

EXAMINING THE INTRICATE RELATIONSHIP BETWEEN LAW AND BIOETHICS

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“Occasionally science makes procedures possible that are so radical, that those at the interface between science and society are called on to define moral standards for society.”¹

Introduction

Imagine a world where we could sit in the cozy comfort of our homes, and have a clone to go out and work hard, while you reap the benefits. Yes, this may not be a distant dream, but a near reality, when human cloning would be possible and permitted. The first successful cloning was that of “Dolly the sheep” in 1997. Dolly, an ewe, was the first mammal to have been successfully cloned from an adult cell, by a biologist Ian Wilmut. She was cloned at the Roslin Institute in Edinburgh, Scotland.²

After that a series of animals like Afghan Hound,³ a cow, a Holstein heifer named "Daisy" was cloned by Dr. Xiangzhong (Jerry) Yang using ear skin cells from a high-merit cow named Aspen at the University of Connecticut on June 10, 1999; also a pig, and even a rhesus monkey,⁴ and the day is not far behind when a human baby would be cloned. We are living in a world driven by technology, and have ushered in a new era of embryonics, cryonics, genetics, stem cell cropping and right up to human cloning.

Science and its development have reaped unimagined benefits on mankind, on context of healthcare. The ideal of scientific freedom is definitely restricted and may fail to achieve its fullest potential when fettered with constrained imposed by society and law. However the balancing of these competing entities with sometimes conflicting

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¹ M. Warnock, *The Ethical Regulation of Science*, 450 (20) Nature 615 (2007).

² http://www.sciencedaily.com/articles/d/dolly_the_sheep.htm (last visited Oct. 17, 2013).

³ <http://news.nationalgeographic.co.in/news/2005/08/photogalleries/dogclone/> (last visited Oct. 19, 2013).

⁴ http://en.wikipedia.org/wiki/List_of_animals_that_have_been_cloned (last visited Oct. 17, 2013).

interests has to be done for extending justice and protection of human rights, by imposing scientific responsibility. Scientists are the gatekeepers of new knowledge and as such they have a special responsibility to the rest of the society.⁵

Law is a tool, or instrument to regulate human conduct. Since times immemorial laws have been developed by man for civilized societies. The role of law thus, in the life of every man is an indispensable and omnipresent one. Every single sphere of human lives today is regulated by a plethora of laws, right from birth to death.

In this scenario the rapidly changing and highly advanced field of biotechnology, has further widened the scope and ambit of the arm of law to stretch out and encompass an area that immediately affects our human bodies. As the relationship between humans and the power of biotechnology to affect the human body becomes very real and so entwined, there arises the need for definitive codes for conduct, termed as bioethics to protect the basic human rights of every individual that may be affected by the role of biotechnology in his life. These may be many a time controversial in nature, as scientific research conflicts with invasion into the basic rights of people.

It is certain thus, that medical research and bioethics are uneasy, but inevitable bedfellows with the law.

Definition of Bioethics

Bioethics is a discipline dealing with the ethical implications of biological research and applications especially in medicine.⁶

Bioethics can be termed as a moral perception relating to ethical biological research, medical practices followed, and are further entwined with contemporary political policies, law and even religious and philosophical beliefs.

The term “bioethics” was coined by Fritz Jahr in 1927, and stems from the combination of two Greek words, *bios* or life and *ethos* or behavior. However he restricted the application of the term to biological research involving animals and plants.⁷

⁵ International Council for Science, *Freedom, Responsibility and Universality of Science*, ICSU Paris13 (2008).

⁶ www.merriam-webster.com/dictionary/bioethics (last visited Oct. 22, 2013).

⁷ F. Lolas, *Bioethics and Animal Research: A Personal Perspective and a Note on the Contribution of Fritz Jahr*, 41(1) Biol. Res.19-23 (2008).

It was much later that the term “bioethics” was extended to include global ethics, when in the year 1970, the American biochemist Van Rensselaer Potter, developed a discipline to represent a link between biology, ecology, medicine, and human values, in order to attain the survival of both human beings and other animal species.⁸

Background

The post Second World War (1939-45) period brought forth the horrifying and gruesome clandestine medical practices that had been carried out on humans especially the Jews, without their consent, during the Nazi regime. These humans experiments, rampant biopiracy, and organ transplants led to the death, permanent health issues and disfigurement, of millions of humans, disclosure of which took place at the post war Nuremburg trials. This led to the first ever International Statement on the ethics of medical research using human subjects, and particularly laying down the fundamental principle of voluntariness of consent, in the form of the Nuremburg Code formulated in 1947.⁹

Further when the United Nations General Assembly adopted the Declaration of Human Rights, 1948, specific mention of rights of human beings subjected to involuntary maltreatment was included in the declaration.¹⁰

In 1966, the International Covenant on Civil and Political Rights categorically stated, “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific treatment.”¹¹

However for the first time the fundamental principles and specific guidelines in respect of human participants in scientific research, were laid down, in the form of the Helsinki Declaration¹² in 1964, which prompted the Indian Council of Medical Research to lay down a policy statement in the form of “Ethical Considerations Involved in Research on Human Subjects,” to regulate clinical research in India.

⁸ Goldim, Jr., *Revisiting the Beginning of Bioethics: The Contributions of Fritz Jahr (1927)*, *Perspect Biol. Med.*, Sum, 377-80 (2009).

⁹ The Nuremburg Code, *Trials of War Criminals before the Nuremburg Military Tribunals under Control Council Law No. 10*, 181-82, Washington D.C., U.S. Government Printing Office (1949).

¹⁰ Universal Declaration of Human Rights, 1948 art. 5.

¹¹ International Covenant on Civil and Political Rights, 1966 art. 7.

¹² World Medical Association Declaration of Helsinki, Helsinki, 1964.

The Belmont Report 1979, that was published by the National Commission for the Protection of Human subjects of Biomedical Research , in respect of Ethical Principles and Guidelines for Protection of Human subjects and expounded the cardinal principles of respect for persons, beneficence and justice, as inherent to any bioethics code.

The Report states the basic ethical principles include:

1. **Respect for Persons:** Individuals should be treated as autonomous agents, and second that persons with diminished autonomy are entitled to protection. Respect for persons demands that subjects enter into research voluntarily and with adequate information.
2. **Beneficence:** The Hippocratic maxim “do no harm” is the foundation of this principle. It means that scientific research must (a) do no harm, (b) maximize benefits. The obligations of beneficence affect both individual and society at large.
3. **Justice:** Fairness in distribution of benefits or what is deserved.¹³

Since then, a number of nations have developed their Bio-ethic Codes, the most recent International documents being the UNESCO’s The Universal Declaration on Human Genome and Human Rights, (1997), The International Declaration on Human Gene Data, (2003), and Universal Declaration on Bioethics and Human Rights, (2005).

The tremendous grass root revolution advances in the field of genetics, genomics and molecular biology have necessitated their regulation to provide adequate safeguards, to protect the rights and welfare of human entities who become the most vital partakers in biotechnological research. Human life has been touched and altered in several ways due to advanced technology used in key areas of social and individual lives of humans.

Few of the areas in which important ethical and legal issues are closely related to each other are:

- Abortion
- ART’s (Artificial Reproductive Techniques), Embryonics
- Sperm and Egg Donation and Surrogacy
- Contraception and population control

¹³ www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (last visited Oct. 20, 2013).

- Euthanasia and issues regarding use and continuation of Life support machines.
- Organ Donation and Transplantation, Bio-harvesting, and Xeno transplantation
- Blood Transfusion
- Genomics and Eugenics
- Recombinant DNA Technology
- Human Cloning and Cryonics
- Genetically modified food
- Nano-medicine
- Transexuality
- Brain Mapping
- Bio-piracy.
- Stem Cell Research

In view of the expanse of the field of biotechnology, and measures taken all over the world to develop Bioethical codes and norms, In India too, the process of regulation was required, taking into consideration the number of these technologies introduced in India and the ongoing research in this field.

Development of Bioethics in India

Considering the enormity of biomedical research undertaken globally and for being in consonance with the requirements of the W.H.O. (World Health organization),¹⁴The Indian Council of Medical Research, New Delhi, brought out the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' in 1980. They were revised in 2000 as the 'Ethical guidelines for Biomedical Research on Human Subjects.' The third revised guidelines published in 2006, take note of these changes, in national policies, Indian culture, addresses ethical issues in specific situations to the extent possible.¹⁵

The numbers of legal, moral, social, and religious issues that arise out of Bio-medical Research have sought to be regulated through 12 General Principles:

- 1. Principle of Essentiality:** Wherein the research must be of advantage and benefit to the human species an ecological environment and well being of the planet.

¹⁴ World Health Organization, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva (WHO 2000).

¹⁵ www.icmr.nic.in/ethical_guidelines (last visited Oct. 22, 2013).

2. **Principle of Voluntariness, Informed Consent and Community Agreement:** An informed and free consent is the most rudimentary of the ethics required to be followed by scientific researchers. Consent of the legal guardian in case of incapability to give consent.
3. **Principle of Non-Exploitation:** In absence of the above principle, likelihood of exploitation due to ignorance or illiteracy of participants would exist.
4. **Principle of Precaution and Risk Management:** Protocols for minimum risks or measures to prevent disasters.
5. **Principle of Professional Competence:** Qualified persons to perform experiments or research and personal integrity of scientists.
6. **Principle of Accountability and Transparency:** Experiments should not be carried on under a veil of secrecy, and measures for checks and balances to ensure accountability of every procedure. Monitoring through keeping of detailed notes and preservation of data.
7. **Principle of Risk Management:** Disaster management in event of any sudden fallacy or error of judgment.
8. **Principle of Maximization of Public Interest and of Distributive Justice to Least Advantaged:** Based on the principles, of autonomy, beneficence, and justice as laid down in the Belmont Report
9. **Principle of Institutional Arrangements:** Duty imposed on the institution for proper recording and preserving of data.
10. **Principle of Public Domain:** Research must be made public through publication.
11. **Principle of Totality of Responsibility:** Professional and moral responsibility.
12. **Principle of Compliance:** General and positive duty, to ensure letter and spirit of the guidelines, and to see that they are scrupulously observed and duly complied with.

As a part of Ethical Review Procedures, it is mandatory that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB).

Religious and Cultural Issues

Consider a case where a orthodox religious man of Jewish or Islamic faith, that does not permit the eating of the meat of pigs, if told that he been transplanted with a heart valve made of pig genetic material., may actually go into a shock if he feels his religious beliefs have been vilified. Pigs are currently the animals of choice as studies have

shown that porcine islet cells and genetic material can be engineered to create human organs. Research in this arena is being carried out extensively.

A religious restriction on the consumption of pork exists in Jewish dietary laws (Kashrut) and in Islamic dietary laws (Halal). Such restrictions originate from the laws of the Hebrew Bible, and from the laws of the Muslim Quran respectively. Among Christians, Seventh – day Adventists consider pork taboo, along with other foods forbidden by Jewish law. The Ethiopian Orthodox Church and Coptic Orthodox church of Alexandria also discourage pork consumption.¹⁶

A new trend of *Cadaver Donor Transplants*, through the modality of making “Living Wills,” is currently in vogue in many countries, for certain organs like eyes that can be harvested from a human corpse, stored scientifically and successfully implanted in a done. The recipient of such donor organs may however some religious or cultural inhibitions in respect of the deceased donor.

Religious and Cultural dilemmas arise out of certain areas of biotechnology, particularly, in cases of contraception, abortion, Assisted Reproductive Technology, (ART), surrogacy, cloning, transplantation of organs and xeno-transplantation.

According to the Indian Council for Medical Research, the fast developing science in the area of cloning, stem cell research, and eugenics or selective breeding, and the ensuing misuse of the same, in the name of racial or ethnic purification, is a grim reminder to the radically racial undercurrents during the Nazi period. The concern has become even more serious in recent years due to the possibility of commercial eugenics. With the breakthrough in DNA Recombinant Technology, that can untangle the mysteries of the human genome sequencing in 2000, further gene therapies for curing genetic diseases, genetic engineering or selection of embryos for sex selection or even designer babies, or to avert genetic abnormalities, *in vitro* fertilization, organ transplantation, nuclear transfer for regenerative therapy has become possible, and has come under the scanner. These issues create conflicts in particularly vulnerable human population. The Human Genome Project (HGP) creates legal issues, about patenting and others in respect of dignity, autonomy and justice and public debate.¹⁷

¹⁶ http://en.wikipedia.org/wiki/Religious_restrictions_on_the_consumption_of_pork (last visited Oct. 17, 2013).

¹⁷ *Id.*

Furthermore, psycho-sociological problems of identity, impact on religious beliefs, family and society bring forth a dearth of problems associated with research

In this arena the role of a strong Code of Bioethics could address these problems. The researcher must be very clear and transparent to the participant in any biotechnological procedure where the religious sentiments arising out of such transplantation of organs from persons of different faith are concerned.

With regard to the early embryonic stage of human life, the Catholic Church for example has raised a loud voice against the artificial termination of pregnancy. Various religious cultures have showed and underpinned the value of life, and the direction that science and technology should take in this regard. It is argued that the global competition in science and technology makes it necessary to transcend the views concerning the value of life propagated by particular religious culture.¹⁸

The socio-legal, and even moral issues in respect of surrogacy, are very complex, and in fact need to be addressed with a comprehensive legislation. Surrogacy involves a conflict of human interests and has inscrutable impact on the primary unit of a family.¹⁹

The moratorium on human germ-line therapy is an example of the recognition that there must be ethical restraints on the use of what is technically feasible. Part of the reason for this restriction is uncertainty about the long-term effects of such interventions. There is also considerable uncertainty about the environmental consequences of the genetic manipulation of plants. These issues are scientific questions that need to be answered before we have an adequate basis of knowledge for reaching final ethical decisions. The use of biotechnology in relation to human beings is governed by the Hippocratic principle that interventions must be for the benefit of the individual person concerned.²⁰

Xeno-transplantation carries with it a host of moral, religious and ethical issues. It means the transplantation of cells, tissues or organs, from one species to another²¹ and more often in context of transplant from animals to humans. The dearth of human led to the search of other resources like animals, most nearest to the Homo

¹⁸ <http://csi.sagepub.com/content/59/2/160.abstract> (last visited Oct. 23, 2013).

¹⁹ 228th REPORT OF THE LAW COMMISSION OF INDIA.

²⁰ John C. Polkinghorne, *Ethical Issues in Biotechnology* (Oct. 21, 2013), <http://www.genethik.de/ethical.htm>.

²¹ CHAMBERS DICTIONARY (10th ed. 2006).

sapiens like apes, simians, and monkeys. However, in additions to the rejection of the animal tissue, more serious concerns regarding transfer of zoonoses or animal diseases, and trans-genesis or the introduction of foreign genes, of animals into humans, would multiply the health issues arising out of xeno-transplantation. Moreover, particularly in some religions like Hinduism, or the Jewish or Muslim religion, the very basic issues of religious sanctions would pose a serious threat to the recipient. Some religious sects advocate practicing vegetarianism, and may oppose the very ideology of xeno-transplantation, and genetically modified foods.

Prohibited Areas of Research

There are certain areas of research, which are universally prohibited:²²

1. Any research related to germ line genetic engineering or reproductive cloning.
2. Any *in vitro* culture of intact human embryo, regardless of the method of its derivation, beyond 14 days or formation of primitive streak, whichever is earlier,
3. Transfer of human blastocysts generated by parthenogenic or androgenic techniques into a human or non-human uterus.
4. Any research involving implantation of human embryo into uterus after *in vitro* manipulation at any stage of development, in humans or primates.
5. Animals in which human stem cells have been introduced at any stage should not be allowed to breed.

Conclusion

Different fields of biotechnology research and development have inspired different reactions and decisions in the last decade. For each innovation, there are clearly more than one public opinion, ethical committee advice and national policy framework. Conversely, in each country, social mobilizations and political regulations do not only depend on general attitudes towards biotechnology, but in great part also on the specific matter of each innovation as it connects with proper national, local or individual issues. In this context, each biotechnological innovation is much more than one item of health, agricultural, and industrial biotechnologies, whose ethical and social

²² See *supra* note 15.

issues would have been addressed once and for all.²³

It has become that law in this field, is required to be developed in the light of social sciences. As law has been defined as an instrument of social change, it will have to spread its wings to encompass every aspect of the pure sciences like biotechnology, to safeguard the interests of the society.

A strong Bioethical commitment giving due respect to the human race, and its beneficial needs must be the foremost of every research program. Even in the race of keeping up with the global scientific developments, we cannot overlook the peculiar needs, characteristics, and diversity of the Indian population. Man should not be made a guinea pig, for experimentation by the elitist classes for their own selfish purposes.

The sustainable development aspect also requires a pragmatic approach, and the Biotechnological Revolution must maintain equilibrium to reduce the experimentation on humanity, without hindering scientific freedom. Precautions must be taken to analyze, whether it is merely greed that spurs our inventions.

Though various nations undertaking vast quantum of biotechnological research, and formulate their own ethical codes, there is a need for common international norms, to have uniform ethical codes, and avoid circumvention of national policies or legislation, that may forbid the application of certain new techniques, due to certain social and demographic reasons. For example when the Pre-Conception & Pre-Natal Diagnostics Techniques Act, (Prohibition of Sex Selection) Act, 1994, makes the sex determination test an offence in India, due to the high rate of female feticide, then Indians may go to other countries where such tests are not prohibited by law.

Such incidents are just representative of the different ethics followed in application of bio-research applications that result in the indirect violation of National Policies, on different, in the absence of common and uniform Bioethics for all countries.

Yes, we can invent and discover, but how far should we? Should man pursue his intellectual and creative pursuits to the extent of destroying beliefs, faiths, human values, humanity and altering

²³ Nicolas Rigaud, *OCED International Futures Project on "The Biotechnology to 2030: Designing a Policy Agenda"* (Feb. 2008), <http://www.biotechnologie.de/BIO/Redaktion/PDF/de/laenderfokus/indien-oecd-vollbericht-mit-anhang.property=pdf,bereich=bi,sprache=de,rwb=true>.

family dynamics? The pertinent question is that, undoubtedly man has always like to experiment, but when given a chance should he play God?

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