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Legislative Framework of Clinical Trial in India: A Critical Appraisal

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ABSTRACT

The word clinical trial is self-explanatory. The need to constantly update medical science is a must for the survival of humanity, however questions arise as to what extent clinical trials should be permitted or how the procedures of such experimentation have to carried on or the importance of 'consent' of persons subjecting themselves to the procedures. It is in this backdrop this article seeks to scrutinize, analyse and dissect clinical trials strictly from the humanitarian-legal point of view. This research has been undertaken with the objectives of understanding India's current legal framework with respect to clinical trials, legislative lacuna and judicial perceptions and receptions of the same.

Keywords: *Drug and Cosmetics Rules, clinical trial, 'consent' of persons, illegal and unethical trials*

I. INTRODUCTION

In the era of Pre & Post COVID-19 every system of the world is solely dependent on the medical jurisdiction and jurisprudence. It is only with the advent and emergence of the vaccines in the world when the era has resumed to work. But before any drug is released into the market it is very essential for the molecule of the drug to be certified and designated as safe. As defined within the Rule 122 DAA of Drug and Cosmetics Rules, 1945 "systematic study of new drug(s) in human subject to generate data for discovering and or verifying the chemical, pharmaceutical and or adverse effects with the objective to determine safety and or efficacy of the new drug". This shall be treated as the definition of clinical trials. Unlike every other subject this process of development and testing is also guided by certain regulatory framework in the country of India.

Now when a drug is to be imposed in India the clinical tests and subjects shall differ from country to country with respect to the population of the country in which the drug shall be imposed. It is very essential that the subject shall be accustomed with the Indian upbringings and immunity system. In fact, during the time of clinical trial there might be a number of pros

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and cons, which shall be informed to the persons who shall administer the test on themselves.

This paper tries to analyse the identification whether the clinical trial scenario in India confirms to rights to choice of an individual which is a fundamental right guaranteed under the Constitution of India, and also existing legal framework is sufficient to fill up the current lacunae in clinical trial.

II. BRIEF HISTORY OF CLINICAL TRIALS IN INDIA

Clinical trial may have a number of side effects and complications in a human body or on the subject after the trial is being conducted. It shall be stated, that it is the duty of the trial conducting authorities to inform the subjects regarding 'entire procedure of treatment' and the associated constrictions as it is the fundamental right of the subject guaranteed under the Constitution of India. This provision shall be analysed further in the paper.

India Witnessed growth in jurisdiction of clinical trial in India from 2009. The number of approvals were increased by more than 200 counts since 2008. The Drug Controller General of India (henceforth referred to as DCGI) granted 65 approvals for conducting clinical trial research in India while the numbers surged to 391 in 2009 and then to 500 approvals in 2010. But what was taken as a strike was the fact that there were multiple death figures that led to the emergence of the Human Rights Cry among the masses.

III. PRINCIPAL LEGISLATION REGULATING CLINICAL TRIALS IN INDIA:

In order to curb the malpractice of drug alteration and fraud in the Indian Pharmaceutical Industry, the Drugs and Cosmetics Act, 1940 came to the scenario. This statute established the body- Central Drugs Standard Control Organisation(CDSCO). The government in order to curb all the illicit activities stated that in order to launch a drug in India by any pharmaceutical companies, it need to carry on a clinical trial in India. This trial is supposed or is required to be performed on a local population in order to analyse the 'safety and efficacy' of new drugs and medicinal products. Thus in order to determine the safety of the entire procedure, and the subjects of the test, incorporated in Schedule Y within itself which consisted of number of rules and procedures for the conduction of clinical trials (Schedule Y of Drugs and Cosmetics Rules, 1945). This was the main response of India to combat and regulate the sudden and exponential growth of clinical trials at the beginning of 21st Century.

IV. CATALYST(S) & THE CHANGE(S) IN THE REGULATORY LANDSCAPE

In the year of 2010, two PIL were filed regarding the violations of right to life of citizens who were subjected to clinical trials and also the safe protocols during the clinical trial. When 500

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cases were reported in the year of 2010 Indian media surged the cry of Human Right violation on the subject. The Death of several girls while the test of HPV was conducted. It stated the fact that 13000 girls aged 10-14 with Gardasil and 10000 with Cervarix. In this trial 254 women in the unscreened control and standard of care group suffered death due to cervical cancer. In another PIL that was filed in 2012, by Swasthya Adhikar Manch, a non-governmental organisation dealing with human rights forum was for the intervention in the matter of illegal and unethical trials that is conducted on the minors, adult women and mentally challenged citizens of the country.

When the court took cognizance of this PIL it criticized the CDSCO for not cross checking on the fact whether the companies who demanded for the research followed the Trial regulation as stated in the statutes of India.

Further as per the 72nd report released by the Department- Related parliamentary standing Committee on Health and Family Welfare reinstated the fact that many of the subjects were illiterate or uneducated which were ethically immoral and led to violation of Human Right as such

V. INFORMED CONSENT: A SORRY STATE OF CLINICAL RESEARCH PROCEDURE IN INDIA

'Right to life is not a mere life with an animal existence, but a life with dignity' as was restated in the landmark precedent of K.S. Puttaswamy V Union of India where life under Article 21 doesn't includes a mere life but life with dignity and liberty. In fact, as Article 21 of the Constitution of India reads, "No person shall be deprived of his life or personal liberty except according to procedure established by law". Article 21 which stands at the highest pedestal shall in no circumstance, without a reasonable cause and a procedure established by law, permit any organ to violate or infringe with 'life' or the fundamentals of 'life'. If at all deemed to be necessary, the same shall be done with the 'procedure established by law'. The importance of consent in a clinical trial lies within the dictum that 'personal liberty' that is guaranteed by the Constitution of India also guarantees the Right to Autonomy. The Hon'ble Supreme Court time and again has reiterated the fact that the personal liberty of an individual shall not be interfered. Subjecting a person to clinical trials without a valid consent will violate the personal autonomy of the individual even at large, as the Hon'ble Court held that 'personal autonomy include both the negative right of not to be subject to interference by other and the positive rights of individual to make decisions about their life, to express themselves and to choose which activities to take part in".

In fact, when the first PIL was filed in 2010 the Supreme Court comprised of the Bench of Justice Gowda and Justice Deepak Mishra asked for the explanation for the reason for the selection of tribal areas and whether the same was done under proper monitoring. This helps us to analyse that there was a differentiation that was caused. This differentiation which can be analysed, be called something arbitrary in nature and shall be held violative of the provisions of the Golden Triangle under the Constitution of India.

It shall be taken into consideration that most of the clinical trials that are being conducted are on people that are mostly from tribal areas. This increases the chances of illiteracy. The question arises on the fact whether a consent without understanding the subject matter shall be held to be a valid consent or not.

The Supreme Court while dealing with the Public Interest Litigation states that the individuals in India shall be considered as humans and not as "guinea pigs".

VI. LACUNAE IN PREVALINING LEGAL FRAMEWORK FOR CLINICAL TRIAL IN INDIA

The Constitutional Safeguards can only be claimed either against a state or a body financed or governed by the state or is to a greater extent directly under the control of the state. But another question remains how shall a person claim their fundamental rights against a private body when the same doesn't qualifies the provisions of Article 12 of the Constitution of India. In fact, during the case of Swastha Adhikar Manch v Union of India, the Court stated that the CDSCO shall provide notification that before a clinical trial is conducted there shall be Audio-video of the consent during the time of trial proceeding and the same shall be deemed to be held mandatory. Later, this audio video of the consent during the time of trial proceeding was restricted to those of 'vulnerable subjects' but the problem arose to the fact that the notification that was provided by the CDSCO didn't bear the definition of who shall be considered as vulnerable subjects.

What shall mandatorily be pointed out as the lacunae is that there exists only rules and regulations, which provides no definitive punishment for the violation of ethical guidelines during the conduction of clinical trials or even if there is blatant violation of procedures in clinical trials.

In order to provide compensation, in January 2013, Rule 122 DAB was enacted by the MoHFW which stated "compensation in case of injury or death during clinical trial". It shall be stated that the rule was too vague as here injuries included 'any injuries' even if it is not a part or caused due to any activities of the trial. This provision was narrowed in 2014, exactly one year after, which stated that the medical compensation shall be provided for 'any' injuries as long

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as required or till such time it is established that the injury is not related to the clinical trial whichever is earlier. Even this reform of 2014 cannot be said to be a very enduring reform as proving that the alleged injury is not caused due to clinical research will be a very hard and an enduring task.

In fact, during the procedure, as could be interpreted from the Rule 122 DAB, if it is proven that the injury is caused due to clinical trial then there shall be additional compensation which shall be provided to be the party.

These lacunae are yet said to be present. The ambiguous nature of law has always been a cause of hindrance. It is still not clear that what the law intends to provide as a compensation. This are said to be a vital lacuna which are yet present in the Clinical trial jurisdiction.

VII. RECOMMENDATIONS

A. Contemporary domestic legislation keeping in line with the international standard, addressing the current needs and precautions that are to be taken into consideration for conducting clinical trials.

B. The legislation further should address the safeguards in respect of investors, researchers or other persons associated and responsible for clinical trials.

C. The legal framework must clear the doubts surrounding compensation as to not discourage medical advancement.

D. Government initiatives have to start to make commoners aware and familiar with the idea of informed consent so that they can recognize and stand up when their fundamental rights of information, choice, bodily autonomy and privacy gets violated in the name of clinical trials.

VIII. CONCLUSION

It is to always remember that the trials that are conducted on are human beings, who under no circumstances can be denied of their life and liberty. This fact was reiterated in the landmark precedent of Kalpana Mehta V Union of India where the court ordered the government to form procedures within a stipulated time for the proper functioning of clinical trials in India during which New Drugs and Clinical Trial Rules, 2019 came into existence. These rules provided strict guidelines for informed consent. The 2019 rule mandates that the subject shall be well informed about any complications or the nature of test. Conducting a test without proper consent, i.e., consent obtained without a proper information shall be said to be infringement to the fundamental rights of an Individual.

The last and the most cardinal principles that should be followed during a clinical trial are the

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three principles as stated in the Helsinki Declaration of 1964 which have stated that all the subjects shall be defended with their – dignity. liberty and justice; there shall exist respect for persons, i.e., the subject of the test shall be provided with proper due care and to the greatest shall be treated like human beings under any circumstances as it may prevail and last but not the least is the principle of Beneficence.

The third amendment to the rules in 2022 which provides deemed consent in case of no consent is received within 90 working days is also not fully satisfying the intention of the Helsinki Declaration as it tends to sub- serve the human rights aspect in the strictest sense, but provides flexibility in administrative decision making.

It is humbly suggested that the post Covid-19 ecosystem makes the amended provisions fragile and prone to misuse & abuse the trust of the subject which requires strong and safe scrutiny for approval and further modification. The amended provision need a strong relook by the Lawmakers in the above light.

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