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Regulation of Clinical Trials and Rights of Participants in India: An Analysis

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ABSTRACT

This paper shall begin with a brief introduction to a few infamous and unethical clinical trials conducted in India in the past. The author shall discuss the role of the Supreme Court of India in a bid to do away with unethical trials and promote the rights of participants in the country and also discuss whether the Court has been successful in mitigating the practice of unethical clinical trials. The author shall also briefly discuss a few aspects of the New Drugs and Clinical Trial Rules, 2019. This paper shall also throw light on why mere interpretations of the fundamental rights guaranteed by the Constitution of India, 1950 is not sufficient in ensuring the various rights of participants to trials and that there is a need for separate or amendment to existing legislations in order to enforce the same. The author shall also highlight some the loopholes in the current legislation pertaining to clinical trials in India by which these trials violate the rights of participants. The author shall conclude by stating why it is pertinent to regulate clinical trials more efficiently and to ensure the rights of participants of those trials in India.

Keywords: *clinical trials, participants, rights, legislation.*

I. INTRODUCTION

India's population, availability of cheap labour, expertise and along with the various facilities that the Government provides, has resulted in the country to become one of the emerging hubs for clinical trials. The diversity in population has also made India an ideal market for clinical trials. Many pharmaceutical companies have zeroed upon India to be their location for clinical trials due to the easy availability of participants. There is no questioning on the increase in employment rates due to such companies conducting trials in India, but the problem with this entire set-up is the fact that these clinical trials have resulted in numerous illegal and unethical practices and the current laws on clinical trials aren't stringent enough to curb the menace.

II. FEW INSTANCES OF UNETHICAL CLINICAL TRIALS IN INDIA

The infamous cervical cancer screening trial was conducted way back in 1998 which involved randomized clinical trials of cervical screening on Indian women in Mumbai, Tamil Nadu and

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Osmanabad by U.S. based company and foundation. These trials were carried out on two groups of women- screened and unscreened. Amongst the 138,624 women who weren't unscreened, 254 women died as a result of the clinical trials.[2] Upon a complaint filed at the United States Office for Human Research Protection in 2011 by a U.S. based pathologist, it was discovered that these women were not given adequate information about the experiment they were participating in nor whether they were placed in screened or unscreened group. It was also found out that women from the lower socio-economic strata weren't screened which led to the question of whether it was ethical to deprive women of screening, which was available, merely based on their socio-economic status. It is saddening to see that the Indian Government did not take responsibility to ensure that the women's families be given some sort of compensation or look to hold the U.S. company liable for any of the damage.

The clinical trials on 1984 Bhopal Gas Tragedy victims, beginning in 2004, also stirred up controversies as it is said to have violated various international ethical principles. One of the main ethical issues was that these trials put the vulnerable and already ill patients at more risk. An approximate of fourteen participants died across the eight different trials that were conducted. None of the victims were aware that they were participating in clinical trials but were given Rs. 200 every time they came for a visit. The companies which conducted these trials, neither paid any sort of compensation to the victims' families nor did they disclose reports deaths of patients within the specified time limit. Although the hospital in question provided treatment to the gas tragedy victims free of charge, it was still instrumental in conducting unethical clinical trials. Many criticised the hospital as it used the victims as guinea pigs for the trials and the hospital made more than Rs. 10 million from the drug companies for helping them conduct the trials. What is to be noticed is that none of the trials required gas tragedy victims alone to be participants, but the hospital still went ahead and conducted trials on them without their knowledge or consent. It is indeed unfortunate that no form of strict action or punishment was imposed by the government on the hospital nor the pharmaceutical companies but only warning letters were issued to the companies, the content of which still remains unknown.

The HPV Vaccine trials in 2009 is another example of gross violation of ethical conduct needed for clinical trials. The HPV vaccine research project was launched in the states of Andhra Pradesh and Gujarat. 24,000 girls, aged between 10- 14, were given these vaccines which were provided by GlaxoSmithKline. Many human rights organizations raised alarms on the manner in which these trials were conducted and it was found that most of these girls happened to be

[2] Bagcchi, S. (2013), "Indian Supreme Court halts approval of new clinical trials until regulatory framework is set up", British Medical Journal News, 347, https://doi.org/10.1136/bmj.f5996

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from trial areas and there was no informed consent obtained from the parents of the girls. It was also found that the girls thought it was 'compulsory' to participate in the trials run by the 'government' and they weren't informed about the nature or purpose of the vaccine. The girls who had taken the vaccines suffered from side-effects and seven of those girls had died as a result of the trials.

III. SUPREME COURT ON CLINICAL TRIALS IN INDIA

The result of the HPV vaccine trials created a lot of unrest in the country with various health activists, media representatives, social groups, etc. asking the ICMR to respond to questions raised on the ethical conduct of the trials. The public were also concerned with the way clinical trials were being conducted in India. The Director General of ICMR did confess to the Indian Parliamentary Standing Committee on Health and Family Welfare, in April 2010, that the HPV Vaccine trials did not abide to the guidelines imposed by the DCGI. The Government failed to take any strict actions on any party even on the confession. This led to a Public Interest Litigation to be filed at the Supreme Court by the women's health activists.[3] The petition was filed against the DCGI, the ICMR, the states of Gujarat and Andhra Pradesh, PATH International, and the vaccine manufacturers Merck and GlaxoSmithKline. This petition highlighted that "more than 150,000 people were involved in at least 1,600 clinical trials and that during 2006-2011 at least 2,163 people have reportedly died in India while, or after, participating in such trials."[4]

In 2013, the Supreme Court heavily criticized the government and the Ministry of Health and Family Welfare and the Central Drugs Standard Control Organization (CDSCO) for not having addressed the menace by taking strict actions on previous issues and for falling into a deep slumber. The Court also labelled the unethical clinical trials on humans by pharmaceutical companies as to causing 'havoc' in the country.[5] The Court further suspended the approvals of clinical trials given by the DCGI and stated that no trials ought to be conducted for investigational drugs or medicines until a mechanism is set up to monitor them. This resulted in a significant drop in the number of clinical trials being conducted in India. The Court had also mandated for videotaped consent to be taken of every participant of the clinical trials in India.[6]

[3] Kalpana Mehta v. UOI, Writ Petition (Civil) No. 558 of 2012
[4] Supra note 2.
[5] Supra note 3.
[6] Ibid

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In the cases of *Rahul Dutta v. UOI*[7] and *Swasthya Adhikar Manch v. UOI*,[8] the Supreme Court ad heavily criticized the Government's inability to curb illegal trials. The Court stated that the untimely death of participants of trial is a gross violation of Article 21 of the Constitution. Amongst the various observations made, one was that "unrestrained clinical trials are causing disaster to human life." This goes to show the improper and poor implementation of ethical principles during medical experimentation and research in India.

The stance taken by the Indian judiciary in the abovementioned cases clearly highlights those clinical trials conducted without informed consent is a violation of the participant's fundamental right to live with dignity. It is also to be noted that the right to live is recognized as an essential human right under Article 3 of the Universal Declaration of Human Rights and hence, unethical and illegal clinical trials are violative of international principles and laws as well.

IV. AFTERMATH OF SUPREME COURT'S RULINGS

The Court's ruling pushed the CDSCO and the Ministry of Health and Family Welfare to relook into the legal mechanism with respect to clinical trials and make those laws more stringent. Hence, three new Rules, in 2013, were added to the Schedule Y of the Drugs and Cosmetics Rules, 1945. The three rules were Rule 122 DAB, Rule 122 DAC and Rule 122 DD.

Previously all serious and unexpected adverse events (SAEs) were underreported and companies did not disclose any compensation which they had provided. With the amendment to the 1945 Rules, Rule 122 DAB lays down that within twenty-four hours of SAE occurrence, investigators are required to report to the DCGI, the sponsor, and the Ethics Committees. The DCGI has the final authority to decide on the causality of SAE. The sponsor shall be liable to pay compensation within thirty days of receiving order from the CDSCO.

The regulatory changes led to prolonged approval timelines due to increase in requirements of regulatory submissions. After the implementation of the three news rules, there was a steep decline in clinical trial approvals, so much so that in 2010 there were 529 clinical trials being approved but in 2016, only 83 trials were approved. Such data suggests that either the government is strictly scrutinizing the applications and taking time to review them or that companies are now hesitant to conduct trials in India after laws becoming stricter.

V. THE NEW DRUGS AND CLINICAL TRIAL RULES, 2019

These rules look to regulate new drugs, clinical trials, new investigational drugs for human use,

[7] Writ Petition (Civil) No(s). 71 of 2019
[8] Writ Petition(s) (Civil) No(s). 33 of 2012

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bioavailability studies and bioequivalence studies and the Ethics Committee. Ethics Committee is one which has to be set up by whoever intends to conduct clinical trials in India. The Ethics Committee is entrusted with the responsibility of timely review of all ethical aspects involved in clinical trials which includes the informed consent of participants.

The rules also mandate that in order to manufacture or import new drugs, permissions must be obtained from the Central Licensing Authority. All applications for conducting clinical trials must also be submitted to the Central Licensing Authority. The 2019 Rules has also included provisions relating to compensation to be paid to participants of trials.

The 2019 Rules aims at improving the speed at which trials are conducted in India and also to fasten the approval for new drugs. The Rules also seek to provide a practical approach while awarding compensation to the injuries or other harm caused during the trials as the Rules have changed the wording from "day of occurrence of a serious adverse event" to "knowledge of the occurrence of a serious adverse event."[9]

New drugs will be automatically approved for use in India if those drugs are in use in select developed countries. The Rules has also reduced the time period for approving applications of new drugs to 30 days (manufactured in India) or within 90 days (for drugs developed outside India).

VI. RIGHTS OF PARTICIPANTS OF CLINICAL TRIALS

Unfortunately, in India there is no codified law or rule on the rights of clinical trial participants. Apart from the Supreme Court verdict in 2013, which mandates videotaped consent of participants, there has been no other concrete measure to ensure these rights. The Nuremburg Trials in Germany gave rise to autonomy and informed consent of the participants taking part in trials.

The Nuremburg trials were infamous for the mass exploitation of human subjects by German scientists and researchers during World War II under the pretext of medical experimentation.[10] This gave rise to the Nuremburg Code which was the first international instrument giving guidelines for ethical clinical trials.

It is unfortunate how participants are lured into trials under the guise of money without having

[9] V. Vennu and P. P. Saini, "India's Clinical Trial Regulatory Changes, Indian Researcher Awareness of Recently Changed Regulations, and the Impact of the New Drugs and Clinical Trial Rules: A Review", INDIAN JORNAL OF PHARMACEUTICAL SCIENCES, https://www.ijpsonline.com/articles/indias-clinical-trial-regulatory-changesindian-researchers-awareness-of-recently-changed-regulations-and-the-impact-of-the-new-dr-4023.html.
[10] Zulfiqar A. Bhutta (2002), "Ethics in International Health Research: A Perspective from the Developing World", Bulletin of the World Health Organization.

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an iota of idea of what they are getting themselves into. The pharmaceutical companies and research organizations use the helpless of below poverty line families to their own advantage and evil gains. The lack of adequate regulations for ensuring ethical clinical trials has helped pharmaceutical companies in getting away with violation of the rights of participants.

Informed consent is one of the most important pillars for ethical clinical trials to be conducted. Informed consent involves providing the potential participants every essential detail about the clinical trials in order to allow them to make a rational decision on whether or not to be part of the trials. One of the problems with such consent forms is that since companies and researchers view it to be more of a legal document to prove the participant's consent, the forms may be complex for laymen to understand. An Indian study conducted revealed how medical students themselves weren't able to remember the study drug and the adverse effects mentioned on the consent form.[11] What this further proves that the people from the lower strata of the society or even educated people will not be able to fully understand the consent form in order to make an informed decision with respect to participation in clinical trials.

Apart from the right to informed consent, the participant must also be given the right to withdraw or discontinue from the trial as and when he/she wants to. Right to privacy and confidentiality of the participant must also be honoured.

Due to the involvement of foreign companies, high costs of litigation, lack of public evidence and other socio-economic issues make it difficult for trial participants to approach the courts and hold the companies or hospitals liable for unethical or illegal trials. Participants must also be given the necessary knowledge and awareness of how to file a complaint or get their grievances redressed in case of violation of their rights.

Unless the rights of participants are brought under a legislation for the specific purpose, companies, doctors and hospitals will continue to exploit the innocent people in the society for their personal gains. It is rather amusing to see that the Indian Parliament is yet to bring a law for the same even after the numerous unethical clinical trials have been conducted in India.

As of now, if a participant's right is violated, they can approach the Court under different laws such as Article 19 (1)(a) of the Constitution if the right to know is violated, Article 21 of the Constitution if the right to privacy is violated, Indian Contract Act, 1872, tort law, etc. but, the lack of one single law addressing this issue is what is being missed in India.

[11] Kamath A, Up R, Shenoy K, "Willingness to participate in a clinical trial and understanding of informed consent information among medical students". Indian J Med Ethics. 2014; 11:16–8.

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VII. CURRENT ISSUES WITH CLINICAL TRIALS IN INDIA

Apart from participants not able to understand the consent forms completely, many doctors are incentivised to make their patients agree to take part in clinical trials. These patients may rely on their wordings of their doctors and sign on consent forms without reading them entirely. Another issue which crops up is that when patients are taken as participants to trials without their knowledge or full awareness of the trial, they often fail to associate the side-effects of the trial to it, which further leads to faulty research. Pharmaceutical and research companies conduct the trials in a very sub-par manner due to their limitations in funding and the Indian laws which allow for them to do so. The policies and rules for clinical trials are weak and there is a lack of specific legislation to regulate biomedical ethics in India. The absence of such a law gives companies the liberty to escape from the stringent laws of the west, recruiting volunteers from a limited population base, high costs and strict bureaucratic regulations and legal accountability.

Article 21 of the Indian Constitution, which guarantees right to life, casts an obligation on the State to preserve human life. Due to lack of efficient and proper guidelines or standards for clinical trials in India, participants often suffer serious effects. Right to life doesn't only mean the mean of death, it includes the right to protection against inhumane or degrading treatment, torture or cruelty. Medical procedures conducted without proper safety measures, consent, monitoring, etc. deny the participants their human dignity to live with.

In 2012, the 59th Rajya Sabha Report on the functioning of the CDSCO highlighted how the regulatory framework in India surrounding medical experimentation is not very stringent and is often violated by parties at their will. The Indian Government has also been negligent on its part even after having cognizance of such a situation.

The Indian Government is aggressively promoting clinical trials in order to receive more inflow of foreign investments without looking to properly set-up policy frameworks and mechanisms to inspect such trial sites; audit clinical trial data and regulate them in the public interest, whenever required.

VIII. CONCLUSION

Although clinical trials on humans is allowed across the globe in the name of beneficial research, it comes with an inherent cost to India. The cost is that of human. This cost is borne by the poor, vulnerable and weak population of India. Clinical trials most certainly cannot be stopped in its entirety, but they can be regulated. The rampant, unregulated conduct of trials can

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be regulated effectively through a decent, ethical and moral framework of laws and regulations. India can take inspiration from the legal systems across the world and also from international conventions dealing with regulation of clinical trials. For example, the UNCHR mandates that states have an obligation to respect, protect and fulfil its citizen's right to health.

Although it is acknowledged that clinical trials are needed newer drugs, medicines, vaccines, etc. in order for them to be developed to promote health, it must be kept in mind that this should not be done at the expense of human rights of the participants. States need to ensure that the rights of citizens are maintained by exercising at least a minimum standard of care while monitoring clinical trials.

The legislature and the judiciary must take more proactive steps in order to curb illegal and unethical clinical trials and look to provide highest degree of transparency and respect to the human rights of its citizens. India has to pass laws for proper regulation of ethical clinical trials, participants' rights and also to provide for compensation to the victims of faulty trials. There must also be a redressal mechanism or forum for participants of trials to approach and get their grievances redressed and the mechanism must include a simple procedure for filing complaints rather than an elaborate one.

With development in science and technology, there is only going to be more drugs and medicines developed and tried on humans. India must ensure that at least in its near future it shall look to pass a law which is stable enough to provide for ethical trials. The law must not only be one on paper but its implementation must also be carried out in an effective and sincere manner.

Therefore, upon summing up the findings, it is of the author's opinion that the current legal regime in India is not sufficient or properly equipped to prevent unethical clinical trials being conducted and there is certainly a need to codify and regulate the rights of participants of these trials.

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IX. BIBLIOGRAPHY

- **Statutes**
  - Constitution of India, 1950
  - Drugs and Cosmetics Act, 1940
- **Case laws**
  - Kalpana Mehta v. UOI, Writ Petition (Civil) No. 558 of 2012
  - Rahul Dutta v. UOI, Writ Petition (Civil) No(s). 71 of 2019
  - Swasthya Adhikar Manch v. UOI Writ Petition(s) (Civil) No(s). 33/2012
- **Rules**
  - Drugs and Cosmetics Rules, 1945
  - New Drugs and Clinical Trial Rules, 2019
  - ICMR Ethical Guidelines, 2017
- **Articles**
  - Arianna Moure (2015), "The Struggle of Regulating Clinical Trials in a Developing Nation: India's Experience", Law School Student Scholarship, 774.
  - Sandhya Srinivasan (2011), "Clinical Trial Industry: No Accountability?", Economic and Political Weekly, 46 (35): 19- 22.
  - Mark Barnes, Jamie Flaherty, Minal Caron, Alishan Naqvee and Barbara Bierer (2018), "The Evolving Regulatory Landscape for Clinical Trials in India", Food and Drug Law Journal, 73(4): 601-623
  - Verheggen, F. W., & Van Wijmen, F. C. (1997), "Myth and Reality of Informed Consent in Clinical Trials", Medicine and Law, 16(1): 53-70.
  - Carolijn Terwindt (2014), "Health Rights Litigation Pushes for Accountability in Clinical Trials in India", Health and Human Rights Journal, 16(2): 84- 95.
  - Molly Tarunima Tagore (2021), "Right to Health and Regulation f Clinical Trials in India", International Journal of Law, Management and Humanities, 4(2): 1228- 1249.
  - Members of Cancer Research Campaign Working Party in Breast Conservation (1983), "Informed Consent: Ethical, Legal, And Medical Implications for Doctors and Patients who Participate in Randomised Clinical Trials", British Medical Journal (Clinical Research Edition), 286(6371): 1117-1121.
  - Ankita Chakravarty and Ambedkar Bhavan (2017), "Unethical Clinical Trials in India: A selective preliminary overview", Eubios Journal of Asian and International Bioethics, 27(2): 66- 68

 [ISSN 2581-5369]

- Bagcchi, S. (2013), "Indian Supreme Court halts approval of new clinical trials until regulatory framework is set up", British Medical Journal News, 347, https://doi.org/10.1136/bmj.f5996
- V. Vennu and P. P. Saini, India's Clinical Trial Regulatory Changes, Indian Researcher Awareness of Recently Changed Regulations, and the Impact of the New Drugs and Clinical Trial Rules: A Review, INDIAN JORNAL OF PHARMACEUTICAL SCIENCES, https://www.ijpsonline.com/articles/indias-clinical-trial-regulatory-changesindian-researchers-awareness-of-recently-changed-regulations-and-the-impactof-thenew-dr-4023.html
- Zulfiqar A. Bhutta (2002), "Ethics in International Health Research: A Perspective from the Developing World", Bulletin of the World Health Organization.
- Kamath A, Up R, Shenoy K, "Willingness to participate in a clinical trial and understanding of informed consent information among medical students". Indian J Med Ethics. 2014; 11:16–8.

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