CHAPTER – VII

RIGHT TO HEALTH AND RECENT SCIENTIFIC DEVELOPMENTS

The human body is a wonderful machine. Attempts have been made since time immemorial to understand the functioning of this machine. Science holds enormous potential for new cures and treatments for a host of diseases, including diabetes, parkinson’s disease, and spinal cord injuries.1 Curious human brain has led to numerous discoveries. Development of assisted reproductive technologies, reproductive and therapeutic cloning break-through in organ transplantations etc. has resulted and provided, on the one hand, a ray of hope for numerous health related problems, on the other hand, also sparked a politically volatile, ethically, socially and legally controversial debate. The object of this chapter is to examine the effect of such recent scientific developments in the field of health.

(A) In Vitro Fertilisation And Surrogacy: Ethical And Legal Perspective

In-vitro fertilization technique for conception of a human embryo outside the mother’s body is a recent scientific development. Generally, the life of sexual organism starts from a single cell; the fertilized egg cell or zygote. By cell division and growth this single cell finally gives rise to the mature organism, which contain different cell types, tissues and organs.2

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"In vitro" literally means "in glass". In vitro fertilization is a technique whereby human life is generated in a laboratory environment glass Petri dish, wherein the mixing of eggs with sperms is done in order to achieve conception.\(^3\) This process begins when sperms and eggs are removed from the respective male and female bodies, then are combined in the laboratory, so to be implanted in the lining of the womb for development.\(^4\) This method of treating infertility is commonly referred to as a test tube baby. University of Wisconsin researchers derived stem cells from 1-week old embryos, also called blastocysts, produced via in-vitro fertilization (IVF) for the treatment of infertility.

The future of child birth in the form of test tube babies, surrogate motherhood through new reproductive and cloning technology will introduce undreamt of possibilities in the sexual arena. Because any reproductive technique that replace the conjugal act under the meaning of conjugal union is violation of the dignity of procreation when human procreation is disconnected from sexual relation the spouses can quickly become objects for sex. It becomes difficult to recognize dignity in each other, especially the pre born child.\(^5\) Though science and technology have made enormous contributions to the society. But the fact is that it is not ethically right rather it is controversial.

Surrogacy is a method of assisted reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child for others to raise. She may be the child’s genetic mother (the more traditional form of surrogacy), or

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\(^4\) Ibid.

\(^5\) Ibid.
she may be implanted with an unrelated embryo. In some cases surrogacy is the only available option for parents who wish to have a child that is biologically related to them. The child may be conceived via home artificial insemination using fresh or frozen sperm or impregnated via IUI (intra-uterine insemination) or ICI (Intracervical insemination) which is performed at a fertility clinic.

Surrogacy can be gestational wherein the surrogate becomes pregnant via embryo transfer with a child of which she is not the biological mother. The child was conceived using egg donation, sperm donation or is the result of a donated embryo. Whereas altruistic surrogacy is a situation where the surrogate receives no financial reward for her pregnancy or the relinquishment of the child (although usually all expenses related to the pregnancy and birth are paid by the intended parents such as medical expenses, maternity clothing, and other related expenses).

Attorney Noel Keane is generally recognized as the creator of the legal idea of surrogate motherhood. However, it was not until he developed an association with physician Warren J. Ringold in the city of Dearborn, Michigan that the idea became feasible. Dr. Ringold agreed to perform all of the artificial

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6 Having another woman bear a child for a couple to raise, usually with the male half of the couple as the genetic father, is referred to in antiquity. For example, the book of Genesis relates the story of Sarah’s servant Hagar bearing a child to Abraham for Sarah and Abraham to raise. Babylonian law and custom allowed this practice to avoid divorce which would likely otherwise be inevitable. http://en.wikipedia.org/wiki/surrogate-mother#history (accessed on August 20, 2009).

7 In traditional surrogacy the surrogate is pregnant with her own biological child, but this child was conceived with the intention of relinquishing the child to be raised by others; by the biological father and possibly his spouse or partner, either male or female. http://en.wikipedia.org/wiki/surrogate_mother (accessed on June 11, 2008).

8 Ibid. The word ‘surrogate’, is rooted in Latin ‘Subrogare’ (to substitute), which means “appointed to act in the place of. The intended parents is the individual or couple who intends to rear the child after its birth.

9 Ibid.

10 Ibid.
inseminations, and the clinic grew rapidly in the early part of 1981. Though Keane and Ringold were widely criticized by some members of the press and politicians, they continued and eventually advocated for the passage of laws that protected the idea of surrogate motherhood.11

There can be several reasons behind surrogate pregnancy. For instance, intended parents may arrange a surrogate pregnancy because a woman who intends to parent is fertile in such a way that she cannot carry a pregnancy to term. Examples include a woman who has had a hysterectomy, has a uterine malformation, has had recurrent pregnancy loss or has a health condition that makes it dangerous for her to be pregnant. A female intending parent may also be fertile and healthy, but unwilling to undergo pregnancy. Alternatively, the intended parent may be a single male or a male homosexual couple. Surrogates may be relatives, friends, or previous strangers. Many surrogates arrangements are made through agencies that help match up intended parents with women who want to be surrogates for a fee. The agencies often help to manage the complex medical and legal aspects involved in this process.12

There is a default legal assumption in most countries that the woman giving birth to a child is that child’s legal mother. In some jurisdictions the possibility of surrogacy has been allowed and the intended parents may be recognized as the legal parents from birth. Many states in America now issue pre-birth orders through courts placing the names of the intended parents on the

11 It has gained some societal acceptance and laws protecting the contractual arrangements exist in eight states in the United States such as Arkansas, California, Arizona, Florida, IDAHO, ILLINOIS, Massachusetts, Nebraska, New Jersey, New Mexico, North Carolina, Texas.http://en.wikipedia.org/wiki/surrogacy#united-states (accessed on September 9,2009)

12 Ibid.
birth certificate from the start. In others, the possibility of surrogacy is either not recognized (all contracts specifying different legal parents are void), or is prohibited.\textsuperscript{13}

Whereas, compensated surrogacy arrangements are illegal in Washington, New Mexico and New York, fertility treatment in Texas and Arkansas is at a fraction of the cost of California.\textsuperscript{14} Commercial surrogacy arrangements are illegal in the United Kingdom. To pay more than expenses for surrogacy is also illegal in the UK, the relationship can be recognized under S.30 of the \textbf{Human Fertilization and Embryology Act, 1990} (HFE Act 1990) under which a court may make parental orders similar to adoption orders.

The concept of surrogacy in India is not new. This phenomenon has been around for over three decades. In 1978, a girl named Kanupriya was born through IVF technology in Kolkata.\textsuperscript{15} Since then, the globalization of reproduction has created ways to connect people in ways never envisioned before, and has redefined the human limitations of pregnancy and child birth.

Commercial surrogacy, or “Womb for rent”, is a growing business in India. In our rapidly globalizing world, the growth of reproductive tourism is a fairly recent phenomenon. Increasing numbers of infertile couples from the U.S. Britain, Taiwan and

\textsuperscript{13} Surrogacy laws vary widely from state to state. Some states require genetic parents to go to court before birth to obtain a “pre-birth order to have their names on the original birth certificate, or to adopt the child. Judges in Massachusetts have granted pre-birth orders. Boston, California, Kentucky are among the states with the most advanced laws. Couples can establish parenthood any time after the start of pregnancy with a court petition. A judgement is usually issued within 24 hrs. http://www.melissabrisman.com/news/courtstruggling.asp. (accessed on July 2, 2009).

\textsuperscript{14} Large number of the surrogate mothers in the USA are military spouses. http://en.wikipedia.org/wiki/surrogate_mother (accessed on June 11, 2008).

\textsuperscript{15} http://www.stanford.edu/group/womenscourage/surrogacy/index.html (accessed on June 11, 2008.)
other countries are looking for surrogate mothers in India, where an English speaking environment and cheaper services are attractive incentives for those exploring surrogacy as a fertility option. In one of the interview, one woman surrogate said,

“I have done this for my kids and because I have one dream as a house we are living in, is a rented place. From the money, I earn as a surrogate mother, I can buy a house it is not possible for my husband to earn more as he is not educated and only earns $50 a month, so nothing is saved”.16

From outsourcing call centers to outsourcing pregnancy, the idea of a couple impregnating a woman located halfway across the world is nothing short of fantastical. Future projections of this practice range from opportunity to exploitation – from rural women in India uplifted out of poverty to a futuristic nightmare of developing country baby farm17. In the case of surrogacy in India, it is hard to tell that whether these women are exercising their own personal rights, or whether they are forced to become surrogate mothers due to their mother-in-law’s or husband’s desire to fulfill material and financial needs. Some argue that being a surrogate mother is a choice that enhances a women’s rights, the right to enter surrogacy arrangements is a natural extension of the right to personal autonomy.18

Opponents of surrogacy argue that the practice is equivalent to prostitution, and by virtue of that similarity, it should be disallowed on moral grounds. Contract pregnancy transforms what is “specifically women’s labor into a commodity,” an exchange of monetary compensation for the use of women’s

16 Ibid. In places like the Akanksha infertility clinic in Anand, women are paid $5000 to $7000 to carry another couple’s child.
17 Ibid.
bodies. Surrogacy contracts are "dehumanizing and alienating since they deny the legitimacy of the surrogates perspective on her pregnancy." Surrogate mother tries to avoid developing a special bond with the child in her, and views the pregnancy as merely a way to earn the much-needed money.

In other words, surrogacy demeans the unique mother child bond as women can now solely be used as "breeder machines". Although gender equality seems to improve for women of higher status that are able to afford surrogate mothers, the fear is that surrogacy will exploit the poor. It is unclear that poorer women will voluntarily lease their bodies for reproductive ends. The payment for bodily services dehumanizes the surrogate mother and exploits her reproductive organs and capability for personal gains of the wealthy.

In fact, outsourcing surrogacy is an exploitative practice in India that degrades women and takes advantage of their poverty and lack of opportunities for personal gains. Currently, no law exist to protect the surrogate mother in case of birth complication forced abortion etc. Since the poor and illiterate women can earn many times more than middle class by surrogacy, it has perpetuated surrogacy as a more lucrative occupation. The hands off approach of the Indian Government, is not only creating a black market of fertility services and mushroom growth of fertility clinics and sperm banks, but also endangering the safety of surrogate mothers.

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19 Ibid.
20 Ibid.
Since 2002, commercial surrogacy has almost become legal in India, rather India has become a sort of leader, in making it as a viable industry rather than a rare fertility treatment. This is the reason that has led critics to allege that surrogacy business is exploiting poor women in country like India already having with an alarmingly high maternal death rate. 23

One main factor for flourishing of medical tourism in relation to surrogacy in India is the low cost of the entire process. At nearly one-fifth the price of what a surrogate would charge in the home country in the west, the bargain is a clincher here. According to estimates which might be conservative – the business of surrogacy in India is already touching $445-million a year. 24

Surrogate motherhood as an arrangement, in which a woman carries and bears a child for another person or persons, but takes no ownership of the child born has raised moral, ethical social and legal questions about both the woman and the ‘Commissioned baby’. 25

According to Preeti Katyar, a woman lawyer,

“... if surrogacy becomes an avenue by which women in richer countries choose poorer women in our country to bear their babies, then it is economic exploitation, a kind of biological colonization”. 26

25 The ethical debate on surrogacy has often looked to religious roots and cultural background. In Jewish law, a childless couple falls within the category of personal suffering and there exists a clear obligation to assist them in every permissible way, as long as no one is harmed in the process. The catholic church is not accepting the assisted reproduction. “Surrogate mothers: out sourcing pregnancy in India,” http://India-Merinews.com/catfull.jsp?articleID=136421 (accessed on July 3, 2008).
The Ministry of Women and Child Development is examining the issue of surrogate motherhood in India for bringing up a comprehensive legislation. Former Union Minister for Women and Child Development, Renuka Chowdhury said: "... we do not want surrogacy to become unfettered like organ trade." A draft legislation on surrogacy – prepared by the Indian Council of Medical Research (ICMR) has recommended strict penalties for offenders and a tight regulation on ART (Assisted Reproductive Techniques). The draft law restricts the number of embryo transfers a mother can go through to three times for the same couple, if the first two attempts fail. It also adds that no woman should act as a surrogate for more than three live births in her life.

Section 3.10.6 of the ICMR guidelines, states, “A relative, a known person as well as a person unknown to the couple may act as a surrogate mother for couple. In case of a relative acting as a surrogate, the relative should belong to the same generation as the woman desiring the surrogate”. This experts believe, is ludicrous as it propels childless couples needlessly towards commercial surrogacy. In fact, invitro fertilization (IVF) experts says that in 90% of the surrogacy cases in India, the mother is related to the children’s couple while only in five percent cases, the surrogacy is altruistic, and in the remaining five percent commercial. Section 3.10.5 of the guidelines states that “a surrogate should be younger than 45 years” without mentioning the minimum age. So does that mean an 18 year old or someone

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28 In fact these are the only guidelines framed by the ICMR and the Ministry of Health and Family Welfare in 2005.
even younger, can become surrogate mother? These guidelines are skewed and thoughtless.

Undoubtedly, assisted reproductive technologies (ART) such as artificial insemination, invitro fertilization, surrogate motherhood have proven to be a blessing for many infertile couples. But along with potential benefits, these have posed various complex legal, ethical problems relating to family law and basic human rights which includes such as right to dignity, right to privacy, right to know, procreative liberty, right to individual autonomy, commercialization of human bodies etc. In the context of donor anonymity, it has been expressed that it is wrong since as the child has right to know the identity of gamete donor. The bifurcated role of woman in surrogate arrangements is prompting renewed assessment of the meaning of motherhood and designation of maternal rights.31

As courts have struggled to define the parameter of procreative choice, the right to procreation has received its most extensive legal expression as a right not to procreate. Included in the right to procreate is the right to conceive. In the abortion case, the mother’s conception is only biological in origin. In the surrogate mother’s case, the initiating mother’s conception is only mental. Different kinds of protection are required for conceivers to realize different kinds of procreative intent. Courts in abortion cases must balance the rights of a mother and a child, whereas courts in surrogate cases must balance the rights of two mothers

30 Section 3.10.5 of the guidelines reads as: “A Surrogate mother should not be over 45 years of age. Before accepting a woman as a possible surrogate for a particular couple’s child, the ART Clinic must ensure (and put on record) that the woman satisfies all the testable criteria to go through a successful full term pregnancy.” (http://blog.indiansurrogacylaw.com/few-basics-from-the-icmrguidelines/ (accessed on July 6, 2009).

and a child. However, in both cases, the fundamental right of conception as a predicate of the right to procreate is at stake. Because even infertile mothers can exert their right of psychological conception, they too have a procreative right that courts should preserve.\(^{32}\)

It is submitted that the government must seriously consider enacting a law to regulate surrogacy and related IVF/ART technologies in India in order to protect and guide couples going in for such an option. Without a foolproof legal framework, patients will invariably be misled and the surrogates exploited.

(B) Reproductive and Therapeutic Cloning Technologies

The term cloning is an ambiguous one, as it can refer to various processes. Clone means one or a group of genetically identical cells, organism or plants derived by vegetative reproduction from a single parent; also, a DNA population, derived from a single hybrid DNA molecule by replication in a eukaryotic or bacterial host cell. As is well known, many plants can clone themselves, and have presumably been doing so since life began.\(^{33}\)

Human cloning is the creation of a genetically identical copy of a human being, human cell, or human tissue. The term is generally used to refer to artificial human cloning, although

\(^{32}\) In the United States, the issue of surrogacy was widely publicized in the case of Baby M, in which the surrogate and biological mother of Melissa Stern ("Baby M") born in 1986, refused to cede custody of Melissa to the couple with whom she had made the surrogacy agreement. The courts of New Jersey eventually awarded custody to Melissa’s biological father William stern and his wife Elizabeth stern rather than to the surrogate Mary Beth Whitehead. http://enwiki.org/wiki/ surrogate-mother (accessed on June 11, 2008).

human clones in the form of identical twins are common place, with their cloning, part of the natural process of reproduction.

In general biological terms, human cloning is defined as “the asexual replication of an existing genome or individual, or a replica of a DNA sequence, such as a gene, produced by genetic engineering.” 34

First report of successful cloning of lambs that went unnoticed was soon followed by arrival of “Dolly” in 1997. She inherited not only the genetic material in the parental nucleus but also the small amount of DNA which exists outside the nucleus of each cell and which in this case came from the donor egg. Soon there were reports of cloned mice and large farm animals.35

Every living thing is made of cells. Although most cells within an animal or human being are committed to fulfilling a single function in an organ like the skin or heart, a unique and important set of cells exists that is not so specialized. These stem cells that retain the ability to become many or all of the different cell types in the body, play a critical role in repairing organs and body tissues throughout life. Although the term “stem cells” refers to these repair cells within an adult organism, a more fundamental variety of stem cells is found in the early stage embryo. These embryonic stem cells may have a greater ability to become different types of body cells than adult stem cells.36

The earliest embryonic stem cells are referred to as totipotent, indicating that they can develop into an entire organism because they can produce both the embryo and the

tissues required to support it in the uterus. These totipotent cells have the ability to form any type of cells present in the human body. Additionally, each totipotent cell is capable of developing into a complete embryo. Later in development, embryonic stem cells lose the ability to form these supporting tissues, but are still able to develop into almost any cell type found in the body. These pluripotent embryonic stem cells are the current focus of intense research interest.37

Reproductive cloning is where the intent is to produce more or less identical fetuses and babies and where the egg is implanted into the mother. Therapeutic cloning, by contrast, could be where stem cell lines are developed with a view to medical application. The nucleus of a cell donated by one person would be transferred to an egg mother cell and the embryo would be grown to generate stem cells which could be induced to form whichever type of cell or tissue was required for therapeutic purposes, such as brain tissue, muscle or skin. The essential difference is that here the object would not be to produce another human being but to treat an existing human being as a source of spare parts for another.38 Dolly was created by reproductive cloning technology.

**Applications/Possible Advantages**

Human reproductive cloning would said to produce few benefits. For example, such cloning hope to create a fertility treatment that allows parents who are both infertile to have children with at least some of their DNA in their offspring, or for those couples who because of a high risk of genetic disease or

37 Ibid
other factors cannot or do not wish to conceive a child.39 Similarly, human therapeutic cloning could provide genetically identical cells for regenerative medicine, and tissues and organs for transplantation. Such cells, or the cloned tissue or organ is a genetic match to the recipient thus eliminating the possibility and risk of tissue rejection.

Some scientists, suggests that human cloning might obviate the human aging process. How this might work is not entirely clear since the brain or identity would have to be transferred to a cloned body. Some scientists suggested the terms “replacement cloning” to describe the generation of a clone of a previously living person, and “persistence cloning” to describe the production of a cloned body for the purpose of obviating aging, although it maintains that such procedures currently should be considered merely a science fiction.40

Since stem cells are so inherently versatile, they could be potentially used to repair and replace damaged human tissue. Stem cells are expected to cure a variety of diseases, from Parkinson’s disease to cancer. Parkinson’s disease occurs when certain neurons in the part of brain called the ‘substantia nigra’ are impaired. These cells produce a chemical known as dopamine, which allows coordinated functioning of the body’s muscles and if impaired, causes slowness of movement, rigidity, and tremors. Scientists are attempting to revitalize the damaged brain cells and reverse the disease. Cell replacements through transplantation are also being experimented with. Gene therapy has enormous potential since it could result in the development of ‘viruses’ that can be engineered to deliver genes that increase the supply of

39 supra note 3.
40 Ibid.
dopamine or promote regeneration of neurons thus effectively bring a halt to the spread of the disease.\textsuperscript{41}

Alzheimer's disease can also be cured through this research. Alzheimer patients suffers from brain disorder that slowly destroys memory and thinking skills and eventually the ability to carry out even simple tasks. This deadly process once begun, is irreversible, hence, gene therapy has the capability to be successful here as well. Scientists have shown that skin cells from patients suffering from Alzheimer's can be taken and then modified to secrete a protein found in healthy brains called the nerve growth factor, which maintains the health of the nerve cells. The cells can then be implanted into those degenerating areas of the brain among sufferers of the disease. Clinical trials have revealed that the rate of degeneration of the brain cells have considerably reduced as a result of this type of treatment.\textsuperscript{42}

Heart disease and cancer can also be cured by this technology. Stem cell research in this area attempts to prevent the blocking of ventricles and perform the job being done by 'balloon therapy' and new age stents. Adult stem cells have been used for years to treat leukemia and other forms of cancer, and this has opened up new avenues for stem cell therapy.\textsuperscript{43} Scientists are now attempting to produce them in huge quantities and then replace them in the body.\textsuperscript{44}

\textbf{Ethical And Moral Issues Pertaining To Stem Cell Research}

\textsuperscript{41} supra note 1 at 187.
\textsuperscript{42} \textit{Id} at 188.
\textsuperscript{43} Ibid.
\textsuperscript{44} Recently, scientists in South Korea reported making nearly a dozen cloned human embryos that are genetic twins of patients with various medical problems and have isolated from those embryos batches of stem cells with the potential to replace failing tissues in those patients. The experiments mark a significant advance in therapeutic cloning, the fast-faced but controversial field that aims to make customized heart tissues for heart attack patients, nerves for patients with spinal cord injuries, and a host of other laboratory-grown spare parts genetically tailored to the patients who need. The Tribune 21 May, 2005.
Stem cell research is at the center of a raging controversy due to its ethical implications. Although few debate the potential marvels that mastering stem cells could provide by way of medical advancements in the treatment and prevention of life threatening diseases, many object strenuously to the measures being taken to reach that goal.

The study of adult stem cells is not disputed since harvesting them causes no harm. However, the harvesting of embryonic stem cells is another matter altogether, since it requires the destruction of early-stage embryos, known as blastocysts. Further blastocysts are surpluses obtained from in vitro fertilization clinics with the consent of the patients. However, for the people whose moral beliefs state that human life begins at the moment of conception, embryonic research is simply unacceptable, reproductive cloning technology is both unethical and illegal.

Most prominent arguments for ban on human cloning include that human beings have a right to be born, in a human way and not in the laboratory and that life is meant to come from God through the blessed relationship of a man and a woman. When embryos are made in a test tube or a petrie dish “they can be frozen, poured down the sink and treated as objects rather than subjects of infinite human value.” Catholic teaching opposes cloning, whether therapeutic or reproductive, as the process is the same in either case; only the purpose is different. The official opinion of the Roman Catholic Church is that “every possible act of cloning humans is intrinsically evil” and can never be justified.

Hinduism and Islamic views with relation to human cloning are not unanimous.\textsuperscript{46}

In other words, cloning, particularly reproductive is considered unnatural as it not only affects human dignity and violates the individual's right to genetic uniqueness but also consequentially lead to unjustified health and psycho social risks for the progeny. The notion of "human dignity" is commonly used ethical justification for cloning laws on the basis that reproductive human cloning necessarily infringes with the notions of human dignity. The act of cloning can be implicated as an intention to "violate the rights of the clone in the future", because the person cloned would not be created for their own benefit but someone else's. This is an instrument way of using another human, as a means to someone else's ends, which is an unacceptable human control. Cloning is "replication" and not "reproduction". The sexual nature of the process is "unnatural", and found only in the lowest forms of life. Thus, cloning degrades human dignity.\textsuperscript{47}

There are physical and psychological risks also even more deaths and lethal birth defects can be expected during experimentation. Many attempts at animal cloning produced disfigured monsters with severe congenital abnormalities. Some of the defects may not be revealed until a clone is mature. Similarly, children may suffer psychological risks like they may feel that he or she is different from others and a copy of someone else. A cloned child may feel that their future is constrained by the life path of their gene donor, and thus unbearable emotional

\textsuperscript{46} supra note 33 at 126.
\textsuperscript{47} Id at 127.
pressures in trying to establish his or her identify, may shatter the clone’s personality.48

Main risk of human cloning is that it would allow third parties to impose biological predetermination. Widespread practice of human reproductive cloning will encourage a form of eugenics as people arbitrarily decide what traits are desirable that may possibly lead to degradation of the quality of parenting and family life. Parents having complete control over the genome of their children might begin to view children as objects i.e. it might lead to the objectification of children and larger society may not recognize them as individuals.49 Thus, reproductive cloning would have an adverse impact on the social definition of family.

Although a global comprehensive treaty relating to cloning technologies is lacking yet, different countries have framed laws to cope with emerging medico legal problems. Fifteen States in the United States have laws pertaining to human cloning. The issue was first addressed by California legislature in 1997, which banned reproductive cloning, or cloning to initiate a pregnancy. Since then, Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, and Virginia have enacted measures to prohibit reproductive cloning. Rhode Island law does not prohibit cloning for research and, California and New Jersey human cloning laws specifically permit cloning for the purpose of research.50

In 2001, USA enacted Human Cloning Prohibition Act to regulate use of cloning technology.51 United Nations Declaration

48 Ibid.
49 Ibid.
on Human Cloning prohibits the practices which are contrary to human dignity, such as the reproductive cloning of human-beings shall not be permitted. The legal committee recommended to the General assembly to adopt all measures necessary to protect adequately human life in the application of life sciences as well as measure necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.

The precise legal position in the U.K. on cloning is uncertain. The British Parliament passed the 1990 Human Fertilisation and Embryology Act, (herein after called as HFE Act) which has remained the cornerstone of the UK’s regulatory framework in this area. Under the said Act 1990, it is legal to carryout research on human embryos up to 14 days after fertilization. This statute has enabled research to be licensed for certain specific purposes, mostly related to improving the understanding and treatment of infertility or miscarriages, or to the development of new methods of contraception. The Act has made creation of embryos specifically for research legal.

The Human Fertilisation and Embryology Authority has been setup to oversee that embryos must not be used or kept outside the human body at a stage of development beyond 14 days, and it must be shown that it is ‘necessary or desirable’ to

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55 Ibid.
use embryos to achieve the aims of the research. The legislative framework for embryo research has been amended, extended and judicially reviewed between 2001 and 2003 and as a result, the government introduced the **HFE (Research Purposes) Regulation 2001**.56

In 2002 Parliament passed **Human Reproductive Cloning Act**. This Act prohibits anyone placing an embryo in a woman if it has been created in anyway other than by fertilization. The first of its kind in the world, the UK Stem Cell Bank is set up to manage these resources under an ethical governance framework. This Bank has two functions as a repository for all stem cell types (adult, fetal, embryonic) and as a supplier of cell lines for basic research and clinical applications. At a legal level, donors are protected by requirement for informed consent. The HFE Act 1990 stipulates that UK donors of embryos for research should be given appropriate counseling and such relevant information as is proper to make a decision whether to donate or not.57

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56 The HFE (Research Purposes) Regulations 2001 extended the purposes for which research licences could be authorised namely (1) increasing knowledge about the development of embryos (2) increasing knowledge about serious disease or, (3) enabling any such knowledge to be applied in developing treatments for serious disease. These regulations were introduced to extend the list of purposes for which such research could be licensed by the HFE Act. The 2001 provisions allowed for ‘therapeutic cloning’ i.e. through cell nuclear replacement, the creation of an embryo by taking egg (or oocyte) from which the nucleus had been removed, and replacing it with the nucleus of a donor cell (e.g. human skin cell). Human Reproductive Cloning Act, 2001 prohibits the placing in a woman of a human embryo which has been created otherwise than by fertilisation. The Act has declared such act as an offence. http://www.publications.parliament.uk/pa/cm200607/cmselect/272/27205.htm. http://www.opsi.gov.uk/acts/acts2001/UKpga-20010023-en-1 (accessed on August 20, 2009).

57 Schedule 3 of HFE Act, 1990: Consents to use of Embryos Part-3 Procedure for giving consent.
(1) Before a person gives consent under this schedule -
(a) he must be given a suitable opportunity to receive proper counseling about the implications of taking the proposed steps, and
(b) he must be provided with such relevant information as is proper.
Currently therapeutic cloning is allowed under license from the Human Fertilisation and Embryology Authority. The first licence was granted on August 11, 2004 to researchers at the University of Newcastle to allow them to investigate treatments for diabetes, Parkinson’s disease and Alzheimer disease.\textsuperscript{58}


Controls on human cloning in Britain could be overturned by a new legal challenge from anti-abortion activists. The move comes amidst worldwide controversy over claims from an American religious sect to have engineered the birth of the world’s first cloned human babies. Anti-abortion campaigners object to it as it involves the creation and then destruction of life. The law has to be revisited or its going to happen anyway through the courts\textsuperscript{61} since anyone wanting to research therapeutic cloning duplicating

\textsuperscript{58} supra note 34. Australia had prohibited human cloning, but in December 2006, a bill legalizing therapeutic cloning and the creation of human embryos for stem cell research was passed in the House of Representative within certain regulatory limits, making therapeutic cloning legal.

\textsuperscript{59} The preamble of the charter emphasises on resolving to share a peaceful future based on common values and it reaffirms, enjoyment of fundamental rights and duties with regard to other persons, to the human community and to future generations. \texttt{http://www.europarl.europa.eu/charter/pdf/text-en.pdf} (accessed on August 20, 2009)

\textsuperscript{60} \textit{Ibid.} Chapter 1, Article 3 of the charter reads as, “1. Everyone has the right to respect for his or her physical and mental integrity. 2. In the fields of medicine and biology, the following must be respected in particular:  
- the free and informed consent of the person concerned, according to the procedures laid down by law.  
- the prohibition of eugenic practices, in particular those aiming at the selection of persons. 
- the prohibition on making the human body and its parts as such a source of financial gain.  
- the prohibition of the reproductive cloning of human beings. 
\texttt{http://www.guardian.co.u.k./science/2003/Jan/05/genetics. research}. (accessed on June 11, 2008)

\textsuperscript{61}
human embryos for research or treatments must be licensed and destroy the embryos at an early stage.

The former President Bush as well as the Republican Party in the United States consistently opposed embryonic stem cell research and consistently threatened to cut off federal funding for such projects, a move that proved disastrous for stem cell development. In 2001, President Bush cut off federal funding for embryonic stem cell research limiting it only some 70 odd stem cell batches in existence then. This proved a controversial move especially, since other countries such as UK, Sweden, Belgium South Korea and even India have been far more liberal and supportive of such efforts by their respective scientists and researchers. The present U.S. President Barack Obama has overturned Bush’s Policy on embryonic stem cell research. Obama has issued an executive order that allows federal money to fund expanded embryonic stem cell research which scientists say is, “a great advance for science in general and America in particular”. According to Mr. Obama he was ending what he believed was a false choice between sound science and moral values. The president vowed that the US government will vigorously support scientists who pursue this research and will aim for America to lead the world in the discoveries it one day may yield. He called on Congress to provide the needed funding even though he also asserted that the order would never allow human cloning. Since, “It is dangerous, profoundly wrong and has no place in our society or any society”.

\[\text{Supra note 1 at 190.}\]
\[\text{http://blog.christianitytoday.com/ctpolitics/2009/03/obama_overturns-1.html}\]
Status of Cloning in India

As seen above, stem cells are increasingly used for treating various diseases like diabetes, congenital disorders and efforts are now being made to make the same facilities available to people in India. The Health and Family Welfare Minister stated that the government was planning to bring in legislation to preserve human stem cells for curing many degenerative diseases by using the same for organ culture.64 The need to stop the wastage of stem cells by setting up a stem cell bank in the country was stressed as was the need for creating a conducive atmosphere to ensure the development of generic medicines and the conduct of clinical trials.65 Unlike other governments, the Indian government has been wholly supportive of efforts at stem cell research.

India allows experimentation with stem cell research. In India, as medical termination of pregnancy is permitted under the MTP Act of 1971, the resulting fetal tissues that are freely available from the MTP clinics and hospitals, can be utilized for research purposes. Termination of pregnancy for obtaining fetus for stem cell research or for transplantation is not permitted. The main source of embryonic cells will be IVF clinics dealing with infertility treatment where spare or supernumery embryos will be available for the purposes.66

The Indian Council of Medical Research (ICMR) has prepared draft “Ethical Guidelines for Biomedical Research on Human Subjects” in October 2000. In India, only the research programmes and not the therapeutic transplantations are

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64 supra note 1 at 190.
65 Ibid.
66 Ibid.

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permitted at present. ICMR has also drafted guidelines for stem cell research in 2004. The era of clinical bone marrow, tissue and organ transplantation is poised for breakthrough with the possibility of stem cell transplantation, and therapy. More than 15 labs in the country are involved in this work and out of Rs. 500 crore budget of Department of Biotechnology 30% is allocated for stem cell related research.

India is certainly exhibiting the potential to become a global hub for this kind of research. Call it innovative insurance, more and more young men in Delhi, who are busy chasing fast track careers, but are not yet ready to start a family, are choosing to freeze their sperms to be used when they are ready to revise family. More than 50% of the long term frozen samples in Delhi's sole commercial sperm banking organization. Cryogenie, are of healthy young men who are not ready for procreation and do not want to rely on donor sperms. Sperms are stored in liquid nitrogen at minus 192 degrees celsius. Some are even optimistic enough to suggest that the biotechnology, boom could result in India being a nucleus for stem cell research. Unfortunately, till today there is no specific legislation to regulate HESC research except the ICMR guidelines 2006. The guidelines have categorized stem cell studies into 3 groups namely:

(i) Permissive;
(ii) Restricted; and
(iii) Prohibited Research area

67 Ibid.  
In-vitro studies on established lines from any type of stem cells including HES, HEG, HSS or fetal adult stem cells are kept in the permissible research area.

In the prohibited research is placed any in vitro culture or manipulation of human embryo beyond 14 days after fertilization, formation of primitive streak, which ever, occurs early. Even implantation of any embryo through IVF procedure into human uterus is also kept in this category.

The guidelines provide for continuous upgradation of all these categories depending on scientific progress in this field. Informed consent to have abortion and the donation of fetal material for research/therapeutic purposes must be taken separately and the identity of the donor and the recipient should be kept confidential. For this, responsibility is placed both on investigators and institutions in this regard.\(^{71}\)

The guidelines also provide for adequate mechanism in the form of setting up of National Apex Committee for Stem Cell Research and Therapy (NACSCRT) and Institutional Committees at Institutional Level (IC-SCRT) for reviewing and monitoring research in this field. All institutions and investigators carrying out research in this area should be registered with these two regulatory bodies and without prior approval of these bodies; no research work can be carried out. Similarly all clinical trials in this field should have prior approval of Ethics Committee of NACSCRT and ICSCRT and of Drug Controller General of India (DCGI).\(^{72}\) The guidelines not only provide for Intellectual Property Rights (IPR) protection in this field of research but also talk about exchange of biological material and international collaboration.

\(^{71}\) Id at 171.

\(^{72}\) Ibid.
after due permission of funding agencies such as DBT, ICMR, DST. In case of conflict between scientific and ethical perspective of international collaborations and domestic side, the Indian ethical guidelines shall prevail.\textsuperscript{73}

In India there is no specific legislation to this effect. The present ICMR draft guidelines are not very clear about the penalty clause. Therefore, there is an urgent need to translate these guidelines into the Act of Parliament as already available in many countries including U.K. All nations of the world and international bodies should try to form uniform policies in this direction. Stringent penalties must be provided so to avoid misuse of any kind with regard to embryo research.\textsuperscript{74}

(C) **Organ Transplantation Technologies**

In the past, death was declared only when the heart stopped beating. Advances in medical sciences now allow death to be determined very precisely by measuring brain functions. When brain activity has totally ceased, breathing and heart function can no longer continue independently, and then the individual is truly dead. Brain function is essential for human life, hence, the death of the brain implies that the person is dead. Usually a patient with brain stem death is an ideal organ donor, as they are put on ventilators which allow temporary independent functioning of lungs and heart.\textsuperscript{75} In other words, organ transplantation in human beings is a major break through of modern science.

Transplantation (grafting) is the replacement of a failing organ or tissue by a functioning one. Transplantation was a dream in antiquity. The Hindu deity **Lord Ganesha** had his head

\textsuperscript{73} Ibid.
\textsuperscript{74} Id at 172.
replaced by an elephant’s head by Lord Shiva, soon after birth (Rigveda, 1500.B.C.) In the Christian tradition Saints Cosmas and Damian are famous for replacing the diseased leg of a true believer with the leg of a dark-skinned moor, thereby, becoming the patron saints of physicians and surgeons. Transplantation may be from the same person, from the same species, genetically close parent or sibling, living unrelated person, or cadaver or from different species.76

With the advancement of science and technology it has become possible to remove organ from living as well as deceased persons and to transplant such organs to save the lives of suffering human beings. The vital organs which can be donated are the kidneys, heart, lungs, liver and pancreas. Heart and liver donation are a matter of immediate life, and death organs can be procured from two sources, live related donors and cadaver organ donors. In the living donor programme, blood relatives like brother, sister, parents, children and first cousins are preferred as donors. For due renal transplants they are preferred source as the tissue is likely to have a good match. Living donors can donate only a few organs like one kidney, a portion of the pancreas and a part of the liver. On the other hand, a cadaveric donor can donate all organs after brain death. A transplant team will, however,

76 Saints cosmas ad Damian are regarded as the Patrons of physicians and surgeons and are sometimes repeseted with medical emblems. They were twin brothers and christian martyrs born in Arabia who practised the “art of healing”. These brothers never charged a fee for medical services cosmas and Damian miraculously replaced the ulcerated leg of a chirstian with the undiseased leg of moor. http://www.absoluteastronomy.com/topics/saints_cosmas_and_Damian#encyclopedi a. http://www.catholicculture.org/culture/liturgicalyear/calendar/day.cfm?date=2009-09-26. http://www.answers.com/topic/organ_transplant? Cat= health (accessed on June 10, 2008)
assess the medical suitability of the potential donor before organs are actually taken out for transplant.\textsuperscript{77}

But, the gap between demand and supply is even more acute in countries where religious or cultural considerations inhibit organ donation. In the middle east, religious precepts discourage, and in places, prohibit cadaveric organ donation. Islamic teaching emphasize the need to maintain the integrity of the body at burial, and although many religious leaders have sanctioned organ donation as a gift of life, others continue to object to the practice. Despite the support of most medical technologies and deeply ingrained habits of gift loving, transplantation from cadaveric sources is still rare. Heart transplantation is not performed at all and the limited number of kidneys donated come from living related persons.\textsuperscript{78} And this very scarcity, has provided incentives to physicians, hospital administrators, and government officials in a number of countries, to pursue ethically dubious strategies for obtaining organs. They are motivated less by a desire to meet the need of their country’s patients than to secure payments from foreign nationals. Specifically, the world wide shortage has encouraged the sale of organs commercially all over the world.

In fact, the increasingly successful organ transplants has not only created availability of such organs but also consequently, led to an organ trafficking. Though there is no reliable data on organ trafficking yet, it is widely believed to be on the increase with brokers reportedly charging wealthy patients between $100,000 and $200,000 for a transplant. In 2002 over 6000

\textsuperscript{77} http://www.indmedica.com/hospad/pindex1cfm?haid=29&iid=4
\textsuperscript{78} Ibid.

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Americans died while waiting for organs, according to UNO’s report. More than 80,000 people in the U.S. alone are in the waiting list. More than 2 million people need organ transplants in China, 50,000 waiting in Latin America (90% of which are waiting for kidneys), as well as thousands more in the less documented continent of Africa. Donor bases vary in developing nations.

In Latin America the donor rate is 40-100 per million per year, similar to that of developed countries. However, in Uruguay, Cuba and Chile, 90% of organ transplants came from cadaveric donors. Cadaveric donors represent 35% of donors in Saudi Arabia. There is continuous effort to increase the utilization of cadaveric donors in Asia, however, the popularity of living, single kidney donors in India yields India a Cadaveric donor prevalence of less than one per million population. As per reports about 1.5 lakh new patients suffer end-stage renal failure every year and only 3500 get kidney transplants in India.

One of the driving forces for illegal organ trafficking and “transplantation tourism” is the price differences for organs and transplant surgeries in different areas of the world. For instance, despite efforts of international transplantation societies, it is not possible to access an accurate source on the number, rates and outcomes of all forms of transplantation globally; the citizens waiting for organ transplant in the US and other developed nations, there are long waiting lists in the rest of the world.


China does 10,000 transplants a year, and experts say that at least 90% of organs are taken from executed prisoners, without signed consent, since has taboos against donating organs of deceased family members.


Ibid. It is estimated that about 1,50,000 people are diagnosed with kidney failure in India every year, for whom the only way out is an organ transplant. However, it is believed that number of transplants have fallen from 3600 in 2002 to a little more than 2000 in the year 2004. Also see The Times of India September 8, 2009 at 1. Around 4.5 lakh patients require organ transplants annually where as only 35000 organ transplants have taken place in India in the last 10 years. At present 0.1% of all donation are cadaver see The Times of India August 24 2009.
in Latin America a kidney may cost more than $10,000, Kidney in South Africa have sold for as high as $20,000. The Voluntary Health Association of India reports the prospect of such a small fortune has enticed about 2,000 impoverished Indians to sell a kidney every year.\textsuperscript{83} Although these prices are still unattainable to the poorer citizens of the world.

Transplantation of human organs and tissues which saves many lives and restores essential functions for many otherwise untreatable patients both in developing and developed countries, has been a topic for ethical scrutiny and health care policy making for more than thirty years. In 1991, the World Health Assembly approved a set of guiding principles which emphasized voluntary donation, non-commercialization and a preference for cadavers over living donors and for genetically related over non-related donors.\textsuperscript{84}

Similarly, in 1985, 1987, 1994 and again in 2006, the World Medical Association resolved to condemn the purchase and sale of human organs for transplantation. The advances in medical sciences especially in surgical techniques, tissue typing and immuno-suppressive drugs, have made possible a significant increase in the rates of successful transplantation of organs. In the light of these developments, there is a need for renewed reflection on ethical issues concerning organ donation and transplantation and on principles relevant to the resolution of these issues. The World Medical Association, in October 2006, has also undertaken to revise the principles concerning

\textsuperscript{83} In January, 2008 the big Delhi City hospitals came under kidney racket scanner. The police found the links of Doctors into the Rs. 100 crore kidney scan. Whenever there was any delay in the operation, the patient would be shifted to one of these hospitals and offered treatment which was mostly dialysis. 'Big city hospitals come under kidney racket scanner' The Times of India, January 30, 2008.

transplantation, and developed the policy to provide guidance to medical association, physicians and other healthcare providers as well as to those who develop policy and protocols bearing on these issues. 85

It is very clear that the primary obligation of physicians is for the well being of a patient who needs a transplant, but it does not justify unethical or illegal procurement of organs. Physicians have responsibility to society, which include promoting the fair use of resources, preventing harm and promoting health benefit for all this may include promoting donation of organs. The World Medical Association encourages its members to support the development of comprehensive, coordinated national strategies concerning organ procurement in consultation and cooperation with all relevant stakeholders. Some types of organ transplantation have become established and part of important health care services. The medical profession has an obligation to promote policies and protocols to procure organs for needed treatment consistent with societal values.

As per, the World Medical Association, the potential donor’s wishes are paramount. In the event that the potential donor’s wishes about donation are unknown and the potential donor has died without expressing a clear wish about donation, the family or a specified other person may serve as a substitute decision-maker and may be entitled to give or refuse permission for donation unless there are previously expressed wishes to the contrary. In the case of living donors, special efforts should be made to ensure that the choice about donation is free of coercion. Financial

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incentives for providing or obtaining organs for transplantation can be coercive and should be prohibited. Individuals who are incapable of making informed decisions, for example minors, or mentally incompetent persons, should not be considered as potential living donors except in extraordinary circumstances and in accordance with ethics committee review or established protocols.

The World Medical Association also says that there should be explicit policies open to public scrutiny governing all aspects of organ donation and transplantation, including the management of waiting lists for organs to ensure fair and appropriate access. Policies governing the management of waiting lists should ensure efficiency and fairness. Criteria that should be considered in allocating organs include severity of medical need, length of time on the waiting list, and medical probability of success, measured by such factors as type of disease, other complications. There should be no discrimination based on social status, lifestyle or behaviour. Physicians who are asked to transplant an organ that has been obtained through a commercial transaction should refuse to do so and should explain to the patient why such a medical act would be unethical, because the person who provided the organ risked his or her future health for financial rather than altruistic motives, and because such transactions are contrary to the principle of justice in the allocation of organs for transplantation.

The World Health Organization (WHO) has found the sale of organs as violative of the Universal Declaration of Human Rights.

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86 Ibid.
87 Ibid
as well as its own Constitution. The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment for organs should be prohibited. The WHO enjoins physicians not to transplant organs if they have reasons to believe that the organs concerned have been the subject of commercial transactions.

The WHO's Committee on Morals and Ethics of the Transplantation Society (1971) affirmed that the sale of organs by donors living or dead is indefensible under any circumstances. Principle 5 of the Draft Guiding Principles on Human Organ Transplantation, prepared by the Director General of WHO reads as:

“The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited”.

The other relevant principles given by WHO are as follows:

(a) transplantation should be preferably from the bodies of deceased persons;
(b) adult living persons may donate, but in general, such donors should be genetically related to the recipient and
(c) no transplantation should take place from a living minor.

The prohibition on sale of organs is sought to be defended on two broad grounds, viz; of inequity and practical

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88 Article 3 of UDHR says everyone has the right to life, liberty and security of person. Article 4 reads as: No one shall be held in slavery or servitude, slavery and the slave trade shall be prohibited in all their forms.
90 books.google.co.in/books?isbn=0762307641 (accessed on August 20, 2009).
91 Sapna Khajuria, Saugata Mukherjee, 'Organ Transplantation: Legal Framework', 39 JLI at 305 (December 1997). By adoption of this Act, the various state legislatures prohibited all organ sales.
consideration. Thus, the sale of organs is seen as being a way for the rich to obtain priority essential care, the inequity being compounded by the corollary that the poor, who would form the pool of such donors, would be positively disadvantaged in the role of supplier. A monetary inducement to donate is so coercive that it deprives some sellers of the ability to give free consent to this potentially risky operation. Commercial organ sale may lead to a collapse of the voluntary donation system, resulting in an overall decrease in available organs, as has happened in the case of commercial blood market.\textsuperscript{92} Commercial organ market is indeed immoderate and outrageous particularly in case of kidney’s. The International Council of the Transplantation Society also unequivocally insists:

“No transplant surgeon/team shall be involved directly or indirectly in the buying or selling of organs; tissues or in any transplant activity aimed at commercial gain.”\textsuperscript{93}

While principles of WHO had a great influence on professional codes and legislation, these principles do not directly address safety concerns and they face challenges from leaders in the field who urge that policies be changed to allow the use of “incentives” to increase the numbers of organ for transplantation from the involvement of organ donation programs in commercialized organ trafficking, which apparently occurs in a number of countries where payment for organ is supposedly outlawed.\textsuperscript{94}

Consequently, the existence and distribution of organ transplantation procedures in developing countries, while almost

\textsuperscript{92} Id at 307.
\textsuperscript{93} Ibid.
always beneficial to those receiving them, raise many ethical concerns. Both the source and method of obtaining the organ transplant are major ethical issues to consider, as well as the notion of distributive justice. The WHO argues that transplantations promote health, but the notion of “transplantation tourism” has the potential to violate human rights or exploit the poor, to have unintended health consequences, and to provide unequal access to services, all of which may cause harm. Regardless of the “gift of life”, in the context of developing countries; this might be coercive.

**Provisions of Transplantation of Human Organs Act, 1994**

The Indian government in order to address the problem of shortage of organ donors, and the other obstacles that patients in need of this remarkable new medical technology must confront, has tried to regulate this issue through enactment of **Transplantation of Human Organs Act, 1994.**

The Act provides for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs for therapeutic purposes and for matters connected therewith or incidental thereto.

Who can be a donor? The Act necessitates that the donor must be not less than eighteen years of age, and must voluntarily authorize the removal of any of his human organs for therapeutic purposes. Consent of the donor must of course be informed.

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95 The said Act 1994 received presidential assent on July 8, 1994 which came into force with a gazette notification in 1995. It contains total 25 sections. The Transplantation of Human Organs Rules, 1995 has also been framed.

96 Supra note 91 at 300.

97 Sec. 2(f) of Transplantation of Human Organs Act, 1994.

98 Id, Sec. 12: No registered medical practitioner shall undertake the removal of transplantation of any human organ unless he has explained in such manner as may be prescribed all possible effects, complications and hazards connected with the removal and transplantation to the donor and the recipient respectively.
The Act prohibits removal of organs by any person other than a registered medical practitioner, as defined in section 2(n)\footnote{Id, Sec. 3(4). says (1) Any donor may, in such manner and subject to such conditions as may be prescribed authorize the removal, before his death, of any human organ of his body for therapeutic purposes. (2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorized it any time before his death, the removal of any human organ of his body, after his death for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall unless he has any person to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor. (3) Where no such authority as is referred to in sub section (2), was made by any person before his death but no objection was also expressed by such person to any of his human organs being used after his death for therapeutic purposes the person lawfully in possession of the dead body of such person may unless he has reasons to believe that any near relative of the deceased person has objection to any of the deceased person’s human organs being used for therapeutic purposes, authorize the removal of any human organ of the deceased person for its use of therapeutic purposes. (4) that the authority given under sub-section (1) and sub-section (2) or, as the case may be, sub-section(3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ, but no such removal shall be made by any person other than the registered medical practitioner.} and also no hospital or place is legally authorized to remove the human organs unless appropriate authority like state or central government authorizes and register it.\footnote{Id, Sec. 14, states about registration of hospitals engaged in removal storage or transplantation of human organs – (i) No hospital shall commence any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes after the commencement of this Act unless such hospital is duly registered under this act: provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this act, shall apply for registration within sixty days from the date of such commencement: provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement or this act unless such hospital has applied for registration and is so registered or till such application is disposed or, whichever is earlier. (ii) Every application for registration under sub-section (1) shall be made to the appropriate authority in such form and in such manner and shall be accompanied by such fees as may be prescribed. (iii) No hospital shall be registered under this act unless the appropriate authority is satisfied that such hospital is in a position to provide such specialized services and facilities, possess such skilled manpower and equipment’s and maintain such standards as may be prescribed. Also visit at http://202.54.104.236/intranet/eip/legislation/up-loadstransplantation-of-human.pdf. (accessed on July 2, 2009)}
In furtherance of its object of preventing commercial dealings of human organs, section-19 of the said Act criminalizes any such transaction, including offers to supply any human organs for ‘payments’, and making or receiving any payment for the supply of any human organs. Payment as defined in section 2(k) means payment in money or money’s worth, but does not including any payment for defraying or reimbursing the cost of removing, transporting or preserving the human organ to be supplied or, any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body. Section 9(1) provides that no human organ shall be removed from the body of a live donor and transplanted into a recipient, unless the donor is a near relative of the recipient. The said Act 1994 has provision relating to punishment for removal of human organ without authority or punishment for commercial dealings in human organs.

101 Id, Sec. 2(k) reads as “Payment” means payment in money or money’s worth but does not include any payment for defraying or reimbursing –
(i) The cost of removing, transforming or preserving the human organ to be supplied, or
(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body.

102 Id, Sec. 9(1);

103 Id, Section 18 reads as (i) Any person who renders his services to or at any hospital and who, for purposes of transplantation, conducts, associates with or helps in any manner in the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees.

(ii) Where any person convicted under sub-section (1) is a registered medical practitioner his name 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 offence.


104 Section 19 of transplantation of human organs Act 1994 states that whoever (a) makes or receives any payment for the supply of, or for an offer to supply, any human organ, (b) seeks to find a person willing to supply for payment any human organ, (c) offers to supply any human organ for payment (d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an
It may be pointed out that essential provisions of the Act as explained above are very much similar to legislation existing in USA and UK. Developing countries have forged various policies to try to increase the safety and availability of organ transplants to their citizens. China has made selling of organs illegal as of July 2006 and claims that all prisoner organ donors have filed consent. However doctors in other countries, such as the United Kingdom, have accused China of abusing its high capital punishment rate. Despite these efforts, illegal organ trafficking continues to thrive and can be attributed to corruption in health care systems, which has been traced as high up as the doctors themselves in China, Ukraine and India and the blind eye economically strained governments and health care programs must sometimes turn to organ trafficking. Some organ deals are also insulated. Japanese citizens living in China can take advantage of Japan’s strict organ transplant laws and sell Chinese organs to Japanese citizens at home.

In India, the former Union Health Minister Dr. Anbumani Ramadoss expressed the government’s intention to amend the

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offer to supply, any human organ, (e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities 10 of or include the initiation or negotiation of any arrangement referred to in clause (d); or (f) publishes or distributes or causes to be published or distributed any advertisement (a) inviting persons to supply for payment of any human organ (b) offering to supply any human organ for payment, or (c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d) shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees: provided that the country may, for any adequate and special reason to be mentioned in the judgement, imposed a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees.


supra note 96 at 304,

Ibid. Only a few certified hospitals are allowed to perform organ transplants in order.
Transplantation of Human Organ Act, 1994 so to introduce stringent punishment – i.e. higher jail terms (2-7 years from the present six months to 5 years) and financial penalties (Rs. 1 lakh from the present Rs. 10,000) for those indulging in illegal organ trade. Another proposed amendment, had been in relation to not having the team of doctors doing the transplant in the authorized committee of every hospital undertaking transplants. Instead, the committee would include government officials and other citizens with high social standing.107 The government also proposed to speed up plans for more facilities like the Organ Retrieval Banking Organisation at AIIMS. Ten centres replicating ORBO, each costing Rs. 10 crore, have been planned in different cities where organs would be stored.108 The Hon’ble High Court of Delhi, had in Sept. 2004 constituted a Review Committee to examine various provision of the Act and the Rules made there under. The Report of the committee was put in the public domain and the Health Ministry had drafted the Transplantation of Human Organ and Tissues (Amendment) Bill, 2008. The said amendment Bill would cover both organs and tissues.109

Now, the Union Law Ministry has cleared the long pending amendment to the said act where under swapping of vital organs between willing but incompatible donors is legalized. Under the new amendments, punishment against those involved in commercial organ trade is being made harsher and cognizable. All those involved in the organ trade racket, including doctors will be punished with imprisonment from 2 to 7 years along with fine

107 “Ramadoss wants longer jail term for organ traders”, The Times of India, January 30, 2008
108 Ibid
ranging from Rs. 10,000/- to 20,000. The proposed amendment also and entitle living organ donors to sops like a 50% discount on second class rail tickets, life long free medical checkup and care in the hospital where organ donation takes place, and customized life insurance policy of Rs. 2 lakhs etc.

It is submitted that in case the proposed amendments are come out, it will make it simpler for genuine patients to receive a legal donor. Swapping of vital organs will help exchange of organs between two unknown families and also help bringing down illegal organ trade. This will be a significant step as the current rules restricts organ transplant between blood relatives (father, mother, son, daughter, wife, husband, sister and brother), near and distant relatives and those having love and affection towards the patient.

It is pertinent to state here that in India the present Act 1994 is oblivious to realities, and denies the worth of personal experience and prevailing public and professional standards in confronting and resolving the day to day ethical issues of medical practice. Organ transplants generate increasingly vexing legal and ethical questions as medical technology becomes more complex. Some controversial issues surrounding the subject are donor consent, idea for organ donation and transplants from terminally disabled infants. The biggest failure of the present Indian health system is absence of public health system. Demand disproportionate to supply has created a fertile ground for mushrooming unauthorised hospitals and nursing homes often

110 The Bill will be introduced likely in the next session of parliament. In India presently 30,000 liver transplants are required every year and India also need 2.5 lakh eyes donated every years while it manages only 25,000 of which 30% can not be used. See The Times of India September 8, 2009 at 1
111 Id at 5
112 Ibid.
run by quacks and crooks, medical mercenaries and illegal organ traders. Regulation of medical services ought to be made uniform throughout the country. Registration and licencing of centres staff would facilitate frequent inspections and ensure compliance with law.113

In *Kuldeep Singh and Anr. v. State of Tamil Nadu & Ors.*,114 the Supreme Court emphasized on the object of the enactment of the said Act 1994 and observed that it is for regulation of removal, storage and transplantation of human organs for therapeutic purpose and for prevention of commercial dealings in human organs, the court also held that since object of the Act being to find out true intent behind donor's willingness to donate organ, the Authorization Committee of State where recipient was undergoing medical treatment, was not required to examine claim of the petitioners.

Hence, there is an imminent need for regulatory measures to ensure that human organ transplants are kept within the realm of legitimate surgical procedure and do not degenerate into criminal butchery.115

Besides, the above discussed implications of new scientific developments in the realm of health and human life, both science

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113 *Human Harvest*, The Times of India, 29th January 2008.

114 Manu/SC/0238/2005 (paras 2,16). In the instant case, the petitioner no. 1 is undergoing treatment at Chennai for renal disorder and is permitted to undertake kidney transplantation. Petitioner no. 2 wanted to donate one kidney to petitioner no. 1 to save his life. The gesture was actuated by love and affection and there, no other consideration involved. It was indicated to the petitioner that NOC is to be issued by the Authorisation committee of State of Punjab as both the petitioners belong to State of Punjab. The Authorization Committee of State of Tamil Nadu cannot issue such a certificate. The judgement was delivered by Hon'ble judges Arjit Pasayat and S.H. Kapadia. See also *Jeewan Kumar Raut and Anr. v. Central Bureau of Investigation*, Criminal Appeal Nos. 1133-1134 of 2009 (Arising out of SLP (Crl.) Nos. 1035-1036 of 2009). Where Justice S.B. Sinha, while delivering the judgement observed that this Act (TOHO) is a special Act .... [And] It is a well-settled principle of law that if a special statute lays down procedures, the ones laid down under the general statutes shall not be followed. *Ibid*, (Paras, 12,20)

and law are also facing challenges in relation to human right to health due to increased use of mobile phones, computers, plastic bags, genetically modified foods, use of microwave and use of botox etc. Hence, it becomes imperative to study how human health gets affected with the use of these and what precautionary steps should be taken to check resulting health hazards.

(D) Health Hazards of Mobile Phones/Computers

Mobile phone, computer application are recent scientific achievements in modern era, but studies shows that mobile phones users may be placing their health at risk. The study done in several cities of U.S. among nearly 300,000 mobile phone users revealed that the cause of accidental death had been the increasing minutes of use of the mobile phone.116 One research conducted in UK showed that the mobile phone exposure an hour before sleep adversely affects deep sleep. It also could result in lack of concentration and confusion. There is also a rising fear regarding human health getting affected due to exposure to electromagnetic fields. One of the big concerns regarding the effects from exposure to non-ionizing electromagnetic fields is the cancer and related syndromes.117

In mid-1992 a lawsuit was filed in an US court in Florida by David Reynard alleging that using a cell phone had caused his wife a fatal brain cancer. But, the suit was dismissed by the Federal Court in 1995 for lack of valid scientific evidence.118

In addition to the radiation caused by the mobile phone, base stations and associated antennas are another source of radiation. The radiated energy is restricted to certain safe margin

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117 Ibid.
118 Ibid.
indicated by the International Commission on Non-Ionising Radiation Protection. A survey study in France dealt with individually reported symptoms from people living within 300 meter radius of towers in rural areas and 100 meter in urban areas. Symptoms reported were fatigue, headache, sleep disturbance and loss of memory. Many people believed that the towers in the radio mobile systems caused symptoms such as anxiety, nausea and tiredness. Some users of mobile phones reported feeling of several unspecified symptoms during and after the phone use, ranging from burning and tingling sensations in the skin of the head, fatigue dizziness, loss of mental attention, disturbed reaction time and memory retentiveness, headaches, disturbance of the digestive system. All of these feelings were typical of electrical sensitivity and attributed to psychological stress.

In the light of this, WHO issued in the year 2000, guidelines to be strictly adhered worldwide so to protect everyone in the population: mobile phone users, those who work near or live around base stations, as well as people who do not use mobile phones. It recommended adoption of precautionary measures by governments of each nation and individuals like limited use of cell phones, use of “handfree” devices so to keep phones away from the head and body, not to use mobile phones while driving and reduction of exposure to RF fields etc.

Mobile phones may also interfere with certain electro medical devices, such as cardiac pacemakers and hearing aids. In

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119 Ibid.
121 Ibid.
hospital intensive care departments, mobile phone use can be a danger to patients and should not be used in these areas. Similarly mobile phones should not be used in aircraft as they may interfere with its navigation systems.\textsuperscript{122}

Guidelines also suggested need for fences or barriers or other protective measures for some base stations (principally, those located on building rooftops) so to preclude unauthorized access to areas where exposure limits may be exceeded. Setting base stations near kinder gardens, schools and playgrounds should need special consideration. Also an open communication and discussion between the mobile phone operator, local council and the public during the planning stages for a new antenna can help create public understanding and greater acceptance of a new facility.\textsuperscript{123}

Cell phones are an inevitable part of our lifestyle and work environment. At the same time, it is not logical to eliminate the radiation of these systems, radiation is an inherent characteristic thereof. The Indian courts are also giving attention to the mobile phone health hazards.

In \textit{Reliance Infocom Ltd. v. Chemanchery Grama Panchayat & Others},\textsuperscript{124} the Kerala High Court gave a general direction to the TRAI to make periodical inspection to ascertain whether radiation emanated from the mobile base stations would cause any health hazards to the people of the locality. This

\textsuperscript{122} \textit{supra} note 116.
\textsuperscript{123} \textit{Ibid.}
\textsuperscript{124} AIR 2007 Kerala 33. The division Bench comprised of K.S. Radhakrishanan and K. Padmanabhan Nair, J.J. (In the instant case, in para 8 at 37) it was pointed out that the licence granted be cancelled by the Panchayat on the basis of an apprehension that the radiation might cause health hazards to the people of the locality. The court said that if the installation of tower and the emission of electromagnetic waves causes any air pollution, affecting human health, the pollution board can take appropriate measures under \textit{Air (Prevention and control of pollution) Act, 1991}.
judgement shows that radiation hazards posed by mobile handsets are real and in a way justifies the growing international concern and the expensive and costly researches ongoing for more than a decade in this regard.

Indeed, an effective system of health information and communications among scientists, governments, industry and the public is needed to raise the level of general understanding about mobile phone technology and reduce any mistrust and fears, both real and perceived. This information should be accurate and at the same time be appropriate in its level of discussion and understandable to the intended audience.

(Di) Health Hazards of Computer Use

Similarly, there are several health problems associated with computer use which in the present times has become indispensable and one of the health hazard resulting from its use is called Cumulative Trauma Injuries (CTD’s)\textsuperscript{125}

Cumulative Trauma Injuries (CTD's)

As with any task done repeatedly, working on a computer for long periods of time can cause inflammation of tendons, nerve sheaths and ligaments and damage to soft tissues. Depending on an individual’s sensitivity to the repeated movements of keyboarding, the cumulative effect can be disabling. Resulting conditions are called Cumulative Trauma Disorders (CTD’s). Different types of forearm and wrist CTDs from computer use are carpal tunnel syndrome,\textsuperscript{126} tenosynovitis,\textsuperscript{127} epicondylitis,\textsuperscript{128}


\textsuperscript{126} This syndrome may be associated with repetitive occupational trauma (cumulative trauma disorders), wrist injuries, rheumatoid arthritis, pregnancy and other conditions. Symptoms include burning pain impairment of sensation in the distribution of the median nerve may occur. http://ctd.
If you experience pain, numbness, tingling, or weakness in muscles or movement of arms, hands, and fingers, it could be a sign or symptom of a CTD.

Neck and shoulder pain and stiffness can occur from improper placement of the computer monitor, mouse or document you are working from. Many people who use computers for prolonged periods of time complain of eyestrain, eye fatigue, eye irritation and blurred vision. Computers give off very low frequency and extremely low frequency radiation. Radiation is strongest at the back of the computer machine. The backs of computer monitors should be at least three to four feet from the user. Unfortunately, there are no regulatory mechanism or guidelines issued either by the WHO or any nation including India to deal with various health hazards resulting from excess use of computers.

**The Plastic Hazards:**

Before the advent of poly-bags, people did shop, buy things, bring eatables from the market, and did the same marketing as is done now. The raw material for the bag was decided by its usage,

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127 It is an unusual manifestation of leprosy even though musculoskeletal manifestations are seen in a large proportion of cases. Symptoms include pain, swelling, and difficulty in moving the particular joint where the inflammation occurs. (http://medind.nic.in/jaaAo2/3fjaat0213p69.pdf. (accessed on July 2, 2009).

128 It is also referred as "tennis elbow". It is a very common cause of elbow pain that occurs overtime from repeated use of the muscles of the arm and forearm, leading to small tears of the tendons (a structure that connects muscle to bone). (http://en.wikipedia.org/wiki/) (accessed on July 2, 2009)

129 It is a common condition that can cause significant pain. Tendonitis occurs when there is inflammation of tendons- the point where a muscle attaches. It can affect all parts of body. (http://en.wikipedia.org/wiki/) (accessed on July 2, 2009)

130 It is a swelling that often appears on or around joints and tendons in the hand or foot. It is most frequently located around the wrist and on the fingers. (http://en.wikipedia.org/wiki/- Ganglion-cyst) (accessed on July 2, 2009)

131 Ibid.
such as cloth bags for lighter items, Gunny bags/Jute bags for voluminous and heavier goods. The bags were washable and reusable. But the onset of the use of plastic bags gradually, exposed its numerous health hazards. From mega grocery store chains and retail outlets to pushcart vendors, eateries and restaurants, the plastic bag is found to be the wonder solution to storage and cartage. Hence plastic bags are ubiquitous in cities, towns and hill stations.

The land littered by plastic bag garbage not only presents an ugly and unhygienic seen but also this “Throw away culture” resulting from their use has found their way into the city drainage system, resulting in blockage as well as erosion of soil, creating unhygienic environment resulting in health hazard and spreading of water borne diseases. The waste materials collected are of all types including plastic materials. In the form of plastic cups, plastic bottles etc. indiscriminately are burnt on the roadside polluting the area with thick smoke which produce toxic gases posing a health hazard. Inhaling of such gases causes lung diseases and even cancer.

Whereas burning of waste material in public is a serious offence and violation of municipal corporation bylaws. Use of plastic bags has resulted in killing of hundred of thousands of birds, whales, and turtles every year the world over.

Surprisingly, the world annual average usage of plastic is alarming 18 kg per year. And average Indian uses one kilogram of

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133 The first plastic sandwich bags were unveiled in 1957 in US [http://www.alternet.org/environment/61607](http://www.alternet.org/environment/61607) (accessed on July 2, 2009).

plastics per year.\textsuperscript{135} And more than a 100 million tones of plastic is produced world wide each year.\textsuperscript{136}

The Plastics Committee of Pollution Control Board said that the daily use of grocery bags for sundry purposes is the real culprit as far as the volume and dispersing is concerned. In Bangalore, an estimated 500,000 polybags are used per day every day forming about 25% of all forms of plastics used.\textsuperscript{137} Consequential harmful effects of poly bags can be following.\textsuperscript{138}

- Rag pickers are prone to skin infections, respiratory ailments while collecting polybags for recycling.
- Recycled polybags are not suitable to carry food.
- Polybags being non-biodegradable accumulate in the soil suffocating the plant and animal life.
- Animals may eat/swallow the polybags. Recently a local newspapers Carried a cover story “Polybags kill 18 deer in the national park in Bangalore”. On post-mortem, passage with polybags eaten caused the death.
- Polybags are silent killers.
- Drains clogged by plastic bags
- Soil life suffocated by menace of polybags
- Therefore, non-biodegradable plastic accumulation has become a growing monster.

Polythene bags dumped near residential houses are breeding places for mosquitoes which causes dengue fever, filariasis and
malaria. Use of polythene bags less than 40 micron thickness cause more harm not only to the environment, but public health as well.

In brief, the plastic hazard caused due to non-judicial usage of plastic poly bags and their subsequent disposal into water bodies, land and burning, results in the gradual loss of the existing ecological balance and causes related health hazards.

Keeping in mind, the environmental pollution caused due to extensive use of used polythene packaging material, many states in India including the Union Territory, Chandigarh has imposed a ban on the use of plastic bags.

Further, it can be stated that plastic recycling can be used as an alternative method to prevent plastic from entering our environment and thus reducing the menace. The plastic weaving concept or recycling technology is based on the fact that plastic bags which are thin an have average life time of 2 to 3 hours and are discarded. They are responsible for clogging, choking, flooding death and destruction. Instead if they are


The name of states which includes ban of plastic bags use are: Andhra Pradesh, Delhi, Goa, Himachal Pradesh, Orissa, Nagaland, Pondicherry, Punjab, Tripura, U.P., Mumbai, H.P. Bangladesh band its use in 2002 to solve the problem of blocked drains and flooding,. Infact, the three R's of polythene use i.e. reuse, reduce and recycle which is a popular mantra amongst school children, must be taken seriously now by each one of us along with total ban on it’s use or atleast use of thin poly bags http://cesorissa.org/pdf/newsletter8.pdf. (accessed on July 2, 2009)

The Chandigarh Administration has imposed a complete ban on the use and sale of polythene bags in the city. The date of notification is 30th July, 2008. It is imposed from 2nd October 2008. The orders have strictly banned the use, storage import, selling, transportation and disposal of polythene and plastic carry bags by any person in the city. No shopkeeper, vendor, wholesaler, retailer, trader or hawker can use polythene anymore. Violators of this act can be given rigorous imprisonment extended upto five years or fine of Rs. One lakh or both depending on the extent of violators. For the habitual violators, an additional fine of Rs. 5,000 per day shall be imposed and there are provisions of imprisonment upto seven years depending upon the violation. http://www.igovernment.in/site/Chandigarh-imposes-complete-ban-on-using-polybags/ (accessed on August 20, 2009)

collected, even from roads, they can be washed cleaned, dried cut into strips and woven into the basic plastic textile fabric which can then be stitched into various products like mats, folders, handbags and purses. In this manner, plastic waste becomes more manageable and less destructive.\textsuperscript{143}

(F) Impact of Genetically Modified Foods on Human Health

Right to food is a basic right enshrined in the Constitution of India, but with the advent of globalization and liberal government policies genetically engineered food is available for Indian masses. Genetically modified foods have made a big splash in the news recently. The genetic engineering of plants and animals is looming as one of the greatest and most intractable environmental challenges of the 21\textsuperscript{st} century. Already this novel technology has invaded our grocery stores and our kitchen pantries by fundamentally altering some of our most important staple food crops.\textsuperscript{144} European environmental organization and public interest groups have been actively protesting against GM foods for a long time, and recent controversial studies about the effects of genetically-modified corn pollen on monarch butterfly Caterpillars have brought the issue of genetic engineering to the forefront of the public consciousness. In the US, U.S. Food and Drug Administration (FDA) has held open meetings to solicit

\footnotetext{143}{\textit{Ibid.}}

\footnotetext{144}{Besides EU and US many non European Countries including some developing countries have either banned the entry of GM foods or have imposed strict restriction on their commercial use. For example Japan, South Korea, Newzeland and many nations in Africa has enacted GMO Consumer legislation and has introduced mandatory labeling for all foods containing GMOs. Operational field testing regulation have also been implemented in Argentina, Brazil, Mexico, Chile, Costa Rica, Cuba, India, Philippines. \texttt{http://www.centerfor foodsafety.org/geneticall7.cfm} (accessed on July 3, 2008)
public opinions for regulating the government approval of GM foods.\textsuperscript{145}

Question arise what are genetically-modified foods?

The term GM Foods or GMOs (genetically-modified organisms) is most commonly used to refer to crop plants created for human or animal consumption using the latest molecular biology techniques. These plants have been modified in the laboratory to enhance desired traits such as increased resistance to herbicides or improved nutritional content. The enhancement of desired traits has traditionally been undertaken through breeding, but conventional plant breeding methods can be very time consuming and are often not very accurate. Genetic engineering, on the other hand, can create plants with the exact desired trait very rapidly and with great accuracy. For example, plant geneticists\textsuperscript{146} can isolate a gene responsible for drought tolerance and insert that gene into a different plant. The new genetically modified plant will gain drought tolerance as well. The best known example of this is the use of B.T.\textsuperscript{147} genes in corn and other crops. Like Bt cotton crystal protein genes have been transferred into corn, enabling the corn to produce its own pesticides against insects such as the European corn borer.\textsuperscript{148}

Reason given in favour of GM goods is that the world population is increasing day by day, hence ensuring an adequate food supply for this booming population is going to be a major

\textsuperscript{145} http://mm.csa.com/discovery guides/gm food/overview.php (accessed on July 3, 2008)

\textsuperscript{146} A plant geneticist is a scientist involved with the study of genetics in botany. Typical work is done with genes in order to isolate and then develop certain plant traits. The occupation has since grown to encompass advancements in biotechnology that have led to greater understanding of plant breeding and hybridization. Enwikipedia.org/wiki/plant-geneticist. (accessed on July 5, 2009)

\textsuperscript{147} B.T. or Bacillus thuringiensis, is a naturally occurring bacterium that produces crystal proteins that are lethal to insect larvae.

\textsuperscript{148} supra note 145.
challenge in the years to come and GM foods promise to meet this need in a number of following ways like:

(a) **Pest-resistance** crop losses from insect pests can be staggering, resulting in devastating financial loss for farmers and starvation in developing countries. Farmers typically use many tons of chemical pesticides annually. Consumers do not wish to eat food that has been treated with pesticides because of potential health hazards, hence, growing GM goods such as B.T corn can help to eliminate the application of chemical pesticides.\(^{149}\)

(b) **Herbicide tolerance**: For some crops, it is not cost effective to remove weeds by physical means such as tilling, so farmers will often spray large quantities of different herbicides (Weed Killer) to destroy weeds, a time-consuming and expensive process, that requires care so that the herbicide does not harm the crop plant or the environment. Whereas, crop plants genetically engineered to be resistant to one very powerful herbicide, could help prevent environmental damage by reducing the amount of herbicides needed e.g. Monsanto\(^{150}\) has created a strain of soyabeans genetically modified. A farmer grows these soyabeans which then only require one application of weed killer instead of multiple applications.

(c) **Disease resistance/cold tolerance**: There are various viruses, fungi, bacteria that cause plant diseases. Plant biologists are working to create plants with genetically engineered resistance to these diseases. An antifreeze gene from cold water fish has been introduced into plants such as tobacco and potato. With this

\(^{149}\) *Ibid.*

\(^{150}\) Monsanto is an agricultural company. Farmers around the world use its innovative products to address on farm challenges [http://www.monsanto.com](http://www.monsanto.com) (accessed on July 19, 2008).
antifreeze gene, these plants are able to tolerate cold temperatures that normally would kill unmodified seedlings.

(d) Nutrition Malnutrition is common in the world where impoverished people rely on a single crop such as rice for their diet. However rice does not contain adequate amount of all necessary nutrients to prevent malnutrition. But if rice could be genetically engineered, vitamin and nutrient deficiencies could be alleviated. Researchers at the Swiss Federal Institute of Technology For Plant Sciences have created a strain of “golden” rice containing high content of vitamin A.151

Inspite of the above discussed advantages of genetically modified crops/foods, environmental activists, religious organizations, public interest group, professional association and other scientists and government officials have all raised concern about its actual health benefits. It is estimated that upto 45 percent of US corn and 85 percent of soyabean is genetically engineered. It has also been estimated that 70-75% percent of processed foods on supermarket shelves – from soda to soup, crackers to condiments – contain genetically engineered ingredient.152

Main Health Hazards of GM Foods are:

With regard to human health, the principal hazards identified due to use of GM foods are accrued toxicity, allergenicity and horizontal gene transfer, in particular, as far as development of antibiotic resistance is concerned.

(a) Toxicity A number of plants produce toxins as a protection against insect and fungal pests. These are parts of their innate defence systems and, as such, are important to maintain.

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151 supra note 145.
152 Ibid.
They are generally present at such low levels that humans and animals are able to tolerate them. Through genetic modification, however, plants which do not naturally contain toxins may become toxic or increase their levels of toxins.153

(b) Allergenicity Similarly, a GM Food containing DNA derived from a species that has known allergenic effects may acquire allergenicity. An example of this kind is that of the soyabean variety genetically modified to contain, a certain protein from Brazil nut, in order to increase its nutritional value. The modified soyabean turned out to have acquired the same allergenic qualities as the parental crop, the Brazil nut.154

Allergenicity may also be caused by novel proteins that the organism produces, or produces, in increased quantities, as result of the genetic modifications. This was the case with the famous 'Maize', genetically modified to contain a plant pesticide protein which kills insects and which was believed to be potentially allergic. This maize, initially registered by the US government for animal feed and industrial purposes only, had to be withdrawn from production altogether when it turned out that maize for human consumption had been contaminated.155

(c) Horizontal Gene Transfer The transfer of gene is risk to human health especially, in case of transfer of antibiotic resistance marker genes. During the creation of GMOs, antibiotic resistance gene are placed into the vectors which carry the inserted gene of interest as 'markers' so as to determine whether

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154 Ibid.
155 Ibid.
the gene of interest has been successfully inserted into the genome of a plant cell. The cells are treated with the antibiotic in question. Even though used only as markers, the antibiotic resistance genes may remain in the GMO. The use of technology without antibiotic resistance genes has been encouraged by a FAO/WHO expert panel.156

(d) Environmental Adverse Effect of Genetic Engineering on Agriculture

As for environmental impacts of the use of genetic engineering are concerned in agriculture it could lead to uncontrolled biological pollution, threatening numerous microbial, plant and animal species with extinction, and the potential contamination of non-genetically engineered life forms with novel and possibly hazardous genetic material.

Despite these long term and wide-ranging risks, the US congress has yet to pass a single law intended to manage them responsibly. Despite the fact that our regulatory agencies have failed to adequately address the human health or environmental impacts of genetic engineering on the federal level, the existing laws are grossly manipulated. Among many bizarre examples of these regulatory anomalies is the current attempt by the Food and Drug Administration (FDA) in the US to regulate genetically engineered fish as “new animal drugs”.157 In Europe seeing the adverse effect on human health of GM Foods, most of the states such as Switzerland have banned the use and production of GM foods.158 The scientific evidence of health risks resulting from GM foods is

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156 This would be particularly relevant if antibiotic resistance genes, used in creating GMO's were to be transferred although the probability of transfer is low, the use of technology without antibiotic resistance genes has been encouraged by FAO/WHO expert panel. http://www.epha.org/a/3404 (accessed on July 6, 2009)
158 Many European Consumers are demanding the right to be informed whether food they consume has been genetically modified or not.
foods/plants found in the US are novel allergens, herbicide resistant, plants and also damage to human embryos. Test conducted on animals to know the effect on health of GM food/plants has shown adverse results. For example flavr savr tomato given to rats resulted in death of within fortnight. Similarly, GM forage maize given to chickens resulted in death of many chickens as those fed on non-GM feed. New Castle University research on gene transfer study found that eating food containing GM soya results in the inserted genes transferring to human gut bacteria.

Therefore it is evident that the general public is the guinea pig for GM food, and today's drugs may not be able to combat the diseases that may arise from eating the food. Human health can be seen as the greatest factor when considering the manufacturing of GM food. New diseases and/or viruses through the use of GM food is increasing and people are not aware of risks. Antibiotics or pesticides have not yet been created to combat the superbug and this is a concern for humans as it will infect people, and crops altogether.

India allowed commercial production of its first GM Crop, Bt Cotton, only in 2002. However, since then, India made a rapid progress in the production of GM cotton, having an area of about


Many children in the US and Europe have developed life-threatening allergies to peanuts and other foods. There is possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions. http://www.csa.com/discoveryguides/gmfoods/overview.php (accessed on July 3, 2008)


GM technology arrived in India in 1995 when the American biotech giant Monsanto formed a joint venture with India's Maharashtra Hybrid seeds Company (MAHYCO).
10 million acres under Bt Cotton in 2006. India is a large importer of soyabean oil (mostly crushed out GM soyabean. In addition, after the Union Government allowed commercialization of transgenic cotton, the country produces GM cotton seed from which is produced cotton seed oil and cotton seed cake/extraction (animal feed). But neither cotton nor the derivative products are marketed as transgenic variety. Currently, neither imported food products nor domestically produced ones are subject to labeling requirement from the point of view of genetic modification. Under existing Indian law, import of GMOs is subject to a prior licence to be issued by the Government. But no such licence is insisted upon for imported soyabean oil and the authorities turn a blind eye. In India also activists from 14 states of India, consisting of farmers organization, NGOs, consumer groups and women federations have pledged to keep India free of genetically modified foods and crops. The pledge was taken in a two day meeting (on February 25 and 26, 2008) held at Hyderabad. Which reviewed the available evidence on GM technology and its ramifications. The said coalition for GM free India has resolved to intensify the campaign to educate, create awareness and build public opinion against hazardous implications of the technology.

For GM foods, there is now a proposed amendment to make labeling mandatory under the Prevention of Food Adulteration Act, 1954 under the Ministry of Health and Family Welfare. GM

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164 States like, Orissa, Kerala and Uttarakhand have already declared themselves GM free food states. For details visit at Activists Promise a GM Free India http://www.doccentre.net/Tod/Tod1-Activists-promise-GM-free-India.php (accessed on August 20, 2009).
imports are being regulated through the Environment Protection Act 1986’s and 1989 Rules. Presently the Indian Bio-safety regulatory framework consists of “Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms and cells” framed in 1989. Under these besides GEAC, other following agencies are created:

- Review Committee on Genetic Manipulation (RCGM).
- Recombinant DNA Advisory Committee (RDAC).
- Institutional Bio-Safety Committees (IBSC).
- State Bio-Safety coordination committees (SBCC).
- District Level Committees (DLC).
- Bio-Safety Guidelines for Research.

Processed GM Foods will now be monitored and regulated by the Food Safety and Standards Authority of India (FSSAI) which has been established under the new Food Safety and Standards Act of 2006. The Act aims to establish a single reference point for all matters relating to food safety and standards by moving from multi level, multi departmental control to a single line of command. Under the said act manufacturing, distribution, sale import of GM foods is regulated as per the provisions of the Act and which can be done only as per the notification of the Central government in this regard. The Act also defined GM food. The said Act contains 101 sections. The food safety and standards authority of India has been set-up under the Chairmanship of Dr. P.I. Suvrathan. It is an autonomous statutory authority setup under the food safety and standards Act 2006 for laying down science based standards for articles of food and to regulate their manufacture, storage distribution, sale and import, to ensure availability of safe and wholesome food for human consumption. http://www.fssai.gov.in/EO1/Fresh-EO%20for%20consult/FSSAI.doc. http://supreme court caselaw.com/food-safety-standards-authority-of-India-(FSSAI).htm (accessed on August 20, 2009).

Section 22 of the Food Safety and Standards Act 2006 reads as: (1) Genetically modified foods, organic foods proprietary foods, functional foods etc.- save otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of 367
Act also provides for penalty for selling food not of the nature or substance or quality as demanded by the purchaser which extend as fine upto Rs. five lakh, whereas penalty for misbranded food can be extended to Rs. three lakhs and upto Rs. ten lakh penalty can be imposed for misleading advertisements as to the nature or quality of such food. The Act also empowers Judicial Magistrate under the provision of CrPC 1973, to pass a sentence of imprisonment for a term upto one year.\textsuperscript{167} The said Act shall have overriding effect not with standing anything inconsistent therewith contained in any other law for the time being in force.\textsuperscript{168} Till recently GM Food clearance were done at the end of the genetic engineering approval committee (GEAC) which comes under the Ministry of Environment and Forests.\textsuperscript{169} The Government of India has also amended the \textbf{Foreign Trade (Development and Regulation) Act, 1992} in 2006 whereunder imports of genetically modified organisms for food, feed or processing industrial processing, research and developments for commercialization or environmental release would be allowed only with the approval of the GEAC. Simultaneously all Shipments carried a declaration regarding the product being Genetically modified. Failing such

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food, irradiated food, organic foods, foods for special dietary uses, functional, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

\textsuperscript{(2)} Genetically engineered or modified food means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology.

\textsuperscript{167} Id, for details see Sections 48, 50, 52, 53, 56, 73.

\textsuperscript{168} Id Section 89.

\textsuperscript{169} \url{http://www.annieappleseedproject.org/gemofoprmabe.html} (accessed on July 3, 2009)
labeling on such GM material, the importer is liable for penal action under the Act.170

The existing protocol for safety tests and impact monitoring in India is extremely inadequate despite growing scientific evidence of the impact of GM Foods on Public Health. The report by Greenpeace on GM Food proliferation in India, titled “genetic gamble: safe food – the end of choice?”, was released on October 14, 2008, comes down heavily on the Indian government’s liberal policy on genetic modifications to food inspite of evidence of the health hazards involved. The report says, not a single study in the public domain has established the safety of these crops either with respect to human health or the environment. The report is extremely critical of the fact that GM foods are being approved without independent verification of their safety and there is no provision to allow consumers to know whether the food is dangerous for consumers health. Moreover the results of the field trials tests of various GM food and crops are kept secret.171

In short, the haphazard and negligent agency regulation of biotechnology has had serious consequences for consumers and


171 This is despite the fact that in order to bring about greater transparency in field trials of GM crops, the Hon’ble Supreme Court in the case Aruna Rodrigues & Ors. v. Union of India & Ors. (Commt. Pet (c) No. 295/2007 in WP(C) No.260/2005) on April 8, 2008, directed the Union Government to display all data on the toxicity and allergenicity of GM crops on the website of Genetic Engineering Adversary Committee (GEAC) the regulatory body under the ministry of Environment and Forests. The Court also halted further GM field trial approvals in the country. The quoram for the judgement consisted of Hon’ble Chief Justice and Justice R.V. Raveendran. 


the environment despite a finding by FDA scientists in the USA that these foods could pose serious risks. So far, there has been a complete abdication of any responsible legislative or regulatory oversight of genetically engineered foods in India. It is submitted that now is a critical time to challenge the government’s negligence in managing the human health and environmental threats from biotechnology.

(G) **Use of Botox and its Health Risks**

As we know, science has spared no field untouched, it has discovered a treatment for wrinkles too. Botox injection is the most common cosmetic operation. Botox is a drug made from a toxin produced by the bacterium clostridium botulinum. It is the same toxin that causes a life threatening type of food poisoning. A new study warned in London that Botox injections can lead to depression. Scientists have found that they also stop people from being able to express their feelings visually that leads to them keeping emotions bottled up inside and perceiving the world in a negative way. There are other risks of Botox like headache, temporary eyelid droop, nausea, squint/double vision, facial pain, redness at the injection site and muscle weakness. Pregnant women and people having any problem related to nervous system are not advised to take Botox. Sometimes it gives temporary relief of spasticity but may cause paraesthesias and muscle damage if used repeatedly. Again, till today, there is no regulatory mechanism or laws/guidelines to check the abuse of Botox either under any Central Law or under ICMR guidelines.

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The Hidden Health Hazards of Microwave Cooking

Microwave ovens are an important cooking and food heating tool in many modern homes. The research shows that microwave oven cooked food suffers severe molecular damage. When eaten, it causes abnormal changes in human blood and immune system. Persons working in microwave fields have reported headaches, eyestrain, over all fatigue and disturbance of sleep. These effects have been associated with the interaction of the microwave fields with the central nervous system of the body. The heating of milk in a microwave actually destroys much of the milk’s nutritional value; and the milk’s natural immunity and disease fighting qualities are negated. Other negative effects from microwave ovens include brain damage by causing electrical impulses in the brain to become confused or simply “short out” due to eating the reduced or altered nutritional content of “microwaved” food. Eating microwaved food have also been linked to heart attacks and cancers and can result in memory loss, lack of concentration, and lower mental development in children. Many plastic microwavable containers being noted to cause cancers. And, again there is no law or guidelines of the governments of the world to monitor the use of microwave cooking.

Briefly speaking, the rapid industrialization, unsafe working environment, improper installation and incorrect handling of mechanical devices generating electromagnetic waves at home and exposure to cooking fuel, has resulted in escalating environmental

\[\text{http://www.ccohs.ca/oshanswers/phys/microwave-ovens.html (accessed July 6, 2009)}\]
\[\text{http://www.greenprophet.com/2008/08/12/.../microwave-oven-health/ (accessed July 6, 2009).}\]
pollution and deterioration in the quality of indoor air. This exposes even the foetus to many known and unknown pollutants with recognized harmful effects. So, the foetus is no longer sheltered in the mother’s womb. It is threatened by the noxious environmental pollutants generated by modern agricultural and industrial practices crossing the physical barrier between a mother and her foetus. Noxious environmental pollutants generated by agriculture and industrial variants are playing havoc with the growth of the foetus.

We must remember that science does not exist in isolation from the larger community that feels effect of its research. The complex sensitive issue like when human life actually deems to begin i.e. at the conception or at the time of birth can only be addressed if scientific research is in congrunce with fundamental values. In the end, it can be said that both law and science without conscience ultimately result in the death of the soul, and this has to be avoided for better future of mankind.

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179 Ibid.
180 supra note 70 at 173.