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Medical Experimentation: Ethico-Legal Concerns

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Abstract - The researcher in this paper has discussed about the concept of the Clinical Trials in our country and its relevance in modern life. Along with the concept, the author has further discussed about the ethical and legal concerns related to the clinical trials conducted on human subjects. With the development of every new drug, the step which comes further is to test that drug to examine its efficacy and safety for human consumption. The examination of the said drugs can be made through medical experimentation. There are various laws which regulate theses trials.

Keywords - Drugs, Ethics, Human subjects, Laws, Modern Life, Regulations.

I. INTRODUCTION

Scientific advancement and patients' safety are two side of same coin. We cannot have one at the cost of other. Whenever we talk about medical profession we Indians compare it to the work of humanity, we treat doctors like gods in our life. Medical profession is known for its ethnicity and is also bound by various national and international guidelines.

Human experimentation has become a need in modern life to test the quality of the drug. Misuse of these human subjects has led to violation of ethics. Though, there are several guidelines which make companies under obligation to abide by them but it is gradually seen that there is an increase in misuse of the experimentation. Specially, the people of vulnerable groups, women, children and the mentally disabled people are being victimized by these pharma companies and do gross violation of human rights.

The participants who are involved in the trials are entitled to know everything about the trial and the risks as well as the benefits involved in the trial. By the virtue of human being everyone has equal right to have health facilities in our country.

The next issue of Informed consent during clinical trials. When a said pharma company starts conducting a clinical trial, they need human subjects on which they can experiment their drugs. Now, the human subjects are not forced by the companies to get experimented by them. They voluntarily participate in the necessary for the company before they start a trial. The participants should be wholly informed about the trial, its impact and consequences, about the risks and benefits. Then after they can give consent to the company to involve in the clinical trial. There is a lack of implementations of methods related to the consent procedure in India. There is a need of a proper judicial system which makes necessary for the companies to give proper justification about the participation of the human subjects in the clinical trials. And in the case of infringement of human rights strict action should be taken against the company.

Human Experiments are not new to the world and have been practiced in ancient history. However, no laws and regulations were established in early period to protect the subjects of such experiments. The recognition of human rights and needs for regulations were not assessed in early period as the experiments were mainly practiced on prisoners, slaves, family members or the experimenter himself. It was only after World War II and Nuremberg doctor's trial, the first regulation of international law towards human experimentation was made vide Nuremberg Code. However, the Code had little impact on worldwide research practices, as it was not binding under the law of individual states.[1] The code was criticized and its significance was disregarded by the physicians who considered it as "too uncompromising and too inhospitable to the advancement of science".[2] Thereafter, in the year

1 *Paul S. Appelbaum Et Al., Informed Consent: Legal Theory And Clinical Practice 219 (1987); Karine Morin, The Standard of Disclosure in Human Subject Experimentation, 19 J. LEGAL MED. 157, 170 (1998) (noting the lack of response to the Nuremberg Code in the U.S. scientific community).*

2 *Ileana Dominguez-Urban, Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally, 30 CORNELL INT'L L.J. 245, 282 (1997) (citing Jay Katz, Human Experimentation and Human Rights, 38 ST. Louis U. L.J. 7, 17 (1993)). Professor Katz has found that physicians disregard the doctrine of informed consent, inter alia, "to get research underway, advance science, and obtain research grants for the sake of protecting their laboratories and professional advancement." Jay Katz, The Consent Principle of the Nuremberg Code: Its Significance Then and Now, in George J. Annas & Michael A. Grodin, The Nazi Doctors And The Nuremberg Code: Human Rigrrs In Human Experimentation 231 (1992).*

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1948 the United Nations adopted and reclaimed the Universal Declaration of Human Rights (UDHR). Although the declaration was not binding but it promoted human, civil, economic and social rights as part of the foundation of freedom, justice and peace in the world. Later, in every declaration, convention or guidelines on biomedical research, clinical research, biology and science technology adopted by the World was in the lights of UDHR.

One of the few other regulations adopted internationally to streamline human experimentation are as below:

1. Declaration of Helsinki:

This was the first international regulation written by physicians for physicians.[3] Prior to the Declaration of Helsinki, the World Medical Association adopted the Principles for those in Research and Experimentation, which included the principle that "informed consent must be in writing for experimentation on both sick and healthy patients. This Declaration was originally adopted in June 1964 and has since been amended multiple times. The Declaration of Helsinki lays out the basic principle that, "In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time." The Declaration was later amended, and it laid down that in case of experiments with vulnerable subjects, an informed consent be obtained by a doctor who is not involved in the experiment and has no connection in the research in any manner. Such consent was preferred to be in writing. In effect this amendment relaxes the process as compared with Nuremberg Code as it allowed consent by legal guardian in case the subject is legally incompetent. The Declaration had distinguished guidelines for therapeutic and non-therapeutic research and made consent mandatory on in the latter case. In spite of amendments the Declaration was not entirely detrimental to the rights of informed consent. The Declaration also laid down process of review of the research protocols by an independent committee which resulted in improvement from Nuremberg Code.

2. UNESCO Declarations:

On recognizing the violation of human rights towards unethical human experimentation in 1970s, UNESCO started involvement in the field of bioethics. In the year 1993 the UNESCO started bioethics program for progress of life sciences which included testing on humans. Three Declarations on the bioethics and human rights adopted by UNESCO since 1997 are as below:

- **Universal Declaration on the Human genomes and Human Right, adopted in 1997**

  The research on Human genomes under this declaration prohibited all kinds of discrimination based on genetic characteristics and respected human dignity, freedom and human rights.

- **Universal Declaration on Human Genetic Data, adopted in 2003**

  The Declaration laid regulations towards collection, processing, storage and use of human genetic data.

- **Universal Declaration on Bioethics and Human Rights, adopted in 2005**

  This Declaration laid down international standard-setting to help states make laws on the dilemmas that was caused by the rapid developments in science and technology.

3. WHO Guidelines for Ethics Committees:

The WHO alongwith and Council of the International Organization of Medical Societies (CIOMS) worked towards making the International Ethics Guidelines for Biomedical Research involving Human Subjects to serve as a model for states drafting national legislation on human research. It surpassed the Helsinki Declaration in safeguarding the vulnerable subjects to experiments. Its purpose was to safeguard dignity, rights, safety and well-being of all actual or potential research participants.

4. Convention on Human rights and Biomedicine:

This Convention was drafter in 1997 on the lines that "interests of human beings should always come before interest of science of society". This convention was the first legally binding international treaty to govern human experimentation. The Convention banned all kinds of discrimination based on genetic characteristics and allowed the genetic engineering only for preventive, diagnostic or therapeutic reasons provided it does not result in change of genetic make-up of a person's descendants. The Convention however allowed the research which entails only minimal risk and minimal burden for the individual concerned. The additional protocols required approval of inter disciplinary committee to examine the ethical and legal acceptability of the research before research is undertaken.

3 *World Medical Association, Principles for Those in Research and Experimentation, 2 WORLD MED. J. 14 (1955) [hereinafter WMA Principles]. The WMA Principles, like the Nuremberg Code, specifically state that they are binding on physicians, as compared with subsequent international standards, which state that they merely serve as recommendations. Bernard Dickens, The Challenge of Equivalent Protection, in CLINICAL TRIALS IN DEVELOPING COUNTRIES II).*

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Impact of internationally adopted regulations and clinical trials in India:

According to international instruments of medical ethics[4] *all experiments on human must be conducted in line with three ethical principles A) Respect for persons, B) Beneficence, C) Justice. These ethical principles are transformed to laws.*

The position of the Doctor in India is at par with God. They are given the status higher as a life savior and his position fall in the category of Basic needs of the individual. To respect the status given to the Doctors and Medical Practitioners it is their obligation to exercise their duties with highest Degree of care to cure diseases and to give treatment so as to save the life. However, with the blind fold of lucrative benefits and compensation the Medical Practitioner and associated groups have diverted themselves from the motive to save lives of every individual to benefit of the society at the cost of loss of lives of many. Clinical trials conducted on humans is an alarming unethical practice happening all over the world which has violated human rights at large. Thus, the concept of clinical trial is controversial since its emergence. Moreover, no strong precedent penalizing the culprits have been passed yet to cause fear of law and order. The culprits get away with the charges of misconduct by filling pockets of the subjects and the authorities and make statements about successful results obtained by the trials which will cause benefit to society at large. Even if the result of experiment is ultimately beneficial to others or even to subject himself, this does not mean that therapy served an important purpose.

Furthermore, due to globalization India has become a target place for participants for clinical trial. The illiterate and poor population of India is the easy baits for the big pharma fishes. The weak regulatory framework has resulted in many tragedies costing lives of many. The researcher believes that such clinical trials are important for development of medicine.

Following are few such concerns, which has to be addressed and regulations at international level are not adequate:

- *P*rotection of rights, safety and well-being of human subjects to the clinical trial;
- Amendment requires in the existing protocols and guidelines;
- Formation of inter disciplinary and ethical committee for reviewing the clinical trials;
- Constant check on the competence of such formed committees;
- Balancing interest of society at par with individual's interest;
- Pre and Post health services to the subjects for minimising risks involved;
- Evaluation and check on the competence and qualification of Researchers, Experimenters and Authorities appointed for taking consent from the subjects;
- Transparency with Media, Government, NGOs, research organisations and social groups in resolving issues at threshold.[5]

II. CONCLUSION

It can be concluded that the role of Legislature, Judiciary in this matter is not sufficient which has to be verified as per the need of society and development of Science & technology.

When we want to understand the situation in India we must begin with the critical examination of the human rights violations in clinical trials conducted in India. We need to find solutions to the problems so that trials in India can be conducted with strict regulations encouraging more research in the same field. General rules of international law for the protection of human rights and should govern the formulation and application of monitory principles so that achieving the target number of patients would remain ignored and patients life would be considered of prime importance. The controversies relating to clinical trials are not something which can be decided by formulation of regulations in black and white letters. Rather it's grey interface of elements like law, ethics, scientific development, human rights and social good. As these scientific tests and trials involve application of advanced technologies, there is a need of well framed rules and laws for the conduct of these tests and trials.[6] We cannot allow the pharmaceutical industry to go further in the direction in which it seems to be headed today, i.e. in the direction where medical ethics, rules and human rights are sacrificed for earning target profits. The guidelines of the Indian

[4] Council for International Organization of Medical Sciences, CIOMS, 2002 available at https://cioms.ch/ accessed on 15th March 2013.

5 Mrityunjoy Seal, Clinical Trials in India and Role of a Legal Expert in the Ethics Committee available at https://www.latestlaws.com/articles/clinical-trials-in-india-and-role-of-a-legal-expert-in-the-ethics-committee-by-mrityunjoy-seal/ assessed on 25th March 2017

6 Priyesh Sharma, Future of Clinical Trials in India, available at http://www.mondaq.com/india/x/247668/food+drugs+law/Future+Of+Clinical+Trials assessed on 22nd March 2017.

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Council for Medical Research have weak legal sanctions.[7] There is a need for a stringent regulatory mechanism so that the participants are fully protected. Only when the laws and order is stringent the judicial decisions will be passed creating for protection of trial participants thereby creating strong precedents.

Ending clinical trial is not the solution. Such trials are absolutely necessary to provide the society with innovative and safe medical products. Since India has been made a market hub not only clinical trial but also for sale of pharma products, it is high time that advantage of this situation be taken by the Indian Government to revise its own policies to dilute the regulatory hurdles faced by the foreign pharmaceutical companies conducting trials in India and to bring the laws governing clinical trials at par with international trials.[8]

III. SUGGESTIONS

- ✓ Increase accountability through public access.
- ✓ Increase the powers of an Investigating/ Police authorities
- ✓ Set up Mechanism for Audio-Visual Recording of Informed Consent.
- ✓ Ethics committees shall work unbiased.
- ✓ The permissions for Global trials has to be taken from the Union health secretary ,Central government and State Government.
- ✓ The Biomedical Research on Human Participants (Promotion and Regulation) Bill, has to be passed.
- ✓ Compensation-, even if injury or deaths are not directly related to the CTs.
- ✓ Establish the new drug trial mechanism on recommendations of Prof. Ranjit Roy Chaudhury experts committee.
- ✓ Develop Standard Trial & design must be modified- to suit the targeted drug consumers.

7 Ibid

8 Hitt Sharma and Sameer Parekh, Clinical Trials Regulatory Frame Work in India- Pharmaceutical Regulatory Affairs: Open Access, ISSN: 2167-7689 available at http://www.witnesslive.in accessed on15th March 2013.

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