CLINICAL TRIALS IN INDIA: A WAY TOWARDS IMPOVERISHMENT?

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ABSTRACT

Drug trials in India have been a matter of contemporary concern, especially in light of the Public Interest Litigation ("PIL") filed by Swasthya Adhikar Manch in the Supreme Court of India. The PIL was filed keeping in mind the numerous deaths that were reported from the trial site due to unethical research that was being carried out by the sponsors without the necessary licenses from the Drugs Controller of India. Developing countries like India have become preferred sites for trials mainly because of the ease of finding participants. People from economically weaker sections of society participate in these trials in the hope of monetary compensation and free drugs. On the contrary, participants are provided with sub-standard care, inadequate remedies and compensation in case of any unfavourable events, inadequate protection from laws, minimal government interventions in case of emergencies and inadequate consent mechanisms, thereby resulting in inevitable impoverishment of the participants. This paper seeks to make a detailed analysis of clinical trials in India as a source of impoverishment, mostly among the economically and socially weaker sections of the society.

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I. INTRODUCTION

Clinical trials in India have been in news for the last decade. There have been various instances of death of participants in clinical trials, especially in states like Madhya Pradesh, Andhra Pradesh and Gujarat. Swasthya Adhikar Manch, an Indore based NGO filed a PIL[2] in the Supreme Court to bring to light the deaths caused by unethical research that was being carried out on children, mentally challenged people, tribals and dalits who were incapable of giving free informed consent[3]. The PIL mentioned the various irregularities like violation of ethical guidelines, violation of laws governing clinical trials and medical ethics, inactive role by ethical committees, thereby alleging a violation of Articles 21 and 32 of the Constitution of India.

Another PIL[4] was filed by Gramya Resource Centre for Women when seven deaths were reported in Andhra Pradesh and Gujarat during the Human Papilloma Virus ("HPV") vaccination trials on tribal girls. The sponsors[5] had

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2 Swasthya Adhikar Manch, Indore & Anr. v. Union of India & Ors., Writ Petition (Civil) No. 33 of 2012.

3 Divya Rajagopal, *PIL filed against illegal drug trials*, THE ECONOMIC TIMES, (Feb. 6, 2012), *available at* http://articles.economictimes.indiatimes.com/2012-02-06/news/31030826_1_drug-trials-pil-drug-controller; *See also,* Alishan Naqvee & Abhijeet Das, *Clinical Research in 2015: The Ghost of Christmas past, present and yet to come*, THE FINANCIAL EXPRESS, (Dec. 24, 2014), *available at* http://www.financialexpress.com/article/pharma/latest-updates/clinical-research-in-2015-the-ghost-of-christmas-past-present-and-yet-to-come/22744/. There have also been other similar instances of unethical trials. Quest Life Sciences, a clinical research organisation has been issued a warning by the WHO for major lapses in the trial of a vaccine for HIV. For further information, *see, Quest Life Sciences Under WHO Fire Over Lapses in Clinical Trials*, NDTV PROFIT, (Jul. 7, 2015), *available at* http://profit.ndtv.com/news/corporates/article-quest-life-sciences-under-who-fire-over-lapses-in-clinical-trials-778998.

4 Kalpana Mehta & Ors. v. Union of India & Ors., Writ Petition (Civil) No. 558 of 2012.

5 The research was being conducted by an NGO, the Programme for Appropriate Technology in Health and was funded by Bill and Melinda Gates Foundation.

violated norms by not only allegedly using "unproven and hazardous" drugs but also initiating the project without appropriate license from the Drugs Controller of India[6].

In both these cases, the court applauded the efforts of the NGOs to bring into notice the problems that clinical trial participants were facing. They had asked for suggestions from the National Human Rights Commission and other stakeholder organizations. They had also asked the Department of Health and the Central Drugs Standard Control Organisation to provide their statement on the matter. However, the government and the drug control authority failed to provide any satisfactory solution thereby keeping the entire situation in a legal limbo.[7]

Third world countries like India and Africa have become favoured locations for trials mostly due to the liberal or inadequate laws and largely uneducated people who lack the freedom of choice due to absence of economic sufficiency.[8] Clinical trials in have therefore been largely criticised due to some major controversies[9] surrounding them: While issues of

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6 *Supreme Court admits PIL on cancer cervical vaccine trial*, THE TIMES OF INDIA, (Jan. 8, 2013), *available at* http://timesofindia.indiatimes.com/city/indore/Supreme-Court-admits-PIL-on-cancer-cervical-vaccine-trial/articleshow/17933564.cms.

7 *Supreme Court asks NGOs to suggest methods to strengthen Clinical Trials*, HUMAN RIGHTS LAW NETWORK, (2013), *available at* http://www.hrln.org/hrln/newsroom/media-reports/1326-supreme-court-asks-ngos-to-suggest-methods-to-strengthen-clinical-trial-laws.html.

8 Mohammed Imran, Abul K. Najmi, Mohammad F. Rashid, Shams Tabrez & Mushtaq A. Shah, *Clinical Research Regulation in Indian History, Development, Initiatives, Challenges and Controversies: Still long way to go*, 5(1) J. PHARM. BIOALLIED SCI. 2 (2013).

9 Ezekiel J. Emanuel, David Wendler, Jack Killen & Christine Grady, *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*, 189(5) J. INFECT. DIS. 930 (2004). *See also*, Cecilia Nardini, *The Ethics of Clinical Trials*, 8 E CANCER MEDICAL SCI. 387 (2014), *available at*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894239/.

inadequacy of laws and need for ethical regulations have been widely researched on, not much has been written about the link between clinical trials and the resulting impoverishment.

This paper makes a detailed analysis of clinical trials as a means of impoverishment, by way of analysing the trials using the Capabilities Approach as propounded by eminent scholars like Amartya Sen and Martha Nussbaum. Part II links the lack of economic freedom to enrolment in clinical trials while seeking to find whether such involvement can result in further impoverishment[10]. This part further talks about the impoverishment caused due to exclusion from participation of certain groups in clinical trials, mainly on grounds of age and gender[11]. Part III looks into the loopholes in the existing legislations and policy measures which act as a means of impoverishment. Part IV examines the changes that need to be brought about in the existing laws in order to address impoverishment due to clinical trials. The paper concludes with an enquiry as to whether legislative efforts can help in addressing such impoverishment.

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10 Emanuel et al., *id*, 933.

11 It has been found that elderly people with multiple diseases are mostly excluded from clinical trials. *See*, A. Cherubini, S. Del Signore, J. Ouslander, T. Selma & J.P. Michael, *Fighting against age discrimination in clinical trials*, 58(9) J. AM. GERIATR. SOC. 1791 (2010). Also, in USA, in most of the clinical trials involving sophisticated drugs for cancer, it has been found that mostly white males participate as subjects. Such racial and gender based discrimination lead to impoverishment of women and the black population due to lack of adequate represention thereby leading to lack of information on the effectiveness of the drugs on them. For further reading, *see*, G. Marie Swanson & Amy J. Ward, *Recruiting Minorities into Clinical Trials towards a Participant-Friendly System*, 87(23) J. NAT. CANCER. INST. 1747 (1995). *See also*, Amy Westervelt, *Excluding women from Clinical Trials is Hurting our Health,* (May 1, 2015), *available at*, http://food.ndtv.com/health/excluding-women-from-clinical-trials-is-hurting-our-health-759762.

II. IMPOVERISHMENT AND CLINICAL TRIALS IN INDIA

A. Impoverishment due to Participation in Clinical Trials

Clinical trials have been very popular in developing countries like India. As was stated by the Drugs Controller General of India ("DCGI"), India is preferred as a trial site by most pharmaceutical companies due to its "*trained English speaking human resource pool and a large, diverse and treatment-naive [untreated] population with six out of the seven genetic varieties of the human race*."[12] However, the trials have largely exploited participants more than they have helped them. The adverse effects can be felt especially among the economically weaker sections of India who lack income autonomy, which has the instrumental value to allow "substantive freedom of choice to lead the kind of life that a person has reason to value"[13].

They participate in such trials in lieu of a meagre economic incentive and free drugs that would otherwise have been beyond their reach[14]. A further issue is the information asymmetry that exists between the researchers and participants, thereby resulting in absence of free informed consent. Since most

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12 Sandhya Srinivasan, *Ethical concerns in Clinical Trials in India: An Investigation,* CENTRE FOR STUDIES IN ETHICS AND RIGHTS, (Feb., 2009), *available at* http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Ethical_concerns_in_clinical_trials_in_India_An_investigation.pdf

13 AMARTYA SEN, THE IDEA OF JUSTICE 231-232 (Allen Lane, 2009). (Sen defines capability as "the substantive freedoms a person enjoys to lead the kind of life he or she has reason to value". While Sen argues that poverty due to capability inadequacy cannot be used synonymously with poverty due to lowliness of income, he concedes that the two concepts are related given that income is an important means to capabilities.). *See also*, AMARTYA SEN, DEVELOPMENT AS FREEDOM 90-91 (OUP, 1999).

14 Imran et al., *supra* note 6, at 2.

people in India are illiterate[15], the participants are not aware of the subject matter of the trial and their rights in such instances. In most cases, they do not know about the recourse that is to be taken if they suffer from some injury or death due to the trial. Their consent also cannot be called free since the economic incentive obscures their thought process.

The Belmont Report, that was brought out by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, raised the concern that certain populations, such as prisoners, children, incapacitated or socioeconomically disadvantaged are enrolled in trials because of their impressionability and not because the research is significant to their disease[16]. The report focuses on the need to maintain individual and social justice while selecting subjects for clinical trials. The participants who are considered "undesirable" should not be selected solely for research that involves greater risk unless that study is relevant to such class of people[17].

As Sen asserts, freedom of choice and individual agency is intrinsically important to well-being[18]. This lack of free informed consent leads to a major deprivation of human capability. The participants are therefore deprived of

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15 *India's illiterate population largest in the world, says UNESCO report*, THE HINDU, (Jan. 30, 2014), *available at* http://www.thehindu.com/news/national/indias-illiterate-population-largest-in-the-world-says-unesco-report/article5631797.ece. (Education For All Global Monitoring Report (GMR), released worldwide by UNESCO in 2014 stated that while India's literacy rate rose from 48 % in 1991 to 63 % in 2006, the population growth cancelled the gains).

16 Part C of the Report speaks about the selection of subjects. *See*, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, (Apr. 18, 1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#xselect.

17 *Id.*

18 SEN, *supra* note 10, at 236.

their right to make an informed choice, which is an integral aspect of their right to life and personal liberty[19]. Lack of free consent also goes against the basic ethics of clinical trials as has been stated in the Nuremberg Code[20] that was developed by judges adjudicating in the Nuremburg Trials. The Code enumerates the importance of human rights and individual autonomy.

Drawing from the findings of the Belmont Report and the Nuremburg Code, one can infer that such minimal ethical standards are necessary for not just clinical trial participants in developed countries but also the people in developing countries. This mind set can largely be seen in the CIOMS guidelines that were jointly prepared by the World Health Organisation and the Council for International Organisations of Medical Sciences[21]. Of the CIOMS guidelines, guidelines 4, 5, 14, 15, 16 and 17 are the most relevant for the discussion on consent and protection of vulnerable groups. While guideline 4 talks about the essential requirement of informed consent for both competent adults and incapacitated individuals, guideline 14 speaks of the importance of protection of clinical trial participants from any form of exploitation.

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19 Many judicial decisions have stated that the right to be informed is a part of Art 19 and 21 of the constitution. Some of the cases which have said so include State of U.P. v. Raj Narain, AIR 1975 SC 865, Benett Coleman v. Union of India, AIR 1973 SC 106 and S.P. Gupta v. Union of India, AIR 1982 SC 149.

20 The Nuremberg Code, 1947, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, (Nov. 7, 2005), *available at* http://www.hhs.gov/ohrp/archive/nurcode.html. (Principle 1 states, "The voluntary consent of the human subject is absolutely essential").

21 CIOMS & WHO, *Council for International Organisation of Medical Sciences, available at* www.cioms.ch (last visited Sept. 30, 2015).

The International Guidelines that have been discussed above and are the basic principles that are followed by pharmaceutical countries in the developed world is mostly missing in India. One form of exploitation that can be noticed is that the participants of trials that are conducted in India are used for research while the benefits of the tested drugs are mostly reaped by developed countries[22]. An analogy can be drawn with Marion Young's concept of exploitation where oppression occurs through a steady process of transfer of results of the trials on the impoverished for the benefit of people in developed countries[23].

This majorly leads to deprivation of their capabilities. Lack of basic healthcare facilities in case a participant is adversely affected in the process of clinical trials is another domain where there is further deprivation of capabilities. Studies have shown that most research sponsors do not keep facilities for treatment in cases of emergency on the pretext that such economically weaker people would not have been able to access these costly medicines anyway[24]. This not only leads to a violation of the formal principle of justice[25] but also leads to a violation of their fundamental right to health[26] and right against discrimination[27].

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22 Emanuel et al., *supra* note 7, at 933.

23 IRIS MARION YOUNG, JUSTICE AND THE POLITICS OF DIFFERENCE 48 (Princeton University Press, 1990).

24 Marcia Angell, *The Ethics of Clinical Research in the Third World*, 337(12) NEW ENG. J. MED. 849 (1997).

25 The formal principle of justice states that unequal treatment of individuals who are equal in all respects is morally wrong. This principle was propounded by Aristotle and authors like Rawls, Nagel and Dworkin have discussed this in their writings. *See*, David B. Resnik, *Unequal Treatment of Human Research Subjects*, 18(1) MED. HEALTH CARE PHILOS. 23 (Feb., 2015).

26 The right to health has been declared as part of Right to Life by the Supreme Court in numerous instances like Consumer Education and Resource Centre v. Union of India, AIR 1995 SC 636, Paschim Banga Khet Mazdoor Samity & Ors. v. State of West Bengal, AIR 1996 SC 2426 and Paramanand Katara v. Union of India & Ors., (1989) 4 SCC 286.

27 Article 14 of the Constitution.

The 59th Report of the Central Drugs Standard Control Organisation had observed that the "regulatory framework in India was not as stringent as that of the US, UK and Australia"[28]. Despite such cognizance of an inadequate regulatory framework, the Indian Government has mostly been negligent. They have failed to give effect to the fact that rights are indivisible in nature; a violation of right to life under Article 21 would inevitably lead to a violation of the right to health, right to livelihood, right to equality and so on[29]. The judiciary on the other hand has particularly noted the various instances of illegal clinical trials in the country.

In *Rahul Dutta v. Union of India*[30] and *Swasthya Adhikar Manch v. Union of India*[31], the judges have highly criticised the government for its failure to curb illegal trials. The courts further stated that the untimely death in such trials was grossly violative of the fundamental principles guiding Article 21 of the Constitution. While the Swasthya Adhikar Manch Case is still ongoing, one can only hope that the Supreme Court, by way of a continuing mandamus would take up the matter and direct the government to amend the laws to make them in line with internationally acceptable standards. Unless the judiciary and the legislature do away with their passivity regarding this particular issue, keeping in mind their role as the creator and protector of rights, the situation would never improve.

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28 The Department Related Parliamentary Standing Committee on Health and Family Welfare, *Fifty Ninth Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO), available at*, http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%200no2OHealtho2Oand%2OFamilyo20VWelfare/59.pdf (last visited Sept. 4, 2015).

29 The Supreme Court in Maneka Gandhi v. Union of India, AIR 1978 SC 597 stated that Art 14, 19 and 21 are indivisible.

30 Misc. Bench No. 12280 of 2010, Allahabad High Court.

31 Writ Petition (Civil) No. 33 of 2012.

B. Impoverishment due to Lack of Representation in Clinical Trials

While participation in clinical trials can be a form of impoverishment when done so without free informed consent and proper safety mechanisms, impoverishment can also be caused in India by the way of exclusion of certain groups from the trials. Drawing from Harsh Mander's [32] analysis on the subject, exclusion results in "*inequitable social attainments, capabilities, development, justice and dignity outcomes*". Exclusion has specially affected children, women and the elderly people who have often been barred from participation in drug trials. A 2014 report by the Mary Horrigan Connors Center for Women's Health & Gender Biology at Brigham and Women's Hospital[33] asserts that females are mostly excluded from human studies and even in cases where they are included, their representation is either very poor or the data collected is not analysed separately on the basis of gender.

There is a failure to recognise the fact that medicines have different effects on males and females[34] and therefore such trials conclusively infer as to whether a particular drug will be beneficial to all. This leads to a violation of the right to health of women. The 2014 report can be said to apply to the

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32 Harsh Mander and Gitanjali Prasad have used this definition of exclusion in the introduction to their India Exclusion Report 2013-14, *available at* http://www.indianet.nl/pdf/IndiaExclusionReport2013-2014.pdf, at 4.

33 Paula Johnson, Therese Fitzgerald, Alina Salganicoff, Susan Wood & Jill Goldstein, *Why women's health can't wait*, MARY HORRIGAN CONNORS CENTER FOR WOMEN'S HEALTH & GENDER BIOLOGY AT BRIGHAM AND WOMEN'S HOSPITAL, (2014), *available at* http://www.brighamandwomens.org/Departments_and_Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf.

34 Amy Westervelt, *The medical research gender gap: How excluding women from clinical trials is hurting our health,* THE GUARDIAN, (Apr. 30, 2015), *available at* http://www.theguardian.com/lifeandstyle/2015/apr/30/fda-clinical-trials-gender-gap-epa-nih-institute-of-medicine-cardiovascular-disease.

context of India as well. While there are very few reports directly connecting exclusion of women and participation in clinical trials in India but as can be concluded from the findings of the World Economic Forum, India ranks extremely low in terms of gender equality[35]. Given the vast prevalence of gender inequality, it is evident that women remain largely excluded from most social and economic activities.

Children also suffer from certain deprivations of human capabilities like the capability to live the normal length of the life due to their lack of representation in clinical trials. There are a number of factors that result in the lack of representation of children in such trials - lack of funding, dearth of investigators trained to deal with children, lack of participants and the complexity with the issue of consent for children[36]. Parents are at times reluctant to enroll their child for trials in the fear that he or she will be treated as a guinea pig and will be exposed to the potential risks of research.

There is a lack of understanding regarding the importance of free informed consent and the complex consent forms lead to creation of doubt among parents regarding the entire trial process[37]. The result of such exclusion implies that doctors usually extrapolate data based on the effect of the drug on adults[38]. The failure to recognize children as a separate group, and the

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35 Anita Raj, *Gender equity and universal health coverage in India,* LANCET, (JAN. 11, 2011), *available at* http://dx.doi.org/10.1016/S0140-6736(10)62112-5.

36 Patrina H.Y. Caldwell, Sharon B. Murphy, Phyllis N. Butow & Jonathan C. Craig, *Clinical trials in Children*, 364 LANCET 803, 806 (2004).

37 *Id.*, 807.

38 Pathma D. Joseph, Jonathan C. Craig & Patrina H.Y. Caldwell, *Clinical trials in Children*, 73(9) BRIT. J. CLINICAL PHARM. 357 (2013).

ignorance of their unique physiological needs, leads to the deprivation of their basic capabilities. It also violates their basic right to health.

Furthermore, elderly people form a large chunk of the population in India. However, their importance in the social and medical setup occupies a very insignificant proportion due to the multiple incidences of diseases that families mostly consider as a burden to their economic budget[39]. There have however been very few efforts to adapt to the changing socio-economic needs and come up with models of healthcare that would be conducive to the elderly people. Given such general indifference towards the health of elderly people, older participants have a higher possibility of exclusion due to a variety of factors.

Greater chances of trial related injury or death, higher risk of adverse effects from drugs due to existing multiple comorbidities, inability to understand the requirements of free informed consent and dependence on family members to travel till the trial site[40] many a times force the older participants to sit out of the trials. Sponsors have also been accused for fixing arbitrary upper age limits for trials[41].

Such arbitrary guidelines set by sponsors violate the right to non-arbitrariness under Article 14 of the constitution. Elderly people and children also suffer from deprivation due to the coupling of disadvantages. Apart from

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39 Ramesh Verma & Pradeep Khanna, *National Program of Health-Care for the Elderly in India: A Hope for Healthy Ageing*, 4(10) Int'l J. Prev. Med. 1103-1107 (Oct., 2013).

40 Cherubini et al., *supra* note 9, at 1792.

41 R. Briggs, S. Robinson & D. O' Neill, *Aegism and Clinical Research*, 105(9) IR. MED. J. 311(2012).

the other factors that lead to their exclusion, deprivation is also caused due to unnecessary paternalism and marginalization caused by extreme, asymmetrical dependency on their family or state[42].

As Young states, "*being a dependent in our society implies being legitimately subject to the often arbitrary and invasive authority of social service providers*."[43] Every person is dependent at some point of time in their lives and dependency should not be a cause of deprivation due to lack of freedom of choice. Thus, clinical trials not only exploit the impoverished but also direct some people into impoverishment by denying them their basic capabilities and violating certain basic rights like the right to health, right to equality and the right to life.

C. *Violation of Rights and Deprivation of Capabilities of the Impoverished due to Clinical Trials*

Martha Nussbaum, in an effort to study how impoverishment leads to depravation of human capabilities and basic human rights argued that there were certain minimal human capabilities that no legislation should degrade in any manner[44]. She draws a link between rights and human capabilities thereby maintaining that the violation of a right inescapably leads to the violation of basic human capabilities[45]. A correlation can be drawn between the list of

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42 Martha Nussbaum, *Capabilities as Fundamental Entitlements: Sen and Social Justice* in *Capabilities, Freedom and Equality: Amartya Sen's Work from a Gender Perspective* 59 (Agarwal, et al. ed., Oxford, 2007).

43 YOUNG, *supra* note 20, at 54.

44 Nussbaum, *supra* note 33, at 42-46. (Nussbaum states that Capabilities Approach provides a foundation through which rights can function while rights become an instrument for ensuring certain capabilities. The enjoyment of a right is realized only when one has the relevant capability to function. Capability Approach therefore looks at rights in a substantive manner).

45 Nussbaum, *supra* note 33, at 47-49.

essential human capabilities that Nussbaum has mentioned and the manner in which the rules regulating clinical trials in India violate them.

Lack of access of participants to adequate healthcare in trial related injury or deaths due to trials affect the freedom to live to the end of human life of normal length. Exclusion from participation also denies participants the right to get medicines that have been proven to be effective on them, thereby violating their right to health. Further, failure to get the best possible care in instances of adverse effects in clinical trial denies participants the freedom to have a good health. This is therefore an outright violation of Article 21 of the Constitution.

The next capability the trials affect is the right to be able to imagine, think and reason in an informed manner. The senses, imagination and thought, which as per Nussbaum are intrinsic to the life of an individual is affected since there is an absence of free informed consent. Trials further affect the ability of the impoverished people to form a conception of the good and to engage in critical reflection about the planning of one's life due to the economic incentive and free medical treatment that is promised by the sponsors to the participants.

Furthering Nussbaum's claims, clinical trials in India also affect the right of individuals to be treated as a dignified being whose worth is equal to that of others. Sponsors do not keep facilities for treatment in cases of emergency on the pretext that such impoverished people would not have been able to access these costly medicines anyway. The capability of affiliation which

also entails non-discrimination on the basis of sex or age is affected when women, children and the aged are not adequately represented in trials.

One can thus find a broad connection between the theoretical foundations that Nussbaum had laid down and the practical way in which clinical trials are conducted in India. It is therefore imperative to look at the regulations dealing with clinical trials and the changes that the law must undergo so as to make the trials more conducive to protection of rights of the participants.

III. LEGISLATIONS AND ADMINISTRATIVE MEASURES AS A MEANS OF IMPOVERISHMENT

Impoverishment is furthered by existing regulations governing clinical trials in India. The legislations which mostly regulate trials - the Drugs and Cosmetics Act 1940[46] and Schedule Y[47] of the Drugs and Cosmetics Rules, 1945, including the 2013 amendment to the rules[48], suffer from major loopholes. While the amendment has brought in some positive provisions, certain lacunae fail to be addressed.

Rule 122DAC of Schedule Y necessitates permission from Drugs

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46 Drugs and Cosmetics Act, 1940, *available at* http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf.

47 Schedule Y of the Drugs and Cosmetics Rules, 1945, *available at* http://cdsco.nic.in/html /D&C_Rules_Schedule_Y.pdf.

48 Mrinali Mudol, *Latest amendments in 2013 to the Drugs and Cosmetics Rules, 1945*, MONDAQ, (Jun. 11, 2013), *available at* http://www.mondaq.com/india/x/244304/Healthcare /Latest+Amendments+ In+2013+To+The+Drugs+And+Cosmetics+Rule+1945. See also, Manoj Karwa, Saurabh Arora & Shilpa Garg Agarwal, *Recent regulatory amendment in Schedule Y: Impact on Bioequivalence studies conducted in India*, 5(4) J. BIOEQUIV. & BIOAVAIL. 174 (2013).

Controller General, India, Ethics Committee and mandatory registration with the Indian Council for Medical Research ("ICMR") for conducting a trial. The Central Drugs Standard Control Organisation ("CDSCO") is authorized to inspect trial sites. In instances of non-compliance of rules, the DCGI can recommend the discontinuation or suspension of the trial while cancelling the permission of the investigator, sponsor and his representatives from conducting future trials. Such a move came as late as 2013 before which there was no mechanism for registering a clinical trial, thereby leaving no scope for accountability and grievance redressal. However, certain concerns still remain. There is major lack of training among personnel conducting such inspections[49] and thus the effectiveness of the amendment remains a matter of concern.

Rule 122DAB provides for free medical treatment, in cases of injury as long as necessary and financial compensation, in case of trial-related injury or death, to be decided by the DCGI. Payment for medical treatment and compensation has to be made by the sponsor and failure to provide the same would lead to the suspension or cancellation of the trial. Such a provision is progressive given that it promotes the right to life and health of participants. However, the provision fails to distinguish between "injury" and "trial related injury" thereby leaving it open to interpretation and abuse by sponsors who enjoy a higher bargaining power[50]. The DCGI has fixed the basic

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49 Sandhya Srinivasan, *Ethical concerns in Clinical Trials in India: An Investigation,* CENTRE FOR STUDIES IN ETHICS AND RIGHTS, (Feb., 2009), *available at* http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Ethical_concerns_in_clinical_trials_in_India_An_investigation.pdf, at 5.

50 Vidya Krishnan, *Government tightens guidelines for Clinical Trials*, LIVEMINT, (Oct. 22, 2015), *available at* http://www.livemint.com/Industry/Z7SPMRvBh9Ap1sxo8iOcGI/Government-tightens-guidelines-for-clinical-trials.html.

compensation at a floor minimum of Rupees Eight Lakhs[51]. Many critics have raised the concern that such a high amount may act as a factor to induce more and more economically weak people into clinical trials thereby vitiating the concept of free informed consent.

Amendments[52] have been made in the "informed consent form" to include an undertaking by the sponsor to pay for the medical treatment and compensation in case of injury or death. However, the major flaw remains with the informed consent forms which require consent to be in writing. Given that most of the impoverished people who are enrolled in such trials are illiterate, written consent fails to provide effective safeguard[53]. While an order by the government[54] has brought in provisions for recording of consent, its implementation has been lacking due to poor infrastructure.

Rule 122DD mandates the registration of Ethics Committee, which is responsible for approving clinical trials and conducting periodic reviews. The rules however fail to put up any responsibility on the ethics committee in case

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51 Compensation Formula, CENTRAL DRUGS STANDARD CONTROL ORGANISATION, (2013), *available at* http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf. Formula to determine the quantum of compensation in case of clinical trial related injury (other than death), CENTRAL DRUGS STANDARD CONTROL ORGANISATION, (Nov., 2014), *available at* http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf

52 Rule 122 DA of Schedule Y.

53 If policy mandates that only literate people be included in clinical trials so as to do away with the shortcoming of written informed consent, the illiterate people, who form a major chunk of the population would be excluded with is another reason for impoverishment.

54 Order of the Office of Drugs Controller General, MINISTRY OF HEALTH AND FAMILY WELFARE, (Nov. 19, 2013), *available at* http://www.cdsco.nic.in/writereaddata/Office%20Order%20dated%2019.11.2013.pdf.

of trial related deaths or injury. The 2013 Amendment Bill[55] to the Drugs and Compensation Act envisaged placing the entire responsibility on the ethics committee. The standing committee on health was however of the opinion that the responsibility must be divided equally among the sponsors, investigators and ethics committee[56]. Lack of any clarity in this regard makes it difficult for families of victims to claim compensation.

The other major lacuna in the law includes absence of demarcation between trials involving simple medicinal drugs, medicinal drugs for gene therapy and special medicinal drugs. There should be separate requirements for permission and separate methods of calculating compensation for different kinds of drug trials, depending on the potential severity of their effects[57]. The only law governing clinical trials is Schedule Y of the Drugs and Cosmetics Rules. However, the law suffers from numerous errors. While the government should assume the role of the protector and provide with adequate rights and safety mechanisms their people, the unhelpful amendments clearly show the lackadaisical attitude of the government towards an important issue like clinical trials.

The PIL filed by Swasthya Adhikar Manch has brought to the fore the

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55 The Drugs and Cosmetics (Amendment) Bill, 2013, *available at* http://www.prsindia.org/uploads/media/Drugs%20and%20Cosmetics/drugs%20and%20cosmetics%20bill.pdf.

56 79th Report on The Drugs and Cosmetics (Amendment) Bill, 2013, MINISTRY OF HEALTH AND FAMILY WELFARE, (2013), *available at* http://www.prsindia.org/uploads/media/Drugs%20and%20Cosmetics/SCR-Drugs%20and%20cosmetics.pdf.

57 Ashna Ashesh & Zubin Dash, *Inadequacies of Clinical Trial Regulations in India*, 5 NUJS L. REV. 379, 395 (2012).

important role that free informed consent can play in clinical trials. Keeping that in mind, one can say that the Indian laws still lack very important features that are present in the jurisprudence of other developed countries. Laws in the UK, for instance, classify incapacitated people into three groups – people who had consented to participation before incapacitation, people who had neither consented nor negated their consent and people who had repudiated their consent before incapacitation. The third group of people cannot be used as participants of trial while the second group of people can participate only if the legal representatives consent to it[58].

India creates no such distinction thereby treating all incapacitated people as a homogenous group whose inclusion in trials can be done by the consent of their legal representatives. Such a provision fails to respect the autonomy of the third set of incapacitated people thereby depriving them of their basic human capabilities. This provision also has the potential to be misused given that economically weaker people would consent to the involvement of their incapacitated relatives, in return for financial benefits and free medical care.

Schedule Y does not provide for separate guidelines regarding participation of women and children in trials. Such an absence leads to discrimination against them by excluding them from participation or participation under reduced autonomy. There is a lack of punitive measures and criminal penalties in the act and rules. Severe penalties can act as a

[58] *Id.*, 398.

deterrent for future sponsors and encourage them to conduct trials in a manner that does not further impoverish participants. Additionally, the current system suffers from an absence of a settled grievance redressal mechanism for participants[59]. A mere compensation may not be sufficient to address issues of physical and psychological transformations that an impoverished person undergoes in a clinical trial. It is critical to look at clinical trials as affecting participants in multiple ways.

Unfortunately, a number of progressive legislations and policies have not yet been implemented. The Ethical Guidelines for Biomedical Research on Human Subjects[60] which was released by the ICMR in 2000 is one such example. These guidelines are progressive and in consonance with the CIOMS International Ethical Guidelines[61] as they provide separate guidelines for women and children trial participants and recognize the possibility of undue influence and coercion in certain relationships[62]. The guidelines have however failed in its realization due to lack of statutory backing. The CIOMS guidelines, before being brought out proclaimed, underwent a detailed study of special groups like children and women as participants of trials.

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59 There should be proper awareness about who to approach in case of trial related injury or deaths. Participants and their families should also be made aware of their rights, the methodology and procedure of the experiment, the cost benefit analysis, the compensation policy, alternative methods available and the benefits arising from commercialization.

60 Ethical Guidelines for Biomedical Research on Human Subjects, INDIAN COUNCIL FOR MEDICAL RESEARCH, (2000), *available at* http://icmr.nic.in/ethical_guidelines.pdf.

61 The Council for International Organisations of Medical Sciences brought out the International Ethical Guidelines for Biomedical Research involving Human Subject in 1993 and amended it in 2002. The guidelines can be viewed at http://www.cioms.ch/publications/layout_guide2002.pdf.

62 Such people who may take a decision under undue influence can include a person who is not well versed with medical terminology, an illiterate person, a prisoner, an employee and so on.

The reason for a special study was to "*emancipate them from the constructs of patriarchal society that is largely prevalent in developing countries*"[63]. However, it is to be noted that Schedule Y was enacted with no such prior studies being conducted. This move is especially surprising since in a country like India, where the society is largely patriarchal, such a study would have played a major role in curbing the undesirable practices of gender discrimination. Additionally, in absence of any specific provisions protecting women and the elderly in particular, there is a great possibility of men from the economically weaker sections dominating their partners or elderly parents from participating in the trials for monetary gain.

The Drugs and Cosmetics (Amendment) Bill, 2013[64] which has prescribed penal consequences for the use of sub-standard drugs and medical devices has also not seen the light of the day. Lack of proper regulations, absence of uniform standards, arbitrary guidelines and ineffective implementation of legislative provisions has led to denial of fundamental principles defining the scope of Right to life and Right to Health under Article 21[65]. Article 21 of the Constitution does not allow for the deprivation of life and personal liberty, except according to fair, just and reasonable procedure established by law. In the absence of a fair, just and reasonable procedure established by law, such deprivation of right to life and health can be argued to be unconstitutional.

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63 Ashesh & Dash, *supra* note 56, at 400.

64 *Supra* note 46.

65 Article 21 of the Constitution does not allow for the deprivation of life and personal liberty, except according to fair, just and reasonable procedure established by law, as has been held in Maneka Gandhi v. Union of India, AIR 1978 SC 597.

IV. HOW CAN IMPOVERISHMENT BE ADDRESSED?

Given that existing legislations act as a means of impoverishment, certain changes should be brought about in the legal provisions so that the impoverished can enjoy their freedom in the substantive sense. Clinical trials largely involve people who are not economically well off because of the economic incentive and free medical treatment that they offer. This can be majorly addressed if basic public health facilities and essential medicines are made cheaper and more accessible. The exorbitant amount of basic minimum compensation needs to be given only after proper scrutiny of the conditions of the participant and whether the participant has given free informed consent.

The compensation should not influence the thought process of the economically weaker sections of the society in any manner. The laws regarding voluntary informed consent needs to be amended. A more consultative and participatory approach will also help address the problems of disadvantaged groups like women, children and the aged. The people lacking sufficient means should be effectively made aware of the possible benefits and risks of the trial. There needs to be clarity in Schedule Y as to signing of consent for incapacitated people and requirement of consent in writing. Audio visual mode of consent taken by objective observers may help overcome the lacunae.

It is essential to have separate requirements for permission for different kinds of drug trials depending on the severity of their effects. There is also a need for an international standard of training for personnel conducting investigations at trial sites. The Supreme Court had ordered the government

to file its response regarding its failure to supervise the HPV vaccination trials[66]. However, the government in April 2015 responded saying that it could not hold the sponsors liable due to inadequacy of penalty clauses in the existing laws[67]. While the laws must provide for penal provisions for sponsors, investigators and ethics committee for any trial related injury or death, there is a need to clarify definitions of 'injury' and 'trial related injury'.

In June 2016, the Cabinet withdrew the Drugs and Cosmetics (Amendment) Bill, 2013 stating that there were many new areas of law, namely areas involving stem cells, medical devices and clinical trials that were to be included in the bill[68]. While this may seem as a welcome move, the scrapping of the bill to include other new provisions can also be seen as a delaying tactic by the government.

The delay essentially fails to acknowledge the importance that participation in clinical trials hold. However, it is also necessary to understand that amendments and policy changes with regard to clinical trials alone cannot themselves do away with impoverishment and violation of rights. The biggest problem in India is effective enforcement of laws and when laws are flouted, there is a lack of redressal mechanisms thereby rarely leading to penalty of violators. While implementation of laws need to be done strictly, other

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66 *Supra* note 3.

67 *Can't penalize US NGO for violating drug trial norms*, THE INDIAN EXPRESS, (Apr. 18, 2015), *available at* http://indianexpress.com/article/india/india-others/cant-penalise-us-ngo-for-violating-drug-trial-norms/.

68 Jyotsna Singh, *Cabinet withdraws drugs and cosmetics amendment bill*, LIVEMINT, June 22, 2016, *available at* http://www.livemint.com/Industry/EY23lZyuBPOHbpvNqFmN4K/Govt-to-revise-drugs-law-draft-new-rules-for-medical-device.html.

government schemes promoting literacy, access to health care, micro insurance, employment and access to food will have to be simultaneously dealt with in order to do away with impoverishment. Any person will be able to make an informed choice only if he has the "freedom to choose the kind of life that he has reason to value"[69]. One needs to enjoy a combination of economic, social and political freedom in order to live a life free of any coercion.

V. CONCLUSION

Clinical trials operate within a regime where the advancement of science and technology is considered to be the most important and immediate need for the greater good of the society. This leads to a *hierarchisation* of rights in which the right to life and health of an individual is considered to be subservient to the right of the society to avail an advanced drug. Such *hierarchisation* raises concerns over whether the utilitarian notion of greatest good for the greatest number is a valid justification for violation of inalienable human rights. Economically weaker people need to be looked at as citizens and not merely as 'subjects' of the state. There is a duty on the state to not only avoid and protect from deprivation but also to aid the deprived[70]. Proper regulations need to be introduced and numerous government schemes need to be improved concurrently so as to grant every individual their right to a dignified existence. The job of the legislature has to be supplemented by the

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69 SEN, *supra* note 10.

70 HENRY SHUE, BASIC RIGHTS: SUBSISTENCE, AFFLUENCE AND US FOREIGN POLICY 60 (Princeton University Press, 1980).

role of the judiciary. The judiciary needs to take cognizance of the fact that it has been conferred with the role of the protector of rights by the Constitution of India.