the laws does not mention prohibited grounds of discrimination. In this growing age of technology, if an instance of discrimination on the basis of genetic characteristics arises we will have to possibly rely on the wider interpretation of Article 21 as violating the basic dignity which is highly inadequate. The same situation prevails even regarding inter-country adoption which is regulated by Supreme Court decisions.

30 http://international.westlaw.com/result/documenttext.aspx?rp=%2fWelcome%2fWorldJournals%2fdefault.wi&efdate=1%2f01%2f0001+12%3a00%3a00+AM&r=CLID_QRYRLT9561147&cxt=RL&v=2.0&fc=0&b=1&as=CNT&fn=top&rs=WLIN7.06&eq=Welcom e%2fWorldJournals&blinkedcitetst=False&db=WORLD-JLR%2cLAWREV-PRO%2cCLMLR%2cHVR%2cYLJ%2cMELULR%2cCUSLJ%2cUITORMLJ%2cHKLJ%2cUKHR-
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33 Regarding adoption among Hindus Hindu Adoption and Maintenance Act 1956 has been passed by the government. Regarding adoption among Christians and other communities there exists Indian Adoption Act.
34 Lakshmi Kant Pandey v. Union of India AIR 1984 SC 469.
The other major issue of human right concerns relates to genetic privacy. Pertaining to India this can occur when the individual genetic information is accessed by social agents or disclosed to third parties by medical practitioners. It has to be mentioned that right to privacy is not explicitly finds a place among the fundamental rights. But it is worth mentioning that despite the lack of an explicit right to privacy recognized in the Constitution, in India, right of privacy has been culled out of the provisions of Article 21 of the Constitution and other provisions relating to the fundamental rights read with the Directive Principles of State policy. India is a signatory to the International Covenant of Civil and Political Rights, 1966. Referring to Article 17 of that Covenant and Article 12 of the Universal Declaration of the Human Rights, 1948, The right to Privacy has been held to include the right to safeguard his own privacy, that of his family, marriage, procreation, motherhood, child-bearing, education etc. and no person can publish anything relating to such matters without the consent of the person concerned. The Supreme Court in People’s Union for Civil Liberties (PUCL) v. Union of India held that, the right to privacy is a part of right to “life” and “personal liberty” enshrined under Article 21 of the Constitution, and it cannot be curtailed except according to the procedure established by law.

The right to medical privacy was more specifically in issue in the context of disclosure of the outcome of the blood test in Mr. “X” v. Hospital “Z", in which the appellant’s blood sample was tested and he was found to be HIV positive which resulted in the appellant’s proposed marriage being

35 Supra note 18 See Constitution of India under the wider interpretation of Art 21 Supreme court has carved out a place for privacy in India through a catena of cases like Sheela Barse v. State of Maharashtra 1987, 4 SCC 373, Prabha Dutt v. Union of India 1982, 1 SCC 1, State through Supdt., Central Jail, N.D. v. Charulata Josh 1999, 4 SCC 65.
39 1997, 1 SCC 301.
40 1998, 8 SCC 296.
called off. The Supreme Court held that the right to privacy has been culled out of the provisions of Article 21 and other provisions of the Constitution. However, the right was not absolute and may be lawfully restricted for prevention of crime, disorder or protection of health or morals or protection of rights and freedom of others. It was held that, having regard to the fact that the appellant was found to be HIV (+), its disclosure would not be violative of either the rule of confidentiality or the appellant’s right of privacy as “A”, whom the appellant was likely to marry, was saved in time by the disclosure, otherwise, she too would have been infected with the dreadful disease if the marriage had taken place and consummated.

Thus Courts in India has always ruled that the Right to life under Article 21 and 19 is wide enough to cover constitutionally protected privacy interests. 41 Decisions have noted that infringements on privacy and personal autonomy must be justified by a compelling interest. 42 If we go by the trend of these decisions it is very clear that though there is not even a single case decided till now directly touching upon the issue of genetic privacy. Indian society is socially very close knit one and one of the problems which will surround the judiciary and policy makers will be to decide whether genetic privacy is individual or familial since the genetic traits are shared among family and generations.

But these interpretations also have the same defects as our argument regarding genetic discrimination. Even if a person is able to prove violation of genetic privacy it can be claimed only against authorities qualifying as

42 In India, the Supreme Court has held that disclosure of confidential medical information for public interest does not violate Right to privacy may be justified in some circumstances When the right to health is weighed against the right to privacy, the right to health will override because privacy interest must be placed in the context of other rights and values Mr. X v. Hospital Z, 1998, 8 SCC 296.
state under Article 12 of the constitution. But with the HGP the threat of violations of privacy happens mostly in the hand of private players. This can be more in a country like India where people are illiterate and ill informed. The recent kidney scam is a reminder where the ignorance and poverty of the poor was misused to endanger the lives. In India the need for Informed consent and right to information in relation to medical processes are not very well settled statutorily and legally. The requirement of Informed consent and information is scattered among some ethical documents prepared by ICMR laying down ethical guidelines for biomedical research on human beings. These requirements are only in the form of ethical guidelines lacking statutory compliance. At present the only possible way of enforcement of the requirement of informed consent and flow of information whether in relation to research or medical processes is through the Consumer Protection Act. Before this Act in relation to medical negligence a person could proceed under law of torts. But they had its own drawbacks. In case of torts the person could easily avoid the liability by claiming that he had acted reasonably which is the base of civil law. The Consumer Protection Act was enacted in response to public opinion generated by the consumer movement in India. The Act aims to protect the rights of consumers through settlement of disputes by consumer tribunals at the district, state, and national level. The Act defines consumer “as any person who buys goods or hires services for a consideration.”

43 Supra note 18, See Constitution of India Art 12 reads In this Part, unless the context otherwise requires, "the State" includes the Government and Parliament of India and the Government and the Legislature of each of the States and all local or other authorities within the territory of India or under the control of the Government of India.

44 The Indian Council of Medical research brought out the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' in 1980 and revised these guidelines in 2000 as the 'Ethical Guidelines for Biomedical Research on Human Subjects'.

45 Consumer Protection Act was passed in India In order to protect the consumers from exploitation and to save them from adulterated and substandard goods and deficient services the Consumer Protection Act came into force on 15th April, 1986.

46 Id., Section 2d (ii) [hires or avails of] any services for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred
as a consumer who obtains professional services from a physician for a fee (consideration). As a result, consumer tribunals started receiving complaints of negligence from patients against physicians and hospitals and awarded compensation in several cases. The case of genetic privacy violations can be easily interpreted to be part of deficiency in service which is defined under the Act as any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service. But the problem is that as of now the Act does not apply to government physicians and hospitals as it has been held that the services provided by them are free and not for a consideration. But there is a vociferous demand to bring the government-run health system under the Act.

Criminal Law and Genetic Issues

Another problematic area of HGP is the possible threat it poses to the concept of mens rea the cardinal principle of criminal law. But in India it is not expected to make a major impact on its legal system the reason being though the Indian Penal Code (IPC) recognizes and accepts mens rea to be an essential ingredient of criminal offences. It tries to bring out the

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47 Id., at Section 2 (o) "service" means service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, [housing construction], entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service.


49 Supra note 45 Section 2(g) Consumer protection Act.

50 Consumer Unity and Trust Society v. State Of Raj. and Ors. 1991 (1) CPR 241 (NC)]. The National Commission held that persons who availed themselves of the facility of medical treatment in a Government Hospital are not "consumers " as defined in Consumer Protection Act, and the said facility cannot be regarded as service "hired " for consideration.
concept through an objective analysis. If at all a case arises in India which brings the issue of genetic factor as a defence, in the absence of explicit mention of genetic condition as an exception, it has to fall upon the general exceptions mentioned in IPC specifically on provisions relating to Insanity Section 84 provides* "Nothing is an offence which is done by a person who, at the time of doing it, by reason of unsoundness of mind, is incapable of knowing the nature of the act, or that he is doing what is either wrong or contrary to law." 51 But even this in not expected to bring much result as is evident from the judicial decisions which has only recognized legal insanity as a defence and not medical insanity. The judicial decisions have clarified that it is not the medical unsoundness of mind which is the focus the question is whether at the time of committing the act that person is capable of knowing the nature of the act or whether it is wrong.52 The courts have further clarified that these will be ascertained from the accompanying circumstance and conduct of person concerned.

Another area of legislative response importance to our discussions relates to the relevancy of DNA evidence in criminal investigations, trials, civil cases and the issue of DNA profiling. The discovery of DNA technology has profound impact not only in the field of genetic biology, but also in the field of law enforcement. The crime scenario in the 21st century has become very complex. The modus operandi of crime has become scientific; hence it is essential to use science and technology in apprehending the criminals. Improved testing technologies are emerging, that provides efficient and effective DNA evidence possessing which promise to widen the use of DNA evidence and thus aids in search of truth by exonerating the innocent. The development of DNA technology furthers the search for truth by helping police and prosecutors in the fight against

51 Indian Penal Code 1860, Section 84.
violent crime. Through the use of DNA evidence, prosecutors are able to conclusively establish the guilt of a defendant. So, the importance of DNA technology in the administration of Justice in any form of society and in any part of the world cannot be denied. The potential for collecting DNA evidences from the victim, suspect and the crime scene is almost unlimited. In India too, DNA technology is used for solving serious problems of crime detection/investigation and other relevant cases. The best example of this can be seen in the famous Tandoor Murder Case,\textsuperscript{53} in which DNA test verified the mutilated body. This means that old cases can now be solved and possibly prosecuted using current forensic technology. Similarly in Trikambhai v. State of Gujarat, the High Court convicted solely salivary DNA found at the place of offence.\textsuperscript{54} Other cases which relied on DNA evidences include Sajeera v. P.K Salim\textsuperscript{55}, Priyadarshini Matoo’s Case, Kasturba Ghandhi Police Station Case etc.\textsuperscript{56} In India there are more than 1500 cases in which DNA testing was taken into consideration for solving the problem of law enforcement. The question will become more relevant in wake of new revelations arising out of HGP.

If we have to analyze the legislative and judicial response regarding DNA evidence and testing Indian criminal justice delivery system continues to contend with several Laws that are in force, having their origins in the colonial era, such as the Indian Penal Code, 1860, the Indian Evidence Act, 1872, and some already more than twenty-year-old laws, such as the Code for Criminal Procedure,(Cr.P.C) 1973. With the rapid progress in science and the advent of new tools of biology, some rethinking in the form of amendments or enacting new legislations become obligatory. The Constitution of India, by Article 51 A (h) and (j), declares that, it shall be

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\textsuperscript{53} Sushil Sharma v. State of Delhi Administration 1996 Cr. L.J. 3944.
\textsuperscript{54} 2000 Cr.L.J, 205.
\textsuperscript{55} 2000 Cr.L.J. 108
\textsuperscript{56} Vipul Dharmani, DNA Technology and its Perspectives, SSLC online Journal available at http://www.symlaw.ac.in/phpmyfaq/index.php?action=artikel&cat=4&id=12&artlang=en (visited on 2-09-2008)
the duty of every citizen of India “to develop the scientific temper, humanism and the spirit of inquiry and reform”; and “to strive towards excellence in all spheres of individual and collective activity so that the nation constantly rises to higher levels of endeavour and achievement.” 57

The Parliament is legislatively competent to make laws with respect to the Union agencies and institutions for professional, vocational or technical training, promotion of special studies or research, or scientific or technical assistance in the investigation or detection of crime and with respect to coordination and determination of standards in institutions for higher education or research and scientific and technical institutions. 58

The constitutional provisions take care of the scientific developments that may take place and may be put to use for the benefit of the people. The Constitution provides efficient scales for balancing between public and private interests and the courts have put to use its provisions for an effective social engineering to protect both the cherished human rights recognized by the Constitution and the paramount public interest in a welfare State. If we analyze the specific legislative responses in India, it is clear that there is no specific provision or law which conclusively deals with genetic testing or admissibility of DNA evidence.

Under Section 45 of the Indian Evidence Act, 1872, it has been, inter alia, provided that, when the court has to form an opinion upon a point of science, or art, or as to identity of handwriting or finger impression, the opinions upon that point of persons specially skilled in science or art or any question as to identity of handwriting or finger impressions are relevant facts and such persons are called experts. 59

The expression opinions upon a point of science of persons especially skilled in science are capable of application to all future advances in science which enable an expert opinion on a point. The courts have opined that medical

57 Supra note 18, See Constitution of India Art 51.
58 Id., at 9th schedule (Entries 65 and 66 of the Union List).
59 Supra note 17, Indian Evidence Act 1872 Section 45.
evidence is only an evidence of opinion and is hardly decisive. It is not substantive evidence. But they say that the opinion of the doctor who has held the post-mortem examination and of the forensic science laboratory is reliable. The Supreme Court of India has further stated that unless there is something inherently defective in the medical report, the court cannot substitute its own opinion for that of the doctor.60 The Supreme Court of India has held: ‘A medical witness called in as an expert and the evidence given by the medical officer is really of an advisory character based on the symptoms found on examination. The expert witness is expected to put before the court all materials inclusive of the date which induced him to come to the conclusion and enlighten the court on the technical aspects of the case by explaining the terms of science so that the court although not an expert, may form its own judgment on these materials after giving due regard to the expert’s opinion because once the expert’s opinion is accepted it is not the opinion of the medical officer but that of the court.61 Thus, it can be said that the laws and courts in India are still not clear on the matter on the criteria of admissibility of scientific matters and confusion still prevails. It is submitted that this provisions is not sufficient to cover the various issues arising out of HGP.

Section 54 of Cr.P.C. provides for medical examination of the accused in case if there are any injuries on his person.62 The use of this provision was elaborated by The Law Commission at its 37th report and has stated that to facilitate effective investigation; provisions are made authorizing

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62 Code of Criminal procedure Code ,1973 Section 54 Cr P.C provides “When a person who is arrested, whether on a charge or otherwise, alleges, at the time when he is produced before a Magistrate or at any time during, the period of his detention in custody that the examination of his body will afford evidence which will disprove the commission by him of any offence or which Magistrate shall, if requested by the arrested person so to do direct the examination of the body of Such person by a registered medical practitioner unless the Magistrate considers that the request is made for the purpose of vexation or delay or for defeating the ends of Justice.”

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examination of the arrested person by a medical practitioner if such an examination can provide evidence about circumstances under which alleged offence was being committed. In Ananth Kumar v. Andhra Pradesh the expression 'examination of the person' was held to include physical examination, medical test of blood, semen, sputum, urine etc. Thus under these provisions DNA Test can be done by medical practitioner. Further section 53 of Cr.P.C. also allows for taking medical examination. Under Sections 156 & 174 of Cr.P.C. Predominance of legal spirit demanded that the Court must be empowered to order for DNA testing (medical examination), so as to facilitate justice. To facilitate these provisions more, Justice Mali math Committee recommended that DNA expert being included in the list of experts under Section 295(4) of Code of Criminal Procedure, 1973. Further the Committee Report also recommended for amendment of Section 482 of Cr.P.C, 1973, in the following words

"Every Court shall have inherent power to make such order as may be necessary to discover truth or to give effective order under this Code or to prevent abuse of the process of the Court or otherwise to secure the ends of the justice." By using this provision the court will be better equipped with more powers of investigation like the Courts of inquisitorial system.

63 Law Commission of India 37th report on Code of Criminal Procedure Code. 64 1977 Cr.L.J 1797 (AP). 65 Supra note 62, Cr.P.C at section 53 provides (1) When a person is arrested on a charge of committing an offence of such a nature and alleged to have been committed under such circumstances that there are reasonable grounds for believing that an examination of his person will afford evidence its to the commission of an offence, it shall be lawful for a registered medical practitioner, acting, at the request of a police officer not below the rank of sub-inspector, and for any person acting in good faith in his aid and under his direction, to make such all examination of the person arrested as is reasonable necessary in order to ascertain the facts which may afford such evidence, and to use such force as is reasonably necessary for that purpose. 66 Id., at section 156 (1) provides (1) Any officer in charge of a police station may, without the order of a Magistrate, investigate any cognizable case which a court having jurisdiction over the local area within the limits of such station would have power to inquire into or try under the provisions of Chapter XIII. 67 Report of Committee on Reforms of Criminal Justice System, Government of India, Ministry of Home Affairs, Vol. I, India, March (2003). 68 Ibid.
DNA testing can also be carried out with the help of this provision. The Justice Mallimath Committee has recommended for amending Section 4 of Identification of Prisoner’s Act, 1920 on lines of Sec.27 of Prevention of Terrorism Act, 2002 (POTA). Sec.27 of POTA provides that the police officer while investigating any case can request the Court of Chief Judicial Magistrate or the Court of Chief Metropolitan Magistrate, as the case may be, in writing for obtaining samples of handwriting, fingerprints, blood, saliva etc. from any accused person. If these recommendations are implemented, it will be possible for the investigating agencies to go for DNA testing in identifying the culprit.

DNA testing and its usefulness in civil cases also can not be ignored. This can be helpful in paternity/maternity dispute, legitimacy of the child in child abandonment cases, property disputes, inheritance, maintenance, and many other issues. DNA is necessary to reach the finality and justness of the issue. Regarding legitimacy it is however not clear whether DNA test can be used in cases governed by Sec.112 of The Indian Evidence Act, 1872.

The Rule of Law based on the dictates of the Justice has always made the Courts inclined towards upholding the legitimacy of the child, unless the facts are so conclusive and clinching as to necessarily warrant a finding that the child could not at all have been begotten to the father and as such the legitimacy of the child is rank justice to the father. The raison d’etre under the Evidence Act is against the illegitimisation of a child and is based on public policy and that a child should not suffer on account of lapses of parents. It is also the normative legislative intention that when certain fact is considered as conclusive proof of another fact, the judiciary
generally disables the party in disrupting in such proof. Courts have always desisted from lightly or hastily rendering a verdict and that too, on the basis of slender material, which will have the effect of branding a child as a bastard and his mother as unchaste women.  

Courts have generally ruled that in view of the provision of Sec.112 of the Evidence Act, there is no scope of permitting the husband to avail of blood test for dislodging the presumption of legitimacy and paternity arising out of the Section. The only exception provided in Indian Evidence Act is in the form of an outlet to a party, who wants to escape from the rigor of that conclusiveness. In such cases, it’s the DNA test which helps the Courts to decide on the contentious issue based on aspect of conclusiveness. In our country, initially the judges took very conservative views regarding the application of DNA evidence in resolving the paternity/maternity dispute cases. The Hon’ble Supreme Court in Gautam Kundu v. State of West Bengal expressed the most reluctant attitude in the application of DNA evidence in resolving the paternity dispute arising out of a maintenance proceeding. It laid some guidelines regarding permissibility of blood tests to prove paternity:

1. That the Courts in India cannot order blood test as a matter of course.
2. Whenever applications are made for such prayers in order to have roving inquiry, the prayer for the blood test cannot be entertained.
3. There must be a strong prima facie case in that the husband must establish non access in order to dispel the presumption arising under Sec.112 of Evidence Act.
4. The court must carefully examine as to what would be the consequences of ordering the blood test.
5. No one can be compelled to give sample for analysis.

74 1993, 3 SCC 418.
In Kamti Devi v. Poshi Ram\textsuperscript{75}, the Court gave priority to social parentage over biological parentage and thereby rejected DNA evidence by observing that though the result of a genuine DNA test is said to be scientifically accurate it is not enough to escape from the conclusiveness of Section 112 of the Evidence Act, 1872. In Sharda v. Dharmpa\textsuperscript{76} the Supreme Court took a very positive view regarding importance as well as admissibility of DNA evidence in matrimonial cases. The Supreme Court categorically observed that:

1. A matrimonial court has the power to order a person to undergo medical test.
2. Passing of such an order by the court would not be in violation of the right to personal liberty under Article 21 of the Indian Constitution.
3. However, the court should exercise such a power if the applicant has a strong prima facie case and there is sufficient material before the court. If despite the order of the court, the respondent refuses to submit him to medical examination, the court will be entitled to draw an adverse inference against him.

Thus it can be very well seen that courts are generally very reluctant to accept or permit DNA testing in these cases. It is submitted that when our Evidence Act was enacted, the legislature did not anticipate the revolutionary changes in society by virtue of advancement of science and technology and as such, though society has changed, law is lagging behind. Therefore, the Evidence Act is required to be changed in the light of the changing social condition.

It is pertinent to note that of late, on the basis of the recommendations made by the Mali math Committee\textsuperscript{77} the Law Commission of India

\textsuperscript{75} 2001, 5 SCC 311.
\textsuperscript{76} 2003, 4 SCC 493.
\textsuperscript{77} Supra note 67 See Committee on Reforms of Criminal Justice System.
proposed that Section 112 of the Evidence Act should be revised as follows:  

The fact that any child was born during the continuance of a valid marriage between its mother and any man, or within two hundred and eighty days,

(i) After the marriage was declared nullity, the mother remaining unmarried; or

(ii) After the marriage was avoided by dissolution, the mother remaining unmarried; shall be conclusive proof that such person is the legitimate child of that man, unless

(a) It can be shown that the parties to the marriage had no access to each other at any time when the child could have been begotten; or

(b) It is conclusively established, by tests conducted at the expense of that man, namely,

(i) Medical tests, that, at the relevant time, that man was impotent or sterile, and is not the father of the child; or

(ii) Blood tests conducted with the consent of that man and his wife and in the case of the child, by permission of the court that, that man is not the father of the child; or

(iii) DNA genetic printing tests conducted with the consent of that man and in the case of the child, by permission of the court that, that man is not the father of the child; and

Provided that the court is satisfied that the test under sub-clause (i) sub-clause (ii) or sub-clause (iii) has been conducted in a scientific manner according to accepted procedures, and in the case of each of these sub-clauses (i) or (ii) or (iii) of clause (b), at least two tests have been conducted, and they resulted in an identical verdict that, that man is not

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the father of the child. Provided, further that where that man refuses to undergo the tests under sub-clauses (i) or (ii) or (iii), he shall, without prejudice to the provisions of clause (a), be deemed to have waived his defence to any claim of paternity made against him.

Explanation I.—For the purpose of sub-clause (iii) of clause (b), the words ‘DNA genetic printing tests’ shall mean the tests conducted by way of samples relatable to the husband and child and the words ‘DNA’ mean ‘deoxyribonucleic acid’.79

Further in civil cases another section which can be used to permit DNA testing is Section 151 of Code of Civil Procedure. It gives inherent power to the Courts to investigate up to any extent as may be necessary for the ends of justice ought to prevent abuse of the process of the court.80 Again DNA test can be very useful in cases related to Succession and inheritance. Under Hindu Marriage Act, 1955 an illegitimate child legitimised by the virtue of Sec 16 inherits the property of his parent’s property in which the father is the coparcener.81 Thus under such circumstances to establish the legitimacy or illegitimacy of such children and to inherit the property, the DNA test can be the perfect medical evidence for inheritance or non inheritance of the properties.

Again Section 125, The Code of Criminal Procedure, 1973 states that it’s the duty of the man to maintain his wife, legitimate or illegitimate children, parents as long as they can’t maintain themselves. So the man can take the defence that the children doest belong to him. So in these situations DNA test provide the ultimate conclusive remedy to determine the paternity and maternity of the child, so that they can claim maintenance.

80 Civil Procedure Code 1908 section 151 provides “Nothing in this Code shall be deemed to limit or otherwise affect the inherent power of the Court to make such orders as may be necessary for the ends of justice or to prevent abuse of the process of the Court”.
But what is to be remembered that in all these cases Judiciary is reluctant to use DNA evidences.

Thus it is obvious that in India, we don’t seem to have realized how vast the potential of science technology is. DNA technology has made a drastic improvement in the methodology of providing different types of disputes of civil and criminal cases. Established in the middle of 19th century, today in India there are about 21- well established forensic labs, 4 of them being administered by the Central Government. The scientific methods are being adopted in crime investigation or civil cases in India in an organized way from 1849 onwards. It is imperative to incorporate DNA technology in an Indian Legislation or to draft an exclusive independent enactment on the use of DNA technology in Indian Courts. In India, The Code of Criminal Procedure, 1973, Indian Evidence Act, 1872 are too old. An exclusive law or Act as in America, England, and New Zealand and in Canada should be legislated by our Parliament, so that this technique could be effectively used as valuable evidence in the administration of Criminal and Civil Justice.

The legal question that may arise in India in wake of DNA evidence may relate to whether or not it is legal for the courts to ask the accused to supply a sample of his DNA for the analysis. What is of concern here is that does forcing the accused to provide a sample of his DNA amount to a violation of the protection against self-incrimination? Also, if the accused refuses to give the sample then does that mean that an adverse inference will be drawn against him? In the case of Gautam Kundu v. State of W.B. there was a question of disputed paternity. The Court held that no person can be compelled to give sample of blood for analysis against his/her will.

83 Supra note 18 at Art 20(3) (3) which reads No person accused of any offence shall be compelled to be a witness against himself.
84 Supra note 74.
and no adverse inference can be drawn against him/her for this refusal. The Supreme Court held that Article 20(3) of the Constitution gives protection to a person not to be a witness against himself. However, "to be a witness" is not equivalent to "furnishing evidence" in its widest term and significance. Being a witness has been interpreted to mean imparting some sort of knowledge in testimony. From this it appears that there will be no constitutional restriction on the collection of samples for DNA analysis. Again In *Raman Lal Bhogi Lal Shah v. V.K. Guha*\(^85\), Supreme Court held that protection under Article 20(3) is only against the person being compelled to be a witness against himself. It doesn’t mean that he need not give information of matters which don’t tend to incriminate him. Further In *D.J Vaghela v. Kantibai Jethabai*\(^86\) and *Neeraj Verma v. State of UP*\(^87\) the High Court held that obtaining of blood, semen, saliva, urine etc; under Section 53 of Cr.P.C, is not violative of Article 20(3) of the Constitution which permits protection against self incrimination.

**DNA Profiling Indian Initiative**

In the wake of HGP various jurisdictions had come up with national DNA bank for the various reasons which include research and efficient criminal investigations. The conviction rate in India is about 10 per cent at present and it is expected that if a DNA data bank was created, the conviction rates could go up to 90 per cent.\(^88\) The government has already set up a DNA profiling advisory committee to advise on legislation.\(^89\) Keeping in mind the unfolding potential of DNA profiling in the country, The DNA Profiling Bill, drafted by the Department of Bio technology is under consideration by the parliament.\(^90\) The major objective of the act

\(^{85}\) AIR 1973 SC 116.  
\(^{86}\) 1985 Cr.L.J 974 (Guj).  
\(^{87}\) AIR 1994 SC 234.  
\(^{90}\) Draft DNA profiling Bill 2007
"To regulate the use of Deoxyribose Nucleic Acid (DNA) analysis of body substance profiles and making provision for establishment of DNA Profiling Board consisting of eminent scientists, administrators, law enforcement officers, etc. to lay down standards for laboratories, collection of body substances, custody trail from collection to reporting and establishment of a databank and to create policies for use and access to information from such data bank, appointment of a DNA Databank Manager to supervise, execute and maintain the databank, etc. and for matters connected therewith or incidental thereto.  

For this the Bill contains provisions relating to DNA profiling Board consisting of experts from the field of, molecular biology, human genetics population biology, bioethics, social sciences, law and criminal justice. The main functions of the board is advisory which consists of advising concerned Ministries and Departments of the Central Government and the State Governments on the size of DNA laboratory, their strategic location, creation of new DNA Laboratories and up gradation of existing DNA Laboratories; further they are supposed to advise planning organizing and managing DNA laboratories. Further it is empowered to make recommendations regarding progress in DNA profiling technologies and try to spread its dissemination uniformly. Special attention will be paid to the maximization of the use of DNA technologies in administration of justice. Further realizing the importance of international collaboration Bill seeks to establish procedure which will enhance cooperation of international agencies.

It obligates the government to establish a DNA data bank under various categories. At the same time the bill taking into account the possible

91 Id., at Introduction to the Bill lists the purpose of the Act
92 Id., at Section 13-17 deals with the compositions and functions of the DNA profiling Board.
93 Id., at Section 13 (1) (i).
94 Id., at section 13(XI).
95 Id, at. Section 13 (1) (v).
misuse of such data and human right concerns arising makes special provisions for confidentiality and privacy concerns. Special emphasis is given to tackle the ethical and human right concerns emanating from DNA profiling with special emphasis to privacy and civil liberties concerns.

Realizing clearly the potential for misuse of DNA technologies the bill makes elaborate provisions for DNA laboratories. The Bill envisages compulsory approval and continuous monitoring for DNA laboratories. As a corollary the Bill confirms the power on the DNA profiling board to with draw the earlier approval in case of misuse of or the failure of laboratories to confirm to the guidelines under the Bill. The bill for the efficient functioning of the act elaborately lays down standards, quality control, quality assurance and obligations on DNA laboratory.

Acknowledging the growing demands of establishing a National DNA databank the Bill contains provisions regarding the establishment of national and state DNA databanks. The data can be collected under the following categories like crime scene index, suspects index, offenders index, missing persons index, volunteers index, etc. Relishing the potential of functional creep the Bill contains a very significant safeguard the bill lays down that in case of offenders index once the order of acquittal has come the immediate expunge of DNA analysis of such

96 Id., at Section 13 (xx).
97 Id., at Section 14-18 deals with approval of laboratories.
98 Id., at Section 17 (i) ceases to undertake DNA procedure or any procedure related to it; or (ii) has failed to comply with any of the conditions subject to which the approval has been granted to it; or (iii) fails: (a) to comply with provisions of any law for the time being in force or any direction issued by the DNA Profiling Board under the provisions of this Act or direction issued by any other regulatory Authority to DNA laboratory.
99 Id., at Section 19-28 deals with standards and quality control
100 Id., at Section 33(1) (1) The Central Government shall, by a notification published in the Gazette of India, establish a National DNA Data Bank.
101 Id., at Section 33(4) Every DNA Data Bank shall maintain following indices for various categories of data, namely: (i) a crime-scene index; (ii) a suspects' index; (iii) an offenders' index; (iv) a missing persons' index; (v) unknown deceased persons' index; (vi) a volunteers' index; (vii) such other indices as may be specified by regulations.
The only possible chance of permanent retention of DNA samples seems to be that of the convict.\textsuperscript{102}

If you look at DNA profiling from a non criminal point of view a community based DNA profiling of the Kutchi Dassa Oswal (KDO) Jains, was undertaken by the top scientists of the country led by Lalji Singh,. Over the past 30 years, KDOs as they are known, have found their numbers dwindling. The experts will trace the reasons for such a drastic decline in population as well as map its susceptibility to certain diseases and disease prevention, especially cardio-vascular disorders.\textsuperscript{103} Further a proposal to profile the DNA of all entrants into the armed forces has been put up to the three service chiefs in a military drive to better understand the biological requirements and health histories of officers and soldiers. DNA profiling is a standard practice in the armed forces of the US and UK. On approval by the three chiefs and then the government, the Armed Forces Medical College (AFMS) plans to set up its first profiling centre at its College in Pune.\textsuperscript{104}

Besides these constitutional and legislative responses certain statutory provisions are important to our discussion

**Statutory Provisions**

**Labour Laws**

Labour Law provisions assume significance in relation to possible genetic discrimination in employment. But it is sad to note that our labour law provisions do not contain any explicit provisions relating to what are the

\textsuperscript{102} \textit{id.}, at Section 37 The Data Bank Manager shall, on receiving a certified copy of the order of the court that has become final establishing that the conviction of a person included in the DNA data bank has been set aside, expunge forthwith the DNA analysis of such person from the DNA index.

\textsuperscript{103} "Second phase of DNA profiling of Kutchi Jains", \textit{The Times of India} edn Ah\textsuperscript{m}hadabad, 23 April (2004).

\textsuperscript{104} "DNA profiling of armed forces entrants proposed", \textit{The Indian Express}, 2 January (2006).
possible non grounds of discrimination. Perhaps it is implicitly taken that whatever the ground mentioned under constitution is applicable here also. The same viewpoints can be raised in relation to the various service laws. The only provisions under labour law which talks of some grounds of disqualification is under section 67 of the Factories Act which provides that no child who has not completed the age of 14 year shall be allowed to work in factory. Further Equal Remuneration Act prohibits discrimination against women in terms of wages regarding equal work. It is worth mentioning that International Labour Organization (ILO) guidelines concerning discrimination in respect of employment and occupation prohibits discrimination in the workplace on the basis of genetic make up. India is a signatory to ILO convention and there is no reason that why we should not adopt those guidelines under our labour laws.

**Indian Patent Act**

Recent advances in science and technology have brought with them many questions. One of these, affecting the state of medicine, is the advent of gene patenting. This is going to be a very serious topic of discussion in any genome discourse. The legislative structure of patenting in India it is governed by the Patent Act 1970 and subsequent amendments. The Patent act is based on the concept on inventiveness.

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106 Id., at 710.
108 The Patent Act was enacted in 1970, but later it was amended in 1999 and 2005.
109 Id., at Section 2 clause (j) Clause (j) defines invention as follows: (j) "invention" means a new product or process involving an inventive step and capable of industrial application; further section S.2 (1) (ac) lays down the criteria for an invention to be patentable are, (1) an invention must be novel, (2) has an inventive step and, (3) is capable of industrial application. There are some products and processes, which are not patentable in India. They are classified into two categories in the patent Act, a) Those which are not inventions (S.3), b) Invention relating to atomic Energy (S.4). Various types
regretfully noted that the patent Act is conspicuous by its silence on genetic patenting even after its amendments which has taken place well after the developments in HGP has take place and we have witnessed countries like USA started issuing genetic patents.\textsuperscript{110} The only sections which can be of any help is section 3(b)\textsuperscript{111} and 3 (j), which identifies plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable.\textsuperscript{112} Even these sections do not provide a clear stand. Thus any issue of genetic patenting is presently left to judicial interpretation of whether it amounts to invention or not.

The most commonly heard arguments from those critical of the private sector's control over biotechnology is that no patents should be granted on DNA sequences because such stretches of DNA are 'natural', and

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of non-patentable inventions under Section 3 are as follows: 3(a) An invention which is frivolous or which claims anything obvious contrary to well established natural laws. Merely making in one piece, articles, previously made in two or more pieces is frivolous. Mere usefulness is not sufficient Perpetual motion machine alleged to be giving output without any input is not patentable as it is contrary to natural law. 3(b) An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment. 3(c) The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature; 3(d) The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; (f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way; (g) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture; (h) a method of agriculture or horticulture; (i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.
\end{quote}

\textsuperscript{110}US has started issuing Gene patents after the famous case of \textit{Diamond v.Chakrovarty}, 1980 447 US 303.
\textsuperscript{111}Supra note 108, at Section 3(b)
\textsuperscript{112}Id., at Section 3(j)
therefore cannot qualify as inventions which is what the patent system was set up to protect. On ethical grounds, an equally strong argument is made that if the human genome - and all its contents - belongs to anyone, it should be commonly owned by all mankind. Staking claims to the sequences that make up individual genes, even if previously unknown is portrayed as the ultimate form of "bio piracy". A ban on patenting genome sequences would be both impractical and unrealistic and tighter rules are needed on the conditions under which such patents are granted.

**Legislative Response and Reproductive Issues**

The role of human geneticists in past has been controversial. The ugliest face of this co-operation was the massacre of millions under the Nazi eugenics movement. In light of the attempts made by some human geneticists to underplay the role of environmental factors in gene expression, exaggeration of the ultimate potentialities of the Human Genome Project upon decoding 100,000 odd genes and the projected power of the genetic engineering in breaking the species barriers, the expert has also the potential to act as the devil. The main disturbing aspect of DNA technologies is the positive eugenics as we, the human beings, does appear to have an urge to improve our own race, by genetic manipulations.\(^{113}\) It may be quite possible to use the information to enhance non-disease characteristics.\(^{114}\) These issues will require a look at present statutory response touching upon the issue of abortion, prenatal diagnostic techniques etc

The issue of abortion will get complicated with the knowledge gathered from HGP gain prominence. How effectively can the world deal with these new technologies and issues are to be seen. The present legislation dealing with these issues are scattered under various statutes like Indian


Legal Provision Against Prenatal Sex Determinations

The traditional Indian society regards the male child as the preferred progeny. Recent years have witnessed mushrooming of amniocentesis and ultrasound facilities in the private sector in cities and towns for antenatal sex determination. These facilities have a large clientele belonging to the middle classes who resort to termination of pregnancy if a female foetus is diagnosed. The problem has reached scandalous proportion in several parts of the country. The state governments are finally waking up to face the situation in response to demands by women’s groups.¹¹⁵

The unethical exploitation of prenatal sex determination techniques and subsequent abortion of female foetus has generated a good deal of discussion on account of its, more or less, social acceptability not only in India but also in many other countries - especially the developing ones.¹¹⁶

India officially banned prenatal sex-determination, when the Parliament passed on 26 July 1994, the Pre conception and Prenatal Diagnostic Act.¹¹⁷ This Act was explicit in regulating the establishment and functioning of Genetic Counselling Centres, Genetic Laboratories, and

¹¹⁷ The Pre Conception and Pre-natal Diagnostic Techniques(Regulation and Prevention of Misuse) Act,1994, was enacted and brought into operation from 1st January, 1996, in order to check female foeticide. Rules have also been framed under the Act. The Act prohibits determination and disclosure of the sex of foetus. It also prohibits any advertisements relating to pre-natal determination of sex and prescribes punishment for its contravention. The person who contravenes the provisions of this Act is punishable with imprisonment and fine.
Genetic Clinics. The law specifies that prenatal diagnostic techniques can be conducted only in case of

- chromosomal abnormalities;
- genetic metabolic diseases;
- haemoglobinopathies;
- Any other abnormalities or diseases as may be specified by the Central Supervisory Board of the Government. 118

The defaulters are liable to prosecution and punishment with imprisonment up to 3 years and a fine up to Rs. 10,000.119 But the conviction rate under the act is less. The tests continue as before, due to the society's acceptability to this bioethical law is still not there, because complex interaction of social, cultural, economic and religious factors favours males. Moreover, this bioethical law has been enacted too late.120

**Medical Termination of Pregnancy Act**

This Act came into existence in 1971. This law guarantees the right of women in India to terminate an unintended pregnancy by a registered medical practitioner in a hospital established or maintained by the

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118 Id., at Section 4Clause 2 Pre conception and Prenatal Diagnostic Techniques Regulation and Prevention of Misuse) Act, 1994
119 Id.at section 23 provides Offences and penalties.- (1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or is employed in such a Centre, Laboratory or Clinic and renders his professional or technical services to or at such a Centre, Laboratory or Clinic, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

(2) The name of the registered medical practitioner who has been convicted by the court under sub-section (1), shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offences.

Government or a place being approved for the purpose of this Act by the Government. Not all pregnancies could be terminated.\textsuperscript{121}

Medical termination of pregnancy is permitted under the law provided "the continuance of the pregnancy would involve a risk to the life of the pregnant woman or a grave injury to her physical or mental health"; or "there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped."\textsuperscript{122}

The Medical Termination of Pregnancy Act explains that pregnancy caused by rape, or failure of contraception by a married couple, would fall within the purview of the first indication as the anguish caused by these situations is presumed to constitute "grave injury to the mental health of the pregnant woman."\textsuperscript{123}

Medical termination of pregnancy can be performed up to 20 weeks of gestation. For gestation up to 12 weeks, any medical practitioner can make the decision. When the length of gestation is over 12 weeks, two or more medical practitioners are required to form an opinion regarding the indications for termination of pregnancy.\textsuperscript{124} The case of Niketa and Harish Mehta who had petitioned to the High Court of Mumbai for the abortion of their 24 week old foetus highlights the loophole of the Medical Permanency Act. Their basis for the plea was that their unborn child

\textsuperscript{121} The act was passed to provide for the termination of certain pregnancies by registered Medical Practitioners and for matters connected therewith or incidental thereto.

\textsuperscript{122} S. Gour, Lyon's Medical Jurisprudence for India at 100, (1988).

\textsuperscript{123} The Medical Termination of Pregnancy Act, 1971, Section 3 Explanation 1.

\textsuperscript{124} Id., at Section 3 of the Act lays down, Notwithstanding anything contained in the Indian Penal Code (45 of 1860), a registered medical practitioner shall not be guilty of any offence under that Code or under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act.

(2) Subject to the provisions of sub-section (4), a pregnancy may be terminated by a registered medical practitioner, - (a) Where the length of the pregnancy does not exceed twelve weeks if such medical practitioner is, or (b) Where the length of the pregnancy exceeds twelve weeks but does not exceed twenty weeks, if not less than two registered medical practitioner are, of opinion, formed in good faith, that - the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health; or (ii) there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities to be seriously handicapped.
suffers from a congenital heart blockage and misplacement of arteries. Court dismissed the petition and observed that medical experts did not express any "categorical opinion that if the child is born it would suffer from serious handicaps. The court further held that a foetus is a living being. The problem is that the Indian abortion law says that a foetus cannot be aborted after 20 weeks of pregnancy. Perhaps this position was correct at the time of drafting of the legislation but now scientific advancements make it possible to detect certain congenital defects well after 20th weeks and this will get a boost with the information flowing out of HGP. Further this case has brought out various uncomfortable questions like the legal status of foetus, whether parental decisions are absolute, whether we need to follow the position of USA declaring the right to abortion as a fundamental right and when does the life begins etc.

Regarding the question of whether the foetus is a legal person the Mumbai High Court single bench announced in 2008 that "When the statute refers to a person, the reference is to a human being, which exists in the world. It is true that a foetus may have a life or may have signs of life. However, a foetus becomes a human being or a person only after he or she is born therefore, the 'death' of a foetus in the womb cannot be termed as a death of a person."

The misuse of both the act is expected to increase in the wake of knowledge form HGP. The majority of misuse will arise out of the desire of parents to have a perfect super baby meaning any foetus that does not fit into the definition of perfection will be denied a chance to be born perhaps in many cases based on its potential to develop certain infirmities. Against these misuse the Code of Medical Ethics developed by The Medical

Council of India (MCI) does not seem to deter the defaulters. It is the statutory body empowered to grant licenses to physicians to practice medicine and to prescribe standards of conduct and ethics for the medical profession. It also has the power to take action against a physician who is guilty of professional misconduct. The Code of Ethics of the MCI incorporates a declaration to be signed by the applicant physician that includes the following statements: "I will maintain the utmost respect for human life from the time of conception"; "Even under threat, I will not use my medical knowledge contrary to laws of humanity"; "I will practice my profession with concentration and dignity"; and "I will maintain by all means in my power, the honour and noble tradition of medical profession." It appears that these regulations are not satisfactory to control or prevent the issues arising in the wake of HGP.

Institutional Framework and Initiatives

Department of Biotechnology

The Department of Biotechnology (DBT) was set up under the Ministry of Science and Technology in 1986 to give a new impetus to the biological development in India. The department through various committees, deliberations projects promoted and accelerated the pace of development of biotechnology in the country. Regarding the human Genome research and the issues arising out of it the National Bioethics

126 In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956 (102 of 1956), the Medical Council of India, with the previous approval of the Central Government, made the following regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners, which is in short known as Code of Ethics.

127 The Medical Council of India was established in 1934 under the Indian Medical Council Act, 1933, now repealed, with the main function of establishing uniform standards of higher qualifications in medicine and recognition of medical qualifications in India and abroad. The number of medical colleges had increased steadily during the years after Independence. It was felt that the provisions of Indian Medical Council Act were not adequate to meet with the challenges posed by the very fast development and the progress of medical education in the country. As a result, in 1956, the old Act was repealed and a new one was enacted. This was further modified in 1964, 1993 and 2001.

128 Medical Council of India, Code of Medical Ethics, 1970.
Committee was constituted with the approval of the Minister of Science & Technology, Government of India, in November 1999. The committee has scientific and legal experts covering the areas of basic research, genetics, genomics, education and legal aspects. This Committee was mandated to deliberate on various issues concerning ethical aspects of the human genome. The efforts and deliberations of the committee resulted in framing Ethical Guidelines for Biomedical Research on Human Subjects.

Ethical Guidelines for Biomedical Research on Human Subjects. An Overview

National Bio ethics committee of Department of Bio-technology came up with certain policy recommendations on the lines of Universal Declaration of Human Genome and Human Rights. These policies are in consonance with the Ethical Guidelines for Biomedical Research on Human Subjects developed by the Indian Council of Medical Research in 2000. The major objects of the policy recommendations are clear from the introduction of the document which reads “The purpose of this document is to outline the national ethical policies for the human genome, genetic research and services. It is intended that this document will provide guidance for researchers, service providers, ethics committees, institutions, organizations and the public on how such research and services should be designed and conducted so as to conform to recognized ethical principles and values.”

Throughout the policy document the ethical standard a researcher has to follow has been given lot of significance. The major ethical principles underlined by the document includes

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130 Ibid.
131 Ibid. purpose
Autonomy: Choice of participation is autonomous, voluntary and based on informed consent; persons or groups with diminished autonomy should be given protection.

Privacy: Identifiable information (clinical, genetic, etc.) of individuals or groups is confidential and should be protected.

Justice: There should be no discrimination against individuals (born or unborn including embryo) or groups. No harm should be done and benefits should be maximized.

Equity: There should be equitable access to information, tests and procedures.\(^\text{132}\)

Like the Universal Declaration and other declarations relating to medical research this document has recognized and acknowledged the importance of informed consent in the context of research settings. The document elaborately lays down the essential elements of what constitute a valid informed consent. The document requires the consent to be voluntary and put forth a duty on the researcher to explain the benefits and risk associated with the research in the best possible manner understood by the participant. For this the document recognizes the significance of genetic counselling.\(^\text{133}\) The document makes the requirement of consent mandatory by providing that in case of persons incapable of consenting the consent of legal and close relatives needs to be taken.

Further in case of research involving a group the group consent is mandatory. Thus it is very clear that under no circumstance a research

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\(^{132}\text{Ibid.}\)

\(^{133}\text{Ibid., the document provides Individuals, laboratories or institutions providing genetic testing services should be licensed or registered by the appropriate Governmental authority. Such service providers should operate in accordance with nationally accepted standards for scientific accuracy, confidentiality of information and bioethics. No disclosure of results of genetic testing should be made to the patient in the absence of genetic counselling.}\)
can proceed without obtaining the consent of participant or research subject. The only exception seems to be for research based on information in databases or samples in repositories, which provide that consent of the participants, are not required if the samples are unidentified. In order to avoid future legal and incidental problems which may arise the document requires the consent to be documented. As a corollary to the consent issue the document recognizes the participant’s right not to be informed of the results of research.

A positive element of the document relates to the compensation principle. The document provides each participant in a research the right to demand compensation from the investigator for any injury or harm arising from his/her participation. For this document envisages necessary legal liability agreements entered into between the researcher and the participating individual. Apart from emphasizing the ethical requirement for research the document has paid certain attention to the possible ethical and legal issues arising out of the human genome research. The document comes out heavily against all sorts of discrimination based on genetic characteristics. The document for this envisages the effective and proactive role of media and education to wipe out the notions of racial prejudice.

134 Ibid., The document lays down before recruitment of any individual/group in human genome and genetic research, consent of the participants must be obtained. The ethical and legal requirements of consent have two aspects: the provision of information and the capacity to make a voluntary choice. So as to conform with ethical and legal requirements, obtaining consent should involve (a) provision to participants, at their level of comprehension and in a language or method understandable to them, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research; and (b) the exercise of a voluntary choice to participate. Where a participant lacks competence to consent, a person with lawful authority to decide for that participant must be provided with that information and exercise that choice is, therefore, recommended that:

(i) A researcher must explain the purpose of the research, the foreseeable risks and benefits of participation and alternative procedures, if any. (ii) Consent obtained from each participant, and the participating group (where applicable), must be documented.

135 Ibid., Immediate and effective measures, particularly in the fields of teaching, education, culture and information, shall be implemented with a view to removing prejudices based on genetic characteristics and variability.
The intellectual property issue which occupies a very prominent place in any human genome discourse has also been touched upon by the document which comes out against patenting of human body material in its natural state. But the positive aspect of the declaration lies in acknowledging the contribution of research subjects. The document envisages benefit sharing basis and advocates that national and international agencies to contribute a certain percentage of their share to the benefit of the community out of which the genetic material has been derived. This it is submitted is a positive and laudable step as it is not only in consonance with the principles of natural justice but also in conformity with the principle of body parts as one's own property. Further the requirement of benefit sharing satisfies the legal standard or stand against unjust enrichment.136 Realizing and acknowledging fully well that human genome research is an international effort the document encourages collaboration and dissemination of knowledge.137 Corollary to this the document pays special attention to the dissemination of knowledge resulting from the research.138 This is based on the conviction that benefits arising out of research are to be available for the benefit of humanity. Another positive aspect of the document is evident from the fact that it is not a mere declaration of certain principles the document envisages an implementing mechanism.139 The document thrust the responsibility on

136 Ibid., the document also lays down it will be obligatory for national/international profit making entities to dedicate a percentage (e.g., 1% - 3%) of their annual net profit arising out of the knowledge derived by use of the human genetic material, for the benefits of the community. Protection of Intellectual Property Rights (IPR) must be ensured and adequate safeguards taken for sharing of benefits arising from clinical trials based on pharmacogenomic studies in a given population.

137 Ibid., the document contains provision for encourage human genetic research, to promote international dissemination of scientific knowledge concerning the human genome and to foster scientific and cultural cooperation, collaborative research with other countries may be undertaken, with appropriate protection of intellectual property rights.

138 Ibid., the document provides that Researchers should be encouraged to disclose their findings, after these have been scientifically validated. (whether publicly or privately funded) and the methods used should normally be published, with appropriate IPR protection.

139 Ibid., National or an Institutional Ethical Review Committee must clear all genomic/ stem cell research involving humans to be undertaken in India. The Ethical Review Committee will ensure that national ethical policies and recommendations are followed.
Ethical Review Committee which will ensure that national ethical policies and recommendations are followed.

**Indian Council of Medical Research**

The Indian Council of Medical Research (ICMR), is the apex body in India for the formulation, coordination and promotion of biomedical research, it is one of the oldest medical research bodies in the world.\(^{140}\) The Council's research priorities include control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery. All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. The Council promotes biomedical research in the country through intramural as well as extramural research.\(^{141}\) In relation to research in the area of biotechnology research the council has played a major role. Realizing the ethical challenges faced by the researchers and medical professional’s council came out with ethical guidelines for biomedical research on Human subjects.\(^{142}\) It is to be mentioned that this guideline is in consonance with the Universal Declaration of Human Genome and Human Rights and the only existing ethical guidelines on the area.\(^{143}\)

**Ethical Guidelines for Biomedical Research on Human Subjects: An Overview**

The guidelines have been framed taking into account the atrocities committed on human subjects in the name of research and the

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140<http://www.icmr.nic.in/abouticmr.htm> (last visited on 4-2-2008).
141 Ibid.
subsequent international developments to develop certain principles to overcome any such future incidents.\(^{144}\)

Throughout the guidelines the ethical standard a researcher has to follow has been given lot of significance. The major ethical principles for any type of research undertaken on human beings includes Principles of essentiality, voluntariness, informed consent and community agreement, non-exploitation, privacy and confidentiality, accountability and transparency etc. These principles form the core of any research involving human subjects. The principles of essentiality seem to suggest that research on humans should be undertaken only when their participation is essential for the result. Principles of voluntariness emphasis on voluntary participation of the subject. The voluntariness to be gathered from the informed consent given by the subject regarding research. This principles runs through the entire texture of guidelines. The concept of non-exploitation implies that even if the participation of the subjects was voluntary they need to be remunerated. Principles of privacy lay down that as far as possible the identity of the participants to be kept confidential and should not be disclosed without having some scientific purposes. Principles of accountability stresses upon the need to conduct research.

Further the guidelines make it mandatory that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC). The guidelines also emphasize that the IECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC. The Ethics Committees should be entrusted not only

\(^{144}\) International response is seen in Nuremberg Code, which is a set of research ethics principles for human experimentation set as a result of the Subsequent Nuremberg Trials at the end of the Second World War. Helsinki Declaration 1964 Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, and the 35th World Medical Assembly, Venice, Italy, October 1983and ‘International Ethical Guidelines for Biomedical Research involving Human Subjects’ by Council for International Organizations of Medical Sciences (CIMOS)in 1993.
with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved programmes to foresee the compliance of the ethics during the period of the project.

Special care has been provided regarding special categories of subjects. It is provided that children will not be involved in research that could be carried out equally well with adults. The same principle is followed in the case of dependants. The guidelines suggest that pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.\textsuperscript{145}

As noted the principle of informed consent runs along the guidelines it obligates the investigator to obtain the informed consent of the prospective subject. If an individual is not capable of giving informed consent, the consent of legal guardian must be obtained. In case of children, the consent should be obtained from child’s parent or legal guardian. Some children, who have not reached the legally established age of consent, but are able to understand the nature of investigation, can give their agreement to serve as research subjects. This agreement is known as ‘Assent’. In older children, the consent should be supplemented by assent. The consent can be waived only in exceptional cases.

Further the investigator is obliged to safeguard the confidentiality of research data, which might lead to the identification of the individual participants. Data of individual participants can be disclosed only under certain circumstances like

\begin{itemize}
  \item only in a court of law under the orders of the presiding judge or
\end{itemize}

\textsuperscript{145} Supra note 142 See Guidelines.
there is threat to a person’s life or
in cases of severe adverse reaction may be required to communicate to drug registration authority or
If there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority.\textsuperscript{146}

Further as a corollary to the principle of non exploitation the guidelines lays down that research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, their dependents are entitled to material compensation. In addition the guidelines states that at the end of the trial every participant should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified or available by the study. Realizing the need for interdependency, the guidelines' emphasis on international collaboration and cooperation.

Realizing the special nature of human genome research the declarations comes up with certain additional safeguards for research subjects in genomics Guidelines states that clinical research in the area of human genetics and human genome, including gene therapy, is subject to general ethical considerations of protection from harm and voluntariness of participation. It concerns not only the individual but also the family, community or society from which s/he has been drawn. Therefore, the additional considerations are identified. One of the additional safeguard relates to importance attached to genetic counselling. The reason seems to be since the harm is not only be physical, but also psychosocial which may produce anxiety and depression or damage familial relationship.\textsuperscript{147}

\begin{footnotes}
\item[146] Ibid.  
\item[147] Ibid.
\end{footnotes}
Since genetic studies may reveal information about the likelihood of individual members of the family being either carriers of genetic defects or being affected by the disease. Special privacy and confidentiality concerns arise in genetic family studies. The guidelines provide within families each person is an individual who has the right to keep the information about him or herself confidential, meaning family members are not entitled to know each other’s diagnosis. 148

**Drawbacks of the Existing Mechanisms**

In the year 2000, The Indian Council of Medical Research (ICMR) laid down comprehensive ethical guidelines within which biomedical research should function. The council, however, lacks statutory power to ensure that they are being implemented. There are several instances where ethical norms in research in India have been clearly flouted. For example, in the year 1994, investigators had told 10 patients most sex workers infected with HIV in Mumbai that they were being administered a miracle vaccine.149

**Concluding Remarks.**

In a country like India where the even the sex of the foetus can be misused., where organs are sold for a price to where the pressure to survive among the poor can predominate over all ethical values of concern to the western nation, The problem has to be handled at a totally different level and dimension. 150

In the absence of change in the attitude of the people, it is impossible to thrust upon the people any bioethical concept. Mere enactment of the laws

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148 Ibid.
does not change deep rooted customs or social norms prevalent in the society - especially the one having a large number of illiterate and poor people. The enactment of these laws merely leads to more corruption and more malpractice. The need remains in educating people with respect to the ills of a particular custom. The approach has to be a committed one, multi-directional and consistent for a period of time to bring in any appreciable changes in the cultural concepts of a population and this is not something which is impossible to achieve. Till such awareness percolates into the minds of the concerned people, it is our duty as the privileged ones, to safeguard the interests of the unsuspecting humanity from exploitation by their educated and informed brethren whether they are doctors, human geneticists or the politicians. The first step in this direction is the enactment of laws with stringent deterrents based on the currently acceptable international bioethical principles across the cross-cultural boundaries. Every new technology has to pay a price and there is need for regulatory laws governing gene technology, human embryo manipulation, DNA testing and evidentiary value, genetic privacy and discrimination in the country\textsuperscript{151}

\textsuperscript{151} Id. at 115.