THE RIGHT TO HEALTH UNDER INTERNATIONAL LAW WITH SPECIAL REFERENCE TO CLINICAL TRIALS AND PERSONALISED MEDICINE

Thesis submitted to Jawaharlal Nehru University

for award of the degree of

DOCTOR OF PHILOSOPHY

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DECLARATION

I declare that the thesis entitled **"The Right to Health under International Law with Special Reference to Clinical Trials and Personalised Medicine"** submitted by me for the award of the degree of **Doctor of Philosophy** of Jawaharlal Nehru University is my original work. The thesis has not been previously published or submitted for any other degree of this University or any other University.

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CERTIFICATE

We recommend that this thesis be placed before the examiners for evaluation.

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DEDICATED TO

THE POOR AND VULNERABLE

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Tenzin Jangchup Khampa

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ABBREVATIONS

AAAQ	Availability, Accessibility, Acceptability and Quality
ADE	Adverse Drug Effect
AIDS	Acquired Immune Deficiency Syndrome
ANADA	Abbreviated New Drug Application
APIC	Association for Professionals in Infection Control
ART	Assisted Reproductive Technology
AZT	Azidothymidine
BPL	Below Poverty Line
CBD	Convention on Biological Diversity, 1993
CD	Communicable Disease
CDC	Centers for Disease Control and Prevention
CDSCO	Central Drug Standard Control Organisation
CEDAW	United Nations Convention on the Elimination of All Forms of Discrimination Against Women, 1979
CESCR	United Nations Committee on Economic, Social and Cultural Rights 1966
CRPD	United Nations Convention on the Rights of Persons with Disabilities 2006
CRC	United Nations Convention on the Rights of the Child, 1989
CT	Clinical Trial
DCG (I)	Drug Controller General of India
DDA	Disability Discrimination Act
DT	Demographic Transition
DALY	Disability-Adjusted Life Year
ECtHR	European Court of Human Rights
EDs	Ethical Drugs
EFPIA	Europe Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ESC	Economic and Social Council
ESCR	Economic, Social and Cultural Rights

FDA	Food & Drug Administration
FDCs	Fixed-Dose Combinations
FDI	Foreign Direct Investment
FFS	Fee for service
GA	General Assembly
GATS	General Agreement on Trade in Services
GBV	Gender Based Violence
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
Govt.	Government
GoI	Government of India
GSK	Glaxo Smith Kline
HCWs	Health-care Workers
HDI	Human Development Index
HGP	Human Genome Project
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human Immunodeficiency Virus
HR	Human Rights
H5N1	Avian Influenza A
ICAO	International Civil Aviation Organisation
ICCPR	International Covenant on Civil and Political Rights, 1966
ICESCR	International Covenant on Economic Social and Cultural Rights, 1966
ICMR	Indian Council of Medical Research
ICPD	International Conference on Population and Development
ICSI	Intracytoplasmic Sperm Injection
IHR	International Health Regulations
IND	Investigational New Drug
IVF	In Vitro Fertilisation
LDCs	Least Developed Countries
MAR	Medically Assisted Reproduction

MCC	Medicines Control Council
MDG	Millennium Development Goals SDGs
MIC	Methy-Iso-Cyanate
MEA	Ministry of External Affairs
MOHAFW/MH&FW	Ministry of Health and Family Welfare
MRAs	Medicines Regulatory Authorities
MRSA	Methicillin-resistant Staphylococcus aureus
NCD	Non-Communicable Disease
NDA	New Drug Application
NDD	Non-directed Donation
NGO	Non-Governmental Organisation
NHGRI	National Institutes of Health's National Human Genome Research Institute National Human Genome Research Institute
OAS	Organisation of American States
OH	Occupational Health
OIHP	Office International D'Hygine Publique
OPV	Oral Polio Vaccine
OTC	Over-the-Counter
PGD	Pre-implantation Genetic Diagnosis
PGx	Pharmacogenomics
PHC	Primary Health Centers
PhRMA	Pharmaceutical Research and Manufacturers of America
PM	Personalised Medicine
PPP	Public Private Partnership
RBA	Right Based Approach
RTH	Right to Heath
R&D	Research and Development
SDGs	Sustainable Development Goals
SR	Special Rapporteur

STD	Sexually Transmitted Diseases
TCC	United Nations Tobacco Control Convention
TB	Tuberculosis
THO	Transplantation of Human Organs
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRIPS Agreement	WTO Trade Related Aspects of Intellectual Property Rights
UCC	Union Carbide Company
UDHR	Universal Declaration on Human Rights
UCIL	Union Carbide India Limited
U.N	United Nations
UNGA	United Nation General Assembly
UNGASS	United Nations General Assembly Special Session
UNOS	United Network for Organ Sharing
U.S	United States
VRE	Vancomycin-resistant Enterococci
WASH	Water, Sanitation and Hygiene
WHA	World Health Assembly
WHO	World Health Organisation
WTO	World Trade Organisation
YF	Yellow Fever

Chapter-I

INTRODUCTION

Since time immemorial health and disease are accepted to be saddled with trouble, misery and pain for all Homo sapiens. Hence, recognition of health as a right cannot be understood, until one encounters the same suffering and threat from its mild attack. Accompanying to this, challenges carrying prospects through research and development (R&D) make scientific technologies and therapies to function. But late detection, incorrect suggestion may lead to providing wrong medication to patients or health sufferers. Such research experiments may land in damaging individual's health either through minimal side effects or by permanent disability.[1] On the other hand burden from communicable diseases (CDs) or non communicable diseases (NCDs) may act as a serious health challenge from one country to another. Moreover, present threats such as CDs and NCDs are like Ebola, Swine flu, HIV/AIDS, Obesity, TB, Hyper-tension, etc. To tackle with CDs outbreak, the World Health Organisation (WHO) in 1969 took an initiative to engage its member states to take regulatory measures at country level where reporting through surveillance for prevention and control of diseases can be possible. The International Health Regulation (IHR) made it possible and in its Article 6(1) it directs all member states that:

> "During an epidemic the notifications and information required under Article 3 and Article 5 shall be followed by subsequent communications sent at regular intervals to the Organisation".[2]

This indicates that all the member States of the WHO[3] within 24 hrs have to report on epidemics. By telegram or telex through state health administers help for informing every occurrence/arrival or resistance of disease/s in their or neighbouring

[1] Armelagos, George J., Barnes, Kathleen C., and Lin, James. (1996), "Disease in Human Evolution: The Emergence of Infectious Diseases in The Third Epidemiological Transition", (Reprinted from) *National Museum of Natural history Bulletin for Teachers,* p.1; available at: www.facstaff.unca.edu/cnicolay/cluster/disease-evol.pdf

[2] Article 6(1) of WHO, IHR 1969 in WHO, (1983), World Health Organisation. International Health Regulations (1969). 3rd ed. Geneva: The World Health Organisation; 1983; available at: www.nszm.cz/cb21/archiv/material/worldhealthdeclaration.pdf

[3] All the U.N member countries can become member of WHO by accepting its constitution. At present there are 194 countries as its members. WHO, (2016), WHO/Countries-World Health Organisation"; available at: www.whi.int.countries

region. The direction is not just states about reporting but in the Article 9(2) of IHR 1969 firms its mandate by stating that:

> "In addition to the notifications and information required under Articles 3 to 8 inclusive, each health administration shall send to the Organisation weekly a report by telegram or telex of the number of cases of the diseases subject to the Regulations and deaths, during the previous week in each of its towns and cities adjacent to a port or an airport, including any imported or transferred cases; a report has to be send by airmail of the absence of such cases during the periods referred to in subparagraphs (a), (b) and (c) of paragraph 2 of Article 7". [4]

Reporting and taking measures on information and evidence on arrival of disease or infection with time elapse demands disease prevention and control act or law for a country. Such measure can assists in international traffic of ports and airports. Similarly facts about an area, *"free from infection and no evidence of reoccurrence"* becomes obligatory to report to the WHO by the health administration under Articles 7.1, 7.2, 7.2(a), 7.2(b)(i), 7.2(b)(ii), 7.2(c)(i) and 7.2(c)(ii) of IHR 1969.[5] A Chinese case study published in 2007, revealed that reporting within a country about communicable disease can help in identifying and treating individual sufferers. Such prevention and control of disease was observed for tuberculosis (TB) infected Chinese individuals, who produced weakness in physical condition since 2003 outbreak of SARS. Measure of 2004 internet reporting system in China brought nationwide legal regulating system, having complete records of 37 communicable diseases.[6] Implementation of electronic reporting data base about occurrence and sufferers name made day go lesser by 1 day from 29 days[7] by regular updating internet reporting data. Records were carried in one data base, from all over local district level to central level in China; this measure supported the initiative of Directly Observed Treatment Short course (DOTS) for TB. In 1992 China[8] made global TB

[4] Articles 9(2) of WHO, IHR 1969 in WHO, (1983), World Health Organisation. International Health Regulations (1969). 3rd ed. Geneva: The World Health Organisation; 1983; available at: www.nszm.cz/cb21/archiv/material/worldhealthdeclaration.pdf

[5] Articles 7(1), 7(2), 7(2)(a), 7(2)(b)(i), 7 (2)(b)(ii), 7(2)(c)(i) and 7(2)(c)(ii) of WHO, IHR 1969 in WHO, (1983), World Health Organisation. International Health Regulations (1969). 3rd ed. Geneva: The World Health Organisation; 1983; available at: www.nszm.cz/cb21/archiv/material/worldhealthdeclaration.pdf

[6] Wan, Liya., Cheng, Simming., and Chin, P Daniel., (2007), "A New Disease Reporting System Increases TB Case Detection in China". NCBI. Bulletin of World Health Organisation, Beijing, p.5; available at: www.ncbi.nlm.nih.gov>PMC2636671

[7] Ibid, p.6.

[8] Ibid, p.2.

control target by DOTS, which became possible in China by 2005 and the target about 70% case of TB were detected along with 85% TB cases were treated successfully.[9]

Therefore reporting system becomes an obligating requirement in respect of health and its protection or control of infectious diseases. The United Nations (UN) Charter also obliges the Economic and Social Council (ESC) to make initiative regarding all the UN member states in respect of health and related matters, so suggestions and recommendation regarding such matters can be given to General Assembly (GA), member of the UN and to specialised agency concerned.[10] The ESC recommends all the UN members to respect and observe human rights and fundamental freedoms concerning health and its social, economic, education, etc determinants.[11] In competence power of the ESC it may prepare draft conventions for GA regarding health matters.[12] Moreover, the ESC following the rules set by UN, though it can call for international conferences on matters falling within its competence.[13]

In spite of rigorous challenges for reporting of evidence and maintaining records of death/ infection notification during the outbreak of CDs, all the individual States'/nation, organisations and specialised agencies, etc should cooperate and function together to overcome such challenge. Besides, every nation should learn from each other to work for healthcare of its people. The Alma-Ata of 1978 rightly affirms that:

> "The attainment of health by people in any one country directly concerns and benefits every other country".[14]

This statement provides reality of international relationship making all different individual states come together and work in regard to humanity, friendship and health of individuals without borders and discrimination based on colour, sex, race, religion, creed, ethnicity, etc. On the other hand, when incidence about death occurrence comes, revelation for NCDs appears from 2011 WHO. So as to counting figure of death facts from 57 million deaths in 2010 about 36 million individuals died

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[9] Ibid, p.10.
[10] Article 62(1) of the UN Charter; available at: www.treaties.un.org/doc/publication/ctc/uncharter.pdf
[11] Article 62(2) of the UN Charter, ibid.
[12] Article 62(3) of the UN Charter, ibid.
[13] Article 62(4) of the UN Charter, ibid.
[14] For instance refer (Principle No. IX), the Alma-Ata 1978. In *Declaration of Alma-Ata International Conference on Primary Health Care*, Alma-Ata, USSR, 6-12 September 1978; available at: www.who.int/hpr/NPH/docs/declaration_almaata.pdf

only due to NCDs.[15] Understanding for NCDs has always been as neglected diseases like diarrhoea that has been rooting mainly in developing countries[16] since ages and has no much interest for pharmaceutical industries and developed worlds. Besides, NCDs also comprise diseases like cardiovascular, cancers, obesity, hyper-tension, diabetes, chronic respiratory diseases, and chronic lung diseases, etc that also exist in developed worlds.[17] Accepting, truth for NCDs as neglected disease in 2010, the Millennium Development Goals (MDGs) drafters had forgotten to address about NCDs. Despite MDGs are related to improving condition of poor and most vulnerable people by the help of all its eight MDGs.[18] Additionally, in 2012, the UN task team for post-2015 development agenda by Sustainable Developmental Goals (SDGs)[19] accepted that through the MDGs no effect was taken for increasing NCDs and just identified it as a

> "priority for social development and investments in people".[20]

This acceptance of negligence became reviewers based for MDGs agenda only when NCDs started leading acceptance for diarrhoea problem due to water, sanitation and hygiene fact in developing world and increasing diabetes, obesity and hyper-tension suffering globally. Further, NCDs in comparison to CDs are considered less devastating. But the modern and competing world direction for both either NCDs or CDs both lead threat for prevention and control of disease in a country population. Subsequently, analysing the increasing burden of diseases and rising risk factors in both developed and developing countries, led early deaths of economic generating

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[15] For further details, see, WHO, (2011), "*WHO Global Status Report on Non-Communicable Diseases 2010*", p.vii; available at: www.who.int/nmh/publications/ncd_report_full_en.pdf

[16] Ibid.

[17] Ibid.

[18] The eight MDGs are: Goal 1: Eradicate extreme poverty and hunger; Goal 2: Achieve universal primary education; Goal 3: Promote gender equality and empower women; Goal 4: Reduce Child Mortality; Goal 5: Improve maternal Health; Goal 6: Combat HIV/AIDS, malaria and other diseases; Goal 7: Ensure environmental sustainability; Goal 8: Develop a global partnership for development. For details refer, MDG Gap Task Force Report 2012, (2012) "*Millennium Development Goal 8-The Global Partnership for Development: Making Rhetoric a Reality*", United Nations Publications, New York, p. ix-x.

[19] The UN General Assembly Resolution 70/1 of 25 September 2015 entitled *Transforming our world: the 2030 Agenda for Sustainable Development*; available at: www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E

[20] Ralston, Johanna. (2012), "Why Non-Communicable Diseases Must Be Part of any New Development Goals", *Guardian News and Media Limited*, UK, December 2012, p. 1-3; available at: www.guardian.co.uk/global-development/poverty-matters/…/non-communicable-diseases-development-goals

population. This hinders the Demographic Transition (DT)[21] in population of a society and their impacts on Disability-Adjusted Life Year[22] (DALY). Moreover, the framework of policies and laws in preparing health as a right as to perceive all its dimension and determinants to improve protection through right based approach (RBA). Further, the debate surrounding universal access and coverage is likewise, increasing socio political and economic concern to address the international human rights.

THE RIGHT TO HEALTH

Health as we understand today is incomplete when there is no legal right attached to it. The political agenda's provided by the Govt. of a country through different schemes and policies limit health rights with unequal distribution of facilities and benefits. RTH is considered to be attached with freedom and entitlement[23] to make enjoyment of health possible mentally, physically[24] and socially. Facts and lessons on health torture, discrimination, etc have been existing in human history[25] or in present world[26] especially on poor, vulnerable and weak section of the society in

[21] Demographic transition is the process of change in population of a society. This theory consists of four stages: Stage I/Pre Transition, when there is high death rate and birth rates this process lead to low growth rate. Africa has this process and some of the places are like Niger, Angola, Zambia, Malawi and etc. Stage II/Early transition when rapid decline in death rate and continued high birth rate occurs this leads to very high growth rate eg: India is in this process. Stage III/Late transition, when rapid decline in birth rate and continued decline in death rate occurs this leads to decline the growth rate. This is the stage of Japan. Lastly, in the Stage IV/Post transition, low death and birth rates leads to low growth rate. Europe is the best example and the countries will be like Russia, Germany, Bulgaria and etc; For further detail, see, the PAPP, (2016), "The Demographic transition", *Population Analysis For Policies & Programmes*, Iussp.org; available at: www.papp.iussp.org>PAPP101_s01_010

[22] DALY is a measure overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. This explains the potential years of life lost due to premature death. Also see, the WHO, (2016), "Metrics: Disability-Adjusted Life Year (DALY)", Health Statistics and Information System, Global Health Estimation. WHO: Geneva; available at: www.who.int>global_burden_disease

[23] (The Paragraph 8), The *General Comment No. 14: the Right to Highest Attainable Standard of Health* (Article 12 of the International Covenant on Economic, Social and Cultural Rights) 2000. UN document E/C.12/2000/4, 11 August 2000; available at: www.refworld.org/pdfid/4538838d0.pdf

[24] Article 12(1) of *International Covenant on Economic Social and Cultural Rights* (ICESCR) U.N.G.A. Res. 2200A (XXI) of 16 December 1966 (entered into force 3 January 1976, in accordance with article 27); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[25] The Medical Case, *U.S.A. v. Karl Brandt, et al* US Military Tribunal, Nuremberg, (1951), "Trials of War Criminals before the Nuremberg Military Tribunal under Control Law", November 21, 1946-August 20, 1947, 10 (II), Washington DC. US Government Printing Office; available at: www.archives.gov/research/captured-german-records/microfilm/m887.pdf . and available at: www.nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=transcript .

[26] *Swasthya Adhikar Manch, Indore & Anr. v. Ministry of Health & Family Welf. & Ors*. (2012), WP (C) 33 of 2012, Order Dated 3rd January 2013, with W.P(C)No. 79 of 2012; available at: www.cdsco.nic.in>writeddata ; and www.sacw.net>article9730

the name of scientific and biomedical achievement. Considering health as a right, understanding changes depending on different health requirements of individuals/society or community. Such differences in availing arrangements can be based on diseases, medicines and other health determinants like water, shelter, insurance, medicines, biotechnologies and environment, etc. Since, many a time in need of basic necessities requirements many individuals get discriminated as well as get victim in name of financing their healthcare and treatment. Health disparities generate health as a right based approach (RBA). The Paragraph 3 of the General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR (2000) in RBA favour states that:

> "(T)he right to health is closely related to and depends upon the realisation of other human rights, as contained in the International Bills of Rights, including the right to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health".[27]

The RTH has developed through both health care and other essential conditions needed for health. Definitely health as a right must be affordable to every individual without any discrimination. The Article 25(1) and (2) of Universal Declaration of Human Rights (UDHR) 1948 supports health as a right without discrimination and it states that health is meant for the well-being of individual and his/her family along with other health determinants including during the condition of widowhood, old-age, unemployment and other beyond control circumstances.[28] UDHR pressures its member states to take special care and assistance for childhood or during motherhood and provide same social protection to children born in or out of wedlock.[29] Since, the RTH is a condition[30] to be healthy and have social protection through available and affordable resources provided by the government in a country to its people. Many a time factor influencing an individual's health can be so

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[27] For further details, see Paragraph 3, of the *General Comment No. 14: the Right to Highest Attainable Standard of Health* (Article 12 of the International Covenant on Economic, Social and Cultural Rights) 2000. UN document E/C.12/2000/4, 11 August 2000; available at: www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[28] Article 25(1) of the UDHR 1948; available at: www.unhchr.ch/udhr/

[29] Article 25(2) of the UDHR 1948; ibid.

[30] The term condition may refer to the Article 12(2)(d) of the International Covenant on Economic and Social Cultural Right (ICESCR) 1966 that states "the creation of condition which would assure to all medical attention in event of sickness". For details, see, Article 12(2)(d) of ICESCR 1996; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

protected and prevented through society and community he/she lives. Moreover, education and awareness on prevention relating to sexually transmitted diseases, treatment for urgent medicare, provisions during emergency situation like disaster relief or humanitarian assistance and control of epidemic, endemic, occupational and other disease. Joint efforts through State and individuals for updating modern technologies as health equipments can help during surveillance, data collection, curing and treating patients especially in epidemiology case or for programmes like immunisation and disease control strategies.[31]

Moreover, health when looked through social justice, it is essential to study determinants of health like biological, environment, behaviour and socio-cultural condition, health services; socio-economic condition; aging of the population, gender, information and communication, science and technologies and etc, along with health dimensions.[32]The WHO states that health is multidimensional but three are main and they are:

> "i) Physical Health: physical health means perfect function of body. The physical functioning of the health where every organ is functioning to its optimum capacity and some of the agents for its developments are alcohol awareness, nutrition, sexual health, tobacco use and other related areas., ii) Mental Health: mental means refers to broad array of activities directly or indirectly related to the mental well being and not just absence of mental disorder. Mental health carries major and minor illness such as Schizophrenia, Manic Depressive Psychosis, Paranoia, Neurosis or psychoneurosis, personality and character disorder , and iii) Social Health: Social well being means to harmony and integration within the individual, between each individual and other members of society and between individuals and the world in which they live. It has been as the quantity and quality of an individual's interpersonal ties and the extent of involvement with community. Social health is rooted in "positive material environment" and "positive human environment" which is concerned with the social relationship of the individual". [33]

The enactment and enforcement of RTH is constantly emerging as an important condition created by the governments to provide healthier lives as well as

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[31] For further details see, the paragraph No.16 on "the Right to Prevention, Treatment and Control of Disease" of the General Comment no. 14: the Right to the Highest Attainable Standard of Health (Article 12 of ICESCR) 2000; available at: www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[32] Park. K. (2005), "*Park's Textbook of Preventive Medicine and Social Medicine*", Banarasidas Bhanot Pub. Jabalpur p.12, 17-18; and Kumar, Avanish (2007), "*Human Rights to Health*", Noida: Satyam Law International, p. 24-40.

[33] For further details, see, Paragraph 2 of the WHO, (2011), "*Constitution of the WHO"* Basic Document forty-fifth edition supplement, October 2006. Fifty first World Health Assembly; available at: www.who.int/governance/eb/who_constitution_en.pdf ; and Park. K. (2005), "*Park's Textbook of Preventive Medicine and Social Medicine*", Banarasidas Bhanot Pub. Jabalpur, p.12.

save lives to individuals.[34] The rights-based discourse and implications of the RTH for accessing medicines, insurance and genetic technologies require attainment of adequate standard of health and socio-economic condition with social security environment to with dignity and without discrimination. Thus the right to health has its meaning in a wider sense. Health in its RBA has two main components that can legally be enforced based on freedom and entitlement. The paragraph 8 of the General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR (2000) states that:

> "... The right to health contains both freedom and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health". [35]

In view of the above issues of health options and awareness include individual free choices through consent and knowledge to opt or withdraw from the health facility and arrangements as an individual wants to perceive. In case of clinical trial (CT) experiment, it is based upon an individual choice to be the subject as well as to opt for it or not. From this point of view the new modern method of treatment like personalised medicine (PM) is not an exception.

Right to Health under International Law

The Right to Health (RTH) is an established principle under international human rights treaties and according to World Health Declaration of the WHO, it states that:

> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity; the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition". [36]

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[34] Gostin, Lawrence O. (1999), "Turning Point: Collaborating for a New Century in Public Health", *Public Health law: Power, Duty and Restraint*, University of California Press and Milbank Memorial Fund 2000, p.3.

[35] Paragraph No. 8 of the *General Comment No. 14: The Right to Highest Attainable Standard of Health* (Article 12 of the International Covenant on Economic, Social and Cultural Rights) 2000. UN document E/C.12/2000/4, 11 August 2000; available at: www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[36] Paragraph 2 and 3 of the WHO, (2011), "*Constitution of the WHO"* Basic Document forty-fifth edition supplement, October 2006. Fifty first World Health Assembly; available at: www.who.int/governance/eb/who_constitution_en.pdf

Moreover, the Geneva Conventions 1949 that form the bedrock of modern International Humanitarian Law (IHL) provides health assistance during armed conflict, violence to life and person, placed as *hors de combat*.[37] United Nations Education, Scientific and Cultural Organisation (UNESCO) works to impart dignity, equality and mutual respect of health biology and medicine of individuals and their concerns regarding application of genetics in the field of intellectual property, micro-organisms, scientific research ethical and moral rights, etc.[38] The International Labour Organisation (ILO) also looks after occupational health safety and adequate working environment with strategic procedures to control occupational accidents and diseases by employers and provide insurance institutions.[39] Taking into account the minimum age for employment, it has laid down directive to give adolescents below 18 years, a special protective measure.[40] Moreover, concerns regarding problem relating to early marriage, pregnancy, sexual and reproductive health issues has led to obligation for the ILO members to reform, their legislation, where-ever required, in providing special protection measure to adolescent.[41]

WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) directs its member states to constitute national emergency understanding public health crisis and extreme urgency.[42] TRIPS Agreement provides right to member states to have compulsory licensing grant for determining grounds for granting licenses.[43] TRIPS Agreement also promotes transfer of technology to the least developed countries along with giving relaxation in respect of pharmaceutical

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[37] Common Article 3 of the Geneva Convention 1949; available at: www.icrc.org/Web/Eng/siteeng0.nsf/html/genevaconvention

[38] UNESCO has 195 member states and is a specialised agency. For details, see, the Universal Declaration on the Human Genome and Human Rights 1997; available at: www.unesco.org/shs/human_rights/hrbc.html

[39] ILO as first institution raised awareness for insurance. For further details, see, Convention Concerning Occupational Safety and Health and the Working Environment (1998); available at: www.ilo.org/ilolex/english/subjlst.html

[40] Adolescence is the healthy population and they have right to enjoy highest attainable health along with well balanced manner of development. These developments are challenges to health and for individual's identity dealing safe and supportive milieu. For detail, see, General Comment No. 4 Adolescent Health and Development in the Context of the Child (2003); available at: www.unhchr/tbs/doc.nsf/(symbol)/CRC.GC.2003

[41] ILO has 187 members including Cook Islands; ibid.

[42] Doha Declaration on the TRIPS Agreement and Public Health, (2001); available at: www.wto.org/english.thewto_e/mindecl_trips_e.htm

[43] Ibid.

products.[44] Furthermore, the Article 38(1)(a),(b),(c),(d) and 38(2) of the UN Charter, specifically mandates the International Court of Justice (ICJ) to apply:

> "a) international conventions, whether general or particular, establishing rules expressly recognised by the contesting states; b) international custom, as evidence of a general practice accepted as law; c) the general principles of law recognised by civilized nations; d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly quailfied publicists of the various nations, as subsidiary means for the determination of rules of law. 2) This provision shall not prejudice the power of the Court to decide a case *ex aequo et bono*, if the parties agree thereto".[45]

RTH has been embedded in significant number of international and regional human rights instruments[46] governing the conduct of states, organisations and individuals. So that, health as a fundamental right can be achievable by responsibility of international community to respect, protect and fulfill it.[47] Likewise the International Health Regulations (IHR) 2005 of WHO that entered into force on 15 June 2007 mandates disease surveillance regulation under international law for protection and control from disease threat and to control minimum interference with world traffic. The IHR functions to strengthen the use of epidemiological principles as applied as internationally:

> "(T)o detect, reduce or eliminate the sources from which infection spreads, to improve sanitation in and around ports and airports, to prevent the dissemination of vectors and, in general, to encourage epidemiological activities on the national level so that there is little risk of outside infection establishing itself".[48]

These regulations are not only limited to specific diseases but also applicable to other health risks. Moreover, all the WHO members have to implement these regulations by amending their domestic laws. Traditionally, the RTH is still remains lowest priority in the Constitutions of most of the countries.[49] For instance in India

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[44] Ibid.

[45] Article 38(1)(a),(b),(c),(d) and 38(2) of Chapter II of the UN Charter 1945; see The *Charter of the United Nations* and Statute of the International Court of Justice (1945), San Francisco; available at: www. treaties.un.org/doc/publication/ctc/uncharter.pdf

[46] The Paragraph 2, of the General Comment No. 14: The Highest Attainable Standard of Health (Article 12 of the ICESCR) 2000; available at: www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[47] Christin Erk. (2011), "Health, Rights and Dignity-Philosophical Reflections on an alleged Human Right," *Ontos verlag, Heusenetamm*, p.9.

[48] The Paragraph 2 of WHO, IHR 1969 in WHO, (1983), World Health Organisation. International Health Regulations (1969). 3rd ed. Geneva: The World Health Organisation; 1983, p.5.

[49] Finland is the first countries to bring 1992 Act on Status and Rights of Patients (No. 785/1992) that deals with patients rights, self determination, record, etc. Moreover, the Act of Status and Rights of Social Welfare clients (No.812/2000) provides similar facilities like the No.785/1992. As well as the Act on Patient Injuries (No.585/1986) provides compensation for medical damages. For details, see, The General Information-Patient Rights. (2008), "National Patient Rights Legislation-Finland", *Europatientrights.eu;* available at: www.europatients.eu>countries>signed

RTH is granted as after taking into account socio-economic rights contained in Article 47 of Directive Principles of State Policy (DPSP) from the Constitution of India and not as a fundamental right.[50] At, international level, the preamble of the WHO Constitution along with International Covenant of International Economic and Social Cultural Right (ICESCR) 1966, affirms the validity of health as a fundamental right of every human being to enjoy physically as well as mentally.[51]

Interestingly most of the countries have not felt the need of health as a right. But continuous attacks of diseases and its expenses on health have played significant role in the life of every individual. The medicare and medicaid expenses have raised demand for need of health security. The scientific technology and development demand new scientific knowledge either through R&D or biotechnology. It has come with the help of the International Covenant on Economic Social and Cultural Rights (ICESCR) in Articles 12(2)(c) and 12(2)(d). It states:

> "(T)he steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for: … the prevention, treatment and control of epidemic, endemic, occupational and other diseases; … the creation of conditions which would assure to all medical service and medical attention in the event of sickness".

The development of modern technology in medical sphere or health field has widened the arena of the Right to Health. New technology in health care provides accuracy along with correct prediction or detection for suffering as well as pain. The demand for personalised medicine also puts acknowledgement for acceptance creation of condition for treatment and care. Such development of technology can only be possible when successful clinical trials are made on human subjects. Medicines producing promising result for healthcare can only provide condition of health care possible.

Health rights are now a global concern. This awareness came to light during the second Presidential debate for the candidates of 2008 election of the United States (U.S). The then Senator and Presidential candidate, Barack Obama, was pointedly

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[50] Article 47 of the Indian Constitution states that: "the State shall regard the raising of level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health". For details, see, Article 47 of the Constitution of India, (1947), Ministry of Law and justice, p.20; available at: www.lawmin.nic.in>legislation

[51] Article 12(1) of ICESCR 1966 and preamble of the WHO Constitution; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

asked: "Is health care in America a privilege, a right, or a responsibility?" To this Senator Obama replied:

> "(W)ell, I think it should be right for every American. In a country as wealthy as ours, for us to have people who are going, bankrupt because they can't pay their medical bills-for my mother to die of cancer at the age 53 and have to spend the last months of her life in the hospital room arguing with insurance companies because they are saying that this may be a pre-existing condition and they don't have to pay her treatment, here's something fundamentally wrong about that." [52]

This statement underscores that when in a developed country like US if health care is not duly provided then, how will the developing countries provide for the basic health needs of people.[53]

BACKGROUND OF THE STUDY

In order to perform duties, rights have come as a claim that is accepted by all peaceful member States of the world. Similarly, to perform work one needs to be healthy physically and mentally. To observe such obligation it becomes duty of government to provide its people reasonable health with all possible socio-economic resources.[54]

Scope and Core Content of the Right to Health

Increasing contact of diseases through the mode of travel that started with ships from Europe to rest of the world has since been playing a major role in spreading diseases around the globe. As the world is getting closer, the spreading of diseases may affect large number of individuals. In order to overcome these threats preparedness and response measures need to be identified.[55] The global health security measures for control and surveillance of spread of emerging and re-emerging infectious diseases was felt during outbreak of pandemic influenza (Severe Acute

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[52] Clapham, Andrew and Robinson, Mary (eds) (2009), *Realising the Right to Health*: *Swiss Human Rights Book,* Vol. 3, Zurich: Ruffer & Rub, p.16; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html

[53] The Paragraph 4, of the "Health and Human Rights" in The PHA, (2000), "the Peoples Charter for Health", People's Health Assembly (PHA), adopted on 8 December 2000, Savar, Bangladesh; available at: www.phmovement.org/pdf/charter/phm-pch-english.pdf

[54] Martin Rothblatt (2004), *"Your life or Mine : How geoethics can resolve the conflict between public and private interests in xenotransplantation"* Ashgate, England, Martin, 2004, p.106

[55] Armelagos, George J., Barnes, Kathleen C., and Lin, James. (1996), "Disease in Human Evolution: The Emergence of Infectious Diseases in The Third Epidemiological Transition", (Reprinted from) *National Museum of Natural history Bulletin for Teachers,* p. 5-6; available at: www.facstaff.unca.edu/cnicolay/cluster/disease-evol.pdf

Respiratory Syndrome) in 2003. Since, diseases have no borders and domestic level protection is difficult to handle, most governance's response become important, as public health emergencies. Due to such emergencies, the WHO's *International Health Regulations* came up as a working proposal for disease control and surveillance.[56]

WHO functions through the help of its Constitution, health research agendas, setting norms and standards on health measures by articulating evidence based policy, supplying technical support to countries with monitoring health trends.[57] Some of the examples include the WHO International Code of Marketing of Breast-milk Substitutes 1981[58] and the 2003 Framework Convention on Tobacco Control. WHO has mandate to work for global health perspective.[59] So, it becomes duty of international community with the partnership of the host countries to invest in health arrangements for providing basic survival requirements for providing well-functioning health arrangements in poor countries.[60] At present for the domestic application of right to health, ICESCR and UDHR function as an obligating legal mechanism with other regional legal mechanisms.

Moreover, the ICESCR considers two main principles of international law. The first principle highlights the Vienna Convention on the Law of Treaties of 1969 that ordains for giving effect to treaty obligations, the States should modify their domestic laws. On the other hand, for the second obligation, every individual has a right to receive an effective remedy by all the competent national tribunals for every act relating to the violation of fundamental rights guaranteed by the law or by the Constitution of that country, under Article 8 of the UDHR and *General Comment No. 9 on Domestic Application of the Covenant 1999,* (Paragraph 3).[61]

In this connection, the General Comment No. 14, 2000 of Committee on Economic, Social and Cultural Rights in the Paragraph 1 and 3 provides that:

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[56] Gian, luca burci. and Riikka, Koskenmaki. (2009), "Human Rights Implications of Governance Responses to Public Health Emergencies: The Case of major Infectious Disease Outbreaks", p. 346.
[57] WHO, Fact sheet no 31, p.29; available at: www.ohchr.org/Documents/Publications/Factsheet31.pdf
[58] The governments are required to adopt these codes as by not be provided any promotion or advertisement on the breast milk substitutes to the general public, nor shall the pregnant women be supplied with free samples of any breast milk substitutes. For details, see, Gostin, Lawrence O. and Mok, Emily A. (2009), "Grand challenges in global health governance" *British Medical Bulletin*, Oxford University Press, p.9.
[59] Ibid.
[60] Ibid. p. 9-16.
[61] Sinha, Manoj Kumar. et al. (2008), *"Right to Health in the Context of HIV/AIDS in India and Africa",* Manak Publishers, New Delhi: Olutunji, Oyelade S, & Babafemi, Odunsi S, p. 60-61.

> "(H)ealth is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.; ….The right to health is closely related to and dependent upon the realisation of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health".[62]

The ambiguity of RTH leads to what individuals can be entitled for and what obligations may fall on the State. On the other hand having so many of international human rights instruments do not ascertain the appropriate human right to health. It does not seem to be clear as to what it actually implies from a legal stand point.[63] In a way it is also controversial and philosophical in nature.[64] Besides, some health workers like the physicians and doctors find it hard to practice it in their daily duty routines. Moreover, understanding of legal concepts is so wide that they cannot grapple with it in practice.[65] It is generally understood that a State/government itself cannot provide good health to individuals if related need of the entire scientific, legal and social sphere are not taken together in achievement of RTH. New understanding in health sector shows that genetics, eating habits and lifestyles too play a major role in ill health. The General Comment no. 14 considers health demands need to be followed through its four essential inter-related elements AAAQ i.e. Availability, Accessibility, Acceptability, and Quality.[66]

Thus there is a legal obligation falling on the part of governments to provide basic access to medicine, along with information relating to quality and availability of medicine to public either through proper labeling of manufacturing details. Taking into account priority of the States' budgetary system, however, financial credit for health requirements should not limit itself for just health care system. It should also balance out other priorities of health like pricing, licensing, competition and other

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[62] The Paragraphs 1 and 3, of the General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR (2000); available at: www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En

[63] Toebes, Brigit, (1999), "Towards an Improved Understanding of the International Human Right to Health "Human Rights Quarterly, 21(3):661-679, p.675; available at: www.siteresources.worldbank.org/EXTAFRREGTOPGENDER/Resources/durban_speech.pdf

[64] Ruger, J. P. (2009), Health and social justice. Oxford: Clarendon Press, p.119

[65] Beracochea, Elvira. et al. (2011), "*Rights-Based Approaches to Public Health*", (eds) Springer Publishing Company, LLC: Newyork. Veinstein, Corey. and Dabney Evans.

[66] Riedel, Eibe. (2009), "The Human Rights to Health: Conceptual Foundations" in ed Andrew Clapham and Marry Robinson, *Swiss Human Rights Book,* 3, p.21-39.

relevant laws. Some other factors that may facilitate the access to essential drugs include rational selection in use of medicine; sustainable adequate financing; affordable prices; and reliable health and supply system.[67] There are lessons available from India and Africa for HIV/AIDS that indicate effect of commercialisation on human rights to health and the access for being healthy.[68]

Moreover, the fact has come to light during unavailability of vaccine for Human Immunodeficiency Virus (HIV) (+) that there was no possibility of prevention and cure. For this reason, preventing diseases through public awareness, campaigns, and individual behaviour; change in a supportive environment, requiring time and patience become important.[69] In terms of treatment for HIV increasingly effective and affordable anti-retroviral treatments (ART) have come as help only for those who have access to the drugs, and could afford it.[70] In fact investigation reveals that increasing rates have always impeded innovation as well as its availability and affordability through TRIPs Agreement and patent regime limits lifesaving drugs like HIV/AIDS etc. TRIPs Agreement is considered to be an unequal treaty that compels developing countries with onerous burden having no recognition of human rights, including the right to health and food.[71] Moreover, the flexibility could be extended through the special and differential treatment to developing countries in WTO Agreement. But, this flexibility is on the other had been more beneficial for the developed and pharmaceutical industries.[72]

Clinical Trials and Right to Health

Treatment and cure came as a mantra for illness, suffering and pain. But such development cannot be possible in producing healing and preventing disease, infection or virus without knowing its result and expending formulas by creating

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[67] Mahabal, Kamayani Bali. (2004), "Access to Essential Drugs: A Human Rights Issue", *Health Action* 17(12), p.35-37.
[68] Sinha, *Monoj Kumar*. *Oylelade Olutunji. S and Odunsi S. Babafemi* (2008), in their fifth chapter of the book "Right to Health in context of (Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome) HIV/AIDS in India and Africa", p.162.
[69] Narain, Jai. P. (2004), "AIDS in Asia: the Challenge Ahead", ed *Sage Publication India*, p.1.
[70] Ibid.
[71] Nirmal, B.C. (2009), "Human Right to Health, Access to Drugs and Global Medical Patents*". Indian Journal of International Law*, p.405 and 407.
[72] Ibid.

condition to assure medical benefits.[73] To understand health needs and its requirement through help of medical experiment or clinical trial one has to be subject of the ongoing or conducted experiment. Since human subjects are the last expending object to reveal outcome and research analysis through experiments result collected from formulations and data experimented on it. The concern for the Right to Health for clinical trial directive for patient's rights brings human value and dignity. Such consideration raises issues on humanity, so that no degrading treatment or forceful experiments occur. In this context Article 5 of the UDHR 1948 states:

> "No one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment".[74]

Thus no human subject should be tortured, given degraded or inhuman treatment. When experiment on such subjects is conducted through his/her consent for the knowledge of ongoing experiment, such subject should not be punished or treated inhuman. [75] Further, use of human subjects for any kind of drug trial requires free consent of the patient/individual so as to avoid torturous or cruel behaviour while enrolling or volunteering in any research experiment that the subject is participating.[76] However, sometimes many individuals who are undergoing research experiments without their consent or knowledge have no clue of what their experiment/treatment could lead to. Moreover, the Human Rights Committee General Comment No. 20 (1992) of ICCPR tries to explain that no trial subject should be in any form of detention or imprisonment as well as parties to the committee of ICCPR should provide proper information regarding valid consent of trial subject.[77] The grounds of consent should be based on the permissible knowledge and results contributing towards the development of the biomedical research and bio ethics. The Nuremberg Code[78] (1947) principles on permissible medical experiments states that trial should be for good of the society and not random or unnecessary in nature.[79]

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[73] Article 12(2)(d) of the ICESCR 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[74] Article 5 of the UDHR 1948; available at: www.unhchr.ch/udhr/

[75] Article 7 of the International Covenant on Civil and Political Rights 1966; available at: www.unhchr.ch/html/menu3/b/a_ccpr.htm

[76] Ibid.

[77] The *General Comment No. 20* (1992), Human Rights Committee, General Comment 20, Article 7, 44th session 1992, Compilation of General Comments and General Recommendations. Adopted by Human Rights Treaty bodies. U.N Doc. HRI/GEN/1/Rev.1 at 30 (1994); available at: www.ohchr.org>

[78] Stephen. P. Marks (2004), p.9-10. and Office of NIH History, "*The Nuremberg Code*", in Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law, Washington, DC:

If voluntary consent on the experiment is provided then it should be based on free power of choice, having sufficient knowledge and understanding of elements of the issue and having awareness of the subject matter involved in the experiment. The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, 2008 in paragraph 22 states that:

> "(I)n any research on human beings, each potential subject must be adequately informed of the aims, methods, source of funding, any possible conflicts of interest, institutional affiliations of researcher, the anticipated benefits and potential risk of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed".[80]

The 1949 Geneva Convention and the 1977 Protocols, on international humanitarian law, have also prohibited human experiment done without their consent and knowledge.[81] The WHO Proposed International Guidelines on ethical issues in Medical Genetic and Genetic Services 1997 that has also addressed experimentations done on the humans[82]. Thus various legal efforts have been put to prohibit the human experimentation without free consent and these efforts try to protect the personal autonomy of an individual, determining on their health status.[83] The physicians and other health care workers have a moral duty to maintain patient's privacy. However, if the patient's medical information is disclosed or revealed to a third person, then the patient might face discrimination, stigmatization, denial and humiliation. In order to observe the leading International Standards on Ethics and Clinical Trials, the Guidelines 21-22 emphasis the right to health responsibility of pharmaceutical companies. Guidelines 9-14 emphasis the importance of effective, transparent and accessible monitoring and accountability mechanisms. These mechanisms should

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U.S Government Printing Office, 2 (10), p.181-182; available at: www.history.nih.gov/research/downloads/nuremberg.pdf .

[79] The Principle No.2, of the Nuremberg Code 1947; ibid.

[80] The paragraph 22 of the Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects, 1964, (2008); available at: www.wma.net/en/30publications/10policies/b3/17c.pdf

[81] Article 11 protection of Persons in, Protocol Additional to the Geneva Convention of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I): Grave Breaches 1977; available at: www.icrc.org/ihl.nsf/webCONVFULL/OpenView

[82] The Convention on the Protection of Human Rights and Dignity of Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicines (1997), the Council of Europe, (COE), Oviedo, 1997, 4I.V.; available at: www.mpil.de/en/hp/embryo/regionl/CPHR04041997.pdf

[83] Kumar, Avanish (2007), "*Human Rights to Health*", Noida: Satyam Law International, p.70.

monitor, and hold to account, pharmaceutical companies in relation to their policies and practices on Clinical Trials.[84]

In early 2009, the National Institutes of Health's ClinicalTrials.gov registry a portal of federally and privately supported clinical trials in United States and around the world featured 50,629 trials with sites in 152 countries. Some scholars[85] have noted shift for search of new regions for patients when the recruitments in patients became harder in the US and Western Europe due to ethical norms and human value. The clinical trials and the clinical study is now openly recruiting through I to IV phases in regions like North America, Europe, Asia-Pacific, South America, Middle East, Oceania and Africa. The clinical trial contributes towards the issues of human experiments and their obtained consent of knowledge, as medicines without testing cannot be prescribed or launched in markets. The EvaluatePharma and PhRMA (Pharmaceutical Research and Manufacturers of America) estimate that in 2009 for phase 1, 2 and 3 pharmaceutical and biotechnology industry has spend an estimated $10.2 billion on phase 1 trials, $16.1 billion on phase 2 and $40.5 billion on Phase 3 trials and in 2016 it is estimated $11.9 billion for phase 1, $18.8 billion for phase 2, and $47.3 billion for phase 3 trials.[86]

Drug Development and Marketing

Prevention, care, treatment and support have led towards right to essential medicines with the help of the right to health (RTH). The development of drug, its production, distribution, along with pricing of medicines through research and development (R&D) makes health system stronger. When CTs take place such experiments result in revealing therapeutic benefits of these medicines. Treating diseases makes the functioning of health systems stronger and better functioning. As such drug becomes part of a rational system of quality treatment and care, as well as on infrastructure, and can be delivered to all areas where they are required without

[84] Hunt, Paul. and Khosla, Rajat. (2010), "Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)" *The PLoS Medicine Debate*, United Kingdom, p.17. available at: www.who.int/medicines/areas/human_rights/HuntPLOSMed_2010.pdf

[85] Oppenheimer (2008) "Active Clinical Trials by Phase and Country/ Region: A 2008 Analyzis" Statistics on Drugs Development: Costs/Complexity, Development Time, Success Rates ed. PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011, p.204.

[86] Ibid.

hurdle and prohibition.[87] In the present scenario, when lifestyle has become so much busy and competitive, to relieve pain and suffering dependency on medicines/drugs has become one of human nature. This dependency of consuming medicine for two or three treatment together may lead to fixed-dose combinations (FDC)[88] or sometimes due to counterfeiting drugs the drug may itself cause adverse drug effect (ADE) to the body. So, it becomes important to know the information by labeling[89] the drug product for the benefit of the drug consumer so that he/she can know what combination can react to his/her body.[90] It is understood only when increase in specific diseases, infection and deaths occur; then regulation for monitoring new drug approval and its marketing through R&D and labeling process throughout the world becomes important. On the other hand the approval of new drug by inspection and throughout its clinical process is a long procedure. Whereas, the Article 12 (2)(c) of the ICESCR states that for realisation of right to health steps for "prevention, treatment and control of epidemic, endemic, occupational and other diseases"[91] should be carried. This prevention can only be possible when accurate and treating drugs comes in market.

Safety of drug product can only be assured, when the manufacturing data's through proper experiments and revelation provides benefiting treatment and not random business traits. Article 13 of Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights (2003) states that:

> "(T)ransnational Corporation and other business enterprises shall act in accordance with fair business, marketing and advertising practices and shall take all necessary steps to ensure the safety and quality of goods and services they provide, including

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[87] Marks, Stephen P. (2009), "Access to Essential Medicines as a Component of the Right to Health" *Health: A Human Rights Perspective.* Clapham, Andrew and Robinson, Mary (eds), *Realising the Right to Health*: *Swiss Human Rights Book*, Vol. 3, Zurich: Ruffer & Rub, p.80-81; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html

[88] FDC are the combination products that are available with two or more active biological product with effect in single one drug. They are mostly banned. For details, see, Gautam, Chandler S. and Saha, Lekha., (2007), "Fixed Dose Drug Combinations (FDCs): Rational or Irrational: A View Point", *British Journal of Clinical Pharmocology (BJCP)*, Blackwell Publishing Ltd, p.795-796.

[89] In India the labeling of drug other than homeopathic medicines should be made in manner of the Rule 96 of the Drug and Cosmetic Rule 1945. For instance, see, Rule 96 of *the Drug and Cosmetic Act 1940*, (2016), Bare Act: With Short Comments, Professional Book Publishers, p. 125-130.

[90] Chandy, Sujith J. and Mathew, Binu S. (2006), "Patient Information and Medication Labeling: An Area of Concern", *Indian Journal of Medical Ethics*, p. 1-2; available at: www.ijme.in/index.php/ijme/article/view/656/1628

[91] Article 12(2)(c) of the ICESCR 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

> observance of the precautionary principle. Nor shall they produce, distribute, market, or advertise harmful or potentially harmful products for use by consumers".[92]

Since, it becomes important to produce medicines/drugs for the health safety and security of individuals. Transnational Corporation and other business enterprises should ensure quality of goods services and safety of the product by labeling it properly. So far, the Centre for Medicine Research International (CMR) in 2004, found that global pharmaceutical Research and Development[93] (R&D) expenditure exceeded US$56 billion.[94] In 2009 Evaluate Pharma,[95] estimates that the top 500 pharmaceutical and biotechnology companies spent $124.5 billion on worldwide R&D and likewise, Evaluate Pharma holds a prediction that the R&D spending in 2016 will reach $145.5 billion by 500 pharmaceutical and biotechnology companies.[96] The sale of R&D spending is shifting from Europe and the US to other regions of the world including Asia, Africa, Australia and Latin America. Although Europe Federation of Pharmaceutical Industries and Associations (EFPIA), have said that Europe falls behind U.S., but U.S. is facing significant challenges as well. Disease control needs epidemiological surveillance, implementation of immunisation programmes and other disease control strategies including pharmaceutical and non-pharmaceutical interventions during outbreaks of infectious diseases etc.[97]

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[92] Article 13(F). "Obligations with Regard to Consumers Protection", from Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights (2003); available at: www.ap.ohchr.org/documents/dpage_easpx/s=58

[93] The total expenditure on R&D's activities (e.g., salaries, other personal-related to consumable and supplies, and appropriate share of overhead to cover administration, depreciation, space, charge, rent, etc.) related to personnel- related costs related to ethical pharmaceuticals, which include chemical entities, biological products, biotech entities, gene therapy products, or vivo diagnostics. This expenditure includes capital R&D expenditure on R&D conducted by means of grant or contracts to other companies or institutions and proportional costs for joint ventures. For further details, see, Mathieu, Mark P. (2010), "Parexel's Bio/Pharmaceutical R&D Statistical Source Book 2010/2011" Trends in Worldwide Pharma and Biotech R&D Expenditure, 2002-2016. Evaluate Pharma (30 April 2010), Parexel International, p.343.

[94] The data is based on R&D trend worldwide expenditure from 1993-2008, in CMR International 2005/2006 Pharmaceutical R&D Factbook. For further details, see, Oppenheimer (2008), "*Active Clinical Trials by Phase and Country/ Region: A 2008 Analyzis*" Statistics on Drugs Development: Costs/Complexity, Development Time, Success Rates ed. PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011, p.204.

[95] Evaluate Pharma, tracks and forecast more than 2,500 companies and over 26,000 active products from early-stage R&D through post marketing. For further details, see, Mathieu, Mark P. (2010), "Parexel's Bio/Pharmaceutical R&D Statistical Source Book 2010/2011" Trends in Worldwide Pharma and Biotech R&D Expenditure, 2002-2016. Source- Evaluate Pharma (30 April 2010), Parexel International, p.343.

[96] Ibid.

[97] Gian, luca burci. and Riikka, Koskenmaki. (2009), *"Human Rights Implications of Governance Responses to Public Health Emergencies: The Case of major Infectious Disease Outbreaks"* in ed Andrew Clapham and Marry Robinson, Swiss Human Rights Book, p.347.

Pharmaceutical Companies lack medical R&D for neglected diseases because of profit driven system for direct result of patent and requirements of drug development expenses. Need of an alternate mechanism[98] for innovation in medicine is required. So that low-priced effective medicine should be manufactured and produced.[99]

In 1977 for first time the improvement of health as a greater social justice was brought by the WHA Geneva and the first essential medicine list was published. The main aim of the 30th WHA was to provide social and economical productive life to all individual, which is well known as, the health for all by the year 2000 (HFA 2000).[100] After two years the WHA published the Essential Drugs and National Drug Policy. The number of people with access to essential medicines has grown roughly from 2,100 million in 1977 to an estimated 3,800 million in 1999. By 1999, 66 countries had formulated or updated a national drug policy within the previous 10 years, compared with 14 countries in 1989.

By the end of 1999, 156 developed and developing countries had national or institutional lists of essential drugs for different levels of care, in both the private and public sectors; 127 of these lists had been updated in the previous five years, and 94 were divided into levels of care. There is substantial evidence that the use of national lists of essential drugs has contributed to an improvement in the quality of care and to a considerable saving in drug costs.[101]

For accessing low cost and quality medicines, numerous settings compelled the World Health Assembly (on 24 May 1999) to unanimously adopt a Resolution on Revised Drug Strategy[102], which obligates WHO to intensify its activities in six areas:

> "i) national drug policies; ii) pharmaceuticals and trade agreements; iii) drug information and drug promotion; iv) drug quality; v) drug donations; and vi) Partnerships.[103]

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[98] An example can be taken for TB Alliance, R&D, Vaccines and FIND for diagnostics as all the three partnership receive most of their funding from Bill and Melinda Gates Foundations. There are some renewed actives from drug companies also like Tibotec and Otsuka. For details, see, Angerer, Tido von Schon. (2009) "Drug- Resistant Tuberculosis", p.300-301; available at: www.swisshumanrightsbook.com/SHRB/shrb_03_files/20_453_Annas.pdf

[99] p.300, ibid.

[100] Dillon, H.S. and Philip, Lois. (1994), *"Health Promotion and community Action for Health in Developing countries"*. Geneva: WHO, p.1-2.

[101] The WHO. (2000) WHO medicines strategy. Framework for action in essential drugs and medicines policy 2002-2003. Geneva: World Health Organisation; 2000. WHO/EDM/2000.1.

[102] The World Health Assembly, (1999), Revised Drug Strategy, Resolution EB103/1999/RI, 24 May 1999.

[103] Sinha, Manoj Kumar. et al. (2008), *"Right to Health in the Context of HIV/AIDS in India and Africa",* Manak Publishers, New Delhi: Olutunji, Oyelade S, & Babafemi, Odunsi S, p.165.

These six strategic ways can help in revealing the quality and effectiveness of the drug supply whereas answer for hidden partnership or profits will be monitored. On the other hand, it becomes duty of pharmaceuticals manufacturers to provide affordable and quality drugs since they have maximum profit gain through its supply. An example can be seen when the Supreme Court of India (on 1 April 2013), denied a patent for Novartis breakthrough medicine Glivec (imatinib mesylate). The production of same generic medicine by Cipla Ltd. and Ranbaxy Ltd. cost $175 than about $1,900 per month by Glivec.[104] On the other hand Novartis patent has been denied since 2006. So far, this decision may have discouraged innovative drug discovery essential to advancing medical science for patients. But it has paved way for the generic medicines which are cheaper and affordable.[105]

Personalised Medicine and Health Challenges

Achieving healthcare standards and making possibility of treatment go without fail, personalised medicine (PM) has come up taking such health challenge. Since transfer of technology and scientific inventions are making unnoticeable achievements. PM is considered to be new revolutionary achievement in health providing individuals with a right to accurate treatment. PM has come universally as precision or individualised medicine. PM that is considered as revolutionising medical care by scholars,[106] came as a gift through the United States (U.S) Human Genome Project (HGP) to control the wrong medication, with the help of pharmocogenonomics (PGx) by using knowledge of molecular biology and

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[104] Glivec is a life-saving medicine for certain forms of cancer, patented in nearly 40 countries including China, Russia, and Taiwan. Novartis filed a Special Leave Petition with the Indian Supreme Court in 2009 challenging the denial of the Glivec beta crystal form patent on two grounds, based on Sections 3(d) and 3(b) of the Indian patent law. In addition to seeking a patent for Glivec, the company filed the case to help clarify these unique aspects of the patent law. In fact refer to the Case *Novartis AG v. Union of India & Others*, (2013), For further details, see, Access Campaign: Medecines Sans Frontieres, (2012), "Timeline of Key Events in Novartis's Attack on The Pharmacy of the Developing World", mafaccess.org; available at: www.msfaccess.org/content/timeline-key-events-novartiss-attack-pharmacy-developing-world; *Novartis v. Union of India & Others*; see, Abbott, Fredrick M., (2013), "Inside Views: The Judgment In *Novartis v. India*: What The Supreme Court Of India Said", By Intellectual Property Watch; available at: www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/ ; also see, In the Supreme Court of India, Novartis AG v. Union of India & Others with Civil Appeal No 2728 of 2013 Arising out of SLP(C) No. 32706 of 2009, Supreme Court of India; available at: www.supremecourtofindia.nic.in/outtoday/patent.pdf

[105] Ibid.

[106] Ginsburg, Geoffrey S. and McCarthy, Jeanette J."PersonalisedMedicine: revolutionizing drug discovery and patient care", (2001), TRENDS in Biotechnology. 19 (12), p.491; available at: www.144.206.159.178/ft/1057/46499/828224.pdf

genetics.[107] PM try to assure better diagnostic tests, greater predictability of disease course with more successful therapies by targeting right treatments to the right patients along with improved patient safety. Method of using PM is by selecting drugs and their proper dosage for individuals understanding body genotype structure, adverse side effects or reaction of body by compounds and elements combination. This treatment includes personal genetic information data that may lead to concerns regarding privacy, confidentiality and data safety.[108] These concerns can in future discriminate and stigmatise individuals based on medical information that the individual's gene or DNA may provide to others. The Universal Declaration on Human Genome and Human Rights 1997 also states Article 7 that:

> "Genetic data associated with an identifiable person and stored or processed for the purposes of researcher any other purposes of research or any other purpose must be held confidential in the conditions set by a law".[109]

The stored data's should be kept confidentially and privacy should be maintained so that no unauthorised research takes place. It has been observed during treatment PM helps in replacing traditional approach of trial and error practice. Since PM is a process for patients care and safety during drug discovery and its development throughout clinical trials by screening and selection of patients.[110] The technological sound environment with transfer of technology in private sector due to high R&D spending is supposed pocket friendly to people. The licensing technologies to private companies and awarding grants for innovative research, the project of HGP creates sphere of multibillion-dollar U.S. biotechnology industry by PGx applications.[111] On the other hand WHO Medicine Strategy-Countries at the Core 2004-2007 estimates over 10.5 million lives a year would have been saved in 2015 through expanding access to existing interventions for infectious and non-

[107] Ibid.
[108] Ibid.
[109] Article 7 in "the Right of the Person Concerned" of the Universal Declaration on the Human Genome and Human Rights 1997; available at: www.unesco.org/shs/human_rights/hrbc.htm .
[110] Ibid.
[111] Stergiopolos, Sotirios G., (2012), "What is Personalized Medicine", in Lawrence A. Husick, (eds.) (2012) "*From the Bench to the Boardroom: Planning for personalised Medicine",* Baltimore, MD: Johns Hopkins University, Managing Innovation in the Life Sciences, p.6-7; available at: www.lawhusick.homeftp.net/Innov8/Innov8_files/PersonalizedMedicineClassBook.pdf

communicable diseases with the help of social and economic growth for maternal and child health.[112]

Since understanding access to healthcare and its arrangements on time, enjoyment of highest attainable standard of health can be possible for individuals without delay. Presently, in US, the market size of personalised medicine in 2015 was $344-452 billion as compared to $225-232 billion in 2009. This estimation in U.S has been increasing by pay for performance (P4P). The PricewaterhouseCoopers estimates that current total market estimation is of $232 billion[113] in U.S. and is projected to grow by 11% annually, doubling size to total of $452 Billion. According to PricewaterhouseCoopers, core segments are primarily based on diagnostic tests and targeted therapies estimated at $24 billion that has grown by 10% annually to $42 billion in 2015.[114]

Funding for Medical R&D through Insurance Coverage

Health sector requires insurance to fund new developments and clinical Trials (CT). RTH can only be possible when healthcare arrangement is possible to patients. Whereas physicians or sponsors for drug manufacturing, trial, compensation, production and marketing have to be accountable in creating a better healthcare system.

Social-security and protection during vulnerable time, creates a condition for sustaining health facility in the event of sickness, treatment and care. In present days insurance is observed as a health support for financing healthcare and other arrangements as social-security. The UDHR 1948 mentions in Article 3 that every individual has "a right to life, liberty and security of person".[115]

This security can help in achieving health standard, medical care and wellbeing of individuals and family members in the event of disability, old-age,

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[112] The WHO Medicine Strategy-Countries at the Core 2004-2007 argued for 2015 in 2004. For details see, Boxtel, Chris. J. Van., Santoso, Budiono., and Edwards, I. Ralph., (eds.) (2008), *Drug Benefits and Risk: International Textbook of Clinical Pharmacology*, The Netherlands: IOS Press and Uppasala Monitoring Centre, p.ixi; available at: www.books.google.co.in/books?id=xQqVbRqA2N8C&printsec=frontcover#v=onepage&q&f=false

[113] Mathieu, Mark P. (2010), "Parexel's Bio/Pharmaceutical R&D Statistical Source Book 2010/2011" An Assessment of the Personalised Medicine Market Size, 2009-2015. PricewaterhouseCoopers 2009.

[114] Coopers, Pricewaterhouse (2009) "An Assessment of the Personalized Medicine Market Size, 2009-2015", Products in Development of Pharmaceutical, ed. PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011

[115] Article 3 of UDHR 1948; available at: www.unhchr.ch/udhr/

sickness, unemployment, widowhood and other circumstances beyond control. Social security can help during special care and assistance requirement as protection during motherhood and childhood without discriminating the legitimate or illegitimate one.[116] On the other hand the ICESCR, through Article 12(2)(d), states that there should be "creation of condition to assure all medical service and medical attention in the event of sickness".[117] Such creation can only be possible through social security and insurance is the only alternative in this commercial world.

Growing and demanding new scientific and biomedical technologies in health regime charges high for quality healthcare. Achievement of right to life and security by accessing quality and better health service during financial constrain can be overcome by facilities of such arrangements when insurance comes up. Article 22 of the UDHR states for supporting the healthcare access through its security arrangement as insurance and that is:

> "Everyone, as a member of society, has the right to social security and is entitled to realisation, through national effort and international co-operation and in accordance with the organisation and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality".[118]

Thus, it seems, insurance acts as a healthcare access in the event of sickness and supports during expenditures without harming ones dignity in inflating commercial world. Basic health requirement can be served without difficulty during financial crisis. Insurance, as a social security, supports and protects financing help to patient or health consumers along with hospital, research organisation and undergoing CTs. The General Agreement on Trade in Services (GATS) in the World Trade Organisation (WTO) by sector classification scheme makes health insurance fall under the financial services sector. The World Health Organisation (WHO), states that about 150 million people annually suffer financial strains and 100 million people get pushed below poverty line. Government; public private partnership (PPP); non-governmental organisation (NGO) or Private sector health coverage facilities may become optional.[119] While managing, healthcare security from insurance during the condition of sickness, accidents, research, etc. policies and financing companies take

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[116] Article 25(1) and (2) of UDHR 1948; available at: www.unhchr.ch/udhr/

[117] Article 12(2)(c) of the ICESCR 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[118] Article 22 of the UDHR 1948; Ibid.

[119] Mavalankar, Dileep., and Bhat, Ramesh., (2000), "Health Insurance in India Opportunities, Challenges and Concerns", *Indian Institute of Management Ahmedabad,* p.2.

great interest in government FDI policies and arrangements. It could be done by selecting insurance companies' interest policies and itemised charging plan.[120] This practice negligently, makes the insurance taker forget the exclusion clause that excludes various hidden insurance benefits and surcharge as interest. They further overlook to compare their retained coverage plan based on the fluctuating market prices. Besides, the health care cost or options provided to individuals through insurance by the company maintain their doubts about the prospects and issues of their investments in health coverage. So far, observing the growing economic and social differences the Alma-Ata Declaration of 1978 states (paragraph III) that:

> "(E)conomic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and to the reduction of the gap between the health status of the developing and developed countries. The promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace".[121]

Thus it suggests that in lieu of attaining health standards one should take care of promoting and protecting health security through social developments and contribution and not destroying peace and gaining profits through vulnerable times. Since, people's good health contributes maximum in a countries economic growth and development than their insolvency and ill health.

DEFINITION AND RATIONALE

The interface of pain, suffering, disability, disease and limitation in human life provides ample grounds for characterising much of human conditions as unfortunate. The RTH under international law understanding through different international human rights instruments, specialised organisations provide fragmented health issues. It seems different approaches on health rights by different international bodies make the definitional understanding of RTH more complex and ambiguous in implementation.

The review of existing literature clearly shows there is need of proper definition of RTH. Although, some scholars try to address these problems at normative level still research is lacking for a comprehensive understanding through

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[120] Bowers, Kevin., (2011), "Assessing the impact of healthcare reform on insurance", *International Law Office*, Insurance & Reinsurance - Hong Kong, Globe Business Publishing Ltd, p.1. available at: www.internationallawoffice.com/newsletters/detail.aspx?g=1f4a5c60-ed19-40aa-a60e-cbfc7c2c7e3d

[121] Appendix I and *Declaration of Alma-Ata International Conference on Primary Health Care*, Alma-Ata, USSR, 6-12 September 1978; available at: www.who.int/hpr/NPH/docs/declaration_almaata.pdf

legal perspective. Therefore, it is a constrained situation that warrants holistic study. The study is more relevant in this era of growing disease. The scope of research focuses on six main issues i.e. the legal jurisprudence of right to health; the problems of clinical trials; social security demands and health insurance; drug production and its safety; regulation of personalised medicine; and finally, to analyse some of the decided cases. So that proper understanding of RTH through reference of clinical trials and personalised medicine can be understood as a whole.

OBJECTIVE AND SCOPE OF STUDY

International law seems to recognise RTH through fragmented approach of understanding that leads no clarity of what exactly the right to health means. The regulatory framework obligations to protect right to health through many organisations or committees makes its nature hard for countries to implement it as a whole. Moreover, many a time RTH is denied and takes condition of discrimination into various forms by the state(s) and society on the basis of social, economic, race, place, gender and disease. Therefore, there are many complexities in realising the right to health, identifying of issues and protection. In view of the above background the proposed study tries to examine the following objectives:

1. To understand the definition of Right to Health so that Clinical Trials and Personalised Medicine approach can be understood.
2. To examine different needs of healthcare access through health security as insurance, drug regulation and labeling.
3. To examine RTH as right based approach through International, Regional and Indian law in order to regulate practices of Clinical Trials and Personalised Medicine.
4. To study the elements of discrimination by the state(s) and society in administrating RTH facilities and practices for executing Clinical Trials and Personalised Medicine.
5. To analyse and revise the need for a new International Convention on Right to Health.

RESEARCH QUESTIONS

1. What is the status of 'right to health' in relation to clinical trials and personalised medicine?
2. Whether the health system can ensure accessibility along with affordability of right to health through drugs regulation?
3. Is the right to health denied and discriminated by state(s) and society for an individual who undergoes clinical trials?
4. Is there need to have International Convention on Right to Health?

HYPOTHESES

1. Right based approach is required for an effective realisation of right to health especially in clinical trial and personalised medicine.
2. The implementation mechanism of the right to health, personalised medicine and clinical trials has to be strengthened at international, level for making them effective and meaningful.
3. The existing laws, policies and practice of the state(s) suffer from adhocism, inadequacy and are discriminatory in nature.

RESEARCH METHODOLOGY

During the course of research interdisciplinary approach was adopted, secondary data source and internet web were used for data collection and interpretation.

The proposed study is mainly based on analytical method using primary and secondary source materials at international, regional and Indian levels. The study has tried to examine all primary sources of materials, like the United Nations Conventions, Resolutions, Guidelines, Reports, Comments, Guidelines of UN and WHO are included along with various specific laws dealing the sphere of health, biomedical and drug security. Secondary sources include books, articles from academic journals and relevant website materials. Pictographic representation such as flow chart, table etc. have also been used.

LIMITATIONS OF THE STUDY

The Right to health issue is very vast area. This has been kept in mind in wake of this study. Understanding the demand for examining scientific, technological and

biomedical developments have encouraged research study on clinical trial and personalised medicine. But, existing socio-economic conditions, recruiting patients and subject's privacy brought difficulty in analysing its actual reason. Compiling all the work in one proper arrangement with so much material available in each sphere was difficult task. Moreover, legal analyses on these cutting-edge spheres are limited. The work looks into human rights issues and concern accepting reality of healthcare and financing burden. The study views regulating and implementing provisions laid down in international, regional or country specific mechanisms. Through legal view point undergoing studies of clinical trial and personalised medicine have brought to the force concerns on regulatory and implementation challenges. Since these areas cover more work in bio-medical and economic perspectives than law. Healthcare support and rights for vulnerable and poor individuals required to look at issues of social security or insurance during financial crisis. Overcoming challenges of costly healthcare spending the study takes into account rising reactions through medicines and obligation for labeling of drugs. In fact regulatory factors can establish health care access for affordability and delivery of health supplies on time by personalised medicine. This work has gone through many difficult and hard tasks while arranging study through scientific factors like personalised medicine as a need for development of RTH.

The study on the other hand has following limitations in terms of covering various related issues:

1. The research work tries to be more specific towards RTH and its arrangements with identification of health as a right.
2. The research has tried to analyze scientific health developments as a basic need of technically support health arrangements.
3. Arranging such big sphere into one crisp understanding through legal perspective was a challenging task.
4. Resource and time were the limitations; however an honest effort has been made to provide a clear picture on the issue of RTH with special reference to clinical trials and personalised medicine.

SCHEME OF THE CHAPTERS

The present study entitled "the Right to Health under International Law with Special Reference to Clinical Trials and Personalised Medicine" covers an impact of health rights drawn through access to healthcare and human rights. This research brings two new health concepts clinical trial and personalised medicine, as well as, highlighting the legal perspective drawn on it. Further this work, acknowledging the requirement of RTH, provides mandatory outlook towards drugs warning and labeling along with regulation practice. The need to afford health care through social security provides an atmosphere of understanding insurance plan and system so that condition of RTH is met to the maximum extent. The study is spread across seven chapters as follows:

Chapter I: Introduction

This chapter provides background of the study by bringing out relevance of the subject in the present scenario. It identifies the need and scope of RTH.

Chapter II Right to Health under International Law

This chapter seeks to trace the evolution of the right to health, its sources and implementation with emerging jurisprudence on health rights. It further focuses on all possible international and regional instruments relating to RTH with some selected cases. In this section elements of health rights and its components have been analysed taking into account need for individuals health safety and rights that are mandatory in unequal world scenario.

Chapter III: Right to Health and Clinical trials

This chapter analyses relates to laboratory developments through the efficiency and safety of controlled trials made on test subjects. It also analyzes on the regulatory mechanism practiced under international law for clinical trials by examining individuals' rights based on different nation-states jurisdiction. Accordingly, in consideration with clinical trials the concerns on ethical issues, confidentiality and privacy rights has also been discussed through some case studies. Further the work also covers issues of negligence and policy implications during its regulation.

Chapter IV: Drug Regulation and labeling Implications

This chapter examines need for drug regulation and labeling so as to understand authentication for CT work. This chapter also tries to look into regulatory direction of labeling drug product in order to reliability and safety in medicinal consumption.

Chapter V: Personalised Medicine: Regulations, Challenges and Solutions

This chapter deals with the regulatory and implementation mechanism of individualised medical care or the personalised medicine. It also examines liability issues dealing with patents rights, medical privacy, confidentiality, ethics and economics concerning biomedical issues.

Chapter VI: Insurance Coverage on Clinical Trials and Personalised Medicine

This chapter examines possibilities of insurance coverage to the individuals who undergoes clinical trials. Moreover, it also looks into the scope whether the person who is affected by personalised medicine i.e. ADE will be able to claim compensation even if the individual is not covered under any insurance. The access to healthcare through social security as support for financing health arrangements attain significance in this respect. Issues of health burden for downtrodden and vulnerable, has been explored to understand social-security arrangements on health coverage by private and public healthnce companies and funding resources.

Chapter VII: Conclusions

The last chapter sums up intermediate research findings arrived at in all the chapters. It also seeks to recommend some suitable suggestions based on the basis of analyses done. The chapter attempts to look at RTH as right based approach combining all fragmented sphere of health requirements like access, security, quality, technology etc., together so no more deficiency is found under RTH law.

Chapter-II

THE RIGHT TO HEALTH UNDER INTERNATIONAL LAW

INTRODUCTION

The right to health (RTH) understanding comes from the perspective of human rights arrangements, through security, protection, care and facilities to condition of environment. Such highest attainable standard of health can only be possible through attainment of health mentally, physically and socially. In this regard the General Comment No. 14, 2000 of Committee on Economic, Social and Cultural Rights (CESCR) provides that:

> *"*Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity". [1]

This explains that RTH is not merely a physical fitness but includes rights towards social difference to health. In order to understand RTH, it becomes important to realise it through all the possible aspects that may fall under human rights arrangements to form its accurate meaning so that international acceptance can be possible and understood at universal level. Through the creation of conditions of stability and wellbeing based on the principles of equal rights and self-determination.[2] Now the question is how and what parameters would make a conducive and stable convention/treaty/law which is acceptable universally.

THE CONCEPT OF RIGHT TO HEALTH

The development of right to health (RTH) has progressed by the consciousness from death and suffering that came through disease, hygiene and infections in human life. This consciousness has come permissibly, by support of the Chief in a society/Government (Govt.) in way of policies, regulations along with medical professions. Likewise the Declarations like Alma-Ata 1978 and Peoples' Charter for Health 2000 address socio-economic differences and demanding technological sphere in RTH. Examining differences and discrimination based health

[1] The General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR (2000) in paragraph 1.

[2] Article 55, *"The Charter of the United Nations and Statute of the International Court of Justice"* (1945), San Francisco; available at: www.treaties.un.org/doc/publication/ctc/uncharter.pdf .

facilities it becomes necessary to understand RTH under international law perspective. A binding RTH clause can be provided in every state/country for individual or community needs. By means of such right no possibility of discrimination will arise based on one's age, race, gender, religion, caste, abilities, socio-economic condition or ethical background.[3]

The health history shows its development through various stages, observing different health concerns internationally so that account of basic and essential health rights can be experienced for well-being of an individual, group or society. The meaning of RTH arrives as a customary international law[4] with the help of international human rights treaties. The Preamble to the UN Charter states that determination of RTH will only come by UN member states when establishment of:

> "conditions under which justice and respect for obligations arising from treaties and other sources of international law can be maintained, and to promote social progress and better standards of life in large freedom"[5]

Treaty obligation and respect need to be followed so as to maintain better standard of health and progress. Acceptance for RTH as understood legally comes from meaning provided by the Universal Declaration of Human Rights (UDHR),[6] World Health Organisation (WHO), the International Covenant on Economic, Social and Cultural Rights (ICESCR)[7] and so on.[8] Besides, the Torture Convention, Article 5

[3] Article 56 of the UN Charter 1945, Ibid; see, Appendix C; and the principles of the PHA, (2000), "the Peoples Charter for Health", People's Health Assembly (PHA), adopted on 8 December 2000, Savar, Bangladesh; available at: www.phmovement.org/pdf/charter/phm-pch-english.pdf

[4] The customary international law is ongoing and established practice of law, enforced through international relations and international law. That has been considered to be in practice for longstanding among nations. For details, see, Goldsmith, Jack L., and Posner, Eric A., (1998), "A Theory of Customary International Law", *John M. Olin Law & Economics Working Paper No.63*. 2nd Series, Chicago; p.1, 4, 5, 7 and 8; available at: www.law.uchicago.edu/files/files/63.Goldsmith-Posner.pdf

[5] Preamble of "the *Charter of the United Nations and Statute of the International Court of Justice*" (1945), San Francisco; available at: www.treaties.un.org/doc/publication/ctc/uncharter.pdf

[6] Human Rights (HR) are set of individual and collective rights, protecting and promoting since 1948 through international and domestic law. The UDHR mentions health as part of the right to an adequate standard of living creating binding obligations through customary international law. For details, see, UDHR 1948, Article 25. In *Universal Declaration of Human Rights,* (UDHR), Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/81.

[7] The ICESCR under Articles 2-5 lays obligation on States to provide RTH by collaborating through international assistance either individually or collectively. The Covenant states that states should make adoption of legislative measures to provide standards made in ICESCR through available resources along with implementation over time rather just as once. For details, see, ICESCR 1966, Articles 2 to 5 and Article 12 of the ICESCR 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

of the UDHR, Article 3 of the ICESCR, Articles 3, 7, 24, 26, in the ICCPR and the WHO Constitution by its (Preamble, paragraph 3) states that RTH should be enjoyed without discrimination or torture based on "race, religion, sex, political belief, economic or social condition".[9] No health settings (Service providers) or subjects should be differentiated on individuals, health rights should be provided to the individual's best needs and requirements. The UN text and WHO[10] affirm RTH as a fundamental right of every human being from the understanding of life with dignity[11] under international human rights.[12] An example emanates from the Indian case of, *Paschim Banga Mazdoor Khet Samity v. State of West Bengal & Anr*[13] (1996). In this case the Supreme Court of India used the right to life to secure the right to emergency medical care and ruled that such an essential obligation could not be avoided by pleading financial constraints. The Court held, the view that violation of the right to life under Article 21 of the Indian Constitution has taken place. Awarding compensation to the victim, it stated right to emergency medical care forms a core component of RTH. Such reconceptualisation of the right to life imposes a positive obligation on the state to safeguard the life of every person, stating that "preservation of human life was of utmost importance". Likewise, significance of RTH does not simply mean the word right to be healthy.[14] But it should also consist of access for

[8] The various International Conventions recognizing RTH are: the 1965 ICERD (Article5(e)(iv)), the 1966 ICESCR (Article12), the 1979 CEDAW (Articles 11(1)(f),12&14(2)(b)), the 1989 CRC (Article24), the 1990 International Convention on the Protection of the Rights of All Migrant Workers & Members of Their Families (Articles 28,43(e)&45(c)), the 2006 CRPD (Article25); Fact Sheet No. 31, "*The Right to Health"* WHO Switzerland, p.1; available at: www.ohchr.org/Documents/Publications/Factsheet31.pdf

[9] The WHA (1998), "Constitution of the World Health Organization", World Health Assembly Health for all policy for the twenty first century Agenda item 19 World Health Declaration 16 May 1998 Fifty-first WHA51.7, pp.1. Paragraph 3, Preamble of the WHO Constitution.

[10] Fact Sheet No. 31, "*The Right to Health"* WHO Switzerland, pp.1; available at: www.ohchr.org/Documents/Publications/Factsheet31.pdf

[11] WHA (1998) World Health Assembly Health for all policy for the twenty first century Agenda item 19 World Health Declaration 16 May 1998 Fifty- first WHA51.7.

[12] For further reference, see, Fact Sheet No. 31, "*The Right to Health"* WHO Switzerland, pp.1; available at: www.ohchr.org/Documents/Publications/Factsheet31.pdf

[13] In this case person named Hakim Seikh, an agriculture labourers organisation Paschim Banga Khet Majdoor Samiti fell from a train on 8 July 1992 at Mathurapur Station in West Bengal. He was referred and transferred to various Govt. hospitals in Calcutta and admitted in none. At last, went to Calcutta Medical Research Institute, a private hospital from 9 July 1992 to 22 July 1992 for his treatment. Feeling aggrieved by indifferent and callous attitude on part of medical authorities at various State run hospitals in Calcutta in providing treatment for the serious injuries sustained by Hakim Seikh the petitioner he field the case. For details, see, *Paschim Banga Khet Mazdoor Samity v. State of West Bengal & Anr* on 6 May, 1996, (4) 37, JT 1996 (6) 43, 1996: (4) SCC, 37, 1996 SCALE (4)282.

[14] Paragraph No. 8, *the General Comment No. 14*; available at: www.refworld.org/pdfid/4538838d0.pdf

effective basic health requirements that is integrated by health system along with essential health determinants.[15] The General Comment no. 14 (paragraph 8) states that RTH contains both freedom and entitlement to health:

> "The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health".[16]

Thus health as a right may not just provide freedom to choose for one's own health but also provide facilities for betterment. In fact developments on health, leads us to define or analyze concept of word RTH based on present progress and development. Paul Hunt[17] the first UN Special Rapporteur (SR) on RTH, tries to explain acceptance on health rights can be possible through collective association i.e. when "social institution, no less than a court system or a political system".[18] Article 6(1) of the International Covenant on Civil and Political Right (ICCPR) 1966 states that "every individual has inherent right to life and law should protect his/her life".[19] The ICCPR states that RTH should be provided to every individual irrespective to its citizenship or nationality. It becomes a duty of every country to provide every individual with RTH. This requires every State has to amend its laws for RTH. Like, in Sweden an asylum seeker or an individual having no papers can take right to

[15] Health determinants are: safe drinking water & adequate sanitation; safe food; adequate nutrition & housing; health working & environmental conditions, Health related education & information; Gender equality; and Maternity/child/elderly facility. For details, see, Clapham, Andrew and Robinson, Mary (eds) (2009), *Realising the Right to Health*: *Swiss Human Rights Book*, 3, Zurich: Ruffer & Rub, p.16-17; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html

[16] Paragraph No. 8, the General Comment No. 14; available at: www.refworld.org/pdfid/4538838d0.pdf

[17] Paul Hunt is first U.N SR on the RTH by Resolution 2002/31 or E/CN.4/2002/31. Duty of SR is to monitor, examine & report publicly on human rights (HR) situation based on health condition/ thematic HR problem of a country. Mr. Anand Grover of India became second SR on the RTH in 2008 June. For further details see, Hunt, Paul. (2003) Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations, Paul Hunt: UN Special Rapporteur on the Right to Health, Health and Human Rights Working Paper Series No 4, p.1-12; and; also see, The United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable physical and mental health (2006); as well as see, The General Assembly of the UN Special Rapporteur, (2008), "*Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine*". Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health (UN document: A/63/263, dated 11 August 2008); available at: www.ohchr.org/.../GuidelinesForPharmaceuticalCompanies.doc

[18] Ibid.

[19] Article 6(1) of the International Covenant on Civil and Political Right (ICCPR) 1966; available at: www.unhchr.ch/html/menu3/b/a_ccpr.htm

emergency healthcare along with dental care.[20] In the European Union for temporary stays like business trip, study, holiday or planned healthcare treatment, an individual is entitled to same rights to health care but need to carry European Health Insurance Card (EHIC) or pay the fee and get reimbursement once you return back in private health care to respective country. But, EHIC cannot be used in Denmark by non-EU nationals and Croatian cannot use their EHIC in Switzerland.[21]

To find steady social, economic and political justice for health one still needs to rely on international instruments. One can obtain healthcare facilities without any delay. The WHO Constitution (paragraph 10 of the Preamble) insists that the government need to take measures for providing adequate health and social benefits to its people.[22] This provision of WHO states health is ultimate goal for the welfare of individuals and no one can be discriminated in receiving such health arrangements. The principles of the Peoples Charter for Health, People's Health Assembly (PHA), 2000 affirms RTH health as a fundamental right and every country should provide its individuals with highest possible level of health. Such formulation on universal, comprehensive Primary Health Care (PHC) should be from the 1978 Alma Ata Declaration health policies. It becomes the responsibility of the Governments to:

> "ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay; The participation of people and people's organisations is essential to the formulation, implementation and evaluation of all health and social policies and programmes; Health is primarily determined by the political, economic, social and physical environment and should, along with equity and sustainable development, be a top priority in local, national and international policy-making".[23]

In a way quality healthcare need to attain top priority in local, national and international policy-making without financial constraints.

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[20] Region Skane, (2016), "Health care in Sweden for Foreign Citizen", 2 March 2016,; available at: www.skane.se/en/Health-care/rules-and-rights-in-health-care/health-care-in-sweden-for-foreign-citizens/

[21] EU, (2016),"EU-Health cover for temporary stays_Your Europe-Europa" 27 June 2016; available at: www.europa.eu/youreurope/citizens/health/Unplanned-healthcare/temporary-stay/index_en.html

[22] The WHA (1998), "Constitution of the World Health Organization", World Health Assembly Health for all policy for the twenty first century Agenda item 19 World Health Declaration 16 May 1998 Fifty-first WHA51.7, p.2; Paragraph 10, Preamble of the WHO Constitution.

[23] For details see, Appendix C; and the principles of the PHA, (2000), "the Peoples Charter for Health", People's Health Assembly (PHA), adopted on 8 December 2000, Savar, Bangladesh; available at: www.phmovement.org/pdf/charter/phm-pch-english.pdf

Development of Health Protection as a Concept

The compliance for unpredictable and recurring events[24] makes country's preparedness more challenging and risky.[25] It becomes duty of all sovereign states to fight against such threats. In May 2005, the World Health Assembly (WHA) adopted International Health Regulations (IHR) for surveillance and response on health emergencies. IHR is the only development found in use of international law as a legally binding regulation on all WHO members for global health surveillance system, protecting and preventing during public health emergencies.[26] WHO has constructed five main stages of pandemic influenza[27] and its phases describing how it occurs, retreats and reoccurs. The influenza phase makes the construction easy to understand about spread of diseases either by animals to humans; humans to humans; or from environment to human.[28]

Good work has been done in the process of controlling CDs, but, still human is considered helpless during its spread and threat. During transportation and its safety of trade and economics infected individual or an individual arriving from infected area are quarantine and isolation for surveillance process that is against human rights.[29] The case of *United States v. Shinnick* (1963)[30] informs us about surveillance and health emergency. An individual was isolated for 14 days in a hospital. For the reason that, a report circulated about smallpox infected person in Stockholm prior to the isolated individuals visit. She had visited Stockholm on 25 July 1963 and during

[24] Since the 16th century, the ranging intervals are considered to be between 10-50 years with different severity and impact levels. See (2010), "Pandemic Influenza Preparedness and Response: A WHO Guidance" *WHO and Global Influenza Programme*, WHO Press, Geneva Switzerland, p.13.

[25] WHO (2010), "Pandemic Influenza Preparedness and Response: A WHO Guidance" *WHO and Global Influenza Programme*, WHO Press, Geneva Switzerland, p.3 and 8.

[26] Baker, Michael. G. and Fidler, David. P., (2006), "Global Public Health Surveillance under New International Health Regulations", *Emerging Infectious Diseases*, 12 (7), p. 1058; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3291053/#R17 .

[27] WHO, available at: www.who.int/influenza/resources/documents/PIPbrochure.pdf?ua= .

[28] Sigerist, H.E. (1951), "*A History of Medicine*", Volume I. Primitive and Archaic Medicine. New York. Oxford University Press, p.564.

[29] Under human rights every individual has right to live freely and without discrimination with dignity; Article 3, 6 and 7 of UDHR; available at: www.unhchr.ch/udhr/ .

[30] In this case Mrs. Ellen Siegel was in isolation for small pox incubation period of 14 days since she had come from Stockholm when it was considered to be smallpox infected. Also see, United States of America ex rel. *Ellen Siegel, Relator v. Thomas L. Shinnick, and John Doe* said name being fictitious, the person in charge of the US of public Health Hospital at Stapleton, Staten Island, New York and having custody of said Ellen Siegel, Respondents No. 63-M-888, 219 F. Supp.789 (Eastern District Court of New York 1963); available at: www.law.justia.com>federal>district-courts

her arrival she did not present any valid certificate of vaccination against small pox.[31] The earliest case addressing State's right to quarantine an individual has been of *Gibbons v. Ogden* 22 US 1 (1824).[32] In *Gibbons,* the US Supreme Court explained that:

> "(S)tates have the power to authorise quarantine under their police powers which proves that sometimes State has to be more stringent and vigilant for its people".[33]

This shows that state authority is the ultimate individual's welfare. Moreover, at present for isolation and quarantine disease like HIV/AIDS 13 countries completely banned HIV(+) people from entering into their territory, at least 106 countries have HIV(+) specific travel restrictions, while around 20 countries follow rigid policies like the proof of being HIV(-).[34] These measures may be saving and protecting healthy individuals but on the other hand it violates the right of availing health facilities or services by HIV(+) individuals along with denying them from the fundamental principles of the RTH.[35]

Traditionally, ships were carriers of infection, pandemics and viruses from one country to another. But, mode of travel has changed it to aviation. In old days reveal civil authorities took measures to fight and prevent spread of diseases leading to formation of quarantine measure.[36] These quarantine measures seek to isolate sick or contagious individuals from healthier ones, as well as screen them for forty days so that the disease reaction can be known.[37] The word quarantine and isolation seems same and intersecting but not so quite similar. According to CDS quarantine means "to separates and restricts the movement of people who were exposed to a contagious

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[31] Ibid.

[32] Gibbons v. Ogden (1824) 22 US 1, 9 Wheat. 1, 6 L. Ed. 23 (1824); available at: www.lawnix.com/cases/gibbons-ogden.html

[33] Kourinian, Arsen., (2010) "History of Abuse and Lack of Protection: The Need to Update California's Quarantine Powers in Light of the H1N1 Influenza Outbreak", *Loyala of Los Angeles Law Review*, 43, p.697.

[34] Kaseketi, Rev. Annie. (2008) "Discrimination, Isolation, Denial: Travel Restrictions against People living with HIV" *The Ecumenical Advocacy Alliance*. Zambia, p.3.

[35] Article 25(1) of the UDHR 1948; the Article 12(2)(d) of ICESCR 1996.

[36] Quarantine word evolved from Italian word quarantenara and quaranta giorni, during plague ridden days of 14 and 15 century when Venice used to isolate the ships. For reference, see, Fidler, P. David., Gostin. Lawrence. O. and Markel, Howard., (2007), "Through the Quarantine Looking Glass: Drug Ressitant Tuberculaosis and Public Health Governanace, Law, and ethics" *Journal of Law and Medicine*, 35 (4), p.619.

[37] Musto, David F., (1986), "Quarantine and the Problem of AIDS", *The Milbank Quarterly,* AIDS: The Public Context of an Epidemic, 64 (1), p.97

disease to see if they become sick". [38] Moreover isolation means "to separates sick people with a contagious disease from people who are healthy".[39] Venice is considered as one of the first cities for controlling plague spread through ships, crews, travelers and cargos in about 1374. In 1403, the first maritime quarantine station or lazaretto was set by the Municipality in the island of Santa Maria di Nazareth.[40] Besides this vigilant approach encouraged other countries or ports to adopt such preventive and restrictive measures for health safety and security in order to safeguard health rights to its people. Thus, the RTH beside quarantine measure has various contemporarily experiences likewise.[41]

Moreover, to regulate police power and states authority individuals rights are neglected. In the *Kirk v. Board of Health*,[42] Supreme Court of South Carolina (1909), which was in favour of quarantine measure, affirmed that:

> "(S)tates have the right, under their police powers, to quarantine and isolate individuals from the community who have been in contact with a contagious disease. Moreover, at certain times, the rights of individuals must be undermined for the protection of the overall community".[43]

Such surveillance and quarantine to control health threat is viewed as health protection and prevention and not against human rights. Further, it is important to

[38] CDC Centre for Disease Control and Prevention, (2015) "Quarantine and Isolation", CDC 24/7: Saving Lives, Protecting People; available at: www.cdc.gov/quarantine/
[39] Ibid.
[40] Fidler, P. David., Gostin. Lawrence. O. and Markel, Howard., (2007), "Through the Quarantine Looking Glass: Drug Ressitant Tuberculaosis and Public Health Governanace, Law, and ethics" *Journal of Law and Medicine*, 35 (4), p.619.
[41] Ibid.
[42] In this case Mary Kirk, a missionary in Brazil got infected by anaesthetic leprosy. To avoid its spread to others, the Local Board of Health (Aiken) ordered for her isolation. Arrested on the grounds of section 1099 of Civil Code that states: "the said board of health has power and it is their duty to make and enforce all needful rules and regulations to prevent the introduction and spread of infectious or contagious diseases by the regulation of intercourse with infected places, by the arrest, separation, and treatment of infected persons, and persons who shall have been exposed to any contagious or infectious diseases. The board with the consent of the town or city council has power to establish one or more hospitals and to make provisions and regulations for the management of the same during the prevalence of any contagious or infectious diseases within the town or city". Moreover the Constitutional law governing health regulation also states that "the isolation of infected person does not violate the right to enjoyment of liberty and property as the right does not allow injuring others by liberty or property... the health board must inquire and take action promptly when public health is endangered". But Miss Krik of old age claimed that "the place where she is about to be kept, is actually a pest house, coarse and comfortless which is used for imprisoning Negros having small pox and other dangerous infection, the hospital also had a horrible smell which came from the city dumping located nearby the hospital". For details see, Lawrence, O. Gostin. (2010) *Public Health and Ethics: A Reader*, Chapter 7- public health and protection of individual rights, p.388-394. University of California Press.
[43] Ibid.

know, as well as acknowledge that even the religious pilgrimages were not left. When Haj[44] travelers, used to travel in the Red Sea during Ottoman Empire in 1882-1956, in order to keep security check and prevent healthier individuals, their isolation took place in quarantine station of the Red Sea. These measures of ships reporting brought continuous modification and improvement in public health, foremost by making each sovereign state to look for protective and surveillance measure of their peoples' health through International health regulation (IHR) of WHO.[45] As an international treaty, the new IHR of 2005[46] adopted on 23 May, 2005 by the World Health Assembly (WHA) having ten parts along with nine annexure containing 66 articles states its purpose in the Article 2 that it "provides response to the international spread of disease that restricts public health and interference with international traffic and trade". [47]

Recent prevalence on quarantine in news through a newspaper named "The New York Times",[48] dated May 30, 2007. Highlighted, during an individual suffering from unusual i.e. potentially deadly strain of drug resistant tuberculosis[49] left from his home Atlanta to travel Europe, in places like Rome, Prague, Czech Republic and Montreal creating a public health threat and emergency. Further against the advice of state, local and federal public health authorities he flew for two weeks internationally and then reentered in the United States (U.S) from Canada, where he became the first individual since 1963 to be quarantined in the US.[50] The WHO surveillance list did

[44] Haj is considered the fifth pillar of Islam through pilgrimage to Mecca during the month of Dhu al-Hijja; at least once in a lifetime a Muslim (religion) is expected to make a religious journey to Mecca and the Kaaba. For details, see, Basch, Paul. F. (1999), "*Textbook of the international health"* Second Edition, Oxford University Press, Inc. Newyork. Oxford, p.22-23, 36.

[45] Ibid.

[46] Fidler, David P. and Gostin, Lawrence O. (2006), "The New International Health Regulations: An Historic Development for International Law and Public Health" *Journal of Law, Medicine & Ethics*, Faculty Publications. Paper 370. Indiana University, Digital Repository, Maurer Law, p.85-86; available at: www.repository.law.indiana.edu/facpub/370

[47] WHO (1983), "International Health Regulation 1969", 3rd Edition, Geneva, WHO.

[48] Lawrence K. Altman, TB Patient Is Isolated after Taking Two Flights, N.Y. Times (May 30, 2007); available at: www.nytimes.com/2007/05/30/us/30tb.html .

[49] Fidler, P. David., Gostin. Lawrence. O. and Markel, Howard., (2007), "Through the Quarantine Looking Glass: Drug Ressitant Tuberculaosis and Public Health Governanace, Law, and ethics" *Journal of Law and Medicine*, 35 (4), p.617.

[50] Jaikumar, Arjun K., (2014), *"Red Flags in Federal Quarantine: The Questionable Constitutionality of Federal Quarantine after NFIB V. Sebelius",* Columbia Law Review, 114 (3), p. 677; also see, Fidler, P. David., Gostin. Lawrence. O. and Markel, Howard., (2007), "Through the Quarantine Looking Glass: Drug Ressitant Tubernculaosis and Public Health Governanace, Law, and ethics" *Journal of Law and Medicine*, 35 (4), p. 617-618.

not contain MDR-TR till 2007. Thus, health security and surveillance measure has become one of the public health emergencies.[51] On the other hand mandate directed by police power points towards impact of good governance for health security from threat of diseases or just isolation with indifferent nature to the vulnerable individual.[52]

Threat of disease spread and surveillance in the Indian context is visible in the draft of Indian Aircraft (Public Health) Rules 2015 that provides exercise powers through section 8A[53] of the Aircraft Act, 1934 (22 of 1934) and in supersession of the Indian Airport (Public Health) Rules, 1954 to look into matters of health threats. According to the draft Indian Aircraft (Public Health) Rules 2015, it is mandatory and advisable law forwarded by the Ministry of External Affairs (MEA) and the Ministry of Health & Family Welfare (MOHAFW). To control spread of polio virus by travelers got effective from 1 March 2014. Polio infected seven countries like polio endemic nations of Afghanistan, Pakistan, Nigeria and having circulation of polio virus importation by Somalia, Kenya, Syria and Ethiopia has been decided to carry vaccination requirement of oral polio vaccine (OPV), whether inbound or outbound travelers from residents of such countries to India or from India to such countries.[54].

The need of Indian Aircraft (Public Health) Rules 2015 seems of great importance after the case of Ebola quarantine in New Delhi airport that took place on

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[51] Ibid

[52] Ibid

[53] Section 8A states in Power of Central Government to make rules for protecting the public health-that: "b[Subject to the provisions of section 14,] the c[Central Government] may, by notification in the c[Official Gazette,] make d[rules] for the prevention of danger arising to the public health by the introduction or spread of any infectious or contagious disease from aircraft arriving at or being at any aerodrome and for the prevention of the conveyance of infection or contagion by means of any aircraft leaving an aerodrome and in particular and without prejudice to the generality of this provision may make, with respect to aircraft and aerodromes or any specified aerodrome, rules providing for any of the matters for which rules under sub-clauses (i) to (viii) of clause (p) of sub-section (1) of section 6 of the Indian Ports Act, 1908, may be made with respect to vessels and ports].
[a] Inserted by the Aircraft (Amendment) Act, 1936 (7 of 1936), S.2.
[b] Inserted by the Aircraft (Amendment) Act, 2007 (44 of 2007)
[c] Substituted for the words" G.G. in C." and "Gazette of India" by A.O.1937.
[d] See the Indian Aircraft (Public Health) Rules, 1954, Published in Gazette of India, 1955, Part II, Sec.3 p. 2095". For further reference, see, The Aircraft Act, 1934, (XXII of 1934): 1-14; available at: www.dgca.nic.in/airact/aircraftact.pdf

[54] File No. L-21021/73/2013-PH(IH), (2014), Ministry of Health and Family Welfare (MOHFW), Government of India (GoI), Directorate of Health Services, PH (IH) Section, 28-Feburary-2014. Nirman Bhavan, New Delhi. Under Dr. Prabha Arora, Assistant Director General, International Health, p.1-6; also see, Appendix D for the format of Health Certificates under the Annexure 1 to 5 of Indian Aircraft (Public Health) Rules, 2015, GoI .

10 November 2014.[55] In this case a 26 year old Indian man who was declared Ebola free in Liberia under the WHO's standards.[56] Further, isolation based on theoretical understanding of risk for sexual transmission by Indian officials was a strong reaction.[57] Further, quarantine measures to protect individuals health was visible in UK for the supply of less than 5% of fresh fruit and vegetables that were exported from India. Alphonso mango and four vegetables[58] got temporarily banned in UK from India from the group of standing committee on plant health. About 207 consignments having fruits and vegetables were contaminated with pests like fruit flies and other quarantine pests. Further, to admit the acceptance for quarantine[59] measure not just limits to detaining incoming ships or vessels before entering a State or country for screening purposes for disease like plague, yellow fever, cholera, etc. Quarantine method also helps in screening and detaining controlling of contagious diseases for trade and travel preventing and protecting individuals health.

On the other hand NCDs are lifestyle diseases like heart disease, drug addiction, lung cancer and obesity relating to the lifestyle changes. WHO estimates growing overweight or obese problem kills at least 2.8 million adults each year.[60] To overcome obesity problem in 2004, WHO adopted "global strategy for diet, physical

[55] Bloomberg Business, (2014), "*India Quarantines Man Cured of Ebola After Semen Samples*", 19 November 2014, Bloomberg Business; available at: www.bloomberg.com/news/articles/2014-11-18/india-quarantines-man-cured-of-ebola-after-semen-samples

[56] RT Questions More. Live, (2014), "India Quarantines Ebola Survivor over Virus Traces in Semen Samples", 19 November 2014, Ebola Outbreak, RT Questions More. Live, News; available at: www./rt.com/news/206743-ebola-india-semen-quarantine/ ; also see, Bloomberg Business, (2014), "India Quarantines Man Cured of Ebola After Semen Samples", 19 November 2014, Bloomberg Business; available at: www.bloomberg.com/news/articles/2014-11-18/india-quarantines-man-cured-of-ebola-after-semen-samples

[57] Earth Changing Extremities: Yamkin (2014), "India quarantines Ebola Survivor over virus trace in semen samples", Virus Alert, Earth Changing Extremities: Yamkin, ; available at: www.yamkin.wordpress.com/tag/ebola-virus-2/page/2/

[58] The four vegetable temporarily banned by European Commissionin 28 member European Union are: i) taro plant; ii) eggplant; iii) snake gourd; and bitter gourd. For reference, see, The Hindu, (2014), "EU bans Indian Alphonso mangoes, 4 vegetables from May 1", 28 April 2014, London, International: World; available at: www.thehindu.com/news/international/world/eu-bans-indian-alphonso-mangoes-4-vegetables-from-may-1/article5956482.ece

[59] Quarantine is an Italian word for forty. Some say might be Moses wandered in dessert alone for 40 years.

[60] For Instance, see, Fact Sheet No. 311, "Obesity and Overweight", WHO (2012) World Health Organisation, May 2012; available at: www.who.int/mediacentre/factsheets/fs311/en/index.html ; also see, Park. K. (2005), "*Park's Textbook of Preventive Medicine and Social medicine*", Banarasidas Bhanot Pub. Jabalpur, p. 316.

activity and health".[61] In developing countries such as India, where traditional lifestyles persist, risks of illness and death are connected with lack of sanitation, personal hygiene, poor nutrition, elementary human habits, custom and cultural pattern.[62] Investigation, exposes unhealthy dietary worsen behavioral changes and metabolic including physiological risk factors like high sugar, blood pressure and cholesterol, etc.[63] It is important to follow proper lifestyle habits like adequate nutrition, sufficient physical activity and enough sleep, etc.[64] The acceptance of death, disability and diseases led to promote and protect respect for human rights as an international framework. Articles 12(2) and 12(2)(c) of ICESCR 1966 states to achieve RTH realization during Communicable Diseases (CDs) and NCDs:

> "(S)teps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary like the prevention, treatment and control of epidemic, endemic, occupational and other diseases".[65]

Parties to the ICESCR have to make proper preventing, treating and controlling obligation so that realisation for RTH can be achieved to its fullest. The most essential human right for every individual pertains to absence of discrimination on the ground of class, physical standards of differently abled,[66] unsound mind, male, female, children or elderly person. At present situation the obligation is to pay consideration towards the requirement of the individual. These obligations come directly on member states with the help of all the International Conventions especially with the Article 25(1) and (2) of the UDHR 1948,[67] the ICESCR 1966.[68] On the other hand WHO and UN keeps track of developing diseases and health fights with new

[61] The WHO's, World Health Report 1995 relating to lifestyle revealed that 70-80% of the deaths occur in developing countries and 40% in developed world. See, the World Health Report 1995: Bridging the Gaps. Geneva: WHO 1995, p12.
[62] Park. K. (2005), "*Park's Textbook of Preventive Medicine and Social medicine*", Banarasidas Bhanot Pub. Jabalpur, p.18.
[63] WHO (2011) WHO Global Status Report on non-communicable diseases 2010, p.v.
[64] Article 11 of the ICESCR 1966.
[65] Articles 12(2) and 12(2) of ICESCR 1966.
[66] The Convention on the Rights of Persons with Disabilities (CRPD) 2006 has the definition of the RTH under the CPRD is explained under Articles 16(4), 22(b), 25, 25(a) 25(b), 25(c), 25(d), 25(f), 25(e), 26, 27(1)(a), 27(1)(b). Also see, Articles 16(4), 22(b), 25, 25(a) 25(b), 25(c), 25(d), 25(f), 25(e), 26, 27(1)(a), 27(1)(b) of the CRPD 2006; and Rana, Y. Sonam. (2004), "Law, Ethics and HIV/AIDS in South Asia: A study of the Legal and Social Environment of the epidemic in Bangladesh, India, Nepal and Srilanka" *United Nations Development Programme*, p.14.
[67] Article 25(1) and 25(2) of the UDHR 1948.
[68] Article 12 (1); 12 (2) (a) (b) (c) and (d) of the ICESCR 1966.

legal arrangements such as the IHR; [69] Framework Convention on Tobacco Control 2003;[70] WHO Outbreak Communication Guidelines 2010; the Global Strategy to Reduce the Harmful Use of Alcohol 2010; WHO Pandemic Outbreak Communication Guidelines 2005; and etc. The other main health related developments under the UN auspices, apart from Covenant, the Conventions, the UDHR include: the UN Guidelines on HIV/AIDS;[71] the UN Tobacco Control Convention[72] (TCC) and the UN Convention on the Rights of Persons with Disabilities[73] (CRPD).

Medical Knowledge and Health Care Liability

The process of medical development has brought the concept of health through drug and biotechnology. Medicine is one of the essential sources of RTH and access to medicine became an important concept of health in order to provide relief for suffering and pain. In earlier times correct detection of illness was hardly available. In order to provide relief for known sufferings, formerly magical remedies and socio-cultural beliefs based on religious practices were performed. But, advancement in medicinal/scientific practices acknowledged the doctor as first man of the society and the nurse as first lady.[74] WHO Constitution in its preamble (paragraph 8) states that "health attainment can only be possible when every individual gets benefit from the physiological, medical and related knowledge to its fullest".[75] Similarly, the Declaration of Helsinki on Ethical Principles for Medical Research

[69] *International Health Regulation* (2005) A Brief Introduction to Implementation in a national legislation January 2009. WHO/HSE/IHR/2009.2 .

[70] WHO, (2003), "*WHO Framework Convention on Tobacco Control*", Fifty six World Health Assembly, came into force on 27 February 2005 Geneva, Switzerland; and WHO, (2013), "Protocol to Eliminate Illicit Trade in Tobacco Products", FCTC, WHO Framework Convention on Tobacco Control, Geneva, Switzerland.

[71] *International Guidelines on HIV/AIDS and Human Rights*, OHCHR/UNAIDS; available at: www.ohchr.org/Documents/Publications/HIVAIDSGuidlinesen.pdf

[72] UN News Centre, 2010. "UN Tobacco Control Convention Marks Fifth Anniversary" UN Daily News, available at: www.un.org/apps/news/story.asp?Cr=health&NewsID=33911#.VMXun9KUdIw ; also see, WHO, (2013), "*Protocol to Eliminate Illicit Trade in Tobacco Products*", FCTC, WHO Framework Convention on Tobacco Control, Geneva, Switzerland.

[73] The UN Standard *Rules for the Equalisation of Opportunities for People with Disability 1993* Resolution 48/96; and *General Comment No. 5: On Persons with Disability,* (1994). *United Nations Convention on the Rights of Persons with Disabilities 2006;* available at: www.un.org/disabilities/convention/conventionfull.shtml.

[74] Park. K. (2005), "*Park's Textbook of Preventive Medicine and Social medicine*", Banarasidas Bhanot Pub. Jabalpur, p. 1.

[75] The WHA (1998), "Constitution of the World Health Organisation", World Health Assembly Health for all policy for the twenty first century Agenda item 19 World Health Declaration 16 May 1998 Fifty-first WHA51.7, p.2. (Paragraph 8), Preamble of the WHO constitution.

Involving Human Subjects (2002) underscores that it is important to promote and safeguard health of people:

> "It is the duty of the physicians to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to fulfillment of this duty".[76]

Thus it becomes duty for physician to promote and safeguard health of individuals through his/her best knowledge and conscience. Genetics and biomedical research in health along with modern technology has developed health care more meaningful.

The RTH debate on pharmaceutical has limited its understanding by centering on access of medicine especially with the life saving drugs. The developing and least developed countries like Africa and India has always raised the issue of concern towards fundamental human rights and principles of equality, discrimination and etc arising out of health requirements. On the other hand, the commitment of the pharmaceutical companies in providing contribution to neglected diseases like malaria, diarrhea and etc. as well as providing R&D towards vulnerable diseases and basic access for health care gives boost to those health treatments that directly falls in developing countries categories.[77] RTH has to be implied with the help of other human rights like right to access medicine and treatment. Sometimes the unethical practice of scientist and doctor's to invent their own creation keep aside their pledged ethics of profession as stated in the declaration of Geneva 1994.[78] One of the

[76] The principle no. 2 of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2002).

[77] DeRoo, Pier. United Nations Global Compact, "Note from the Co-Chairs of the Human Rights Working Group: Human Rights, Access to Medicines and the Pharmaceutical Industry", p.2; available at: www.unglobalcompact.org/docs/issues_doc/human_rights/Human_Rights_Working_Group/Pharma_Access_to_Medicine_GPN.pdf

[78] The Declaration of Geneva, 1994 provides with physician's Oath at the time when they are admitted as a member of the medical profession. By the pledge the physicians takes an oath: "I solemnly pledge myself to consecrate my life for humanity; I will give to my teachers the respect and gratitude which is their due; I will practice my profession with consciences and dignity; The health of my patient will by my first consideration; I will respect the secrets which are confined in me keep secrets of patient even after the patient died; I will maintain by all means in my power, the honor and noble traditions of the medical profession; My colleagues will be my sisters and brothers; I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient; I will maintain utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity; I make these promise solemnly, freely and upon my honor". For details, see, The Declaration of Geneva (1994), the Physician's Oath.

unfortunate truths is about the Nazi incident. In this criminal act twenty three doctors were charged before the International Military Tribunal in Nuremberg for war crimes and crimes against humanity. In this regard to act against war crimes and crimes against humanity the Common Article of the Geneva Convention states that:

> "During armed conflicts not of an international character each party have to apply these provisions: all individuals either member of armed force or an innocent should not be harmed and treated humanely who is not an active part in the hostilities, and those placed hors de combat by sickness, wounds, detention, or any other cause. No one should be degraded founded on its colour, race, birth, faith, religion, sex or wealth, or any other criteria. As well as there should not be violence to life of person degrading or cruel treatments, mutilation or torture. The sick or injured should be collected and during conflict impartial humanitarian body can offer service like the International Committee of the Red Cross".[79]

In this context the International Covenant on Civil and Political Rights too speaks on torture and degrading behaviour towards victims of war crimes in Article 7, that "no individual should be tortured or treated inhuman. As well as no one should be human subject without his/her consent".[80] Moreover, the Human Rights Committee General Comment No. 20 1992 prohibits all medical experiments without consent (Article 7) by stating that:

> "(S)ince limited information is provided on medical or scientific experimentation conducted without open permission of the person concerned. Special protection is required for vulnerable subjects and those who cannot provide valid consent, and in particular individuals who are under detention or imprisonment. Moreover, these individuals should not be subjected to any conducting tests that may harm their health".[81]

It has been revelation that these concentration camps in fact brought modern science into existence with predictions and accuracy. The human experiments conducted at the concentration camps of Auschwitz, was the largest German camp of WWII Buchenwald, Ravensbrueck, Dachau and Sachsenhausen during Nazi period exposed torture and immoral way of experimenting human subjects.[82] Observing inhuman behaviour, some physicians want support and moral and legal protection during ethical practice of health. The Declaration Concerning Support for Medical

[79] Common Article 3 of the Geneva Convention (1949), adopted by the Diplomatic Conference for the Establishment of International Conventions for the Protection of Victims of War, held in Geneva, from 21 April to 1 August 1949. Entered in force on 21 October 1950.
[80] Article 7 of the International Covenant on Civil Political Rights 1966.
[81] Article 7 of the Human Rights Committee General Comment No. 20 1992.
[82] In fact see, Wells, S.D. (2012), "*25 Amazing (and Disturbing) Facts about the Hidden History of Medicine*", Truth Publishing, Inc. p.1-2; available at: www.nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=medical

Doctors Refusing to Participate in, or to Condone, the Use of Torture or Other Forms of Cruel, Inhuman or Degrading Treatment in 1997[83] came up to support such doctors/physicians. Besides, there are three main ethical principles according to the International Ethical Guidelines for Biomedical Research Involving Human Subjects 2002 and they are: i) respecting human autonomy and self-determination for personal choice or protection to impair and vulnerable; ii) Beneficence so that subject gets less harm and maximum benefits; iii) Justice by treating with moral conduct.[84]

The essence of health rights is shaping itself differently and facilitating those individuals who can afford for their own health care. In view of the fact that, market sphere is increasing by the pharmaceuticals products. Correspondingly, individuals' desire to live more has endorsed it into the commercial business for survival. Still one cannot neglect that worldwide major cause of morbidity and mortality has come from Adverse Drug Event (ADE) or the drug reaction. Further, an alternative method looking into immune and non immune mechanisms has been developing through Personalised Medicine (PM) and this process of delivery has been looked as more effective targeted therapeutics without an error. PM came as new biotechnological development after the completion of human genome project by the U.S Department of Energy and the National Institutes of Health in 2003. In the course of series of cases based on ADE, this new technology of PM has brought an evolution towards minimising the ADE by individual patient-based genetic predisposition of direct selecting medication dosage along with maximal efficacy and safety towards health care.[85]

Occupational Hazards and Health Safety

The development of health rights began from input expansion of concern for socio-economic condition of workers. Deteriorating health by working for excessive

[83] Preamble and Resolution of the Declaration Concerning Support for Medical Doctors Refusing to Participate in, or to Condone, the Use of Torture or Other Forms of Cruel, Inhuman or Degrading Treatment 1997.

[84] General Ethics Principles of the International Ethical Guidelines for Biomedical Research Involving Human Subjects 2002.

[85] U.S News Health, (2013), "Personalized Medicine", The Basics on Personalized Medicine-U.S News Health, Duke Medicines: *U.S News & World Report LP*; available at: www.health.usnews.com/health-conditions/cancer/personalized-medicine , p.1-3.

hours forced to lay health standards,[86] and framing of functioning hours. Time frameworks came as first health measure for occupation and safety due to raising sickness absence and employment disability information.[87] The Health and Morals of Apprentices Act 1802 by England is observed to bring such occupational performance plan in function. Children in textile industry were just permitted for 12 hours a day. That changed to 9 hours by the Factory Act of 1883 for children of 9 to 12 years. Besides, children of 13 to16 years were made to work for 12 hours on daily basis.[88] But, for children under age of 10 and adult workers had no proper health or safeguard guideline in United States (US) or in Britain. In 1830's evolution for limiting hours of work for wage earners began for shorter hours of work as competent citizens. As the wage workers found working sun to sun i.e from early morning to day time, was contrary with citizenship and there was no proper consideration for wage earner. This movement led by majority numbers of men representation named it as men's hour laws discriminating women and children, creating vulnerability by privileges of men. In 1852 came enactment of first 10 hour law for women workers by Ohio of US. The first law by 1879 of Massachusetts in US set a pattern for other states to realise; reduction of hours contributes to less workers' fatigue with less absenteeism and higher morale, as well as lower accident rates. The years since 1920 came up as a progress in reducing the maximum workday and workweek for women workers, establishing standards measure for a day of rest, and meal as well as rest periods, prohibiting or regulating night work, and providing various other standards for working conditions.[89]

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[86] Hagan, Philip. E., Montgomery, John F., and O'Reilly. James T. (2001), "*Accident Prevention Manual for Business and Industry, Administration and Programs*, National Safety Council, 12 ed., Itasca, Illinois. U.S. A, p.4-5.

[87] Blomhoff, A., Van Wely, Dr.P.A., and Smulders, Dr.P.G.W., (1994), "Work and Health: Risk Groups and Trends", Research Team of TNO Institute of Preventive Health Care, Scenario Report Commissioned by the Steering Committee on Future Health Scenarios, Kluwer Academic Publishers, Netherlands, ISBN 0-7923-2733-0, E.W. Bergsma, STG, Rijswik: 1-197, p.107.

[88] Basch, Paul. F. (1999), "*Textbook of the international health"* Second Edition, Oxford University Press, Inc. Newyork. Oxford. p.32-34.

[89] The hours of employment in this line refers in context of women of USA which is related to the maximum workdays and work week, as well as it too includes the hours of work and they are such as: a) days of rest-this means that a 6 days week work with prohibit employment on Sunday according to the blue laws and some places Sunday became a legal holiday like in Montana; b) meals or rest periods-this time frame for meals varied from one-third to one hour, which is provided through statute, orders or regulations according to each State that implemented it. But in some places like Kentucky and Wyoming combined meal and rest period were provided together. Whereas, some states provided rest period for a 10 min within each half day of work; and c) night work-this is an arrangement of time that

Sudden increase in workers injuries and deaths, demanded workers health protection by use of hazardous substances in working environment along with other production and distribution manufacturing. Moreover, since 1898 efforts were on the rise making employer financial liable. To investigate such understanding, a study on serious nature of occupational accidents and deaths, in 1906 by the Russell Sage foundation came up with sponsoring of Pittsburg Survey. This survey was carried in Allegheny County of Pennsylvania and constructed a death calendar[90] for the county. It showed that when in an average two deaths takes place a year due to industrial accidents in such a small county, what scenario or situation would lead for an entire US? As a result, Pittsburg survey cleared that accidents and death rate were severe important issues and needed a safety progress to be carried out toward industrial accidents.[91]

The Convention Concerning Occupational Safety and Health and the Working Environment (1981) comprising the principles of national policy states that:

> "Each member shall, in the light of national conditions and practice, and in consultation with the most representative organisations of employers and workers, formulate, implement and periodically review a coherent national policy … to prevent accidents and injury to health arising out of, linked with or occurring in the course of work, by minimising, so far as is reasonably practicable, the causes of hazards in the working environment". [92]

The national policies of a country for health safety and prevention of accidents or injury should be periodically reviewed, implemented or formulated. So minimization of incidents related to accident/injury and control in working hazards environment can be possible. Such a of firm measure can be visible in the case of Supreme Court (SC) of India, in its first Public Interest Litigation[93] (PIL) plea on

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specified that women's were prohibited employment at night specially adult women's or if they employed women workers they followed maximum hour standards different from those established for day work or regulate the conditions under which women may be employed after specific evening hours. The prohibited employment timing began at 9 pm through midnight and extended to 6, 7, or 8 am. This prohibition of working hours for women was followed in states like Puetro Rico, etc. Also see, Hathi Trust Digital library, (1962), "Growth of Labor Law in the United States" Hour Legislation: Hours of work for women, *Hein Online.* U.S Dep. of Labour, Washington, p. 73, 74, 78, 79 and 80.

[90] Death calendar carried out the survey that highlighted industrial accidents accounted for an average of nearly two deaths per day throughout the year. For details, see, ibid.

[91] Ibid; p.5 and 6.

[92] Articles 4(1) and 4(2) of the Convention Concerning Occupational Safety and Health and the Working Environment 1981.

[93] PIL of India came in 1979, under trial prisoner's case of *Hussaninara Khatoon v. State of Bihar: AIR 1979 SC 1360*. Observing accountability of State, particularly in order to provide remedies for social

health. In the *Workmen of Slate Pencil Manufacturing Industries v. State of Madhya Pradesh,* (1980),[94] the apex court for the first time gave directions to the manufacturing companies to install safety measures in the factories because workers were dying at young age due to dirt congestion in their lungs. Moreover, the court held that if direction of safety measures are not followed the manufacturing Industry will be closed down. Since health measure was an important issue and need of the generation, Theodore Roosevelt,[95] during his Presidential election demanded need for workers' compensation law. However, in the beginning it only favored federal employees. Subsequently it came to the other common workers. The United States Supreme Court in 1916 declared workers' compensation to be constitutional, which was held in *New York Central Railroad Co. v White* (1917), observing this many states passed compulsory workers' compensation laws.[96]

At the same time, insurance companies started to relate the cost of premiums for workers' compensation insurance to the cost of accidents. As well as the employer or the management holders began to understand the close relationship between successful production and safe production.[97] The Convention Concerning Occupational Safety and Health and the Working Environment (1981) states that:

> "To give effect to policy referred in Article 4 of this Convention, the competent authority or authorities shall ensure … determination, where the nature and degree of hazards … governing the design, construction and layout … commencement of their operations, major alterations … safety of technical equipment used at work, …

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wrongs affecting fundamental rights of society, who due to social, economic or other disability, do not have access to the courts. The Supreme Court (SC) is competent to entertain PIL only to the extent it is necessary to enforce fundamental rights. In order to liberalise traditional rule locus standi i.e access to justice, Judges like Krishnan Iyer and P.N.Bhagwati came forward converting much of the constitutional litigations into PIL. For details, see, Desai, Bharat H., (2014), "Enforcement of the Right to Environment", *Asian Judges Network on Environment*, p.28,39; available at: www.asianjudges.org>uploads>2014/3

[94] For details, see, *Workmen of Slate Pencil Manufacturing Industries v. State of Madhya Pradesh,* Civil Writ Petition No.5143 of 1980

[95] In 1908, Presidential election Theodore Roosevelt stated that the number of accidents which result in the death or crippling of wage earners is simply appalling. In a very few years it runs up a total far in excess of the aggregate of the dead in any major war. For details, see, Hagan, Philip. E., Montgomery, John F., and O'Reilly. James T. (2001), "*Accident Prevention Manual for Business and Industry, Administration and Programs*, National Safety Council, 12 Edition, Itasca, Illinois. U.S. of America, p.5.

[96] *New York Central Railroad v. White,* (1917), 243 U.S. 188, 37 S.Ct. 247, 61 L.Ed. 667 (1917); available at: www.biotech.law.lsu.edu/cases/adlaw/nycrc_v_white.htm ; also see, www.supreme.justia.com/cases/federal/us/243/188/

[97] Hagan, Philip. E., Montgomery, John F., and O'Reilly. James T. (2001), "*Accident Prevention Manual for B-usiness and Industry, Administration and Programs*, National Safety Council, 12 Edition, Itasca, Illinois. U.S. of America, p. 4-7.

> application of procedures defined by the competent authorities … work process and of substances and agents the exposure to which is to be prohibited, limited or made subject to authorization or control by the competent authorities; health hazards … exposure to several substances or agents … establishment and application of procedures for the notification of occupational accidents and diseases, by employers … holding of inquiries, … in the course of or in connection with work … publication, annually, of information on measures taken in pursuance the policy referred to in Article 4 of this Convention and … other injuries to health … account national conditions and possibilities to examine chemical, physical and biological agents in respect of the risk to the health of workers".[98]

These safety measures state that account of accidents and diseases related to occupation has to be notified along with insurance institution. The tort law case (Bhopal Gas Leakage) *Union Carbide Corporation v. Union of India and Others,* on 14 February (1989) laid down an, absolute liability of the company. Reacting to the tragedy, India enacted the Bhopal Gas Leak Disaster Act (1985) whereby the Government of India took over all claims related to the Bhopal disaster and claimed US $ 3.3 billion from UCC in the US courts. Later when the case was transferred to India from the US Court on basis that UCIL was a separate entity, owned, managed and operated exclusively by Indian citizens in India. The Central Bureau of Investigations (CBI) contended that UCIL as well as UCC officials had been responsible for negligence. In an out-of-court settlement, in 1989, the Union Carbide agreed to make *ex-gratia* payment of US$ 470 million which was actually just the insurance amount of US $350 million + interest. So it came to be just 15% of the original claim of US $3 billion. In the aftermath of this case, comprehensive Environment Protection Act (1986) and Public Liability Insurance Act (1991) came up. Along with two articles inserted in 1976 in, amendment to the Constitution of India, i.e. Article 48 A and 51 A (g), the State as well as the citizens both are now under constitution to oblige to conserve, protect and improve the environment. In 1987, a Bhopal District Court charged Union Carbide officials, along with CEO Warren Anderson, for culpable homicide, grievous assault and other serious offences. In 1992, a warrant was issued for Anderson's arrest[99] that was never given effect to. So Anderson could never be brought to justice!

[98] Articles 11, 11(a), 11 (b), 11(c), 11(d), 11(e) and 11(f) of the Convention Concerning Occupational Safety and Health and the Working Environment 1981.

[99] In end of October 2003 compensation was awarded to 554895 for injuries received and 15310 survivors for those that were killed. The average amount to the families of the dead was US $ 2200. In 2006, the second circuit court appeals in New York City upheld the dismissal of the remaining claims

To observe safety problems of workers, criminal statutes were framed during the industrial period in the U.S. But later the criminal offence turned into civil offence matter due to strict liability that indicates any violator whosoever does not follow the directions, has committed an offence.[100] Understanding the occupational health safety requirements by the employers still the practice of inequity among women and child workers from men workforce was being followed. Till 1913, women's working hours of employment was not so considered. Their fragility and over time duty for the employer was no constrain as they had to pay less as well as make them work as male workers without considering their vulnerability to physical health standards as comparison to men.

The Convention on the Elimination of All Forms of Discrimination Against Women 1979 states [Articles as 11(1) and 11(1)(f)] that:

> "States Parties shall take all appropriate measures to eliminate discrimination against women in the field of men and women … employment in order to ensure, … equality of men and women, the same rights, in particular: the right to protection of health and safety in working conditions, including the safeguarding of the function of reproduction.".[101]

In the aftermath of time framework, the new employment category focusing on health came up as pre-employment or health screening examination[102] for the

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in case of *Bano v. Union Carbide Corporation*. Federal class litigation and others is presently pending in the second circuit court of appeals in New York. Further the litigation seeks damages for personal injury, medical monitoring and injunctive relief in the matter of cleanup of drinking water supplies for residential areas near Bhopal plant. A related complaint seeking similar relief for property damage claimants is stayed pending of the outcome of the Sahu appeal before the federal district court in the southern district of New York. For details see, *Union Carbide Corporation v. Union of India and Others*, etc on 14 February, 1989. JT 1989 (1), 296 1989 SCALE (1)380; available at: www.indiankanoon.org/doc/654007/ ; also see, www.icmrindia.org/free%20resources/casestudies/The%20Bhopal%20Gas%20Tragedy1.html ; www.bmhrc.org/Bhopal%20Gas%20Tragedy.html ; www.preservearticles.com/201101143273/case-study-of-bhopal-gas-leak-disaster.html ; www.greenpeace.org/usa/en/campaigns/toxics/justice-for-bhopal/

[100] Frank, Nancy., (1983), "From Criminal to Civil Penalties in the History of Health and Safety Laws", *Social Problems*, 30, (5): 532. University of California Press. Thematic Issue on Justice (Jun., 1983), the Society for the Study of Social, p.532; available at: www.jstor.org/stable/800270

[101] Articles 11(1) and 11(1)(f) of the Convention on the Elimination of All Forms of Discrimination Against Women 1979.

[102] Pre-employment health screening examinations involved an assessment of i). the applicant and ii) job. As well as specific job related defects like: a) the work demands high standard of physical and mental fitness; b) worker needs to enter a hazardous environment to which he was not exposed before like compressed air, deep sea diving, ionising radiation and, lead, etc. c) Industries that have statutory obligations to examine workers before they commence employment like work involving exposure to inosing radiations and lead, etc.; d) The work containing specific hazards to the community at large e.g transport, health care or catering). As many employers are reluctant to employ an applicant if his/her general health is such that he/she is likely to fall off sick for substantial periods. Many people suffer

workers. This criterion of pre-employment examination got highlighted through the case of *Green v. Walker* (1990).[103] This case acknowledged the liability of occupational health doctors for their negligence in health surveillance. The ARA/GSI International had employed Sidney C. Green as an offshore cook. In addition to this the employees in ARA/GSI were required to undergo annual physical examination that included through examination of the physical system like urine test, x-rays of chest and spine etc. According to the outlined protocol Dr. Walker was asked to examine and conduct these tests. On 6 May 1985 Sidney Green submitted his annual employment physical with Dr. Leslie Walker and submitted the report to ARA/GSI International where all Green test results were found to be normal and classified him as "employable without restriction", which was best possible rating on the report provided by Dr. Walker. But, one year later Green got diagnosed with lung cancer, necessitating extensive diagnostic and surgical procedures. Thus, Sidney and Joni Green individually and on behalf of their daughter filed a suit against Dr. Walker claiming that due to negligence to diagnose the beginning of the cancer during the physical examination conducted in May 1985, Dr. Walker, failed to disclose the findings timely. It lessened the chances of Sidney Green survival and life expectancy as he died due to lung cancer. This case pointed towards liability for occupational health doctors of United States if they negligently fail to diagnose medical condition.[104] The doctor owed a duty of care to the employee, which is one of the new developments in health standards of industrial management. In this regard the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects) 2002 states in (Principle 2) that "to promote safety of individual's health

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from chronic bronchitis and asthma but no-one knows how many cases are occupationally linked. There were on average 150,000 deaths per annum from cancer in Great Britain between 1996 and 2000; it is thought that approximately 4 per cent could be occupationally linked. In a Consultative Document issued by the Health and Safety Commission (HSC) in 1984 was laid. The principal regulations are now the Control of Substances Hazardous to Health (COSHH) Regulations 2002. There is an Approved Code of Practice (2002) which has been extended with an appendix on control of substances that cause occupational asthma. For details, see, K Kloss, Diana. M. (2005) "*Occupational Health Law*", Blackwell Science: a Blackwell Publishing Company, Great Britain, p. 20,135-136.

[103] For details see, *Green v. Walker* (1990) No. 89-3569, 910 F .2d 291 (1990), available at: www.leagle.com/decision/19901201910F2d291_11159.xml/GREEN%20v.%20WALKER

[104] Ibid.

physical duty is to work with full conscience and knowledge".[105] Similarly, the World Association International Code of Medical Ethics 1983 states that:

> "A physician shall only act in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient; a physician shall use great caution in divulging discoveries or new techniques or treatment through non-professional channels; a physician shall certify only that which he has personally verified".

The direction of applying patient's interest is by informing him/her all discoveries found during checkup including the new ones. In fact it is the doctor who needs to certify only the verified things made for pre-employment examinations. The case of *Betesh v. United States* (1974)[106] states the same revelation. The general principle of negligence during care of duty will only fall when it arises at least to perform the examination carefully. Likewise, when a nurse examined women for breast cancer and did not refer to the doctor will make her liable for negligence in *Sutton v. Population Services Family Planning Ltd* (1981).[107] In addition to the above statement a doctor using health volunteer for research whether therapeutic or not will have a liability of negligence if he causes damage to the volunteer.[108]

Health Financing through Social Security

There are growing technological advances on the one hand and demand for quality health care services on the other hand. It has led to need for financial health support from Government or private institutions to help during medical research and development (R&D) along with services of medicate and medicare etc. Health, considered as a human right, is still struggling for social security from insurance providers. But, insurance provider sees health as evergreen profit business by policy

[105] Principle 2 of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2002).

[106] Betesh v. United States of America, (1974), 400 F Supp 238 (1974); available at: www.leagle.com/decision/1974638400FSupp238_1606.xml/BETESH%20v.%20UNITED%20STATES

[107] In this case Mrs. Sutton went to Well Women Clinic for a health check as she thought she had a lump in her breast. The nurse after examination could not find or feel it, so she did not refer the matter to the doctor as she had to do it according to her role of diagnostician. As her employer was a private health organisation she was held vicarious liable despite her disobedience to instructions as she was still acting as a nurse in course of her employment. In this case the damages were less and the judge found that all that would have been achieved by an earlier referral was more years' life. For details see, Sutton v. Population Services Family Planning Ltd. (1981), *The Times*, 7 November 1981.

[108] Kloss, Diana. M. (2005) "*Occupational Health Law*", Blackwell Science: a Blackwell Publishing Company, Great Britain, p. 51,52 and 54.

and premiums. When clinical trials are conducted on human subjects, in order to serve during negligent harm or non negligent harm insurance cover helps the R&D.[109] Funding of the insurance can be made from two main sources like the government and private. During clinical trials private companies like Blue Cross/Blue Shield Association have been involved e.g is for supporting bone marrow transplantation in women with advanced breast cancer.[110] The insurance cover can be set by compliant to the local regional Ethics Committee application process.[111] Health financing or security can benefit clinical research to fullest extend along with providing benefits to individuals who seek it.

Historically, social security concept came with workers compensation and employs funds by the workers.[112] But changing individual's social and economic difficulty or requirements for sustainability and demanding health facility and arrangements needs insurance as a social security. Accessibility and affordability need to be ensured for every individual irrespective of his/her ability to finance healthcare. Since escalating health care costs, coupled with demand for healthcare services, lack of easy access of people from low income group to quality health care requires health insurance.[113] Moreover, it is emerging as an alternative mechanism for financing health care security. The ICESCR of 1996 obliges its member states to every step for realizing health services and medical attention during sickness assuring a condition for better health.[114] The Article 22 of the UDHR (1948) affirms that every citizen should have a right to social security keeping in mind States resources and through

[109] Finance Division, "2016", "Clinical Trials Insurance: Requirements and Coverage", University of Cambridge; available at: www.finance.admin.cam.ac.uk/policy-and-procedures/financial-procedures/chapter-18-insurance/clinical-trials-insurance

[110] HJ. Aaron,. and H. Gelband. (2000), "Paying for Patient Care in Clinical Trials-Extending Medicare Reimbursement in Clinical Trials", *National Academies Press*, Washington; available at: www.ncbi.nlm.nih.gov/books/NBK225267/

[111] Finance Division, "2016", "Clinical Trials Insurance: Requirements and Coverage", University of Cambridge; available at: www.finance.admin.cam.ac.uk/policy-and-procedures/financial-procedures/chapter-18-insurance/clinical-trials-insurance

[112] Malik's .P.L. and Malik, Sumit., (2016) "Employees' Provident Funds and Miscellaneous Provisions Act, 1952 [Act 19 of 1952]", 32 Edition, Eastern Book Company, p.5.

[113] The Convention on the Rights of Persons with Disabilities (CRPD) 2006 states in its Article 25(e) that the health insurance or life insurance which is permitted by domestic or national laws by fair and reasonable manner to access and afford the RTH should also be provided to disabled individuals without discrimination. For details, see, Article 25(e) of the Convention on the Rights of Persons with Disabilities and Optional Protocol, p.18 available at: www.un.org/disabilities/documents/convention/convoptprot-e.pdf

[114] Article 12(2) and 12(2)(d) of ICESCR 1966.

national or international co-operation. So that individual's development and dignity is not harmed.[115]

World Health Organisation (WHO) estimates that every year, 150 million people suffer financial catastrophe and 100 million are pushed below poverty line (BPL). So, to manage the expenditure on their health care, individuals and communities explore various available financing options for their security purpose whether through government; public private partnership (PPP); non-governmental organisation (NGO) or Private health coverage facilitator.[116] Majority of the people compare before taking the cost of quality services from government and private health insurance and most of them thrust aside governments' imperfect health care aids. Paying premium or payroll tax, according to the type of plan for health coverage or service benefit the individual selects according to itemised charging plan.[117] These options of comparison without knowledge of exclusion clause indirectly make them eliminate various hidden insurance benefits. Moreover, insurance providers often try to exclude or neglect retained coverage plan by interest rates based on fluctuating market prices so that the insurance company would benefit. Moreover, by providing quality of health care service during emergency, individuals forget that they are receiving less than interest rates bank takes for loans. Eventually opting health care cost or options where there is always hidden sub-clause through insurance companies.

Health insurance can be defined as a contract where an individual or group purchases in advance health coverage by paying a fee called "premium".[118] Health insurance refers to a wide variety of policies. These range from policies that cover the cost of doctors and hospitals to those that meet a specific need, such as paying for long term care. Even disability insurance, which replaces lost income if you cannot work because of illness or accident, is considered health insurance, even though it is not specifically for medical expenses. The concept of health insurance was mooted in

[115] Article 22 of the UDHR 1984.

[116] Mavalankar, Dileep., and Bhat, Ramesh., (2000), "Health Insurance in India Opportunities, Challenges and Concerns", *Indian Institute of Management Ahmedabad,* p.2.

[117] Bowers, Kevin., (2011), "Assessing the impact of healthcare reform on insurance", *International Law Office,* Insurance & Reinsurance - Hong Kong, Globe Business Publishing Ltd, p.1; available at: www.internationallawoffice.com/newsletters/detail.aspx?g=1f4a5c60-ed19-40aa-a60e-cbfc7c2c7e3d

[118] Principle of Insurance: Module-2 (2016), "Essentials of Insurance Contract", Diploma In Insurance Service; available at: www.nios.ac.in>media>VoclnsServices

year 1694 by Hugh the elder Chamberlen from Peter Chamberlen family.[119] In insurance, health insurance is a most complicated business segment, due to its selective modes and option for moral hazard, data unavailability and problems in information gap. Changing disease pattern, institutional buildup, growing technologies and political affairs play major role in formulating, assessing and implementing health sectors policy formation.[120]

Health insurance classification scheme under the General Agreement on Trade in Services (GATS) of the World Trade Organisation (WTO) makes health insurance fall under financial services sector. Financial services are divided into two sectors. They are: i) insurance and ii) banking and other financial services.[121] Despite, health insurance falling under the first category, many countries commitments are arranged through the second category that falls for banking and other financial services for health insurance i.e non-life insurance. The Indian scenario is a part of such model. However, life insurance companies are allowed to sell health insurance products. In India insurance is a federal subject and is governed by the Insurance Act 1938 and the Insurance Regulatory and Development Authority Act, 1999. In India the Insurance business is divided into four classes:

> "a) Life insurance; b) Fire insurance; c) Marine insurance; and d) Miscellaneous insurance. Life insurers transact life insurance business and general insurance transact the rest. Health insurance falls under the miscellaneous insurance business but there is no clear demarcation as the same is also offered by the life insurance companies".[122]

The historical background of insurance has come from the financial contracts made through cargo ships during the industrial revolution. This wage based economy throughout the industrialized nations started to provide sum of money from factory owners or donations collected by workers[123] for ill or injured workers as required,

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[119] Anitha, J. (2010), "Emerging Health Insurance in India-An Overview", Health, Long Term Care, Mortality & Morbidity, *10th Global Conference of Actuaries*, Institute of Actuaries of India, p.81; available at: www.actuariesindia.org/downloads/gcadata/10thGCA/Emerging%20Health%20Insurance%20in%20India-An%20overview_J%20Anitha.pdf

[120] Ibid.

[121] Kumar, R. (2013), "Trends in Indian Health Insurance Industry", Chapter 4, *Shodhganga*, p.89; available at: www.shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/9222/13/13_chapter%204.pdf ; also see, the Insurance Act 1938 and the Insurance Regulatory and Development Authority Act, 1999.

[122] Ibid.

[123] In later phase more systematic arrangements were made among some industries, like in the mining. Where, sickness funds were created by the owners or collected donations from the workers. Moreover,

whether for medical services, disability support or funeral expenses and care for the worker's widow and orphans. In most of the European countries the government started instituting national health plans throughout late 1800s and 1900s. That ensured access to medical services for workers and their families. On the other hand, in the US, the government[124] played a small role in financing and insuring health care in comparison to other industrialised nations. The popularity of health insurance began during the Great Depression during 1930s.[125] One of the early plans was the nonprofit enterprise Blue Cross. This nonprofit enterprise provided health insurance for hospitalisation[126] that covered populations instead of individuals along with new technologies attracting desirable physicians and establishing an environment of treatment and cure. Later on, Blue Shield health insurance plan brought physicians[127] care coverage, this new insurance plan of full fee for service (FFS) reimbursement i.e. paying all the allowable costs meeting accepted standards of care enhanced both the political as well as financial status of physicians compared to other health care professionals in US.

The World War II brought exemptions from federal wage and price control regulation that stimulated the widespread of health insurance plans in US as the federal government enacted wage and price controls in the interest of national security and exempted health insurance premiums from tax for both employees and employers. According to records in 2000, employers' insurance plans accounted for about $443.9 billion or 34.2% of health care expenditures. Main force for FFS reimbursement health insurance coverage came in 1960s through the initiatives of President Lyndon B. Johnson's War on Poverty. Programs at federal level provided coverage for elderly and poor Americans and their family through The Social Security Acts of 1965.

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some factories stated hiring of company doctors for sick and injured workers as well as for their families.

[124] The word government in here indicates to the Federal, State and local levels.

[125] The 1930s brought the beginning of many technologies such as improved sanitation, surgical techniques and diagnostic equipment. For further reference, see, Student Resources in Context, (2003), "Medicines and health in the 1930s: Overview", DISCovering U.S History; available at: www.ic.galegroup.com>ReferenceDetailsPage

[126] Hospitalisation benefits were considered to be benefiting from risk pooling i.e spreading the risk of health care costs across the entire population of predominantly healthy consumers paying the plan's premiums. Due to which hospitals' began to benefit from hospitalisation insurance plans such as Blue Cross, because rather than their historical reliance on charity supplied by religious groups and donors, hospital managers could now be reasonably sure that their charges would be paid in full.

[127] Physicians' have historically been charging for their services. So, to appreciate their working and reward them without failure this insurance plan came up as a boon in medical industry.

Medicare and Medicaid expenditures totaled $427.1 billion or 32.9% i.e. nearly a third of national health expenditures in 2000.[128] So far, for the national health insurance struggle in the US, with universal, publicly provided health care services generally encourages the RTH. But, the realisation of this right has repeatedly thwarted by corporate interests, without doubt led by self-interested insurance sector. Furthermore, RTH as opposed to the right to healthcare is still far from achieved if a national health service is implemented in US.[129]

Health insurance is advancing more towards health security. On the opposite side the conflicting supply of insurance frauds too lies within such security. The case of *M.P. Means, et al. v. Independent Life and Accident Insurance CO, et al.* (1997),[130] has been evident in explaining when insured person has been paying regular premiums for hospitalisation policy for more than forty years and as insurer tried to use the policy was told that his insurance had been terminated at the age of seventy and they were not liable to pay for the insurance. So far, the need of health insurance for paying medical needs as user fee has not just produced concern for poor or marginalised families like BPL etc. But is also considered as requirement for burdening countries where still no private insurance schemes have come to existence properly like in parts of Africa.[131] Because it has been observed that through charging fees for services primarily benefit the user, such benefits can be seen throughout tertiary-level curative care, governments can free up and reallocate tax-financed

[128] Penner, Susan J., (2004), "*Introduction to health Care Economics & Financial Management: Fundamental Concepts with Practical Applications*", Lippincott Williams & Wilkins, A Wolters Kluwer Company. United States of America, p.32.

[129] Birn. Anne-Emanuelle., (2008), "Introduction: Special Section: Health and human Rights: Historical Perspective and Political Challenges", *Journal of Public Health Policy*, 29 (1), p.37.

[130] In this case the Plaintiffs i.e M.P Means, et al., alleges that they had purchased two hospitalization insurance policies from the Defendants i.e the Independent Life and Accident Insurance Company in 1954. Under the terms of the purchased policies and insurance benefits, the benefits were to be reduced in by 50% when the insured were reaching age 65 and the same got terminated when the insured reached the age of 70. But, besides the entire cutback in benefits of the insurance, still the Plaintiffs purchased another hospitalization policy from the Defendants in 1971, which had too got terminated the day before the insurers became eligible for Medicare. However, in the present condition the Plaintiffs, were still continually paying their insurance premiums, which was neither refunded nor were they told about the expiry of their policies, or that these benefits in the policies were covered under Medicare and Medicaid. Further according to this case how fraudulently an insurance company can make you pay is discussed in this case. For details, see, *M.P. Means, et al. v. Independent Life and Accident Insurance. CO*, et al. 963 F. Supp. 1131 (M.D. Alabama 1997); available at: www.law.justia.com/cases/federal/district-courts/FSupp/963/1131/1645373/

[131] Mwabu, Germano., "Health Development in Africa", *Economic Research Papers No.38*, African Development Bank; available at: www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/00157610-EN-ERP-38.PDF , p.12.

health expenditures to activities that yield benefits that extend beyond the individual. These include public health services directed to community health, immunisations, and communicable diseases. Likewise, Sub Saharan experience with user fees has proved that in order to survive for the simple reason private-for-profit and private voluntary clinics, including church missions, must recover costs through user fee.[132]

Depiction of Human Rights in Right to Health

The conceptualisation of social justice based on human rights, raises concern for violation and structural issues of health care system and health rights arrangements. It requires codification of the health right with a right based approach (RBA). In order to codify human rights to health, these three documents are: i) the UDHR; ii) the ICESCR; and iii) ICCPR. Besides, WHO also has recognised promotion of health and respect, protection and fulfillment of human rights are inextricably linked. RTH can be established through legal enforcement when domestic constitution implements human rights treaties. Many a times social justice movements, willing judiciaries and political parties representatives work in the interest of majority and not just elites, to help in cry of effective legal framework for RTH.[133]

A RBA formed by human rights principle need countries to abide by their international human rights obligations for providing policies and programs by national health plans with sub-national responsibilities. Further, it has been felt that law restricting drug prescription for extremely skilled health professionals might limit drug access with few such qualified health workers, as well as criminalisation of sex between men might restrict the homosexuals to come for access to medical services due to fear of discrimination or report to authorities.[134]

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[132] Shaw, R. Paul., and Ainsworth, Martha. (1995), "*Financing Health Services through User Fees and Insurance: Case Studies from Sub-Saharan Africa*". The International Bank for Reconstruction and Development, the World Bank: USA, p.11; available at: www.elibrary.worldbank.org/doi/pdf/10.1596/0-8213-3396-8

[133] Birn. Anne-Emanuelle., (2008), "Introduction: Special Section: Health and human Rights: Historical Perspective and Political Challenges", *Journal of Public Health Policy*, 29 (1), p. 33, 35-36.

[134] Gruskin, Sofia., Bogecho, Dina., and Ferguson, Laura. (2010), "Right-Based Approaches to health policies and programs: Articulations, ambiguities, and assessment", *Journal of Public Health Policy*, Macmillan Publications Ltd. 31 (2), p. 130-131 and 134.

Individuals Vulnerable to Ill-health

It seems issues of discrimination, stigmatisation and humiliation have raised socio, economic and political aspects in the debate on health rights.[135] Moreover, health being fundamental right should be provided "every human being without distinction of race, religion, political belief, economic or social condition".[136] Among all women; children; elderly person; migrants; refugee; differently-abled; mentally unfit; sex workers; drug abused; and homosexuals are considered as one of the most vulnerable people, whose health rights need to be sfeguarded. A need to know the root cause of suffering becomes important. Genetics or biotechnological updation in medical upgradation may help in their vulnerability. Since shame and secrecy that stigma[137] brings can deny them access to resources publically, they need to know about informed decision about their sexuality and sexual health, genetic suffering, etc. This realisation of discrimination in RTH has also been visible in the commitment No. 13 of the Declaration of Commitment on HIV/AIDS 2001 that states:

> "Noting further that stigma, silence, discrimination and denial, as well as a lack of confidentiality, undermine prevention, care and treatment efforts and increase the impact of the epidemic on individuals, families, communities and nations and must also be addressed".[138]

The above commitment shows that health condition of an individual can create discrimination, denial and stigmatization and publicising his/her vulnerability to shame and helplessness. However, medical information of a patient may make his/her condition more vulnerable when disclosure of confidential disease or suffering is made to third person. Discrimination, stigmatisation, denial and humiliation from the outside world or from his/her own family/relatives and spouse may occur. The case of *Mr. X v. Hospital Z* (1998) SC 3662[139] of India, brought to lime light issue of cancellation of the appellant's marriage due to disclosure of being HIV(+). Further,

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[135] WHO, (2011), "*Constitution of the WHO"* Basic Document forty-fifth edition supplement, October 2006. Fifty first World Health Assembly; Available at: www.who.int/governance/eb/who_constitution_en.pdf

[136] Ibid; Paragraph 3 of the Preamble.

[137] Stigma lies at the root of discriminatory actions, leading people to engage in actions or omissions that harm or deny services or entitlements to others. For details, see, Kate, Wood., and Aggleton, Peter., (2002), "*Promoting Young People's Sexual and Reproductive Health: Stigma, Discrimination and Human Rights*", Thomas Coram Research Unit Institute of Education, University of London. Safe Passage to Adulthood, University of Southampton Highfield, Southhampton UK, p.1.

[138] The Commitment No.13 of the Declaration of Commitments on HIV/AIDS, (2001), Resolution adopted by the General Assembly, United Nations, A/Res/S-26/2. 26th Special Session, Agenda item 8.

[139] AIR 1999 SC 495, JT 1998 (7) SC 626, 1998 (6) SCALE 230.

this incident resulted in stigmatisating and critiquing appellant and banishing him from his own community. In this case it was found that right to privacy was culled out,[140] from the right to life and right to healthy life of the Indian Constitution. As the Supreme Court of India has observed, "two clashes of fundamental rights are there in right to privacy as part of right to life and right to lead a healthy life under Article 21 of the Indian Constitution. Right advancing public morality or public interest would only be enforced by the court". This decision upheld that sometimes right to privacy is not treated as absolute human rights.[141]

RTH is not just entirely restricted to the sphere of state actors like a country it also includes actions by individuals, society having responsibility to promote human rights and secure universal recognition and observance on health. Though it is primary duty of the Government to provide RTH to its citizens, still everyone has a role to play with realisation of human rights concerning public and private actors. In this process corporations have responsibility to support RTH.[142] The International Guidelines on HIV/AIDS and Human Rights (with Revised Guildelines 6) (1998, 2002), in Guideline No. 5, states that:

> "States should enact or strengthen anti-discrimination and other protective laws that protect vulnerable groups, people living with HIV/AIDS and people with disabilities from discrimination in both public and private sectors, ensure privacy and confidentiality and ethics in research involving human subjects, emphasize education and conciliation, and provide for speedy and effective administrative and civil remedies".[143]

Currently, elderly people are the new individual that has appears as burden for the families and communities who try to limit their care and services to minimum. The Medical Association Declaration on the Abuse of Elderly (1990) points out that elderly patient requires assistance for their daily activities they usually suffer from "pathological troubles such as motor disturbances and psychic and orientation

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[140] The culled out means the selection made on the desirable (worthy) basis. The case highlights on the Article 21 of the Indian constitution read with Directive Principles of State Policy. Ibid.

[141] Ibid.

[142] DeRoo, Pier. United Nations Global Compact, "Note from the Co- Chairs of the Human Rights Working Group: Human Rights, Access to Medicines and the Pharmaceutical Industry",:1-13; available at: www.unglobalcompact.org/docs/issues_doc/human_rights/Human_Rights_Working_Group/Pharma_Access_to_Medicine_GPN.pdf , p. 1-2.

[143] Guideline No. 5 of the International Guidelines on HIV/AIDS and Human Rights (with Revised Guildelines 6) (1998, 2002) Issued by the Office of the High Commissioner for Human Rights and Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1998, updated in 2002,

disorders".[144] However in reality families and communities try to limit their care and services to minimum and consider them as burden. Elderly abuse and their care need physical as well as mental support so that they can die in peace and with dignity. Besides, the General Comment No. 6 of the ESCR of Old Persons (1995) under its Article 12 (paragraph 34 and 35) states that:

> "(R)ight of elderly persons should enable them to enjoy decent standards of physical and mental health, ranging from preventive, curative and rehabilitative health treatment of chronic and degenerative diseases and protection from high hospitalisation costs. In this regard, measures should include regular check-ups for both the sexes; physical as well as psychological rehabilitative measures for maintaining functional capacities of elderly persons; adoption of healthy lifestyles from beginning (food, exercise, elimination of tobacco and alcohol, etc.) and sparing them avoidable pain and enabling them to die with dignity.[145]

In regard to the vulnerable condition of women and female sex workers the Convention on Elimination of all forms of Discrimination against Women 1979 (Article 6) states that "all member states should take appropriate measures, including legislation, for suppressing every forms of traffic in women and exploitation of prostitution of women"[146] But this type of ongoing discrimination and stigma encountered by sex workers clearly highlights their plight and exploitation due to their involvement in prostitution.[147] The Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others, approved by General Assembly resolution 317 (IV) of 2 December 1949, mentions Article 16 that:

> "(A)ll the State parties to the present Convention shall take or encourage, through their public and private educational, health, social, economic and other related services, measures for the prevention of prostitution and for the rehabilitation and social adjustment of the victims of prostitution and of the offenses referred to in the present Convention".[148]

In spite of this, move for rigorous anti prostitution laws and policies around globe has led to imposition of harsh and repressive measures against sex workers. Discrimination and stigmatisation is making it difficult for them to safeguard their own health and lives. It also becomes hard for them to ask their clients health prior

[144] The World Medical Association Declaration on the Abuse of the Elderly (1989, 1990) 41st World Assembly, Hong Kong, September, 1989 and editorially revised at the 126th Council Session, Jerusalem, Israel, May 1990.
[145] General Comment No.14 (2000) on the right to highest attainable of health paragraph 25.
[146] Article 6 of the Convention on Elimination of all forms of Discrimination against Women 1979.
[147] Offering sexual intercourse for pay; Ibid.
[148] Article 16 of the Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others, approved by General Assembly resolution 317 (IV) of 2 December 1949.

involving in any physical activity. Thus, the International Convention on Economic, Social and Cultural Rights and the Convention on the Elimination of All forms of Discrimination try to exclude discrimination practices against women in the health care system and assures them equal access, as men, to health-care services. The Committee on the Elimination of Discrimination against Women further in the General Comment No. 15 at the Ninth Session (1990) urged nations to:

> "(F)ollow preventive and control strategies to mitigate Acquired Immunodeficiency Syndrome (AIDS) and recommend the nations to provide public awareness on the risks of HIV/AIDS especially, and focus on the vulnerable position of pregnant women and children". [149]

Apart from this, prisoners in prison are also one of the vulnerable who are stigmatised and discriminated not just in society as well as in prisons, as one knows that many of the prisoners get punished as well as humiliated in prison.[150] Many of the incidences speak on prisoner's vulnerability but all are silent and only on records.[151] So, to understand their vulnerability in accessing medical care it is important to understand that prisoners have right to medical examination on arrest or beaten abuse or torture made by police. However, stigma, discrimination and violation of human right that is inter-connected may vary. Like the case of *Victor Rosario Congo v. Ecuador*, Case 11.427 (1997)[152] whose complaint was made on date 14th September 1990 on behalf of a mentally ill prisoner. Mr. Victor Rosario Congo was assaulted with a garrote by the guard named Osorio causing severe injuries, he was stripped naked in the prison by other prisoners and also denied medical care as well as he was kept unclothed in the cell for three months. The medical examiners from the office of the District Attorney confirmed that the prisoner had marks caused by beatings and dirty bruises all covered with mud on his body. On 18th October 1990 the prisoner Congo was requested to be moved immediately to a hospital by the third transfer Agent in El Oro but his late transfer to the Men's Social Rehabilitation Centre in

[149] Paragraph 1 and Recommendation a) and c) of the Committee on the Elimination of Discrimination against Women further in the General Comment No. 15 of ninth session (1990) A/45/38.
[150] ICRC, International Committee of the Red Cross: Health and Human Rights in Prisons, "Extract from HIV in Prison: A Reader with particular relevance to the newly independent states, chapter 2 p.9-18, World Health Organisation-Europe HIPP (Health in Prisons Project) 2001", p.1-10; available at: www.icrc.org/eng/resources/documents/misc/59n8yx.html
[151] The Centre for Prisoner health and Human Rights, "Resource for Prisoners, Families, Advocates: Getting Needed Medical Care for Prisoner," Prisioners Legal Servise Organisation, p.1-5; available at: www.brown.edu/Research/Prisonerhealth/resources.html
[152] Report No. 12/97, InterAm.C.H.R., OEA/Ser.L/V/II.95 Doc. 7 rev. at 257 (1997).

Guayaquil on 24th October 1990, and again to Luis Vernaza Hospital on 25th October 1990 resulted in his death without being subjected to proper heath care. So in compliance with the report 29/99 on 13th April 1999 the Inter-American Commission on Human Rights (IACHR) in the city of Washington approved the agreement.[153]

The United Nations (1990) Basic Principles for the Treatment of Prisoners states that:

> "(A)ll prisoners have access to the health services available in the country without discrimination on the grounds of their legal situation".[154]

The prisoners also have the "right to enjoy highest attainable standard of physical and mental health".[155] Moreover, when refugees and their health condition are examined an understanding comes that one needs to come across the death toll. Likewise the Angolan refugees in Zambia who died due to lack of access to clean water triple their death rates. Iraqi refugees in turkey were forced to drink polluted streams water causing them cholera and typhoid. Moreover, in one event where UNHCR's medical coordinator observed that children under 5 years of age die in Tanzania's Lukhole refugee camp due to acute respiratory tract infection, that occurs from cold since mother's had to take their children early morning along with them while going for work in farms.[156] Lastly, access to information, privacy, education, participation and reduction in health and health care barriers along with equality are some of the crucial issues surrounding health rights. Due to these barriers, health has always been looked through equity point of view and not equality. Health discrimination, stigmatisation, social exclusion and humiliation have been responsible

[153]The State of Ecuador had to acknowledge its international accountability by American Convention for the violation of the Article. 4 dealing with the right to life as stated under Article. 4(1), 4(2), 4(3), 4(4), 4(5) and 4(6) of American Convention; Article. 5(1) that deals with every person through American Convention has the right to have his physical, mental and moral integrity respected; Article. 5(2) stating no one shall be subjected to torture or to cruel, inhumane, or degrading punishment or treatment. All persons deprived of their liberty shall be treated with respect for the inherent dignity of the human person as said in the American Convention; Article. 25 dealing with the right to judicial protection through 25(1), 25(2)(a), 25(2)(b) and 25(2)(c) of American Convention; and Article. 1(1) which says that the State Parties to the American Convention have undertaken to respect the rights and freedoms recognised and insured to all persons subject to their jurisdiction the free and full exercise of those rights and freedoms, without any discrimination on reasons of race, colour, sex, language, religion, political or other opinion, national or social origin, economic status, birth, or any other social condition. And by paying compensation of US $ 30,000 (thirty thousand US dollars); see, ibid.

[154] The United Nations (1990) Basic Principles for the Treatment of Prisoners.

[155] Lars Moller, et. al (2007) "Health in Prison", *A WHO Guide to the Essentials in Prison Health* WHO (Europe). Stover, Heino., Jurgens, Ralf., Gatherer, Alex., and Nikogosian, Haik, p.3.

[156] Hathaway, James C., (2005), "*The Right of Refugees under International law*", Cambridge University Press, New York, p.507-508.

for this situation. Article 7 of UDHR 1948 states that: "All are equal before law and entitled to equal protection of the law, against any discrimination and incitement to such discrimination".[157] Still the health facilities are obtained by privileges of richer and elite section of the world and those who cannot afford and avail these health facilities have to wait till these health services become rights and accessible. In view of access to essential medicines by poor individuals, there appear three components of their vulnerability:

> "i) pharmaceutical research neglects diseases concentrated among the poor. This fact of drug research as negligence towards poor is known as the 10/90 gap. The raising reality towards global health research made for accounts only 10 percent for 90 percent of global disease burden;[158] ii) the poor face high priced medicine during the launch of medicines in the initial years. The cost of medicine is more than cost of production, this difference exists from patent as a grant of exclusive right to produce and distribute medicine; and iii) lack of access to essential medicine by poor individuals is lack of sufficient local health infrastructure. Due to scarcity of clinics, doctors, hospitals, nurses and diagnostic equipments may lead the affluent individual victim of circumstances".[159]

The new form of discrimination that is likely to evolve in the coming days is through genetics.[160]

Legal and Ethical Issues

The growing scientific and modern technology has led to the discrimination relating to right to privacy[161] from the data's and information collected with the help of closed-circuit surveillance cameras, DNA of individual/group as well as other

[157] Article 7 of the UDHR 1948.

[158] Global burden diseases like diarrhea, tuberculosis and malaria that account over 20 per cent in world, receives less than 1 per cent of all public and private funds that is meant for health research. Diseases that are confined to the tropics tend are the one most neglected. Since 1975-2004 out of 1556 new drugs approved only 18 were for tropical diseases and 3 for tuberculosis. There is a need to look into the requirements of poor diseases like diarrhea, dengue, etc. But still limited facilities are provided for these diseases due to limitation of financing or funding.

[159] Pogge, Thomas., Rimmer, Matthew., and Rubenstein, Kim., (2015), "Introduction: Access to essential medicines: public health and international law", in Thomas, Pogge. Matthew, Rimmer. and Kim, Rubenstein. (eds) "*Incentives for Global Public Health Patent Law and Access to Essential Medicines*": 1-32. Cambridge University Press. p.4-6.

[160] For instance See, Genome FAQs Files, (2011), Human Genome Project Information, Frequently Asked Questions, U.S Department of Energy-Office of Science, pp.1-3,6 and 8; available at: www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml

[161] Article 19 of ICCPR (International Covenant on Civil and Political Rights) and Article

genetic information or providing insurance company with personal details.[162] The world has witnessed exploitation of economically, physically and socially weak and illiterate individuals in the health industry. In fact paragraph 3 of the General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR (2000), states that:

> "The RTH is closely related to and depends upon the realisation of other human rights, as contained in the International Bills of Rights, including the right to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the RTH".[163]

Still the reality of health as a right in business[164] and commercial world has no meaning. For instance, in organ surgeries, the supply of organ transplantation will not stop till the demand exists for damaged and non-functioning organ. This requirement is many a time looked through need of elite and rich peoples. Since poor cannot even think of changing or getting surgery without any insurance policy or financial support. Further, the famous dictum states the value of financial side "when you can buy one, why donate?" This proverb exposes the reason for increasing illegal racketing in organ transplantation. Supplementary, when illegal racket activities in organ donation and transplantation raised in India. In 1994 the legislation of Transplantation of Human Organ (THO) Act came in practice. This act of THO accepted "brain death" as a form of death and made the sale of organ a punishable offence.[165]

However, it appears that the choice to donate is an ethical or moral decision of the donor. This involves two different perspective based on ethical issues they are: i) whether or not to donate one's own organs and/or tissues after death; and ii) whether or not to donate the organs and/or tissues of a relative who has just died. This decision

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[162] Clapham, Andrew., (2007), "*Human Right: A Very Short Introduction*", Oxford University Press: New York, p. 116.

[163] Paragraph 3 of the General Comment no. 14: the Right to the Highest Attainable Standard of Health through Article 12 of ICESCR 2000.

[164] For instance, see, Nadir, Nupur. (2008), "Law and Medicine: An Analysis of the Organ Transplantation Law in India", *Legal Service India.com.*:1-10; available at: www.legalserviceindia.com/article/1224-Organ-Transplantation-Law-in-India.html ; p.6-8; and see, Thakur, Bhartesh Singh. (2013), "Kidney Racket: Mastermind Doctors Get 7-yrs Jail", (1-3). *The Hindustan Times*, Panchkula, p.1-3; available at: www.hindustantimes.com/punjabkidney-racket-mastermind-doctors-get-7yr-jail/article1-1030675

[165] Shroff, Sunil. (2009), "Legal and Ethical aspects of Organ Donation and Transplantation", *Indian Journal of Urology*, 25 (3), p.348-349.

involves informed choice i.e. a freely chosen thinking by oneself without any influence of others and which is compatible with ethical beliefs of individual concerned.

In general, when one makes donation the idea is that the dead body should be treated with respect. This feeling includes benefiting others through transplantation in order to be remembered after life in death.[166] Living organ donation by an individual can be made in two ways: i) donation through one-half of a paired organ set like kidney; and ii) donation of organ through a portion that can still be able to function without that part, like liver, a lobe of lung i.e called as splitting organ into pieces. Donation of an organ is not necessarily made to a relative or known person this kind of donation can be made to a stranger by the donor that can be initiate as a non-directed donation (NDD). Non-directed donors make their organ donation to transplant centre or either nationally sponsored organ procurement organisation and offer one of their organ for transplantation to anyone who needs it.[167]

Worldwide, the transplantation of organ first time became possible through live donation of a single kidney in 1954, along with other organ parts during 1990s. Legally the organ donation can be taken from living, genetically related individuals. From living, unrelated individuals organ donation takes place in special circumstances when no unauthorised payment is made to the donor; or from cadavers. Besides, enormously the need of organ and tissue transplantation requirement is growing demand worldwide. It has been revealed that in UK approximately 900 individuals every year become organ donors while over 6000 people wait for organs. In US 70,000 individuals are waiting for transplantation and have merely 5,500 individuals as cadaveric donors every year. In India 4,000 people donates kidney, whereas 2,00,000 individuals need kidney transplant every year. Further, to promote organ donation in India, the Government has planned to provide lifelong free medical check-up and care for the family in the hospital where the organ donation is made. The cost seems to be Rs. 2 lakh for three years as a customised life insurance policy

[166] NHMRC (1997), "Donating Organs after Death: Ethical Issues", Ethical Issues, Discussion paper No.1, National Health and Medical Research Council (NHMRC), Commonwealth Department of Health and Family Services, Australia; available at:www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e29.pdf , p.1 and 3.

[167] CBE, (2004), "Ethics of Organ Transplantation", Centre for Bio Ethics (CBE), University of Minnesota, p.7; available at: www.ahc.umn.edu/img/assets/26104/Organ_Transplantation.pdf

with one time premium to be paid by the recipient in case of death and for close ones of the organ donor preferred status in the waiting list of organ transplantation will be provided if required in future.[168]

Presently, some of the organ and tissues that are being successfully transplanted in human bodies include artery, bone, cartilage, eye, heart valve, liver, lung, nerve, pancreas, tendon, and thymus. In fact now banks have been established for artery, blood, bone, eye, pituitary etc. Further, transplantation of tissues and organs involves concern of family members along with the patient and doctors. For making the donation active by them it incorporates these features: a) donation by a person to be effective during his lifetime; b) donation by a person to be effective at his death; c) donation by next-of-kin of a cadaver; and d) use by medical examiners, doctors and others of cadaver tissue and organs. In case if a minor donates his/her tissues or organ consent of his/her parents or guardian is necessary. This clause came in practice through the incident of *Bonner v. Moran* (1941) where skin transplantation took place from a 15 year old minor to his cousin without either parents' knowledge or consent.[169] In the case *Sirianni v. Anna* (1967) it was held that in a rescue doctrine the donor cannot claim tortfeasor of the donee.[170] Moreover, in 1963 a trial took place on elderly person in order to experiment whether a weak, ill patients having disease other than cancer would reject foreign cancer cells or not and the U.S. Public Health Services and the American Cancer Society financed this experiment for solution under two doctors[171] from Sloan Kettering Institute which was un ethical

[168] Nadir, Nupur. (2008), "Law and Medicine: An Analysis of the Organ Transplantation Law in India", *Legal Service India.com,* p.2,3,6 and 8; available at: www.legalserviceindia.com/article/1224-Organ-Transplantation-Law-in-India.html

[169] Bonner v. Moran (1941), 126 F.2d 121(D.C. Cir. 1941); available at: www.cirp.org/library/legal/lebit/3.html

[170] In this case a mother donated her kidney to her son. When, her son recovered damages through cause of action by his physician for the loss of his kidney. The mother sued the physician for negligence in the treatment of her son. But this case rejected the plea due to the rescue doctrine. For details, see, Sirianni v. Anna (1967), 55 Misc. 2d 553 Sup. Ct. Erie County 1967; available at: www.law.utexas.edu/transnational/foreign-law-translations/german/case.php?id... ; www.leagle.com/decision/196760855Misc2d553_1449/SIRIANNI%20v.%20ANNA

[171] These two doctors injected ill and weak elderly patients with cancer cells without any written consent, nor information about the cancer cell being inoculated to them. After observing those patients for several weeks it concluded that weak elderly patient had same capacity of rejecting foreign cancer cell as well patients did (Hyman v. Jewish Chronic Disease Hosp., 15 N.Y. 2d 317, 206 N.E.2d 338,258, N.Y.S.2d 397 (1965)).

experiment violating human rights[172] and claiming right to property as for the guardians or family members by their consent came up as new directive. Through this incident it was exposed that the entire elderly patient who were being experimented where not informed about getting inoculated with foreign cancer cell in their weak body. Moreover, in 2010 The Swiss pharmaceutical giant Roche received the Public Eye Award,[173] from Swiss non-governmental organisation, Berne Declaration and Green Peace for conducting clinical trials with organs taken from executed prisoners of China on moral grounds at the same time Roche claimed that conduct of clinical trials made in China were in accordance to the local regulations and industry ethical standards. But this incident of human organs experiment of executed prisoners raises the issue of conflicts between profit and ethical consideration, along with human rights violation as mentioned in the CellCept drug.[174] In order to provide organ transplantation in human body distributive justice[175] is required. This concept of distributive justice came from the University Of Washington School Of Medicine. The United Network for Organ Sharing[176] (UNOS) encourages all the transplant centre's to consider distributing organs through: i) medical need; ii) probability of success; and iii) time on waiting list.[177] Moreover, the Article 21 of the Universal Declaration on Bioethics and Human Rights 2005 states that:

> "(D)uring transnational practice States both at national and international levels should take appropriate measures in combating bioterrorism and illicit traffic during organ, genetic resources and genetic related materials, samples and tissues".[178]

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[172] Ford. Thomas J, (1969) "Human Organ Transplantation: Legal Aspects", *Catholic Lawyer*, 15, p.136-138, 142

[173] Public Eye Awards, (2016), "The Final Public Eye Awards 2015", Berene Declaration; available at: www.bernedeclaration.ch/campaigns/public-eye-awards/ ; also see, www.swissinfo.ch/eng/roche-velified-in-davos-for-transplant-drug/8185350 publiceye.ch praquat in India

[174] Stirling, Judith Schrempf. (2013) "Roche's Clinical Trials with Organs from Prisoners: Does Profit Trump Morals?", *Management Faculty Publications. Paper 37*: 1-40. Robin School of Business, University of Richmond, UR Scholarship Repository, p. 3-5.

[175] Distributive justice means: i) to each person an equal share; ii) to each person according to need; iii) to each person according to effort; iv) to each person according to contribution; iv) to each person according to contribution; v) to each person according to merit; and vi) to each person according to free-market exchanges CBE, (2004), "Ethics of Organ Transplantation", Centre for Bio Ethics (CBE), University of Minnesota, p.15; available at:www.ahc.umn.edu/img/assets/26104/Organ_Transplantation.pdf

[176] UNOS was established by United States Congress to maintain nationwide all computer registry of patients who require organs, through the National Organ Transplant Act (NOTA) 1984; Ibid. p.17 and 18.

[177] Ibid.

[178] It has been perceived that this declaration does not provide necessary group of stakeholders, guidance for applying during different stages of application. Yim, Seon-Hee,. Chung. Yeun-Jun,. (2013), "Introduction to International Ethical Standards Related to Genetics and Genomics", *Genetics*

The Human Genome Initiative came with an aim to produce a complete map of the DNA structure of all human genes early in the 21st century. DNA determines the essence of personal identity raising legal issue on protection of personal identity as right to privacy. In privacy terms genetic information carries individuals' encoded information relating to DNA molecule, which is just like any other medical information for prevention and treatment of diseases. But, this information is very sensitive than ordinary medical information. This can lead to social stigma on individuals who have or are perceived to have certain defects or deficiencies in their genetic makeup.

The Universal Declaration on the Human Genome and Human Rights (1997) states that:

> "No one shall subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity; … Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in conditions set by law".[179]

The genetic blueprint can be used to discriminate an individual against his/her employment or insurance contexts. Insurance companies might unfairly initiate premiums or limit coverage offers for having genetic predisposition towards Huntington's Disease or increased susceptibility to cancer. An employer may refuse to hire or fire an individual on the basis of his/her genetic information relating disabilities or low productivity in job. There are four traditional strands to an individual's right to privacy. These concern (i) intrusion upon the plaintiff's seclusion or solitude, (ii) public disclosure of embarrassing private facts about the plaintiff, (iii) publicity that places the plaintiff in a false light in the public eye, and (iv) appropriation, for defendant's advantage, of plaintiff's name or likeness. The right to genetic privacy[180] will provide an extent in determining an individual how to prevent

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& Informatics, The Korea Genome Organisation, 11 (4), p.218-223. available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3897849/. p.221 ; and Article 21 of the Universal Declaration on Bioethics and Human Rights 2005.

[179] Article 6 and 7 of the Universal Declaration on the Human Genome and Human Rights 1997, General Conference of UNESCO, 29th Session on 11 November 1997, Records at Conference, Vol.29, p.41-46.

[180] Vogenberg, F. Randy., Barash, Carol Issacson., and Pursel, Michael., (2010), "Personalised Medicine: Ethical, Legal and Regulatory Issues" *Pharmacy and Therapeutics: A Peer-Reviewed*

others, like health care providers, employers, or law enforcement officials from acquiring their genetic information.[181] The right to genetic privacy has brought the concern for patients as well as the regulatory regulations to determine whose right becomes primary and the limits for such entitlement. Because when clinical research is made on human subjects the data security mishap arises ethically for the use of personalized medicines or any other scientific research without any prior knowledge and consent of the subject. Further this right may too provide an individual to block or limit access to his/her genetic information, once lawfully assembled, by third parties.[182]

In order to bring scope in diagnostic testing the declaration of Inuyama 1990 of the Council for International Organisation of Medical Sciences, stresses on confidentiality of the tests result. Moreover, the declaration states the requirement to obtain the needs of developing countries and their due share of the benefits that ensures Human Genome Project. The declaration acknowledges public concern about genetic knowledge so that education to public and open discussion can be made. So that while using gene therapy it is should be cautious of using germ line therapy so that the germ cells should not affect the descendants of patients. Moreover, the European framework serves as a model in regard to application of biologic and medicine with the help of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997. Moreover, the aim of the Council of Europe Convention is to protect the identity and dignity of all human beings and that guarantees each individuals without discrimination respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Further, the Convention for the Protection of Human Rights and Fundamental Freedoms 1950 states that "genetic testing with prediction can only be performed when such tests is made for health purposes or for health purposes that link with scientific research and are subject to appropriate genetic. The interventions on human genome can only take place during

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Journal for Management Care and Hospital Formulary Management, 35 (11), p.624-626, 628-631, 642. available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC2993070/

[181] Ibid. p.626.

[182] Miller III, Hugh. (1998), "DNA Blueprints, Personhood, and Genetic Privacy" *Health Matrix*, 8, p. 180-185.

preventive, therapeutic or diagnostic reason. As well as when there is no modification made from the descendant genome".[183]

Legal Implementation of Right to Health

The rights based approach[184] (RBA) for health uses International Human Rights treaties and norms to make the government responsible by the obligations they have to follow through the treaties they have signed, ratified and implemented at state/country level. The 1993 Vienna World Conference on Human Rights affirms that :

> "(I)t is the duty of States to promote and protect all human rights[185] and fundamental[186] freedoms, regardless of their political, economic and cultural systems".[187]

In order to avail, afford and access health care provision along with social measure and its services, treaties, multilateral treaties and regional instruments have established health as one of the fundamental right of every human being[188] It implies that every member state has to provide enjoyment of the highest attainable standard of health. Further, depending on the growing unregulated private sector and deteriorating public health system is creating challenge in utilising such rights in different states and countries. Moreover, at present health care system is getting more integrated into

[183] Yim, Seon-Hee,. Chung. Yeun-Jun,. (2013), "Introduction to International Ethical Standards Related to Genetics and Genomics", *Genetics & Informatics*, The Korea Genome Organisation, 11 (4): 219-220; also see, the Convention for the Protection of Human Rights and Fundamental Freedoms 1950; available at: www.webcache.googleusercontent.com/search?q=cache:wBAi62bpMUkJ:www.mhcirl.ie/documents/information/European%2520Convention%2520of%2520Human%2520Rights%2520and%2520Fundamental%2520Freedoms.pdf+&cd=5&hl=en&ct=clnk&gl=in

[184] The Right Based Approach (RBA) came in 1997. Kofi Annan, then UN Secretary General, called for integration of human rights into all of its work. Also see, Gruskin, Sofia., Bogecho, Dina., and Ferguson, Laura. (2010), "Right-Based Approaches to health policies and programs: Articulations, ambiguities, and assessment", *Journal of Public Health Policy*, Macmillan Publications Ltd. 31 (2): p.134-135.

[185] Human rights are "those minimum rights which every individual must have against state or other public authority by virtue of his being a member of human family, irrespective of any other consideration". For details, see, Basu, Durga Das, (1994) "*Human Rights in Constitutional Law*", New Delhi: India.

[186] Fundamental human rights norms enjoy universal protection by customary international law; Ibid.

[187] Vienna Declaration and Programme of Action, adopted by the World Conference on Human Rights in Vienna on 25 June 1993; available at: www2.ohchr.org/english/law/pdf/vienna.pdf

[188] All human rights are indivisible, whether they are civil and political rights, such as the right to life, equality before the law and freedom of expression; or economic, social and cultural rights, such as the rights to work, social security and education, or else collective rights, such as the rights to development and self-determination, are inseparable, interrelated and interdependent.

research, advocacy strategies and tools, including monitoring; community education and mobilisation; litigation and policy formulation.[189]

The United Nations (UN) International Covenant on Economic, Social and Cultural Rights (ICESCR) in its Article 12, interpreted RTH as an inclusive right. RTH is not just limited to access to health care and medicine services but also includes the underlying determinants of health. Health determinants are much broader then it implies and it includes in itself: safe drinking water; adequate sanitation; and an adequate supply of safe and nutritious food;[190] healthy occupational and environmental conditions; and access to information, including information about sexual and reproductive health; etc.

RTH encloses freedom to non-consensual medical treatment that takes place in name of research or forced sterilisation leading to torture and other cruel inhuman or degrading treatment or punishment. RTH holds entitlements that provide equal opportunity for each individual to attain highest health level so that right to prevention, treatment and control of disease along with essential medicines. These entitlements also include facilities like equal and timely access to basic health services, provisions for health related education provided at national and community levels etc. Such entitlement becomes more meaningful when it provides maternal, child and reproductive health facilities as these are the most vulnerable at present[191] along with healthcare for the elderly people.

In order to further understanding of RTH, the United Nations Committee on Economic, Social and Cultural Rights (CESCR)[192] set out the key elements for health

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[189] Rajan. S. Irudaya. (2006), Population Ageing and Health in India, Centre for Enquiry into Health and Allied Themes (CEHAT), Mumbai; p.iii.

[190] According to the book "Dead Doctors Don't", Dr. Joel D. Wallach revealed that if a human wants to live more than hundred years of age then s/he should take all essential nutrients to live more than hundred years and they are: 60 minerals, 16 vitamins, 12 essential amino acids, and 3 essential fatty acids as daily supplements. If there is depleted of minerals in soil, due to pesticides ridden soil then then vegetables also do not contains it. As well as, human body cannot produce essential nutrients by themselves. Moreover, if we miss essential nutrients for several months, then development of deficiency disease occurs and due to which natural cause of death comes. This information was revealed through the study of 500 species and after comparing them on 3,000 humans; Wells, S.D. (2012), "*25 Amazing (and Disturbing) Facts about the Hidden History of Medicine* ", Truth Publishing, Inc. p.34-35.

[191] Fact sheet No. 31, WHO and Office of the United Nations High Commissioner for Human Rights *"The Right to Health"* WHO Switzerland, p.3-4; available at: www.ohchr.org/Documents/Publications/Factsheet31.pdf

[192] CESCR is the UN human right treaty body which monitors States Parties' compliance with the International Covenant on Economic, Social and Cultural Rights (ICESCR).

rights. These elements are AAAQ that puts forward health care and underlying determinants facilities for individuals, especially paying particular attention towards vulnerable and marginalised individual/groups in society. Another important development, at the international level, was the appointment in 2002 of an independent expert by the UN Commission on Human Rights, now replaced by the UN Human Rights Council, of a UN Special Rapporteur[193] on the right to the enjoyment of the highest attainable standard of physical and mental health. That has enabled the UN to take stock by monitoring and reporting on the enjoyment of the RTH.

RTH at national level is increasingly looking forward to enshrine itself in respective Constitutions. RTH is beginning to see a significant amount of jurisprudence being generated like in the American case. President Barack Obama, during his Presidential election in 2008, stated about health as a right after experiencing his own mother's condition along with many other American individuals who become insolvent through health care expenses incurred for specialised and rare disease treatments.[194]

The UN system is now increasingly embracing a human RBA as its common and overarching framework for analysis and programming in all sectors. This shows the goal of the UN's actions is explicitly setting towards realisation of human rights. Moreover, such principles include equality and non-discrimination, the right to participation, accountability and rule of law. Equality demands that actions in health go beyond statistical averages and identify vulnerable and marginalised groups. In addition, beyond identifying the most vulnerable, these groups should be engaged as active participants and generators of change. This is not only to ensure that health policies and programmes are inclusive. It responds to one of the greatest challenges for global development particularly those living in poverty, can take more control over their lives. Finally, human rights based approach focuses on building the

[193] According to the UN Special Rapporteur the definition for Right based Health System advocates people centre approach to health care, the collection of disaggregated data, and use of human rights based indicators. See, Gruskin, Sofia., Bogecho, Dina., and Ferguson, Laura. (2010), "Right-Based Approaches to health policies and programs: Articulations, ambiguities, and assessment", *Journal of Public Health Policy*, Macmillan Publications Ltd. 31 (2), p.131.

[194] Clapham, Andrew and Robinson, Mary (eds) (2009), *Realising the Right to Health*: *Swiss Human Rights Book*, Vol. 3, Zurich: Ruffer & Rub, p.16; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html

capacity of rights holders to claim their rights and duty-bearers to meet their obligations.[195]

It has been felt that human rights perspective on health helps shape understanding about who is disadvantaged and who is not as well as who is included and who is left out. Still, academics, the United Nations (UN), government agencies, and non-governmental organisations (NGOs) are struggling with how to operationalise a rights-based approach (RBA) to health.[196]

Status of Right to Health in Contemporary International Law

The recognition of the RTH in contemporary international law comes through rights provided with the help of international and regional legal instruments. The Alma-Ata Declaration of 1978 is the first international conference on primary health care adopted in Alma-Ata, Kazakistan. This unique conference brought together all governments, health and development workers, and the world community to protect and promote health for all humankind. Moreover, for the first time a declaration was based on health and human rights. It also reflected the socio-economic condition along with socio-cultural and political characteristics of the countries in application of biomedical and health services research. Further, the declaration reaffirmed that:

> "(H)ealth which is a state of complete physical, mental and social well being, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector".[197]

Based on the principles of the a) Alma-Ata 1978; and b) WHO 1946 Constitution, WHO came with (by Resolution WHA 48.16) the "Health for all policy

[195] Nygren-Krug, Helena. (2014), "Health and Human Rights-A Historical Perspective", UN Special No. 673 Mail. May. OMS/WHO, pp.2; Available at: www.unspecial.org/UNS673/t24.html.

[196] Gruskin, Sofia., Bogecho, Dina., and Ferguson, Laura. (2010), "Right-Based Approaches to health policies and programs: Articulations, ambiguities, and assessment", *Journal of Public Health Policy*, Macmillan Publications Ltd. 31 (2), p.129.

[197] The declaration was held from 6-12 September1978. The declaration has X principles along with a preamble. The main concern of the declaration is to provide primary health all over the world and make primary health care as fundamental right. Understanding the need of New International Economic Order by looking into health through health status of the developing and developed country so that of technical cooperation can also be included in it. The declaration also urges WHO, UNICEF and other international organisation, etc to help technically and financially at national and international commitments to primary health care. Moreover, the principle of Alma-Ata is used by most of the countries for framing health policies. See, "*the Declaration of Alma-Ata International Conference on Primary Health Care"*, Alma-Ata, USSR, 6-12 September 1978; and also see, Appendix I.

for the twenty first century 1998". It reaffirmed commitments to the principles of the WHO Constitution stated:

> "(I)t is imperative to pay the greatest attention to those most in need, burdened by ill-health, receiving inadequate services for health or affected by poverty. We reaffirm our will to promote health by addressing the basic determinants and prerequisites for health. We acknowledge that changes in the world health situation require that we give effect to the "Health-for- All Policy for the twenty-first century" through relevant regional and national policies and strategies".[198]

By observing the economic, social and political barriers within health and health status, the Peoples' Charter for Health (2000) came in support of people centered health sector, so that international and national policies supporting commodity for private health care can be opposed. It called upon governments to ensure free and universal access of public health services, along with heath research and perfection in training of health personnel's, pressure government to adopt and implement health and drug policies, regulate private medical sector as well as promote support patients and consumers right. The principles of People's Charter for Health are:

> "a) (T)he attainment of the highest possible level of health and well-being is a fundamental human right, regardless of a person's colour, ethnic background, religion, gender, age, abilities, sexual orientation or class; b) the principles of universal, comprehensive Primary Health Care (PHC), envisioned in the 1978 Alma Ata Declaration, should be the basis for formulating policies related to health. Now more than ever an equitable, participatory and intersectoral approach to health and health care is needed; c) Governments have a fundamental responsibility to ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay; d) the participation of people and people's organisations is essential to the formulation, implementation and evaluation of all health and social policies and programmes; and e) health is primarily determined by the political, economic, social and physical environment and should, along with equity and sustainable development, be a top priority in local, national and international policy-making".[199]

So far when recognition of RTH in multilateral treaties is seen, basic elements are directly or indirectly derived from some of the international instruments are:

i) Universal Declaration of Human Rights (UDHR) 1948; ii) International Covenant on Civil and Political Rights (ICCPR) 1966; iii) International Covenant on Economic, Social and Cultural Right (ICESCR) 1966; iv) International Convention on

[198] Fifty-First World Health Assembly, Agenda Item 19, WHA 51.7, 16 May 1998; also see, Appendix II.

[199] A People-Centered Health Sector, The PHA, (2000), "the Peoples Charter for Health", People's Health Assembly (PHA), adopted on 8 December 2000, Savar, Bangladesh; also see, Appendix III.

the Elimination of all forms of Racial Discrimination, (ICERD) 1965; v) Convention Against Elimination of All Forms of Discrimination Against Women (CEDAW) 1979; vi) The Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT) 1984; vii) Rights of the Child (Children's Convention, or CRC) 1989; viii) The Convention on the rights of protection of the rights of Migrant Workers and Members of their families (CMW) 1990; ix) General Comment No.14. 2000; x) The Convention on the Rights of Persons with Disabilities (CRPD) 2006.

The United Nations UDHR (1948) sought to convey RTH through the standard of living and other related human rights. In its Article 25(1) and (2) the UDHR states that:

> "1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. 2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection". [200]

Moreover, the two Covenants also came to supplement the UDHR mandate. The ICCPR 1966[201] provides for health rights by defending observation in its Article 6(1) and 7:

> "**6**(1) every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life. **7)** no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation".

The definition provided in the ICESCR seems to be most comprehensive. Article 12 of the ICESCR[202] provides a definition of the RTH as:

> "1) The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the

[200] Article 25(1) and (2) of UDHR.
[201] The ICCPR came in force on March 23, 1976 by resolution 2200A (XXI). The Covenant on Civil and Political Rights was adopted by 106 to 0 votes.
[202] The Covenant came in force on January 03, 1976 in accordance with the provision of Article 27 of International covenant on Economic Social and Cultural Rights 1966. It consists of a preamble and 31 Articles which are divided in five parts. The Covenant on Economic, Social and Cultural Rights was adopted unanimously by a 105 to 00.

> reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness".

Further, pointing towards the RTH, as stated in ICESCR 1966, "the General Comment No. 14: the Right to the Highest Attainable Standard of Health (Article 12) of 2000" came to assist State's parties' to implement the Covenant. They are to follow the reporting obligation, after observing and experimenting the State parties reporting pattern since many years. The General Comment No. 14 is the normative form of the contents in Article 12. Further, the General Comment No.14 [paragraph 12(a), 12(b), 12(c), and 12(d)] states that there are four essential elements for RTH and health care system depending on the arrangements provided through the State Parties i.e AAAQ (availability, accessibility acceptability and quality). They can further be elaborated as:

> "a**)**Availability**.** Functioning public health and health care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs.[203] b) Accessibility**.** Health facilities, goods and services[204] have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions**:** Non-discrimination**:** health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalised sections of the population, in law and in fact, without discrimination on any of the prohibited grounds.[205] Physical accessibility**:** health facilities, goods and services must be within safe physical reach for all section of the population, especially vulnerable and marginalized groups, such as ethnic minorities and indigenous population, women, children, adolescents, older person, persons with disabilities and person with HIV/AIDS. Accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including rural areas. Accessibility further includes adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to building for persons with disabilities. Economic accessibility **(**affordability**):** health facilities, goods and services must be affordable for all.

[203] WHO, (1999), "WHO model List of Essential Drugs", WHO Drug Information, 13(4).

[204] Unless expressly provided otherwise, any reference in this General Comment to health facilities, good and services includes the underlying determinants of health outlined in paragraphs 11 and 12(a) of this General Comment.

[205] Paragraph 18 and 19 of this Convention that states on Non-Discrimination and Equal Treatment.

Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publically provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households. Information accessibility**:** accessibility includes the right to seek, receive and impart information and ideas[206] concerning health issues. However accessibility of information should not impair the right to have personal health data treated with confidentiality. c**)** Acceptability**:** All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned. d**)** Quality**:** As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation".[207]

Table 1: Recognition of the Right to Health in Multilateral Treaties

TREATY	ADOPTED	SIGNATORIES	STATE PARTIES	ENTRY INTO FORCE	ARTICLES
UN Charter	26 June 1945	49 (original members)	193	24-Oct-45	55, 55(a), 55(b), 55(c), 56, 57(a), 57(b), 58, 59, 63(1), 63(2)
UDHR	10 December 1948	48	-	-	3, 5, 7, 17(1), 17(2), 22, 25(1), 25(2), 27(1), 27(2)
ICCPR	16 December 1966	74	168	23-Mar-76	6(1), 7
ICESCR	16 December 1966	71	164	3-Jan-76	9, 11, 12(1), 12(2), 12(2)(a), 12(2)(b), 12(2)(c), 12(2)(d), 15(1), 15(1)(a), 15(1)(b), 15(1)c)
ICERD	21 December 1965	88	177	4-Jan-69	5(e)(iv)
CEDAW	18 December 1979	98	185	3-Sep-81	11(1)(f), 12, 14(2)(b)
CAT	10 December 1984	83	159	26-Jun-87	1,2,3,4
CRC	20 November 1989	140	193	2-Sep-90	24
CMW	18 December 1990	177	48	1-Jul-03	28, 43(e), 45(c)
CRPD	30 March 1907	160	164	3-May-08	25

[206] Article 19(2) of the ICCPR 1966. In this General Comment the issue of accessing information is related to health.
[207] Paragraph 12(a), 12(b), 12(c), and 12(d) of the General Comment No.14, 2000.

The Charter of United Nation (1945) in its Article 57 states that:

> "1) The various specialized agencies, established by intergovernmental agreement and having wide international responsibilities, as defined in their basic instruments, in economic, social, cultural, educational, health, and related fields, shall be brought into relationship with the United Nations in accordance with the provisions of Article 63; 2) Such agencies thus brought into relationship with the United Nations are hereinafter referred to as specialized agencies".

The UN agencies like ILO 1919; FAO 1943; World Bank IBRD 1944; WHO 1946; UNICEF 1946; UNHCR 1949; UNAIDS 1989; UNDP1996; and etc. Moreover the UN agencies make arrangements to provide correct medication, health care, pre and post natal, health education, precautionary and preventive measures and with all other basic health requirements along with promoting breastfeeding, discouraging unhealthy food habits, ensuring access to basic shelter, housing and sanitation, with an adequate supply of safe and clean drinking water, by distributing nutritional information.

The regional instruments on RTH in Africa, America and Europe are functioning according to their regional charter and conventions. But, the Asian level is still in sub regional form.[208] In African region through the Organisation of African Unity[209] (OAU), the African Charter on Human and Peoples' Rights (ACHPR) of 1981provides with the definition of RTH and it implements it with the help of the African Commission on Human and Peoples' Rights known as "the commission", that functions to ensures protection and promote human right in Africa.[210]

The African Charter on Human and Peoples' Rights (ACHPR) 1981 in Article 16(2) ensures that the state parties to the charter shall take the required procedures in protecting the health of their people and guarantee medical assistance when they fall sick. There is also a definitional part in ACHPR Article 16(1) stating:

> "1) Every individual shall have the right to enjoy the best attainable state of physical and mental health; 2) State Parties to the present Charter shall take the necessary

[208] Gruskin, Sofia. and Tarantola Daniel. (2005), "Health and Human rights" ed *Perspectives on health and human rights* Gruskin, Sofia., Grodin, Michael A., Annas, George J. and Marks, Stephen P: 3-57. Taylor and Frances Group, LLC. p.9.

[209] In 1963 with 32 independent member States' the Organisation of African Union was established in Addis Abeba (Ethiopia). It has 53 members and moving from political liberalised phase to economic integration with peace and security for their socio-economic development process. The OAU adopts the mandate to achieve health, sanitation and nutritional corporation by harmonising their policies. In the field of health preventive medicines and public health measures are being applied all over Africa.

[210] Article 30 of the African Charter on Human and Peoples Right 1981.

> measures to protect the health of their people and to ensure that they receive medical attention when required".[211]

This proves, African health system was conscious since 1981 itself. Moreover, it has been found the most of the health and development workers work more on African regions. The report of the first Special Rapporteur (SR) on the RTH "Paul Hunt" proves that much work has been done for African health system. Still due to indifference of ethnic and tribal constraints within the region, it has not allowed attainment of health to the full extent.

The American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988) provides for the definition of RTH in American region known as the Organisation of American States (OAS). The Inter-American Commission on Human Rights and the American Court on Human Rights functions to provide RTH to the OAS. The American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988) [Article 10(1)] provides that:

> "(E)veryone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well being; … to ensure the exercise of the right to health, the State parties … recognize health as a public good and, … adopt following measures to ensure that … Primary health care, that is, essential health care made available to all individuals and families in the community … extension of the benefits of the health services to all individuals subject to the State's jurisdiction.. Universal immunization against the principal infectious diseases … prevention and treatment of endemic, occupational and other diseases … education of the population on prevention … health problems … health needs to whose poverty makes them the most vulnerable".[212]

It has been observed that America is still struggling to provide quality of health. Moreover, health as a right has always been in demand in the USA since the time of President Theodore Roosevelt[213] raised issue of the workers compensation act. President Franklin Roosevelt[214] brought economic security to health[215] in 1944 by

[211] Article 16(1) and 16(2) of the African Charter on Human and Peoples' Rights (ACHPR) 1981. It was adopted on 27 June 1981.

[212] Article 10(1) of the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988).

[213] In 1908, Presidential election Theodore Roosevelt stated that the number of accidents which result in the death or crippling of wage earners is simply appalling. In a very few years it runs up a total far in excess of the aggregate of the dead in any major war.

[214] In the second bill of rights i.e. a bill of economic security which included economic health security.

[215] The US health insurance can be both private as well as public, most of them are covered by the employer in the family (under group plans, which are less than the individual policy) In such type of Insurance the premium is paid by the employer and the rest by the employee. Ozden, Melik., (2006), "The Right to Health: A Fundamental Human Right Affirmed by the United Nations and Recognized in

emphasising on right to adequate medical care and the opportunity to achieve and enjoy good health.[216] However, in 2008, Presidential election, Barack. Obama demanded health as a right and not a privilege.[217]

The European region works with the help of the European Commission on Social Rights. The European Social Charter[218] (1961, as revised in 1996) undertook measures by defining right to health as:

> "(E)nsuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed inter alia: 1) to remove as far as possible the causes of ill-health; 2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; 3) to prevent as far as possible epidemic, endemic and other diseases, as well as accidents."[219]

It can be observed that the RTH in European Social Charter is still a right where prevention and advisory function is followed. The health right needs more enhancements in health care and health services then just being in protective form.

Table: 2 Recognition of RTH in the Regional Instrument

TREATY	ADOPTED	SIGNATORIES	STATE PARTIES	ENTRY INTO FORCE	ARTICLES
African Charter on Human and People's Rights	**27-Jun-81**	**42**	**53**	**21-Oct-86**	**16(1), 16(2), 24**
Additional Protocol to the American Convention on Human Rights	**22-Nov-69**	**19**	**25**	**18-Jul-78**	**10(1), 10(2), 11(1)**
European Social Charter	**18-Oct-61, Revised 3-May-1996**	**4/47**	**15/40**	**23-Mar-76**	**11(1), 11(2), 11(3)**

Regional Treaties and numerous National Constitutions", Human Rights Programme of the Europe-Third World Centre (CETIM), Geneva, 1-63; available at: www.cetim.ch/legacy/en/documents/bro4-sante-an.pdf , p. 28-29

[216] Annas, George.J. (2009), "Bioethics and Genomics":321-329 in Andrew Clapham and Mary Robinson (eds.) *Realising the Right to Health*: *Swiss Human Rights Book*, Vol.3, Zurich: Ruffer & Rub; available at: www.swisshumanrightsbook.com/SHRB/shrb_03_files/20_453_Annas.pdf , p.9.

[217] Clapham, Andrew and Robinson, Mary (eds) (2009), *Realising the Right to Health*: *Swiss Human Rights Book*, Vol. 3, Zurich: Ruffer & Rub; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html , p.16.

[218] Adopted 18 October 1961 and revised in 1966.

[219] The European Social Charter Art. 11, "The right to the protection of health". Several articles of the Charter are also devoted to related rights. For example, art. 12, "The right to social security"; Article 13, "The right to social and medical assistance"; Article 14 "The right to benefit from social welfare services". It was adopted on 27 June 1981.

Essential Components or Elements of Right to Health

In formation of legal arrangement of RTH, to important to realise all possible diverse core elements for the health rights. While understanding the RTH certain extent it embraces a wide range of socio-economic factors leading to condition wherein an individual can live a healthy life that includes the underlying health determinants like potable drinking water, food and nutrition; housing; adequate sanitation, healthy working condition, healthy environment, health security, scientifically sound health care, socially and technically working health team and education concerning health problems, etc. So it becomes important to know that RTH elements come through:

Table 3: Core Human Rights Elements of RTH

CORE RIGHTS	INCLUDE
Adequate Standard of Living	Food, Housing
Freedom from Torture, Degrading or Inhuman Treatment	Dignity of Human Being, War Crimes and Crimes Against Humanity, Death Penalty, Medical Research involving Human/animal Subjects, Exercise of Self Determination
Highest Attainable Standard of Health	Biological and Socio-Economic Condition, Access to Drug, Medical Care and Services, Application of Biology and Medicines, Association and Assembly
Right to Education	Adolescent Health and Development, Access to Information
Right to Social Security	Insurance, Worker Compensation Act
Reproductive Rights	Harmful Traditional Practices, Violence against Women
Protection of the Environment	Water, Hygiene and Sanitation, Occupational Health Safety,
Right to Work	Medical and Professional Ethics, Elimination of Worst forms of Child Labour, Responsibility of Transnational Corporation
Non-Discrimination and Equal Treatment	Freedom from Abuse of Elderly and Domestic Violence, Protection and Promotion of the Rights with Dignity of Persons with Disability
Right to Prevention, Treatment and Control	Control of Epidemic, Endemic, Occupational and other diseases, Urgent Medical Care during Accidents, Disaster Relief and Human Assistance during Emergency

These core elements of rights for RTH, as stated in the Table No. 3, have been drawn from the text of all international, regional and UN instruments. It is an obligation on states to apply these elements as health rights in their domestic Constitutions. In India, RTH is not yet included as a fundamental right though in several cases it has been provided under the umbrella of vital Right to Life under

Article 21. India provides health facilities through policies. The Indian Constitution directs the State to ensure social and economic justice by giving effect to Part IV of Directive Principles of State Policy (DPSP) enshrined in Part IV. These relevant Articles of DPSP provide:

> "i) Article 42 that states on work and maternity relief; ii) Article 47 affirms on duty of State to raise the level of nutrition and standard of living as well as to improve public health; along with iii) Article 38 that imposes liability on State "social order" but without public health it is not possible; iv) Article 39 (e) states on related workers to protect their health; v) Article 41 imposes duty on State to public access; and vi) Article 48 states on pollution free environment".[220]

Conclusion

The RTH, as we understand today has developed through different stages of analysis and study. The concept of health development came through the sufferings and diseases that led to disability and death for many of the individuals. To understand the death, suffering and their causes, reasons were explored through its source and infection. For many years it was believe that diseases came through ships due to which stringent and strict legal measures such as quarantine and isolation came up. However, gradually, came to be known that diseases can spread in through mode of travel or through dirt and surrounding environment. The findings as regards water contamination causing cholera by John Snow led to awareness of sanitation and hygiene. The curiosity of healing the pain led to medicinal development that started its root from ayurvedic, herbal, to allopathic drugs. Professional ethics was laid by the Hammurabi Code that brought strict and harsh punishment for negligence. The sanitation and hygiene exposed the reason for spread of diarrhea and cholera need for proper toilets and right pee, etc. Further, industrialization brought proper time age specific time framework of working including a free day in a week to relax and workmen compensation or insurance security. The insurance facility brought access to health care during emergency and as a support during financial constrain. So that when required atleast proper health arrangements can be provided.

RTH is closely related and dependent on other human rights based on socio-economic and political condition. Discrimination that lead to stigmatization and humiliation either due to vulnerable diseases or vulnerable condition of being

[220] Articles 38, 39 (e), 41, 42, 47 and 48 of the Indian Constitution.

prisoner, refugee, displaced person, old person, gay, children and women, etc. The vulnerable have mostly become victims of treatment and care as well as victims of scientific research. The ethical norms and guidelines provided by the various declarations, all in some way state that professional ethics should be followed while conducting any scientific research for the betterment of the future. No degrading or inhuman behaviour should be followed as well as concern and exercise of self-determination should be followed.

When human rights and health is observed together it helps in understanding severity of injustice. The legal instruments state the need of scientific and technical health acquaintance along with financial cooperation by international organisation. Moreover, stress on scientific research to provide essential medicines is provided along with the drug regulation and marketing arrangements.

The international human rights instruments states "health as a fundamental right indispensible for the exercise of other human rights". RTH contains both freedom and entitlements as well as while taking the account of individual's biological and socio-economic conditions along with the State's available resources it is the duty of the State to provide RTH to its people.

The regional arrangements of Europe, America and Africa health as an enjoyment of highest level of physical, mental and social well being. None of them properly states health as a right. Since Africa demands health protection through receiving medicines and Europe and America as a protective shield during sickness through educational facilities along with protective and preventive measures for disease, accidents and immunization.

The Indian sphere of health arrangements comes through policy packages. India provides RTH in derogative form with the help of Article 21 Right to life. India needs to firm its health rights and needs it as a fundamental right not as a principle or through the budget policy.

The RTH is still not strongly implemented in many countries the sphere of allowing RTH depends according to the resource and demand of one country e.g for Africa RTH means access to medicines. But a country like India where demand is not just access to medicine but also to afford, avail, and access quality health care with proper working force and technology, an understanding about health as a right comes

strongly. At present the direct and indirect linkages of health and human rights in all different arrangements of international human rights raises need for a new International Convention for Right to Health. It could incorporate all the defaults and arrangements of health, care, facilities as well as services together with the human rights perspective. It will, in turn, strongly discourage discrimination, inhuman or degrading conditions including in situations of transfer an organ or opting for research trial. Thus it seems to be important to look into drug regulation and labeling of products so that control in reacting medicines as well as banned drugs can be known. The issue of clinical trials will be examined in the next chapter.

Chapter-III

RIGHT TO HEALTH AND CLINICAL TRIALS

Introduction

Clinical trial (CT) or research experiment is a method to develop drugs or manufacture medicine that helps individuals. CT is a creation of condition for medical service and attention;[1] providing RTH to individuals. Biomedical research includes both medical and behavioural studies pertaining to human health[2] that is analyzed and reviewed through human and animals investigation collected after the laboratory test gives positive results. Thus, observing RTH responsibility, government produces medicine through private/government pharmaceuticals for treating and curing individuals from ample number of diseases and unavoidable health sufferings. On the other hand, health rights raise issues of ethics in the profession and consent by the human subjects. While conducting trial projects, accountability of ethical committees or regulatory bodies to monitor and inspect permitted trials becomes important for such sites and measures. Moreover, no subject during the trial should be treated as inhuman or in degrading condition. Free consent of subject becomes important so that medical or scientific experiment does not turn into punishment or torture.[3] Acceptance of "moral, ethical and legal concepts"[4] stated in the Nuremberg Code (1947), medical professionals and practitioners follow ten principles for assurance of permissible rules in CT. The International Covenant on Civil and Political Rights obliges its member states to follow ethical and human rights behaviour".[5]

[1] Article 12(2)(d) of ICESCR 1966.U.N.G.A. Res. 2200A (XXI) of 16 December 1966 (entered into force 3 January 1976, in accordance with article 27); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[2] The Preamble to the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) The Council for International Medical Sciences (CIOMS) in collaboration with the World health Organisation (WHO), Geneva, Switzerland; available at: www.cioms.ch/frame_guidelines_nov_2002htm

[3] Article 7 of the ICCPR 1966. United Nations Doc. A/6316 (1966); The General Assembly Resolution 2200A (XXI); available at: www.unhchr.ch/html/menu3/b/a_ccpr.htm

[4] The Ten Principles of the Nuremberg Code 1947. The Trials of War Criminals before the Nuremburg Military Tribunals under Control Council Law No. 10, Nuremberg, Germany, October 1946 April 1949, Washington D.C: U.S. G.P.O, 1949-1953, 2; available at: www.jewishvirtuallibrary.org/jsource/Holocaust/Nuremberg_Code.html

[5] Article 7 of the ICCPR 1966. United Nations Doc. A/6316 (1966), The General Assembly Resolution 2200A (XXI); available at: www.unhchr.ch/html/menu3/b/a_ccpr.htm.

To understand clinical trial as a RTH, one needs to interpret information and analysis of collected physiological, pathological and epidemiological process and findings to help in medical care and disease prevention.[6] Indian expressions on clinical trial definition are coined in the India's Rule 122 DAA of Drugs & Cosmetics Rules, 1945 (D & C Rules) that defines clinical trials as:

> "(S)ystematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and / or efficacy of the new drug". [7]

This definition provided by the Rule 122 DAA of Drugs & Cosmetics Rules, 1945 of India, clearly mentions that clinical trials are made for the new drugs in order to check its authenticity and efficacy on human beings so that the discovered drug can be launched in the market with proper testing and analysis.

In order to identify the rights of patients, privacy, etc. through the help of human rights to health during clinical trials of drugs on human subjects, an overview of the regulatory mechanism has to be made so that monitoring of clinical trial/research experiment can be done properly and without any error or default.

CLINICAL TRIAL INTERVENTION ON HUMAN SUBJECT

The development of CT/research experiment on human subject came to promote and safeguard health of people. The Declaration of Helsinki in its principle No. 2 states that physician's duty is to dedicate his/her knowledge and conscience to safeguard health of people.[8] It becomes responsibility of the physician or researcher to prepare accurate facilities to protect individuals during estimation of possible disability, injury or death.[9] CTs is broadly considered of two types. They are: i)

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[6] The preamble of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) The Council for International Medical Sciences (CIOMS) in collaboration with the World health Organisation (WHO), Geneva, Switzerland; available at: www.cioms.ch/frame_guidelines_nov_2002htm.

[7] Rule 122 DAA of Drugs & Cosmetics Rules, 1945 (D & C Rules).

[8] The Principle no. 2 of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2002). *World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects*, 1964, (2008); available at: www.wma.net/en/30publications/10policies/b3/17c.pdf

[9] The Principle No.7 of the Nuremberg Code 1947. Trials of War Criminals before the Nuremburg Military Tribunals under Control Council Law No. 10. Nuremberg, Germany, October 1946- April 1949. Washington D.C: U.S. G.P.O, 1949-1953, 2; available at: www.jewishvirtuallibrary.org/jsource/Holocaust/Nuremberg_Code.html

therapeutic and ii) non therapeutic trials.[10] Therapeutic trials are those CT in which subjects are enrolled and provided with specific treatment to study its impact. Non-therapeutic trials in CT mean those studies that are not for treatment but conducted to study advance level of disease and its impact, e.g. the study of collected tissue specimens to examine the cellular structure of cancer tumor. These two trial methods are used to determine effectiveness and understand safety of treating process for a disease and health suffering. Each trial is aimed at improving survival rates or reducing side effects or late effects of treatment. CT is a method that provides base towards personalised medicine and is a method to know labeling of drugs and its effect.

Both therapeutic and non-therapeutic trials are studied as prevention, treatment or diagnostic and screening trials that help in preventing particular medical conditions that people have or may suffer. These trials are also made in order to prevent reoccurring of particular medical conditions.[11] CTs are carried out in three phases, known as Phase 1, 2 and 3[12] prior to launch of the drug in market. The Phase 1 studies are of basic clinical trials dealing with how drugs are tested to evaluate the dosage of the treatment, and how often the treatment can be administered by maximum tolerated dosages (MTD). As it is unknown whether the treatment will be effective against a particular disease, so people with variety of diseases are enrolled. Drugs are given at gradually increasing dosage until there are unacceptable side effects produced from dose-limited toxicities, (DLT). Phase II studies uses result from phase I studies regarding MTD and DLT. The treatment is targeted on patients that responded promising in Phase 1 trials. Phase III studies are made on newly born children.

Registration is compulsory while conducting CTs. In the U.S, registration and result reporting for Phase II, III and IV trials on pharmaceutical drugs is obligatory. This policy came in existence since the amendment of 2007 FDA Act. In European Commission registration of Phase II to IV is necessary in the European Medicines Agency Trial Registration along with EuroPharma database. In Argentina, Brazil,

[10] Cure Search, (2012), "What is a Clinical Trial?", Research Cure Search for Children's Cancer National Childhood Cancer Foundation, *Cure Search*, pp. 1-3; available at: www.curesearch.org/ArticleView2.aspx?id=8724
[11] Ibid.
[12] Ibid.

India and Japan the registration is made through Ministry of Health. Whereas, for South Africa the process of registration is yet to be finalized.[13]

Risk, Burden and Benefits during Human Intervention

CTs intervention starts through recruiting human and animals as subject participants, to know effects on vulnerable infectious diseases either on sufferers or healthy participants. Enrolling of human subjects becomes necessary to know treatment for medical research.[14] CT has risk, is a burden and has benefits. Each time, when a subject gets enrolled he/she has expectation of getting maximum benefit prior to initial stage that is hard to predict.[15] On the other hand it is responsibility of researcher and institutional review boards (IRBs) to minimize risks and burdens and maximize benefits of research by gathering informed consent of the participant.[16] The only option of availing drugs and therapy for the disease sufferer like cancer fighting provides benefit as well as burden from new experiment that is unavailable as drug or therapy.[17] Conducting CTs carries human rights and ethical issues concerning research participants. Non-therapeutic trials by poor drug products and poor outcomes followed during research may lead death and severe side effects to the subject.[18]

A crucial question arises for marginalised and oppressed populations when they are enrolled without consent and knowledge.[19] The rising research on biomedical field in order to find accurate treatment to cure sufferings without error brings international standards for review. Problem arises during international research experiment because targeted subjects are specially poor and vulnerable sections of

[13] Lemmens, Trudo., and Telfer, Candice., (2012), "Access to Information and the Right to Health: The Human Rights Case for Clinical Trial Transparency", *The American Journal of Law, Medicines and Ethics*, 38, Boston University School of Law, p.72.
[14] Declaration of Helsinki para 3; available at: www.wma.net/e/policy/b3.htm.
[15] Ulrich, Connie.M., et.al. (2016), "Cancer Clinical Trial Participants' Assesment of Risk and Benefits", HHS Public Access: PMC, AJOB Empir Bioeth, US National Liberary of Medicine, National Institute of Health, 7 (1), p.8; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC4689188/
[16] Ibid. p.9.
[17] News-Medical Life Sciences, (2016), "Benefits and Burdens: of Participating in Clinical Research Trials", News-Medical.net-AZom.com Limited; available at: www.news-medical.net/news/20120407/Benefits-and-burdens-of-participating-in-clinical-research-trials.aspx
[18] For details, see, Singh, Anil., "Unethical Clinical Trials: Is it Really True", *LinkClick*, Department of Pharmocology, PDU Medical College, Rajkot; available at: www.pdumcrajkot.org/LinkClick.aspx?fileticket=LV7BWn4U_pU%3D&tabid=73.
[19] Ibid

developing countries.[20] Despite the fact that, study on CT starts first learning potential treatment in laboratory by animal experiments so that humans experience becomes possible. This requirement of animal experiment for enhancing research trial as future prospects was stated in the Principle No.3 of the Nuremberg Code of 1947:

> "The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment".[21]

The undergone study, based on animal trials, provide promise for human trials. It requires human volunteer as a research subject. It helps in determining safety and effectiveness of experimental treatment under controlled conditions. In fact use of personalised medicine (PM) in treatment or therapy by CT supports permit or supply of drugs for wider use, in general population. Treatment studies by CT provide promising pharmacological activity with safety profiles. CT begins on human subjects according to a protocol that is formulated under law and regulation of a country by the review of ethical committee.[22] Reaching CT procedure itself carries thousands of drug failure. From about 1 out of every 20 tested compounds only promising, safe and effective drug is approved for marketing.[23]

During CT process participating subjects of trials may both benefit as well as risk themselves from unidentified experimenting results and side effects. There are four main benefits that eligible participants are considered to facilities themselves from CT and they are: a) capacity to better own health care; b) get accessibility for treatment that is not available in market; c) gaining proper access with monitoring to adequate medical and health care facilities; and d) helps in analyzing results for others through contributing medical knowledge.[24] CT benefit is not just limited to individuals but also brings improvement in medical care. Even when enrolled participant does not benefit completely from CT. Collected information and

[20] Mills, Edward J and Singh, Sonal (2007) "Health, Human Rights, and the Conduct of Clinical Research within Oppressed Populations", *Globalization and Health*, 3 (10), p.1-13; available at: www.globalizationandhealth.com/content/3/1/10
[21] The Principle No.3 of the Nuremberg Code 1947.
[22] Para 13 of the Declaration of Helsinki; available at: www.wma.net/e/policy/b3.htm
[23] Lee, Chi-Jen., et al. (2006), "Clinical Trials of Drugs and Biopharmaceuticals", *Taylor and Francis Group*, LLC. Boca Raton, FL.: CRC Press. Lee, Lucia H., Wu, Christopher L., Lee, Benjamin R., and Chen, Mei-Ling, p.1.
[24] Ibid.

knowledge understanding by the positive and negative feedback values can help society and physician or researchers to add in research findings.[25]

Three main risks involved during participation are: a) treatment may lead to serious or unpleasant side effects; b) treatment may not be effective to the participant; c) treatment may need excessive time and attention together with health examinations through hospital visit and stays.[26] It becomes important to discuss with the physician and understand carefully all the benefits and risk by participating in a CT. Only when knowledge is fully gathered and acceptance by the subject of trial then informed consent document needs to be filled and signed by the participant. But, if the subject is dissatisfied from the conducting trial he/she may freely leave CT process at any stage.[27]

There are protocols based on scientific requirements and research involving human subjects must match to accepted scientific principles of the State and country. It becomes mandatory to provide prior knowledge of scientific literature, other relevant sources of information, and adequate laboratory and appropriate animal experimentation on the research experiment that has to be conducted. CT study conducted on healthy volunteers is examined to compare the study along with side effects and reaction for disease.[28]

Design and performance for every research study involving human subjects must be clearly explained and of reasonable process in a research protocol. The protocol encloses an ethical consideration that involves a specification and should specify principles. Details of funding, institutional affiliations, potential conflicts of interest, incentives for subjects, sponsors and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study has to be mentioned. Above all, CTs protocol

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[25] Novartis, (2014), "Clinical Trials: Benefits& Risks", Novartis AG; available at: www.novartisclinicaltrials.com/TrialConnectWeb/benefits.nov

[26] Lee, Chi-Jen., et al. (2006), "Clinical Trials of Drugs and Biopharmaceuticals", *Taylor and Francis Group*, LLC. Boca Raton, FL.: CRC Press. Lee, Lucia H., Wu, Christopher L., Lee, Benjamin R., and Chen, Mei-Ling, p.1.

[27] Novartis, (2014), "Clinical Trials: Benefits& Risks", Novartis AG; available at: www.novartisclinicaltrials.com/TrialConnectWeb/benefits.nov.

[28] Pa. Hershey., and Gilbert. Scott., (2015), "The Medical Minute: How Clinical Research Studies benefit Patients", PENN STATE NEWS, 14 April 2015; available at: See, www.news.psu.edu/story/352233/2015/04/09/medical-minute-how-clinical-research-studies-benefit-patients

should contain proper arrangements for post trials provisions;[29] Apart from it, research participants have to go through long and complex process. One of the main complex processes is that clinical research gets completed only when drugs are researched on participants and to society at large.[30] Results from different participants during human trials determine the type of drug and its effect based on dosage. Recent development on CT practice has brought cryonic preservation of bodies. This process provides hope to get cured and live long life. The case of a 14 year old girl, suffering from cancer was cryogenically frozen[31] on 17 October 2016 for experimentation. Since the girl desired to live through cryonic preservation till her cure is found. She won her case by the High Court of London on 6 October 2016, when her parents disagree to her last will. Cryonic preservation also known as humanorgan preservation research trust charity is legal but still there is no proper regulatory mechanism.[32] CT in itself has countless scientific and biomedical technologies emerging with complexity demanding proper health law to regulate and monitor innovative progress for betterment and welfare of individuals.

But the traditional observance of CT states that women are in higher risk for neglected opportunities that are revealed during CT while finding preventive treatment and diagnoses. Discrimination in various studies endures first drug trail are solely based on man, leaving women aside. These studies are moreover referred as "first in man" studies for new drug trials. Discrimination in trial findings make women vulnerable towards new drugs, moreover scientific explanation provided on this ground is that drug absorbs and metabolises during different stages of the

[29] Articles 21-22 of the Helsinki Declaration on Scientific Requirements and Research Protocols, 2013, p. 4-5.

[30] Pharmaceutical Research and Manufacturers of America (PhRMA): Research, Progress Hope, (2015),"Medicines in Development: Explore the latest Progress on Medicines in Development", *PhRMA*, Washington, DC, p.1; available at: www.phrma.org/innovation/meds-in-development#sthash.eVyoYY8U.dpuf

[31] A process to preserve life after legal death is ordered, so that experimental procedure to preserve life can be possible till the future medical technology brings cellular and molecular level advancement. See, ALCOR, (2016) "Memory Preservation Study Results", ALCOR-Life Extension Foundation; available at: www.alcor.org/

[32] The patient was visited by Justice Peter Jackson on 6 October in hospital as she could not appear in the court. She was legally dead on 17 October and cryogenically frozen to be preserved. For details, see, Rayner, Gordon. Finnigan, Lexi. And Bodkin, Henry., (2016), "Girl, 14, Who Died of Cancer Cryogenically Frozen after Telling Judge She Wanted To Be Brought Back To Life 'in Hundreds of Years'", The Telegraph News, 18 November, available at: www.telegraph.co.uk/news/2016/11/18/cancer-girl-14-is-cryogenically-frozen-after-telling-judge-she-w/

menstrual cycle[33] prevents women from being trial subjects for new drug. Based on such scientific argument, only one drug/medicine has been found in market of U.S that is intake based on gender at different dosage. Ambien[34] is the example that is consumed by women half of the men consumption. Women are vulnerable to new drugs as well as new drug that comes in market has to be prescribed with proper labeling.

The Helsinki Declaration states most of CT or intervention involves risks and burdens. The CT on human subject would only be possible when risk and burden is overshadowed. It is however, felt that during research on human subject's predictable risks and burdens are required to be assessed prior insuring measures to minimise such risk that has to be monitored continuously and documented by researcher. Identified or revealed conventional settlement or calculated risk and burden should be communicated to research subject along with their family members or community heads. Physicians have responsibility to analyse such risk and burden by him/her selves while undergoing such trials so that physician can be in position to manage such jeopardy. When degree of risk is not known and considered troubling then the physician in authority should immediately stop the study or modify such risk to continue the experiment.[35]

Ethical and Legal Norms Relating Clinical Trials

Clinical trials principles revolve around ethical norms and standards. Ethics is not just limited to moral conduct or humanitarian behavior. But, it even includes medical standards and physician's liability. It was first time globally observed through episode of Nuremberg Germany case,[36] when human subjects like war prisoners and the innocent Jews were being used for scientific research. These research participants

[33] Corrigan, Oonagh P. (2002)"'First in Man': The Politics and Ethics of Women in Clinical Drug Trials" Feminist Review 72, p.41.

[34] Heart Attack is one of the leading deaths in America and Ambien is a cardiovascular drug. On the other hand only one third subjects are women in cardiovascular drug trial. Publichealthwatch, (2014), "New Bill Ends to Stop Bias against Women in Medical Research", June 24 2014; available at: www.publichealthwatch.wordpress.com/2014/06/24/new-bill-ends-to-stop-bias-against-women-in-medical-research/

[35] Articles 16-18 of the Helsinki Declaration: Risks, Burdens and Benefits, 2013, p.3.

[36] The Medical Case, U.S.A. v. Karl Brandt, et al US Military Tribunal, Nuremberg (1951), "Trials of War Criminals before the Nuremberg Military Tribunal under Control Law", November 21, 1946-August 20, 1947, 10 (II), Washington DC. US Government Printing Office; available at: www.archives.gov/research/captured-german-records/microfilm/m887.pdf ; also see, www.nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=transcript

were studied for various scientific and medical experiments from making of painting colours through their skins and bones to medicinal experiment of discovering new drugs to know its effects, treatment and reaction. These human subjects used during Nazi experiments were ignorant of which type of clinical trials and studies they were going through. Only the truth known to them was "gas chambers".[37] The Gas Chambers experiment on prisoners reveals about Nazi phosgene data, this data has been used by the Environmental Protection Agency (EPA) in 1989 for considering air pollution regulations on phosgene gas i.e. a toxic gas used in manufacturing pesticides and plastics.[38] Phosgene gas data explained about affecting eyes, skin, upper respiratory tract and lungs due to dosage differences as well as fluid buildup causes drowning death.[39] This study for environment revealed health hazards and environment are two sides of same coin.

Inhuman treatment, torture and suffering during human experiment for scientific research lead to foundation of the Nuremberg Code, so that ethical and moral norms can come in recognition through legal obligation. The Nuremberg code is a customary international law that consists of ten principle points serving as one of the main guiding principles in medical sphere for clinical research especially made on human subjects. Ten principles of the Nuremberg code, basically states on voluntary consent especially for conducting, experiment on human subjects. So that acknowledgement towards research participant can be made when such study on scientific research is prepared on them. The principles of Nuremberg Code clearly points that when a scientific experiment is conducted it should be for the benefit of human kind and society. The trials should not be experimented if nature of such clinical trial is unnecessary and unprocurable.[40] Meeting failure during such research may cause injury or death and the research should be stop there and then. Experiments that may lead to elements like cheating, malice, pressure, force, racket, cruelty should be avoided by researching team or participant. The research subject should be aware of such conducted experiment and its elements that is being experimented on

[37] Cohen, Baruch.C., (1997-2010), "The Ethics Of Using Medical Data From Nazi Experiments", Jewish Law Articles: Examining Halach, Jewish Issues and Secular Law, pp.9; Available at: www.jlaw.co/Articles/NaziMedEx.html.
[38] Ibid.
[39] Ibid.
[40] The third point of the Nuremberg Code, 1947; p.1.

individual.[41] But sometimes state power becomes more authoritative for weaker and minority individuals whether the vulnerable provides consent or not. The case of *Buck v. Bell* (1927)[42] states on forced sterilisation or salpingectomy during eugenic movement[43] when Carrie Buck a mental age of nine and I.Q of fifteen year old had given birth to feebleminded illegitimate child. To avoid more mentally defective children, the Supreme Court (SC) of Virginia ordered involuntary sterilisation taking away her right to bodily integrity and deprivation of life i.e to enjoy the limbs and faculties of life.[44]

Ethical principle based on the World Medical Association (WMA) Declaration of the Helsinki (1964)[45] came consisting 37 main principles and a preamble for medical research involving human subjects and all human identifiable materials and data. General principles of the Helsinki declaration lays obligation to consider patient's health safety along with ongoing subject's wellbeing as priority.[46] CT should pursue accessibility, effectiveness, efficiency, quality and safety with proper legal evaluating procedure without harming subject's rights and interest. During discovery of improved preventive, diagnostic as well as therapeutic intervention, i.e. methods, procedure and treatments are revealed from participants. Medical research should be subject to ethical standards so that promotion, self determination, integrity, dignity, confidentiality of personal information and respect for health rights of all human subjects can be made. Along with justifiable extend of medical research providing appropriate access to participation in research.

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[41] For details, see, the Nuremberg Code principle one, (1947), p. 1.

[42] *Buck v. Bell*, (1927), 274 U.S 200, *Justia: US Supreme Court*; available at: www.supreme.justia.com/cases/federal/us/274/200/case.html

[43] Based on study of Sir Francis Galton, cruel and unusual punishment was followed in eugenics movement. Forced sterlisation was practiced on minority groups in America by involuntary consent to experiment and control population of same kind. This case highlights about the Virginia statute and all the nine Judges of the bench that took decision against Buck. Ignoring human rights and victim's value of human life. See, Polirstok, Scott., (2016), "Buck v. Bell: A Case Study", Journal of History, Binghamton University, Newyork; available at: www.binghamton.edu/history/resources/journal-of-history/buck-vs-bell.html

[44] Ibid.

[45] The declaration of Helsinki was adopted in Finland by the 18th WMA General Assembly in June 1964. So far nine amendments have taken place in 1975-Japan; 1983-Italy; 1989-Hong Kong; 1996-South Africa, 2000-Scotland; 2002-USA; 2004-Japan, 2008-Korea; and 2013-Brazil. See, The Helsinki Declaration on Scientific Requirements and Research Protocols, 2013, p. 1-6.

[46] It is not just known but even acknowledged by the physicians that medical progress is made through research studies based on research that involves human subjects. For details, see, the Helsinki Declaration 2013, General Principle, Article 5, p. 2.

Emphasis in the Helsinki Declaration has been on placing human rights above all national or international set up for ethical, legal or regulatory measure during CT. As well as, measures to lessens harms for causable environment groups of minority with proper justified research participating facilities should be taken where no subjects gets adversely affected. The International Covenant on Civil and Political Rights, Article 7 states that no one should be degraded, tortured, or treated cruel as well as no trial should be conducted without his/her consent.[47] Researchers, scientist and physicians conducting CT should be proper trained, qualified and educated. An important role falls on the government of a country that proves approval to trials. Indian Council of Medical Research (ICMR) Ethical guidelines for Biomedical Research on Human Participants and Good Clinical Practice guidelines of India suggest providing financial or other assistance to compensate subjects equitably for temporary or permanent impairment or disability. In case of death to their dependents are entitled for material compensation. As well as inconvenience and time spend should also be reimbursed for expenses they incurred due to participation in trial.[48]

Many a time there has been unethical practices since most of CTs are conducted on illiterate, poor and innocent vulnerable patients without their consent and knowledge. The Government directives and initiative for CT, having tied-up with other health affiliates from outside India has suppressed individuals' democracy and dignity. No proper monitoring and reviewing by ethical committees on the approved projects is made, whereas no regulating procedure has been arranged for illegal or authorised joint private ventures.

In fact examples can be given of Khammam district in Andhra Pradesh and Vadodara district of Gujarat. These two experiments were conducted by Program for Appropriate Technology in Health (PATH) with initiative of government and its institution got highlighted when death of some children were reported during trial since April 2010.[49] Children aged 10-14 years were unethically dosed with Human

[47] Article 7 of the International Covenant on Civil and Political Rights (ICCPR), United Nations Doc. A/6316 (1966), General Assembly Resolution 2200A (XXI), Accessed on 21 March 2016; available at: www.unhchr.ch/html/menu3/b/a_ccpr.html

[48] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.71-72; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/

[49] Singh, Anil., "Unethical Clinical Trials: Is it Really True", *LinkClick*, Department of Pharmocology, PDU Medical College, Rajkot; available at: www.pdumcrajkot.org/LinkClick.aspx?fileticket=LV7BWn4U_pU%3D&tabid=73

Papilloma Virus (HPV) i.e virus for breast cancer in government school. This national vaccination programme not only pointed but questioned negligence of duty by many Government organisations of India like Drugs Controller General of India, Ethical Committee Members, Indian Council of Medical Research (ICMR), and PATH.[50] Since an unethical project got license without individuals consent as well as knowledge with governments' permission. Chaos among people questions responsibility and malfunctioning of the government. Further, based on same unethical practice of the CT, the 72nd Parliamentary Standing Committee report came on "Alleged Irregularities in the conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH[51] in India".[52] This report revealed about two different pharmaceutical drugs of HPV vaccine were given to girl aged between 10-14 years in Indian states of Andhra Pradesh and Gujarat. In Andhra Pradesh 13,000 girls were vaccine with Gardasil approved by USFDA brand name MERCK HPV Vaccine.

In Gujarat 10,000 girls were given dose of vaccine Cervarix of GlaxoSmithKline (GSK). The exposure was to introduce the HPV vaccine in Indian Health Care system started in 2009 and was to be completed by 2011. In 2010 a report came about, deaths of 7 girls due to unethical and irregular setting of CT for HPV that stopped experiment. Research so far, had no proper account of post vaccination drugs, no records collection of ADE, Misinformed patients or parents as well as school children were recruited from village institutions.[53]

Based on same footing, other incident came up for cervical cancer screening study, to find death rates without medical care that was conducted on low socio-economic group status of 224929 women for 15 years in three clusters: i) Mumbai Slums; ii) Villages of Osmanabad in Maharashtra; and iii) Dindigul of Tamil Nadu.

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[50] Ibid.

[51] The PATH is an American agency. PATH was funded by Bill and Melinda Gates Foundation, an American Charity, See, Ministry of Health and Family Welfare, "The 72nd Report on Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India", Department of Health Research, Ministry of Health and Family Welfare. The report was presented in Rajya Sabha on 30th August 2013 and laid on the Table of Lok Sabha on 30 August 2013; available at: www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/September/HPV%20Vaccines%20Parliameetnary%20Report%20%20Aug%2031%202013.pdf

[52] The research was conducted with the support of Bill Gates foundation, in partnership with the ICMR and the government of the Andhra Pradesh and Gujrat. See, Dhar, Aarti., (2013), "Govt.'s tie up with PATH for clinical trials kicks up row", The Hindu, 22 October 2013; available at: www.thehindu.com/news/national/govts-tieup-with-path-for-clinical-trials-kicks-up-row/article5258330.ece

[53] Ibid.

Out of these, only 138624 were offered no screening at all.[54] Targeting poor and vulnerable individuals in India has become routine. Cheap screening and treatment for cervical cancer was conducted in three randomised controlled trials conducted by the government and international support to examine such intervention into public health programme. The controlled trial conducted against ethical norms,[55] for testing of Acetic Acid (VIA) cervical cancer, Pap smear and HPV with no proven intervention, placing subjects into more vulnerable condition of more serious risk and irreversible harm. Two of the conducted trials revealed in investigation for unethical designs and practices. Third trial moving on unethical settings, for VIA escaped scrutiny of ethical committees.[56] The Declaration of Helsinki, states in Article 32 that:

> "(B)enefits, risks, burdens and effectiveness of a new intervention must be tested to find best proven intervention, when compelling and scientifically sound methodological reasons use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option".[57]

These underscores that no harm should be made to subjects under trial. As well as the guidelines of the Indian Council of Medical Research (ICMR) state that placebo can be used in situations like: a) self limited disease; b) where no proven prophylactic, diagnostic or therapeutic method exists.[58] But the trials conducted in Mumbai slums were on 150,000 women, villages in Maharashtra had 132,000 women and villages of Tamil Nadu had 71,000 women. On more than 350,000 women unethical practice of CT without proper consent and without proper monitoring of ethical committees proves that India has police authority exposing vulnerability of victims and individuals.

Like the case of two drug trials by *Bayers Rivaroban and Novartis Aliskiren v/s. Enalapril*[59] (2012) accounting for major deaths and establishing "use of Indians

[54] Singh, Anil., "Unethical Clinical Trials: Is it Really True", *LinkClick*, Department of Pharmocology, PDU Medical College, Rajkot; available at: www.pdumcrajkot.org/LinkClick.aspx?fileticket=LV7BWn4U_pU%3D&tabid=73

[55] Srinivasan, Sandhya., (2013), "Editorials: Ethics of 'standard care' in randomized controlled trials of screening for cervical cancer", Indian Journal of Medical Ethics, 10 (3), p.147-148; available at: www.ijme.in/index.php/ijme/article/view/18/813

[56] Ibid.

[57] See, Article 32 of the Helsinki Declaration.

[58] See, ICMR.

[59] See. Mahapatra, Dhananjay. (2013), "2,644 died during clinical trial of drugs in 7 years: Govt to Supreme Court (SC)" The Times of India, 25 April 2013, available at:

for clinical trials as guinea pigs", Swasthya Adhikar Manch fields a Public Interest Litigation (PIL) in this regard and charged that foreign origin pharmaceuticals industries are using Indians for new drug trials as guinea pigs. In the PIL the Swasthya Adhikar[60] claimed that 57303 human subjects were enrolled and 39022 were competed clinical trials. On 6th March 2013 the Supreme Court in its order stated that according to the observed transpires as on the records confirms that none of the human subjects received compensation nor they were paid.[61] In 2008, the drug of Bayer's Rivaroxaban was used for clinical trial on human subjects that resulted in 21 deaths. Out of these twenty one deaths only five people died due to clinical trials and out of these five only two received compensation. Later, after two years Rivaroxaban was used again for human trials and it resulted in 125 deaths and it was claimed once again that only five deaths occurred due to clinical trial. Novartis used Aliskiren vs. Enalapril in 2012 as an investigational product that resulted in 47 deaths and only 1 has been declared as occurrence due to clinical trial of new drug. Moreover, it has been observed that till date most of the drugs that have been permitted in India for clinical trials on human subject are majority in number of foreign origin pharmaceutical companies.[62]

As of 1986, through filed writ petition proceeding in the case of Stree Shakti Sanghatana of Hyderabad,[63] Article 21 was invoked stating on women's right to live life with dignity. The writ tried to ban the use as well as sale of Quinacrine for female sterilisation while going through the controversies of Noerthisterone Enanthate (Net-en). That was introduced by Schering AG, German pharmaceutical and Indian Council of Medical Research (ICMR) in August 1984. As, Justice A.S. Anand had already pronounced that "the Indian women could not be use as guinea pigs..". The

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www.timesofindia.indiatimes.com/india/2644-died-during-clinical-trial-of-drugs-in-7-years-Govt-to-SC/articleshow/19719175.cms

[60] Swasthya Adhikar Manch, indore & Anr. v/s. Ministry of Health & Family Welf. & Ors. (2012), WP (C) 33 of 2012, Order Dated 3rd January 2013, with W.P(C)No. 79 of 2012.

[61] Yadav, Mukesh., Thakur, Parmendra Singh., and Rastogi, Pooja., (2014), "Compensation Issue in Clinical Trials: Recent Indian Scenario", Journal of Acad Forensic Med., 36 (2), p.161.

[62] Mahapatra, Dhananjay. (2013), "2,644 died during clinical trial of drugs in 7 years: Govt to Supreme Court (SC)" The Times of India, 25 April 2013; available at: www.timesofindia.indiatimes.com/india/2644-died-during-clinical-trial-of-drugs-in-7-years-Govt-to-SC/articleshow/19719175.cms

[63] Stree Shakti Sanghathana vs. Union of India Writ Petition C No 680 of 1996 decuided on August 24, 2000.

controversy on Depo Provera,[64] proves to act as contraceptive for women, i.e. injectable hormonal for women, can cause several side-effects like heavy bleeding and hypertension. Additionally, in 1986 for Human Rights violation, the Hyderabad Stree Shakti Sanghatana and Saheli filed a joint writ petition in the Supreme Court, demanding stoppage for such trials. ICMR had contravened its possessing criteria for ethics by violating the Helsinki Declaration on Human Experiment by not providing any informed consent and knowldge to participants (Stree Shakti Sanghathana and vs. Union of India Writ Petition (1996).[65] Devo-provera is an injectable contraceptive containing depot medroxyprogesterone acetate (DMPA) approved by U.S FDA in 1992. Used for preventing pregnancy, by preventing ovulation i.e relasing of ovaries egg, so that the uterine lining gets thin. But in India without Phase III trial of Depo-Provera, the drug was already approved for marketing under Schedule Y of the Drug and Cosmetic Act. The phase III trial in India was approved in Indian market in 1993 by American Multinational Upjohn since bought over by Pfizer. Mandatory requirement for phase III trial is made under item 7 of Appendix I so that safety and efficacy confirmation can be found by data of 100 patients by distributing product in three to four different centers.[66] Further, this drug is subject to last long with hormonal injecting drug like Net En and sub-dermal implants as Norplant with irreversible damages. Most of the analysis on studies conducted for injectable contraceptives and particularly their introduction in the public sphere through National Family Welfare Programme should be completely banned.[67] Further the studies have too indicated that if Depo-Proven and Net-En drugs are taken from

[64] Sarojini, N B. and Murthy. Laxmi. (2005), "Discussion: Why Women's Groups Oppose Injectable Contraceptives", *Indian Journal Of Medical Ethics: National Bioethics Conference*, 2 (1): 1-6; available at: www.ijme.in/index.php/ijme/article/view/702/1715; also see, www.injury.findlaw.com/product-liability/depo-provera.html ; and see, Rajalakshmi, T.K., (2000), "Caution on Two Contraceptives: Women's Group and Activists Warn that two Injectable contraceptives that will be included in the National Family Planning Programme May not Be Completely Safe", 17 (24), 25 Nov-08 Dec 2000, *Frontline*; available at: www.frontline.in/static/html/fl1724/17240820.html

[65] Stree Shakti Sanghathana vs. Union of India Writ Petition C No 680 of 1996 decuided on August 24, 2000.

[66] Ibid.

[67] Sarojini, N B. and Murthy. Laxmi. (2005), "Discussion: Why Women's Groups Oppose Injectable Contraceptives", *Indian Journal Of Medical Ethics*: National Bioethics Conference, 2 (1): 1-6; available at: www.ijme.in/index.php/ijme/article/view/702/1715; and www.injury.findlaw.com/product-liability/depo-provera.html ; also see Rajalakshmi, T.K., (2000), "Caution on Two Contraceptives: Women's Group and Activists Warn that two Injectable contraceptives that will be included in the National Family Planning Programme May not Be Completely Safe", 17 (24), 25 Nov-08 Dec 2000, *Frontline*; available at: www.frontline.in/static/html/fl1724/17240820.html

women having low bone density through poor nutritional status can be dangerous for such women. Severe side effects like deaths can happen through thrombo-embolism; more chances of still births; risk of breast cancer, carcinoma in situ and cervical cancer; risk of delivering babies with down syndrome by the women; risk of getting HIV infection from an infected partner; and irreversible atrophy of the ovaries and endometrium.

In India, the government hospital has many a times acted as living laboratories in the name of family planning programme along with absence of follow-up and monitoring.[68] It also came to light that post marketing surveillance of 5 years required for final stage of CT phase turned into private marketing of the product. Whereas, it is evident that Upjohn made profits through conduct of such research but kept all results of the scientific objective, data and its analysis as secret. The time frame used for post market surveillance was 3 months duration by inoculating 5 injections study on each woman. Monitoring of each woman for 15 months through DMPA is small time frame, for analysing long term effect of a drug. Disclosure on depo-provera express, drug is unsafe for individuals and there is no proven data on its safety.[69] Subsequently experience of the Net En contraceptives use in Patancheru of Andhra Pradesh in 1985 on poor illiterate women without their inform consent reveals fact how Indian women's have always been victim of society and family, having a new group member to abuse them through institutions and organizations. Who are recruiting the innocent poor women without their inform consent and knowledge who have no clue on access to health education.[70]

Many a time, CTs are kept confidential to hide invention and its achievement for patent and novelty success. But, some may get exposed during laboratory failures like the one got highlighted in France in January 2016. When news flashed about six people seriously getting ill and one of them was in Comma during laboratory failure and closing of such site.[71] This type of situation raises issues of negligence through

[68] Ibid.
[69] Ibid.
[70] Ibid.
[71] The Ministry of France, informed that all the six patients as well as one of them who was in Comma has now too recovered and presently all of them are in good health. It has also been stated that due to such trial, the Rennes in Brittany got suspended. For details, see, Reuters, (2016), "Six People Seriously Ill after Medical Trials Go Wrong in France", International News, *The Hindu*, 15 January 2016; available at: www.m.thehindu.com/news/interntional/six-people-seriously-ill-after-medical-trials-go-wrong-in-france/article8112282.ece.

government for not tracking experimenting details and data's along with mandatory laboratory evaluation. But, in some circumstances the unnamed laboratory may be one of the optimum research laboratories.[72] International law obliges to form ethics committee under para 23 of the Helsinki Declaration.[73] Research Ethics and Committees look after ongoing research. As far, the research ethics and committee is set through consideration, comment, guidance and approval of the research protocol, prior to any research is begun. So that the committee can function transparently, that should not be biased towards sponsors, researchers or with any other undue influence. The committee should be qualified and must take all the legal norms and regulations of the country/countries into application along with all the followed international norms and standards so that the safety and protection of the researched subject can be continued following the Declaration of Helsinki. The researchers have obligation to provide the monitoring information to the committee, especially information on the ADE reaction that takes, as well as all the reports during ongoing study. The amendments during the study should only function once consideration and approval by the committee is taken so that the researchers may submit all the findings and conclusion find through the entire study.

The issues' arising in the clinical trials are not just limited to ethical principles[74] but also highlights the call for of international human rights law. Because the ethics declarations like the Helsinki and Nuremberg Code themselves are not binding legal documents, they arguably represent a customary law i.e law based on an established pattern of behaviour that can be objectively verified within a specific field. So that the complexities present in contemporary medical research can be recognised when international research is conducted in developing countries[75] like the case of *Abdullahi v. Pfizer, Inc.,* (2002), U.S. Dist. Lexis 17436[76] on Nigerian

[72] Ibid.
[73] Article 23 of the Helsinki Declaration: Research Ethics Committees, 2013, p. 4.
[74] It has been observed during the XVI International AIDS Conference in Toronto, there were ethical arguments presented through UNAIDS that if during the trial participants turns seroconvert then it is not obligatory legal issue but considered ethical issue where access to effective treatment is not required. See, Mills, Edward J., and Singh, Sonal., (2007) "Health, Human Rights, and the Conduct of Clinical Research within Oppressed Populations", *Globalization and Health,* 3 (10), p.5; available at: www.globalizationandhealth.com/content/3/1/10
[75] Ibid, p. 2-4; available at: www.globalizationandhealth.com/content/3/1/10
[76] In this case Nigerian children were conducted with clinical trials in 1996, with the help of Nigerian Government approval by the Pfizer without informed consent. But, this case was brought in the U.S courts through Alien Tort Statute (ATS), 28 U.S.C 1350. Due to this trial 11 children had died and others were left blind and paralysed. For details, see, Abdullahi v. Pfizer, Inc., (2002) U.S. Dist. LEXIS

children and brought the Alien Tort Statute. For a claim of Alien tort it is mandatory it should have three requirements: (i) there must be alien plaintiffs; (ii) suing for a tort; (iii) committed in violation of international law.[77] An example is available from the Thailand incident where the US state transnational organization funded by the US Centre for Disease Control and prevention (CDC) was questioned for using used needles on the 1,600 IDU patients. Because the US state fund does not provide supply of drug paraphernalia due to which the Bangkok researchers were using unclean needles. The Helsinki Declaration of 2013 states, in Article 17, that all medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

The UN GA Special Session Declaration of HIV/AIDS 2006 that is signed between US and Thailand too expresses under Article 23 for affirmation on accessing essential commodities that includes equipments like sterile injection along with duty to reduce harms relating drug usage. This has raised legal and ethical issues surrounding the Domestic laws, questioning the US policy countered by international norms for provision of clean needles.[78]

Registration of Research Study

Registration and registry of CTs became mandatory to provide transparent public accessibility, comprehensive to improve public confidence in scientific study. CT registration brings disclosure of public needs and acknowledges health innovation therapy with proper monitoring regulations and approved directions for ongoing trials. First time demand for registration of CTs was made during discussion by Institute of Medicine (IOM) Board on Health Sciences Policy through a publication made by the

17436, pp.1 (S.D.N.Y. Sept. 16, 2002), vacated and remanded by, 77 F. App'x 48 (2d Cir. 2003), dismissed at 2005 U.S. Dist. LEXIS 16126 (S.D.N.Y. Aug. 9, 2005); also see, Pfizer Inc., v. Rabi Abdullahi, et al., Supreme Court of The United States, p.9-34; available at: www.scotusblog.com/wp-content/uploads/2009/09/09-34_bio.pdf

[77] Mills, Edward J., and Singh, Sonal., (2007) "Health, Human Rights, and the Conduct of Clinical Research within Oppressed Populations", *Globalization and Health,* 3 (10), p. 2-7; Available at: www.globalizationandhealth.com/content/3/1/10

[78] Ibid, p. 2-3.

International Committee on Medical Journal Editors (ICMJE) in 2004, December.[79] Initiative of IOM brought main framework for CT registry and registration. IOM appointed committee members to discuss on public access to biomedical and clinical research data.

It is suggested to bring in central registry and to follow: i) adequate information about patients and health care providers while enrolling for CT; ii) To hand details of the subject to patient, healthcare provider and others, after completion of CT and prescribe drug available in market; iii) to provide a link for each outcome report of CT in central registry so prevention of selective as well as biased results reporting can be prepared; and iv) Meeting of all first three requirement is essential for protection of proprietary research data and innovation preservation can be made.[80] Observing suggestions for central registry and monitoring of registered clinical data's, committee feels there may include more goals and these are: a) disclosure of data should be made in uniform format whether CT site and funding authority (private or public entities), along with both trial inception and completion; b) arrangement of process that creates interest for confidential and proprietary research data along with wide use of clinical information; c) compliance mechanism that links consequences for noncompliance; and d) Responsibility for managing registry of nonprofit organisation or trusted government agency, like National Library of Medicine (NLM).[81] On 27 June 2005, the IOM committee on clinical trial registries hosted a workshop, discussing on data elements and issues for compliance and implementation at national clinical trial registry. But, still most of the possible content fields for clinical trial registry were not considered for CTs registries discussion carried five main concepts: i) purpose of registry; ii) inclusion/exclusion of exploratory trials; iii) requirement of late disclosure mechanism for certain fields in the registry at the time of trial initiation (hypothesis statement, primary and secondary outcome measures, and projected year of trial completion); iv) timing and format in result reporting for

[79] Leaders of biotech and pharmaceuticals industry, editors from medical journal, representatives from the National Institute of Health (NIH), and Food and Drug Administration (FDA). See, Committee on Clinical trial Registries, Board on Health Science Policy and Independent Report Reviewers, (2006), "*Developing a National Registry of Pharmacological and Biologic Clinical Trials: Workshop Report*", Committee on Clinical Trial Registries: Board on Health Sciences Policy, Institute of Medicine: of the National Academies, National Academics of Sciences, National Academies Press: Washington DC. p. 1-3.
[80] Ibid.
[81] Ibid.

completed trials; and v) proper responsibility for Institutional Review Boards, the FDA, and others in ensuring compliance.

Order of 1 July 2005, made all CT details for first patient enrolment mandatory from 1 September 2005 before publication of articles in any of the ICMJE journals. The international pharmaceutical industry began registering with NLM, but all exploratory CTs were made available in the ClinicalTrials.gov, website; and marketed products for trials result were provided in the ClinicalStudyResults.gov, website.[82] American internet data based on Pharmaceutical Research and Manufacturers started launching internet database from September 2004. Moreover, on global clinical trial registration the World Health Organisation too confirmed its stand and calls together a group to extend a mechanism for recommending requests to delay release of one or more data items until a specified date. There are four potential functions in clinical trials: i) to track the list and status of clinical trial; ii) requited patient's information; iii) to provide complete record of trials so systematic reviews on evidence can be made; and iv) trials report results. This information on data's is one of the requirements essential for the work of editors in medical journal, healthcare providers, health insurers, patients, pharmaceutical companies, researchers and regulators. They can use such sources in their work, however all have different requirements.[83]

The registration for Phase I to Phase IV clinical trials are made so that understanding of health related intervention carried on human subjects can be made through outcome and health effects found during research experiment. The CT is also understood as interventional trials which includes: a) behaviour treatments; b) cells c) devices; d) drugs; e) other biological devices; f) preventive care; g) procedures like radiologic and surgical, etc; h) process-of-care changes; and i) etc.. [84] This acknowledgement about conducting trials and need for its registration states on transparency, accountability and accessibility for re-establishing trust on public by providing the clinical trial data's openly.[85] Further, the International podium to know about the registered clinical trials can be found through primary register of the

[82] Ibid, p. 1-3and 5.
[83] Ibid.
[84] Clinical Trials Registry-India (CTRI), (2016), "Clinical Trial Registry-India: National Institute of Medical Statistics, (Indian Council of Medical Research)", Clinical Trials Registry-India, p1-2; available at: ctri.nic.in/Clinicaltrials/login.php
[85] Ibid.

International Clinical Trials Registry Platform (ICTRP); Available at: www.who.int/ictrp/search/en/ of WHO website.[86] The ICTRP is a search portal that aims to prove single point access system for information on ongoing and completed trial data's in English. These data's are provided by data owners who conduct such trials; besides, it can be stored in any language based on the comfort of data providers'. On the other hand, individual registries to search directly by going country specifics CT details can be viewed at present for Chinese;[87] Dutch;[88] German;[89] Japanese;[90] Korean;[91] Persian;[92] Portuguese;[93] and Spanish[94] countries. Currently, in records of Clinicaltrials.gov web site, of National Institutes of Health (NIH) and Food and Drug Administration (FDA) U.S shows existences of 207,952 conducted studies in 50 States and in 191 countries.[95]

In addition the drug trial being researched on human subject in India is considered to be of worth USD 400 million.[96] The business industry estimated that if such research and development (R&D) in clinical trials functions in India, this research and development (R&D) in clinical trials may bring down cost spending by 60% for the big pharmaceutical companies.[97] Besides, the production of research market is increasing by 30 percent annually.[98] So, understanding such requirement the Indian Trials Registry-India (CTRI) hosted at the ICMR's National institute of Medical Statistics (available at: www.nims-icmr.nic.in), started functioning freely.

[86] WHO, (2016), "International Podium of Registered Clinical Trials", International Clinical Trials Registry Platform (ICTRP); available at: www.who.int/ictrp/search/en/.
[87] Chinese Clinical Trial Registry (ChiCTR); ibid.
[88] The Netherlands National Trial Register (NTR); ibid.
[89] German Clinical Trials Register (DRKS); ibid.
[90] Japan Primary Registries Network (JPNR); ibid.
[91] Clinical Research Information Service (CRiS), Republic of Korea; ibid.
[92] Iranian Registry of Clinical Trials (IRCT); ibid.
[93] Brazilian Registry of Clinical Trials (ReBec); ibid.
[94] Cuban Public Registry of Clinical Trials (PRCEC); ibid.
[95] WHO, (2016), "International Clinical Trial Registry Platform (ICTRP): Frequent Asked Questions, Clinical Trials-International Registry Platform (ICTRP), WHO: p.1-5; available at: www.who.int/ictrp/faq/en/
[96] Vajpeyi, Yogesh., (2013), "Allow Clinical Trials, With Checks Place", The New: Indian Express, 6 October 2013, p.1; available at: www.newindianexpress.com/opinion/Allow-clinical-trials-With-checks-in-place/2013/10/06/article1820662.ece
[97] Krishnan, Vidya. (2013), "Drug Trials in India Causing Havoc to Human Life: SC", *Live Mint and the Wall Street Journal*. Court Says legal, ethical issues invoked: directs govt to monitor and regulate clinical trials of experimental drugs. January 3, 2013. New Delhi, p.4; available at: www.livemint.com/Politics/JrEctTWHys7c3qrPnUU6lK/Drug-trials-in-India-causing-havoc-to-human-life-Supreme.html
[98] Staff Reporter., (2012). "Call to Monitor Drug Trials". Participants are Not Informed About the Drug Trial. *The Hindu*, Thrissur: Kerela. 3 September 2012, p.2; available at: www.thehindu.com/todays-paper/tp-national/tp-kerala/call-to-monitor-drug-trials/article3853067.ece

The ICMR's Institute for Research in Medical Statistic established in 1977 is known as NIMS from 9 November 2005. Where the online public record system for registration of clinical trials in India has started being in practice. This online registry site was launched on 20 July 2007 and since 15 June 2009 it has become mandatory by the Drugs Controller General of India (DCG (I)) in www.cdso.nic.in to register the trial data. In addition, 11 major biomedical journals have declared that only when clinical trials are registered, then only the publication of such report will take place. On the other hand, since 1 October 2015, the clinical trial registry has started an e-learning programme.[99] So far, it has also been evident through records that till 1990s it was government sponsored clinical trials that were being performed in academic medical centres. During a conference set on 10 to 11 October 2008, for the Institute of Clinical Trials Research Mumbai. The DCG (I), Mr. Surinder Singh, stated that about 582 registered clinical trials have been located for conducting clinical trial experiments in India. Out of which 72% are carried out by foreign pharmaceutical industries.[100] In demand for performing clinical research in India many entrepreneurs such as the contract researchers like Quintiles, Covance, Pharmaceutical Product Development (PPD), and ICON Clinical (ICON) have already queued up to set up their clinical research organisations.

It has been felt that the need for online training for clinical research has to be provided so that capacity and capabilities in term of infrastructure and other research investigation[101] can be improved while conducting such trials. Further, records on clinical trials since 2008 estimates that more than 1500 Indians have died as well as about 670 fatalities in 2010 were reported.[102]

Though in October 2012, the case study of *Swasthya Adhikar Manch Indore v/s. Union of India* (2012) WP (C) 33/202, by the Supreme Court of India stated that it may bar clinical trials in the country unless the health ministry provided proper

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[99] Clinical Trials Registry-India (CTRI), (2016), "Clinical Trial Registry-India: National Institute of Medical Statistics, (Indian Council of Medical Research)", *Clinical Trials Registry-India*, p.1-2; available at: www.ctri.nic.in/Clinicaltrials/login.php

[100] Shenoi, Anjali. (2012), "Biomedical Research in India: Law and Ethics at Crossroads", Social Change, *Sage Journals*, 42 (4), p.527-538.

[101] Kannan, Shanthi., (2006), "E-training in clinical trials", 9 January 2006, *The Hindu.* Education Plus, p.1-4; available at: www.hindu.com/thehindu/thscrip/print.pl?file=2006010900920700.htm&date=2006/01/09/&prd=edu&

[102] See, Staff Reporter., (2012). "Call to Monitor Drug Trials". Participants are Not Informed About the Drug Trial. *The Hindu*, Thrissur: Kerela. 3 September 2012, p.1-4; available at: www.thehindu.com/todays-paper/tp-national/tp-kerala/call-to-monitor-drug-trials/article3853067.ece.

information within a month regarding the number of deaths during such programmes. Besides, reimbursement and collective exercise are to be performed while conducting clinical trials for new development of drugs on Indians. In January 2013, The Supreme Court ordered Health Minister to observe and regulate every scientific trial of experimental drug in country. Further, the apex court ordered to revoke the power of the Central Drugs Standard Control Organisation under the Drugs Controller General of India (DCG (I)), which has so far been the nodal agency for monitoring clinical trials in India. After the filed lawsuit in February 2012 by non-profit Organisation i.e. Swasthya Adhikar Manch, had alleged that participants in such clinical trials faced health problems and had even died because of the practice.

The DCG (I) provided about 475 experiments on human subjects that were submitted in court for "new chemical entities" that have not been approved since 2005. Likewise in 2012 approved drugs by the Indian drug regulator caused 11,972 serious adverse events, out of which 506 attributed to clinical trials. None of the victims were compensated. A total of 57,303 subjects have been enrolled in these clinical trials and 39,022 of them have completed these trials. Since 2008, government records showed that 80 deaths were attributed directly due to clinical trials and 40 of these victims have been compensated. For the first time, due to the court's intervention, the horrifying human rights violations in clinical trials came under judicial scrutiny. But it is experienced that DCG (I) is just the enforcement arm of the department of the Central Drugs Standard Control Organisation. By revoking the power of DCG (I) cannot resolve the issue as the department will need to again depend on another officer and his team to do the work.[103]

Further it is felt that registration of research is an important part of clinical research because registration of trial can make the study easy to monitor as well as to analysis what is going wrong. Along with making the ability to understand the liability of clinical practitioners, researchers and sponsors on the human subjects they are examination for.

[103] Krishnan, Vidya. (2013), "Drug Trials in India Causing Havoc to Human Life: SC", *Live Mint and the Wall Street Journal*. Court Says legal, ethical issues invoked: directs govt to monitor and regulate clinical trials of experimental drugs. January 3, 2013. New Delhi, p1-4; available at: www.livemint.com/Politics/JrEctTWHys7c3qrPnUU6lK/Drug-trials-in-India-causing-havoc-to-human-life-Supreme.html

Liability of Clinical Practitioners and Researchers

Requirement of lifesaving drugs as a component of right to health came, when, health threat in developing counties rose in huge number.[104] So in order to provide the treatment naive population with lifesaving drugs, requirement of manufacturing drugs came up. But, in the process of manufacturing medicine/drugs it is essential requirement to do laboratory testing of such medicine/drug so that the effects of medicine/drug can be known. This drug then goes through process of animal testing prior getting it is experimented on humans. When such experiment shows promising results from animal testing then it goes for human trials so that ADE and its results can be observed. Human subjects undergoing such trials have to pass through two main process: i) voluntarily and ii) without consent and knowledge i.e involuntary. Voluntarily means an experiment conducted on human subject with proper legal and ethical consent and knowledge, where the subject knows the risk and benefits hidden during experiment and its conduct.[105] Involuntary consent and knowledge means when individual is not aware of drug experiment or does he/she has proper information about research being conducted on him/her or such trial is conducted under psychological and physical pressure.[106] Moreover, to understand dosage system healthy volunteers subjects can be enrolled by dosing virus of disease for which drug is being manufactured. An example can be of HIV/AIDS that required healthy subjects for trial from age 18 to 41.[107]

The Helsinki Declaration of 2013 having 37 main points states that physicians and researchers should follow all the paragraphs of the declaration that state on

[104] The case, *Minister of Health v Treatment Action Campaign* (TAC) (2002) 5 SA 721 (CC); available at: www.escr-net.org/caselaw/caselaw_show.htm?doc_id=403050

[105] Article 7 of the International Covenant on Civil and Political Rights (ICCPR) 1966.

[106] The case of Kammam in Andhra Pradesh.

[107] The HIV Vaccine was experimented in Kenya, Uganda and Zambiya with Study 20 of 4971 for of: HIV, International AIDS Vaccines Initiative, U.S National Institute of Health, U.S National Liberary of Medicine, U.S Department of Health &Human Services. See, (2011), "A Trial to Evaluate the Safety and Immunogenicity of an Adjuvanted GSK Investigational HIV Vaccine Administered With Ad35-GRIN Investigational Vaccine" ClinicalTrials.gov processed this record on July 21, 2011, NCT01264445 ; available at: www.A%20Trial%20to%20Evaluate%20the%20Safety%20and%20Immunogenicity%20of%20an%20Adjuvanted%20GSK%20Investigational%20HIV%20Vaccine%20Administered%20With%20Ad35-GRIN%20Investigational%20Vaccine%20-%20Full%20Text%20View%20-%20ClinicalTrials.gov.htm

following human rights above all scientific experiment.[108] But, evidences about adverse drug effect (ADE) and ongoing CT examination on human subjects post marketing and in hospitals keeps different track. One of the examples is when disclosure for severe disabilities in newborn babies was found during years 1958-1961. This drug was given to pregnant women to stop symptoms of morning sickness. The German Thalidomide drug was developed by Chemie Grunenthal firm as an anticonvulsant drug. The same drug was sold under the name of Contergan in Germany and considered to be marketed first time in 1957 in Germany and as Distaval in U.K in 1958. Thalidomide drug was developed, produced and marketed without proper guidelines and marketing as well as without any license. To prevent reoccurrence of thalidomide tragedy in 1965 the first European Community Pharmaceutical Directive as 65/65/EEC was issued.[109] This directive in EU came up so that no medical product can be produced without prior authorisation and license.

The question remains as to who is going to be liable for the failure for not providing proper therapy and treatment for disease and health related problems. If drug reacts and side effects occur during drug experiment made on individuals' prior getting marketing approval, then what will be safety measures? Confidentiality clause rises issue on liability is trials are made on human subjects without revealing subjects. Like the case of Dr. Nancy Olivieri who is a hematologist in Toronto and under pressure to conceal her findings so that the reputation of researching university i.e the Toronto University and the Hospital for Sick Children by her two negative research findings, on unexpected risks in the drug for transfusion dependent thalassemia patient and they were: i) the drug did not work on some trial subjects but caused them with heart and liver damage due to iron; and ii) the drug was itself causing liver damages. Furthermore, the two negative finding in the drug of Apotex Inc. through

[108] The preamble specifies that the declaration is addressed to the physician and encourages others who are involved in medical research involving humans to follow this declaration. This declaration is forwarded from the WMA. See, Articles 1 and 2 of the Helsinki Declaration: The Preamble, 2013, p.1.

[109] Moreover, the Thalidomide Tradegy-Grunthal mentions that the reported numbers of sufferers during the period 1957-1961 are considered to be 10,000 individual all over the world. Since 1965, numerous guidelines and regulations on clinical trials have come up. According to Common Hansard: Statement-Thalidomide survivors-14 January 2010, in 1996 the ICH Guidelines for Good Clinical Practice and in 2001 the publications of clinical directives 2001/20/EC came up aftermath of 1965 incident. In 2005 Good Clinical Principle (GCP) Directive 2005/28/EC along with its adoption and enforcement in 2004 UK Law i.e SI 2004/1031 and SI 2006/1928 of 2006; For details see, Stuart, McCully., (2011), "The U.K Clinical Trials Regulations: An Introduction to the regulations and guidelines that govern clinical trials in UK.", GCP Considerations. *Compliance Healthcheck Consulting UK Ltd*., p. 5-6.

efficacy in treatment of an iron chelation drug caused early termination of the drug trial and a legal warning from publishing her findings. This case highlights the drawbacks found in preventing of disclosure through confidential clause, i.e. to extend the time phase of at least to restrict informing or publishing findings in U.S and Canada for clinical research contracts. This clause reveals that there is no time limit for communicating trial data's to any third parties including trial subjects and is binding on the heirs, successors, and assignees of the investigator. Besides, universities and their teaching research institutes performing research has responsibility to protect human subjects[110] and to be equipped with adequate resources like ethic boards/committees, vigilant investigators who are independent from administrators. As well as, requires acknowledging risk and preventing from contracts on using such clauses,[111] where governments should too take initiative to remove such clauses and follow international legal and ethical obligations.

There is a need to take a voluntary participant in order to keep the trust from depleting from CTs and its progress in bettering scientific research and treatment. In March 2001 all the eight affiliated teaching hospitals of Toronto University and the University of Toronto implemented a policy to prevent using the confidentiality clause of disclosure of risks where only two sponsors rejected to sign agreement without having such clause adopting the for new policy. [112]

Legal Obligation During Clinical Trials

The R&D world of drugs/medicines is very wild and large, where the pharmaceutical companies have fastened their lobby over the preference of drugs they want to develop. At presently, contract research organizations (CROs), are emerging as new entity in R&D world since early 1990s. The CROs are considered to recruit voluntary patient more quickly and cheaply than the academic medical centers. The main functioning of the CROs is to locate research sites, recruit patients, and, in some

[110] Articles 3, 4 and 5 of the Nuremberg Code, 1945, p.1.

[111] Articles 6, 7, 8, 9 and 10 of Nuremberg Code 1945 mentions that the degree of risk should be in lieu of consideration for human importance, taking care of all the remote possibilities of risk, injury, disability and death. The research should be conducted by highly qualified as well as skilled individual observing every concern stages of experiment, where the research participants has the liberty to end the experiment at his/her wish where he/she feels the experiment has reached above his/her intolerable point. Moreover the physician too in good faith can end such experiment where he/she believes that such research experiment may cause death, injury and disability to the research participant; ibid.

[112] Baird, Patricia., Downie, Jocelyn., and Thompson, Jon., (2002), "Clinical Trials and Industry", *American Association for the Advancement of Science*, Science, New Series. 297 (5590), p. 2211.

cases, design protocols and perform data analyses. From time to time as condition demands they enroll primary health care providers, hospitals sites, or consortia of therapeutic specialists into their research networks. CROs have claimed to be providing close to half of the number of clinical research personnel who are engaged in drug development activities. The offshore infrastructures that CROs industry helps to tailor on behalf of pharmaceutical firms are adaptable, mobile, and, to some extent, parasitic. They insert themselves in ongoing and unresolved conflicts over market reforms and over the role of the regulatory state in national and local public health sectors. At any given moment, they can be moved somewhere else. National health and regulatory experts play a key role in shaping local understandings of clinical trials, their benefits, and their risks, and they have high stakes in attracting clinical trials to their countries and in keeping them there.[113]

While conducting clinical trials acknowledgement of the research and taking voluntary consent is a significant challenge. This awareness of research and its drawbacks has to be made to the research participant, which cannot be limited by stating minimal risk and burden. This information on voluntary inform consent of the human subject participating in the research, has to be made through detailed description of the risk and burden that the study may lead to. The family members, community heads and legal authorised persons can only give consent for the individual[114] when the benefits and risks are analysed because every individual who is a research participant has a right to know. The right to know came up due to results and incidence that took place while findings produced by whole genome sequencing (WGS). The right to know as stated came from the UNESCO's initiative in 1997 from Universal Declaration on the Human Genome and Human Rights (UDHG&HR). UNESCO accepts that human genome and its result applications can benefit in improving individuals health and humankind in the world. Moreover, such research should respect human rights, dignity, freedom and prohibit all forms of discrimination based on genetic characteristics. This Declaration UDHG&HR was adopted on 11 November 1997 and endorsed by the UN GA on 9 December 1998.

[113] Petryna, Adriana. (2011), "Pharmaceuticals and the right to Health: Reclaiming Patients and the Evidence Base of New Drugs", *Anthropological Quarterly*, 84 (2), p.306.
[114] The Helsinki Declaration, Articles 25-32 on informed consent.

The right to know came first from the UNESCO's initiative in 1997 from Universal Declaration on the Human Genome and Human Rights[115] (UDHG&HR). This Declaration consists of 6 sections with 25 Articles, aiming to promote and develop the scientific and technological consequences relating to biology and genetics to be within the framework of human rights and individuals' fundamental freedom. The Article 5c of UDG&HR states that "the right of every individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected". The Article 4 further adds that "the human genome in its natural state shall not give rise to financial gains." Further, Article 11 states that scientific progress contrary to human dignity such as reproductive cloning of human beings should not be done. But there is no mention for therapeutic cloning.[116]

As well as, to research subject has the right to make their own decisions before accepting any trial. This right is also enshrined in the ethical and legal norms governing clinical trial research since Nuremberg Code of 1947. Moreover, making registration mandatory beyond phase I clinical trials in almost every country helps to evaluate the research obligation and its findings from the ethics and evaluating committee/organization. Most of the countries include the States in U.S and Europe etc. Yet there are instance when unavoidable harm do occur on human subjects who are taking such clinical trials. So, in demand disclosure of clinical data has come in form of clinical study reports. This report includes all data's relating to clinical study like the trial design and basic result, etc.[117]

In India, after accepting the potentiality of clinical trials the GoI modified and amended the Schedule Y that sets guidelines and requirement of clinical trials in the Drug and Cosmetics Rule of 1945. Because, the Schedule Y came with the generic medicines but the inflow of foreign pharmaceutical companies after the strict patent rule from 2005. So the GoI after understanding the regulating importance developed Ethical and Regulatory Guidelines. The Indian Council of Medical Research (ICMR) in 2000 issued ethical guidelines for Biomedical Research on Human Subjects and the

[115] Article 10 of the HDHG&HR 1997.
[116] Yim, Seon-Hee,. Chung. Yeun-Jun,. (2013), "Introduction to International Ethical Standards Related to Genetics and Genomics", *Genetics & Informatics*, The Korea Genome Organisation, 11 (4), p. 220-221; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3897849/
[117] Herder, Matthew., (2014), "Towards a Jurisprudence of Drug Regulation", *Journal of Law Medicine & Ethics* (42), p.244.

CDSCO in 2001 released the Indian Good Clinical Practice (GCP) guidelines.[118] In India the regulating of Clinical trials are followed by guidelines/rules such as Rule 122 A to E of Drugs and Cosmetic Act, Schedules Y of Drugs and Cosmetic Act and Rules there under (Amended in 2005), GCP guidelines issued by CDSCO in 2001 and Ethical guidelines for Biomedical Research on Human Subjects by ICMR.

The Rule 122 DA of D and C Act states that new drug/investigational drug whether used during clinical trial or clinical investigation by an institution should conduct only through the approval of licensing authority designated by central government. Whereas, GoI has strengthened CDSCO and DCG (I) by reorganizing it with the FDA line. DCG (I) and the ICMR have too acquainted the local regulatory according to the international guidelines. The Clinical trial can only be possible when written permission is taken from Independent Ethics Committee (IEC) and DCG (I). The application should be accompanied by form 44 as per the Schedule Y requirement enclosing documents on data's on animal pharmacology, clinical pharmacology, chemical information, pharmaceutical information, toxicology. Other documents to be submitted as per the requirement are the application, case report form, informed consent form, investigator's brochure, investigator's undertaking, patient information sheet, trial protocol. Further, additional requirements for special population studies are there e.g., children, elderly patients, patients with renal or patients having other failure organs, pregnant women, nursing women, and those with specific concomitant medication(s). The protocol has to be reviewed and approved by the IEC having minimum of seven members including clinician, legal expert, social scientist, statistician and a local individual from the community.[119]

Regulating Clinical Trials

The monitoring of clinical trials can be made through understanding of British formation of legal obligation that is applied during conducting of clinical trials by individuals as set by the Medicines for Human Use (Clinical Trials) Regulations 2004. The conditions that are included in the Medicines for Human Use (Clinical

[118] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.4.
[119] Ibid.

Trials) Regulations 2004 are: a) the individual participating in the trial should have full understanding of the objectives of the trial and its risks and potential difficulty that may arise while participating in such trial. This information is provided during the meeting with the member of such research team; and b) a point of contact has to be provided by the researchers so that while enquiring or need of obtaining further information to the patient can be made without difficulty.

The clinical trial for a new medicine these things needs to be kept in place: a) The commencing scientific research is been reviewed by an authentic and expert teams; b) The research should have enough funds to go through with the project; c) Need of home base in hospital, research institute or organization is to be made so that the monitoring on trial can take place; d) Review and approval for medicines and clinical trial authorisation from Medicines and Healthcare Products Regulatory Agency (MHRA) is to be done; and e) For proceeding a recognised ethics committee is required. Moreover, the researchers and others are expected to follow ethical and scientific standards according to the Department of Health's Research governance framework for health and social care that includes: a) prevention of poor performance and misconduct; b) promoting good practice; and c) reducing adverse incidents and ensuring learned lessons.[120]

When the regulation of clinical trial is practiced its main aim is to effectively protect human subject that is involved in the research. As mentioned in the U.S FDA for the principles of good clinical practices (GCPs) and human subject protection (HSP) that is universally recognised. The FDA regulation that is in function since 1970s addresses on the GCPs and HSP along with visits on trial/ non clinical studies sites through FDA's bioresearch monitoring (BIMO) program. This BIMO program supports the marketing and research application submission.[121]

Clinical Trials and Ethics Committee

The Declaration of Helsinki in 1975 with its first review based on ethical practice brought the recommendation of independent committee from whom

[120] Health Unlock, (2015) "Clinical trials and Medical Research-How Trials are Regulated", *NHS Choices: Your Health, your Choice*, Health & Care information You Can Trust, GOV.UK; available at: www.nhs.uk/conditions/clinical-trials/Pages/Howtrialsareregulated.aspx

[121] U.S. Food and Drug Adminstration. (2015), Clinical Trials and Human Subject Protection, *U.S FDA: Protecting and Promoting Your Health*, U.S Department of Health and Human Services; available at: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/

comment, guidance and review of experimenting research had to taken by submitting application while conducting experiment on human subjects. Later the Belmont report of U.S in 1979 came up with requirement of Ethical Committees (ECs) for conducting all clinical trials. In United Kingdom (U.K) the department of Health through the Central Office for Research Ethics Committee (COREC) formed in 2000. The COREC established ten multicenters along with 300 local EC's in U.K., whereas, the COREC became the National Research Ethics Service (NRES) in 2007. The NRES monitors through three ways of authorisation for research ECs (RECs) and they are: i) through Self-Assessment Tool (SAT), that reviews complaint falling under the RECs' through Standard Operating Procedures (SOP) for research ECs in the UK; ii) Reviews by the NRES for on-site, along with accommodation, equipment, membership records, office procedures and reviews, sample study files and training records; iii) Auditor looks after the REC meeting Such REC either receives full accreditation or provisional accreditation. Audit and accreditation are repeated every 3 years. In Canada mostly every academic centre has its own EC known as research ethics board (REB). The REB works with the help of the National Council on Ethics in Human Research for interpreting and implementing the guidelines for ethical issues relating human subjects as well as to provide competent method for functions of REBs. Alternative ethical review models are accepted by for multicenter research. Reviews by external Research Ethics Board following an official agreement between institute and IRB can be made to individual IRBs. As required external, multi-institutional and specialised IRB's can be set regionally, nationally or territorially. Single joint REB can be established by two or more institutions or they may opt for appointing an external REB for delegating the review on research ethics. The review delegation can be made through geographical proximity or other consideration like resources, shared expertise and volume of shares. This type of research ethics review can be beneficial for multi-centric trials because it saves resources and time. In China the Ministry of Health's National Biomedical Research Ethics Committee looks after the biomedical research ethics. Just for professional guidance the local EC's interact with national committees. Mostly the hospitals are the one that have ECs in china which has been there prior 10 years. As well as there also exist IECs like Shanghai Clinical Research Centre that is responsible in conducting clinical research in Shanghai or other places in China. The IECs works in compliance with the WHO,

UNESCO and GCP guidelines. The Department of Health and Human Services takes care of all institutional review boards (IRBs) in USA. The IRBs are registered and approved only after review by the Office of Human Research Protection (OHRP) for functioning through its designation all over federal state. This registration by OHRP for IRB is effective only for three years and has to be registered electronically (in http://ohrp.cit.nih.gov/efile) or through sending written information for registration to OHRP. Moreover, the IRB can be invited through an institution to operate for other institution from a written agreement with an institution. In Japan the GCP mandates all the research conducted by the institutions should have EC unless such institution is too small to operate by its own REC. In that condition the institution can designate REC of other institution. Whereas, the Medical schools along with most of the hospitals have their own EC that functions without government regulation in Japan. There are two types of ECs in Japan and they are: i) Review EC that reviews and monitors clinical trials on drugs; ii) EC that reviews and monitors protocols of researches affiliated with the EC. On the other hand such composition of ECs in Japan has been established during 1988 through the Liaison Society for Ethics Committees of Medical Schools and the ethical guidance provided by the government. The review EC on clinical trials is regulated by the Ministry of Health, Labour and Welfare and works in accordance to the Pharmaceutical law and the Guidelines for GCP.[122]

In Indian context, it has been estimated that nearly 70% of the total cost of a developing molecule i.e a drug, is due to the clinical research. Due to the preferential activities for clinical trials about 20-30% of the global activities of research take place in India. It has also been evident through the report by Planning Commission of GoI's stated that the country requires 30,000 to 50,000 more research personnel, auditors, investigators and qualified staffs to work as ethics committees and data safety management boards.[123]

[122] Walanj, Aparna Sanjiv (2014), "Research Ethics Committees: need for Harmonisation at the National Level, the Global and Indian perspective", Ethika Clinical Research Centre, 5 (2), p. 66-70; available at: www.picronline.org/article.asp?issn=2229-3485;year=2014;volume=5;issue=2;spage=66;epage=70;aulast=Walanj

[123] Eleventh Five Year Plan: 2007-2012, (2008), Social Sector: Volume II; Planning Commission, Government of India, Oxford University Press: New Delhi. Also See, See Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A. (2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.2.

In observing registration of clinical research it was through the Express Pharma on 20th, October 2012, when Professor Ranjit Roy Chaudhury gave comment and suggestions for building confidence among various stake holders to safeguard the rights, safety and well being for trial subjects. Express Pharma is a Fourth nightly insight for Pharma Professionals. In the topic "Unless an ethics committee is accredited, it should not function." These comments and suggestions were to lay an ethics committee or provide patients with more accurate form of information sheet especially translated in his/her mother tongue. Consent from guardian was asked to be taken for those children who are up to 14 years of age and challenged patients. Comment of Dr. Chaudhury was too made on compensation stating still who should be the calculator of the compensation to be received by the patient.[124] Further, acknowledging his/other scholarships in India at present there are 25[125] states that have centers for ethics committee registration.

The 25 different states having ethics committee registration centers works through providing the ethics Committee Registration No. who applies with application and follows the Rule 122DD of the Drugs & Cosmetics Rules 1945 by the Drug Controller General (I) & Licensing Authority of India. The ethics committee registration number is provided as a form having the details of investigation, period for the trial etc. that is given in response to the application submitted by the sponsor/researching authority to the office of registration of Ethics Committees situated at different states of the country.[126]

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[124] Dr. Ranjit Roy Chodhury is the Chairman Task Force for Research, Apollo Hospitals Education & Research Foundation (AHERF). Through this line Professor R.R. Chaudhury tries to emphasis that whether the decision made by ethics committee on compensation be proper calculation as this may too include risk from outcomes. Or whether the calculator be the companies themselves by paying per patient on trial base. As well how many trials can one investigator conduct at a time. As well as there should be a limit how many trials should be conducted by an investigator. See, Chaudhury, Ranjit Roy., (2012), "Unless an Ethics Committee is Accredited, It should not Function", Management, Express Pharma: Fourth nightly insight for Pharma Professionals, 20 October 2012; available at: www.expresspharmarmaonline.com/sections/management/1202-unless-an-ethics-committee-is-accredited-it-should-not-fuction

[125] The CDSCO, (2015), "Ethics Committee Registration", Central Drug Standard Control Organisation (CDSCO), Government of India; Available at: www.cdsco.nic.in/forms/list.aspx?lid=1859&Id=1.

[126] These different states of the Indian territory where Ethics Registration Centres available are (numbers given in the bracket): i) Andhra Pradesh/Telangana (107); ii) Assam (8); iii) Bihar (5); iv) Chhattisgarh (4); v) Delhi (63); vi) Goa (5) vii) Gujarat (124); viii) Haryana (13); ix) Himachal Pradesh (2); x) Jammu & Kashmir (2); xi) Karnataka (108); xii) Kerala (56); xiii) Madhaya Pradesh (13); xiv) Maharashtra (256); xv) Mizoram (1); xvi) Orissa (12); xvii) Pondicherry (8); xviii) Punjab (21); xix) Rajasthan (34); xx) Sikkim (1); xxi) Tamil Nadu (107); xxii) Uttarakhand (6); xxiii) Uttar Pradesh (53); xxiv) West Bengal (44); xv) Jharkhand (25).

Compensation for Clinical Trials

CT is safe but risk involved in it may also land in unfortunate sufferings like side effects or death. Usually three years time period from the date of first notice of sickness or injury is left for CT claims for compensation. Claims for CT can be of two types: i) personal injury claims and ii) group injury claims. The claims are mainly made for rehabilitation in order to access care and support for recovery, medical negligence, defective drugs, and medical products.[127] Such claims can be for monetary and non-monetary benefits where compensation can be provided on different proposed models based on different principles[128] like: a) market model i.e based on supply and demand principle is hard to find subjects for trial based on race, study location etc. But provides high compensation by ignoring risk involved and hiding important data's that can deem for ineligibility of CT; b) wage model is based on egalitarianism principle, where unskilled or little skilled subjects are recruited who are paid less or based on their scale. Since they are from low income group it provides less issue for inter study competition and undue inducement with minimised risk and no discrimination of high or low income group but many a time leads difficulty in achieving timeframe number of targeted subjects; c) reimbursement model is based on the same footing of egalitarianism where it is hard to find subjects but in this model it's hard to hide information or overlook the risk involved during study as different subjects are recruited and compensated according to their qualification; and d) appreciation model where compensation is provided as a token of gratitude or appreciation after completion of any type of CT. Stakeholders should prior beginning CT obtain approval from the Ethics Committee for consideration of compensation to be provided to the trial subjects.[129]

The amount of compensation depends on extent of injury or illness and loss. Depending on the amount through acceptance or contest in court for loss of earning from current and future by not being able to return for work, payment expenses of medical and travel, care and support needs for present and future, Requirement of

[127] IM: Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

[128] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.70-71; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/

[129] Ibid.

home modification along with mobility aids or specialist equipments, trauma and nature of ongoing problems. [130] Compensation can be set on different phases from I-IV and based on its requirement causing injury and loss. Prior, in phase I trial for single dose administration and/or limited repeat dose administration no compensation or access to medicine benefit and gain was provided until investigation ends beyond conventional result. Since in Phase I trial maximum patients or unhealthy volunteers for new chemical or biological entity research based on disease-specific biomarkers; where efficacy is not investigated are recruited.[131] The Association of the British Pharmaceutical Industry (ABPI) brought first guidelines for compensation in 1970 for phase I trial. It has been observed in the principles for Phase I trial that:

> "a) when injury occurs due to participation in trial, it is right of the volunteer to receive appropriate compensation on the basis of negligence or strict liability for company; b) the compensation by the sponsoring company should be stated on the contractual document with the volunteer on proof of causation supported by qualified obligation to pay compensation for injury as quick as possible along with the cost of compensation will be resolved separately through other parties to the research; c) Simple clause of arbitration as provision for injury compensation should be included along with minimum time frame for dispute on implementation of formalities; d)it is stated that volunteers benefitting from Phase I trials will not be covered under such guidelines of Phase I trials"[132]

Compensation for phase I subjects should be stated on contractual document or arbitrarily claimed within minimum time frame. But benefitting subjects will not be qualified to claim compensation. The International Conference on Harmonisation-Good Clinical Practices (ICH-GCP) guidelines state that subjects should be compensated for trial related injury and/or treatment should be provided. ICH-GCP also suggests that sponsors should provide insurance or indemnify the investigator or the researching institution for claims arising from such trial. The Helsinki Declaration states the protocol should carry compensation provisions.[133] In U.S FDA there is no proper instruction on compensation. It is the code of federal regulations that suggests

[130] IM: Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

[131] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf , p, 1-4.

[132] Ibid.

[133] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.71-72; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/

institutional policy will decide on injury based compensation and/or medical treatment that is mentioned in consent document or protocol.[134]

Later, in 1983, when inclusion of "healthy volunteers i.e non-patient volunteer" for studies of Phases II-IV were added compensation was set for them based on risk and benefits formulation. Risk and benefit brought distinction between healthy volunteers and patient volunteer's i.e. target disease participant for Phases II-IV through treatment and adverse side effect (ASE). This division led was formulated for all the phases i.e phase I-IV who have no reasonable prospect of direct benefit or get material side effects by product under research from participation.[135] The new guidelines of 2012 Edition for ABPI on Phase I states that the 1988 non-patient guidelines are now replaced with compensation provisions; and in the 1991 guidelines of CT for Phases II, III and IV are also replaced with the compensation provision.[136] In Phase II-IV the compensation is paid by the sponsoring company when: i) direct participation leads deterioration in health or well being; ii) based on damages the amount is calculated by the English Court, such compensation may be reduced on extent of volunteers partial responsibility, i.e reason of contributory fault or where the payment of such injury has been made under any policy of insurance affected by the company as volunteer benefit; iii) An arbitrator should be appointed in dispute or disagreement of the application of paragraph i) and ii) of above mentioned or the President of the Royal College of Physicians of London should be appointed for arbitrating to consult a barrister of at least 10 years to provide the amount for damages and its payment of compensation; iv) Agreement of paying compensation should be in accordance to the English Court and paragraph iii) is subject to the sole jurisdiction of English Court.[137]

The process of providing compensation through Pfizer a representation of private pharmaceautical company as a sponsored study through its company's guidelines states that volunteers compensation is based on method and timing of disbursement. This incorporates regional laws, regulation and guidelines, the

[134] Ibid.
[135] Ibid.
[136] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf ,p, 1-4.
[137] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf , p. 1-4.

Institutional Review Board or Independent Ethics Committee reviews and approves compensation that is developed on criteria based on human subjects, site, and targeted subjects in same treatment group. In the voluntary informed consent disclosure of compensation amount is made, that accessed through the Pfizer Clinical Research Unit (PCRU) staff line with SOP CRU-RO2-LSOP, Calculation and payment of Subject Compensation at the PCRU. Compensation is provided to enrolled participants in the research with no incurring personal expenses, i.e. direct payment of expenses by the Pfizer, contract research organisation (CRO) vendors or consultants. Involvement of healthy volunteer's for phase I trials permits reasonable compensation for time and effort. Excessive compensation can be received for risks or discomfort that occurs without assumption. Additional consideration for minors participating in research is made along with ccompensations for travel, childcare for siblings and parking can be received by the parents or guardians. But, such compensation should not be made to those parents/guardians who plan to make improper incentives by enrolling minors.[138]

Principle guidelines for Phase II-IV states that the participating volunteer should receive compensation without legal commitment by written assurance to the investigator and from investigator to the relevant research ethics committee and they are: i) the volunteer should receive compensation from the company for bodily injury as well as death; ii) due to the inclusion of patient for trial the compensation should be paid when injury occurs through the administered medicinal product under trial or any clinical intervention or procedure including protocol; iii) During the injury of the child in utero through participation of the mother in clinical trial as well as the child as a volunteer; iv) for more injuries and disability condition provided which excludes temporary pain or discomfort with curable complaints; v) while conducting a trial to remove adverse reaction and causing adverse reaction through the medicinal being researched; vi) exclusion of compensation for such human subjects will be made whose adverse reaction injury was foreseeable or predicted prior conducting research and the patient had freely accepted such trial participation either through written or

[138] Pfizer, (2016), "Compensation to human Research Subjects in Clinical Studies", *2002-2016 Pfizer Inc*; available at: www.pfizer.com/research/research_clinical_trials/compensation_trial_participants.

other consent; and vii) the company is under strict liability to provide compensation if the volunteer is injured due to the drug product used during trial".[139]

In India the quantum of compensation for death through Serious Adverse Events (SAES) during clinical trials has been set by the Drugs and Cosmetic Rules after amendment (vide GSR 53(E) dated 30-January 2013) by inserting Rule 122 DAB and a new Appendix-XII in Schedule Y is considered to pay through help of Independent Expert Committee.[140] The following criteria were finally adopted. Firstly, criteria should not be discriminative in nature due to socio-economic conditions e.g. (a) income, (b) education; secondly, criteria should not discriminate gender/sex; thirdly criteria should not be such which may have minimal impact but may create large variability; fourthly, formula should be such that the inter group variability of compensation value so arrived at, has little scope of discretion, thus avoid possible bias. Thus, the following criteria were finally decided to be incorporated in the compensation formula. i) Age of the subject ii) Risk factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial. The computing the three factors i) age; ii) risk and iii) base amount for SAE/Death related to Clinical Trial:

"Compensation= B*F*R/99.37."[141]

a) B= Base Amount i.e. 8 lakh; b) F= Factor depending on the age of the subject based on Workmen Compensation Act; and c) R=Risk Factor depending on the seriousness and severity of the disease based on scale of 0.5 to 4 (0.5, 0.1, 0.2, 0.3, 0.4). However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs should be given. Thus, it will be seen that the compensation amount will vary from a minimum of Rs.4 lakhs to a maximum of Rs.73.60 lakhs depending on the age of the deceased and the risk factor. The committee will examine cases of SAEs of deaths and decide the final quantum of compensation after due diligence and application of mind on the risk factor and

[139] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf , p, 1-4.

[140] Compensation Formula: Clinical Trial, (2013), Formula to Determine the Quantum of Compensation in the Case of Clinical Trial Related Serious Adverse Event (SAES) of Deaths Occurring During Clinical Trials", GSR 53 (E), *The Drug and Cosmetic Rules, Schedule Y:*1-9; available at: www.cdsco.nic.in/writereaddata/formula2013SAE.pdf

[141] Ibid.

recommend the same to DCG (I) on case to case basis. The committee also considered the above formula as provisionally final.[142]

Conclusion

CT encourages new developments to safeguard and treat human health. Each new trial tries best to reduce side or late effects by understanding the dosage requirement for individual's body type, providing base for personalised medicine. Need of labeling of products by analysis of side effect and reactions based on metabolism demands proper regulatory and monitoring requirement. Registration is a mandatory requirement for ongoing and upcoming trials that has to be approved through ethical committees. CT has never been issueless, it carries two faces of same coin in one hand has burden of producing health achievements and in other hand offering of degrading and torturous suffering to vulnerable and poor individuals. Unethical and degrading and torturous treatment has always been linked with understanding of CT either through the case of Nazi experiment and the eugenic movement, etc; otherwise, through physicians' negligence or commercial nature. The Nuremberg code came as a contribution to suppress unethical nature of scientific experiment.

CT is one of the great and challenging efforts in arena of scientific technology and progress made towards health development. A process that requires voluntarily taken to examine result and effect of the drug product that is/has been developed for treating and curing disease and suffering. CT process that leads availability of drug product after examination and analysis provides promising result for human health treatment. Conducted CTs manufacture drugs/medicines for market approval. Growing international pharmaceutical companies and Government collaboration creates concern for unethical practices that has been followed time immemorial. To overcome the burden of blame game; registration helps in storing and providing secondary formulations in finding practice and knowledge for all illegal or unethical conduct followed in process of CT or sponsoring companies. Since registration carries every detail of the conducted trial from failure to promising result on subjects.

CT intervention has three triangle points' i.e risk, burden and benefits. These three hidden formulas encourage and provide hope to physicians understanding risk

[142] Ibid.

and burden. Moreover supports and provides hope to research participants by enrolling them observing requirement of minimising risk and burden by the research committee or review board while gathering informed consent of the participants. Benefits of individuals are that acknowledgement of one's own healthcare and type, can be gathered for free while treating. As well as such drug and treatment can be availed that has still not launched in market/hospital. Collected documents by CTs help in understanding positive and negative feedbacks during experiment findings that add value for society and scientific health developments.

These development of clinical trial/research experiment on human subject with the help of the Helsinki Declaration by its Principle No. 2 obligates "duty on the physicians to promote and safeguard health of the people. The physician's knowledge and conscience has to be dedicated to fulfillment of this duty". Similarly, the Nuremberg Code of 1947 in its principle No. 7 states on "proper preparation and adequate facilities to protect experimental subject against all remote possibilities of injury, disability, or death" has to be arranged. CTs that is both therapeutic and non therapeutic trials, have to be undergone prior on animal experiment, so that problems and anticipated results can be designed formulating gathered data's and knowledge.

Non-therapeutics trials that leads death and side effects demands monitoring requirement for health rights as it raises ethical issue by requiting subjects without their concern and knowledge. Taking targeted subjects from developing countries like India and Africa, demands proper approval of ethical committees. Once approval is provided registration becomes mandatory, the investigating team has to visit site and monitor trial between every intervals. CT gives way for drug approval for marketing. But this is the half way, where reaching prior to CT thousands of drugs failure makes possibility of one drug come in this stage. Every human intervention should follow a protocol based on scientific and research requirement that is set on the legal principles of the State and Country where such trial is being conducted. Protocol contains details of research design, potential conflict, funding, institutional affiliations, sponsors, etc. along with ethical consideration and post trial arrangements.

Furthermore, CT has been encouraging and incorporating biotechnology and medicine together with scientific development like cryonic preservation. CT being legal still requires monitoring and regulating arrangements. If right to health comes as

a convention then scientific development and monitoring of CT data base along with regulating and monitoring functions can be arranged properly.

The code of Nuremberg provides guidance for permissible medical experiments. The World Medical Association (WMA) Declaration of Helsinki 1964 consisting 37 main principles and preamble provides duty to promote and safeguard the wellbeing of its patient including the human subjects who are involved in medical research. Ethical standards should be maintained during conducting CT; in order to promote self determination, integrity, dignity, confidentiality of personal information and respect for health rights of all human subjects can be made possible. So a justifiable extension towards medical research can be provided. Ethical setup in CT is not a binding legal document, but arguably represents a customary law i.e law based on an established pattern of behaviour that can be objectively verified within a specific field.

Government monitoring and regulating system has many a time led to failure in regulating and monitoring the trial, its approval without proper verification and analysis of risk and challenges during the R&D. The On-site visit has to be made compulsory prior as well as during the research work. The ethical committees should be examined and audited prior granting approval to CT. Meetings along with reviews of authorised research work should be scrutinised by separate investigating teams along with ethical committees. Known voluntary consent is must and human subject who are involved without concern and knowledge in the trial either by the private/government hospitals/institutions or pharmaceutical companies should be strictly liable for their unethical conduct through the base of human rights perspective.

It seems compensation is must either for the subject who is involved in the study or who is brought without consent. The quantum of the compensation as measured for death or injury based on B*F*R/99.37 calculation is minimum of Rs.4 lakhs to a maximum of Rs.73.60 lakhs depending on age of the deceased and risk factor. This amount may not bring mental and physical satisfaction or peace to the family who cannot get the life of an individual that has been a research subject. But reimbursement as a settlement indirectly provides financial support during break down.

Chapter-IV

DRUG REGULATION AND LABELING IMPLICATION

INTRODUCTION

The right to enjoy highest attainable standard of health provides an expression of human values. Human values in health care can only be possible when good clinical practice in drug manufacturing and its production is set. Regulatory and monitoring of drugs can assist in combating counterfeiting drugs. Since drug access has always been a challenge to global health system. Its development through Clinical Trial (CT) assists in manufacturing treatment naive drugs for individuals. The pharmaceutical world takes privileges through novelty and contributes drugs/medicines for consumer health needs.

Labeling of drugs/medicines for consumers is an expression to establish safety and track of the produced drug through CT. Labeling of drug becomes possible when finished product after laboratory and CT is developed producing ideal combination to treat individuals sufferings and pain. Labeling supports in monitoring regulatory facilities by providing individuals awareness on combination and elements used in drug/medicine. This information can help different individuals to know which drug/medicine can provide positive or negative reaction. Drug labeling can facilitate individuals about products safety and date of expiry, etc.

Quality in healthcare can only be produced when monitoring mechanism for finished product is tracked during market approval. Supporting this argument the General Comment No. 14: the Right to Highest Attainable Standard of Health 2000 through Article 12 of the ICESCR in Article 12(d) states that:

> "(H)ealth facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment …".[1]

Drug inventions are conducted scientifically and with drug trials on individuals but often the marketed product after its launching falls under the cases of adverse drug effect (ADE)/reaction providing unsafe products to consumers. Labeling of products is a medium to create a condition to facilitate good and appropriate quality of drug. The ongoing process of expensive and financially sound drug development through CT, labeling etc. raises concern for fair pricing of drugs that can be accessed

[1] Article 12(d) of the General Comment No.14 of ICESCR.

and availed by every consumer without discrimination. In this context paragraph 6 of the Doha Declaration on the TRIPS on Agreement and Public Health 2003 [Article 2 (ii)] provides that:

> "(P)roducts produced under the license shall be clearly identified as being produced under the system set out in its Decision through specific labeling or marketing. Supplier should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price;"[2]

Hence, drug labeling is one of the key elements for marketing approved product. Pre-marketing arrangements guide for safety and quality mechanism through its packing, colouring and shape. So an individual/consumer can differentiate between authentic and counterfeit drugs through drugs layout and information. During labeling process pharmaceutical companies take ample space for patent and its expenses in developing such drug. Labeling of product for consumers benefit pharmaceutical companies to track and supply safe products, against identical counterfeiting goods. Regulation on drugs and its labeling provides a sphere of understanding wider meaning of RTH through drugs quality and standard. Once clinically approved drugs are labeled and prepared for marketing access and availability of quality healthcare becomes possible for treating individuals. Measures to provide authentic drugs to comsumers become important after it is launched in market. The African Charter on Human Right 1981 states in its Article 16(2), that:

> "(S)tate Parties to the present Charter shall take necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick".[3]

Drugs regulation and labeling process found through R&D results and CT provides legitimacy in ensuring drugs quality and efficacy. Regulatory method supports new drugs, traditional i.e. over-the-counter (OTC) and generic medicines fortification in marketing product. Regulation and labeling of drug is a medium to provide right to individuals health, through safe and legitimate drugs produced by the manufacturers.

[2] Article 2(ii) of the WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003).

[3] Article 16(2) of the African Charter on Human and Peoples' Right 1981; available at: www.1.umn.edu/humanrts/intree/z1afchar.html

Regulating Drug Development

Drug development is a scientific creation that is regulated through legal concerns on public health. Genomics/proteomic and biotechnology brought progressive improvement during drug development. This progress in drug development ensures ethical practice and standard of quality to be maintained by drug developer. Pharmacy-companies follow Good Laboratory Practice (GLP) to ensure the quality and ethical considerations are established.[4] While scientific application can provide self development by benefitting researchers as novelty. In the ICESCR 1966 [Article 15(1)(b) and 15(1)(c)] right to self development is a human right that provides benefit to others:

> "(T)o enjoy the benefits of scientific progress and its applications; to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

Thus scientific benefits of drugs developed by researchers have to produce novelty. Novelty benefits should not create havoc and concern for economic and social differences that exist in world of developing and developed. The Alma-Ata Declaration raises concern that primary health should include "practical, scientifically sound and socially acceptable method and technology."[5] In expensive and commercializing world, drugs are considered as one of the profiting business by the pharmaceutical industry. Whether such drug is of conventional or biologic types or medicines based on different scientific technological invention. For keeping such business growing through demand and supply chain, pharmaceutical companies target profitable business of drugs like seasonal diseases and cost-effective drugs for diabetes etc. In fact development of new drug often takes longer time span, specifically from 2 years to 12 years[6] i.e. from discovery to market.

The CT registry in form of clinical study provides transparency in safety and efficacy of drug that is essential to identify prior selling the product in market. Moreover, drug regulatory authorities apply three main standards to evaluate every product: i) safety; ii) efficacy; and iii) quality. The approved drug by authorities' carries decisions of drug regulators and preferred ones get published while negative

[4] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc, p.2-4.
[5] The Principle No. VI of the Declaration of Alma-Ata 1978; also See. Annex I.
[6] Tonkens, Ross., (2005), "A Overview of Drug Development Process", *The Physician Executive*, p.48.

decisions and unapproved therapeutic product are kept unrevealed.[7] In U.S by 1962 for new drug prescription it was mandatory to label "new drug will not poison people body by consuming it". If a drug cannot provide its safety and effectiveness then FDA would not approve the medicine to be sold in interstate.[8]

In US, Federal Food Drug and Cosmetic Act[9] are established to monitor and regulate quality safety and drug procedure for pre marketing. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act provide the FDA with authority to label drugs and biological product. Enact, regulate, and facilitate the approval or review of application regarding labeling of products.[10] This Act is understood to exist after an incident that took place in US during 1937, when 100 people died from diethylene glycol poisoning due to use of sulfanilamide elixir. This led Federal Food, Drug and Cosmetic Act in 1938 to regulate the pre market notification for new drugs.

Similarly, in 1956 when sale of thalidomide[11] sedative and hypnotic sale started from Western Germany that affected about 10,000 babies with phocomelia and other deformities. The US Congress passed the Drug Amendments Act of 1962 so that compliance mechanism of regulating drugs safety and quality could be made through Food & Drug Administration (FDA).[12] Through the appointment of Charles M. Wetherill by President Lincoln in 1862, FDA started in the U.S department of Agriculture having a single chemist. By 2001 there were about 9100 staffs having $1.294 billion budget. The FDA has various disciples of employees including chemists, lawyers, pharmacists, pharmacologists, physicians, microbiologists and veterinarians. About a third of the employees are working out stationed then Washington D.C having 150 field offices and laboratories including five regional offices and twenty district offices. FDA regulates animal feeds and drugs like livestock, pets etc.; biologics i.e vaccines, blood product; cosmetics like safety labeling; drugs i.e. prescript medicines, Over the counter (OTCs), generic etc.; food

[7] Herder, Mattew., (2014), "Towards a Jurisprudence of Drug Regulation", Journal of Law Medicine & Ethics, p.244-245.
[8] Bernstein, Anita., and Berstein. Joseph., (2006-2007), "An Information Prescription For Drug Regulation", Buffalo Law Review, 54, p.569.
[9] Seiden, Jessica., (2016), "Increasing Patient Safety by Permitting Generic Drug Manufacturers to Update Product Safety Labels", Law School Student Scholarship, Seton Hall University, eRepository@Seton Hall. Paper 736, p. 5.
[10] Ibid.
[11] Thalidomide is a sedative and hypnotic that was first soled in Western Germany and later in different 46 countries from 1958-1960.
[12] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", Wiley-Blackwell: New Jersey. 2nd edition, A John Wiley and Sons, Inc., p.211.

like nutrition, dietary supplements etc.; and radiation emitting products like cell phones and lasers, etc..[13] In favor of all new drugs, manufacturing levels can officially meet requirements of the good manufacturing practices.[14]

In Europe formation acceptance of the European Committee (EC) came after 10 years of the EEC Directive 65/65/EEC[15] on administrative, law and regulation relating to medicinal products. This Directive came after learned incident from disaster caused by thalidomide, which forced conception realization for harmonising EC together to look after drug regulation. Two council directives were introduced in 1975 as 75/318/EEC and 75/319/EEC. The first directive 75/318/EEC related to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. Whereas, the second 75/319/EEC is based on approximation of provisions laid down by law, regulation and administrative action of medicinal products. Moreover, 75/319/EEC established an 'old' Committee on Proprietary Medicinal Products (CPMP) as an advisory committee to the EC and introduced the multistate procedure known now as the mutual recognition procedure. Later on Directive 87/22/EEC introduced concentration procedure which is now known as the centralized procedure.

These directives, and following council regulation, were the landmarks for starting harmonisation inside the European Union with the final longstanding aim of creating a 'common market' for medicines. The Council Regulation EEC/2309/93 established the European Medicines Evaluation Agency (EMEA) in 1993 and re-established the CPMP as a 'new' CPMP to formulate opinion of the Agency on questions relating to submission of the applications and granting marketing authorizations in accordance with the centralized procedure.[16]

Patent Application for New Drug

A preplanned design involving high risk capital investment on research project to operational marketing objective has to be carefully verified prior applying patent

[13] Ibid.

[14] Rago, Lembit. and Santoso, Budiono. (2008), "Drug Regulation: History, Present and Future", in Chris.J. Van Boxtel, Budiono. Santoso and I. Ralph. Edwards (eds.) *Drug Benefits and Risk: International Textbook of Clinical Pharmacology*, The Netherlands: IOS Press and Uppasala Monitoring Centre, p.65-66; available at: www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf

[15] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", Wiley-Blackwell: New Jersey. 2nd edition, A John Wiley and Sons, Inc., p.211, 214-215.

[16] 75/318/EEC and 75/319/EEC, 65/65/EEC, EEC Directive. Ibid.

process. Patent application can be filed for new research project as well as patent freedom can be obtained. Besides, main procedure for patent[17] begins when promising results starts showing in pre-clinically examined products. The priority patent application is filled when designing of its strategy is prepared. So that the competing market of drug inventors is aware of the patenting project otherwise this delay may lead to heavy financial loss as well as disastrous consequences for promising project.

In order to understand whether to get patent or not, a priority application is filed so that pre-clinical test of the research project can be made. Moreover, it has also been learned that when foreign patent applications are made during the priority year, the pharmacological tests shows only preliminary results that can afterwards get abandoned due to side effects that may occur in later stage. Perhaps the concern of drug inventors for patenting their product during early stage and protecting their invention rights sometimes leads towards bulk of patent applications with patented products.[18]

From these patented products only 5% cover the marketed pharmaceutical product whereas the left over products will remain inactive in some countries where no payment is made and other countries slowly withdraw[19] the unused patent. This withdrawal of patent takes place observing product examination so that needless expenditure is avoided that occurs during R&D and concerned heavy risk of CT. During patenting activity and drugs R&D procedure, chemical investigation brings new active substance and process for its manufacturing, subsequently unexpected activities might be discovered during biological examination of the new product that facilitate in patenting strategy. So in the process of chemical development sometimes new method of manufacturing can be exposed with the old compound. Here it becomes important to find that process patent covers are taken with care elsewhere the process protection is sought later than the product patent.[20]

It has been observed during the controversy of Glaxo Smith Kline (GSK) in New York. When, antidepressant Paxil treatment was being tested on pedestrian population. As well as in 2004 when Vioxx medicine was producing myocardial infections and cardiac death in population after the drugs where launched in the

[17] Ibid.
[18] Jucker, Dr. E.M. (1982), "Drug Innovation and Patents", HeinOnline, 10 APLA Q.J, p. 82-85.
[19] Ibid.
[20] Ibid.

market. The Attorney General of New York prosecuted on the bases of off labeling and hiding of negative data's and producing only positive data's. This case resulted in bringing out demand of research data to public knowledge.

As access to information befall as component of right to health[21] along with requirement of acknowledging proper labeling of drugs through drug reactions. Further side effects through drugs/medicines have brought the use of pharmacogenomics (PGx) as personalised medicine. Personalised medicine is usage of drug dosage according to the body requirements that is evaluated through genetic revelation of a body which has now come up as a pattern of development for drugs and medicine practice. So that such developed drugs can provide safer, correct and more effectiveness treatment for specific disease etc.[22]

Process of Marketing Approval

The World Trade Organization (WTO) member countries are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to report to the WTO all proposed technical regulations that could affect trade with other Member countries.[23] Article 2(2) of the TBT Agreement in its regulatory goals states:

> "(O)n legitimate regulatory purposes for inspection of technical regulatory when protection for life/health/national-security/environment, safety, and prevention of depictive marketing practice is made. Moreover, the list is not limited; it may include the technical harmonization and quality standards which are legitimate".[24]

Further, such practice of Article 2(2) of the TBT Agreement is widely in use by the developed countries.[25] The TBT Agreement of the Uruguay Round entered into force on 1 January 1995. It has an understanding similar to the Tokyo Round Standards Code. However, adding on the things learned from the Tokyo Round

[21] Lemmens, Trudo., and Telfer, Candice., (2012), "Access to Information and the Right to Health: The Human Rights Case for Clinical Trial Transparency", *The American Journal of Law, Medicines and Ethics*, 38: 63-112. Boston University School of Law, p.69.

[22] PMC, (2007), "Personalised Medicine: Issues affecting adoption of Personalised Medicine", *PMC PM Issues 032107_Final*; available at: www.ashg.org/pdf/newsclip/PMC%20%20Issues%20affecting%20adoption%20of%20personalized%20medicine.pdf , p.1.

[23] South Africa, (2015), "Standards Overview", SABS; available at: www.ita.doc.gov/td/standards/Markets/Africa,%20Near-East%20and%20South%20Asia/South%20Africa/South%20Africa.pdf

[24] Article 2(2) of the Agreement on Technical Barriers to Trade, WTO.

[25] Appleton, Arthur. M., (2003), "United Nations Conference on trade and Development: Dispute Settlement, World Trade Organisation: 3.10 Technical Barriers to Trade", UNCTAD, New York and Geneva. UNCTAD/EDM/Misc.232/Add.22, p.1-46; available at: www.unctad.org/en/docs/edmmisc232add22_en.pdf , p.3-6

experience and ratifying the weaknesses of the Tokyo Round agreement remedies for the WTO's TBT Agreement were made. Firstly, it has been notified that TBT Agreement is a multilateral one not like single undertaking of Uruguay round the other plurilateral agreement that implies for all WTO members. Secondly, the TBT Agreement has stronger enforcement mechanism, being subject to the WTO's Dispute Settlement Understanding (DSU).

The TBT Agreement seeks to achieve a fine balance between permitting Members the regulatory autonomy to protect legitimate interests through the use of technical regulations, standards and conformity assessment procedures and assuring that technical regulations, standards and conformity assessment procedures do not become unnecessary obstacles to international trade. If the TBT Agreement is applied too strictly, the legitimate policy interests of Members will be thwarted. If the TBT is applied too laxly, technical regulations may be used for protectionist purposes and the gains Members have achieved through progressive rounds of tariff reductions may be lost. Some sensitivity is required when dealing with TBT issues. Developing countries fear that trade measures like technical regulations and standards, allegedly taken by developed countries for social policy goals may in reality be for protectionist purposes.

In fact the developed countries fear that the TBT Agreement will be applied too strictly and that trade measures designed to pursue legitimate social policy objectives will be struck down.[26] Further, the patented drug or the drug that is being manufactured for consuming by the patient has to be reviewed or inspected with proper drug approval and marketing authorization procedure prior launching the product in market. So, the set procedure for marketing approval of drugs in a country/State, the process of applying application has to be understood by accepting the required norms of the legal system of that particular country for submitting the form. The acceptance of the procedure makes investigational authorities to examine the chemical standard and requirements in drugs or the process through which it is made.

Article 13 of Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, 2003 states that:

> "(T)ransnational Corporation and other business enterprises shall act in accordance with fair business, marketing and advertising practices and shall take all necessary

[26] Ibid.

> steps to ensure the safety and quality of goods and services they provide, including observance of the precautionary principle. Nor shall they produce, distribute, market, or advertise harmful or potentially harmful products for use by consumers".[27]

So, that no adverse drug event (ADE) occurrence takes place. It's noteworthy to be aware of the two main regional blocks like U.S and Europe Union (E.U) marketing approval practice. Since, these two regional levels are the most advanced countries in technology than India and Africa; it's worthwhile to know their regulating process. So, an analysis with the flaws and best part of their regulating approval procedure for marketing can be examined and adopted in Indian[28] regulating procedure for marketing[29] of drugs.

The Indian drug regulating history dates back from British rule when drugs were imported from foreign countries. Due to which, in the 20th Century, foreign drug manufactures with adulterated drugs flooded. The Giagantic Quinine Fraud brought the GOI to form a drug inquiry committee known as Chopra Committee under Sir Ram Nath Chopra who recommended for the Drug Bill in Legislative Assembly of India. This drug bill amended as The Drug and Cosmetic Act (1940) [D and C Act] and Drugs and Cosmetic Rules (1945). The Central legislation regulates the drug and cosmetic distribution, manufacturing, import and sale, which further led to the establishment of the Central Drugs Standard Control Organisation (CDSCO) and the office of the Controller, the Drug Controller General of India (DCGI). There are two main Ministries that regulate the drugs in India. These are: i) the Ministry of Health and Family Welfare; and ii) the Ministry of Chemical and Fertilizers. The regulation relating patent and export of drugs is made through: i) the Department of Industrial Policy and Promotion; ii) the Directorate General of Foreign Trade under the Ministry of Commerce and Industry; iii) the Chemical Fertilizers etc. Apart from these two Ministries three are other regulating aspects of drugs: the Design Act (2000); the Drug [Price Control] Order 1995 [under the essential commodities Act]; the Drug and Magic Remedies [Objectionable Advertisement] Act (1954); the Factories Act (1948);

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[27] Article 13, "Obligations with Regard to Consumers Protection", from Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights (2003).

[28] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A. (2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.2 and 4.

[29] Prior marketing or selling any drug after labeling in India the Section 96 of the Drug and Cosmetic Rules 1945 has to be followed that states on the manner of labeling in India. Also See Section 96 of the Drug and Cosmetic Rules 1945.

the Indian Patent Act (1970); the Industries [development and Regulation] Act (1951); the Insecticide Act, (1968); the Medicinal and Toilet Preparation [Exercise Duties] Act (1985); the Narcotic Drugs and Psychotropic Substances Act, (1985); the Poison Act of (1919); and the trade and Merchandise Marks Act (1958).

The two developed regions of U.S and Europe can be more advanced and challenging in nature for comparison. The study can be made to observe and analyse how regulating body functions for further perspective of Africa[30] and India. To understand the broad range of responsibilities in providing access to medicines, the African medicines regulatory authorities (MRAs) works hard in spite of limited resources in order to produce generic medicines. The difficulty is not just limited to economic funding. But, lack of skills and capacity for performance along with limited access for latest products is also a setback. As a result, African national MRAs experience limited assessing, approving and registering of innovator products like the vast majority of which are for global chronic diseases, such as diabetes, hypertension and cancer. Moreover confusion and complexity resulting from different technicalities and individual requirements in African markets for different region levels is finding difficulty in supplying medicines by manufacturers for internal supply chain arrangements within pharmaceutical companies in some specific regions. As well as, this dis-connectivity is also found in the arrangements of following the African Medicines Registration Harmonization Initiative (AMRHI) experience of pharmaceutical companies at country level.[31]

While studying, understanding and analysing it is presumed during the basic regulation on drug development that prior coming to the market it has to go through all the process of manufacturing, clinical trials and labeling. This step or process of getting drug approval for marketing is followed by drug manufacturers or pharmaceutical companies. This helps in launching their manufactured drug product in the market without any further legal complication or disorder. This process of market approval is not just limited to U.S[32] drug development and marketing

[30] Narsai, Kirti., Williams, Abeda., and Teeuwisse, Aukeje Kaija Mantel. "Impact of Regulatory Requirements on Medicine Registration in African Countries-Perception and Experiences of Pharmaceutical Companies in South Africa.", Southern Med Review: An International Journal to Promote Pharmaceutical Policy Research, 5 (1): 31-37, p. 32. 33 and 36.

[31] Ibid.

[32] Pharmaceutical Research and Manufacturers of America (PhRMA): Research, Progress Hope, (2015),"Medicines in Development: Explore the latest Progress on Medicines in Development",

approval, but this regulation procedure is also followed through all the countries and regional states.

In 2013 the U.S. Food and Drug Administration approved 34 new medicines, 27 of which were approved by the Center for Drug Evaluation and Research (CDER) and seven by the Center for Biologics Evaluation and Research (CBER). Among the drugs approved were eight medicines to treat cancer, including the first treatments for the first two medicines approved with "*Breakthrough Therapy*" designation, the first antibody-drug conjugate approved for breast cancer, and two for melanoma.[33] In U.S the import of drugs should comply with the applicable requirements of FDA. As far, U.S is one of the countries whose filing of application and reviewing of standard is considered one of an ideal procedure for drug approval. The flow chart in the Figure 3.1 tries to bring out the depiction of the filing request practice for drug marketing application.

In view of the above, an observation can be drawn as to how acceptance/rejection through inspection of the same is made for drug approval for marketing. Besides, for submitting application in U.S for marketing the approval is made for generic or new drug. Figure 3.1 states about prior filling application for new drugs in U.S market; investigational new drug[34] (IND) application is filed. The IND application is a process to start clinical trials in human beings. This procedure begins after filing the application to U.S FDA. But, pre-IND meeting is arranged prior filling the IND application based on the results and R&D of animals design that may support in human trials, the protocols that has been followed during the clinical trial as well as the control of investigational drug observing the manufacturing etc.[35] IND application is an approval process made through the outcome provided by R&D, clinical trials and data analysis made in the findings that was carry forward prior to submitting application for marketing i.e new drug application. On the other hand, for generic drugs abbreviated new drug application[36] (ANDA) is submitted.[37]

PhRMA, Washington, DC; available at: www.phrma.org/innovation/meds-in-development#sthash.eVyoYY8U.dpuf

[33] Ibid.

[34] Kashyap, U. Nitin., Gupta, Vishal., and Raghunandan, H.V., (2013) "Comparison of Drug Approval Process in United States & Europe", Journal of Pharmaceutical Science and Research, 5 (6), p. 131.

[35] Ibid.

[36] Seiden, Jessica., (2016), "Increasing Patient Safety by Permitting Generic Drug Manufacturers to Update Product Safety Labels", Law School Student Scholarship, Seton Hall University, eRepository@Seton Hall. Paper 736: 1-28, p.6.

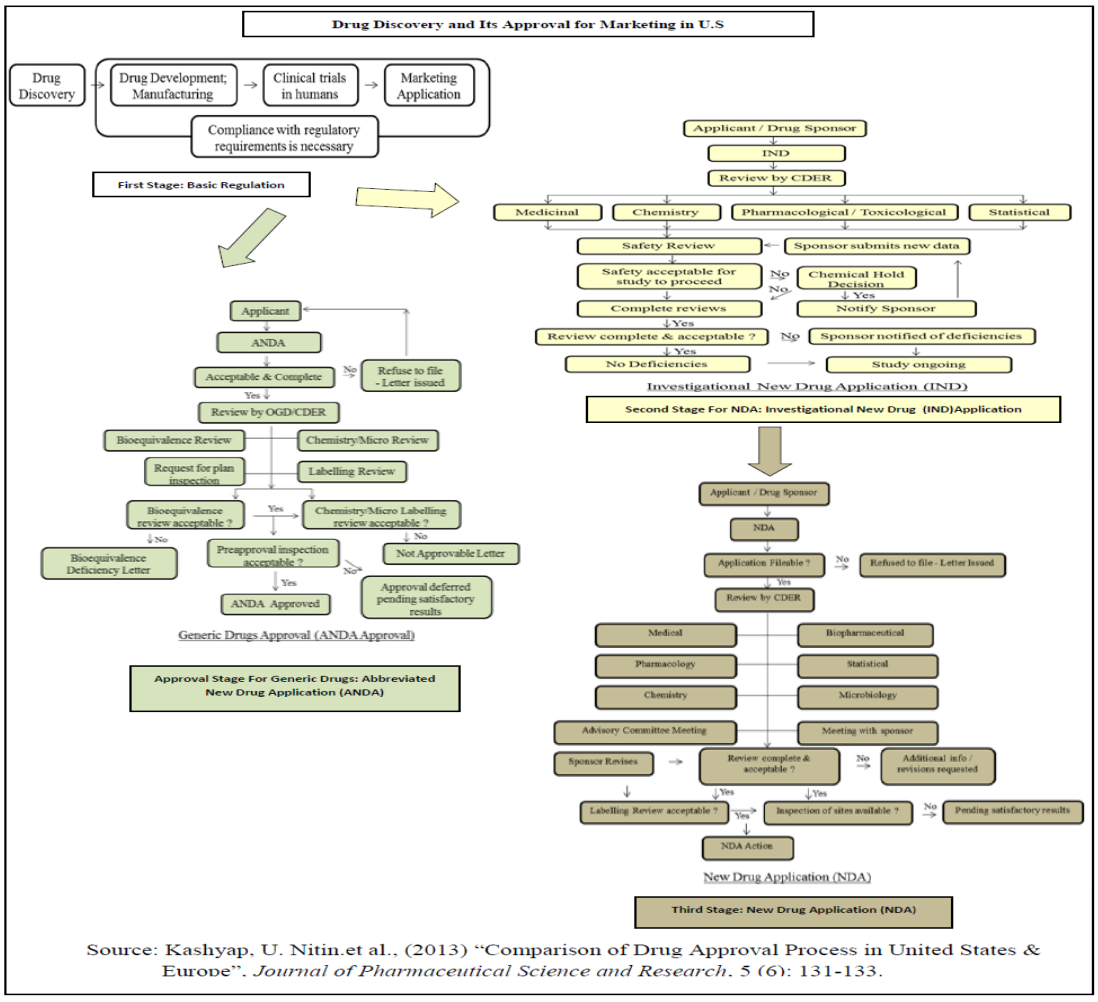
[37] Findlay, Richard J. (1999), "Originator Drug Development", Food & Drug Law Journal, 54, p. 221.

In the ANDA the generic drug manufacturers have to show that the previously approved medicine and the present generic drug contain the same bioequivalent product.[38] Generic drugs usually take three to five years for development, along with the ANDA application. Moreover, these generic drugs are developed when most of the original drug products patent is about to get over generally prior from three to five years. These medicines have already been in the market for at least 5 to 10 years. It is also specified that while developing generic drugs process must include an investment of about $1,000,000 i.e one billion; the active ingredients for the drugs has to be bought or made; a formulation is developed in the process; testing of product is done; standards are set according to available information or U.S Pharmacopeia; and approval of the product that can always have multiple review cycles that takes about more than six months.[39]

This requires only name and previous patented authorities, NOC letter along with their patented details of the present ANDA[40] medicines detail for regenerating it. The following flowchart/Figure 3.1 tries to illustrate procedure for applying application in U.S drug marketing approval. While examining the increasing requirement of generic drugs in 2012 the Congress under the Food and Drugs Administration Safety and Innovation Act enacted new branch of the Generic Drug User Fee Act. The Generic Drug User Fee Act while ensuring the safety of drug provides low cost facility for generic manufacturers to pay as fees. Supplementing cost for examining generic drug application is later scrutinized with speedy approval.[41]

[38] Ibid.
[39] Ibid.
[40] Seiden, Jessica., (2016), "Increasing Patient Safety by Permitting Generic Drug Manufacturers to Update Product Safety Labels", Law School Student Scholarship, Seton Hall University, eRepository@Seton Hall. Paper 736, p. 8.
[41] Ibid.

Figure 3.1: Drug Discovery and Its Approval for Marketing in U.S



Source: Kashyap, U. Nitin.et al., (2013) "Comparison of Drug Approval Process in United States & Europe". *Journal of Pharmaceutical Science and Research*. 5 (6): 131-133.

In the process of filling the application as mentioned in Figure 3.1, it states that the sponsor i.e a firm or institution that finances the project, has to submit the application for IND/NDA. Moreover, Figure 3.1 points about how inspection takes place by Center for Drug Evaluation and Research (CDER) for new drugs and by CDER/(OGD) for generic drug marketing approval application. As, the inspection of IND confirms safety and effectiveness along with no risk on patients' for new drug then NDA[42] application is filled so that request for manufacturing and selling of drugs in U.S market can be confirmed.

There are three types of NDA under Section 505 and they are: i) For application containing full reports of investigations of safety and effectiveness. The investigations the applicant relied on for approval were conducted by or for the applicant, or the applicant has obtained a right of reference or use for the

[42] N.G, Rick. (2009), "Drugs from Discovery to Approval", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc, p. 240.

investigations under section 505(b)(1); ii) under Section 505(b)(2) Application of NDA the investigation for some or all of the applicant relied on for approval were not conducted by or for the applicant, and the applicant has not obtained a right of reference or use for the investigations. Further, Section 505(b)(2) expressly permits the FDA to rely, for approval of an NDA, on data not developed by the applicant, such as published literature or the FDA's finding of safety and/or effectiveness of a previously approved drug product. iii) 505(j) Application, ANDA that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved application i.e. the reference listed drug (RLD). ANDAs do not contain clinical studies as required in NDAs but are required to contain information establishing bioequivalence to the RLD. In general, the bioequivalence determination allows the ANDA to rely on the FDA's finding of safety and efficacy for the RLD.[43]

On the other hand, it is evident in Figure 3.1 that while filling application for generic drugs in U.S the sponsors are not required going through clinical study to confirm its validity. Moreover, they have to directly go for approval stage i.e fill an abbreviated new drug application (ANDA) in U.S to get approval to manufacture generic drug. In ANDA the product description as well as previously approved brand demonstration with bioequivalent[44] invention that is already filled with FDA has to be demonstrated while filling the application form.[45] In bioequivalent requirements the CRO has to be audited by FDA. The reserve sample is required to go through 5 times analysis. It is fasted/fed according to the OGD recommendation and for 5 years samples are preserved from date of filling the application form. So far, no Braille code is required for labeling of medicines as well as changes can be made in drugs through filling of PAS; CBE-30/CBE; and Annual Report.[46]

The example of U.S for sale and marketing of new drugs through marketing approval process. It's important to know and understand that efficacy, potency, purity and safety of drug has to be demonstrated by the Sponsor while filing its approval

[43] Ibid.
[44] Kashyap, U. Nitin., Gupta, Vishal., and Raghunandan, H.V., (2013) "Comparison of Drug Approval Process in United States & Europe", *Journal of Pharmaceutical Science and Research*, 5 (6), p.131-133 and135.
[45] Ibid.
[46] Ibid.

application form. This rule, applies to all the regulating bodies of different country levels, like for European Medicines Agency (EMA) of European Union[47] (EU), for African[48] and Asian level drug regulatory functions through States/nation level. EU has 28 member states.[49]

The European Economic Area (EEA) is formed of plus 28 EU Members like Iceland, Liechtenstein, and Norway. EU operates through a supranational independent institutions and intergovernmental negotiation by the decisions of its member states. There are 24 official languages in 28 EU member states, which follow same rules and harmonised procedures of laws. This includes authorization of medicines and supervision of the safety of medicines. Moreover, the EU's main forums for multilateral international cooperation is the International Conference on Harmonization of technical Requirements for Registration of Pharmaceuticals for Registration of Pharmaceuticals for Human Use (ICH) that brings together Japan, Europe and U.S drug regulation for safety, efficacy and quality for approving new drugs.[50] The Africa regional drug regulatory is working in its evolving phase through the New Partnership for African's Development (NEPAD) programme. So alleviation of poverty and economic and sustainable growth can be possible in Africa. NEPAD also has a technical body established in 2010 by 14th AU Assembly named as NEPAD Planning and Coordinating Agency (NPCA) in replacement of NEPAD Secretariat. So far, in the process of making African regional regulatory framework for drugs regulation African Union (AU) with the help of National Medicines Regulatory Authority in Africa, WHO is establishing African medicines Regulatory

[47] EMA, (European Medicines Agency), Science Medicines Health, (2014) "The European Regulatory System for Medicines and the European Medicines Agency: A Consistent Approach to Medicines Regulation Across the European Union", An Agency of the European Union, European Medicines Agency, United Kingdom, EMA/437313/2014, p. 4-5; available at: www.WC500171674.ema.europe.pdf

[48] NEPAD, (2015), "African Medicines Regulatory Harmonisation Programme (AMRH)", NEPAD: Transforming Africa, AU and WHO; available at: www.amrh.org/wp-content/uploads/2015/10/Call-for-Abstracts-SCoMRA_Deadline-extended_Eng.pdf ; also see, www.amrh.org/programme-officer-communications.html

[49] They are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Solvenia, Spain, Sweden, United Kingdom,

[50] EMA, (European Medicines Agency), Science Medicines Health, (2014) "The European Regulatory System for Medicines and the European Medicines Agency: A Consistent Approach to Medicines Regulation Across the European Union", An Agency of the European Union, European Medicines Agency, United Kingdom, EMA/437313/2014, p.4-5; available at: www.WC500171674.ema.europe.pdf

Harmonization Programme (AMRH).[51] NEPAD got adopted with the help of African Union (AU) in 2001 Lusaka (Zambia) with headquarter in Addis Ababa, capital of Ethiopia. Till date, two Biennial Scientific Conference on Medicines Regulation in Africa (SCoMRA) has been organised; To provide a platform for deliberating on the role of medical products regulation in the implementation of Africa's post 2015 development agenda and Agenda 2063. So that a platform to enhance collaboration and networking among policy makers, regulators, industry, academia, scientific community and civil society can be possible.[52]

However, at the Asian level, their legal norm becomes hard to make the rules obligatory due to its fragmented regional differences within one region. While, this different regional specific regulatory process is not just limited in Asia it is also seen in Africa.[53] At present South Africa has a regulating body named as Medicines Control Council (MCC) that has been developing since last 50 years. MCC works as a regulating body with internationally recognised standards. South African MCC works for its standards through manufacturing, marketing of medicines, distribution and sale through the Medicines and Related Substance Act, (Act 101 of 1965).[54]

In South Africa for importing products the quality or standard should be according to the South African Bureau of Standards (SABS), it is obligatory for the entire chemical, food, electric, electronic, food and health products for public safety. SABS is a specialised agency of Department of Trade and Industry. SABS is recognised internationally by Netherlands-based Raad voor Accreditatie (RvA) SABS follows the standards of: a) International Standard Organisation (ISO); b) International Electro technical Commission (IEC); and c) African Organisation for Standardisation (ARSO). Moreover, for natural and fiber materials the packaging should come with an official certificate that the material has been fumigated. Therefore the Certificate organisation taken for SABS in South Africa are: i) South African National Accreditation System (SANAS); ii) South African Chamber of Commerce and Industry (SACCI). For labeling requirements the name, trade name, or description should be provided along with name and complete address of manufacturer/packer, importer, country of origin of the importer, net weight, number

[51] Ibid.
[52] Ibid.
[53] MCC, (2015), "Overview", Medicines Control Council, E2 Solutions; available at: www.mccza.com/About , p.1-2.
[54] Ibid.

or volume of contents, distinctive batch, lot or code number, month and year of manufacturing and packaging, month and year by which the product is best consumed. All the information for pharmaceutical and industrial products should be in English. Whereas, for food products if genetically modified should indicate it in the label.

In South Africa there are five national standards organisations that looks after commercial and industrial norms and they are: i) South African Bureau of Standards (SABS); ii) Engineering Council of South Africa (ECSA); iii) Council for Scientific and Industrial Research (CSIR); iv) Human Science Research Council (HSRC) and v) Medicines Control Council (MCC). As well as, there is the Pharmaceutical Industry Association of South Africa (PIASA) that is a trade association of companies involved in the manufacture and/or marketing of medicines in South Africa. The membership of 18 companies includes a broad representation of foreign multinational pharmaceutical companies and local and generic companies, both large and small. The pharmaceutical companies supply both the private and public sectors.[55] Mainly the African region has four economic communities and they are: i) Southern African Development Community; ii) East African Community; iii) Economic Community of West African States; and iv) Economic Community of Central African States.[56] But, in Asian level Japan and China have the most developed drug regulatory system due to their demand and supply rates. But the Indian regulatory system is weak, because India progress towards medicines is still slow. The Japan Ministry of health labour and welfare[57] (MHLW) of Japan looks after the regulatory function and for China the State Food and Drug Administration[58] (SFDA) takes care of regulatory function. Japanese pharmaceutical market is the second largest in the world. SFDA is under the state Council and works through the Drug Administration Law of the People's

[55] Narsai, Kirti., Williams, Abeda., and Teeuwisse, Aukeje Kaija Mantel., (2012), "Impact of Regulatory Requirements on Medicine Registration in African Countries-Perception and Experiences of Pharmaceutical Companies in South Africa.", Southern Med Review: An International Journal to Promote Pharmaceutical Policy Research, 5 (1), p. 31 and 36; also see, Santander Trade Portal, (2015), "Packaging and labeling regulation in South Africa" South Africa: Packing and Standards, Export Enterprises SA, Argentina, p.1-3; available at: www.en.santandertrade.com/international-shipments/south-africa/packaging-and-standards

[56] Ibid, p. 31.

[57] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc, p.216.

[58] Ibid, p.217.

Republic of China. China's pharmaceutical market in 2020 is considered to be world's largest market.[59]

The Japanese regulatory body works with MHLW and some offices for New Drugs, biologics, OTC and Generics that is examined through the National Institute of Health Sciences or the infectious Disease Surveillance Centre. MHLW has three main parts and they are: a) the pharmaceutical and Food Safety Bureau (PFSB) takes care of the policies so that safety and efficacy of drugs/medical devices are assured as well as clinical trials, importation and manufacturing of medicines is also reviewed and approved from the Bureau; b) the Health Policy Bureau looks after distribution and production policies so that high quality and Pharmaceutical and Medical Device Agency (PMDA/KIKO) can be produced as well as revisits on clinical protocols along with drug submissions, including bioequivalence and the research and testing on drugs is made through PMDA/KIKO. Moreover, for pharmaceutical and food matters the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) works as an advisory body for MHLW.

On the other hand India[60] has the Central Drugs Standard Control Organisation that regulates drugs through the Ministry of Health & Family Welfare. Indian regulatory system is still struggling with the mandates requirement for drug testing and research and follows least calculative method for drug approval. In India for importing[61] of drugs under Rule 31 of Drugs and Cosmetic Rules to permit the import of drugs having less than 60% residual shelf life is not required for the import of drugs for purpose of test and analysis including clinical trials.[62]

> "Some of the details for filling the fresh registration Certificate for import of drugs is made through submitting Form 41 for drug product (s)/Drug substance(s). Form 41 is filled for pre-screening checklist. Rule 37 is followed in order to acknowledge whether the drug is patented and is propriety medicine. Form 10 licenses for validly of import of drug in bulk quantity, together with fee of Rs. 1000/- has to be paid for single drug and 100/- each for additional drug. Form 8 specify's the destination

[59] Ibid, p.217.
[60] Ibid, p. 4, 216-217.
[61] CDSCO: Form 41, (2015), "Pre-screening Checklist for Fresh Registration Certificate in Form 41 for Drug Product (s)/Drug Substance (s)" Central drugs standard control organisation, Directorate general of health services, Ministry of Health and Family Welfare Government of India (Import & Registration Division), MH&FW, New Dehi, p.1-5. available at: www.cdsco.nic.in/writereaddata/rc%20&%20form%2010%20checklist.pdf
[62] This statement is stated by Dr. G.N. Singh, Drug Controller General of India. Which is forwarded to all zonal, sub zonal and ports offices on 1 December 2015 by import and registration division FDA Bhawa, Kotla Road, New Delhi. F.No. Import/Misc/2015-DC (shelf life less than 60%), Director General of Health Services, Office of Drug Controller General, Import & Registration Division; available at: www.cdsco.nic.in/writereaddata/import%20drugs60%20new(1).pdf

> license for importing drugs. Form 9 stats the manufacturer or Indian agent specific along with seal of Indian Embassy for importing. Permission letter, having Rule 122A for New Drug importers name, is required along with details of wholesale license number i.e Rule 24A. Confirmation of manufacturer's name and its manufacturing site has to be stated as per Form 40. TR-6 Challan fees has to be paid i.e 1500 USD for one site or its equivalent in Indian currency and 1000 USD for one drug or its equivalent in Indian currency. All these arrangements have to be settled through the director general of health services, ministry of Health and Family Welfare, Government of India import and registration division".[63]

Moreover, distribution, import, manufacturing and sale of new drugs[64] and clinical trials takes place under the Drug & Cosmetic Act 1940 & Rules 1945 along with requirements of Schedule-Y in India, It states:

> "New drug according to the Rule 122 E of Schedule Y of the Drug and Cosmetic Act means new molecule along with that new drug which is being first time introduced in a country as well as the drug which shows new indication and new dosage form of an approved drug is also considered as a new drug. Even the fixed dose combination of drug considered having already in use is also considered new drug".[65]

The division of Central Drug Standard Control Organisation (CDSCO) is responsible for registration/import of New Drugs in India. In India registration is not required for import of New Drugs for Testing / Clinical Trial purpose. However, the NOC/Test-License in Form 11 is mandatory. Any individual or Hospital based by doctor's prescription can import new drugs under personal License[66] (11A/ 11B) issued under Drugs and Cosmetics Act, 1940 and Rules 1945.[67] Observing the South Africa, Medicines Control Council (MCC) it operates through members of Council Committee structures these members are external experts who are from academic and institutions mainly of medicinal and pharmacy background. Most of the experts are the evaluators of drug data submitted by the pharmaceutical industry for registration

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[63] Ibid.

[64] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.4.

[65] Ibid.

[66] Licensing and quality control and distribution of drugs are made by CDSCO, Department of Biotechnology, Ministry of Science and Technology (DST), Department of Environment and Forests especially after the decline of vulture population, MOHAFW. For details, see, Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1): 2-9. p.4.

[67] Clinical Development Services Agency "Frequently Asked Questions-New Drug Regulations", Clinical Development Services Agency, An extramural unit of THSTI, Department of Biotechnology, Ministry of Science & Technology, Government of India; available at: www.cdsaindia.in/faqs-new-drug-regulations.

and works as the administrative and technical supporter to the office of the Registrar. The Registrar is also an executive secretary to the council. The Registrar's office is a Chief Directorate/Cluster, Food Control, Pharmaceutical Trade & Product Regulation, within the Department of Health. In order to look after the co-ordination and execution of various activities there are four directors. This cluster is the secretariat to the council, who are doctors, pharmacists, veterinarians, other scientists. The Councils and Committees are expert in biotechnology, chemistry, clinical pharmacology, immunology, internal medicine, medicine safety, neonatology, pediatrics, pharmaceutical chemistry, pharmaceutics, toxicology, veterinary science, virology, complementary medicines and law. The Committees include biological medicines committee; clinical committee; clinical trials committee; complementary medicines committee and legal committee; names and scheduling committee; pharmaceutical and analytical committee; veterinary clinical committee; In order to provide more generic medicine over time for in house technical evaluation of generic medicine is made, so that improving access to medicines as a government policy gets implemented. There are nine active technical council members along with 146 members from different institutions with the South African Country.[68]

The European Union (EU) has reformed the rules for importing into the EU active substances for medicinal products for human use. All imported active substances must have been manufactured in compliance with standards of good manufacturing practices (GMP) at least equivalent to the GMP of the EU. The manufacturing standards in the EU for active substances are those of the 'International Conference for Harmonisation'-ICH Q7.[69]

> "(L)egal provisions include in Annex.1 of Directive 2001/83/EC and Directive 2001/82/EC. In addition, EudraLex Volume 3 includes Scientific guidelines for medicinal products for human use on quality prepared by the Committee for Medicinal Products for Human Use (CHMP) in consultation with the competent authorities of the EU Member States. Similarly, the Committee for Medicinal Products for Veterinary Use (CVMP) states about additional specific guidelines applicable for the veterinary sector i.e. EudraLex Volume 7 Scientific guidelines for medicinal products for veterinary use-7B Immununologicals/Quality. Such guidelines have to be followed in accordance to the practical harmonisation in format of the EU Member States and the EMA explains and validates its complete requirements for the revelation of quality enclosed in the Community Directives. Applicants and

[68] MCC, (2015), "Overview", Medicines Control Council, *E2 Solutions,* p.1-3; available at: www.mccza.com/About.

[69] European Commission, (2015), "Medicinal Products for Human Use", Quality of medicines and Good Manufacturing Practices (GMP)-Major developments, Public Health; available at: www.ec.europa.eu/health/human-use/quality/index_en.htm

> competent authorities refer these guidelines while preparing or assessing an application for a marketing-authorisation. Competent authorities may decline to authorise a medicinal product for marketing. In the case of products has already been authorised, so the competent authorities can suspend, revoke, withdraw or vary a marketing authorisation. Moreover the quality and quantitative composition will also be scrutinised. Furthermore, Member States shall take appropriate steps to ensure that the supply of the medicinal product is prohibited and the product is withdrawn from the market, as under Articles 26, 116 and 117 of Directive 2001/83/EC. The manufacturing or importation of medicinal products, including investigational medicinal products, is subject to a manufacturing or import authorisation. The holder of such an authorisation is obliged to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances i.e. active pharmaceutical ingredients, which have been manufactured in accordance with GMP Part II i.e. Title IV of Directive 2001/83/EC. Article 13 of Directive 2001/20/EC, Title IV of Directive 2001/82/EC. The Commission has adopted the principles and guidelines of GMP for medicinal products in form of Commission Directive 2003/94/EC concerning medicinal products for human use and investigational medicinal products and Commission Directive 91/412/EEC for veterinary medicinal products. In addition, the Commission has published detailed GMP guidelines in line with those principles in EudraLex Volume 4. In this context, the Commission is revising on a regular basis the GMP guidelines, in collaboration with the European Medicines Agency. The guidelines are revised to take into account the advancement of scientific practices. In 2011, the "Chapter 4 on Documentation" , "Annex 11 on Computerised Systems" and "Annex 14 on Manufacture of Products derived from Human Blood or Human Plasma" have been finalised. The EU Community has concluded Mutual Recognition Agreements (MRAs) covering the sector of GMP with Switzerland, Canada, Australia, New Zealand, Japan and Israel. In line with the scope of each MRA the EMA and the Commission have published information as to which areas, including product categories, are under the operational scope of these agreements. On the basis of equivalent provisions for GMP and supervision by competent authorities, the EU and the third country mutually accept results of inspections of manufacturers. Furthermore, the qualified person of the importer in the EU may be relieved of his responsibility to carry out the so-called re-testing. For active substances importation requires by a written confirmation from the competent authority of the exporting third country which, as regards the plant manufacturing the exported active substance, confirms that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union according to Article 46b(2) of Directive 2001/83/EC."[70]

Furthermore, in the process of understanding the marketing procedure for approval in European Union regulatory system for medicines. One must know this marketing approval is made through multiple process of registration and they are: i) centralized: the centralized procedure is process in which biotechnology processes such as genetic engineering has to obtain compulsory approval for marketing this procedure also mandatory for those medicines that are meant for cancer, diabetes, HIV/AIDS, neurodegenerative disorders, auto immune or other immune dysfunctions diseases and orphan medicines i.e meant for rare diseases. Countries like Norway,

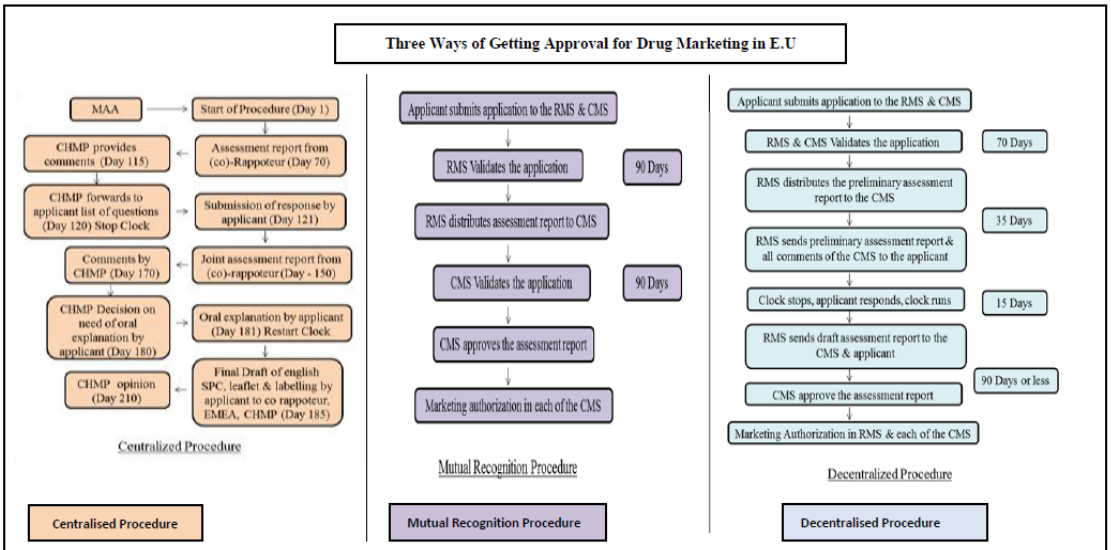
[70] Ibid.

Iceland and Liechtenstein go for single authorization validity. The opinion of EMA is issued in 210 days as well as an assigned Rapporteur evaluates the application; mutual recognition: the mutual recognition procedure is one of the four approval process for marketing of drugs in E.U. This procedure enables the applicant to obtain approval to other concerned member state (CMS) other than the member state i.e Reference Member State (RMS) where approval of the drug is previously obtained. The RMS, is a process when the manufacturers approval of drug gets confirm from one of those applied member states of E.U in which the drug needs to be marketed. When such approval is confirmed through one of applied states the approved states i.e the RMS issues report to CMS about getting the marketing approval on its findings in almost 390 days. Moreover, generic manufacturers are major user of such process; nationalized procedure: the nationalized procedure is the one in which applicant only one member state of E.U is obtained approval for marketing of drug. An application to the competent authority is submitted.

These drugs providing new substance activity that are not mandatory under Centralized procedure can obtain marketing in nationalized procedure. This procedure takes 210 days for approval; and decentralized procedure: In process to get marketing approval from more than one E.U countries, through decentralized procedure. The company can get approval on those products that have not yet been authorised in any of the E.U countries and do not fall under essential drugs list of centralized procedure. This approval takes 210 days, when approval is made by the decision of RMS and CMS. That prepares the assessment report and makes comment on such application. Whereas the national procedure is the one that includes one member state. In the E.U Braille code is compulsory for labeling of medicines, whereas, changes can be made in the approved medicines through filling Type IA Variation; Type IB Variation and Type II Variation.[71]

[71] Kashyap, U. Nitin., Gupta, Vishal., and Raghunandan, H.V., (2013) "Comparison of Drug Approval Process in United States & Europe", *Journal of Pharmaceutical Science and Research*, 5 (6): 131-136, p.133-135.

Figure 3.2: Three Ways of Getting Approval for Drug Marketing in E.U



Source: Kashyap, U. Nitin.et al., (2013) "Comparison of Drug Approval Process in United States & Europe", *Journal of Pharmaceutical Science and Research*, 5 (6): 134.

It is important to note that this regulatory system is based on the network of the 31 European Economic Area (EEA) member states, the European Commission and the European Medicines Agency (EMA). The Figure 3.2 tries to explain how the marketing arrangements are settled in EU authority. The EMA's Committee for Medicinal Products for Human Use (CHMP), as mentioned in the Figure 3.2 looks into the scientific assessment of the application for the recommendation of approving or cancelling the grant for marketing authorization. CHMP or the Committee for Medicinal Products for Veterinary Use (CVMP) works together. However, as this work is limited to human subjects, animal and other subjects are not addressed. Once this authorization is guaranteed it is approved all over EU member States. Centralized procedure is necessary for certain medicines generally innovative drug. Most of the drug do not fall inside the range of the centralized procedure but are authorised by national competent authorities (NCAs) in the Member States.

Figure 3.2 shows that most of companies when go for authorization of a medicine in several Member States, they can use one of the following procedures: Like in order to get simultaneous authorisation the decentralized procedure is applied in more than one EU Member State if it has not yet been authorised in any EU country and it does not fall within the mandatory scope of the centralized procedure; or the mutual-recognition procedure where companies that have a medicine authorised in one EU Member State can apply for this authorization to be recognised in other EU

countries. This process allows Member States to rely on each other's scientific assessments. Rules and requirements applicable to pharmaceuticals in the EU are the same, irrespective of the authorization route for a medicine.[72]

The understanding of drug approval for marketing gives a picture how developed countries goes for minute procedure of scientific testing prior granting the approval for marketing. This calls for appropriate regulation to usher drug product to come in market.

Legal Implications in Accessing Drug

Drug is a substance that induces response of beneficiary or harm to a body.[73] According to Food & Drug Administration (FDA) of U.S the definition for drug is:

> "An active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of a disease, or to affect the structure of any function of the human body, but does not include intermediates used in the synthesis of such ingredient".[74]

FDA states that drug is an ingredient that provides pharmacological work as therapeutic or prophylactic pharmaceutical that benefits human body. Moreover, drugs helps in providing "enjoyment of highest attainable standard of health",[75] measures during sick. Drug access has always been a challenge to global health system. Supplementary, more challenges lie when new emerging illness, old virus as well as reoccurring pattern of diseases hits and it becomes tough to provide RTH facilities.

Since, ongoing R&D through CT keeps taking place in form of new and generic medicines. In embracement of providing essential drugs cartel nature through pharmaceutical companies bring concern towards pricing of drugs. Regulatory process in drug development forces pharmaceutical companies to concentrate towards treatment naïve drugs for marketing. During this process of manufacturing drug the Principles of the Rights of Patients in Europe (1994) provides in its Article 2(1) that:

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[72] EMA, (European Medicines Agency), Science Medicines Health, (2014) "The European Regulatory System for Medicines and the European Medicines Agency: A Consistent Approach to Medicines Regulation Across the European Union", An Agency of the European Union, European Medicines Agency, United Kingdom, EMA/437313/2014, p.2; available at: www.WC500171674.ema.europe.pdf.

[73] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc. pp. 1.

[74] Ibid.

[75] Article 12 (1) of ICESCR (1966); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

> "information about health services and how best to them is to be made available to the public in order to benefit all those concerned".[76]

Labeling helps to insure benefits of manufactured drug and how to use such product. Access to lifesaving medicine is a component of RTH and this requirement is more legal then political in nature.[77] Labeling information also benefits in knowledge about the combination used in drug. This information helps in positive or negative reacting component to one's own body. Drugs whether over-the-counter (OTC) used since over time period are considered safe and can be taken without prior consultation with doctors/physicians. On the other hand, the ethical drugs (EDs) are those medicines that have to be consumed only after consultation and prescription from the physicians/doctors. These medicines can be new drugs or the generic drugs. Like the paracetamol etc.[78]

Dependency on drugs for sickness and suffering may cause adverse drug effect (ADE) or reactions to one's body. Challenges state that treating drugs for illness and suffering of individuals, community or society needs labeling of the product. So that an individual is cautious and avoids consuming the reacting product that is harmful for individual whose cause is still not obtainable without knowing one's own genotype.

Drug development helps in accessing medical facilities and healthcare support without discrimination or deficiency during physical, mental and social conditions. In present modern technologies and scientific world, R&D through CT has sustained healthcare accuracy in such a manner that curing and treatment have become possible for some of the deadliest diseases like TB, HIV/AIDS, etc. However, achievement of technology has many a time become hurdle in achieving RTH for drug access.

The African case of pre-natal HIV/AIDS poor women patients narrates about incapability in accessing internet facility for ordering these medicines. Besides, incompetence and vulnerability deprived them due to their social status. Moreover,

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[76] Article 2(1) of the Principles of the Rights of Patients in Europe, 1994; Available at: The Principles of the Right of Patients in Europe (1994), Endorsed by the WHO European Consultation on the Right of Patients, 28-30 March 1994, Amsterdam, WHO document ICP/HLE121 (28 June 1994); available at: www.who.int/genomics/public/eu_declaration1994.pdf

[77] Lemmens, Trudo., and Telfer, Candice., (2012), "Access to Information and the Right to Health: The Human Rights Case for Clinical Trial Transparency", *The American Journal of Law, Medicines and Ethics*, Boston University School of Law, 38, p.65.

[78] Chandy, Sujith J. and Mathew, Binu S. (2006), "Patient Information and Medication Labeling: An Area of Concern", *Indian Journal of Medical Ethics*, 3 (2), p.1-2; available at: www.ijme.in/index.php/ijme/article/view/656/1628

observation and cry from civil societies for making access of drugs possible for the HIV/AIDS sufferer women's led the government active.[79] Treating individuals is one of achievements of RTH and it can only be possible through availability of drugs either new scientifically improved or traditional practice. Drugs, through CT have become a rational system of quality treatment care, where regulation in its delivery is made as a part of medical infrastructure to all areas where it is needed.[80] Like in all different parts of world as India and African nation or developed nations like America or Europe. Treatment through drugs can be largely supportive and includes discontinuation when same drug turns offending. The Article 12(2)(d) of the ICESCR states that drug labeling is "a condition to assure medical service and attention during sickness".[81]

Access to drugs provides direction on manufacturing and developing of drugs through CT and a vision to cure through scientific creation. This developmental procedure in practice usually neglects the Moral and Ethical principles of an individual so that availability of product is possible in the market.

Healthcare Innovation and Expenses

Role of patent system for discovery and development of drug takes place through its innovation from laboratory achievement; CT on animal and human subjects till it produces promising result. High economic expenses and time taking discovery achievements for potential requirement leads private pharmaceutical manufacturers to play key role. Literature confirms first drug firm were private establishers that invented and produced as dyestuff industry. Dyestuff industries started in Germany, France, Great Britain and Switzerland of European countries, later footed business in USA, other European Countries and Japan. To secure invention and innovation active novelty is provided for achievement through

[79] Minister of Health v. Treatment Action Campaign (TAC) (2002) 5 SA 721 (CC). Also see, Chapter II this thesis.

[80] Marks, Stephen P. (2009), "Access to Essential Medicines as a Component of the Right to Health" *Health: A Human Rights Perspective.* Clapham, Andrew and Robinson, Mary (eds), *Realising the Right to Health*: *Swiss Human Rights Book*, Vol. 3, Zurich: Ruffer & Rub, pp.80-81; available at: www.swisshumanrightsbook.com/SHRB/shrb_03.html

[81] Article 12(2)(d) of the ICESCR 1966, U.N.G.A. Res. 2200A (XXI) of 16 December 1966 (entered into force 3 January 1976); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx.

patenting new product.[82] A particularly pernicious TRIPS-plus provision requirement is exclusive marketing period for first-registered drug, typically five years takes place under U.S. free trade agreements, but sometimes more as in the agreement with Central America.[83] TRIPS Agreement requires an invention to be new[84] for patent. TRIPS Agreement specifies that patents must be available for all discoveries which are new, involve an inventive step and are capable of industrial application. TRIPS also makes scope of protection larger. Article 27(1) in this context states that:

> "patent must be available for all fields of technology which includes pharmaceutical products within its statement".[85]

Patent availability becomes important so that during calculation of economic cost, R&D and providing novelty includes period of exclusivity entail for a sample of essential medicines. This clear demonstration states about financial subsidy to developing country in R&D costs of drug makers, because Type I and Type II diseases are amortised in markets of high-income countries.[86] That is on an average high in number while costing drug/medicine development. Estimation cost is about $1.8 billion for a new compound to; launch in market with limited success rate. Often, process in many tested compounds of new drugs leads to its uncertain performance, due to which companies usually report only one out of ten thousand experienced new drugs reaches to market.

In order to recover these expenses, new drugs gain its revenue through regular patent system.[87] In observing pattern of patent and scientific technology more shift for commercial business, has brought monopoly prices through pharmaceutical companies following abuse of these exclusive rights by excessive prices and seeking patents over minor changes to continue their monopoly. An example can be of Novartis case,[88] which launched a generic drug for blood cancer named as imatinib

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[82] Puymbroeck, Rudolf V. Van. (2010), "Basic Survival Needs and Access to Medicines Coming to Grips with TRIPS: Conversion + Calculation", *Journal of Law, Medicine & Ethics*, Global Health Governance, p.542.
[83] Ibid.
[84] Ibid.
[85] Article 27(1) of TRIPS Agreement.
[86] Puymbroeck, Rudolf V. Van. (2010), "Basic Survival Needs and Access to Medicines Coming to Grips with TRIPS: Conversion + Calculation", *Journal of Law, Medicine & Ethics*, Global Health Governance, p.542.
[87] Tonkens, Ross., (2005), "A Overview of Drug Development Process", *The Physician Executive*, p.48.
[88] Access Campaign: Medecines Sans Frontieres, (2012), "Timeline of Key Events in Novartis's Attack on The Pharmacy of the Developing World", mafaccess.org; available at: www.msfaccess.org/content/timeline-key-events-novartiss-attack-pharmacy-developing-world ; also

mesylate with a brand named Gleevec in 2003 for $200 per patient per month. The same drug cost $2,600 per patient per month in US. Since India complying with TRIPS and patent law requirement signed in 1994 had to change its domestic patent law by granting patents on medicines/drugs no later than 2005. But the law also states that only true medical innovation will be granted patents.[89]

Section 3(d) of the Indian Patent Act specifies new forms and new uses known substances cannot be patented, unless they demonstrate a significant increase in efficacy. Novartis patent application on imatinib mesylate of Gleevec in January 2006 got rejected due to "known substance having new form". In May 2006 two legal files got challenged by Novartis in the Madras High Court. One of the appeals got rejected for patent and the other got declared contrary to the TRIPS Agreement and to the Indian Constitution. In December, an international petition was launched by Medecins San Frontieres calling (MSF) Novartis to drop the case in which 45,000 people had signed the petition. The Madras High Court ruled against Novartis for overturn on Section 3 (d). In order to show efficacy under the requirement of Section 3(d) the Madras High Court asks to show increase in therapeutic efficacy. MSF handed over the petition to Novartis in Basel having close to half a million signatures. In August 2007, the scientist i.e Brian Druker, who discovery imatinib wrote an opinion piece publicly, stating that:

> "(T)he price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort. Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that make the discovery of these medicines possible".[90]

In June 2009, the Intellectual Property Appellate Board (IPAB), which is responsible for hearing appeals on patent applications rejects Novartis's appeal and confirmed that imatinib mesylate does not deserve a patent. IPAB contended that the company was unable to show significant increase in efficacy as required under

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see, Abbott, Fredrick M., (2013), "Inside Views: The Judgment In *Novartis v. India*: What The Supreme Court Of India Said", *By Intellectual Property Watch;* available at: www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said; also See, *Novartis AG v. Union of India & Others* with Civil Appeal No 2728 of 2013 Arising out of SLP(C) No. 32706 of 2009, *Supreme Court of India*; available at: www.supremecourtofindia.nic.in/outtoday/patent.pdf

[89] Ibid.

[90] Ibid.

Section 3(d) of India's patent law. In August 2009, Novartis approached the Supreme Court of India in a new case this time seeking to challenge interpretation and application of Section 3(d) by Indian courts and patent offices. In September 2012 final hearing began in the Supreme Court of India.[91]

The issue of privatization in healthcare has been seen with skepticism in view of fear of its effect on individuals' misery as it benefits some powerful group and discriminate against vulnerable. The Peoples' Charter for Health 2000 (paragraph 1) states that people should:

> "oppose international and national policies that privatise health care and turn it into a commodity".[92]

To discourage privatisation of healthcare in developing countries prior providing patent to any product it becomes important to examine such drug has previously been used by native doctors in more basic forms before present patentee discovers it. If so, national court must refuse such compound of drugs for a patent. Because, traditional medicines or cultural knowledge are treated as a product of nature by developed countries, in that they do not specify requirement of discovery.[93] Since drug/medicine is a known substance that already exists in traditional and cultural form.

Expanding commercialisation and challenging business strategy to obtain patent for product was provided so novelty and result oriented fixture for area of research, development, manufacturing and marketing can be sustains jointly with growing new discoveries and development.

Electronic Drug Supply

At present the new method of infiltration of counterfeit drugs is taking place through the supply chain of internet. In view of availability, a product at low price and ease of purchase through internet helps provide door to door services. This kind of consumer oriented marketing exposure was accounted by the National Association of Boards of Pharmacy of Canada[94] when it found 97% of the internet pharmacies do not

[91] Ibid.
[92] Paragraph 1 of A People-Centered Health Sector of the Peoples' Charter for Health 2000; also see, Appendix-3.
[93] Ozdemir, Aysegul. (2008), "*TRIPS Agreement and Access to Essential Medicines*" Ankara Bar Review, *HeinOnline*, p.92.
[94] National Association of Boards of Pharmacy, (2013) "Internet Drug Outlet Identification Program: progress report for state and federal regulators"; available at:

complaint with the Federal and State law. Because according to a report survey in the sale of internet pharmacies it was found that in the year 2007 the internet pharmacy sale was $4 billion which rose to a big profit business of $11 billion business in 2009.[95]

Such an attaractive business can make things more complicated and hard for a poor and sick individual then saving money, since these medicines will not cure but act as a burden in their illness, making them more vulnerable from the disease. As far these mounting number came it was analysed previously the internet source only sold lifestyle drugs like Sildenafil, i.e a Viagra. But, now internet market has now expanded its supplies towards therapeutic medicines like cancer and cardiovascular drugs or insulin. The U.S FDA whose role is to save its people from the counterfeit medicines and provide secure, save and effective medicines is also helpless. For the reason that, in a study made during 2005 it was found out of 11,000 only 214 online pharmacies were registered and others were running without any legal authority.[96]

Similarly, the medicines which are not used in Canada do not come under the legal preview of scrutiny. This proves that Canadian internet has become the primary source for counterfeiting drugs in U.S. The U.S FDA Act 21, USC Sec 333 (a) (2) of 2010, penalizes drug counterfeiting with a maximum of $10,000 or 3 years in prison, or both. However this Act has not been updated since 1938. Moreover, to educate consumers about the dangers of purchasing prescription drugs online, the FDA has launched a campaign entitled "BeSafeRx: Know Your Online Pharmacy."[97] So, observing the counterfeiting of drugs made through online trading and illegal drugs selling in June 2013, the U.S FDA team up for a global action among 100 other countries for an operation Pangea VI. This operation eliminated 1677 websites selling illegal prescribed drugs along with seizure of $41 million worth counterfeit medicines.[98] The online purchasing of medicines has made the old Latin phrase

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www.awarerx.s3.amazonaws.com/system/redactor_assets/documents/179/NABP_Internet_Drug_Outlet_Report_Apr2013.pdf

[95] Mark Monitor. (2009), "MarkMonitor finds online drug brand abuse is growing"; available at: www.markmonitor.com/pressreleases/2009/pr090928-bji.php

[96] Pociask, Steve., and Fuhr. Joseph P., (2013), "Internet drugs can kill", Huffington Post; available at: www.huffingtonpost.com/steve-pociask/internet-drugs-can-kill_b_4181418.html

[97] U.S Food and Drug Administration. "BeSafeRx: know your online pharmacy"; available at: www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/buyingmedicinesovertheinternet/besaferxknowyouronlinepharmacy/default.html

[98] U.S Food and Drug Administration, (2013), "FDA takes action to protect consumers from dangerous medicines sold by illegal online pharmacies: international Operation Pangea VI combats online sale

remembered "caveat emptor" i.e let the purchaser beware. So in order to control counterfeit drugs all the stakeholders involved should participate equally to control the illegal trade of such dangerous medicines.[99] Since the 1973 Hague Convention on the Law Applicable to Products Liability in its article 3 (1) to (4) states that:

> "(T)he liability of product will fall on: 1) manufacturers of a finished product or of a component part; (2) producers of a natural product; (3) suppliers of a product; (4) other persons, like the physicians and drug prescribers, including repairers and warehousemen, in the commercial chain of preparation or distribution of a product. At last, it shall also apply to the liability of the agents or employees like the nurses, doctors/distributers of the drug persons for specified reasons above".[100]

There is a need for alertness by the international community to protect from counterfeit drugs. It needs to ensure that all public and private stakeholders work together for multi-layered-anti-counterfeiting strategy that posse's threat. Progress in this regard can be seen as a sign through the Declaration of Rome in which the international community took a WHO task force to work together to fight against counterfeit drugs as well as accepted it as a "vile and serious criminal offense" and a threat for global.[101] To tackle this problem increase for security features like developing of electronic track-and-trace facility should be brought as well as regulation for increased secondary wholesale market along with establishment of careful wholesaler market procedure should be brought to keep hold on it. The online purchasers should take in account of the danger that may come through such counterfeiting drugs.[102] So no more adulterated or look like drugs can come near ill health and the vulnerable patient who is going to consume it.

Pharmaceutical Counterfeits

Achieving health rights through R&D or CT process becomes setback for health development when counterfeiting drugs attack market and branded labels. Counterfeiting drugs are substandard drug manufactured reasonably for unlawful

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and distribution of unapproved prescription medicines", Press release; available at: www.fda.gov/ICECI/CriminalInvestigations/ucm358837.html

[99] Blackstone. Ervin A., Fuhr. Joseph P., and Pociask, Steve., (2014) "The Health and Economic Effects of Counterfeit Drugs", American Health & Drug Benefits, Business. Review Article, 7 (4), pp.216-224, p.216, 217, 219, 220 and 222.

[100] Article 3 (1) to (4) of the 1973 Hague Convention on the Law Applicable to Products Liability.

[101] WHO, (2006), "The Declaration of Rome, World Health Organisation (WHO), International Conference on Combating Counterfeit Medicines", February 18, 2006, Rome, Italy.

[102] Yankus, Wyatt., (2006), "Counterfeit Drugs: Coming to a Pharmacy Near You", (Condensed Version), American Council on Science and Health, New York, p.1-14; available at: www.acsh.org/wp-content/uploads/2012/04/20060825_CDrugW_condensed.pdf

profit. Drug shortage can lead to introduction of counterfeiting drugs for economical benefits by corrupted individuals. An estimation state about $75 billion revenue per year is gained by illegal operators, by killing more than 100,000 individuals worldwide through counterfeiting drugs.[103] The World Health Organisation (WHO) defines it as those drugs that are deliberately as well as fraudulently mislabeled through its identity, composition and/or source. These drugs are mislabeled with falsification of source and repacking containing fake elements/substance called as counterfeiting drug. Such substandard, fake, diluted and misbranded drugs have counterfeit global pharmaceutical market through adulterated or falsely labeled drug brands. These drugs are repacked or labeled in near-perfect fake production that can spoil and affects health of every individual who consumes such product. Until expert analyses authenticity of counterfeiting drugs they are hard to identify.[104]

It is now well known that counterfeiting pharmaceutical drugs have become world problem. Such fictitious branded drugs are present more in developing countries like India, China, Brazil, China, Mexico, Latin America, Nigeria, Russia and Southeast Asia.[105] Functioning ring of organised crime groups are so-called as Chinese triads, Colombian drug cartels, Mexican gangs, Russian mafia, and even terrorist groups such as Hezbollah, IRA and ETA.[106] Counterfeiting drugs are hampering global pharmaceutical trade by $512 billion dollar every year and about 5-7% of international traffic operation. Every healthcare industry along with foreign and domestic agencies/governments should join to minimise growing crime of pharmaceutical counterfeit.[107]

Entry of counterfeiting drugs can be possible easily by direct street stores, infiltrating wholesale supplies, internet/online sales and re-imporing of

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[103] Cherici C, McGinnis P, Russell W., (2011), "Buyer beware: drug shortages and the gray market", For Premier Healthcare Alliance; available at: www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf ; also see, Blackstone. Ervin A., Fuhr. Joseph P., and Pociask, Steve., (2014) "The Health and Economic Effects of Counterfeit Drugs", American Health & Drug Benefits, Business. Review Article, 7 (4), p.219-220.

[104] Stearn, Douglas W. (2004), "Deterring the Importation of Counterfeit Pharmaceutical Products," Food & Drug Law Journal, 59, p.550.

[105] ICE Fact Sheet, (2006), "ICE Efforts to Combat Counterfeit Pharmaceuticals", U.S. Immigration and Customs Enforcement (ICE), July 11, 2006.

[106] Satchwell, Graham (2004), "Sick Business: counterfeit medicines and organised crime" London: Stockholm Network, p. 60; also see, Yankus, Wyatt., (2006), "Counterfeit Drugs: Coming to a Pharmacy Near You", (Condensed Version), American Council on Science and Health, New York, p.1-3; available at: www.acsh.org/wp-content/uploads/2012/04/20060825_CDrugW_condensed.pdf

[107] Nelson, Maria., Vizurraga, Michelle., and Chang, David., (2006), "Counterfeit Pharmaceuticals: A Worldwide Problem", The Trademark Reporter, 96 (5): 1068-1100, p.1068,1069.

consignments.[108] For combating counterfeiting drugs specific measures suggested by the WHO for individual national strategy are:

> "a) Strengthening the political determination within individual countries to deal with counterfeit medicines while alerting them to the seriousness of the threat of counterfeit drugs; b) The creation of appropriate legislation to secure drugs in distribution channels, to increase requirements for the renewal of licenses, and for the screening of drugs at the port of entry; c) The establishment of national drug regulatory authorities with effective independent enforcement powers; d) Increase the enforcement of existing drug control laws; e) Creating partnerships between pharmaceutical manufacturers and governmental authorities in order to foster cooperation and communication; and f) Increasing patient awareness and education regarding counterfeit drugs".[109]

Active vigilance and security measures can prevent counterfeiting drugs at local and international market. Understanding the need for security of consumer's health through counterfeiting drug threat it becomes important to provide knowledge on seriousness of such harmful product. Besides, amendment on formation for appropriate legislation during renewal of drug distribution licensing as well as carrying out investigation throughout delivery and supply channels has to be made. To prevent entry of counterfeit drugs in market through government channels, manufacturers of pharmaceutical industries should tie up directly with the government for their finished and approved products for marketing. Else awareness through education and camps are the best medium to acknowledge people. [110]

Tackling of criminal offence can only be possible when enclose cooperation from government and agencies is created and investigators are not influenced by different authorities. Investigators of counterfeiting drugs should have power to accuse or scrutinize brand manufacturers for not tracking records and supplies of their trade products. Since, labeling drugs through barcode, etc. helps the manufacturers to track and identify authenticity of their product.[111] On the other hand, manufacturers complaints that free trade zones provide ample space for lax or absence of governmental control helping widespread and easier distribution of counterfeit products. For instance, lack of appropriate legislation for intellectual property theft or

[108] Ibid.
[109] Bunker, Amy M. (2007), "DeadlyDose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health", Journal of the Patent & Trademark Office Society, Arling, VA. 89, p.512-513.
[110] Ibid.
[111] Nelson, Maria., Vizurraga, Michelle., and Chang, David., (2006), "Counterfeit Pharmaceuticals: A Worldwide Problem", The Trademark Reporter, 96 (5): 1068-1100, p.1068,1069.

to place rights for financially sound pharmaceutical companies' demands need of legal section on counterfeiting drugs.[112]

Two basic implications have been found due to counterfeiting drugs are: i) hazard towards human health; and ii) loss of profits by the rightful patent holder. These two basic implications take away profits from legal patent holder while decreases brand credibility by increasing liability. Labeling of drug products has become one of the safest solutions to control flooding of counterfeiting drugs in marketplace. Besides, counterfeiting drugs has deteriorated new drug inventions because developers are in threat of investing large amount on research, development, and marketing drugs. In addition, lack of novelty holds back new inventions and creation of condition to promote scientific technologies.[113]

In fact progress in health has hampered since 1990's when threat of counterfeiting drugs brought societal burden and profit loss worldwide. Health hazards through counterfeiting drugs stops new drug inventions and bring unfamiliar diseases and injury in rise adding unjustifiable human suffering or death. Raising international health concern together with unavoidable side effects and vulnerability towards individuals' health, causes pain or suffering from infants to old age people, rich to poor and developed to developing countries. Regulatory mechanism has put concern to increase enforcement through technological security, putting directions for controlling entry of legitimate market. In 2003 to control counterfeiting products the U.S. Congress created "drug pedigree" obligation as safety for drug products expanding the Prescription Drug Marketing Act of 1987. This Act brought responsibility of keeping records for every sales transaction that passes through supply chain. The U.S FDA regulatory provision came later adopting electronic tracking technology for the pharmaceutical industry till December 2006.[114] Revelation came Indian markets are circulating with fake drugs like betadine, cocin, voveran, injections of calcium and syrup like cosavil. In addition to, an industry body of ASSOCHAM exposed through a paper titled "Fake and Counterfeit Drugs in India-Booming Biz" that:

[112] Ibid. p.1070-1071.
[113] Bunker, Amy M. (2007), "DeadlyDose: Counterfeit Pharmaceauticals, Intellectual Property and Human Health", Journal of the Patent & Trademark Office Society, Arlington, VA. 89, pp. 494, 514.
[114] Ibid.

> "(N)ear about 25% of Indian drugs are fake, counterfeit or substandard and the fake medicines constitute nearly one third of all drugs sold in the capital Delhi, NCR i.e in regions of Faridabad, Gurgaon and Noida of India".[115]

Such international advertises has subjugated Indian markets ability and values, playing blame game to reduce Indian pharmaceutical status. To overcome challenges and issues of counterfeiting drugs the Center Drugs Standards Control Organisation (CDSCO) accuses international "vested interest" that has tried to hamper Indian labeling on counterfeit drugs. Such misbranding and fake products have not just oppressed Indian pharmaceutical market but damages Indian pharmaceutical reputation at international sphere.[116] Based on this critical situation and damaging Indian drugs reputation the CDSCO launched a scheme to reward people who report about fake drugs and rewards as:

> "20% of the total value of any drugs seized as a result of information-up to a maximum of INR2.5m ($4154) is on offer to members of the public, while government officials and CDSCO offers who report fakes could earn up to INR3m during their careers. The scheme aims to make sure that informants do not "turn hostile" during any resulting trials by providing 25% of the reward upfront, 25% when they give evidence in court and the remainder if the accused is found guilty".[117]

To control and reward counterfeiting drugs the CDSCO effort is to overcome challenge and issue of monitoring market place. Fearing regulating challenges and drawback in developing countries, scholars are of view that research to track counterfeit drugs and its supplies to consumers should be conducted.

Further, evidence of developing countries and condition of counterfeiting drugs issue makes things more complicated like in 1987 about 70% fake drugs for meningitis had killed 300 villagers in Nigeria because of salt water. About 8% of fake drugs are sold by retailers, ranging from cardiovascular drugs to anti-inflammatory medicines. Likewise, in Vietnam, Cambodia, Burma and Laos for sold anti-malaria drugs more than one-third of deficient element is found. Besides in 2001, China

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[115] Singh Jyotsna., (2014), "Fake drugs constitute 25% of domestic medicines market in India: ASSOCHAM", Down to Earth: Subscribe to Common Sense; available at: www.downtoearth.org.in/news/fake-drugs-constitute-25-of-domestic-medicines-market-in-india-assocham-45393

[116] MacDonald. Gareth. (2014), "India's CDSCO to pay people who report fake drugs", In-Pharm, Technologist.com, p.1; available at: www.inpharmatechnologist.com/RegulatorySafety/IndiasCDSCOtopaypeoplewhoreportfakedrugs

[117] Ibid.

exposed about 192,000 patient's death during counterfeit drugs investigation and found about 480,000 counterfeit drugs incidents that led closing of 1,300 factories.[118]

Drug Labeling an Ethical Responsibility

Drug labeling is an area of concern because an individual who is consuming drug/medicine has to be informed about what he/she is consuming. Likewise the case of India can be stated where remains of human and animals tissues where being used. This case about Baba Ramdev, the yoga and ayurveda guru, got highlighted when he was accused for using the tissues of the same without proper labeling or information on the medicine/drugs. This case proved that many of the Indians do not know about drug labeling and its regulation. So far, while understanding about labeling of drugs it just does not confine itself to its instruction or information about the medicines. But the labeling information even includes all the necessary information about the drug/medicine.

In 2002, the United States Food and Drug Administration (US FDA) that enforced revised standardized labeling. By introducing improved print and graphics for over 100,000 over-the-counter (OTC) drug products. According to these new guidelines:

> "(T)he drug facts panel should have the name of the drug, its active ingredient(s), purpose(s), use(s), warning(s), directions, other information, inactive ingredients and questions. Drugs that fail to follow these labeling requirements will be termed as misbranded, but the US FDA gave 2006 as the deadline for the enforcement of this regulation. Countries such as Australia do not make it mandatory to reveal the inactive ingredients".[119]

Drug labeling even includes ethical responsibility and duty for pharmaceutical industry to highlight about the drug/medicines. It has always been condemn and experienced that the labeling of drugs should contain specific warnings with what those medicines can contain side effect or adverse drug effect (ADE).

Liability of Pharmaceutical Industry and Physicians

Drugs liability falls under product liability for prescribed medicines. The manufacturer of the drugs or medicines have responsibility to test the drugs

[118] Bird. Robert. C., (2007-2008) "Counterfeit Drugs: A Global Consumer Perspective", Wake Forest Intellectual Property Law Journal, 8 (3), p. 398-390.

[119] Chandy, Sujith J. and Mathew, Binu S. (2006), "Patient Information and Medication Labeling: An Area of Concern", *Indian Journal of Medical Ethics*, 3 (2), p.1-2; available at: www.ijme.in/index.php/ijme/article/view/656/1628

appropriately prior launching in the market. The regulating organisation or government authority makes sure for the products testing through criteria set by the government or the agency on industrial standards then licenses the manufactured product. Thus when the plaintiff takes legal action there is no liability on the manufacturer but if the injured plaintiff proves the drug defective otherwise. But it has also been found the mostly the doctors/physicians or nurse to prescribe the drug with proper prescription letter and how and when to have the drug/medicine. Except for the over-the counter (OTC) drugs as these drugs has been used over the ages. This explains the relationship between the manufacturer and the ultimate user where the learned intermediary plays the role of prescribing the drug. There are those unavoidable unsafe prescribed drugs that can be useful and curable for the patient but with specific warning for the side-effects can help the manufacture escape from lawsuit. The manufacturer has the duty to label the manufactured product with the specific warning of the drug/medicine may cause to the ultimate consumer either it is susceptible consumer getting the reaction or potential adverse event. As it is the responsibility of the drug manufacturer to provide with such warning instruction. Because, the drug manufacturer or the pharmaceutical industry, themselves are expert in the field of medicine/drugs.[120] The term expert in this line means, the drug manufacturers are scientists or those students who working on particular medicines and these drugs are manufactured after lot of experiment i.e clinical trial and observation collecting data and scrutinizing in all different perspectives and ways.[121]

Labeling of all drugs is not just the liability of the manufacturer. It is the duty of the manufacturer to provide name of the medicine, its composition articulated in the metric system, composition of active ingredients, manufacturers name, address, license number, batch number and dates of manufacturing as well as expiry. The label on packaging of a drug is different from the insert in the package. The insert is approved by an authority that works as drug regulating body.

An insert is the means through which regulation through government takes place between the health care provider and manufacturer. It is a full document that is not required by the patients but if patients receive the insert information it is not illegal. In order to see the labeling the content of the active ingredients has to be

[120] FindLaw, (2015), "Pharmaceautical Drug Liability", *Thomas Reuters*, Chicago, IL, p.1-3; available at: www.injury.findlaw.com/product-liability/pharmaceutical-drug-liability.html
[121] Ibid.

written. For example for liquid measure the oral drugs should be expressed in the content level indicating it with amount of milliliter (ml) i.e 5 ml or percentage of volume. In India the Part IX of the Drugs and Cosmetics Rules looks after the manufactures of all drugs like ayurvedic, siddha and unani. Moreover, the Rule 161 of the Drugs and Cosmetics Rules includes an exhaustive list for labeling. This list includes it is mandatory to provide the ingredients and their quantity used during manufacturing of the drug/medicine. However the traditional drugs manufacturers escape by just quoting the name in ancient text recipe. By revealing in their labels proper quantity and used ingredients either through botanic or official names, during manufacturing of the drug/medicine.

In India most of the clinics that is situated in rural and small towns do not provide any labeling of medicines whereas, they give the pills or tablets into paper cover and provide the syrup in used bottles. These types of clinics usually provide plant medicines or allopathic drugs like paracetamol or other anti-biotic drugs along with mixture for drinking as syrup mixed with brandy. In India it prevails in small towns and rural areas of Uttarakhand, Uttar-Pradesh, Rajasthan, Bihar etc. Doctors are not inquired for the prescription of drugs the patients are supplied for consuming.[122] Because, most of the patients in India, believes that, if doctor has given the medicine/drug then they might have provided the right medicine, which is taken without any doubt.

Just to inform or provide facts about the adverse drug event (ADE) or any side effect being cause by the drug/medicine that is being consumed by the patient or the injured individual. Negligence is observed through the pharmaceutical industry or doctors for not providing labeling and information liability about a drug/medicine that has to be consumed. Moreover, several times these essential details are taken through personal pharmacist or physician/doctor. As well as, media either through international streaming or national news informs about ADE occurred through XY[123] medicine.

Apart from this, health agencies or governments should be particularly observant in monitoring any kind of information or data on ADE occurrence and note

[122] Chandy, Sujith J. and Mathew, Binu S. (2006), "Patient Information and Medication Labeling: An Area of Concern", *Indian Journal of Medical Ethics,* 3 (2), p.1-3; available at: www.ijme.in/index.php/ijme/article/view/656/1628

[123] XY in this line tries to indicate a substitute name for a drug/medicine that can cause any kind of ADE/side effect to individuals, who consumes the medicine/drug.

such facts.[124] So that, drug manufacturers liability falls to inform such details to the consumer through labeling it on the drug. It has been found in a case of Thomas and Wife v. Winchester[125] (1982) that the labeling of drug was mislabeled with deadly poisonous drug belladonna in place of dandelion. The patient Mrs. Mary Ann Thomas was in her critical conditions for some days and after laboratory test found the purchased drug was a false drug and not what she was supposed to consume.

In this case, the defendant, the Dr. Foord, a physician and druggist in Cazenovia, Madison County, negligently labeled and sell the extract of dandelion which is a simple and harmless medicine. This medicine was purchased for Mrs. Mary Ann Thomas due to her ill health from her husband Mr. Thomas. But the medicine started giving reaction like getting unwell, cold, contraction in muscles, dilation of the pupils of the eyes, derangement of mind, giddiness and weakness. She got well soon from the reaction but for some time the medicine produced dangerous. But later when the medicine was administered it turned out to be belladonna and not dandelion. This bottle of drug was labeled as "1/2 lb. dandelion, prepared by A. Gilbert, No. 108, Johnstreet, N.Y Jar 8 oz." which was supposed to be dandelion as labeled by Dr. Foord who purchased it from Jas. S. Aspinwall, a druggist at New York. Jas. S. Aspinwall was too of the expression that the bottle contained extract of dandelion as labeled. But he too bought the bottle from Wincherster, who was dealer of poisonous drugs and Gilbert was his agent who use to prepare the drugs for the defendant for marketing. Name of Gilbert was used on drugs because he was in this business since long time and his name was a sellable attraction. The consequences of belladonna drug and its mislabeling had brought death or great bodily harm for some individuals with no cure. Further, this case highlights about the misguiding and mislabeling of drugs can profit the corrupted but might kill an innocent.[126]

In India the CDSCO (Central Drugs Standard Control Organisation) regulates the medical device industry. Registration is made for only those medical devices that come under "Notified Devices Category" as declared by CDSCO. There are very few product types on this list and they are regulated as "drugs". Registration is not required for import of non notified medical devices in India. For Medical Devices that

[124] Frankenfeld, Christian., (2004), ""Serious" And "Severe"Adverse Drug Reactions Need Defining", *BMJ: British Medical Journal*, 329 (7465), p.573.

[125] Thomas and Wife v. Winchester, (1982) 6 NY 397; available at: www.courts.state.ny.us/reporter/archives/thomas_winchester.htm

[126] Ibid.

do fall under Notified Devices Category as per CDSCO, products are required to have labeling as per the labeling requirements under GHTF guidelines and Rule 96 of the Drugs and Cosmetic Act, In India, medical devices are categorised as "drugs". Some of the labeling requirements in Rule 96 are specific to drugs, but does not pertain to medical devices. Some of the items as notified devices that are labeled under rule 96 are the following:

> "i) product description; ii) number of units of contents; iii) the name of the manufacturer and the address of the premises of the manufacturer where the product has been manufactured; iv) a distinctive batch number, being preceded by the words 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No.' or 'Lot'; v) every product manufactured in India shall bear on its label the number of the license under which it is manufactured, the figure representing the manufacturing license number being preceded by the words "Manufacturing License Number" or "Mfg. Lic. No." or "M.L."; vi) date of manufacture, and the date of expiration.

In addition, these products also need to comply with labeling and local laws as per Drug Price Control order and Standard Weights and Measures Act 1976 & Rules 1977",[127] the manufacturer shall indicate the following information on the package:

> "i) Name and Address of Manufacturer/Importer/Packer; ii) Quantity; iii) Generic Name of Product; iv) Maximum Retail Price (M.R.P.) inclusive of all taxes; v) Date of manufacture/whether imported or packed along with Expiration Date; vi) Contact information that includes name, address, telephone number and Email address for Customer Complaint".[128]

Labeling of Drugs for Adverse Drug Effect

The consumers should be aware of their therapy, this practice in realistic sense means right to know what the patient is being treated with. The prescription drug what an individual patient is going to consume should bare properly label. The process through which such labeling is made on prescribed drug, conducts in directions of the physicians and administering of the pharmaceuticals'. So that Adverse Drug Effect[129] (ADE) or side effect could be avoided while taking such medicine. It has been absorbed that adverse drug reaction (ADR) leads to 5 to 15 percent of therapeutic drug course which has been seen as most common iatrogenic illness that causes major morbidity and mortality worldwide.

[127] GHTF guidelines and Rule 96 of the Drugs and Cosmetic Act of India.
[128] Kasun, R., (2013), "India Medical Device Labeling Regulatory and Quality Solutions LLC (R&Q)", *R&Q: The and Means More, Regulatory and Quality Solutions LLC :1*-2; available at: www.rqteam.com/2013/09/medicaldevicelabelinginindia/.
[129] Riedl, Marc. A. and Casillias, Adrian. M. (2003), "Adverse Drug Reactions: Types and Treatment Options", American Family Physician. Nov1, 68 (9), p.1781-1791.

In the United States, more than 100,000 deaths are attributed annually to serious adverse drug reactions.[130] While assuming the comply procedure for labeling it has been examined that in U.S it is the liability of the prescript drug manufacturers or the repackers to abide by the technicalities of the U.S FDA Act. As well as, there is a requirement to include a copy of the official labeling or "package insert" with every product they distribute. Excluding the concise modified label affixed in the container by the pharmacist himself. So far, the provided instruction about the drug information given to patients is usually restricted to the spoken knowledge as provided by health care professionals because they are in scientific codes.

Since1960s the U.S FDA usually used the physician oriented package insert, a patient oriented label on or around the dispensed drug that is a patient package insert (PPI). Through the suggestion made by a National Food and Drug Advisory Committee along with a filed petition from several consumer interest groups, an initiative came from FDA as a Patient Drug Labeling Project so that possibility of increasing the implementation of PPIs to a broad range of prescription drugs can be explored. So that consumers of the drugs have a right to know what they are consuming or being treated with. This petition was filed by the Centre for Law and Social policy of Washington, D.C.; the Consumer Action for Improved Food and Drug Organisation; Consumers Union; the Women's Equity Action League; the Women's Legal Defense Fund. Moreover, the petition suggested affixing a warning sticker on the container or adding extra supplementary sheets with instructions for use and avoiding safety measures.

The main focus of PPI's petition was to mark those drugs that are being consumed in huge figures. Even without any prescription by the physicians or can be transferred from one person to another. Under the model suggested in the consumer petition, the pharmacist would be primarily responsible for distributing PPIs. Since this project was commenced in 1975, increasing support came for the concept PPI. Two bills in 94th Congress introduced for PPIs and these bills were: i) the Roger Bill, HR-14289 i.e. required almost for all the drugs; and ii) the Kennedy Bill, S-1282 for those drugs going in final phases of Clinical Evaluation. Further, FDA along with the American Medical Association (AMA), the Drug Information Association (DIA) and the Pharmaceutical Manufacturers Association (PMA) organised a national

[130] Ibid.

symposium on PPIs in November 1976 where about 700 people of different discipline joined this symposium. Based on this response a PPIs survey was made on oral contraceptives (OCs). OCs is one of the essential medicines for females; this medicine of OC's was brought in PPIs directive description. So, in order to find out the usefulness of PPI's U.S FDA surveyed previous and present users of OC's pills.

The result of survey that that was completed in 1975 September found that around 53% of the OC's users who read the PPI's instruction remembered the significant side effect of the pill was blood clotting information. As well as, the OC's users wanted the PPI's norms to be followed for their safety. The first product bring PPI's norm was the Isoproterenol inhalators. Moreover, having PPI's instruction will be useful and supportive for those who are having other medicines or allergic to one medicines will stop using the same due to Adverse drug effect (ADE) or idiosyncratic reaction.[131]

The contergan (thalidomide) disaster of West Germany led to reconstruct the regulation of drugs in 1976 Arzneimittelgesetz. Basically, from the Act of 1961, the registration scheme was replaced with strict monitoring procedures and licensing system. Since there was only preventive measure taken for drug related injuries/ adverse drug event (ADE) but observing constitutional objections from the pharmaceutical industry. Strict liability compensation was brought, observing financial ceiling that is put as liability on pharmaceutical industry. These liabilities were placed through a cabinet bill favouring two-tiered system of fault liability that works through compensation fund and insurance solution based around the strict liability.[132]

Moreover, it has been experienced that presently there is no proper definition for serious and severe adverse events; the definition till date is limited to the sphere of adverse drug event. This is well defined by the Council for international Organisations of Medical Sciences. That means fatal, life threatening, leading towards hospitalisation or resulting in severe disability. Moreover, it has been found through the incident of mefloquine i.e Lariam drug taken by the travelers requires information on its label for warning. An example can be taken from the U.S, because since 2003 it

[131] Morris,Louis A., (1977), "Patient Package Inserts: A New Tool for Patient Education", *Public Health Reports 1974-1977*, 92 (5), p.421-423.
[132] Howells. Geraint. G., (1991), "*Product Liability, Insurance and the Pharmaceutical Industry: An Anglo*", Manchester University Press, p.191.

has been delivering a warning label of adverse neuropsychiatric events and rare reports of suicide. This rule of labeling was not followed by U.K till 2004 as highlighted through traveller Zuckerman.

It has been strongly pointed the information on ADE is found through the media, personal physician/doctor or pharmacists. In this arena the advisory of health agency or government needs to be alert and watchful about any ADE taking place through particular medicine/drug either nearby or in other neighbouring country in order to secure and protect its people. Through informing its reaction before or after the drug/medicine com launches in the market.[133]

Moreover, it has been found that the time-frame set for complaining all the fatal or life-threatening or even those assumed unforeseen serious adverse reactions limited to only seven days after the sponsor gets the information about the case satisfies the essential measures; any follow-up information is to be provided within a further period of eight days. All other unforeseen serious adverse reactions limitation time for notifying is within fifteen days. Different regulating bodies for ADR are: Adverse Drug Reactions Advisory Committee, Committee on Safety of Medicine, MedWatch, Vaccine Adverse Event Reporting System and the WHO-Uppsala Monitoring Committee (UMC) international whose database is in Sweden and preserves all information on ADRs.

Moreover, requirement insists the need to bring new monitoring mechanism of Adverse Events Reporting system (AERS) inbuilt in its website and Risk Evaluation and Mitigation Strategies (REMS) by the pharmaceutical companies as required by FDA. Where more systematic review process of drugs before approval can be made as well as framing of priority review setup for Indian specific drugs discovery and marketing can be observed.[134] NPP, takes all the ADE reports, the NPP particularly looks in the information of: (i) All suspected cases of ADE caused through new drugs and 'drugs of current interest'; (ii) every drug that comes in preview of doubt that is consumed or taken; (iii) by suspect on any other drug reaction on the patient's health that includes those drugs that may cause death, is dangerous for consuming or can bring death, can lead to hospitalisation in prior or later stage, can bring disability of

[133] Frankenfeld, Christian., (2004), ""Serious" And "Severe"Adverse Drug Reactions Need Defining", *BMJ: British Medical Journal*, 329 (7465), p. 573.
[134] Ibid.

permanent or partial along with sever or minimal and that which may lead birth abnormality.[135]

It has been evidence from U.S study that some of pharmacists while substituting their drug formulation in manufacturing the drug/medicines. Use the term inert, while using inert they mean inactive ingredients that is biologically dormant. But, sometimes the inert compound gets active biologically during substituting the composition along with the active ingredients in the medicine. Then it should be termed as excipient not inert. In addition if has been found that manufacturers are not bound to disclose the contents of their inert formulation. Such example of excipient induced toxicities based study are made on: i)renal failure and death from diethylene glycol, ii) osmotic diarrhea caused by ingested mannitol, iii) hypersensitivity reactions from lanolin, and iv) cardiotoxicity induced by propylene glycol. Futher, The US FDA insists on inactive ingredients on the label to enable patients to avoid any iatrogenic drug reaction.[136]

In India,[137] National Pharmacovigilance Programme (NPP) comprises one National Pharmacovigilance Centre located at the Central Drugs Standard Control Organisation (CDSCO), in New Delhi. Having, two zonal centres as All India Institute of Medical Sciences, New Delhi for north and east, and King Edward Memorial Hospital, Mumbai for south and west. Five regional centres as Department of Pharmacology, JIPMER Pondicherry, TN Medical College, Mumbai, IGMC Nagpur, Lady Harding Medical College, New Delhi and NRS Medical College, Kolkata and 24 peripheral centers (including some medical colleges and hospitals approved by the Medical Council of India, private hospitals, public health programmes and autonomous institutes).

Since the 59th report of the Parliamentary Standing Committee on Health and Family Welfare of GoI it has been known about the lapses found in part of the Indian drug regulatory bodies, that requires to prevent approving unnecessary drug approvals

[135] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.5.

[136] Chandy, Sujith J. and Mathew, Binu S. (2006), "Patient Information and Medication Labeling: An Area of Concern", *Indian Journal of Medical Ethics*, 3 (2), p.2-3; available at: www.ijme.in/index.php/ijme/article/view/656/1628

[137] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.5.

under waiver clause of 122A, 122B, 122D, 122DA, 122DAA and 122E of the Schedule Y rules and there is requirement of blocking approvals of FDCs that have already been banned in other countries. The Indian regulatory agency still has to learn and understand the obligation of providing safe medication for individuals and in public sphere.

The ADR form[138] can be taken from any pharmacovigilance centre. The completed form, for vigilance should be sent to its secondary pharmacovigilance centre or if there is case of proper doubt, then it can be sent directly to the CDSCO. The information provided is kept confidential. The peripheral centre forwards the submitted form to the regional centre where causality analysis is carried out, after which it is sent to the zonal centre. The data are statistically analysed and forwarded to WHO-UMC.[139]

In order to obtain financial gain many a time medical fraud takes place causing ADE. Most of the physicians and doctors have complains that government do not provide them with sufficient repayment for the services that they provide. Further, lots of the service fees are not reclaimed by the Medicare that government provides. So, due to such less earning and saving none, it becomes necessary to go for free enterprise business earning and charging as much as required.[140] Example can be like, many surgeons ask for removing organs unnecessarily in its place of using other therapeutic alternative.

The doctor may unnecessarily prescribe a drug for treatment as charging more that leads to ADE and victimizes the innocent patient making him/her as a injured party towards medical fraud. This leads overburdening towards health care system and provides doubt for legitimate healthcare services and treatment. Further, there is a ping-ponging system of health care[141] evolving these days in this type of referring not only consumes time and money but unnecessarily creates mental and psychological disturbance to the family wondering what next has happen.

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[138] ADR form is available at: www.cdsco.nic.in

[139] Bhosale, Vivek. V., and Gaur, S.P.S., (2011), "Adverse Drug Reation Monitoring", Current Science, 101 (8), p.1024-1027; available at: www.currentscience.ac.in/Volumes/101/08/1024.pdf

[140] This statement has been taken from personal interview taken from some of the physicians in Vancouver inner-city, general and family physicians, by the author. Further, See for details, Wilson, Paul, R.. Chappell, Duncan., and Lincoln, Robyn., (1986), "Policing Physician Abuse in BC: An Analysis of Current Policies", *Canadian Public Policy/Analyse de Politiques*, University of Toronto Press, 12 (1): 236-244, p.238.

[141] Wilson, Paul, R.. Chappell, Duncan., and Lincoln, Robyn., (1986), "Policing Physician Abuse in BC: An Analysis of Current Policies", Canadian Public Policy/Analyse de Politiques, *University of Toronto Press*, 12 (1), p.237-238.

> "(P)ing-ponging system of health care service means referring a patient to another physician when such reference for additional care is not required".[142]

Further, acknowledging the inspection committee for drugs whether it is U.S FDA, India's CDSCO all the approved drugs by the drug investigating authority are safe and effective. However, still there occurs fault for those some minority population who may get ADE or idiosyncratic reaction from the same check quality cleared drugs. It seems, nothing can be guaranteed as safe and curable for different individual, due to diverse genes and mutation quality in individuals. Moreover, extensive clinical trials performed to know the medicines applicability process, makes the medicines quality better for treatment then accurately providing cure.

As far, the ADE is found it has been observed that most of the warning or prescribed labeling made from the manufacturers contain insufficient. So, to retaliate to get compensation most of the manufacturers of the drugs are sued. In return the manufacturers seek preemption stating their marketing of drugs is limited to specific labeling that inspection authority provides. In this case the U.S FDA[143] can be cited owing to its customary incidents which it has received and cited stating that the prescribed drugs should be governed by the elaborated regulatory framework that is designed to facilitate federal objectives. Moreover, the Court has cited that the changes in drug labeling are made prior taking the FDA permission.[144]

In India, the National Pharmacovigilance Programme (NPP) that got established by the Ministry of Health and Family Welfare in 2010 works for collecting ADR reports all over the country. The NPP comprises of a national coordinating center that receives ADR information from individual pharmacovigilance centers about the cause, source and the personnel involved in an adverse drug event via a vigiflow software interface operated by Uppsala Monitoring Center. Likewise, every country in world has own monitoring organisation for banned drugs.

Prior to launch of the drug to market in India, its safety and efficacy is checked in accordance with the Scheduled Y of Drugs and Cosmetics Act. Whereas,

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[142] Ibid.

[143] *Motus v. Pfizer, Inc*., 358 F.3d 659 (9th Cir. 2004) (applying California law and affirming summary judgment on causation; did not reach the issue of preemption); Colacicco v. Apotex, 432 F. Supp. 2d 514 (E.D. Pa. 2006); Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006); Kallas v. Pfizer, Inc., Civ. No. 2:04-cv-0998 (D. Utah Sept. 15, 2005) (this case settled prior to decision).

[144] Gross, Jodie M. and Curry, Judi Abbott. (2007), "The Federal Preemption Debate in Pharmaceutical Labeling Product Liability Actions", *Tort Trial & Insurance Practice Law Journal*, 43 (1), p.35-37.

like post marketing surveillance as pharmocovigilance is made on the drugs after it is launched in the market along with other countries report. As a result, information can be examined on banned drugs by the Drug Technical Advisory Board (DTAB) under Drugs and Cosmetics Act.

The Act composes a subcommittee of experts, who inspects the information and makes a final decision whether to prohibit the manufacturing, sale and distribution of such drugs or to confine its consumption along with a result to suggest the Government to create proper amendments under Section 26 A of the Drugs and Cosmetics Act that authorises the Central Government to prohibit the manufacture, sale or distribution of such drug or cosmetics.[145] For drug safety and efficacy NPP has made medical schools that will work as pharmacovigilance centers and where personnel's training is provided. NPP plans to set up Centre of pharmacovigilance at Asia Pacific Region level.[146]

To conquer the burden of ADR in 2003 after the competition of the Human Genome Project personalised medicine (PM) came up. PM has come as a revolution in scientific field bringing new acknowledgement towards healthcare paradigm. PM is about curing or treating individuals' disease which is not genetic medicines. Personalised medicines at present is still in its initial stage in India and some other countries while in E.U and U.S hospitals have started working with it.[147]

Regulating the labeling of Drugs

Regulating drugs and their labeling, requires an acknowledgment of those drugs that have been approved for marketing so that, the inquiry in market can be made once the drug is approved. This can be through publishing of decision on approved drugs for marketing like U.S does. But, this guidance through selective approved decisions does not educate and provide proper direction on marketing therapeutic drugs. This made through providing publically positive and negative decision of approved drug. Like the regulators of Australia i.e. Therapeutic Goods

[145] Ahmad, A., Patel, Isha., Sanyal, Sudeepa., Balkrishnan. R., and Mohanta, G. P., (2014), "A Study on Drug Safety Monitoring Program in India" *Indian Journal of Pharmaceutical Science,* 76 (5), p.382.
[146] Ibid.
[147] U.S News Health, (2013), "Personalized Medicine", The Basics on Personalized Medicine-U.S News Health, Duke Medicines: *U.S News & World Report LP, pp.1-4;* available at*:* www.health.usnews.com/health-conditions/cancer/personalized-medicine. p.1-4.

Administration (TGA) and E.U i.e. the European Medicines Agency (EMA).[148] The regulation of labeling drugs can be done by observing whether the drug is misbranded or not. The meaning of misbrand can be understood negatively through Section 502(f) of the Federal Food Drug & Cosmetic Act. This states that:

> "a product is misbranded unless it's labeling bears adequate directions for use, including adequate warnings against, among other things, unsafe dosage, methods, duration of administration, or application?"[149]

For instance, in the U.S, under Section 502(j) of the Federal food Drug & Cosmetic Act:

> "a product is considered misbrand if it is dangerous to health when used in the manner prescribed, recommended, or suggested in its labeling".[150]

In spite of all the efforts, the Indian drugs banned in other countries are still available. The existence of banned drugs in India is as OTC drugs, having changed formulation but containing same brand name. As OTC drugs are available without prescription ignorant general population is unaware of the ADE the drug may cause as well as the pending case laws in court for the banned drugs distribution and supply continues till the judgment is not made for banning the drug. The insufficient data on ADE and its reporting in India proves that still lack of knowledge and practice along with poor pharmocoviligance network exist in India.[151]

In order to know about regulating the labeling it's important to understand the requirement of information provided about prescribed drugs and the acknowledgement on what the patient is consuming. So understanding both the requirements of right to know and health education, PPI becomes a must informant on health based for prescribed medicines. PPI's not just help or educate the consumer on his/her therapy but helps in understanding manufactures and prescribers responsibility.[152]

The practices for permission of the OTC drugs involves, reviewing of OTC drugs labeling by understandable public language along with information based on consumers remark while listing of OTC drugs. Such, OTC drugs should provide

[148] Herder, Matthew., (2014), "Towards a Jurisprudence of Drug Regulation", *Journal of Law Medicine & Ethics* (42), p.244.
[149] Section 502(f) of the Federal food Drug & Cosmetic Act.
[150] Section 502(j) of the Federal food Drug & Cosmetic Act.
[151] Ahmad, A., Patel, Isha., Sanyal, Sudeepa., Balkrishnan. R., and Mohanta, G. P., (2014), "A Study on Drug Safety Monitoring Program in India" *Indian Journal of Pharmaceutical Science,* 76 (5), p.380.
[152] Morris,Louis A., (1977), "Patient Package Inserts: A New Tool for Patient Education", *Public Health Reports 1974-1977,* 92 (5), p. 421, 422 and 424.

accurate monographs, indication of all raw materials employed in developing the drug, dosage, direction for consuming the drug and other labeling information. In order to prevent mix-up and misuse of the product, proper identification of the raw materials intermediates and finished product is required. So, that no mislabeling occurs, whereas, if found necessary packages of such drugs can be sealed along with mishandling and tempering remark of the package.

In fact concerned regulatory authorities are also aware that after such precaution still deviation and changes becomes unavoidable. Sometimes to get approval for handling, reviewing and approval change in raw materials, condition, analytical methods, services, tools, development, computer software, and labeling and packaging. All the alteration of documentation is required along with traceability indication through GMP system. An example can be experiment during GMP Consent Degree that includes.[153]

> "In May 2002, Schering - Plough was fined US $ 500 million for GMP violations by the FDA under the consent decree scheme. The issue centered on the GMP violations of the manufacturing facilities in New Jersey and Puerto Rico. A total of 13 inspections were carried out by the FDA from 1998 to 2002. The non compliances were related to the facilities, quality assurance, manufacturing, equipment, laboratories, and labeling. In addition to the US $ 500 million that Schering - Plough had to pay, it also had to settle about US $ 500,000 for inspection costs, recall several products, suspend or discontinue certain products, and revamp its quality system to ensure future compliance".

These changes have to be reviewed through reference of risk assessment as well as execution takes place after approval. A method need to be adopted so that the quality is not compromised on the drug product for re-examining or re-validating the affected system tools. It becomes necessary to monitor all the ongoing changes so that long term impact can be observed in controlled system. Later, the finished dosage forms are packed in aerosol containers, bottles, blister packs, syringe, tubes or vials. Nowadays, packing contains tamper-proof designs so that reliability of the package can be made.

The labeling of the package is made in accordance to the information submitted to the regulatory authorities. APIs are active pharmaceutical ingredients that include the drug molecules that interact with the receptors or enzymes.[154] Packaging and Labeling of APIs and Intermediates (the International Conference on

[153] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc, pp.330.
[154] Ibid. p.351.

Harmonisation (ICH) (1997) Guide for API: Good Manufacturing Practice), along with finished dosage forms under FDA regulation are:

> "a) Written procedures for receipt, identification, quarantine, sampling, examination, testing, release, and handling of packaging and labeling materials; b) Records of shipment and packaging; c) Containers suitable for intended use; not reactive, additive, or absorptive to intermediates or API and must protect contents from deterioration and contamination; d) Access to labels limited to authorized personnel; e) Reconciliation of quantities of labels issued and used' f) Procedures to ensure correct packaging and labels are used; g) Labeling operations should prevent mix-ups; h) Examination of containers and packages to ensure use of correct labels; i) Transport materials with seals that will alert recipient of the possibility of alteration if seal has been breached".[155]

In U.S is regulated through FDA regulations. The FDA looks after the surveillance and compliance inspection as well as the regulatory authorities takes care of the inspecting of GMP facilities to ensure compliance to GMP. Further, observing all the requirements it adopts system bade approach for facility, equipment and quality; materials; laboratory control; packaging and labeling and production. Further, deficiencies can be reported through Form FDA-483, which leads towards a warning letter and consent decree if unresolved.[156]

Ethical Concern for Drug Pricing

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)[157] and access to medicine has gardened astonishing amount of public attention. The patenting and providing novelty to the discoverer has some way isolated access to medicines and essential care and treatment for the needy and poor individuals who cannot afford it. An example can be of HIV/AIDS where 37.8 million people have been affected with it and 2.9 million have died as well as demand of

[155] N.G, Rick. (2009), "*Drugs from Discovery to Approval*", 2nd edition, Wiley-Blackwell: New Jersey. A John Wiley and Sons, Inc, p.351.
[156] Ibid, p.249, 294, 297, 351 and 355.
[157] Historically, TRIPS Agreement came through Uruguay Round, where World Trade Organisation (WTO) an international organisation was born after trade discussions from September 1986 to April 1994 transforming the General Agreement on Tariffs and Trade. TRIPS Agreement requires its members to provide effective intellectual property rights (IPR). Signing the TRIPS Agreement on 15 April 1994 in Marrakech, Morocco by its member States it required all WTO members to provide certain minimum standards of protection for all kinds of IPR, including patents, copyrights, trademarks, trade secrets and geographical indications. For details, see, Ozdemir, Aysegul. (2008), "*TRIPS Agreement and Access to Essential Medicines*" Ankara Bar Review,*HeinOnlin,* p.90-91.

higher prices for medication by enabling pharmaceutical companies have constantly held back access to medicine.[158]

Research and Development (R&D) acts as a very important role in availing medicine and health services. But, in order to find a cure of a new disease and enjoy the orphan drug benefit is unethical conduct. This unethical conduct is carried many a times like it was done during observing the race of patent on an antibody test kit, like for Human Immunodeficiency Virus (HIV). It has been revealed that Burroughs Wellcome (BW) a private company had enjoyed benefitting by charging $10,000 per patient. Since, Azidothymidine (AZT) was the only drug for HIV treatment available for many years in the market. Besides, BW had also enjoying the special beneficial treatment in US as orphan drugs. The patent by BW benefitted it in many ways as prior it sent the compound to Gallo, National Cancer Institute (NCI) Horwitz that was found as AZT compound in 1985. The compound was already sent in support of patent application to United Kingdom (UK) for AZT. Patent to AZT of British pharmaceutical company BW was provided in 1987 by UK and later in 1988 by United States (US). It is exposed that in 1987, US Food and Drug Administration (FDA) was the one to approve clinical research of AZT, with orphan drug treatment. But, never the least it is also exposed that BW later gave some 4,500 patients with free ATZ worth $10 million.[159]

The paragraph 3 and 4 of the Doha Declaration on the TRIPS Agreement and Public Health WT/MIN/(01)/DEC/2 of 20 November 2001 states that:

> "We recognise that intellectual property protection is important for the development of new medicines … concerns about its effects on price; … TRIPS Agreement … should not prevent … measures to protect public health. … we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we affirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibilities for this purpose".[160]

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[158] Hestermeyer, P. Holger, (2004), "Access to Medication as a Human Right", *Max Planck*, UNYB 8, p.103 and 105.

[159] Hestermeyer, Holger, (2008), "Human Rights and the WTO: The Case of Patents and Access to Medicines" *Oxford Scholarship Online*, p.1, 3-6 Oxford University Press; available at: www.isus-stiftung.de/attachments/article/60/Background_of_the_Debate.pdf

[160] Paragraph 3 and 4 of the WTO, (2001), "*Doha Declaration on the TRIPS Agreement and Public Health"*, WT/MIN (01)/DEC/2 of 20 November 2001. 14 November 2001, World Trade Organisation, Doha, Qatar.

Similarly, strong intellectual property protections and exclusive marketing rights raises ethical concern towards the price of the essential drugs, especially meant for infectious diseases like HIV/AIDS, respiratory infections, malaria and tuberculosis. The patent does not just influence the drug prices. But, in some way it also affects the living conditions of economically weaker sections like BPL individuals who require instant medicines or drugs in absence of generic competition. Additionally, the factual reality is that many a times the Government, itself in such countries is under pressure by multinational pharmaceutical companies of industrialised countries and cannot lower the price of medicines due to concealed constrains.

Therefore, it becomes problem in order to avail the new generation medicines for people who cannot afford it making them poorer attaching their paucity towards harsh sustainability.[161] The MDG in its Target No. 8 E to states that:

> "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries".[162]

Many a times for this reason, new entity or person comes on their behalf and speak for the weaker sections. On this basis the illustrated case of South Africa i.e., Minister of Health v. Treatment Action Campaign (TAC) (2002) 5 SA 721 (CC) highlights that a South African NGO has to come up representing individuals affected by AIDS and joined the case as amicus curiae. Similarly TRIPS and public health problems for developing countries brought the paragraph 6 and 7 of the Doha Declaration on the TRIPS Agreement and Public Health WT/MIN/(01)/DEC/2 of 20 November 2001 that states:

> "We recognise that WHO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002; … We affirm the commitment of development of developed country members to provide incentives to their enterprises and institution to promote and encourage technology transfer to least developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply

[161] Ozdemir, Aysegul. (2008), "*TRIPS Agreement and Access to Essential Medicines*" Ankara Bar Review,*HeinOnline*, p.91-92.

[162] Target 8E of MDG Gap Task Force Report 2012, (2012) "*Millennium Development Goal 8-The Global Partnership for Development: Making Rhetoric a Reality*", United Nations Publications, New York. p.ix-x.

> Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement".[163]

The paragraph 6 places exercising of compulsory licensing, referring governmental authorisation to exploit a patented invention without consent of the patent holder. According to Doha Declaration adopted by TRIPS Council in 2001, each council member has freedom to determine grounds upon which compulsory licenses are granted. However Article 31 of the TRIPS Agreement[164] sates on:

> "*Other Use Without Authorization of the Right Holder*- Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:"[165]

lays out certain procedural restrictions on using compulsory licensing including: i) authorisation on individual merits; ii) prior negotiations; iii) adequate remuneration; and iv) judicial review of the decisions. In addition Article 31 (f) of TRIPS Agreement states that the compulsory license should be predominantly for the supply of domestic market.[166] Article 31 (f) of TRIPS provides hardship on countries with insufficient or no manufacturing capacities as the article does not allow to obtain medicine from other countries whether the issuing country is insufficient to manufacture required medicines. As well as, it cannot obtain the necessary medicine from another country by compulsory licensing where it is manufactured to serve its domestic market.[167]

The usage of human rights based approach has enabled reaching out to the poor and the vulnerable so as to provide a solid basis and high moral. The General Comment No.14 of the Committee on Economic, Social and Cultural Rights

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[163] The WTO, (2001), *"Doha Declaration on the TRIPS Agreement and Public Health",* WT/MIN (01)/DEC/2 of 20 November 2001. 14 November 2001, World Trade Organisation, Doha, Qatar.

[164] Article 31(f) states: "f) any such use shall be authorised predominantly for the supply of the domestic market of the Member authorizing such use;". Article 31(f) of "Agreement on Trade-Related Aspects of Intellectual Property Rights", Annexure IC, 319-351. p.333.

[165] Ibid.

[166] Ibid.

[167] Chung, Laura. (2010), "Use of Paragraph 6 System for Access to Medicine", *N.C. Journal of International Law & Com. Reg*. XXXVI: 138-186). Pp.39-41; The WTO (2003), "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (2003), the General Council of 30, August 2003, WT/GC/M/82; and The WTO, (2001), "Doha Declaration on the TRIPS Agreement and Public Health", WT/MIN (01)/DEC/2 of 20 November 2001. 14 November 2001, World Trade Organisation, Doha, Qatar.

(CESCR) by analysing the RTH including the right to enjoyment of the necessary goods, such as medicines states four elements that are necessary for health care, safety and standards. They are: "i) availability; ii) accessibility; iii) acceptability; and iv) quality".

There are indications towards the developed progress and indicators by the Millennium Developmental Goals (MDG) Task Force for proportion of the population with access to affordable essential drugs on a sustainable basis defines access having medicines constantly available and affordable at public or private health facilities or medicines outlets that are within the reach of one hours walk from homes of the population.

The Political Declaration on HIV/AIDS pandemic by report 2008 of WHO and UNAIDS state that they will follow these three health sector interventions for purposes of monitoring progress toward universal access to treatment: "i) Availability, defined in terms of physical access, economic access or affordability, and socio-cultural acceptability; ii) Coverage: the proportion of people needing the intervention who receive it; and iii) Outcome and impact, as measured in terms of behavior change, lower infection rates, or higher survival rates". WHO's draft Medicines Strategy 2008-2013 commits the organisation to assist its member countries in the implementation of a renewed and re-invigorated Primary Health Care approach, and to renew the focus on the public sector and essential medicines.

WHO's return to the principles of Alma Ata and primary health care[168] is powerfully supported by the report of its Commission on Social Determinants, which includes as one of its overarching recommendations "tackle the inequitable distribution of power, money, and resources". [169] This inequitable distribution has been on grand display in the strenuous efforts for introduction and enforcement of TRIPS-plus conditions. But if countries follow the Commission's exhortation that "[a] core objective of all health-systems policy must be to ensure that everyone has access

[168] *Declaration of Alma-Ata International Conference on Primary Health Care*, Alma-Ata, USSR, 6-12 September 1978.
[169] World Health Organisation. (1998), World Health Organisation "*From Alma- Ata to the year 2000: reflection at the Midpoint*". Geneva: WHO.

to competent, quality care independently of ability to pay," they will need to review critically the application of excessive TRIPS conditionality.[170]

Moreover, the unequal strategy of drug pricing due to heavy spends on R&D leads unaffordable prices on patented and new drugs. Patient's protection through affordable care can be organised on the other hand by insurance. But, different like life and health insurance, etc with uneven interest and premium rates makes it difficult to understand which insurance for what disease and suffering to be taken. The peoples' Charter for Health 2000 rightly states in its preamble that:

> "(H)ealth is a social, economic and political issue and above all a fundamental human right. Inequality, poverty, exploitation, violence and injustice are the root ill-health and the deaths of poor and marginalised people. … powerful interests have to be challenged, that globalisation has to be opposed, and that political and economic priorities have to be drastically changed".[171]

It becomes responsibility of State and Government to look after pricing of drugs so availability can be possible without hazel to every individual.

Conclusion

In today's busy world, dependency on drugs by individuals has increased, due to the expectation of fast healing from the sufferings during sickness. Inventions of drugs are raising the number of escalation in adverse drug effect (ADE) the pre-marketing arrangements of drugs have to be strictly regulated so that innocent drug consumers can know which combination is exposing the risks of consuming any iatrogenic drug reaction to their genotype. So far, to provide scientific approval to the researched and examined drug labeling process is carried to know the safe combination which is not banned in the country.

Though, the WTO through Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health 2003 Article 2 (ii) supplies firm dealings during specific labeling for produced product for marketing. It could be possible by way of "special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price". This information is laid necessary so that drug

[170] Puymbroeck, Rudolf V. Van. (2010), "Basic Survival Needs and Access to Medicines Coming to Grips with TRIPS: Conversion + Calculation", *Journal of Law, Medicine & Ethics*, Global Health Governance, p. 521-522, 540-541.

[171] Paragraph 1 in the Preamble of PHA, (2000), "the Peoples Charter for Health", People's Health Assembly (PHA), adopted on 8 December 2000, Savar, Bangladesh.

consumers can know how best to them is the health service provided through medicine as stated in the Principles of the Rights of Patients in Europe (1994) provides with the understanding through its Article 2(1).

Drugs are part of rational system of quality of treatment and care. Patent rights and sharing of scientific knowledge through the help of Article 15(b) and 15(c) of the ICESCR 1966 makes availability of the right to development in socio-economic condition. Role of patent system for discovery and development of drug through its innovation has brought mostly the private pharmaceutical firms in the market. Moreover, Article 13 of the Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises Regard to Human Rights (2003) also state that protecting consumers rights in "accordance with fair business, marketing and advertising practices and shall take all necessary steps to ensure the safety and quality of goods and services they provide, including observance of the precautionary principle. Nor shall they produce, distribute, market, or advertise harmful or potentially harmful products for use by consumers". Presently, to avoid side effects and long term use of medicines traditional medicines are considered more helpful and natural. About 40% in China and Cambodia, 80% traditional medicine is used in some African countries and mostly developed countries are too trying to adopt this measure. But still its significance gets limited when one needs fast healing and cure.

But, growing counterfeiting drugs in market has also led the requirement of labeling stronger, so that authentic product can be analysed easily. In this regard WHO has suggested some specific measures for individual national strategy like: "Strengthening of political determination within individual countries to deal seriousness of the threat of counterfeit drugs; b) The creation of appropriate legislation to secure drugs in distribution channels, to increase requirements for the renewal of licenses, and for the screening of drugs at the port of entry; c) The establishment of national drug regulatory authorities with effective independent enforcement powers; d) Increase the enforcement of existing drug control laws; e) Creating partnerships between pharmaceutical manufacturers and governmental authorities in order to foster cooperation and communication; and f) Increasing patient awareness and education regarding counterfeit drugs".

The U.S. FDA in 2002, provided new guidelines for labeling: "the drug facts panel should have the name of the drug, its active ingredient(s), purpose(s), use(s),

warning(s), directions, other information, inactive ingredients and questions. Drugs that fail to follow these labeling requirements will be termed as misbranded, Moreover, Australia is one of the countries that does not reveal the inactive ingredients of product.

Moreover, in the US the Packaging and Labeling of APIs and Intermediates along with finished dosage goods is done through Packaging and Labeling of APIs and Intermediates (the International Conference on Harmonisation (ICH) (1997) Guide for API: Good Manufacturing Practice), along with finished dosage forms under FDA regulation.

Drug labeling even includes ethical responsibility and duty for pharmaceutical industry to highlight about the drug/medicines. It has always been condemn and experienced that the labeling of drugs should contain specific warnings with what those medicines can contain side effect or adverse drug effect (ADE). Negligence is observed through the pharmaceutical industry or doctors for not providing labeling and information liability about a drug/medicine that has to be consumed. Moreover, several times these essential details are taken through personal pharmacist or physician/doctor.

The media either through international streaming or national news informs about ADE occurred through XY medicine. Besides, health agencies or governments should be particularly observant in monitoring any kind of information or data on ADE occurrence and note such facts. So that, drug manufacturers liability falls to inform such details to the consumer through labeling it on the drug. The misguiding and mislabeling of drugs can profit the corrupted but might kill an innocent.

Many a time proper language i.e. script of national language or maximum speakers language is not provided while labeling of instructions for consuming drugs. The regulating body needs to be more vigilant in following direction for observing the drugs importations scrutiny as well as requirement for providing proper list of approved and disapproved drugs for marketisation has to be provided. So that the people along with different countries can know the default in particular drug and benefit of approved drugs.

Further, observation on generic medicines has to be made so that after regenerating such drug no further hidden ADE reactions takes place to the individual consuming the medicine. OTC medicines require control, as it has been observed that

these drugs do not provide same functions for different individuals as well as different manufacturers can create different formulation creating reactions along with manufacturers bringing those medicines that have been banned in other countries. The need of labeling the drugs that is being imported and coming in the market. Drugs regulation followed by the different countries through different regulating bodies is need to be analysed so a proper harmonising level of drug regulation and labeling can be made at international level. Still a proper mechanism for detecting the sale of counterfeited drugs is not possible. Moreover, the labeling facility still generates obstruction in letting the cautious instruction for ADE.

Chapter-V

REGULATORY CHALLENGES FOR PERSONALISED MEDICINE

INTRODUCTION

Presently, to obtain safety and peace we are not just conquering terrorism with scientific technology but even looking into treatment as quality of care by identifying vulnerable and targeted diseases. Growing health disparities in treatment creates violation in healthcare and healthy condition. In order to offer possible health condition to individuals, personalised medicine (PM) has come up as an evolution in the field of biotechnology or pharmocogenomic (PGx). The impending concept of PM that is also known as precision or individualised medicine[1] in the health care promises to bring revolution with the help of gnomonic and scientific technology in the field of health care. This promise, of scientist/researcher's in the field of PGx is to bring PM as a molecular analysing method so that no more wrong medication and side effects occurs through consuming particular drug reacting individual's body.[2]

So far, the tripartite obligation under international law affirms countries to respect protect and fulfill individual's right to health (RTH) without any discrimination and disparities in health standards. Article 12(2)(d) of the ICESCR obligates state parties to the Covenant to create such condition in medical service and attention[3] that will assure RTH through technology development. Health right is a basic human right. Science and modern technologies development need to respect human rights. The Universal Declaration on Human Genome and Human Rights (1997), with the help of Rights of the Persons Concerns, states (Article 10) that:

> "(N)o research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people".[4]

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[1] Genetics Home Reference, (2016), "What is the difference between precision medicine and personalised medicine? What about Pharmacogenomics?", The National Human Genome Research Institute (NHGRI), *U.S. National Library of Medicine;* available at: www.ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalised

[2] Ibid.

[3] Article 12(2)(d) of the ICESCR 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[4] Article 10 of the Universal Declaration on the Human Genome and Human Rights, 1997, General Conference of UNESCO, 29th Session on 11 November 1997, Records at Conference; available at: www.unesco.org/shs/human_rights/hrbc.html

The field of biology, genetics and medicine need to take precaution during experimenting and treating/curing their subjects so that individual's human dignity and human rights are not harmed or curtailed. According to the PGx scientist/researchers, PM in the era of modern world can change the trial and error method of practicing medicine. If acceptance of PM comes into practice in daily lives, accuracy in detection of disease/suffering therapy can be possible. Moreover, scientific developments and approaches have never been in crystal clear. At present, difficulty arises in formulating the regulating formation of PM as a health right. Similarly, patient's rights on data safety and privacy/confidentiality, etc. have surrounded its specialty.

Personalised Medicine as a Health Paradigm

Personalised medicine (PM) has come up as a health paradigm, bringing hope in treating human diseases and sufferings by minimising severe side effects through prescription of accurate drug and its dosage according to individuals need. The rising reason for ineffectiveness of drugs as well as growing side effects and reactions has vigilant individuals with adverse drug reaction (ADR) deaths. Since this reason lies in the formation of bringing, PM as an improved scientific method to RTH, it helps bring about perfection in the prescription of drugs, that doctors/physicians prescribe their patients.

This perfection of drug consumption with limitation in side effects can be possible only when, genomic study of individuals' body by dosage system requirement in milliliter (ml) or gram (gm) is drawn during clinical experiments and its analysis. Along with this understanding of genetic requirement analysis environment and lifestyle factor[5] of body needs and reactions are to be examined while researching. This understanding of dosage system through genomic analysis can be understood when an individual suffers tumor, etc. becomes voluntary subject of PM trial. In regard to voluntary consent, the International Convention on Civil and Political Rights (ICPR) 1976 (Article 7) states that:

[5] To understand drug qualities and reactions, precision medicine has been used as a term by the National Research Council over personalised medicine in U.S. For details see, Genetics Home Reference, (2016), "What is the difference between precision medicine and personalised medicine? What about Pharmacogenomics?", The National Human Genome Research Institute (NHGRI), *U.S. National Library of Medicine*; available at: ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalised

> "No one shall be subjected to torture or to cruel, in-human or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."[6]

Since, voluntary consent is a requirement for clinical research subjects' experimentation. PM during this process helps to analyses how particular drug will function according to its modulation. Like, in the advance disease level where no drug works, then genomic testing may help in understanding the root cause of drug resistance in a body and reacting formulation. This study also helps in understanding better therapies requirement of the body. PM helps in identifying a patients risk before disease develop and enable them to take steps towards prevention through medical treatment, lifestyle modification or both.[7] But, this understanding is not just limited here, the genetic/DNA test of individual specifies reactions and allergies towards the curing drug/medicine too, due to molecular intake.

PM is an interchangeable word with individualised or precision medicine.[8] The terminology of PM has come up as a new concept rising for RTH due to progressing awareness of technology and health development. Historically, PM came as a new scientific technology from the delivery of 2003 human genome projects (HGP) completion by the U.S Department of Energy and the National Institutes of Health. The HGP came as a first gene locator that brought, out the order of 3 billion units of DNA. By, identifying all the genes located at vast amount of data making it human genome, so that understanding for complexity of diseases through its correct sequencing can be set. Moreover still, there is lot to learn about controlling elements of genes etc. for the betterment of human health and well being. Currently it is established that about 22,000 to 23,000 genes counts of human genome are present in a human body.[9] Scholars, researchers and policy makers are of vision that genome

[6] Article 7 of the *International Covenant on Civil and Political Rights* (ICCPR), United Nations Doc. A/6316 (1966), General Assembly Resolution 2200A (XXI); available at: www.unhchr.ch/html/menu3/b/a_ccpr.htm

[7] The Caryl and Israel Englander Institute for Precision Medicine, (2016), "Definition-Precision Medicine", Weill Cornell Medicine, The Caryl and Israel Englander, Institute for Precision Medicine, 1300, York Avenue: NY; available at: www.ipm.weil.cornell.edu/about/definition

[8] Brousseau, Zachary., (2015), "New Regulatory Approaches Key to Future of Personalized Medicine", *Regulatory Affairs Professionals Society (RAPS): Driving Regulatory Excellence*, p.1; available at: www.raps.org/Regulatory-Focus/RAPS-Latest/2015/05/13/22160/New-Regulatory-Approaches-Key-to-Future-of-Personalized-Medicine/

[9] Human Genome is a blueprint of human body. It identifies how we look, our body's adaptation as well as reaction for certain medical conditions as well as how are body can fight with diseases, respond to food that we consume, therapies we take along with its metabolism strength. Human Genome consists of total DNA together with its genes. The sequencing actually means that DNA consists of

based medicines may bring better healthcare with the help of genetics and biotechnology. It is necessary that disease and its cause can be reduced by treating the root cause of the suffering by understanding the basic reason for body reactions and allergy from adaptability and gene process.[10]

The research initiative for PM has been conducted in the sphere of lung cancer, cardiovascular disease, coronary artery disease, alzheimer, hepatitis C, smoking cessation, alcohol-use-disorder and HIV/AIDS, etc.[11] The hospitals have also started using PM initiatives on their patient's through direct to consumer base. But, PM is not an established part of clinical practice routine. Like, in India it is only in some large medical institutions, like Medanta is having PM programmes.[12] PM initiative is growing and diseases are still being conducted in phase of clinical studies for PM and genomic studies.

Definition of Personalised Medicine

In regard to the definitional understanding at present only the U.S legal mechanism has defined PM. This understanding of PM many a times is confused with genomic medicine. But, PM and genomics medicines are not same, because in genomic medicine, genetics is the study of heredity and in PM it is about curing or treating individuals' disease through knowing genetic map.[13] Genomic medicine is a subset of personalised medicine. By identifying genetic, genomic and clinical information of an individual body helps for PM. That means for PM when genetic and DNA data's are collected then accurate predictions about an individual's vulnerability towards future developing disease and its route along with its response for treatment

four chemicals known as double helix and their chemical names are abbreviated as: i) A; ii) T; iii) C; and iv) G, that is sometimes referred as code with four letters. Consisting 3 billion pairs of these chemicals having only 2 percent of genes in human genome about 22,000 to 23,000 genes making it chromosomes. For detail, see, Ibid.

[10] Precision Medicine Initiative, (2016), "Precision Medicine Initiative a cohort program", *National Institutes of Health*; available at: www.nih.gov>precision-medicine.

[11] Jameson, Jlarry and Longo, Danl, (2015), "Precision Medicine-Personalised, Problematic and Promising", *the New England Journal of Medicine*", Verginia Tech. Massachusetts Medical Society, p.2230.

[12] Agarwal, Anchal., and Muralidhar, K.S., (2014), "India's First Personal Genomics Clinic Launched by Positive Bioscience and Medanta-The Medicity", *PRNewswire: New Delhi*, 1 August, 2014; available at: www.prnewswire.co.in/newsreleases/indiasfirstpersonalgenomicscliniclaunchedbypositivebiosciencean dmedantathemedicity2695316

[13] U.S News Health, (2013), "Personalized Medicine", the Basics on Personalized Medicine-U.S News Health, Duke Medicines: *U.S News & World Report LP*, p.1-4; available at: www.health.usnews.com/health-conditions/cancer/personalized-medicine

can be predicted accurately for treatment.[14] In the U.S., the NHGRI defines genomic medicines as:

> "(A)n emerging disciple that involves using genomic information about an individual as part of their clinical care (e.g. for diagnostic or therapeautic decision-making) and the health outcomes and policy implications of that clinical use".[15]

Similarly, the National Institutes of Health (NIH), for PM states that:

> "Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle of each person".[16]

The National Research Council of U.S considers "PM is an older term, meaning similar to precision medicine."[17] The Genomics and Personalised Medicine (US) Act 2008 Sec. 2(2) states that:

> "Personalised medicine is the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, help determine a person's predisposition to a particular disease or condition and identify any targeted prevention strategies for that prediction".[18]

With the role of emerging PGx practice in reshaping healthcare. PM makes individuals aware of tendency to know about particular disease they may suffer in long run. So to prevent such condition strategies can help or prevent such identification of diseases. Observing PM development on health needs study by U.S govt. financial statement report indicates that present global market in North America and Europe for the year 2015-2022. Considers IBM, Intel, GE Healthcare, Novartis & Medtronic as key players for PM. Consisting of $88 billion market values cover for comprehensive annual financial report (CAFR) of 12.6% from 2015 to 2022.[19] The

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[14] Ibid.

[15] National Human Genome Research Institute, 30 March 2015; available at: www.genome.gov.27552451/what-is-genomic-medicine

[16] National institutes of health (NIH), Nih.gov, (2016), "What is Precision Medicine?-Genetics Home Reference", USA.gov; available at: www.ghr.nlm.gov>definition

[17] Genetics Home Reference, (2016), "What is the difference between precision medicine and personalised medicine? What about Pharmacogenomics?", The National Human Genome Research Institute (NHGRI), *U.S. National Library of Medicine;* available at: www.ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalised

[18] Article 2(2) of the Genomics and Personalised Medicine (US) Act 2008. H.R 6498 (110th) 15 July 2008; Available at: www.govtrack.us>congress>bills

[19] Business Wires: A Berkshire Company, "Global Precision Medicine Market (2015-2022)-Key Players are IBM, Intel, GE Health Care, Novartis & Medtronic-Research and Markets", Laura Woods, *Press Research and Market*; available at: www.businesswire.com/news/home/20160310005651/en/Global-Precision-Medicine-Market-2015-2022---Key

main aim of these companies is to focus on genetic diseases like oncology following through CNS, CVD, respiratory, skin and other infectious diseases.[20]

The African Charter on Human and Peoples' Right 1981, under Article 16(1) and (2), states that:

> "1. Every individual shall have the right to enjoy the best attainable state of physical and mental health; 2. States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medicinal attention when they are sick"[21]

Thus the African Charter underscores importance of health protection for individuals become possible through ensuring of medicinal attention. Drugs are one of the main components of RTH and essential to promote best attainable state of physical and mental health. Observing the same, at present only American govt. has come out stating in 2016 Budget report for PM. The 44th American President, Barrak Hussain Obama has launched $215 million investment for PM, so that revolutionised health care treatment through patient's power research[22] can be possible in America.

This application of genetic science and technology in pharmaceautical therapy has brought pharmacogenomics[23] (PGx) in practice. To know PGx, one has to understand pharmacology that means science of drug and genomics the study of genes and its functions.[24] Observing, the need for research and development (R&D) during clinical trials, as well as financial constrains have been felt during processing stage of PM by the pharmaceutical industries. To litigate this process and regulations by examining ethical practice and legal norms for gaining the result of PM becomes sometimes difficult. Since, the improved and accurate practice of PM can be a breakthrough invention when R&D or clinical trial process of identifying problems in drug formulation for large group[25] is known.

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[20] Ibid.

[21] The African Charter on Human and Peoples' Rights (1981), Accessed on 23 May 2015; available at: www.1.umn.edu/humanrts/intree/z1afchar.htm

[22] The White House: Office of the Press Secretary, "Fact Sheet: President Obama's Precision Medicine Initiative", 30, January 2015, Briefing Room: Statements and Release, *The White House*, U.S.A gov; available at: www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative

[23] Genetics Home Reference, (2016), "What is the difference between precision medicine and personalised medicine? What about Pharmacogenomics?", The National Human Genome Research Institute (NHGRI), *U.S. National Library of Medicine*; available at: ghr.nlm.nih.gov/handbook/precisionmedicine/precisionvspersonalised

[24] Ibid.

[25] The National Cancer Institute, i.e part of the National Institutes of Health in Bethesda, Md., made a trial to identify whether genetic testing can identify the most effective treatment for women with early stage of breast cancer. From this trial it has been analysed that individual genetic differences states the

Understanding Drug Reaction and Personalised Medicine

Accepting the need to understand injury to health through drugs, PM has come as a boon for medical industry making the healthcare availability and service more accurate minimising the defaults of wrong medication. In fact it provides basic building block for PM to analyse requirements of human body through his/her DNA and genetics buildup along with their lifestyle environment.[26] Moreover, hereditary or family history of diseases calculation can help in controlling some of the predictable diseases of individuals during course of genetic testing for PM. The scientific development through biotechnology has brought accuracy in identifying the root cause of diseases. The PM is believed to be damage/disability controller in the healthcare arena with proper amount of dosage for different body level. With the intention PM will help individuals by tailoring the old method of practice-trial and error. Since, the possibility of PM accuracy predicted to be possible only through the hard analysis and examination work of an average about 17 years. From the data's collected during clinical trials, to find out the validation of research findings conducted on voluntary subjects through its dosage reactions.[27] But, this validation at present stage is also not in perfect assumption. Till level of research findings is not made on end number of subjects. To perfect the accuracy along with its standard of quality according to the drug approval mandates of a country and the importing countries standard has to be kept in view.

Section 124, Part XII of the Drugs and Cosmetics Act 1940 of India states on the standard of drugs in Indian Pharmacopoeia that it is specified in the "immediately preceding edition of the Indian Pharmacopoeia".[28] Moreover, experiments, state that

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metabolising power of certain drug, whether it works effectively or too slow or either the drug provides any toxic level. This information leads doctor to adjust the dose or switch to other medicine before any complication occurs. This trial on breast cancer has been conducted first time for personalised medicine as announced on 23 May 2006 by Dr. Elias A. Zerhouni, NIH director. NIH, (2006), "Personalised Treatment Trial for Breast Cancer Launch", National Institutes of Health, News Release, 23 May 2006; available at: www.nih.gov/news-events/news-releases/personalized-treatment-trial-breast-cancer-launched

[26] Armelagos, George J., Barnes, Kathleen C., and Lin, James. (1996), "Disease in Human Evolution: The Emergence of Infectious Diseases in The Third Epidemiological Transition", (Reprinted from) *National Museum of Natural history Bulletin for Teachers,* 18 (3), p.1-6; available at: www.facstaff.unca.edu/cnicolay/cluster/disease-evol.pdf , p.1-6.

[27] National Human Genome Research Institute, 30 March 2015; available at: www.genome.gov.27552451/what-is-genomic-medicine

[28] Section124 of *the Drug and Cosmetic Act 1940*, (2016), Bare Act: With Short Comments, Professional Book Publishers: New Delhi, p.149.

most of the drugs that work on some individuals may not react the same way on other individuals. But the standard of the drugs have to maintain according to the standards set by a country law in which it is being traded. Since, every individual body has different adaptation and reacting capability based on different genotype structure for which individuals' DNA and genetic test is taken. This test reveals the body structure with what an individual body may adapt and react to in different stage of drugs. The PM comes in preview to treat during specific disease suffering through proper dosage and accurate analysis of bodies' reaction. At present for example, when cancer drug is analysed, as of, only about 25% of the people who take, they can be effectively[29] be treated and not all. While many a times it has been observed that the drugs are dangerous for them who consume it without proper PGx testing.

Similarly, studies keep revealing and exposing about drug reactions and ADE. The Institute of Medicine based in Washington D.C estimated that around 2 million Americans in a year get hospitalised for adverse drug reaction and about 100,000 die per year.[30] PM initiative has been considered to bring help in reducing such numbers of deaths and adverse drug reaction. By identifying in advance the injuries that may arise in human body, genetic coding may help in recognising side effects. As, personalised medicine is not widely used, still this method of genetic testing and its revelation may help predicting minor genetic variation by 6 mercaptopurine toxic response based on its genetic code.[31] Moreover, patients having such genetic variation may too develop life-threatening anemia from the drug.[32]

It has been discovered[33] that with the help of biomarkers during the clinical trial phase, about 12%-50% of the compounds can be studied as PM.[34] This process

[29] NIH, (2006), "Personalised Treatment Trial for Breast Cancer Launch", National Institutes of Health, News Release, 23 May 2006; available at: www.nih.gov/news-events/news-releases/personalized-treatment-trial-breast-cancer-launched

[30] Ibid.

[31] In 2012 FDA approved a new therapy, the drug Kalydeco generally known as ivacaftor for cystic fibrosis (CF) i.e. a severe disease of lung and digestive system for patient with specific genetic mutation. See, F.D.A., (2013), "Paving the Way for Personalised Medicine: FDA's Role in a New Era of Medical Product Development", *F.D.A.*(Food & Drug Administration), U.S. Department of Health and Human Services and U.S Food and Drug Administration, p.3; available at: www.fda.gov/downloads/.../PersonalizedMedicine/UCM372421.pdf

[32] Choo, Kristin., (2006), "Personalized Prescriptions", *ABA Journal* , 92 (9), p.42-43

[33] Tuffs Center for Study of Drug Development for biopharmaceutical companies revealed that Presently, biomakers are being deployed during the R&D towards personalised medicine, so that the biomarkers during discovery stage can help in analysing compound unit like molecules, biology or physical characteristics for diagnosis or treatment guidance that can be known during the trial phase. Moreover, through records it has been evident that these days 60% of biomarker data is used during

can help in reducing the number of ADE/ADR, by revealing preventive measures understanding the patient's genotype with the help of PGx. At present, limited drugs have been allowed by the FDA that rely on PGx data. These genomic data and input from industry are required to co-develop the regulatory guidelines for PGx and diagonistic testing.[35] These regulatory mechanism help in setting the quality of manufacturing drug along with this knowledge of misbrand, adulterated, etc. drugs can be made out of the manufactured drug.

R&D cost for PM since 1996 has been observed by pharmaceutical manufacturers, which is as calculated from $16.9 billion to $48.5 billion spending. That explains less interest and fall in marketing approval of PM due to regulatory and approval facilitators demand of standard for drugs. Till date, when numbers are estimated for new drug approval by FDA, approximately 53 in 1996 to only 24 in 2009 is witnessed. As, the promising PGx observed, this validation has been considered as pipeline for solving root cause of understanding body injury/disease sufferings and pain. Due to its slow arrival to patients vast difference in scientific invention and medical development process is reality of today. While examining the benefit of PM it is known that the unsafe medicine can be converted to safe drug by knowing which patient's body may respond to the drug positively and which patient might get adverse reaction. But two major regulatory problems[36] have been raised at present due to PGx based drug and they are:

> "i) as the generators or sponsors of PGx data are in dilemma whether the FDA framework will regulate its use. Because the FDA has been in existence prior to the invention of PGx; ii) Due to hostile approach of FDA it becomes tough for the sponsors to develop such drugs because addition clinical trials are made for relying on PGx data's".[37]

These two approaches make the marketing of personalised medicine impossible. In fact, raises new modification arrangements in FDA regarding the

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treatment through preclinical development. As well as, about 50% of biomarkers are use during early clinical research and about 30% during late clinical development. For details, see, Ibid.

[34] PhRMA, (2015), "Rx Minute: Biopharmaceutical Companies Embracing Personalized Medicine", *Pharmaceutical Research and Manufacturers of America* (*PhRMA): Research, Progress, Hope;* available at: www.phrma.org/rxminutebiopharmaceuticalcompaniesembracingpersonalizedmedicine.

[35] PMC, (2007), "Personalised Medicine: Issues affecting adoption of Personalised Medicine", *PMC PM Issues 032107_Final*, p.3*;* available at: www.ashg.org/pdf/newsclip/PMC%20-%20Issues%20affecting%20adoption%20of%20personalized%20medicine.pdf

[36] Avery, Matthew., (2010), "Personalised medicine and Rescuing "Unsafe" Drug with Pharmacogenomics: A Regulatory Perspective", Food & Drug Law Journal, 65 (1), p. 37-39, 41, 42 and 43.

[37] Ibid.

development of personalised medicine. However, drugs are classified as erroneously ineffective as it only treats small population of patients. This reason can be drawn through different responses that have been evident from the drug use like for some it might treat, to some it might create adverse reaction and to some poor response with toxity. These flaws in order to be tailored from doctors and physicians prescription to individual patient by testing the genetic variations associated with specific drug reactions. This requires research on which genotype response on the diagnostic test. The labeling of such PGx information will help the physician[38] to determine which drug is safe and through which drug the patient may suffer or get ill.

The first personalised medicine that came out as Herceptin, i.e also known as trastuzumab. This drug is a breast cancer drug marketed by Genentech. Moreover, it has been found that HER2 overexposed patient could use the drug[39] and its validity has been approval by FDA. Whereas, the most recent drug is Advexin, the drug was developed for neck and head cancer with p53 tumor suppressor function.[40] But due to economical drawback for R&D fund made it to drawback.[41]

Since, the scientific technology is hard to understand and only proper and accurate understanding can help in treating the same disease. Due to which it becomes important to have PM as a RTH. As well as the process of approval needs to be strict and proper so that reviewing method for the approval stages can be monitored until the drug product shows positive result and better treatment and cure.

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[38] Ibid.

[39] Genentech was targeting on HER2 patients for Herceptin drug trial. During early trial stage it found patients who did not have HER2 over-expressed, the drug Herceptin did not work on them. So for Phase III trial when FDA approved Genentech to collaborated with Dako Corporartion. Since immunohistochemestry test to measure tumor level in HER2 positive patients was to be made. In 1998, after field approval application for diagonistic test and co-marking the product, Herceptin became the first PGx product. The labeling on the product specifically states that this product can only be used by the metastatic breast cancer patients whose tumor over express the HER2 protein. In the approval response FDA comments that Herceptin would have probably not been allowed if the accompanying diagnostic test would have not responded well.

[40] The Advexin drug is was developed by Introgen Therapeutic based on economic factors. Advexin targets the p53 tumor suppressor function associated with cancer. But during the Phase II trial, the data's exposed out few revelations from the drug that Advexin was effective on the abnormal p53 tumor suppressor gene but not likely to benefit from existing treatment to same subgroup. This correlation was is considered to be discovered during the later phase of phase II trial, which on the other hand is considered was conducting the Phase III trial of the drug. When Introgen for Advexin in 2008 submitted application for market approval based on the prior phase II result. The FDA asked to re start the Phase III trial to demonstrate the efficacy in patient with abnormal p53 gene. However, due to unavailability of economic resource and again conducting another Phase III trial force Introgen to stop development and file for bankruptcy. For details, see, Avery, Matthew., (2010), "Personalised medicine and Rescuing "Unsafe" Drug with Pharmacogenomics: A Regulatory Perspective", Food & Drug Law Journal, 65 (1); pp. 37-39, 41, 42 and 43.

[41] Ibid.

Regulating Personalised Medicine

PM is still in its evolving intervention, in order to get proper and correct prescription. At present PM is being used for combined drugs so that the molecules effectiveness can be known. China has come out with PM intervention where it is going to conduct trials for diabetes and cancer on 4,000 volunteer individuals for four years and 2,000 volunteers are going to be under human genome sequencing test.[42] The Helsinki Declaration trial intervention should also be conducted on humans and on this behalf states that:

> "Medical progress is based on research which ultimately must rest on experimentation involving human subjects". [43]

When such experiments are made on human, these experiments provide betterment of individual health. But, these experiments should be made voluntarily and not without one's consent. According to the International Ethical Guidelines for Biomedical Research Involving Human Subjects in Guidelines No.4 states about individuals consent and it is:

> "For biomedical research involving humans the investigators must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorised representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.[44]

Based on voluntary concern, ethical committee has to review all the process of experiments time to time. These ethical committees should have qualified scientific persons for monitoring the experiment. The Nuremberg Code state that:

> "The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be of those who conduct or engage in the experiment".[45]

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[42] Zeng Changquing, (2016), "China Starts Precision Medicine Research", India Medical Times: Beijing, p.1. available at: www.indiamedicaltimes.com/2016/01/10/china-starts-precision-medicine-research/

[43] *World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects*, 1964 (2008). available at: www.wma.net/en/30publications/10policies/b3/17c.pdf

[44] The International Ethical Guidelines for Biomedical Research Involving human subjects (2002), Prepared by the Council for International Organisations of Medical Science (CIOMS) in Collaboration with the World Health Organisation, Geneva, Switzerland, 2002; available at: www.cioms.ch/frame_guidelines_nov_2002.htm

[45] Nuremberg Code (1947), Trials of War Criminals before the Nuremburg Military Tribunals under Control Council Law No. 10. Nuremberg, Germany, October 1946- April 1949. Washington D.C: U.S.

It seems existing discoveries and new treatments found for personalised medicines are observed in disease like: breast, colorectal and lung cancer along with leukemias and melanomas. Such finding has helped in reduction of adverse drug effect. Obama Administration distributed (2016) budget for research on as:

> "a) $130 million to National Institutes of Health (NIH); b) $70 million to the National Cancer Institute part NIH; c) $10 Million to FDA; and d) $5 million to ONC".[46]

PM requirement in health arena, it becomes important to bring regulating arrangements. When regulating of drugs comes its standard should also be made through professional standard like the Article 4 of the Convention for the protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biomedical and Medicines Convention on Human Rights and Biomedicine (1997) states that:

> "Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards".[47]

So when professionals carry monitoring and obligating standards inspections then the regulatory system of the PM can function more efficiently. Till date, in order to monitor safe and efficient functioning of PM, the different drug regulating bodies over the world with different mechanism of organisation or institute monitor and investigate the processing, manufacturing, labeling or clinical trial of such medicines prior the drugs launches in the market. Likewise, in U.S the FDA functions by providing four main review centers and they are: i) the Center for Devices and Radiological Health (CDRH); ii) the Center for Drug Evaluation and Research (CDER); iii) the Center for Biologics Evaluation and Research (CBER); and iv) the Special Medical Programs are responsible for establishing regulatory pathways and policies for addressing challenges.[48]

G.P.O, 1949-1953, 2, p.181-182; available at: www.jewishvirtuallibrary.org/jsource/Holocaust/Nuremberg_Code.html

[46] The White House: Office of the Press Secretary, "Fact Sheet: President Obama's Precision Medicine Initiative", 30, January 2015, Briefing Room: Statements and Release, *The White House*, U.S.A gov; available at: www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative

[47] Article 4 of the Convention for the Protection of Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: *Convention on Human Rights and Biomedicine* (1997). Council of Europe. Oviedo, 4.IV.1997. Reprinted in 36 ILM 821; available at: www.mpil.de/en/hp/embryo/regionl/CPHR04041997.pdf

[48] F.D.A., (2013), "Paving the Way for Personalised Medicine: FDA's Role in a New Era of Medical Product Development", *F.D.A.*(Food & Drug Administration), U.S. Department of Health and Human

In Europe, European Medicines Agency (EMA) works along with organisations like European Alliance for Personalised Medicine, the European Assosiation for Predictive, Preventive and Personalised Medicine and EuroBioForum to advance personalised medicine[49] (Brousseau, 2015:1-2). In South Africa, Medicines Control Council (MCC) since 50 years has been regulating drugs with internationally recognised standards. South African MCC works for its standards through manufacturing, marketing of medicines, distribution and sale through the Medicines and Related Substance Act, (Act 101 of 1965).[50] But, the Department of Trade and Industry looks at the importing drug products and its quality or standard.

There are five national standards organisations in South Africa that looks after commercial and industrial regulating norms of drug and pharma products and they are: i) South African Bureau of Standards (SABS); ii) Engineering Council of South Africa (ECSA); iii) Council for Scientific and Industrial Research (CSIR); iv) Human Science Research Council (HSRC) and v) Medicines Control Council (MCC). There is the Pharmaceutical Industry Association of South Africa (PIASA) that is a trade association of companies involved in the manufacture and/or marketing of medicines in South Africa.[51]

In India, Central Drugs Standard Control Organisation (CDSCO), and the office of its controller, the Drugs Controller General of India (DCG (I)) is the main office that looks in the regulatory function of drugs/medicines. The regulatory and monitoring function of such regulatory body also looks at the clinical trial, labeling etc. The CDSCO in the Directorate General of Health services, is a division under Ministry of Health and Family welfare, Government of India, headed by DCGI It has

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Services and U.S Food and Drug Administration; available at: www.fda.gov/downloads/.../PersonalizedMedicine/UCM372421.pdf

[49] Brousseau, Zachary., (2015), "New Regulatory Approaches key to Future of Personalised Medicine", 13 May 2015, RAPS pp.1-2; available at: www.raps.org/Regulaory-Focus/RAPS-latest/2015/0...

[50] MCC, (2015), "Overview", Medicines Control Council, E2 Solutions, p.1-2; available at: www.mccza.com/About..

[51] Narsai, Kirti., Williams, Abeda., and Teeuwisse, Aukeje Kaija Mantel. "Impact of Regulatory Requirements on Medicine Registration in African Countries-Perception and Experiences of Pharmaceutical Companies in South Africa.", Southern Med Review: An International Journal to Promote Pharmaceutical Policy Research, 5 (1): 31-37, p. 31 and 36; also see, Santander Trade Portal, (2015), "Packaging and labeling regulation in South Africa" South Africa: Packing and Standards, Export Enterprises SA, Argentina, p.1-3; available at: www.en.santandertrade.com/international-shipments/south-africa/packaging-and-standards

four zonal, three sub-zonal and seven port/airport offices and six laboratories to carry out its activities.[52]

These regulatory bodies function strictly, by regularly examining their manufacturing laboratories for manufacturing practice (GMP) standards incompliance to the specific country requirements. The strictness in inspection monitoring method has led the U.S FDA to ban two contract Pharma of India and three Chinese drug manufacturers. The Indian companies are: i) Cheryl laboratory in Navi Mumbai manufacturing facilities and active pharmaceutical ingredient (API) and ii) Phalanx lab's Vishakapatanam intermediate manufacturer.[53] The Chinese drug manufacturing companies are: i) Xinxiang Pharmaceautical Co.; ii) Xinxiang Tuoxin Biochemical Co.; and iii) Guangzhou Haishi Biological Technological Co..[54] These companies are banned from the shipping list of the U.S. Due to detention without physical examination, refusing inspection based on GMP standards of FDA.

In a way, personalised medicine is developing through clinical trial process to gain its output results to provide the new refined medicinal/drug way of curing individuals and treating the suffering accurately without any side-effects. The labeling of the product plays a vital role in expressing the components and elements used in the drug product that can be helpful to some and dangerous to other human body that are allergic to the components.

Moreover, holding of promise to bring molecular biology, genetics as a medical care will allow more precise diagnoses. This precisions understanding for medicine will make better diagnostic test and accurate predictability of disease stage and suffering. Due to PM therapy, targeting of right treatments to the right patients can be made with improved patient safety. This safety can be made more meaningful when healthcare adopts selecting drugs and their proper dosage to reduce adverse side effects by PM. Besides, till 2015, WHO found that annually 10.5 million lives of child

[52] Imran, Mohammad., Najmi, Abul K., Rashid, Mohammad F., Tabrez, Shams., and Shah, Mushtaq A.(2013), "Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go", Drug Regulation: Import and Export by the Manufacturers, *J Pharm Bio allied Sci*, 5(1), p.2-9.

[53] Brennan, Zachary, (2016), "Two Indian Contract Pharma, API Manufacturers Refuse FDA Inspection" *RAPS*, 16 June 2016; available at: www.raps.org/Regulatory-Focus/News/2016/6/16/25150/Two-Indian-Contract-Pharma-API=Manufacturers-Refuse-FDA-Inspection

[54] Brennan Zachary, (20016), "FDA Continues Crackdown on Noncompliant Chines Pharmaceautical Manufacturer" *RAPS*, 8 April 2016; Available at: www.raps.org/Regulatory-Focus/News/2016/04/08/24728/FDA-Continues-Crackdown-Chinese-Manufactureres.

and maternal health would have been saved by boosting socio-economic developments in direction of making access to medicines along with infectious and non-communicable diseases would have been controlled. It is no surprise that even today there are about 2 billion people in the world with no access to medicine.[55]

The intervention of accessing drugs/medicines can be possible by treating and curing individuals without side-effects. Understanding the development of genomics and molecular biology through PM, that has come to resolve the old method of drug treatment i.e. one size fits all. PM in that consideration can bring better health care along with largely reduced cost spending, having safe and correct medicine.[56]

Moreover, the growing technological sphere, demanding marketing of drug products require new regulatory framework to address the challenges at international level. The EMA, FDA and other regulatory agencies in the world should work together to modify and come out with uniform regulatory mechanism that may concern much lesser population along with reimbursement and informing experimental efficacy. Moreover, the developers of the drug ought to create convincing influence from the prospects produced by progress of the personalised medicine to certainty of ideal health care therapy.[57]

Privacy and Data Collection

PM has also raised issue and concern for data sharing and safety. Since Privacy and confidentiality is one of the basic key components during genetic testing for PM. Moreover, exception to limitation is created through the prescription of the domestic laws and international human rights in order to save human and its kind through healthcare measures and welfare of individuals. The Universal Declaration on

[55] Boxtel, Chris. J. Van., Santoso, Budiono., and Edwards, I. Ralph., (eds.) (2008), *Drug Benefits and Risk: International Textbook of Clinical Pharmacology*, The Netherlands: IOS Press and Uppasala Monitoring Centre, p.ixi; available at: www.books.google.co.in/books?id=xQqVbRqA2N8C&printsec=frontcover#v=onepage&q&f=false ; also see, WHO, (2016), "WHO Medicines Strategy-Countries at the Core-2004-2007", 14 April 2016; available at: www.who.int>medicinesdoc

[56] Vogenberg, F. Randy., Barash, Carol Issacson., and Pursel, Michael., (2010), "Personalised Medicine: Ethical, Legal and Regulatory Issues" *Pharmacy and Therapeutics: A Peer-Reviewed Journal for Management Care and Hospital Formulary Management*, 35 (11), p. 624; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC2993070/

[57] Brousseau, Zachary., (2015), "New Regulatory Approaches Key to Future of Personalized Medicine", *Regulatory Affairs Professionals Society (RAPS): Driving Regulatory Excellence*, p.1-3; available at: www.raps.org/Regulatory-Focus/RAPS-Latest/2015/05/13/22160/New-Regulatory-Approaches-Key-to-Future-of-Personalized-Medicine/

Human Genome and Human Rights 1997 (UDHG and HR) with the help of Rights of the Persons Concerns states (Article 9) that:

> "In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within its bounds of public international law and the international human rights".[58]

Furthermore, such limitation as specified through the Convention for the Protection of Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: *Convention on Human Rights and Biomedicine* (1997) with the help of Private Life and Right to Information [Article 10 (3)] states that:

> "In exception cases, restriction may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient".[59]

Thus it shows the reason why limitations to privacy can be made. By pointing its purpose, as stated in the Article 5 of International Declaration on Human Genetic Data 2003, as:

> "Human genetic data and human proteomic data may be collected, processed, used and stored only for the purpose of: i) diagnosis and health care, including screening and predictive testing; ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, collectively referred to hereinafter as "medical and scientific research"; iii)forensic medicine and civil, criminal and other legal proceedings, taking into account the provisions of Article 1(c); iv)or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and international law of human rights".[60]

It shows that DNA/genetic data need to be stored during healthcare reason or medical and scientific research including legal matters as forensic testing for civil or criminal matters under the UDHG and HR 1997, international law and Human Rights. Understanding the purpose of genetic data and its need, the collection made by 16 million DNA samples that are kept in the Bay Area warehouse of California has raised voice by privacy advocates. This issue rose recently when revelation about

[58] Article 9 in "the Right of the Person Concerned" of the Universal Declaration on the Human Genome and human Rights 1997.

[59] The paragraph 2 in this line refers to 10(2) "Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed". For details, see, Articles 10(2) and 10(3) of Convention for the Protection of Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: *Convention on Human Rights and Biomedicine* (1997); available at: www.mpil.de/en/hp/embryo/regionl/CPHR04041997.pdf

[60] Article 5 of the International Declaration on Human Genetic Data, (2003), UNESCO, 32 Session Paris, 29 September-17 October 2003; available at: www.portal.unesco.org/en/ev.php-URL_ID=17720@URL_DO=DO_TOPIC@URL_SECTION=201.html.

collecting DNA samples for screening of 80 health disorders like sickle cell anemia and cystic fibrosis etc. since last three decades came in news.

This process of collecting bio-bank samples from new born babies has created an atmosphere of tension. When disclosure for sharing information of frozen DNA samples; to the researchers who are paying fees became viral. The use of such data's from storage to the third party use requires public understanding, consent and knowledge from the parents of the baby's whose DNA has been stored as well as an understanding for destroying of such data's through the baby himself/herself after turning 18 can be made.[61]

Since, it becomes hard to keep such data stored in one place. Moreover, use of these data's for research or by third party can led to unidentified threat or exposure to danger by the freeze samples kept for future use. Like the Draft International Convention on the Prohibition of All Forms of Human Cloning (2004) states in its Article 2 Scope of Application (Definition of the crime) as:

> "1. Any person commits an offence within the meaning of this Convention if that person intentionally engages in an action, such as somatic cell nuclear transfer or embryo-splitting, resulting in the creation of a living organism, at any stage of physical development, that is genetically virtually identical to an existing or previously existing human organism, at any stage of physical development, that is genetically virtually identical to an existing or previously existing human organism; 2. Any person also commits an offence if that person attempts to commit an offence set forth in paragraph 1 of this article; 3. Any person also commits an offence if that person: a) Participates as an accomplice in an offence set forth in paragraph 1 or 2 of this article; b) Organises or directs others to commit an offence set forth in paragraph 1 or 2 of this article; c) Contributes to the commission of one or more of the offences set forth in paragraph 1 or 2 of this article by a group of persons acting with a common purpose. Such contribution shall be intentional and shall either: i) Be made with the aim of furthering the criminal activity or criminal purpose involves the commission of an offence as set forth in paragraph 1 of this article; or ii) Be made in the knowledge of the intention of the group to commit an offence set forth in paragraph 1 of this article".[62]

In view of the above, it seems, if any crime is committed intentionally by recreating living organism like cloning or for other offences set in the paragraph 1 or 2 it is a crime. Moreover, if any individual evokes or provides knowledge of the same to commit crime is considered of committing offense along with the group affiliates. Further, storing of DNA and Gene data has led to one of the mysterious significance

[61] McGreevy, Patrick., (2015), "Millions of DNA Samples Stored in Warehouse Worry Privacy Advocates", Sequencing and Genomics, Centre for Genetics and Society, *Los Angles Times, pp.*1-3; available at: www.geneticsandsociety.org/article.php?id=8351

[62] Article 2 of the Draft Convention on the Prohibition of All Forms of Human Cloning (2004); available at: www.ny.un.org/doc/UNDOC/GEN/N03/330/84/PDF/N0333084.pdf/OpenElement

by providing it as special status. The reason for having special status for genetic data is due to cultural significance and valuable information one genotype data may reveal to preserve its importance the Article 4 of the International Declaration on Human Genetic Data 2003 states that:

> "a)Human genetic data have a special status because: i) they can be predictive of genetic predispositions concerning individuals; ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs; iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples; iv)they may have cultural significance for persons or groups; v)due consideration should be given to the sensitivity of human genetic data and biological samples should be established".[63]

The sensitivity of collected biological samples could yield not just the criminal nature but also points towards personal gains of physicians, etc. These data cannot be used for such purposes nor can the data be used for discriminating or stigmatising an individual, family or group. Moreover Article 14 of the International Declaration on Human Genetic Data 2003 states that:

> "a) States should endeavour to protect the privacy of individuals and the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consists with the international law of human rights; b)Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to the third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential; c)Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples; d)Human genetic data, human proteomic data and biological sample collected for medical and scientific research purposes can remain linked to identifiable person, only if necessary to carry out the research and provide that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law; e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed".[64]

The collected genetic/DNA data should be kept safe and secured as well as should not be linked to any identifiable person as well as it should be kept as

[63] Article 4 of the International Declaration on Human Genetic Data, (2003), UNESCO, 32 Session Paris, 29 September-17 October 2003; available at: www.portal.unesco.org/en/ev.php-URL_ID=17720@URL_DO=DO_TOPIC@URL_SECTION=201.html

[64] Article 14; Ibid.

confidential. Moreover, the linking to an identifiable person according to the declaration can be made when the genetic data, human proteomic data and biological sample provides necessary requirements to carry out research but during that phase the privacy should be kept as provided under the domestic laws of the country. Moreover, no employers, insurance company, educational institute or even family members should be revealed of genetic data of an individual. Unless it becomes important for public interest with the help of domestic law and in consists with international human rights.[65]

Reimbursement for Breach of Confidentiality

Breach of confidentiality means that when the privacy of the genetic data taken in due course for PM is revealed to other individual, group or organisation etc. either for profit or through business affairs. The Declaration of Geneva 1948 that provides oath during the time of medical profession, states in one of its principles that:

> "I will respect the secrets which are confined in me, even after the patient has died".[66]

Moreover, the World Medical Association International Code of Medical Ethics 1919 states it is the duty of physicians in general that:

> "A physician shall always maintain the highest standard of professional conduct. A physician shall not permit motives of profit to influence the free and independent exercise of professional judgment on behalf of patients".[67]

Further, the Declaration of Helsinki 1964[68] states in principle 4 and 9 that:

> "Medical progress is based on research which ultimately rest in part on experimentation involving human subjects.[69] Research Investigation should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirements should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration".[70]

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[65] Ibid.
[66] The Declaration of Geneva (1948), Adopted by the 2nd General Assembly of the World Medical Assembly, Geneva, Switzerland, August 1948; available at: www.wma.net/e/policy/c8htm
[67] *World Medical Association International Code of Medical Ethics 1919*, Adopted by the General Assembly of the World Medical Association, London, England, October 1949 and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968 and the 35th World Medical Assembly, Venice, Italy, October 1983, Accessed on 19 May 2014; available at: www.wma.net/e/policy/c8.htm
[68] *World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects*, 1964; available at: www.wma.net/en/30publications/10policies/b3/17c.pdf
[69] Principle 4 of the Declaration of Helsinki (1964); Ibid.
[70] Principle 9 of the Declaration of Helsinki (1964); Ibid.

Moreover, it becomes the duty of the physician to protect the health, privacy, life and dignity of human subject during research experiment and treatment.[71] Further acknowledging the responsibility of privacy and safeguarding confidentiality. The Guideline 18 of the Ethical International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) states that:

> "The investigators must establish secure safeguard of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breach of confidentiality".[72]

When establishment of safeguarding privacy comes in breach of such confidentiality the injured subject should have right to treatment and compensation. The Guideline 19 of the Ethical International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) states that:

> "Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In case of death as a result of their participation, their dependents are entitled to compensation. Subjects must not be asked to waive the right to compensation".[73]

In general, when breach of privacy is conducted the solution has been measured as compensation, through tort measures, etc.[74] In accordance with the available legal mechanism of domestic and human rights law. In setting compensation fair conditions and prescribed law should be looked through to provide individuals from suffered undue damage from the intervention.[75] But when the dispute is between two or more states then, the Article 14 (1) of the Draft Convention on the Prohibition of All Forms of Human Cloning 2004 should come in practice. It states that:

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[71] Principle 10 of the Declaration of Helsinki (1964); Ibid.

[72] Guideline 18 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), The Council for International Medical Sciences (CIOMS) in collaboration with the World health Organisation (WHO), Geneva, Switzerland; available at: www.cioms.ch/frame_guidelines_nov_2002htm

[73] Guideline 19 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), The Council for International Medical Sciences (CIOMS) in collaboration with the World health Organisation (WHO), Geneva, Switzerland; available at: www.cioms.ch/frame_guidelines_nov_2002htm

[74] McGreevy, Patrick., (2015), "Millions of DNA Samples Stored in Warehouse Worry Privacy Advocates", Sequencing and Genomics, Centre for Genetics and Society, *Los Angles Times*, p.1-3; available at: www.geneticsandsociety.org/article.php?id=8351

[75] Article 24 of the Convention for the Protection of Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: *Convention on Human Rights and Biomedicine* (1997). Council of Europe. Oviedo, 4.IV.1997; available at: www.mpil.de/en/hp/embryo/regional/CPHR04041997.pdf

> "1. Any dispute between two or more States Parties concerning the interpretation or application of this Convention which cannot be settled through negotiation within a reasonable time shall, at the request of one of them, be submitted to arbitration. If, within six months from the date of the request for arbitration, the parties are from the date of the request for arbitration, the parties are unable to agree on the organization of the arbitration, any one of those parties may refer the dispute to the International Court of Justice, by application, in conformity with the Statute of the Court".[76]

Article 14(1) in Settlement of dispute of Draft Convention on the Prohibition of All Forms of Human Cloning 2004 provide that if any criminal offence or seizure of any funds[77] regarding the allocation for committing crime and forfeiture takes place as mentioned under Article 2 of the Convention. Then International Court of Justice should be referred as a last resort through application when no other means like negotiation, arbitration, etc. functions vigorously.[78]

Challenges in Implementing Regulation of Personalised Medicine

Implementation of PM can only be possible when regulation is monitored properly. The regulating challenges in PM have been observed whether the researching drug companies are following their liability and responsibility properly or not. When the companies and physicians are approved to conduct experiments for PM research, then the main objective of such companies and physicians is to take proper safeguarding measures during experiment of the volunteering individuals.

Liability and Responsibility for Personalised Medicine

Genetic liability relates mainly with the ethical and social issues that are attached with the functioning of research responsibility and expertise in the related matter. The exercise of scientific activity is well defined by its responsibility under Article 13 of the Universal Declaration on the Human Genome and Human Rights 1997 and it is:

> "The responsibility inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilisation of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical

[76] Article 14(1) of the Draft International Convention on the Protection of All Forms of Human Cloning (2004); available at: www.ny.un.org/doc/UNOC/GEN/N03/330/84/PDF/N0333084.pdf?OpenElement
[77] Article 6; Ibid.
[78] Ibid.

> and social implications. Public and private science policy-makers also have particular responsibilities in this respect".[79]

Article 13 tries to state that if any PM intervention takes place through genomic study of individuals. It should be conducted understanding the socio-ethical implications. Moreover, the Article 14, 15 of the Universal Declaration on the Human Genome and Human Rights 1997 states on the states/countries responsibility to take proper procedures to promote:

> "Intellectual and material conditions through economical, ethical, legal and social implications for research as set in the declaration.[80] Framework of genome exercise should be in consideration to respect human rights, fundamental freedom of human dignity and to protect public health. Moreover, these results should be for peaceful purpose.[81]

Article 16 of the Universal Declaration on the Human Genome and Human Rights 1997 states that every State should:

> "Establish proper independent, multidisciplinary and pluralist ethics committees during various levels of human genome research. So that access to ethical, legal and social issues can be raised during research on human genome and its application.[82]

The formation of ethics committee should work for all different stages of research practice. So that access relating socio-economic ethical and legal issues relating personalised and genome is questioned. Since, the liability and responsibility towards developing of biology and medicines may also lead to:

> "Consciousness that misuse of biology and medicine may lead to acts endangering human dignity. As well as the progress should be used for the benefit of present and future generation".[83]

Moreover, such research should only be carried on when intervention is for:

> "Preventive, diagnostic or therapeutic purpose and not to introduce any modification in genome of descendants. As well as not for choosing sex of the child".[84]

Article 13 and 14 state that during PM when genomic intervention takes place it should be made for the benefit and betterment of future along with present

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[79] Article 13 of the Universal Declaration on the Human Genome and Human Rights, 1997, General Conference of UNESCO, 29th Session on 11 November 1997, Records at Conference, Vol.29, p.41-46, Accessed on 25 May 2015; available at: www.unesco.org/shs/human_rights/hrbc.htm

[80] Article 14; Ibid.

[81] Article 15; Ibid.

[82] Article 16; Ibid.

[83] The Preamble, of the Convention for the Protection of Human Dignity of the Human Being with Regard to the Application of Biology and Medicine: *Convention on Human Rights and Biomedicine* (1997). Council of Europe. Oviedo, 4.IV.1997; available at: www.mpil.de/en/hp/embryo/regional/CPHR04041997.pdf

[84] Article 13 and 14 of Ibid.

generation. So that no more selecting of sex for unborn or modification in any therapeutic changes of descendants is done any longer.

In understanding the liability for drugs/medicines, the pharmaceutical liability issue comes in representation. Such acknowledgement for product liability existed since the 1973 Hague Convention on the Law Applicable to Products Liability [Article 3 (1) to (4)] provided that the liability of product will fall on:

> "1) manufacturers of a finished product or of a component part; 2) producers of a natural product; 3) suppliers of a product; 4) other persons, like the physicians and drug prescribers, including repairers and warehousemen, in the commercial chain of preparation or distribution of a product".[85]

Liability shall also apply to the agents or employees like the nurses, doctors/distributers of the drug persons for specified reasons above. Since, estimation of pay for performance (P4P) in U.S for PM total market size in 2009 was compared as $225-232 billion to $344-452 billion in 2015. So far, as estimation goes about $232 billion[86] is estimated for the total U.S market. On the other hand the PricewaterhouseCoopers[87] projects that in 2015 its size has doubled and has raised annually 11% i.e. $452 billion. The core segments are estimated $24 billion to $42 billion in 2015 comprising of primary diagnostic tests and targeted therapies. Moreover, when estimation of 2015 for market is increasing then responsibility and liability should be monitored more strictly.

There is responsibility for expertise in extending the benefits to individuals, like the paragraph 8 of the Preamble to the WHO Constitution that states:

> "The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health".

Moreover, holding of promise to bring molecular biology, genetics as a medical care through PM, will allow more precise diagnoses. As such better diagnostic tests, greater predictability of disease course, more successful therapies by targeting right treatments to the right patients, and improved patient safety by selecting drugs and their proper dosage would help in reducing adverse side effects.

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[85] Article 3 (1) to (4) of the *Hague Convention on the Law Applicable to Products Liability* (1973), 2 October 1973; Available at: www.hcch.net/index_en.php?act=conventions.text&cid=84.

[86] Mathieu, Mark P. (2010), "Parexel's Bio/Pharmaceutical R&D Statistical Source Book 2010/2011" An Assessment of the Personalised Medicine Market Size, 2009-2015. PricewaterhouseCoopers 2009.

[87] Coopers, Pricewaterhouse (2009) "An Assessment of the Personalized Medicine Market Size, 2009-2015", Products in Development of Pharmaceutical, ed. PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011.

PM may lead to increased concerns regarding privacy[88] and discrimination based on medical information and uncertainty about the costs of research and of medical care.

The patient right to privacy came as concern during the potentiality of ethical, legal and social implication needs arising through the project data of U.S Human Genome Project. This project brought the transfer of technology from the federal government to the private sector. In which licensing of technology for private companies in way of innovation was provided. This largest scientific project brought the awarding of grants of multibillion dollar for U.S biotechnology industry and encouraged development for new medical application.[89] The personalised medicine also endorses to replace the traditional approach of trial-and-error practice of medicine, through patients care and safety during drug discovery and its development throughout clinical trials by screening and selection of patients.[90]

Ambiguity in Volunteering

PM has come through investigations for genetics of disease through clinical trial network and patient's registry by the rate of examining the drugs on the recruited study participants.[91] Still such effort of advancing and escalating use of PM rotates at the establishment phase. Primarily, the future of medicines through PM is predicted to be more healthcare supportive through less spending and accurate treatment. The regulators and sponsors on the other hand are putting their efforts and challenges that poses through the potentiality of PM. The Obama's initiative on PM has brought modern scientific technology as a positive dimension of healthcare. In FDA researchers for PM human subjects tries to keep with the privacy and security of the participants providing ample space for changes in current health care arrangements in the view of Next Generation Sequencing Method.[92] Understanding the arrangements

[88] Stergiopolos, Sotirios G., (2012), "What is Personalized Medicine", in Lawrence A. Husick, (eds.) (2012) "*From the Bench to the Boardroom: Planning for personalised Medicine",* Baltimore, MD: Johns Hopkins University, Managing Innovation in the Life Sciences, p.6-7; available at: lawhusick.homeftp.net/Innov8/Innov8_files/PersonalizedMedicineClassBook.pdf

[89] Ibid.

[90] Ginsburg, Geoffrey S. and McCarthy, Jeanette J., (2001), "PersonalisedMedicine: Revolutionizing Drug Discovery and Patient Care", TRENDS in Biotechnology. 19 (12), p.491; available at: www.144.206.159.178/ft/1057/46499/828224.pdf

[91] F.D.A., (2013), "Paving the Way for Personalised Medicine: FDA's Role in a New Era of Medical Product Development", F.D.A. U.S. Department of Health and Human Services and U.S Food and Drug Administration, p.3.

[92] The White House: Office of the Press Secretary, "Fact Sheet: President Obama's Precision Medicine Initiative", 30, January 2015, Briefing Room: Statements and Release, *The White House*, U.S.A gov;

of providing personalised diagnostics and therapeutics approach the physicians and the doctors are considered the key providers of the initiative promise yet this challenge is kept determining through safety and efficacy of the drug that exists through the help of PGx i.e genetic profile, physiology and metabolic process.

These days concern surrounds from insurance constraints that continues during health cost as well as personal risk that may arise through genome information. Where need of individuals right to refuse unwanted information associated with other health risks exists.[93] In genetic information increase of discriminating fear among patients from volunteering for research of new genomic-based clinical trials has led to formation of the Genetic Information Non-Discrimination Act (GINA) of 2008 in US. This Act prohibits discrimination at workplace and by health insurance issuers. In this direction North Carolina has come up as the first state in U.S to prevent discrimination based on the presence of the sickle cell trait. Presently, 48 states and the District of Columbia have passed laws preventing genetic discrimination in health insurance providers and 35 states along with the District of Columbia prevent genetic discrimination in employment.[94]

Surveys reveal that more than two thirds of people are concerned about unresolved legal protection that might prevent use of genetic information through genetic privacy. Through this obligation the usage of genetic information can be prevented in sphere of research and development from scientist/researchers.[95] In contrast, this information may be misused during insurance and employment requirements. A fear for genetic discrimination revealing family history and all

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available at: www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative

[93] Vogenberg, F. Randy., Barash, Carol Issacson., and Pursel, Michael., (2010), "Personalised Medicine: Ethical, Legal and Regulatory Issues" *Pharmacy and Therapeutics: A Peer-Reviewed Journal for Management Care and Hospital Formulary Management*, 35 (11), p.625; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC2993070/

[94] Genome.gov., (2016) "The Genetic Information Non-Discrimination Act 2008", Genome.gov; available at: www.genome.gov/10002077genetic-discrimination/&ei=Sml40sB8&Ic=en-IN&s=13&host=www.google.co.in&ts=146894577&sig=AKOVD660Q/D660QoDKezOePrZDSh0eMksS13V7-A

[95] This need is felt through the scientists and healthcare professionals so that once a healthcare information technology (HIT) develops then it will be useful to find different diseases characteristics through records and data's available based on molecular and genomic profile. Moreover, better tailoring of treatments can be made for long term health and economics outcomes by biomarkers disease as well as linking them with clinical and scientific researches. For detail, see, PMC, (2007), "Personalised Medicine: Issues affecting adoption of Personalised Medicine", p.3; available at: www.ashg.org/pdf/newsclip/PMC%20-%20Issues%20affecting%20adoption%20of%20personalized%20medicine.pdf

genetic information of the targeted individuals may lead towards unnecessary inequity/biasness[96] during work and other sphere of interest.[97] So far, strong enforceable mechanism is required in this direction. It has also been found that in order to gain public trust, as well as to provide accurate and reliable genetic tests to individuals without fear and suffering. In 2000 the U.S department of Health and Human Service (HHS) came out with rule for creating genetic testing specialty, which came in existence in 2006 through the Centre for Medicaid Services (CMS). In order, to get the FDA regulatory approval the development of drugs and its diagnostic testing becomes essential since its trial phase to the prescription of the drug to the patient. So that coverage decisions along with timely and transplant process can be introduced while implementing PM through its regulatory process.[98]

Moreover, the revelation of data sharing becomes important so as to know exact treatment. Since genetic study becomes important for understanding PM, same way in a case study of Yana Hill, who was suffering from Asthma as well as was in her pre natal stage. Was helped through medicines and nebulizer for her asthama, she was even able to deliver healthy baby.[99] The author's i.e Lindsey Konkel study of 2015 observed that discrimination has always prevailed. Since most of the trials are made on Americans and for their benefits in US as the funds supports them more. On the other hand, African-Americans are three times more likely to die from asthama as they are prescribed with the most common drug Albuterol. It has been revealed that in a trial study, African American as well as Puerto-Ricans did not respond to the drug Albuterol.

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[96] Through HIPPA this benefit was felt when protection of unauthorised disclosure of the workers medical information to employers. But, the enforcement of rules was found weak when the insurers request for genetic information or genetic tests application for policy. Moreover, while in order to fill certain gaps in HIPPA, the Genetic Information Nondiscrimination Act (GINA) 2005 has come up that explicitly prohibits employers and health insurers from discriminating against individuals on the basis of genetic risk factors. But still it is in implementing process. See, pp.1; Ibid.

[97] In U.S there are limited sphere of protection provided for genetic information. These medical and genetic privacy are provided in: a) the Americans with Disabilities Act (ADA) 1990, of title 42, U.S.C. Sections 12101 et seq.; b) the Electronic Communication Privacy Act (ECPA) of 1986, of title 18 U.S Code (U.S.C). Sections. 2510-2521, 2701-2710; c) the Heath Insurance Portability and Accountability Act (HIPPA) 1996, of title 42 U.S.C Sections. 1320d et seq.; and the Privacy Act 1974, of title 5,U.S.C Section 552a. See, pp.1; Ibid.

[98] PMC, (2007), "Personalised Medicine: Issues affecting adoption of Personalised Medicine", *PMC PM Issues 032107_Final, American Society of Human Genetics,* p.1-4; available at: www.ashg.org/pdf/newsclip/PMC%20-%20Issues%20affecting%20adoption%20of%20personalized%20medicine.pdf

[99] Konkel, Lindsey., (2015) "The Racial Discrimination Embedded in Modern Medicine", Tech & Science, *Newsweek*, 20 October 2015; aavailable at: www.newsweek.com/2015/10/30/racial-discrimination-modern-medicine-384961.html

In same way Asian American genetic makes them hepersensitive while using warfarin. Moreover the Pacific Islanders get genetic trait making them poor responders to blood thinner clopidogrel making them more risk prone towards heart attacks. In order to get rid of one size fits all research in direction of personalised medicine is made so no more genetic discrimination in prescribed medicine comes. But, till yet from 96% of research participants on diseases relating to genetics have more Caucasians i.e. people from Europe. While, in U.S there is only 30% population of African-Americans and Hispanics. So, this understanding leads that still there is genetic discrimination through racial health disparity gap and need of understanding minority participants misinform research initiative is important.[100]

Economics of Personalised Medicine

PM when looked through economics/business profits surrounds less income for pharmaceautical market as the therapy leads towards more objectives that is researched like genome, lifestyle and environment during its development. The economics of PM has surrounded itself with more political sphere than considering exact treatment. PM has been surrounded with issues of gene data. It is considered to be less attractive investment with more time taking and examining of accuracy in treatment through observance for pharmaceutical companies.

On the other hand, the medicine/drug developed for the general population without personalised efforts like one drug fits all, so that more incentive and less effort can be developed for a particular disease/infection/virus. The high level of non-responders from general drug has lead to lose many lives along with increase in deteriorating health. Through the help of PGx accurate and exact drug can be provided to the patient with correct dosage level from the pharma industry. Presently, the inclusion of PGx in the normal trial is presumed to have been creating small market along with expensive therapy where need of third party with fixed reimbursement rates for treating the disease may be placed.[101] In 2003 when a survey by the National Cancer Institute on physician use of genetic testing was made it was found that requirement of training and providing confidence to administer PM has to

[100] Ibid.

[101] Avery, Matthew., (2010), "Personalised medicine and Rescuing "Unsafe" Drug with Pharmacogenomics: A Regulatory Perspective", *Food & Drug Law Journal*, 65 (1): 37-66. p. 43-44.

be made through physicians, nurses medical students and healthcare professionals.[102] As well as, the survey by the Centre for Disease Control in 2005, found that electronic health records (EHR) are only being used by one quarter of physician based offices either wholly or partly in U.S. as this medical information in U.S in not as adequate due to its limitation of complete accessibility of electronic data's due to cost maintenance and cost of purchasing on this behave the U.S Government has started providing incentives and support.[103] Moreover, the U.S government issued an executive order 133356 in 2004 through the President so that a nation wise health IT reporting could be made, and this direction was to "provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care" to the Secretary of Health and Human Services (HHS)[104]

Understanding the politics involved in stabling the sphere for personalised medicine has lead to accepting personalised medicine in the growing disease and infectious world. President Obama's initiative (January 2015) brought biomedical research help worth $215 million investment. It aimed at research study for personalised medicine on 1 million Americans in which the underrepresented minorities are considered as high priorities for next two generations.[105]

Conclusion

The Universal Declaration on Human Genome and Human Rights 1997 with the help of Rights of the Persons Concerns states in its Article 9 that "In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within its bounds of public international law and the international human rights". The Genomics and Personalised Medicine (US) Act 2008 Sec. 2(2) provide a definition

[102] This requirement for personalised medicine is always felt when incorporation of the concept of personalised medicine like genetics, genomics and PGx is looked through medical circulars. Moreover, just limited Universities provide comprehensive education programs on genomic and they are like: a) The Duke University; b) the Harvard Medical School; and c) the University of California.

[103] Moreover, in 2007 about 68% of hospitals in U.S implemented EHRs and there are wholly i.e. 11% as well as partly i.e 57% users of EHRs.

[104] PMC, (2007), "Personalised Medicine: Issues affecting adoption of Personalised Medicine", *PMC PM Issues 032107_Final;* available at: www.ashg.org/pdf/newsclip/PMC%20-%20Issues%20affecting%20adoption%20of%20personalized%20medicine.pdf , p.1,2,3.

[105] Konkel, Lindsey., (2015) "The Racial Discrimination Embedded in Modern Medicine", Tech & Science, *Newsweek*, 20 October 2015; available at: www.newsweek.com/2015/10/30/racial-discrimination-modern-medicine-384961.html

that "personalised medicine is the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, help determine a person's predisposition to a particular disease or condition and identify any targeted prevention strategies for that prediction".

It has been revealed that with the help of biomarkers about 12%-50% of the compounds during the clinical trial phases are studied as personalised medicines. The Preamble (para 8) of the WHO Constitution states that "The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health". Moreover, personalised medicine which is also precision medicine has come as a health revolution. This new technique of scientific development has led more accuracy in health treatment with the help of PGx study. Physicians and researchers are acquainting to adapt themselves with this new method so that no more trial and error concept gets repeated. Challenges are arriving for regulation in this concept due to its scientific genome testing data leading towards privacy/confidentiality, sharing of information with the private/public state/non-state actors.

The regulatory function formation also gets influenced due to product liability as health/clinical trials leads research sponsors/researchers organisation is responsible and for drug fraudulence/adulteration the pharmaceutical company who produces the product is liable. In same, footing for leading personalised medicines prescription who will be liable will it be the pharmaceutical companies/researching sponsors or organisations. Moreover, political sphere has been surrounded in its development due to less incentives and profits. Since the severe scrutiny in authorising drugs for market approval and getting performing the research in very large investment with less profit makes the pharmaceutical companies to hold its evolution. Personalised medicine has been considered as ultimate healthcare therapy since its development because it is considered to bring hope of treatment, in this growing world of disease with different lifestyle, genes and environment setting.

Chapter-VI

Insurance Coverage on Clinical Trials and Personalised Medicine

INTRODUCTION

Insurance is viewed as beneficial to society through its risk eliminating, cost benefit analysis on health. In compliance with health regulation, insurance companies rely on control of the authorities to participate along with other participant's rather encouraging inappropriate costs-benefit trade-offs. Health regulation formalities increases complains for insurers to monitor control or impose appropriate penalities and premium increase for insured companies. So, existing health regulation standards are not cut short.

Insurance liability threatens to levy a cost on the liable party, who will protect against the risk and if materialized the affected individual will move to his insurer to cover the loss. The connection between liability and insurance is made not to involve in risk spreading but to adopt a joint and several liability approach in other terms called as 'deep pocket' approach. As a consequence of this approach, fault-based liability is primarily unsuited with insurance because of its intention aspect. On the other hand, strict liability theory partially relies on insurance as a mechanism of compensation. [1]

Though there are various insurance schemes covering almost all the spectrums of an individual's life, "The major types of insurance available in different countries are: a) life insurance; b) medical insurance; c) private liability insurance; d) public and pollution liability insurance; e) fire insurance; f) insurance of debts; g) travelers insurance; h) aviation insurance; i) liability insurance for businesses and professionals; j) marine insurance; k) social insurance and l) motor vehicle insurance".[2]

[1] Reis. Tarcísio Hardman,. (2011), "Compensation for Environmental Damages under International Law: The Role of the International Judge", Woltrs Kluwer: Law & Business: Volume 17, Kluwer Law International BV: Netherlands, Great Britain, p. 142.

[2] Haas, Peter., Mangeat, and Eversheds Schmid., (2009), "International Insurance Law and Regulation: Commentary", Switzerland, Oceana, Oxford University Press, Inc. : New York; available at: www.eversheds.com/documents/global/switzerland/Publications/PHA_09_International_Insurance_Law_and_Regulations_Switzerland.pdf

One can possibly argue that financial security is essential to a strict liability regime, since it protects public authorities and other victims against the insolvency of the operator and at the same time it protects the operators against liabilities. In contrast, the difficulties in developing a regulation in the field of clinical trials and personalised medicines a reliable insurance mechanism unavailable sin this sector.[3]

"In fact financial constrains is one of the basic outfall in healthcare sector especially during new drug development. To boost pharmaceutical business strategy and innovation in R&D spending, global sales of the product is required i.e. above US$ 1 billion per year. In comparison, The OCDE data of 2009[4] reveals that in accounting of patent holding just 5.5% patents was from BRIICS and five developed countries France, Germany, Japan, United Kingdom (UK) and United States (US) have 70% patents filed for new pharmaceutical drugs".[5]

The development of new drug can be a hope for curing the diseases, but availability of social security towards health sector can reduce cost or monetary burden to the victims/individual. On the other, if government considers health as a right it makes an obligation on the government to provide social security for Medicaid and medicare with all reasonable medical facilities for free of cost to its citizens. The new drug development by researchers on the participating subjects need to be insured which supports as security for the subjects.

On the other hand, the development in new scientific technologies bring modern equipments in every sphere of life including healthcare. To avail this new enhanced technological health facilities individuals opt for insurance coverage due to limited government's free services and arrangements. As insurance coverage provides better quality, timely service, hygiene facilities in hospital on patient or health consumers.

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[3] Reis. Tarcísio Hardman,. (2011), "Compensation for Environmental Damages under International Law: The Role of the International Judge", Woltrs Kluwer: Law & Business: Volume 17, Kluwer Law International BV: Netherlands, Great Britain, p. 142.

[4] The accounting of R&D patent came in 2004-06 under the Patent Co-operation Treaty with the BRIICS (Brazil, Russia, India, Indonesia, China and South Africa). See, Roberts, Marc.J., "Pharmaceutical Reform: A Guide to Improving Performance and Equity", The World Bank Publications, p.39; available at: www.books.google.co.in/books?id=mT7ImUC6A7kC&pg=PA39&lpg=PA39&dq=insurance+coverage+on+health+R%26D&source=bl&ots=utFsTrlKFX&sig=UVXTzP3qUcx_F_FKxiAynOaOe6o&hl=en&sa=X&ved=0ahUKEwi7vOrCpbLRAhUMuI8KHePZA_IQ6AEIPzAE#v=onepage&q=insurance%20coverage%20on%20health%20R%26D&f=false

[5] Ibid.

Legal History of Health Insurance

Insurance as a new component of health rights connects individuals' health arrangements to discovery new drugs and in turn enabling expensive health development. But it was during 1930s great depression financial contract was brought into practice when many suffered of diseases, illness and even death due to hunger and economic constrains.[6] Insurance coverage as social security arouse due to the demand for hospitalisation services for workers and their families providing efficient physicians, new technological environment. Before the great depression physicians charged heavily as full fee for service (FFS) and it was considered as physicians care coverage for physicians to work impartially for sick individual.[7] This FFS system in turn increased insurance consumers looking for accessing balanced and proper treatment in health care facilities.

These facilities led access of information about health facilities available to consumers. Moreover, the Principles of the Rights of Patients in Europe (1994) provides with the understanding through its Article 2(1) that:

> "Information about health services and how best to them is to be made available to the public in order to benefit all those concerned".[8]

In addition to, the information to know what the consumer is purchasing in the health insurance create the health insurance sphere as a contract for his /her health coverage. Moreover, one can define health insurance as a contract where an individual or group purchases in advance health coverage by paying a fee called "premium".[9] Health insurance, provides various plan covering comprehensive health policies. These policies range from covering the cost of doctors and hospitals depending on the individuals specific needs to the long term care. Presently, disability insurance has come to replace lost income during the bread-earner suffers illness or accidents and cannot work anymore. "In a remarkable initiative, India has introduced *"Pradhan Mantri Jeevan Jyoti Bima Yojna"* Rs.2 lakh to dependent during death of policy

[6] Student Resources in Context, (2003), "Medicines and health in the 1930s: Overview", DISCovering U.S History, Available at: www.ic.galegroup.com>ReferenceDetailsPage
[7] Ibid.
[8] Article 2 (1) of the Principles of the Rights of Patients in Europe (1994); available at: www.who.int/genomics/public/eu_declaration1994.pdf
[9] Principle of Insurance: Module-2 (2016), "Essentials of Insurance Contract", Diploma In Insurance Service; available at: www.nios.ac.in>media>VoclnsServices

holder for premium of Rs.330 a year for 18-70 yrs individuals".[10] In India the health insurance in India is not provided specifically for medical expenses it is just a claim during last resort of life or death suffering. There is need to understand India's Health situation and thereby applying principles of insurance keeping in view the social realities and national objectives and individual's right for healthcare.[11]

"In detection of compliant for RTH through international health insurance as a health requirement for sickness and during accident some of the states/regions came out with legal regulations/constitutional mandates. Like, Switzerland in Europe has compulsory health insurance and since 1999, it had 109 insurance companies that offered compulsory health insurance. All of these insurance companies followed requirements of law relating to health insurance by registering themselves to the Federal Office for Social Insurance. In 1890, constitutional mandate for legislating health insurance for accident and sickness was brought by Switzerland government. This understanding of health insurance through European legal framework for international health insurance becomes important due to big numbers of banks in Switzerland. On the other hand, it is considered that attempts of introducing health insurance by Switzerland in 1899 were also not an easy task.

The health insurance of Switzerland is considered to be based on the German health insurance model. But, the approval process had to go through extreme level of changes and modification. The initial step was rejected by referendum that led to changes in proposal for resubmission which got passed through legislation in 1911". [12] The revision of the rejected proposal proved prerequisite of funds is important in health insurance to get benefit packages[13]. This requirement in Switzerland can be analysed for consciousness during getting approval for health insurance. The health

[10] BI India Bureau, (2015), " Insurance Scheme Modi Launched and How they Benefit You", Finance; available at: www.businessinsider.in/8-Insiuarnce-Schemes-Modi-Launched-and-how-they-benefit-you/articleshow/47418104.cms

[11] Anitha, J. (2010), "Emerging Health Insurance in India-An Overview", Health, Long Term Care, Mortality & Morbidity, *10th Global Conference of Actuaries*, Institute of Actuaries of India: 81-82; available at: www.actuariesindia.org/downloads/gcadata/10thGCA/Emerging%20Health%20Insurance%20in%20India-An%20overview_J%20Anitha.pdf

[12] European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.17; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

[13] The benefit packages in this line refers to ambulatory care, drugs and hospital stays of limited duration, and to allow people a certain degree of freedom to change funds; p.6 and 7. Ibid.

insurance of Switzerland approves that in order to avail government subsidy in health insurance registration has to be made under the government office like the Federal Office for Social Insurance, with its rules and regulations providing defined package of benefits. The revised rules highlighted how benefits of changing funds through package of benefits can be made under certain conditions defined in the law. Some of the main reasons are:

> "a) change of office/company or job occurs since funds may be related to specific company or professional association; b) 10% limit in different contribution by men and women is prepared; c) if the address of residence changes; and d) prohibition for making funds in profit is made".[14]

This scrutiny of fund subsidisation has brought direction on the number of per insured individuals by the government of Switzerland. This direction led to mechanism for applying of insurance law whether the concern area accepts and declares it as compulsory or not for its people as per the region. Prior, it was considered to be from unpredictable calculations of demand for services where financial decline had appeared the referendum got failed. This direction of Switzerland confirmed only limited reforms will take place for insurance agreement.

"By 1964, in health insurance sector the system of partial reform was an enlightenment leading revised funds for subsidies based on age and gender along with user fees. The instant fee to patients incorporates a deductible for those over the age of 20 years and a coinsurance for all patients on all services. The subsidies were designed on the source of fund's expenses from the earlier year and amounted to 30% of average total expenditure. The financial problems that had occurred early in 1911 to 1964 continued till the partial reforms, with no bankruptcy in the funds, but the number of funds had declined significantly. The reforming of the system was again undertaken through partial modification due to rising rate of expenditure in the health system".[15] Further challenges toward reform, includes two referenda in 1974 and 1987 that had also failed. One reason for the failure of both reforms was that it contained a complex mix of reform proposals involving cost control, the benefit package, maternity insurance and compulsory insurance. Each component had significant opposition, and the accumulation of this conflict of interest contributed to the failure of the referenda. The revised health insurance law, which was passed by

[14] Ibid; p.6.
[15] Ibid; p.7.

the parliament on 18 March 1994, was approved by referendum on 4 December 1994 and came into force on 1 January 1996. It pursued two fundamental objectives: to strengthen solidarity and to contain costs.[16]

Insurance as a Social Security to Health

Sickness and illness leads every individual to hospital and to avail standard healthcare[17] but one can only access such services through financial support or by paying full cost for medicare or medicaid. Taking insurance schemes for healthcare and treatment socially secures unexpected health expenditure. "Insurance is taken by individuals based on payment of premium or contribution as economic active and inactive insured persons of a country or state. Economic active insured individuals are who can pay for themselves through contributory insurance. Inactive insured individuals are those who are dependent on institute of social security, or receiving social assistance for disability etc. so state budget can make contributory insurance through schemes".[18]

For example, in Albania the social security insurance provided to economic inactive individuals who are registered in National Employment Service as unemployed, or children below 18 year old and students below 25 years by contributions paid by income of economic person and the state budget. Beside stateless person and foreign nationals based on universal principle of health insurance also avail health insurance facility by constitution provision referring them as "anyone" living in Albania.[19] This method of providing social insurance security should also be implemented in other countries like India.

Since the government health facilities and arrangements are limited the insurance as a security mode become the choice for making availability and affordability of quality healthcare. Since insurance is equity based and just limited

[16] European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.6-7; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

[17] Article 12 of ICESCR 1966. U.N.G.A. Res. 2200A (XXI) of 16 December 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[18] Mano, Laure, "Implementation of the Constitutional Right to Health Insurance in the Albanian Legislation", Juridical Current, 16(4), p. 87 and 88; available at: www.eds.b.ebscohost.com.ezproxy.jnu.ac.in/eds/pdfviewer/pdfviewer?sid=9c1cb51f-a1c5-44ca-9054-64dbde839162%40sessionmgr120&vid=0&hid=103

[19] Ibid; p.88.

facilities are arranged still insurance based support should be available to every individual. Every country has responsibility to provide universal health insurance to its citizen and people and the Article 9 of the ICESCR 1966 states that:

> "The State Parties to the present Covenant recognise the right of everyone to social security, including social insurance".[20]

These words specify that right of individuals for creation of a condition to assure health service and care on time during illness and sufferings under social insurance.[21]

Health Insurance and Legal Practice

Insurance in health has become a backbone in legal terms; comes under the General Agreement on Trade in Services (GATS) of the World Trade Organisation (WTO) sector classification scheme. Health insurance falls under the financial services sector. Financial services are divided into two sectors:

> "1) Insurance; and 2) banking and other financial services".[22]

Insurance falling under financial service states it's functioning through business operating market system.[23] Implying requirement of insurance as a security base it has to be understood as target oriented health insurance. So that vulnerable and downtrodden can benefit by crediting premiums in a systematic way for accessing mandatory or required quality healthcare. On the other hand the research trial failure patient be provided with proper medical treatment till required by insuring company for research trials who help in finding cure.

Through arrangements of the WTO there are four different sub sectors for insurance policy that helps in distinguishing different sphere of health insurance requirements based on interest rates credited by insurance selectors are:

> "a) life, accident and health insurance, b) non-life insurance, c) reinsurance and retrocession, and, d) services auxiliary to insurance, including broking and agency services".[24]

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[20] Article 9 of ICESCR 1966, Ibid.
[21] Article 12.2(d) of ICESCR 1966, Ibid.
[22] Kumar, R. (2013), "Trends in Indian Health Insurance Industry", Chapter 4, pp.88-122; Available at: www.shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/9222/13/13_chapter%204.pdf.
[23] Ibid.
[24] Ibid; and also See, European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.17; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

Though the term "health insurance" seen under the first category, many country covers health insurance services in the second category i.e non-life insurance. However, life insurance companies are allowed to sell health insurance products[25] informing its customers exact policies rates and offers.

Patients Protection and Affordable Care Act

"The concept of human right to health observing progressive realisation of the 'highest attainable standard of physical and mental health' supposed to be possible through health policies".[26] Ensuring availability, accessibility, acceptability, and quality[27] of health care, makes such assumption acceptable, through understanding laid in the 2010 Patient protection and Affordable Act or the Affordable Care Act (ACA) of US for healthcare. Moreover, the ACA tries to bring a model for realising universal health coverage following to the right to health.[28]

"The US Government has played a key role in the development of a right to health under international law and the implementation of these rights-based norms through US health care policy. During response on existential threats of the Second World War, President Franklin Delano Roosevelt announced in 1941 that the Allied Alliance would be founded upon four 'essential human freedoms': freedom of speech, freedom of religion, freedom from fear and freedom from want. Reflecting threats to human dignity, it was the final of these 'Four Freedoms', freedom from want that introduced a state obligation to provide for the health of its people. As the basis by which the United States came together with the international community to create a new post-war system of human rights under international law, the United Nations (UN) would seek to prevent deprivations like those that had taken place in the Great Depression and World War II".[29] As the United States had not previously developed a national health care policy, dropping national health insurance from the 1935 Social

[25] Kumar, R. (2013), "Trends in Indian Health Insurance Industry", Chapter 4, p.88-122; available at: www.shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/9222/13/13_chapter%204.pdf
[26] Article 9 of ICESCR 1966 and Article 22 of UDHR.
[27] Article 12 (a), (b), (c) and (d) on Availability, Accessibility, Acceptability and quality (AAAQ). In General Comment No. 14: The Right to Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights) 2000. UN document E/C.12/2000/4; available at: www.refworld.org/pdfid/4538838d0.pdf
[28] Meier, Benjamin Mason. and Gable, Lance. (2013), "US Efforts to Realise the Right to Health through the Patient Protection and Affordable Care Act", Human Rights Law Review 13(1), Oxford University Press. p.167; available at: www.bmeier.web.unc.edu/files/2013/10/167.full_.pdf
[29] Ibid; p.168.

Security Act, President Roosevelt's 1944 State of the Union Address called for a "Second Bill of Rights" that would entitle every American to the "right to adequate medical care and opportunity to achieve and enjoy good health".[30]

President Truman in 1948 in his State of the Union observed:

> "Our ultimate aim must be a comprehensive insurance system to protect all our people equally against insecurity and ill health"[31]

George[32] in the work states that health is now no more a privilege but a right and stated:

> "Senator Ted Kennedy predicted to thunderous applause at the Democratic National Convention that Barack Obama would "break the old gridlock and guarantee that every American will have decent, quality health care as a fundamental right and not just as a privilege."[33]

According to the work of George, the Obama administration launched a national health plan, but not as a human right benefitting only most effective lobbyists and not individuals as per se.[34] "The work of John Arras and Elizabeth[35] Fenton has also tries to point that RTH does not define benefit through need of minimum medical benefit package. But, legislative adoption of this right is a necessary step toward making the definition of a minimum benefit package politically relevant. They also stated that only political process can adopt and implement the RTH".[36] The right to get health care is major problem for the individuals who are poor and financial constrained. If health insurance is politically available then can it help in accessing health cost and expenditures through funds and budget for health? (As it is financial service sector).

While availing of health insurance, the individual needs to be able enough to pay the premiums on time, if any laps in payment of premium occurs, then the amount of savings may stop. For example, in State Bank of India if laps occurs and only six months will be given for revival of the same from the due date of first unpaid and in life time (alive), with all arrears and satisfactory health report or otherwise premium

[30] Ibid. and Annas, George J. (2009), "The American Right to Health", Another Voice: Hastings Center Report, 39(5) p.3; available at: www,jstor.org/stable/40407641
[31] Annas, George J. (2009), "The American Right to Health", Another Voice: Hastings Center Report, 39(5) p.3; available at: www,jstor.org/stable/40407641
[32] Ibid
[33] Ibid.
[34] Ibid.
[35] Writers of an essay Bioethics and Human Rights: Access to Health-Related Goods.
[36] Annas, George. J., (2009) "The American Right to Health", *The Hasting Centre Report*, 39 (5):3. p.3.

policy will lapse.[37] At present, during emergency cases the victims can be taken directly hospital and demand health care. But, the hidden cost during emergency situation sometimes lead to pay huge bill of those drugs/medicines which governments do not provide for free. In this situation a condition of sphere to get RTH is needed. Demanding and atmosphere of support from Government and other international sphere have led social security and need of health condition. The Peoples' Charter for Health 2000 by the principles stated in the tackling the determinants of health, by looking in the economic challenges into the health that:

> "The economy has a profound influence on people's health. Economic policies that prioritise equity, health and social well-being can improve the health of the people as well as the economy; Political, financial, agricultural and industrial policies which respond primarily to capitalist needs, imposed by national governments and international organisations, alienate people from their lives and livelihoods. The processes of economic globalisation and liberalisation have increased inequalities between and within nations; Many countries of the world and especially the most powerful ones are using their resources, including economic sanctions and military interventions, to consolidate and expand their positions, with devastating effects on people's lives; This Charter calls on people of the world to: Demand transformation of the World Trade Organisation and the global trading system so that it ceases to violate social, environmental, economic and health rights of people and begins to discriminate positively in favour of countries of the South. In order to protect public health, such transformation must include intellectual property regimes such as patents and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement; Demand the cancellation of Third World debt; Demand radical transformation of the World Bank and International Monetary Fund so that these institutions reflect and actively promote the rights and interests of developing countries; Demand effective regulation to ensure that TNCs do not have negative effects on people's health, exploit their workforce, degrade the environment or impinge on national sovereignty; Ensure that governments implement agricultural policies attuned to people's needs and not to the demands of the market, thereby guaranteeing food security and equitable access to food; Demand that national governments act to protect public health rights in intellectual property laws; Demand the control and taxation of speculative international capital flows; Insist that all economic policies be subject to health, equity, gender and environmental impact assessments and include enforceable regulatory measures to ensure compliance; Challenge growth-centred economic theories and replace them with alternatives that create humane and sustainable societies. Economic theories should recognise environmental constraints, the fundamental importance of equity and health, and the contribution of unpaid labour, especially the unrecognised work of women".[38]

In view of the above, when one starts understanding the economic constrains and need of demanding cancellation for third world debt as well as asking help from the World Bank and or IMF for the interest of peoples' health; government must

[37] SBI Life Insurance, (2016), "Revival of Lapse Policy", Mumbai; available at: www.sbilife.co.in/sbilife/content/11_4162

[38] The Principles pointing towards tackling the determinants of health in the economic challenges of the Peoples' Charter for Health 2000; and also see, Annexure III.

ensure economic policies to health as well as provide fundamental importance to health along with quality and affordability of available healthcare. The 1948 United Nations Universal Declaration of Human Rights, Article 25, says that to achieve RTH in proper sense:

> "everyone has a right to a standard of living adequate for health and well being.[39]

UDHR mentions one can enjoy the right to be healthy provided social security of health through insurance for proper standard of well-being. Further, most individuals compare government with private health insurance to access the cost of quality services and lunge aside governments' imperfect health care aids. According to the type of plan for health coverage or service benefit the individual selects and pays premium or payroll tax.[40] This practice accidentally, many a time makes them forget, about the exclusion clause that excludes various hidden insurance benefits. As well, they further overlook to compare their retained coverage plan for availing and accessing the quality of health care services and user fees according to the rising market prices. Lastly, health care cost or options provided to individuals through insurance by the company maintain their doubts about the prospects and issues of their investments in health coverage.

Observing the need of right to health insurance, in Albania implementation of "mandatory insurance of health care" came up. Through the Constitution of the Republic of Albania by its Article 55 that states:

> "Citizens enjoy equally the right to health care from the state. Everyone has the right to health insurance in accordance with the procedure established by law." [41]

The right to mandatory health insurance assures socio-economic right to health with the help of ICESCR Articles 9 and 12.[42] Further, every State has a legal

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[39] Article 25 of UDHR 1948. G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810, Accessed on 3 June 2014; available at: www.unhchr.ch/udhr/

[40] Bowers, Kevin., (2011), "Assessing the impact of healthcare reform on insurance", *International Law Office*, Insurance & Reinsurance - Hong Kong, Globe Business Publishing Ltd: 1-5. p.1; available at:www.internationallawoffice.com/newsletters/detail.aspx?g=1f4a5c60-ed19-40aa-a60e-cbfc7c2c7e3d

[41] The Republic of Albania on 24 February through Law no. 10383 dated 24.2.2011 "on mandatory insurance of health care in the." Mano, Laure, "Implementation of the Constitutional Right to Health Insurance In the Albanian Legislation", Juridical Current, 16(4), p.85; available at: www.eds.b.ebscohost.com.ezproxy.jnu.ac.in/eds/pdfviewer/pdfviewer?sid=9c1cb51f-a1c5-44ca-9054-64dbde839162%40sessionmgr120&vid=0&hid=103

[42] Articles 9 and 12(d) of the ICESCR 1966. *International Covenant on Economic Social and Cultural Rights* (ICESCR) U.N.G.A. res. 2200A (XXI) of 16 December 1966 (entered into force 3 January 1976, in accordance with article 27); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

responsibility to provide this right to its people without discrimination and through equal access. In India, the present Prime Minister effort of bringing *"Pradhan mantri suraksha bima yojana"* of 2 lakhs for Rs. 12 per year premium and health insurance of 700-800 a year for cover of Rs 50,000 for individuals 18-40 shows that, still there is need, to do more in regard to bring social security during health emergency.[43]

Insurance Coverage on Health Experiments and Care

During financial expenditures that arises due to healthcare treatment insurance brings social security. Such treatment which ensues because of trial failure treatment or normal treatment due to natural diseases or lifestyle suffering can be availed through insurance. To avail this insurance policy one has to choose particular type of policy by paying premium to insurance company and taking future prospects. Increase in enterprise medical doctors and private facilities has led to doctors setting own choice of fee structure for service.[44] But, these doctors forget they are gaining financial reward by fraudulence charges and providing just limited healthcare standard for treatment and observing research study funded by government[45] in their name. Stressed consumers are left drifting about their vulnerability. Availing health as equity based cannot be delivered as access to healthcare and research outcomes are provided through social security as insurance. Benefits of health insurance lies during suffering and their spending help to avail standard healthcare facilities and arrangements.

Insurance monetarily supports every new health development for cure as well as treatment. It also motivates researchers as supporting instrument and covering every participants with health coverage in case of research failure. Example can be of determining cryogenically frozen practice where bodies are cryonic preserved to find cure.[46] Insurance supports such claims due to hidden benefits by interest rates and

[43] BI India Bureau, (2015), "8 Insurance Scheme Modi Launched and How they Benefit You", Finance, 25May 2015; available at: www.businessinsider.in/8-Insiuarnce-Schemes-Modi-Launched-and-how-they-benefit-you/articleshow/47418104.cms

[44] Hardyment, A.F. (1984a) "Suzuki, and Others," *British Columbia Medical Journal*, 26 (10), p.608.

[45] Wilson, Paul, R.. Chappell, Duncan., and Lincoln, Robyn., (1986), "Policing Physician Abuse in BC: An Analysis of Current Policies", Canadian Public Policy/Analyse de Politiques, *University of Toronto Press*, p.236-237.

[46] The case of cancer patient of 14 year old girl, highlighted insurance as a right based approach that should be targeted oriented during vulnerability and suffering without laying much condition. The High Court of London on 6 October 2016 by Justice Peter Jackson order cryogenically frozen her body on 17 October 2016. For details, see, Rayner, Gordon. Finnigan, Lexi. And Bodkin, Henry., (2016), "Girl, 14,

little chances of failure to support financing loans. Insurance funding takes place prior protocol provisions and complex understanding of rewarding profits. On the other hand insurance companies can be partner or functioning body of institutes and colleges that provides maximum number of promising results.[47] Protocols for post trial provisions set in CTs arrangements[48] having long and complex process may sometimes get rejected due to ongoing funding process. But if encouraging such parties by insurance funding as a social security can help for research failures and trial error.

Insurance coverage can help in supportive difficult process to find various scope of treatment for disease through discovery of innovative medicine required in market. Insurance policy can help downtrodden by providing benefit in sufferings by integrating target oriented system for new dimension of medicate and medicare. Insurance in some of developed countries like Canada helps equity method for providing tax redemption in health insurance through mode of premium. Financing health care expenditure leads requirement of health insurance policy so that affordability in quality of health standards can be possible during need and treatment.

Insurance as a right has been demanded for security based for solving world health issue. The arrangements of health insecurity found in Medicaid and Medicare can support[49] health as a fundamental right as provided under UDHR 1945,[50] ICESCR 1996 and international organisation as WHO, UNICEF, UNESCO etc. along with different countries domestic legislation.

Who Died of Cancer Cryogenically Frozen after Telling Judge She Wanted To Be Brought Back To Life 'in Hundreds of Years'", The Telegraph News, 18 November, available at: www.telegraph.co.uk/news/2016/11/18/cancer-girl-14-is-cryogenically-frozen-after-telling-judge-she-w/

[47] Pharmaceutical Research and Manufacturers of America (PhRMA): Research, Progress Hope, (2015),"Medicines in Development: Explore the latest Progress on Medicines in Development", *PhRMA*, Washington, DC, p.1; available at: www.phrma.org/innovation/meds-in-development#sthash.eVyoYY8U.dpuf

[48] Articles 21-22 of the Helsinki Declaration on Scientific Requirements and Research Protocols, 2013, p. 4-5.

[49] Annas, George.J. (2009), "Bioethics and Genomics" pp. 321-329 in Andrew Clapham and Mary Robinson (eds.) *Realising the Right to Health*: *Swiss Human Rights Book,* Vol.3, Zurich: Ruffer & Rub available at: www.swisshumanrightsbook.com/SHRB/shrb_03_files/20_453_Annas.pdf

[50] *Universal Declaration of Human Rights*, (UDHR), Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810; available at: www.unhchr.ch/udhr/

Public and Private Health Insurance

State health insurance is public health insurance and private insurance companies providing health insurance plans are private health insurance. In private health insurance one has to pay premium depending on the plan. On the other hand in public insurance are those in which only enrolment fee and co-payments fee i.e flat amount of fee is paid.[51] "Public health insurance are those that are registered with the government and private non-registered provide other types of insurance and have a small share providing market of supplementary health insurance policies".[52]

The public health insurance is paid by public health fund like budgets and is subsidised by the govt. Private insurance has to be paid in part or entirely by the person who is opting for such private health insurance and based on the type of insurance. Private health insurance can be purchased or provided by an employing company. In US individuals above 65 years and individuals with certain disability like kidney diseases of end stage etc are included in the public health insurance medicare. There are four components like A, B, C and D[53] are there in medicare:

> "A Part A covers hospital visits, home health care, hospital care and skilled nursing facilities. Part B covers doctors' visits, including some preventive care. Part C is an option run by private insurance companies that includes Parts A and B and often other services such as prescription drugs. Part D covers prescription drugs and is also run by private insurance companies".[54]

Medicare is not only the public health insurance but children health insurance and medicaid cost coverage also govt. financed insurance. Lower income group/family are covered under Medicaid public health insurance facility whose eligibility criteria are set using parameters such as income, family size, pregnancy, disability and immigration status of the states and funds of state as well as the federal govt. Further, Social security of getting Medicaid being provided to those working individuals with disability.[55]

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[51] Cohealthinfo. (20"What is the difference between public and private health insurance" Colorado; available at: www.cohealthinfo.com>difference/&ei=pt93ANtM&lc=en-lN&s=1&m=13&host=www.google.co.in&ts=1469619877&sig=AKOVD668l9fq5Dtvj3dx-BbNUMlvemakfQ

[52] WHO-Switzerland, (2000), *"Switzerland: Health Care Systems in Transition",* AMS 5012667 (SWI), Target 19 200(R), European Observatory on Health Care Systems, WHO/Europe-World Health Organisation, p.17; available at: www.euro.who.int>assests>pdf_file

[53] Matuza, Jacqueline. (2015), "Public Vs. Private Health Insurance", 9 September 2015, LIVESTRONG.COM; available at: www.livestrong.com/article/75148-public-vs.-private-health-insurance/

[54] Ibid.

[55] Ibid.

In many of the countries, health insurance is attracting substantial additional tool to finance health care. "The former insurance pattern was public health insurance as Bismarck's Germany or the UK / NHS funded through taxes and aimed at the broad common coverage".[56] Due to the dissatisfaction in the public funding of health care services and rising income of people every country has more private health insurance selectors these days.[57] Moreover, private health insurance provides wide ranges of quality and assistance they can benefit by selecting the type of insurance.

In developing countries, private health insurance begins between large multinational companies having professionals as well as filtering more towards group coverage. Further, there is even existence of informal insurance arrangements among communities. Like in India, as surveyed by NGOs to reduce the risk for poor during emergency of health expenditure community based health insurance are existing.[58] Sometimes, the drawback in private health insurance is felt when arrangements set for risk pool are so less that doing business with private health insurance leads no benefit since there is no proper incentive under the fixed schemes.[59] "In order to observe health insurance growth arrangement, covering, financing, provision and regulation have to be properly improved through quality. Business efficiencies, fair conduct, and relevant social imagination should boost its arrangements. As well as, presently there is need of balancing in professional accountability and better standard of quality care".[60]

Implications of Insurance for Public Health

Health insurance has come up as a social security during medical treatment and sickness. Since the UDHR in its Article 22 states that in accessing healthcare security national effort and international co-operation along with resources of each state and organisation or development and dignity should function in providing

[56] Srinivasan R. (2001), "Health Insurance In India", Health and Population-Perspectives and Issues 24(2): 65-72, p.65 medIND, available at: www.medind.nic.in/hab/t01/i2/habt01i2p65.pdf
[57] Ibid; p.66.
[58] Ibid; p.65.
[59] Ibid; p.66.
[60] Ibid.

insurance security.[61] Moreover, it is a right of everyone to have social security to health through social insurance.[62]

Presently, the most controversial issue in insurance is how to manage for paying health services. As, it has been observed rising user fee may lead to burden on insurance premium expenditure. "Like, in Africa during 1980s and early 1990s using of technical health economics models in conjunction with broad political economy frameworks i.e the econometric studies proved that if user fees comes in play then the health sector may improve service quality and lead to greater utilisation. However, strong opposition was faced during its implementation in Africa and other parts of world as this design of health policy not only harmed individuals or societies with low income group but also brought the concern how to manage the difficulty of instituting such mechanism for financing broadly accessible health services".[63]

But still, health policy in Africa got stronger through grassroots and political support of pressure groups by the Government playing the dominant role in financing health care. The places in Africa like Benin, Burkina, Cameroon, Congo, Cote d'Ivoire, Egypt, Faso, Ghana, Lesotho, Mali, Nigeria, Rwanda, Swaziland, Sudan, Tanzania, Uganda, Zimbabwe, and so on. Implemented the user fee where compulsory public medical insurance schemes, financed via general taxation takes place. But still in many parts of Africa still doesn't has private insurance schemes for support of private health care financing where Government still plays a dominant role.[64] During the tertiary level curative care is felt.

It has been observed that by charging fees for services that primarily benefit the user, such as tertiary-level curative care, governments can free up and reallocate tax-financed health expenditures to activities that yield benefits that extend beyond the individual. These include public health services directed to community health, immunizations, and communicable diseases. Countries in Sub−Saharan Africa have considerable experience with user fees for the simple reason that private−for−profit

[61] Article 22 of the UDHR 1948. G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810; available at: www.unhchr.ch/udhr/

[62] Article 9 of ICESCR 1966; Ibid.

[63] Mwabu, Germano., "Health Development in Africa", *Economic Research Papers No.38,* African Development Bank; available at: www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/00157610-EN-ERP-38.PDF ; p.12.

[64] Mwabu, Germano., "Health Development in Africa", *Economic Research Papers No.38,* African Development Bank, pp.12; Available at: www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/00157610-EN-ERP-38.PDF.

and private voluntary clinics, including church missions, must recover costs to survive. In Tanzania, with a per capita income of only $100 in 1990, nine of eighteen non-governmental dispensaries recovered 100 percent of their operating costs from user fees, and seven of twenty-one NGO hospitals recovered more than 75 percent of their operating costs. (Mujinja and Mabala, 1992). In Uganda, with a per capita income of $170, four mission hospitals recovered 7895 percent of their operating costs, the balance being provided by donors (World Bank, 1993a). In the Central African Republic, with a per capita income of $390, two private hospitals recovered 5580.[65]

The health care policy and law has been considered looking through public and private health insurance at the center and is considered for being basic means of transform. As well as, an industry looks after its own benefits and right, functions according to the health facilities and delivery of medical technologies. The Eight Annual Symposium on Access to Health Care is considered for bringing legal and policy issues for the health insurance arena investigative past, current and future trends. Five major themes have been considered for exploring and they are:

> "i) The first theme is based on the changing posture of regulators in overseeing health insurance offerings, focusing on current developments in state departments of insurance and the expanding role of federal authorities in oversight of the field in the wake of the ACA; ii) The second theme will explore how initiatives in cost control and benefit design are impacting provider and beneficiary obligations; iii) The third theme will concentrate on the increased role of private insurers in public programs exploring, in particular, the expanded role of insurers in managed care; iv) The fourth theme will focus on the emerging structural components of coverage from the ACO to co-ops and how such structures are being shaped and regulated; and v) The fifth theme is based on health care marketplaces, current status and future evolution".[66]

Since health subject and its utilization through facilities of insurance is also a challenging issue to its access for patient satisfaction. Since public sector has been underfunded as well as the free services available in government hospitals speaks about low quality services and attention. In India only government employees are covered under the social security of health insurance scheme through Central Government Employees under Central Government Health Scheme (CGHS) and ESIS (Employees State Insurance Scheme).

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[65] Shaw, R. Paul., and Ainsworth, Martha. (1995), "*Financing Health Services through User Fees and Insurance: Case Studies from Sub-Saharan Africa*". The International Bank for Reconstruction and Development, the World Bank: USA, p.11; available at: www.elibrary.worldbank.org/doi/pdf/10.1596/0-8213-3396-8

[66] The 5 major themes of the Eighth Annual Symposium on Access to Health Care.

The public health insurance may lead in creation of accountability. Since, the private health insurance leads competition benefit but cannot provide rights for poor. Making two tier health insurance system selectors take one who can afford and one who cannot. Need of fair, long-term support, without fraud and malpractice above all honest marketing must prevail with proper guidance.[67]

Scope of Public or Social Insurance Funds

Public health insurance bodies are governed by public law and government where sum of fixed amount is paid by law depending on the policy selection. Public health insurance funds do not provide cash benefits but benefits through contracts with hospitals and doctor association.[68] Study state in rising competition law, the Public Health Insurance Funds (PHIF) in EU has been decreasing in policy market. So that pace in public management strategy can be kept for benefiting the risk adjustment. In EU the system of risk structural compensation of state is present between the PHIF so that by authority of the state and PHIF can get certain amount of risk adjustment per capita for insured persons. The criterion depends on the age, sex and increasing death due to common diseases.[69] Since, PHIF are governed by government and functions in state and federal level with cooperating and contracting by hospitals and health services. The PHIF collects contribution in a central budget.

In 2007 through Act to "Strengthen Competition in Statutory Health Insurance System" fixed rate of contribution was set. The rate at present is 15.5% of work income to 44.550 Euro earners per year. An extra fund charge raises according to the extra per income payment. Since the observation in two cases of haemophilia, risk selection in some PHIF came in practice especially for disable, chronically ill and other expensive patients will not be provided good care.[70] Since, rising market competition has also influenced PHIF to act in discriminating nature. That is the

[67] Srinivasan R. (2001), "Health Insurance In India", *Health and Population-Perspectives and Issues* 24(2), p. 66, 67, 68, 69 and 70. medIND, available at: www.medind.nic.in/hab/t01/i2/habt01i2p65.pdf

[68] Gronden, Johan Willem van de., Szyszczak, Erika., Neergaard, Ulla., and Krajewski. Markus, (2011), "Health Care and EU Law", *Springer Science & Business Media*, p.321 and 322; available at: https://books.google.co.in/books?id=BGuE9zxI6KYC&pg=PA321&lpg=PA321&dq=scope+of+public+insurance+funds&source=bl&ots=AZH8m53dBw&sig=RYdg1MtdbIwgmFjjBVDTjG7epXE&hl=en&sa=X&ved=0ahUKEwii9t-Hi5XOAhXBto8KHapICscQ6AEIHDAA#v=onepage&q=scope%20of%20public%20insurance%20funds&f=false.

[69] Ibid.

[70] Ibid.

source for poor and vulnerable groups of family and individuals to access health care facility.

Rising prices in medicines especially for IP-induced product have also led the issue of its cost financing. In 2006, $550 billion was estimated for medicines market for high income countries. Since the global pharmaceutical players exercise some monopoly power to negotiating lowering the drug prices. Government works to provide government or social insurance funds for such high prescribed drug prices. For OECD pharmaceutical expenditures outside U.S, public or social insurance funds account for the great majority.[71] The governments of wealthier countries provide access to patented higher prices medicines with government subsidised insurance and other social mechanisms. But these arrangements of subsidies cannot be possible in low income countries.[72] Seeing as, in US the public subsidies for drug prescriptions has led growth for retail markets as well as just 27% public fund in 2005 developed due to increase in prescription drugs. Private insurance companies also provide these arrangements of Part D of Medicare and in this context hospital has topped $200 billion.[73] Since PHIF pays about $10 billion a year in US for hospital visits, nurse attendance etc. still access to drug remains a problem. As well as the private insured receive large tax subsidy. Moreover, in US more than 47% coverage of outpatient pharmacy expenditures is made by Private insurance.

In 2005 outpatient pharmaceutical amounts 10% of US health spending. About $102.3 billion health insurance as a tax is taken by employed US citizens who are exempted from income tax per fiscal year as estimated in 2004. As regard, $10 billion tax supports domestic pharmaceutical market expenditure. In health research expenditure it was analysed that about 45% of direct expenditure comes from public funds as estimated to $56.1 in 2003. With both public and private funds global expenditure on health research was $125.8 billion.[74]

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[71] Outterson, Kevin., 2008 "Should Access to Meicine and TRIPS Flexibilities Be Limited to Specific Desieases" *American Journal of Law O Medicine,* 34(2008), pp. 323-324, Boston University School of Law.

[72] Outterson Kevin., (2006), "Access to Global Disease Innovation" INT- World Health Organisation, WHO IGWG; 15 November 2006, pp.1; Available at: www.who.int>public_hearing>first.

[73] Ibid; p.324, also see, Matuza, Jacqueline. (2015), "Public Vs. Private Health Insurance", 9 September 2015, LIVESTRONG.COM; available at: www.livestrong.com/article/75148-public-vs.-private-health-insurance/.

[74] Outterson, Kevin., 2008 "Should Access to Meicine and TRIPS Flexibilities Be Limited to Specific Desieases" *American Journal of Law O Medicine,* 34(2008), p. 323-324, Boston University School of Law.

In India ESIS and CGHS are two main schemes functioning for factory workers and central government employees. But due to poor standard of public healthcare delivery, unregulated private market, etc. are under immense criticism in delivering quality of health care. Further, NGO running schemes like Voluntary Health Service in Chennai provides with a Medical Aid Plan where every households gets free annual health checkup and discounted rate of inpatient services by paying annual premium based on joint monthly income.[75] The WHO has set target of at least 5% expenditure from gross national product.[76] Moreover, the Indian government is looking forward in making health budget GDP to 2.5%.[77] But, present total expenditure for health is only 1.62% of the whole budget and out of which National Health Mission has a share of less than 1%. On top of this Indian government is moving for public private partnership instead of providing free healthcare services.[78]

Health Insurance: Indian Scenario

Health is a fundamental right under International instrument, but, in India health has till date been provided by Articles 38, 39, 41, 42, 47 and 48 of the Indian Constitution that directs the State to ensure social and economic justice through its Part IV of Directive Principles of State Policy (DPSP).[79] The Article 21 only comes in function during emergency like accident or denial of admission provides health as a right.[80]

In India the insurance is governed by Insurance Regulatory and Development Authority Act 1999 and Insurance Act of 1938. There are 52 insurance companies out of which 24 are life insurance business and 28 non-life insurance. Life Insurance Corporation is the only sole public sector company among all life insurance industry. Insurance laws (Amendment) Act 2015 provides government ownership and control

[75] Prinja, Shanker., Kumar. Manmeet., and Kumar Rajesh., (2012) Indian Journal of Community Medicine, 37(3), p.142-149; available at: www.medind.nic.in/iaj/t12/i3/iajt12i3p142.htm

[76] Shodhganga, (2005) "Chapter-4 Trends in Indian Health Industry", p. 86; available at: www.shodhganga.inflibnet.ac.in/bitstream/10603/9222/13/13_chapter%204.pdf

[77] The Hindu, (2015), "Centre moots health as a fundamental Right"-The Hindu, Jan 1 2015; available at: www.M.thehindu.com>news>articles6742882.

[78] Sharma, Neetu Chandra and Singh, Shruti., (2016) "India's Health Woes: Budget for National Health Mission Remains Staged at Rs 19,000 crore", 2 March 2016, *indiatoday.in* p.1-2; available at: www.indiatoday.intoday.in/story/indias-health-woes-budget-for-the-national-health-mission-remains-stagnated-at-rs-19-000-crore/1/6098.

[79] For details, see, Articles 38, 39, 41, 42, 47 and 48 of the Constitution of India, (1947), Ministry of Law and justice, India:1-103; Available at: www.lawmin.nic.in>legislation.

[80] For details, see, Article 21 of the Constitution of India, (1947), Ministry of Law and justice, India:1-103; Available at: www.lawmin.nic.in>legislation.

with Foreign Investment Cap in an Indian Insurance Company from 26% to the Limit of 49%. In 2014-2015 fiscal years the premium collected by Indian insurers is 3.30% of GDP. Per capita premium underwritten i.e. insurance density in India during FY 2014-15 is US$ 55.0.[81]

The business of insurance is divided in four classes and they are: a) Life Insurance; b) Fire Insurance; c) Marine Insurance; and d) Miscellaneous.[82] So far health insurance is a general insurance but the same is also provided by the life insurance companies. The concept of general insurance has its root in risk sharing and loss pooling. Since health insurance came as employee's coverage for hospitalisation and dental along with treatment for non-surgical eye.[83] In India the private sector is more dominant then the public health insurance. The total health expenditure is about 5% GDP where public expenditure is just 0.9% and private expenditure of 4.0% including both self financing along with employees or community financing.[84] Moreover, by bringing public private partnership and just 2.5% for health budget of total GDP[85] does not solve insurance problem in India.

Insurance Coverage on Clinical Trials

CT is safe but risk involved in it may also land in unfortunate sufferings like side effects or death. Usually three years' time period from the date of first notice of sickness or injury is left for CT claims for compensation. Claims for CT can be of two types: i) personal injury claims and ii) group injury claims. The claims are mainly made for rehabilitation in order to access care and support for recovery, medical negligence, defective drugs, and medical products.[86] Such claims can be for monetary

[81] Kalyani. K. Nikita. "India Insurance Market", Know IRDAI, Source: Annual Report (2014) & (2013-2014). Insurance Regulatory and Development Authority (IRDA): Consumer Education Website; Available at: www.policyholder.gov.in/indian_insurance_market.aspx.

[82] Shodhganga, (2005) "Chapter-4 Trends in Indian Health Industry", p. 86; available at: www.shodhganga.inflibnet.ac.in/bitstream/10603/9222/13/13_chapter%204.pdf

[83] Ibid; p.86-87.

[84] Ibid; p.99.

[85] Sharma, Neetu Chandra and Singh, Shruti., (2016) "India's Health Woes: Budget for National Health Mission Remains Staged at Rs 19,000 crore", 2 March 2016, indiatoday.in p.1-2; available at: www.indiatoday.intoday.in/story/indias-health-woes-budget-for-the-national-health-mission-remains-stagnated-at-rs-19-000-crore/1/6098 ; also see, The Hindu, (2015), "Centre Moots Health as A Fundamental Right", The *Hindu*, Jan 1 2015. available at: www.M.thehindu.com>news>articles6742882

[86] IM: Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

and non-monetary benefits where compensation can be provided on different proposed models based on different principles[87] like: a) market model i.e based on supply and demand principle is hard to find subjects for trial based on race, study location etc.

Thus it provides high compensation by ignoring risk involved and hiding important data's that can deem for ineligibility of CT; b) wage model is based on egalitarianism principle, where unskilled or little skilled subjects are recruited who are paid less or based on their scale. Since they are from low income group it provides less issue for inter study competition and undue inducement with minimised risk and no discrimination of high or low income group but many a time leads difficulty in achieving timeframe number of targeted subjects; c) reimbursement model is based on the same footing of egalitarianism where it is hard to find subjects but in this model it's hard to hide information or overlook the risk involved during study as different subjects are recruited and compensated according to their qualification; and d) appreciation model where compensation is provided as a token of gratitude or appreciation after completion of any type of CT. Stakeholders should prior beginning CT obtain approval from the Ethics Committee for consideration of compensation to be provided to the trial subjects.[88]

The amount of compensation depends on extent of injury or illness and loss. Depending on the amount through acceptance or contest in court for loss of earning from current and future by not being able to return for work, payment expenses of medical and travel, care and support needs for present and future, Requirement of home modification along with mobility aids or specialist equipments, trauma and nature of ongoing problems. [89] Compensation can be set on different phases from I-IV and based on its requirement causing injury and loss. Prior, in phase I trial for single dose administration and/or limited repeat dose administration no compensation or access to medicine benefit and gain was provided until investigation ends beyond conventional result. Since in Phase I trial maximum patients or unhealthy volunteers

[87] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.70-71; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/

[88] Ibid.

[89] Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

for new chemical or biological entity research based on disease-specific biomarkers; where efficacy is not investigated are recruited.[90] The Association of the British Pharmaceutical Industry (ABPI) brought first guidelines for compensation in 1970 for phase I trial. It has been observed in the principles for Phase I trial that:

> "a) when injury occurs due to participation in trial, it is right of the volunteer to receive appropriate compensation on the basis of negligence or strict liability for company; b) the compensation by the sponsoring company should be stated on the contractual document with the volunteer on proof of causation supported by qualified obligation to pay compensation for injury as quick as possible along with the cost of compensation will be resolved separately through other parties to the research; c) Simple clause of arbitration as provision for injury compensation should be included along with minimum time frame for dispute on implementation of formalities; d)it is stated that volunteers benefitting from Phase I trials will not be covered under such guidelines of Phase I trials"[91]

Compensation for phase I subjects should be stated on contractual document or arbitrarily claimed within minimum time frame. But benefitting subjects will not be qualified to claim compensation. The International Conference on Harmonisation-Good Clinical Practices (ICH-GCP) guidelines state that subjects should be compensated for trial related injury and/or treatment should be provided. ICH-GCP also suggests that sponsors should provide insurance or indemnify the investigator or the researching institution for claims arising from such trial. The Helsinki Declaration states the protocol should carry compensation provisions.[92] In U.S FDA there is no proper instruction on compensation. It is the code of federal regulations that suggests institutional policy will decide on injury based compensation and/or medical treatment that is mentioned in consent document or protocol.[93]

In 1983, when inclusion of "healthy volunteers i.e non-patient volunteer" for studies of Phases II-IV were added compensation was set for them based on risk and benefits formulation. Risk and benefit brought distinction between healthy volunteers and patient volunteer's i.e. target disease participant for Phases II-IV through treatment and adverse side effect (ASE). This division led was formulated for all the

[90] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf ; p.1-4.
[91] Ibid.
[92] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.71-72; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/
[93] Ibid.

phases i.e phase I-IV who have no reasonable prospect of direct benefit or get material side effects by product under research from participation.[94]

The new guidelines of 2012 Edition for ABPI on Phase I states that the 1988 non-patient guidelines are now replaced with compensation provisions; and in the 1991 guidelines of CT for Phases II, III and IV are also replaced with the compensation provision.[95] In Phase II-IV the compensation is paid by the sponsoring company when: i) direct participation leads deterioration in health or well being; ii) based on damages the amount is calculated by the English Court, such compensation may be reduced on extent of volunteers partial responsibility, i.e reason of contributory fault or where the payment of such injury has been made under any policy of insurance affected by the company as volunteer benefit; iii) An arbitrator should be appointed in dispute or disagreement of the application of paragraph i) and ii) of above mentioned or the President of the Royal College of Physicians of London should be appointed for arbitrating to consult a barrister of at least 10 years to provide the amount for damages and its payment of compensation; iv) Agreement of paying compensation should be in accordance to the English Court and paragraph iii) is subject to the sole jurisdiction of English Court.[96]

The process of providing compensation through Pfizer a representation of private pharmaceautical company as a sponsored study through its company's guidelines states that volunteers compensation is based on method and timing of disbursement. This incorporates regional laws, regulation and guidelines, the Institutional Review Board or Independent Ethics Committee reviews and approves compensation that is developed on criteria based on human subjects, site, and targeted subjects in same treatment group.

In the voluntary informed consent disclosure of compensation amount is made, that accessed through the Pfizer Clinical Research Unit (PCRU) staff line with SOP CRU-RO2-LSOP, Calculation and payment of Subject Compensation at the PCRU. Compensation is provided to enrolled participants in the research with no incurring personal expenses, i.e. direct payment of expenses by the Pfizer, contract research organisation (CRO) vendors or consultants. Involvement of healthy

[94] Ibid.
[95] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf , p.1-4.
[96] Ibid.

volunteer's for phase I trials permits reasonable compensation for time and effort. Excessive compensation can be received for risks or discomfort that occurs without assumption. Additional consideration for minors participating in research is made along with compensations for travel, childcare for siblings and parking can be received by the parents or guardians. But, such compensation should not be made to those parents/guardians who plan to make improper incentives by enrolling minors.[97]

The main guidelines for Phase II-IV state that the participating volunteer should receive compensation without legal commitment by written assurance to the investigator and from investigator to the relevant research ethics committee and they are: i) the volunteer should receive compensation from the company for bodily injury as well as death; ii) due to the inclusion of patient for trial the compensation should be paid when injury occurs through the administered medicinal product under trial or any clinical intervention or procedure including protocol; iii) During the injury of the child in uterus through participation of the mother in clinical trial as well as the child as a volunteer; iv) for more injuries and disability condition provided which excludes temporary pain or discomfort with curable complaints; v) while conducting a trial to remove adverse reaction and causing adverse reaction through the medicinal being researched; vi) exclusion of compensation for such human subjects will be made whose adverse reaction injury was foreseeable or predicted prior conducting research and the patient had freely accepted such trial participation either through written or other consent; and vii) the company is under strict liability to provide compensation if the volunteer is injured due to the drug product used during trial".[98]

In India the quantum of compensation for death through Serious Adverse Events (SAES) during clinical trials has been set by the Drugs and Cosmetic Rules after amendment vide GSR 53(E) dated 30-January 2013 inserting Rule 122 DAB and a new Appendix-XII in Schedule Y is considered to pay through help of Independent Expert Committee.[99] The following criteria were finally adopted. Firstly, criteria

[97] Pfizer, (2016), "Compensation to human Research Subjects in Clinical Studies", *2002-2016 Pfizer Inc*; available at: www.pfizer.com/research/research_clinical_trials/compensation_trial_participants

[98] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf. p, 1-4.

[99] Compensation Formula: Clinical Trial, (2013), Formula to Determine the Quantum of Compensation in the Case of Clinical Trial Related Serious Adverse Event (SAES) of Deaths Occurring During Clinical Trials", GSR 53 (E), *The Drug and Cosmetic Rules, Schedule Y:*1-9; available at: www.cdsco.nic.in/writereaddata/formula2013SAE.pdf

should not be discriminative in nature due to socio-economic conditions e.g. (a) income, (b) education; secondly, criteria should not discriminate gender/sex; thirdly criteria should not be such which may have minimal impact but may create large variability; fourthly, formula should be such that the inter group variability of compensation value so arrived at, has little scope of discretion, thus avoid possible bias.

Thus, the following criteria were finally decided to be incorporated in the compensation formula. i) Age of the subject ii) Risk factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial. The computing the three factors i) age; ii) risk and iii) base amount for SAE/Death related to Clinical Trial:

"Compensation= B*F*R/99.37."[100]

a) B= Base Amount i.e. 8 lakh; b) F= Factor depending on the age of the subject based on Workmen Compensation Act; and c) R=Risk Factor depending on the seriousness and severity of the disease based on scale of 0.5 to 4 (0.5, 0.1, 0.2, 0.3, 0.4). However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs should be given. Thus, it will be seen that the compensation amount will vary from a minimum of Rs.4 lakhs to a maximum of Rs.73.60 lakhs depending on the age of the deceased and the risk factor. The committee will examine cases of SAEs of deaths and decide the final quantum of compensation after due diligence and application of mind on the risk factor and recommend the same to DCG (I) on case to case basis. The committee also considered the above formula as provisionally final.[101]

Conclusion

Article 22 of the UDHR supports the healthcare access through its security and that is: "Everyone, as a member of society, has the right to social security and is entitled to realisation, through national effort and international co-operation and in accordance with the organisation and resources of each State, of the economic, social

[100] Ibid.
[101] Ibid.

and cultural rights indispensable for his dignity and the free development of his personality". Apart from it, Article 9 of ICESCR states that health of poor individual should be: "protected through social security and social insurance". Moreover, understanding its development the concept of Health Insurance came during the industrial revolution through financial contracts made in cargos of ships. 1930s great depression brought health insurance more popularity where medical services for workers and families grew along with the hospitalisation covering populations as a whole together, providing new technologies and efficient physicians. The later phase of insurance too brought full fee for service (FFS) for physicians care coverage appreciating and rewarding at the same time. Further, the exemption of taxes for those who fills health insurance premium led to increasing credit towards insurance. So far, the present segment deals with financing of health care and requirement of health insurance to afford it and its challenging support helping the needy and vulnerable. Because presently, medical graduates feel it is their right to be a free enterprise doctors i.e practice out wherever they like and set their own fees. So that they can gain financial reward and engage in extensive fraud along with charging more on government funded medical programs. Health insurance came as a savior to such tricky situation by helping those who cannot afford their healthcare. Health Insurance can be defined as a contract where an individual or group purchases in advance health coverage by paying a fee called "premium.

The argument for using right in health care as a debate has raised the issuance of insurance as important. Presently two statements are frequently been used as: i) "everyone has the right to health care" and ii) "health care is a human right." These two statements creates an atmosphere of tension for health care when it is not provided as a right, e.g as in U.S. However, RTH care has to be looked through its determinants and all the broad concepts it may lead from its existing various forms. For example, existence the right to purchase health care or health insurance has come up but what about the insolvent/poor individuals who cannot purchase their own health. There should be direction on government's responsibility to look after such individuals/communities/society. So, those individuals can get RTH without any mental/physical/financial constraints. Present available programs for right to walk into hospitals emergency rooms and demand health care creates a sphere of tension where

existence of financial distress leads towards bankruptcy through big bill. If existence of RTH comes then no individual can be put into financial distress.[102]

The 1948 UDHR (Article 25), says everyone has a right to a standard of living adequate for health and well being, and it specifically mentions medical care.[103] Ironically, medical care comes through economical spending depending on how much working people can be requited. This unfortunate financial constrain confirms debate towards its existence for health finance and funds. An issue on the eligibility of insurance holder has surrounded problem for who can access the insurance facility and how privacy through hospital can be generated for personal information that have to be made confidential.

The usage of word "right" for health care has been looked as the concept of a right which is effortless, influential, troubling and implies no argument beyond it. However, the study has found that the RTH care explains broad dimension of understanding health rights. Providing health care rights requires infringement upon other rights, moral judgments, and a complex allocation of resources. Effortless statements for health like: "everyone has a right to health care" are meaningless until it does percolate down to the ground level.

[102] Mecikalski. Mark. B., (2011), "Right to Health Care: What Does It Means?", J Clin Sleep Med., Oct 15, 2011; 7(5), p.437.
[103] Article 25 of UDHR; available at: www.un.org/en/documents/udhr/index.shtml.

Chapter-VI

Insurance Coverage on Clinical Trials and Personalised Medicine

INTRODUCTION

Insurance is viewed as beneficial to society through its risk eliminating, cost benefit analysis on health. In compliance with health regulation, insurance companies rely on control of the authorities to participate along with other participant's rather encouraging inappropriate costs-benefit trade-offs. Health regulation formalities increases complains for insurers to monitor control or impose appropriate penalities and premium increase for insured companies. So, existing health regulation standards are not cut short.

Insurance liability threatens to levy a cost on the liable party, who will protect against the risk and if materialized the affected individual will move to his insurer to cover the loss. The connection between liability and insurance is made not to involve in risk spreading but to adopt a joint and several liability approach in other terms called as 'deep pocket' approach. As a consequence of this approach, fault-based liability is primarily unsuited with insurance because of its intention aspect. On the other hand, strict liability theory partially relies on insurance as a mechanism of compensation. [1]

Though there are various insurance schemes covering almost all the spectrums of an individual's life, "The major types of insurance available in different countries are: a) life insurance; b) medical insurance; c) private liability insurance; d) public and pollution liability insurance; e) fire insurance; f) insurance of debts; g) travelers insurance; h) aviation insurance; i) liability insurance for businesses and professionals; j) marine insurance; k) social insurance and l) motor vehicle insurance".[2]

[1] Reis. Tarcísio Hardman,. (2011), "Compensation for Environmental Damages under International Law: The Role of the International Judge", Woltrs Kluwer: Law & Business: Volume 17, Kluwer Law International BV: Netherlands, Great Britain, p. 142.

[2] Haas, Peter., Mangeat, and Eversheds Schmid., (2009), "International Insurance Law and Regulation: Commentary", Switzerland, Oceana, Oxford University Press, Inc. : New York; available at: www.eversheds.com/documents/global/switzerland/Publications/PHA_09_International_Insurance_Law_and_Regulations_Switzerland.pdf

One can possibly argue that financial security is essential to a strict liability regime, since it protects public authorities and other victims against the insolvency of the operator and at the same time it protects the operators against liabilities. In contrast, the difficulties in developing a regulation in the field of clinical trials and personalised medicines a reliable insurance mechanism unavailable sin this sector.[3]

"In fact financial constrains is one of the basic outfall in healthcare sector especially during new drug development. To boost pharmaceutical business strategy and innovation in R&D spending, global sales of the product is required i.e. above US$ 1 billion per year. In comparison, The OCDE data of 2009[4] reveals that in accounting of patent holding just 5.5% patents was from BRIICS and five developed countries France, Germany, Japan, United Kingdom (UK) and United States (US) have 70% patents filed for new pharmaceutical drugs".[5]

The development of new drug can be a hope for curing the diseases, but availability of social security towards health sector can reduce cost or monetary burden to the victims/individual. On the other, if government considers health as a right it makes an obligation on the government to provide social security for Medicaid and medicare with all reasonable medical facilities for free of cost to its citizens. The new drug development by researchers on the participating subjects need to be insured which supports as security for the subjects.

On the other hand, the development in new scientific technologies bring modern equipments in every sphere of life including healthcare. To avail this new enhanced technological health facilities individuals opt for insurance coverage due to limited government's free services and arrangements. As insurance coverage provides better quality, timely service, hygiene facilities in hospital on patient or health consumers.

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[3] Reis. Tarcísio Hardman,. (2011), "Compensation for Environmental Damages under International Law: The Role of the International Judge", Woltrs Kluwer: Law & Business: Volume 17, Kluwer Law International BV: Netherlands, Great Britain, p. 142.

[4] The accounting of R&D patent came in 2004-06 under the Patent Co-operation Treaty with the BRIICS (Brazil, Russia, India, Indonesia, China and South Africa). See, Roberts, Marc.J., "Pharmaceutical Reform: A Guide to Improving Performance and Equity", The World Bank Publications, p.39; available at: www.books.google.co.in/books?id=mT7ImUC6A7kC&pg=PA39&lpg=PA39&dq=insurance+coverage+on+health+R%26D&source=bl&ots=utFsTrlKFX&sig=UVXTzP3qUcx_F_FKxiAynOaOe6o&hl=en&sa=X&ved=0ahUKEwi7vOrCpbLRAhUMuI8KHePZA_IQ6AEIPzAE#v=onepage&q=insurance%20coverage%20on%20health%20R%26D&f=false

[5] Ibid.

Legal History of Health Insurance

Insurance as a new component of health rights connects individuals' health arrangements to discovery new drugs and in turn enabling expensive health development. But it was during 1930s great depression financial contract was brought into practice when many suffered of diseases, illness and even death due to hunger and economic constrains.[6] Insurance coverage as social security arouse due to the demand for hospitalisation services for workers and their families providing efficient physicians, new technological environment. Before the great depression physicians charged heavily as full fee for service (FFS) and it was considered as physicians care coverage for physicians to work impartially for sick individual.[7] This FFS system in turn increased insurance consumers looking for accessing balanced and proper treatment in health care facilities.

These facilities led access of information about health facilities available to consumers. Moreover, the Principles of the Rights of Patients in Europe (1994) provides with the understanding through its Article 2(1) that:

> "Information about health services and how best to them is to be made available to the public in order to benefit all those concerned".[8]

In addition to, the information to know what the consumer is purchasing in the health insurance create the health insurance sphere as a contract for his /her health coverage. Moreover, one can define health insurance as a contract where an individual or group purchases in advance health coverage by paying a fee called "premium".[9] Health insurance, provides various plan covering comprehensive health policies. These policies range from covering the cost of doctors and hospitals depending on the individuals specific needs to the long term care. Presently, disability insurance has come to replace lost income during the bread-earner suffers illness or accidents and cannot work anymore. "In a remarkable initiative, India has introduced *"Pradhan Mantri Jeevan Jyoti Bima Yojna"* Rs.2 lakh to dependent during death of policy

[6] Student Resources in Context, (2003), "Medicines and health in the 1930s: Overview", DISCovering U.S History, Available at: www.ic.galegroup.com>ReferenceDetailsPage
[7] Ibid.
[8] Article 2 (1) of the Principles of the Rights of Patients in Europe (1994); available at: www.who.int/genomics/public/eu_declaration1994.pdf
[9] Principle of Insurance: Module-2 (2016), "Essentials of Insurance Contract", Diploma In Insurance Service; available at: www.nios.ac.in>media>VoclnsServices

holder for premium of Rs.330 a year for 18-70 yrs individuals".[10] In India the health insurance in India is not provided specifically for medical expenses it is just a claim during last resort of life or death suffering. There is need to understand India's Health situation and thereby applying principles of insurance keeping in view the social realities and national objectives and individual's right for healthcare.[11]

"In detection of compliant for RTH through international health insurance as a health requirement for sickness and during accident some of the states/regions came out with legal regulations/constitutional mandates. Like, Switzerland in Europe has compulsory health insurance and since 1999, it had 109 insurance companies that offered compulsory health insurance. All of these insurance companies followed requirements of law relating to health insurance by registering themselves to the Federal Office for Social Insurance. In 1890, constitutional mandate for legislating health insurance for accident and sickness was brought by Switzerland government. This understanding of health insurance through European legal framework for international health insurance becomes important due to big numbers of banks in Switzerland. On the other hand, it is considered that attempts of introducing health insurance by Switzerland in 1899 were also not an easy task.

The health insurance of Switzerland is considered to be based on the German health insurance model. But, the approval process had to go through extreme level of changes and modification. The initial step was rejected by referendum that led to changes in proposal for resubmission which got passed through legislation in 1911". [12] The revision of the rejected proposal proved prerequisite of funds is important in health insurance to get benefit packages[13]. This requirement in Switzerland can be analysed for consciousness during getting approval for health insurance. The health

[10] BI India Bureau, (2015), " Insurance Scheme Modi Launched and How they Benefit You", Finance; available at: www.businessinsider.in/8-Insiuarnce-Schemes-Modi-Launched-and-how-they-benefit-you/articleshow/47418104.cms

[11] Anitha, J. (2010), "Emerging Health Insurance in India-An Overview", Health, Long Term Care, Mortality & Morbidity, *10th Global Conference of Actuaries*, Institute of Actuaries of India: 81-82; available at: www.actuariesindia.org/downloads/gcadata/10thGCA/Emerging%20Health%20Insurance%20in%20India-An%20overview_J%20Anitha.pdf

[12] European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.17; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

[13] The benefit packages in this line refers to ambulatory care, drugs and hospital stays of limited duration, and to allow people a certain degree of freedom to change funds; p.6 and 7. Ibid.

insurance of Switzerland approves that in order to avail government subsidy in health insurance registration has to be made under the government office like the Federal Office for Social Insurance, with its rules and regulations providing defined package of benefits. The revised rules highlighted how benefits of changing funds through package of benefits can be made under certain conditions defined in the law. Some of the main reasons are:

> "a) change of office/company or job occurs since funds may be related to specific company or professional association; b) 10% limit in different contribution by men and women is prepared; c) if the address of residence changes; and d) prohibition for making funds in profit is made".[14]

This scrutiny of fund subsidisation has brought direction on the number of per insured individuals by the government of Switzerland. This direction led to mechanism for applying of insurance law whether the concern area accepts and declares it as compulsory or not for its people as per the region. Prior, it was considered to be from unpredictable calculations of demand for services where financial decline had appeared the referendum got failed. This direction of Switzerland confirmed only limited reforms will take place for insurance agreement.

"By 1964, in health insurance sector the system of partial reform was an enlightenment leading revised funds for subsidies based on age and gender along with user fees. The instant fee to patients incorporates a deductible for those over the age of 20 years and a coinsurance for all patients on all services. The subsidies were designed on the source of fund's expenses from the earlier year and amounted to 30% of average total expenditure. The financial problems that had occurred early in 1911 to 1964 continued till the partial reforms, with no bankruptcy in the funds, but the number of funds had declined significantly. The reforming of the system was again undertaken through partial modification due to rising rate of expenditure in the health system".[15] Further challenges toward reform, includes two referenda in 1974 and 1987 that had also failed. One reason for the failure of both reforms was that it contained a complex mix of reform proposals involving cost control, the benefit package, maternity insurance and compulsory insurance. Each component had significant opposition, and the accumulation of this conflict of interest contributed to the failure of the referenda. The revised health insurance law, which was passed by

[14] Ibid; p.6.
[15] Ibid; p.7.

the parliament on 18 March 1994, was approved by referendum on 4 December 1994 and came into force on 1 January 1996. It pursued two fundamental objectives: to strengthen solidarity and to contain costs.[16]

Insurance as a Social Security to Health

Sickness and illness leads every individual to hospital and to avail standard healthcare[17] but one can only access such services through financial support or by paying full cost for medicare or medicaid. Taking insurance schemes for healthcare and treatment socially secures unexpected health expenditure. "Insurance is taken by individuals based on payment of premium or contribution as economic active and inactive insured persons of a country or state. Economic active insured individuals are who can pay for themselves through contributory insurance. Inactive insured individuals are those who are dependent on institute of social security, or receiving social assistance for disability etc. so state budget can make contributory insurance through schemes".[18]

For example, in Albania the social security insurance provided to economic inactive individuals who are registered in National Employment Service as unemployed, or children below 18 year old and students below 25 years by contributions paid by income of economic person and the state budget. Beside stateless person and foreign nationals based on universal principle of health insurance also avail health insurance facility by constitution provision referring them as "anyone" living in Albania.[19] This method of providing social insurance security should also be implemented in other countries like India.

Since the government health facilities and arrangements are limited the insurance as a security mode become the choice for making availability and affordability of quality healthcare. Since insurance is equity based and just limited

[16] European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.6-7; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

[17] Article 12 of ICESCR 1966. U.N.G.A. Res. 2200A (XXI) of 16 December 1966; available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[18] Mano, Laure, "Implementation of the Constitutional Right to Health Insurance in the Albanian Legislation", Juridical Current, 16(4), p. 87 and 88; available at: www.eds.b.ebscohost.com.ezproxy.jnu.ac.in/eds/pdfviewer/pdfviewer?sid=9c1cb51f-a1c5-44ca-9054-64dbde839162%40sessionmgr120&vid=0&hid=103

[19] Ibid; p.88.

facilities are arranged still insurance based support should be available to every individual. Every country has responsibility to provide universal health insurance to its citizen and people and the Article 9 of the ICESCR 1966 states that:

> "The State Parties to the present Covenant recognise the right of everyone to social security, including social insurance".[20]

These words specify that right of individuals for creation of a condition to assure health service and care on time during illness and sufferings under social insurance.[21]

Health Insurance and Legal Practice

Insurance in health has become a backbone in legal terms; comes under the General Agreement on Trade in Services (GATS) of the World Trade Organisation (WTO) sector classification scheme. Health insurance falls under the financial services sector. Financial services are divided into two sectors:

> "1) Insurance; and 2) banking and other financial services".[22]

Insurance falling under financial service states it's functioning through business operating market system.[23] Implying requirement of insurance as a security base it has to be understood as target oriented health insurance. So that vulnerable and downtrodden can benefit by crediting premiums in a systematic way for accessing mandatory or required quality healthcare. On the other hand the research trial failure patient be provided with proper medical treatment till required by insuring company for research trials who help in finding cure.

Through arrangements of the WTO there are four different sub sectors for insurance policy that helps in distinguishing different sphere of health insurance requirements based on interest rates credited by insurance selectors are:

> "a) life, accident and health insurance, b) non-life insurance, c) reinsurance and retrocession, and, d) services auxiliary to insurance, including broking and agency services".[24]

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[20] Article 9 of ICESCR 1966, Ibid.
[21] Article 12.2(d) of ICESCR 1966, Ibid.
[22] Kumar, R. (2013), "Trends in Indian Health Insurance Industry", Chapter 4, pp.88-122; Available at: www.shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/9222/13/13_chapter%204.pdf.
[23] Ibid.
[24] Ibid; and also See, European Observatory on Health Care Systems, (2000), "Health Care Systems in Transition: Switzerland", WHO Regional Office for Europe, Government of Norway, Government of Spain, European Investment Bank, World Bank, London School of Economics and Political Science, London School of Hygiene & Tropical Medicine (2000), AMS 5012667 (SWI), Target 19, 2000 (R):1-90. Switzerland, p.17; available at: www.euro.who.int/__data/assets/pdf_file/0003/96411/E68670.pdf

Though the term "health insurance" seen under the first category, many country covers health insurance services in the second category i.e non-life insurance. However, life insurance companies are allowed to sell health insurance products[25] informing its customers exact policies rates and offers.

Patients Protection and Affordable Care Act

"The concept of human right to health observing progressive realisation of the 'highest attainable standard of physical and mental health' supposed to be possible through health policies".[26] Ensuring availability, accessibility, acceptability, and quality[27] of health care, makes such assumption acceptable, through understanding laid in the 2010 Patient protection and Affordable Act or the Affordable Care Act (ACA) of US for healthcare. Moreover, the ACA tries to bring a model for realising universal health coverage following to the right to health.[28]

"The US Government has played a key role in the development of a right to health under international law and the implementation of these rights-based norms through US health care policy. During response on existential threats of the Second World War, President Franklin Delano Roosevelt announced in 1941 that the Allied Alliance would be founded upon four 'essential human freedoms': freedom of speech, freedom of religion, freedom from fear and freedom from want. Reflecting threats to human dignity, it was the final of these 'Four Freedoms', freedom from want that introduced a state obligation to provide for the health of its people. As the basis by which the United States came together with the international community to create a new post-war system of human rights under international law, the United Nations (UN) would seek to prevent deprivations like those that had taken place in the Great Depression and World War II".[29] As the United States had not previously developed a national health care policy, dropping national health insurance from the 1935 Social

[25] Kumar, R. (2013), "Trends in Indian Health Insurance Industry", Chapter 4, p.88-122; available at: www.shodhganga.inflibnet.ac.in:8080/jspui/bitstream/10603/9222/13/13_chapter%204.pdf
[26] Article 9 of ICESCR 1966 and Article 22 of UDHR.
[27] Article 12 (a), (b), (c) and (d) on Availability, Accessibility, Acceptability and quality (AAAQ). In General Comment No. 14: The Right to Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights) 2000. UN document E/C.12/2000/4; available at: www.refworld.org/pdfid/4538838d0.pdf
[28] Meier, Benjamin Mason. and Gable, Lance. (2013), "US Efforts to Realise the Right to Health through the Patient Protection and Affordable Care Act", Human Rights Law Review 13(1), Oxford University Press. p.167; available at: www.bmeier.web.unc.edu/files/2013/10/167.full_.pdf
[29] Ibid; p.168.

Security Act, President Roosevelt's 1944 State of the Union Address called for a "Second Bill of Rights" that would entitle every American to the "right to adequate medical care and opportunity to achieve and enjoy good health".[30]

President Truman in 1948 in his State of the Union observed:

> "Our ultimate aim must be a comprehensive insurance system to protect all our people equally against insecurity and ill health"[31]

George[32] in the work states that health is now no more a privilege but a right and stated:

> "Senator Ted Kennedy predicted to thunderous applause at the Democratic National Convention that Barack Obama would "break the old gridlock and guarantee that every American will have decent, quality health care as a fundamental right and not just as a privilege."[33]

According to the work of George, the Obama administration launched a national health plan, but not as a human right benefitting only most effective lobbyists and not individuals as per se.[34] "The work of John Arras and Elizabeth[35] Fenton has also tries to point that RTH does not define benefit through need of minimum medical benefit package. But, legislative adoption of this right is a necessary step toward making the definition of a minimum benefit package politically relevant. They also stated that only political process can adopt and implement the RTH".[36] The right to get health care is major problem for the individuals who are poor and financial constrained. If health insurance is politically available then can it help in accessing health cost and expenditures through funds and budget for health? (As it is financial service sector).

While availing of health insurance, the individual needs to be able enough to pay the premiums on time, if any laps in payment of premium occurs, then the amount of savings may stop. For example, in State Bank of India if laps occurs and only six months will be given for revival of the same from the due date of first unpaid and in life time (alive), with all arrears and satisfactory health report or otherwise premium

[30] Ibid. and Annas, George J. (2009), "The American Right to Health", Another Voice: Hastings Center Report, 39(5) p.3; available at: www,jstor.org/stable/40407641
[31] Annas, George J. (2009), "The American Right to Health", Another Voice: Hastings Center Report, 39(5) p.3; available at: www,jstor.org/stable/40407641
[32] Ibid
[33] Ibid.
[34] Ibid.
[35] Writers of an essay Bioethics and Human Rights: Access to Health-Related Goods.
[36] Annas, George. J., (2009) "The American Right to Health", *The Hasting Centre Report*, 39 (5):3. p.3.

policy will lapse.[37] At present, during emergency cases the victims can be taken directly hospital and demand health care. But, the hidden cost during emergency situation sometimes lead to pay huge bill of those drugs/medicines which governments do not provide for free. In this situation a condition of sphere to get RTH is needed. Demanding and atmosphere of support from Government and other international sphere have led social security and need of health condition. The Peoples' Charter for Health 2000 by the principles stated in the tackling the determinants of health, by looking in the economic challenges into the health that:

> "The economy has a profound influence on people's health. Economic policies that prioritise equity, health and social well-being can improve the health of the people as well as the economy; Political, financial, agricultural and industrial policies which respond primarily to capitalist needs, imposed by national governments and international organisations, alienate people from their lives and livelihoods. The processes of economic globalisation and liberalisation have increased inequalities between and within nations; Many countries of the world and especially the most powerful ones are using their resources, including economic sanctions and military interventions, to consolidate and expand their positions, with devastating effects on people's lives; This Charter calls on people of the world to: Demand transformation of the World Trade Organisation and the global trading system so that it ceases to violate social, environmental, economic and health rights of people and begins to discriminate positively in favour of countries of the South. In order to protect public health, such transformation must include intellectual property regimes such as patents and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement; Demand the cancellation of Third World debt; Demand radical transformation of the World Bank and International Monetary Fund so that these institutions reflect and actively promote the rights and interests of developing countries; Demand effective regulation to ensure that TNCs do not have negative effects on people's health, exploit their workforce, degrade the environment or impinge on national sovereignty; Ensure that governments implement agricultural policies attuned to people's needs and not to the demands of the market, thereby guaranteeing food security and equitable access to food; Demand that national governments act to protect public health rights in intellectual property laws; Demand the control and taxation of speculative international capital flows; Insist that all economic policies be subject to health, equity, gender and environmental impact assessments and include enforceable regulatory measures to ensure compliance; Challenge growth-centred economic theories and replace them with alternatives that create humane and sustainable societies. Economic theories should recognise environmental constraints, the fundamental importance of equity and health, and the contribution of unpaid labour, especially the unrecognised work of women".[38]

In view of the above, when one starts understanding the economic constrains and need of demanding cancellation for third world debt as well as asking help from the World Bank and or IMF for the interest of peoples' health; government must

[37] SBI Life Insurance, (2016), "Revival of Lapse Policy", Mumbai; available at: www.sbilife.co.in/sbilife/content/11_4162

[38] The Principles pointing towards tackling the determinants of health in the economic challenges of the Peoples' Charter for Health 2000; and also see, Annexure III.

ensure economic policies to health as well as provide fundamental importance to health along with quality and affordability of available healthcare. The 1948 United Nations Universal Declaration of Human Rights, Article 25, says that to achieve RTH in proper sense:

> "everyone has a right to a standard of living adequate for health and well being.[39]

UDHR mentions one can enjoy the right to be healthy provided social security of health through insurance for proper standard of well-being. Further, most individuals compare government with private health insurance to access the cost of quality services and lunge aside governments' imperfect health care aids. According to the type of plan for health coverage or service benefit the individual selects and pays premium or payroll tax.[40] This practice accidentally, many a time makes them forget, about the exclusion clause that excludes various hidden insurance benefits. As well, they further overlook to compare their retained coverage plan for availing and accessing the quality of health care services and user fees according to the rising market prices. Lastly, health care cost or options provided to individuals through insurance by the company maintain their doubts about the prospects and issues of their investments in health coverage.

Observing the need of right to health insurance, in Albania implementation of "mandatory insurance of health care" came up. Through the Constitution of the Republic of Albania by its Article 55 that states:

> "Citizens enjoy equally the right to health care from the state. Everyone has the right to health insurance in accordance with the procedure established by law." [41]

The right to mandatory health insurance assures socio-economic right to health with the help of ICESCR Articles 9 and 12.[42] Further, every State has a legal

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[39] Article 25 of UDHR 1948. G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810, Accessed on 3 June 2014; available at: www.unhchr.ch/udhr/

[40] Bowers, Kevin., (2011), "Assessing the impact of healthcare reform on insurance", *International Law Office*, Insurance & Reinsurance - Hong Kong, Globe Business Publishing Ltd: 1-5. p.1; available at:www.internationallawoffice.com/newsletters/detail.aspx?g=1f4a5c60-ed19-40aa-a60e-cbfc7c2c7e3d

[41] The Republic of Albania on 24 February through Law no. 10383 dated 24.2.2011 "on mandatory insurance of health care in the." Mano, Laure, "Implementation of the Constitutional Right to Health Insurance In the Albanian Legislation", Juridical Current, 16(4), p.85; available at: www.eds.b.ebscohost.com.ezproxy.jnu.ac.in/eds/pdfviewer/pdfviewer?sid=9c1cb51f-a1c5-44ca-9054-64dbde839162%40sessionmgr120&vid=0&hid=103

[42] Articles 9 and 12(d) of the ICESCR 1966. *International Covenant on Economic Social and Cultural Rights* (ICESCR) U.N.G.A. res. 2200A (XXI) of 16 December 1966 (entered into force 3 January 1976, in accordance with article 27); available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

responsibility to provide this right to its people without discrimination and through equal access. In India, the present Prime Minister effort of bringing *"Pradhan mantri suraksha bima yojana"* of 2 lakhs for Rs. 12 per year premium and health insurance of 700-800 a year for cover of Rs 50,000 for individuals 18-40 shows that, still there is need, to do more in regard to bring social security during health emergency.[43]

Insurance Coverage on Health Experiments and Care

During financial expenditures that arises due to healthcare treatment insurance brings social security. Such treatment which ensues because of trial failure treatment or normal treatment due to natural diseases or lifestyle suffering can be availed through insurance. To avail this insurance policy one has to choose particular type of policy by paying premium to insurance company and taking future prospects. Increase in enterprise medical doctors and private facilities has led to doctors setting own choice of fee structure for service.[44] But, these doctors forget they are gaining financial reward by fraudulence charges and providing just limited healthcare standard for treatment and observing research study funded by government[45] in their name. Stressed consumers are left drifting about their vulnerability. Availing health as equity based cannot be delivered as access to healthcare and research outcomes are provided through social security as insurance. Benefits of health insurance lies during suffering and their spending help to avail standard healthcare facilities and arrangements.

Insurance monetarily supports every new health development for cure as well as treatment. It also motivates researchers as supporting instrument and covering every participants with health coverage in case of research failure. Example can be of determining cryogenically frozen practice where bodies are cryonic preserved to find cure.[46] Insurance supports such claims due to hidden benefits by interest rates and

[43] BI India Bureau, (2015), "8 Insurance Scheme Modi Launched and How they Benefit You", Finance, 25May 2015; available at: www.businessinsider.in/8-Insiuarnce-Schemes-Modi-Launched-and-how-they-benefit-you/articleshow/47418104.cms

[44] Hardyment, A.F. (1984a) "Suzuki, and Others," *British Columbia Medical Journal*, 26 (10), p.608.

[45] Wilson, Paul, R.. Chappell, Duncan., and Lincoln, Robyn., (1986), "Policing Physician Abuse in BC: An Analysis of Current Policies", Canadian Public Policy/Analyse de Politiques, *University of Toronto Press*, p.236-237.

[46] The case of cancer patient of 14 year old girl, highlighted insurance as a right based approach that should be targeted oriented during vulnerability and suffering without laying much condition. The High Court of London on 6 October 2016 by Justice Peter Jackson order cryogenically frozen her body on 17 October 2016. For details, see, Rayner, Gordon. Finnigan, Lexi. And Bodkin, Henry., (2016), "Girl, 14,

little chances of failure to support financing loans. Insurance funding takes place prior protocol provisions and complex understanding of rewarding profits. On the other hand insurance companies can be partner or functioning body of institutes and colleges that provides maximum number of promising results.[47] Protocols for post trial provisions set in CTs arrangements[48] having long and complex process may sometimes get rejected due to ongoing funding process. But if encouraging such parties by insurance funding as a social security can help for research failures and trial error.

Insurance coverage can help in supportive difficult process to find various scope of treatment for disease through discovery of innovative medicine required in market. Insurance policy can help downtrodden by providing benefit in sufferings by integrating target oriented system for new dimension of medicate and medicare. Insurance in some of developed countries like Canada helps equity method for providing tax redemption in health insurance through mode of premium. Financing health care expenditure leads requirement of health insurance policy so that affordability in quality of health standards can be possible during need and treatment.

Insurance as a right has been demanded for security based for solving world health issue. The arrangements of health insecurity found in Medicaid and Medicare can support[49] health as a fundamental right as provided under UDHR 1945,[50] ICESCR 1996 and international organisation as WHO, UNICEF, UNESCO etc. along with different countries domestic legislation.

Who Died of Cancer Cryogenically Frozen after Telling Judge She Wanted To Be Brought Back To Life 'in Hundreds of Years'", The Telegraph News, 18 November, available at: www.telegraph.co.uk/news/2016/11/18/cancer-girl-14-is-cryogenically-frozen-after-telling-judge-she-w/

[47] Pharmaceutical Research and Manufacturers of America (PhRMA): Research, Progress Hope, (2015),"Medicines in Development: Explore the latest Progress on Medicines in Development", *PhRMA*, Washington, DC, p.1; available at: www.phrma.org/innovation/meds-in-development#sthash.eVyoYY8U.dpuf

[48] Articles 21-22 of the Helsinki Declaration on Scientific Requirements and Research Protocols, 2013, p. 4-5.

[49] Annas, George.J. (2009), "Bioethics and Genomics" pp. 321-329 in Andrew Clapham and Mary Robinson (eds.) *Realising the Right to Health*: *Swiss Human Rights Book,* Vol.3, Zurich: Ruffer & Rub available at: www.swisshumanrightsbook.com/SHRB/shrb_03_files/20_453_Annas.pdf

[50] *Universal Declaration of Human Rights*, (UDHR), Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810; available at: www.unhchr.ch/udhr/

Public and Private Health Insurance

State health insurance is public health insurance and private insurance companies providing health insurance plans are private health insurance. In private health insurance one has to pay premium depending on the plan. On the other hand in public insurance are those in which only enrolment fee and co-payments fee i.e flat amount of fee is paid.[51] "Public health insurance are those that are registered with the government and private non-registered provide other types of insurance and have a small share providing market of supplementary health insurance policies".[52]

The public health insurance is paid by public health fund like budgets and is subsidised by the govt. Private insurance has to be paid in part or entirely by the person who is opting for such private health insurance and based on the type of insurance. Private health insurance can be purchased or provided by an employing company. In US individuals above 65 years and individuals with certain disability like kidney diseases of end stage etc are included in the public health insurance medicare. There are four components like A, B, C and D[53] are there in medicare:

> "A Part A covers hospital visits, home health care, hospital care and skilled nursing facilities. Part B covers doctors' visits, including some preventive care. Part C is an option run by private insurance companies that includes Parts A and B and often other services such as prescription drugs. Part D covers prescription drugs and is also run by private insurance companies".[54]

Medicare is not only the public health insurance but children health insurance and medicaid cost coverage also govt. financed insurance. Lower income group/family are covered under Medicaid public health insurance facility whose eligibility criteria are set using parameters such as income, family size, pregnancy, disability and immigration status of the states and funds of state as well as the federal govt. Further, Social security of getting Medicaid being provided to those working individuals with disability.[55]

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[51] Cohealthinfo. (20"What is the difference between public and private health insurance" Colorado; available at: www.cohealthinfo.com>difference/&ei=pt93ANtM&lc=en-lN&s=1&m=13&host=www.google.co.in&ts=1469619877&sig=AKOVD668l9fq5Dtvj3dx-BbNUMlvemakfQ

[52] WHO-Switzerland, (2000), *"Switzerland: Health Care Systems in Transition",* AMS 5012667 (SWI), Target 19 200(R), European Observatory on Health Care Systems, WHO/Europe-World Health Organisation, p.17; available at: www.euro.who.int>assests>pdf_file

[53] Matuza, Jacqueline. (2015), "Public Vs. Private Health Insurance", 9 September 2015, LIVESTRONG.COM; available at: www.livestrong.com/article/75148-public-vs.-private-health-insurance/

[54] Ibid.

[55] Ibid.

In many of the countries, health insurance is attracting substantial additional tool to finance health care. "The former insurance pattern was public health insurance as Bismarck's Germany or the UK / NHS funded through taxes and aimed at the broad common coverage".[56] Due to the dissatisfaction in the public funding of health care services and rising income of people every country has more private health insurance selectors these days.[57] Moreover, private health insurance provides wide ranges of quality and assistance they can benefit by selecting the type of insurance.

In developing countries, private health insurance begins between large multinational companies having professionals as well as filtering more towards group coverage. Further, there is even existence of informal insurance arrangements among communities. Like in India, as surveyed by NGOs to reduce the risk for poor during emergency of health expenditure community based health insurance are existing.[58] Sometimes, the drawback in private health insurance is felt when arrangements set for risk pool are so less that doing business with private health insurance leads no benefit since there is no proper incentive under the fixed schemes.[59] "In order to observe health insurance growth arrangement, covering, financing, provision and regulation have to be properly improved through quality. Business efficiencies, fair conduct, and relevant social imagination should boost its arrangements. As well as, presently there is need of balancing in professional accountability and better standard of quality care".[60]

Implications of Insurance for Public Health

Health insurance has come up as a social security during medical treatment and sickness. Since the UDHR in its Article 22 states that in accessing healthcare security national effort and international co-operation along with resources of each state and organisation or development and dignity should function in providing

[56] Srinivasan R. (2001), "Health Insurance In India", Health and Population-Perspectives and Issues 24(2): 65-72, p.65 medIND, available at: www.medind.nic.in/hab/t01/i2/habt01i2p65.pdf
[57] Ibid; p.66.
[58] Ibid; p.65.
[59] Ibid; p.66.
[60] Ibid.

insurance security.[61] Moreover, it is a right of everyone to have social security to health through social insurance.[62]

Presently, the most controversial issue in insurance is how to manage for paying health services. As, it has been observed rising user fee may lead to burden on insurance premium expenditure. "Like, in Africa during 1980s and early 1990s using of technical health economics models in conjunction with broad political economy frameworks i.e the econometric studies proved that if user fees comes in play then the health sector may improve service quality and lead to greater utilisation. However, strong opposition was faced during its implementation in Africa and other parts of world as this design of health policy not only harmed individuals or societies with low income group but also brought the concern how to manage the difficulty of instituting such mechanism for financing broadly accessible health services".[63]

But still, health policy in Africa got stronger through grassroots and political support of pressure groups by the Government playing the dominant role in financing health care. The places in Africa like Benin, Burkina, Cameroon, Congo, Cote d'Ivoire, Egypt, Faso, Ghana, Lesotho, Mali, Nigeria, Rwanda, Swaziland, Sudan, Tanzania, Uganda, Zimbabwe, and so on. Implemented the user fee where compulsory public medical insurance schemes, financed via general taxation takes place. But still in many parts of Africa still doesn't has private insurance schemes for support of private health care financing where Government still plays a dominant role.[64] During the tertiary level curative care is felt.

It has been observed that by charging fees for services that primarily benefit the user, such as tertiary-level curative care, governments can free up and reallocate tax-financed health expenditures to activities that yield benefits that extend beyond the individual. These include public health services directed to community health, immunizations, and communicable diseases. Countries in Sub−Saharan Africa have considerable experience with user fees for the simple reason that private−for−profit

[61] Article 22 of the UDHR 1948. G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810; available at: www.unhchr.ch/udhr/

[62] Article 9 of ICESCR 1966; Ibid.

[63] Mwabu, Germano., "Health Development in Africa", *Economic Research Papers No.38,* African Development Bank; available at: www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/00157610-EN-ERP-38.PDF ; p.12.

[64] Mwabu, Germano., "Health Development in Africa", *Economic Research Papers No.38,* African Development Bank, pp.12; Available at: www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/00157610-EN-ERP-38.PDF.

and private voluntary clinics, including church missions, must recover costs to survive. In Tanzania, with a per capita income of only $100 in 1990, nine of eighteen non-governmental dispensaries recovered 100 percent of their operating costs from user fees, and seven of twenty-one NGO hospitals recovered more than 75 percent of their operating costs. (Mujinja and Mabala, 1992). In Uganda, with a per capita income of $170, four mission hospitals recovered 7895 percent of their operating costs, the balance being provided by donors (World Bank, 1993a). In the Central African Republic, with a per capita income of $390, two private hospitals recovered 5580.[65]

The health care policy and law has been considered looking through public and private health insurance at the center and is considered for being basic means of transform. As well as, an industry looks after its own benefits and right, functions according to the health facilities and delivery of medical technologies. The Eight Annual Symposium on Access to Health Care is considered for bringing legal and policy issues for the health insurance arena investigative past, current and future trends. Five major themes have been considered for exploring and they are:

> "i) The first theme is based on the changing posture of regulators in overseeing health insurance offerings, focusing on current developments in state departments of insurance and the expanding role of federal authorities in oversight of the field in the wake of the ACA; ii) The second theme will explore how initiatives in cost control and benefit design are impacting provider and beneficiary obligations; iii) The third theme will concentrate on the increased role of private insurers in public programs exploring, in particular, the expanded role of insurers in managed care; iv) The fourth theme will focus on the emerging structural components of coverage from the ACO to co-ops and how such structures are being shaped and regulated; and v) The fifth theme is based on health care marketplaces, current status and future evolution".[66]

Since health subject and its utilization through facilities of insurance is also a challenging issue to its access for patient satisfaction. Since public sector has been underfunded as well as the free services available in government hospitals speaks about low quality services and attention. In India only government employees are covered under the social security of health insurance scheme through Central Government Employees under Central Government Health Scheme (CGHS) and ESIS (Employees State Insurance Scheme).

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[65] Shaw, R. Paul., and Ainsworth, Martha. (1995), "*Financing Health Services through User Fees and Insurance: Case Studies from Sub-Saharan Africa*". The International Bank for Reconstruction and Development, the World Bank: USA, p.11; available at: www.elibrary.worldbank.org/doi/pdf/10.1596/0-8213-3396-8

[66] The 5 major themes of the Eighth Annual Symposium on Access to Health Care.

The public health insurance may lead in creation of accountability. Since, the private health insurance leads competition benefit but cannot provide rights for poor. Making two tier health insurance system selectors take one who can afford and one who cannot. Need of fair, long-term support, without fraud and malpractice above all honest marketing must prevail with proper guidance.[67]

Scope of Public or Social Insurance Funds

Public health insurance bodies are governed by public law and government where sum of fixed amount is paid by law depending on the policy selection. Public health insurance funds do not provide cash benefits but benefits through contracts with hospitals and doctor association.[68] Study state in rising competition law, the Public Health Insurance Funds (PHIF) in EU has been decreasing in policy market. So that pace in public management strategy can be kept for benefiting the risk adjustment. In EU the system of risk structural compensation of state is present between the PHIF so that by authority of the state and PHIF can get certain amount of risk adjustment per capita for insured persons. The criterion depends on the age, sex and increasing death due to common diseases.[69] Since, PHIF are governed by government and functions in state and federal level with cooperating and contracting by hospitals and health services. The PHIF collects contribution in a central budget.

In 2007 through Act to "Strengthen Competition in Statutory Health Insurance System" fixed rate of contribution was set. The rate at present is 15.5% of work income to 44.550 Euro earners per year. An extra fund charge raises according to the extra per income payment. Since the observation in two cases of haemophilia, risk selection in some PHIF came in practice especially for disable, chronically ill and other expensive patients will not be provided good care.[70] Since, rising market competition has also influenced PHIF to act in discriminating nature. That is the

[67] Srinivasan R. (2001), "Health Insurance In India", *Health and Population-Perspectives and Issues* 24(2), p. 66, 67, 68, 69 and 70. medIND, available at: www.medind.nic.in/hab/t01/i2/habt01i2p65.pdf

[68] Gronden, Johan Willem van de., Szyszczak, Erika., Neergaard, Ulla., and Krajewski. Markus, (2011), "Health Care and EU Law", *Springer Science & Business Media*, p.321 and 322; available at: https://books.google.co.in/books?id=BGuE9zxI6KYC&pg=PA321&lpg=PA321&dq=scope+of+public+insurance+funds&source=bl&ots=AZH8m53dBw&sig=RYdg1MtdbIwgmFjjBVDTjG7epXE&hl=en&sa=X&ved=0ahUKEwii9t-Hi5XOAhXBto8KHapICscQ6AEIHDAA#v=onepage&q=scope%20of%20public%20insurance%20funds&f=false.

[69] Ibid.

[70] Ibid.

source for poor and vulnerable groups of family and individuals to access health care facility.

Rising prices in medicines especially for IP-induced product have also led the issue of its cost financing. In 2006, $550 billion was estimated for medicines market for high income countries. Since the global pharmaceutical players exercise some monopoly power to negotiating lowering the drug prices. Government works to provide government or social insurance funds for such high prescribed drug prices. For OECD pharmaceutical expenditures outside U.S, public or social insurance funds account for the great majority.[71] The governments of wealthier countries provide access to patented higher prices medicines with government subsidised insurance and other social mechanisms. But these arrangements of subsidies cannot be possible in low income countries.[72] Seeing as, in US the public subsidies for drug prescriptions has led growth for retail markets as well as just 27% public fund in 2005 developed due to increase in prescription drugs. Private insurance companies also provide these arrangements of Part D of Medicare and in this context hospital has topped $200 billion.[73] Since PHIF pays about $10 billion a year in US for hospital visits, nurse attendance etc. still access to drug remains a problem. As well as the private insured receive large tax subsidy. Moreover, in US more than 47% coverage of outpatient pharmacy expenditures is made by Private insurance.

In 2005 outpatient pharmaceutical amounts 10% of US health spending. About $102.3 billion health insurance as a tax is taken by employed US citizens who are exempted from income tax per fiscal year as estimated in 2004. As regard, $10 billion tax supports domestic pharmaceutical market expenditure. In health research expenditure it was analysed that about 45% of direct expenditure comes from public funds as estimated to $56.1 in 2003. With both public and private funds global expenditure on health research was $125.8 billion.[74]

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[71] Outterson, Kevin., 2008 "Should Access to Meicine and TRIPS Flexibilities Be Limited to Specific Desieases" *American Journal of Law O Medicine,* 34(2008), pp. 323-324, Boston University School of Law.

[72] Outterson Kevin., (2006), "Access to Global Disease Innovation" INT- World Health Organisation, WHO IGWG; 15 November 2006, pp.1; Available at: www.who.int>public_hearing>first.

[73] Ibid; p.324, also see, Matuza, Jacqueline. (2015), "Public Vs. Private Health Insurance", 9 September 2015, LIVESTRONG.COM; available at: www.livestrong.com/article/75148-public-vs.-private-health-insurance/.

[74] Outterson, Kevin., 2008 "Should Access to Meicine and TRIPS Flexibilities Be Limited to Specific Desieases" *American Journal of Law O Medicine,* 34(2008), p. 323-324, Boston University School of Law.

In India ESIS and CGHS are two main schemes functioning for factory workers and central government employees. But due to poor standard of public healthcare delivery, unregulated private market, etc. are under immense criticism in delivering quality of health care. Further, NGO running schemes like Voluntary Health Service in Chennai provides with a Medical Aid Plan where every households gets free annual health checkup and discounted rate of inpatient services by paying annual premium based on joint monthly income.[75] The WHO has set target of at least 5% expenditure from gross national product.[76] Moreover, the Indian government is looking forward in making health budget GDP to 2.5%.[77] But, present total expenditure for health is only 1.62% of the whole budget and out of which National Health Mission has a share of less than 1%. On top of this Indian government is moving for public private partnership instead of providing free healthcare services.[78]

Health Insurance: Indian Scenario

Health is a fundamental right under International instrument, but, in India health has till date been provided by Articles 38, 39, 41, 42, 47 and 48 of the Indian Constitution that directs the State to ensure social and economic justice through its Part IV of Directive Principles of State Policy (DPSP).[79] The Article 21 only comes in function during emergency like accident or denial of admission provides health as a right.[80]

In India the insurance is governed by Insurance Regulatory and Development Authority Act 1999 and Insurance Act of 1938. There are 52 insurance companies out of which 24 are life insurance business and 28 non-life insurance. Life Insurance Corporation is the only sole public sector company among all life insurance industry. Insurance laws (Amendment) Act 2015 provides government ownership and control

[75] Prinja, Shanker., Kumar. Manmeet., and Kumar Rajesh., (2012) Indian Journal of Community Medicine, 37(3), p.142-149; available at: www.medind.nic.in/iaj/t12/i3/iajt12i3p142.htm

[76] Shodhganga, (2005) "Chapter-4 Trends in Indian Health Industry", p. 86; available at: www.shodhganga.inflibnet.ac.in/bitstream/10603/9222/13/13_chapter%204.pdf

[77] The Hindu, (2015), "Centre moots health as a fundamental Right"-The Hindu, Jan 1 2015; available at: www.M.thehindu.com>news>articles6742882.

[78] Sharma, Neetu Chandra and Singh, Shruti., (2016) "India's Health Woes: Budget for National Health Mission Remains Staged at Rs 19,000 crore", 2 March 2016, *indiatoday.in* p.1-2; available at: www.indiatoday.intoday.in/story/indias-health-woes-budget-for-the-national-health-mission-remains-stagnated-at-rs-19-000-crore/1/6098.

[79] For details, see, Articles 38, 39, 41, 42, 47 and 48 of the Constitution of India, (1947), Ministry of Law and justice, India:1-103; Available at: www.lawmin.nic.in>legislation.

[80] For details, see, Article 21 of the Constitution of India, (1947), Ministry of Law and justice, India:1-103; Available at: www.lawmin.nic.in>legislation.

with Foreign Investment Cap in an Indian Insurance Company from 26% to the Limit of 49%. In 2014-2015 fiscal years the premium collected by Indian insurers is 3.30% of GDP. Per capita premium underwritten i.e. insurance density in India during FY 2014-15 is US$ 55.0.[81]

The business of insurance is divided in four classes and they are: a) Life Insurance; b) Fire Insurance; c) Marine Insurance; and d) Miscellaneous.[82] So far health insurance is a general insurance but the same is also provided by the life insurance companies. The concept of general insurance has its root in risk sharing and loss pooling. Since health insurance came as employee's coverage for hospitalisation and dental along with treatment for non-surgical eye.[83] In India the private sector is more dominant then the public health insurance. The total health expenditure is about 5% GDP where public expenditure is just 0.9% and private expenditure of 4.0% including both self financing along with employees or community financing.[84] Moreover, by bringing public private partnership and just 2.5% for health budget of total GDP[85] does not solve insurance problem in India.

Insurance Coverage on Clinical Trials

CT is safe but risk involved in it may also land in unfortunate sufferings like side effects or death. Usually three years' time period from the date of first notice of sickness or injury is left for CT claims for compensation. Claims for CT can be of two types: i) personal injury claims and ii) group injury claims. The claims are mainly made for rehabilitation in order to access care and support for recovery, medical negligence, defective drugs, and medical products.[86] Such claims can be for monetary

[81] Kalyani. K. Nikita. "India Insurance Market", Know IRDAI, Source: Annual Report (2014) & (2013-2014). Insurance Regulatory and Development Authority (IRDA): Consumer Education Website; Available at: www.policyholder.gov.in/indian_insurance_market.aspx.

[82] Shodhganga, (2005) "Chapter-4 Trends in Indian Health Industry", p. 86; available at: www.shodhganga.inflibnet.ac.in/bitstream/10603/9222/13/13_chapter%204.pdf

[83] Ibid; p.86-87.

[84] Ibid; p.99.

[85] Sharma, Neetu Chandra and Singh, Shruti., (2016) "India's Health Woes: Budget for National Health Mission Remains Staged at Rs 19,000 crore", 2 March 2016, indiatoday.in p.1-2; available at: www.indiatoday.intoday.in/story/indias-health-woes-budget-for-the-national-health-mission-remains-stagnated-at-rs-19-000-crore/1/6098 ; also see, The Hindu, (2015), "Centre Moots Health as A Fundamental Right", The *Hindu*, Jan 1 2015. available at: www.M.thehindu.com>news>articles6742882

[86] IM: Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

and non-monetary benefits where compensation can be provided on different proposed models based on different principles[87] like: a) market model i.e based on supply and demand principle is hard to find subjects for trial based on race, study location etc.

Thus it provides high compensation by ignoring risk involved and hiding important data's that can deem for ineligibility of CT; b) wage model is based on egalitarianism principle, where unskilled or little skilled subjects are recruited who are paid less or based on their scale. Since they are from low income group it provides less issue for inter study competition and undue inducement with minimised risk and no discrimination of high or low income group but many a time leads difficulty in achieving timeframe number of targeted subjects; c) reimbursement model is based on the same footing of egalitarianism where it is hard to find subjects but in this model it's hard to hide information or overlook the risk involved during study as different subjects are recruited and compensated according to their qualification; and d) appreciation model where compensation is provided as a token of gratitude or appreciation after completion of any type of CT. Stakeholders should prior beginning CT obtain approval from the Ethics Committee for consideration of compensation to be provided to the trial subjects.[88]

The amount of compensation depends on extent of injury or illness and loss. Depending on the amount through acceptance or contest in court for loss of earning from current and future by not being able to return for work, payment expenses of medical and travel, care and support needs for present and future, Requirement of home modification along with mobility aids or specialist equipments, trauma and nature of ongoing problems. [89] Compensation can be set on different phases from I-IV and based on its requirement causing injury and loss. Prior, in phase I trial for single dose administration and/or limited repeat dose administration no compensation or access to medicine benefit and gain was provided until investigation ends beyond conventional result. Since in Phase I trial maximum patients or unhealthy volunteers

[87] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.70-71; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/

[88] Ibid.

[89] Irwinmitchell- Solicitors, (2016), "Defective Drug Claims: Clinical Trials Claims", Chambers & Patners, Irwin Mitchell LLP: Scotland, UK; available at: www.irwinmitchell.com/personal/personal-injury-compensation/product-liability-claims/defective-drugs/clinical-trials

for new chemical or biological entity research based on disease-specific biomarkers; where efficacy is not investigated are recruited.[90] The Association of the British Pharmaceutical Industry (ABPI) brought first guidelines for compensation in 1970 for phase I trial. It has been observed in the principles for Phase I trial that:

> "a) when injury occurs due to participation in trial, it is right of the volunteer to receive appropriate compensation on the basis of negligence or strict liability for company; b) the compensation by the sponsoring company should be stated on the contractual document with the volunteer on proof of causation supported by qualified obligation to pay compensation for injury as quick as possible along with the cost of compensation will be resolved separately through other parties to the research; c) Simple clause of arbitration as provision for injury compensation should be included along with minimum time frame for dispute on implementation of formalities; d)it is stated that volunteers benefitting from Phase I trials will not be covered under such guidelines of Phase I trials"[91]

Compensation for phase I subjects should be stated on contractual document or arbitrarily claimed within minimum time frame. But benefitting subjects will not be qualified to claim compensation. The International Conference on Harmonisation-Good Clinical Practices (ICH-GCP) guidelines state that subjects should be compensated for trial related injury and/or treatment should be provided. ICH-GCP also suggests that sponsors should provide insurance or indemnify the investigator or the researching institution for claims arising from such trial. The Helsinki Declaration states the protocol should carry compensation provisions.[92] In U.S FDA there is no proper instruction on compensation. It is the code of federal regulations that suggests institutional policy will decide on injury based compensation and/or medical treatment that is mentioned in consent document or protocol.[93]

In 1983, when inclusion of "healthy volunteers i.e non-patient volunteer" for studies of Phases II-IV were added compensation was set for them based on risk and benefits formulation. Risk and benefit brought distinction between healthy volunteers and patient volunteer's i.e. target disease participant for Phases II-IV through treatment and adverse side effect (ASE). This division led was formulated for all the

[90] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf ; p.1-4.
[91] Ibid.
[92] Pandya, Mansi., and Desai, Chetan. (2013) "Compensation In Clinical Research: The Debate Continues", Perspectives In Clinical Research, 4(1), p.71-72; available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3601710/
[93] Ibid.

phases i.e phase I-IV who have no reasonable prospect of direct benefit or get material side effects by product under research from participation.[94]

The new guidelines of 2012 Edition for ABPI on Phase I states that the 1988 non-patient guidelines are now replaced with compensation provisions; and in the 1991 guidelines of CT for Phases II, III and IV are also replaced with the compensation provision.[95] In Phase II-IV the compensation is paid by the sponsoring company when: i) direct participation leads deterioration in health or well being; ii) based on damages the amount is calculated by the English Court, such compensation may be reduced on extent of volunteers partial responsibility, i.e reason of contributory fault or where the payment of such injury has been made under any policy of insurance affected by the company as volunteer benefit; iii) An arbitrator should be appointed in dispute or disagreement of the application of paragraph i) and ii) of above mentioned or the President of the Royal College of Physicians of London should be appointed for arbitrating to consult a barrister of at least 10 years to provide the amount for damages and its payment of compensation; iv) Agreement of paying compensation should be in accordance to the English Court and paragraph iii) is subject to the sole jurisdiction of English Court.[96]

The process of providing compensation through Pfizer a representation of private pharmaceautical company as a sponsored study through its company's guidelines states that volunteers compensation is based on method and timing of disbursement. This incorporates regional laws, regulation and guidelines, the Institutional Review Board or Independent Ethics Committee reviews and approves compensation that is developed on criteria based on human subjects, site, and targeted subjects in same treatment group.

In the voluntary informed consent disclosure of compensation amount is made, that accessed through the Pfizer Clinical Research Unit (PCRU) staff line with SOP CRU-RO2-LSOP, Calculation and payment of Subject Compensation at the PCRU. Compensation is provided to enrolled participants in the research with no incurring personal expenses, i.e. direct payment of expenses by the Pfizer, contract research organisation (CRO) vendors or consultants. Involvement of healthy

[94] Ibid.
[95] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf , p.1-4.
[96] Ibid.

volunteer's for phase I trials permits reasonable compensation for time and effort. Excessive compensation can be received for risks or discomfort that occurs without assumption. Additional consideration for minors participating in research is made along with compensations for travel, childcare for siblings and parking can be received by the parents or guardians. But, such compensation should not be made to those parents/guardians who plan to make improper incentives by enrolling minors.[97]

The main guidelines for Phase II-IV state that the participating volunteer should receive compensation without legal commitment by written assurance to the investigator and from investigator to the relevant research ethics committee and they are: i) the volunteer should receive compensation from the company for bodily injury as well as death; ii) due to the inclusion of patient for trial the compensation should be paid when injury occurs through the administered medicinal product under trial or any clinical intervention or procedure including protocol; iii) During the injury of the child in uterus through participation of the mother in clinical trial as well as the child as a volunteer; iv) for more injuries and disability condition provided which excludes temporary pain or discomfort with curable complaints; v) while conducting a trial to remove adverse reaction and causing adverse reaction through the medicinal being researched; vi) exclusion of compensation for such human subjects will be made whose adverse reaction injury was foreseeable or predicted prior conducting research and the patient had freely accepted such trial participation either through written or other consent; and vii) the company is under strict liability to provide compensation if the volunteer is injured due to the drug product used during trial".[98]

In India the quantum of compensation for death through Serious Adverse Events (SAES) during clinical trials has been set by the Drugs and Cosmetic Rules after amendment vide GSR 53(E) dated 30-January 2013 inserting Rule 122 DAB and a new Appendix-XII in Schedule Y is considered to pay through help of Independent Expert Committee.[99] The following criteria were finally adopted. Firstly, criteria

[97] Pfizer, (2016), "Compensation to human Research Subjects in Clinical Studies", *2002-2016 Pfizer Inc*; available at: www.pfizer.com/research/research_clinical_trials/compensation_trial_participants

[98] Association of the British Pharmaceutical Industry. (2014), "Clinical Trial Compensation Guidelines", ABPI: Bringing Medicines to Life, U.K: 1-6; available at: www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf. p, 1-4.

[99] Compensation Formula: Clinical Trial, (2013), Formula to Determine the Quantum of Compensation in the Case of Clinical Trial Related Serious Adverse Event (SAES) of Deaths Occurring During Clinical Trials", GSR 53 (E), *The Drug and Cosmetic Rules, Schedule Y:*1-9; available at: www.cdsco.nic.in/writereaddata/formula2013SAE.pdf

should not be discriminative in nature due to socio-economic conditions e.g. (a) income, (b) education; secondly, criteria should not discriminate gender/sex; thirdly criteria should not be such which may have minimal impact but may create large variability; fourthly, formula should be such that the inter group variability of compensation value so arrived at, has little scope of discretion, thus avoid possible bias.

Thus, the following criteria were finally decided to be incorporated in the compensation formula. i) Age of the subject ii) Risk factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial. The computing the three factors i) age; ii) risk and iii) base amount for SAE/Death related to Clinical Trial:

"Compensation= B*F*R/99.37."[100]

a) B= Base Amount i.e. 8 lakh; b) F= Factor depending on the age of the subject based on Workmen Compensation Act; and c) R=Risk Factor depending on the seriousness and severity of the disease based on scale of 0.5 to 4 (0.5, 0.1, 0.2, 0.3, 0.4). However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs should be given. Thus, it will be seen that the compensation amount will vary from a minimum of Rs.4 lakhs to a maximum of Rs.73.60 lakhs depending on the age of the deceased and the risk factor. The committee will examine cases of SAEs of deaths and decide the final quantum of compensation after due diligence and application of mind on the risk factor and recommend the same to DCG (I) on case to case basis. The committee also considered the above formula as provisionally final.[101]

Conclusion

Article 22 of the UDHR supports the healthcare access through its security and that is: "Everyone, as a member of society, has the right to social security and is entitled to realisation, through national effort and international co-operation and in accordance with the organisation and resources of each State, of the economic, social

[100] Ibid.
[101] Ibid.

and cultural rights indispensable for his dignity and the free development of his personality". Apart from it, Article 9 of ICESCR states that health of poor individual should be: "protected through social security and social insurance". Moreover, understanding its development the concept of Health Insurance came during the industrial revolution through financial contracts made in cargos of ships. 1930s great depression brought health insurance more popularity where medical services for workers and families grew along with the hospitalisation covering populations as a whole together, providing new technologies and efficient physicians. The later phase of insurance too brought full fee for service (FFS) for physicians care coverage appreciating and rewarding at the same time. Further, the exemption of taxes for those who fills health insurance premium led to increasing credit towards insurance. So far, the present segment deals with financing of health care and requirement of health insurance to afford it and its challenging support helping the needy and vulnerable. Because presently, medical graduates feel it is their right to be a free enterprise doctors i.e practice out wherever they like and set their own fees. So that they can gain financial reward and engage in extensive fraud along with charging more on government funded medical programs. Health insurance came as a savior to such tricky situation by helping those who cannot afford their healthcare. Health Insurance can be defined as a contract where an individual or group purchases in advance health coverage by paying a fee called "premium.

The argument for using right in health care as a debate has raised the issuance of insurance as important. Presently two statements are frequently been used as: i) "everyone has the right to health care" and ii) "health care is a human right." These two statements creates an atmosphere of tension for health care when it is not provided as a right, e.g as in U.S. However, RTH care has to be looked through its determinants and all the broad concepts it may lead from its existing various forms. For example, existence the right to purchase health care or health insurance has come up but what about the insolvent/poor individuals who cannot purchase their own health. There should be direction on government's responsibility to look after such individuals/communities/society. So, those individuals can get RTH without any mental/physical/financial constraints. Present available programs for right to walk into hospitals emergency rooms and demand health care creates a sphere of tension where

existence of financial distress leads towards bankruptcy through big bill. If existence of RTH comes then no individual can be put into financial distress.[102]

The 1948 UDHR (Article 25), says everyone has a right to a standard of living adequate for health and well being, and it specifically mentions medical care.[103] Ironically, medical care comes through economical spending depending on how much working people can be requited. This unfortunate financial constrain confirms debate towards its existence for health finance and funds. An issue on the eligibility of insurance holder has surrounded problem for who can access the insurance facility and how privacy through hospital can be generated for personal information that have to be made confidential.

The usage of word "right" for health care has been looked as the concept of a right which is effortless, influential, troubling and implies no argument beyond it. However, the study has found that the RTH care explains broad dimension of understanding health rights. Providing health care rights requires infringement upon other rights, moral judgments, and a complex allocation of resources. Effortless statements for health like: "everyone has a right to health care" are meaningless until it does percolate down to the ground level.

[102] Mecikalski. Mark. B., (2011), "Right to Health Care: What Does It Means?", J Clin Sleep Med., Oct 15, 2011; 7(5), p.437.
[103] Article 25 of UDHR; available at: www.un.org/en/documents/udhr/index.shtml.

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APPENDIX- A

Declaration of Alma-Ata 1978

The International Conference on Primary Health Care[1], meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following Declaration:

I

The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector.

II

The existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.

III

Economic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and to the reduction of the gap between the health status of the developing and developed countries. The promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace.

IV

The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

V

Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures. A main social target of

[1] International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978.

governments, international organisations and the whole world community in the coming decades should be the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice.

VI

Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

VII

Primary health care:

1. reflects and evolves from the economic conditions and sociocultural and political characteristics of the country and its communities and is based on the application of the relevant results of social, biomedical and health services research and public health experience;

2. addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly;

3. includes at least: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunisation against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs;

4. involves, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food,

industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors;

5. requires and promotes maximum community and individual self-reliance and participation in the planning, organisation, operation and control of primary health care, making fullest use of local, national and other available resources; and to this end develops through appropriate education the ability of communities to participate;

6. should be sustained by integrated, functional and mutually supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those most in need;

7. relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community.

VIII

All governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system and in coordination with other sectors. To this end, it will be necessary to exercise political will, to mobilise the country's resources and to use available external resources rationally.

IX

All countries should cooperate in a spirit of partnership and service to ensure primary health care for all people since the attainment of health by people in any one country directly concerns and benefits every other country. In this context the joint WHO/UNICEF report on primary health care constitutes a solid basis for the further development and operation of primary health care throughout the world.

X

An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, détente and disarmament could and should release additional resources that could well be devoted to peaceful aims and in particular to the

acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.

The International Conference on Primary Health Care calls for urgent and effective national and international action to develop and implement primary health care throughout the world and particularly in developing countries in a spirit of technical cooperation and in keeping with a New International Economic Order. It urges governments, WHO and UNICEF, and other international organisations, as well as multilateral and bilateral agencies, nongovernmental organisations, funding agencies, all health workers and the whole world community to support national and international commitment to primary health care and to channel increased technical and financial support to it, particularly in developing countries. The Conference calls on all the aforementioned to collaborate in introducing, developing and maintaining primary health care in accordance with the spirit and content of this Declaration.

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APPENDIX- B

Health-for-all policy for the twenty-first century 1998

The Fifty-first World Health Assembly,[1]

Recalling resolution WHA48.16;

Recognising the report "Health-for-all in the twenty-first century" (A51/5) as a framework for the development of future policy,

ADOPTS in the sense of Article 23 of the Constitution the World Health Declaration annexed to the present resolution.

Annex

WORLD HEALTH DECLARATION

I

We, the Member States of the World Health Organisation (WHO), reaffirm our commitment to the principle enunciated in its Constitution that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being; in doing so, we affirm the dignity and worth of every person, and the equal rights, equal duties and shared responsibilities of all for health.

II

We recognise that the improvement of the health and well-being of people is the ultimate aim of social and economic development. We are committed to the ethical concepts of equity, solidarity and social justice and to the incorporation of a gender perspective into our strategies. We emphasise the importance of reducing social and economic inequities in improving the health of the whole population. Therefore, it is imperative to pay the greatest attention to those most in need, burdened by ill-health, receiving inadequate services for health or affected by poverty. We reaffirm our will to promote health by addressing the basic determinants and prerequisites for health. We acknowledge that changes in the world health situation require that we give effect to the "Health-for- All Policy for the twenty-first century" through relevant regional and national policies and strategies.

III

[1] Fifty-First World Health Assembly, Agenda Item 19, WHA 51.7, 16 May 1998.

We recommit ourselves to strengthening, adapting and reforming, as appropriate, our health systems, including essential public health functions and services, in order to ensure universal access to health services that are based on scientific evidence, of good quality and within affordable limits, and that are sustainable for the future. We intend to ensure the availability of the essentials of primary health care as defined in the Declaration of Alma-Ata[2] and developed in the new policy. We will continue to develop health systems to respond to the current and anticipated health conditions, socioeconomic circumstances and needs of the people, communities and countries concerned, through appropriately managed public and private actions and investments for health.

IV

We recognise that in working towards health for all, all nations, communities, families and individuals are interdependent. As a community of nations, we will act together to meet common threats to health and to promote universal well-being.

V

We, the Member States of the World Health Organisation, hereby resolve to promote and support the rights and principles, action and responsibilities enunciated in this Declaration through concerted action, full participation and partnership, calling on all peoples and institutions to share the vision of health for all in the twenty-first century, and to endeavour in common to realise it.

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[2] Adopted at the International Conference on Primary Health Care, 1 Alma-Ata, 6-12 September 1978, and endorsed by the Thirty-second World Health Assembly in resolution WHA32.30 (May 1979).

APPENDIX- C

Peoples' Charter for Health (2000) [1]

PREAMBLE

Health is a social, economic and political issue and above all a fundamental human right. Inequality, poverty, exploitation, violence and injustice are at the root of ill-health and the deaths of poor and marginalised people. Health for all means that powerful interests have to be challenged, that globalisation has to be opposed, and that political and economic priorities have to be drastically changed.

This Charter builds on perspectives of people whose voices have rarely been heard before, if at all. It encourages people to develop their own solutions and to hold accountable local authorities, national governments, international organisations and corporations.

VISION

Equity, ecologically-sustainable development and peace are at the heart of our vision of a better world - a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the flowering of people's talents and abilities to enrich each other; a world in which people's voices guide the decisions that shape our lives. There are more than enough resources to achieve this vision.

THE HEALTH CRISIS

"Illness and death every day anger us. Not because there are people who get sick or because there are people who die. We are angry because many illnesses and deaths have their roots in the economic and social policies that are imposed on us"

(*A voice from Central America)*

In recent decades, economic changes world-wide have profoundly affected people's health and their access to healthcare and other social services.

[1] Adopted on 8 December 2000 by the People's Health Assembly (PHA), a meeting of more than 1,500 people from all over 90 countries in Savar, Bangladesh, from 4-8 December 2000.

Despite unprecedented levels of wealth in the world, poverty and hunger are increasing. The gap between rich and poor nations has widened, as have inequalities within countries, between social classes, between men and women and between young and old.

A large proportion of the world's population still lacks access to food, education, safe drinking water, sanitation, shelter, land and its resources, employment and health care services. Discrimination continues to prevail. It affects both the occurrence of disease and access to health care.

The planet's natural resources are being depleted at an alarming rate. The resulting degradation of the environment threatens everyone's health, especially the health of the poor. There has been an upsurge of new conflicts while weapons of mass destruction still pose a grave threat.

The world's resources are increasingly concentrated in the hands of a few who strive to maximise their private profit. Neoliberal political and economic policies are made by a small group of powerful governments, and by international institutions such as the World Bank, the International Monetary Fund and the World Trade Organisation. These policies, together with the unregulated activities of transnational corporations, have had severe effects on the lives and livelihoods, health and well-being of people in both North and South.

Public services are not fulfilling people's needs, not least because they have deteriorated as a result of cuts in governments' social budgets. Health services have become less accessible, more unevenly distributed and more inappropriate.

Privatisation threatens to undermine access to health care still further and to compromise the essential principle of equity. The persistence of preventable ill health, the resurgence of diseases such as tuberculosis and malaria, and the emergence and spread of new diseases such as HIV/AIDS are a stark reminder of our world's lack of commitment to principles of equity and justice.

PRINCIPLES OF THE PEOPLE'S CHARTER FOR HEALTH

- The attainment of the highest possible level of health and well-being is a fundamental human right, regardless of a person's colour, ethnic background, religion, gender, age, abilities, sexual orientation or class.

- The principles of universal, comprehensive Primary Health Care (PHC), envisioned in the 1978 Alma Ata Declaration, should be the basis for formulating policies related to health. Now more than ever an equitable, participatory and intersectoral approach to health and health care is needed.
- Governments have a fundamental responsibility to ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay.
- The participation of people and people's organisations is essential to the formulation, implementation and evaluation of all health and social policies and programmes.
- Health is primarily determined by the political, economic, social and physical environment and should, along with equity and sustainable development, be a top priority in local, national and international policy-making.

A CALL FOR ACTION

To combat the global health crisis, we need to take action at all levels - individual, community, national, regional and global - and in all sectors. The demands presented below provide a basis for action.

HEALTH AS A HUMAN RIGHT

Health is a reflection of a society's commitment to equity and justice. Health and human rights should prevail over economic and political concerns.

This Charter calls on people of the world to:

- Support all attempts to implement the right to health.
- Demand that governments and international organisations reformulate, implement and enforce policies and practices which respect the right to health.
- Build broad-based popular movements to pressure governments to incorporate health and human rights into national constitutions and legislation.
- Fight the exploitation of people's health needs for purposes of profit.

TACKLING THE BROADER DETERMINANTS OF HEALTH

Economic challenges

The economy has a profound influence on people's health. Economic policies that prioritise equity, health and social well-being can improve the health of the people as well as the economy.

Political, financial, agricultural and industrial policies which respond primarily to capitalist needs, imposed by national governments and international organisations, alienate people from their lives and livelihoods. The processes of economic globalisation and liberalisation have increased inequalities between and within nations.

Many countries of the world and especially the most powerful ones are using their resources, including economic sanctions and military interventions, to consolidate and expand their positions, with devastating effects on people's lives.

This Charter calls on people of the world to:

- Demand transformation of the World Trade Organisation and the global trading system so that it ceases to violate social, environmental, economic and health rights of people and begins to discriminate positively in favour of countries of the South. In order to protect public health, such transformation must include intellectual property regimes such as patents and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement.
- Demand the cancellation of Third World debt.
- Demand radical transformation of the World Bank and International Monetary Fund so that these institutions reflect and actively promote the rights and interests of developing countries.
- Demand effective regulation to ensure that TNCs do not have negative effects on people's health, exploit their workforce, degrade the environment or impinge on national sovereignty.
- Ensure that governments implement agricultural policies attuned to people's needs and not to the demands of the market, thereby guaranteeing food security and equitable access to food.
- Demand that national governments act to protect public health rights in intellectual property laws.

- Demand the control and taxation of speculative international capital flows.
- Insist that all economic policies be subject to health, equity, gender and environmental impact assessments and include enforceable regulatory measures to ensure compliance.
- Challenge growth-centred economic theories and replace them with alternatives that create humane and sustainable societies. Economic theories should recognise environmental constraints, the fundamental importance of equity and health, and the contribution of unpaid labour, especially the unrecognised work of women.

Social and political challenges

Comprehensive social policies have positive effects on people's lives and livelihoods. Economic globalisation and privatization have profoundly disrupted communities, families and cultures. Women are essential to sustaining the social fabric of societies everywhere, yet their basic needs are often ignored or denied, and their rights and persons violated.

Public institutions have been undermined and weakened. Many of their responsibilities have been transferred to the private sector, particularly corporations, or to other national and international institutions, which are rarely accountable to the people. Furthermore, the power of political parties and trade unions has been severely curtailed, while conservative and fundamentalist forces are on the rise. Participatory democracy in political organisations and civic structures should thrive. There is an urgent need to foster and ensure transparency and accountability.

This Charter calls on people of the world to:

- Demand and support the development and implementation of comprehensive social policies with full participation of people.
- Ensure that all women and all men have equal rights to work, livelihoods, to freedom of expression, to political participation, to exercise religious choice, to education and to freedom from violence.
- Pressure governments to introduce and enforce legislation to protect and promote the physical, mental and spiritual health and human rights of marginalised groups.

- Demand that education and health are placed at the top of the political agenda. This calls for free and compulsory quality education for all children and adults, particularly girl children and women, and for quality early childhood education and care.
- Demand that the activities of public institutions, such as child care services, food distribution systems, and housing provisions, benefit the health of individuals and communities.
- Condemn and seek the reversal of any policies, which result in the forced displacement of people from their lands, homes or jobs.
- Oppose fundamentalist forces that threaten the rights and liberties of individuals, particularly the lives of women, children and minorities.
- Oppose sex tourism and the global traffic of women and children.

Environmental challenges

Water and air pollution, rapid climate change, ozone layer depletion, nuclear energy and waste, toxic chemicals and pesticides, loss of biodiversity, deforestation and soil erosion have far-reaching effects on people's health. The root causes of this destruction include the unsustainable exploitation of natural resources, the absence of a long-term holistic vision, the spread of individualistic and profit-maximising behaviours, and over-consumption by the rich. This destruction must be confronted and reversed immediately and effectively.

This Charter calls on people of the world to:

- Hold transnational and national corporations, public institutions and the military accountable for their destructive and hazardous activities that impact on the environment and people's health.
- Demand that all development projects be evaluated against health and environmental criteria and that caution and restraint be applied whenever technologies or policies pose potential threats to health and the environment (the precautionary principle).
- Demand that governments rapidly commit themselves to reductions of greenhouse gases from their own territories far stricter than those set out in the

international climate change agreement, without resorting to hazardous or inappropriate technologies and practices.

- Oppose the shifting of hazardous industries and toxic and radioactive waste to poorer countries and marginalised communities and encourage solutions that minimize waste production.
- Reduce over-consumption and non-sustainable lifestyles - both in the North and the South. Pressure wealthy industrialised countries to reduce their consumption and pollution by 90 per cent.
- Demand measures to ensure occupational health and safety, including worker-centred monitoring of working conditions.
- Demand measures to prevent accidents and injuries in the workplace, the community and in homes.
- Reject patents on life and oppose bio-piracy of traditional and indigenous knowledge and resources.
- Develop people-centred, community-based indicators of environmental and social progress, and to press for the development and adoption of regular audits that measure environmental degradation and the health status of the population.

War, violence, conflict and natural disasters

War, violence, conflict and natural disasters devastate communities and destroy human dignity. They have a severe impact on the physical and mental health of their members, especially women and children. Increased arms procurement and an aggressive and corrupt international arms trade undermine social, political and economic stability and the allocation of resources to the social sector.

This Charter calls on people of the world to:

- Support campaigns and movements for peace and disarmament.
- Support campaigns against aggression, and the research, production, testing and use of weapons of mass destruction and other arms, including all types of landmines.
- Support people's initiatives to achieve a just and lasting peace, especially in countries with experiences of civil war and genocide.

- Condemn the use of child soldiers, and the abuse and rape, torture and killing of women and children.
- Demand the end of occupation as one of the most destructive tools to human dignity.
- Oppose the militarisation of humanitarian relief interventions.
- Demand the radical transformation of the UN Security Council so that it functions democratically.
- Demand that the United Nations and individual states end all kinds of sanctions used as an instrument of aggression which can damage the health of civilian populations.
- Encourage independent, people-based initiatives to declare neighbourhoods, communities and cities areas of peace and zones free of weapons.
- Support actions and campaigns for the prevention and reduction of aggressive and violent behaviour, especially in men, and the fostering of peaceful coexistence.
- Support actions and campaigns for the prevention of natural disasters and the reduction of subsequent human suffering.

A PEOPLE-CENTERED HEALTH SECTOR

This Charter calls for the provision of universal and comprehensive primary health care, irrespective of people's ability to pay. Health services must be democratic and accountable with sufficient resources to achieve this.

This Charter calls on people of the world to:

- Oppose international and national policies that privatise health care and turn it into a commodity.
- Demand that governments promote, finance and provide comprehensive Primary Health Care as the most effective way of addressing health problems and organising public health services so as to ensure free and universal access.
- Pressure governments to adopt, implement and enforce national health and drugs policies.

- Demand that governments oppose the privatisation of public health services and ensure effective regulation of the private medical sector, including charitable and NGO medical services.
- Demand a radical transformation of the World Health Organization (WHO) so that it responds to health challenges in a manner which benefits the poor, avoids vertical approaches, ensures intersectoral work, involves people's organisations in the World Health Assembly, and ensures independence from corporate interests.
- Promote, support and engage in actions that encourage people's power and control in decision-making in health at all levels, including patient and consumer rights.
- Support, recognise and promote traditional and holistic healing systems and practitioners and their integration into Primary Health Care.
- Demand changes in the training of health personnel so that they become more problem-oriented and practice based, understand better the impact of global issues in their communities, and are encouraged to work with and respect the community and its diversities.
- Demystify medical and health technologies (including medicines) and demand that they be subordinated to the health needs of the people.
- Demand that research in health, including genetic research and the development of medicines and reproductive technologies, is carried out in a participatory, needs-based manner by accountable institutions. It should be people- and public health-oriented, respecting universal ethical principles.
- Support people's rights to reproductive and sexual selfdetermination and oppose all coercive measures in population and family planning policies. This support includes the right to the full range of safe and effective methods of fertility regulation.

PEOPLE'S PARTICIPATION FOR A HEALTHY WORLD

Strong people's organisations and movements are fundamental to more democratic, transparent and accountable decisionmaking processes. It is essential that people's civil, political, economic, social and cultural rights are ensured. While governments have the primary responsibility for promoting a more equitable approach to health

and human rights, a wide range of civil society groups and movements, and the media have an important role to play in ensuring people's power and control in policy development and in the monitoring of its implementation.

This Charter calls on people of the world to:

- Build and strengthen people's organisations to create a basis for analysis and action.
- Promote, support and engage in actions that encourage people's involvement in decision-making in public services at all levels.
- Demand that people's organisations be represented in local, national and international fora that are relevant to health.
- Support local initiatives towards participatory democracy through the establishment of people-centred solidarity networks across the world.

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APPENDIX- D

Indian Aircraft (Public Health) Rules 2015

Part -XII- ANNEXURES

ANNEXURE -1

SPECIFIC MEASURES FOR VECTOR-BORNE DISEASES[1]

1. Every conveyance leaving an area where vector control is recommended by World Health Organisation or where vector of yellow fever exists, should be disinsected and kept free of vectors. The presence of vectors on board conveyances and the control measures used shall be included, in the Health Part of the Aircraft General Declaration,

2. Airport health officer shall ensure that various agencies or airport operator undertake control measures for vectors that may transport an infectious agent that constitutes a public health risk to a minimum distance of 400 metres from those areas of point of entry facilities that are used for operations involving travellers, conveyances, containers, cargo and postal parcels, with extension of the minimum distance if vectors with a greater range are present. For such measures airport health officer, may seek assistance from local municipal agency and other concerned agencies.

3. A conveyance may be regarded as suspect and should be inspected for vectors and reservoirs, if-

a) it has a possible case of vector-borne disease on board;

b) a possible case of vector-borne disease has occurred on board during an international voyage; or

c) it has left an affected area within a period of time where on-board vectors could still carry disease.

4. Airport health officer may require application of vector control measures to a conveyance arriving from an area affected by a vector-borne disease including yellow fever, if the vectors for the foregoing disease are present on board.

5. The pilot-in-command shall, during the stay of the aircraft in an airport take such precautions as the Airport health officer may specify in order to prevent rodents gaining access to the aircraft.

[1] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures: 16.

ANNEXURE -2

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES[2]

1. Vaccines or other prophylaxis specified in this annexure or recommended under these rules shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval.

2. Persons undergoing vaccination or other prophylaxis shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the "certificate") in the form specified in this Annexure.

3. Certificates under this Annexure are valid only if the vaccine or prophylaxis used has been approved by WHO.

4. Certificates must be signed by authorised health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.

5. Certificates shall be fully completed in English.

6. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

7. Certificates are individual and shall in no circumstances be used collectively. Separate certificates shall be issued for children.

8. A parent or guardian shall sign the certificate when the child is unable to write. The signature of an illiterate shall be indicated in the usual manner by the person's mark and the indication, that this is the mark of the person concerned.

9. Travelers with exemption certificate for yellow fever vaccination would be permitted entry only after the mandatory quarantine period as provided under these rules related to yellow fever.

10. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in this Annexure if:

a) it embodies medical information substantially the same as that required by such form;

b) it contains a statement in English or in French and where appropriate in another language in addition to English or French recording the nature and date of the

[2] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures: 18

vaccination or prophylaxis and to the effect that it is issued in accordance with this paragraph.

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS[3]

This is to certify that [name] ....., date of birth ....., sex ....., nationality ....., national identification document, if applicable .....whose signature follows ……..... has on the date indicated been vaccinated or received prophylaxis against: (name of disease or condition) ……. in accordance with the International Health Regulations.

Vaccine or prophylaxis	dated	Signature and professional status of supervising clinician	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from …… until ……..	Official stamp of administering centre
1.					
2.					

1. This certificate is valid only if the vaccine or prophylaxis used has been approved by the World Health Organisation.
2. This certificate must be signed in the hand of the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature.
3. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.
4. The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

[3] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures 2: 18.

ANNEXURE- 3

REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS FOR SPECIFIC DISEASES[4]

1. In addition to any recommendation concerning vaccination or prophylaxis, the following diseases are those specifically designated for which proof of vaccination or prophylaxis shall be required for travelers as a condition of entry in to India. Vaccination against yellow fever:

2. Recommendations and requirements for vaccination against yellow fever:

a) For the purpose of this Annexure:

i. the incubation period of yellow fever is six days;

ii. Yellow fever vaccines approved by WHO provide protection against infection starting ten days following the administration of the vaccine;

iii. this protection continues for life long (in case of residents of yellow fever endemic countries) and ten years (in case of residents of countries non-endemic for yellow fever); and

iv. the validity of a certificate of vaccination against yellow fever shall extend for a period of ten years, beginning ten days after the date of vaccination or, in the case of a revaccination within such period of ten years, from the date of that revaccination.

b) Vaccination against yellow fever shall be required of any traveler leaving an area where WHO has determined that a risk of yellow fever transmission is present.

c) A traveller in possession of a valid certificate of vaccination against yellow fever shall not be treated as suspect, even if coming from an area where WHO has determined that a risk of yellow fever transmission is present.

d) Only Yellow fever vaccination certificate from designated by the country and notified to WHO will be accepted.

e) If a traveler is in possession of a certificate of vaccination against yellow fever which is not yet valid, the traveler may be permitted to depart, but the provisions of paragraph (f) of this Annexure may be applied on arrival.

[4] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures:19

f) Any traveler from an area where the WHO has determined that a risk of yellow fever transmission is present, who is unable to produce a valid certificate of vaccination against yellow fever, shall be quarantined until the certificate becomes valid, or until a period of not more than six days, reckoned from the date of last possible exposure to infection, has elapsed, whichever occurs first

ANNEXURE- 4

WHO RECOMMENDED METHODS OF DISINSECTION FOR AIRCRAFTS[5]

As per the IPCS 1995 WHO recommends the following methods of disinsection, and will be
accepted for flight disinsection:

1. Blocks - away method
2. Top on Descent
3. Residual disinsection

2. The details of procedure, disinsectant, chemicals and its validity will be as per the specifications recommended by WHO

3. Proof of disinsection will have to be submitted to the airport health officer on arrival, failing which the airport health officer reserves the right to disinsect the aircraft.

[5] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures:20

ANNEXURE -5

FORMAT FOR GENERAL DECLARATION OF HEALTH[6]

THIS DOCUMENT IS PART OF THE AIRCRAFT GENERAL DECLARATION, PROMULGATED BY THE INTERNATIONAL CIVIL AVIATION ORGANIZATION HEALTH PART OF THE AIRCRAFT GENERAL DECLARATION

Declaration of Health

Name and seat number or function of persons on board with illnesses other than airsickness or the effects of accidents, who may be suffering from a communicable disease (a fever - temperature 38°C/100 °F or greater - associated with one or more of the following signs or symptoms, e.g. appearing obviously unwell; persistent coughing; impaired breathing; persistent
diarrhoea; persistent vomiting; skin rash; bruising or bleeding without previous injury; or confusion of recent onset, increases the likelihood that the person is suffering a communicable disease) as well as such cases of
illness disembarked during a previous stop

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Details of each disinsecting or sanitary treatment (place, date, time, method) during the flight. If no disinsecting has been carried out during the flight, give details of most recent disinsecting

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Signature, if required, with time and date

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Crew member concerned

[6] Indian Aircraft (Public Health) Rules, 2015, GoI. Part XII Annexures: 21.