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THE CASE FOR GENETIC MEDICINES IN INDIA

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Introduction

Biotechnology is an area of immense fascination and interest today because, once the technology has developed sufficiently to manipulate the human genes and the chromosome structure in the DNA, that would, probably, mark the end of many diseases, especially the hereditary genetic diseases. The knowledge of the gene-functions can help us to detect, prevent and treat conditions from cancer to depression and even ageing. It has the potential to revolutionize the very life of human beings in terms of health and well-being. This can radically change the way we practice medicine.

India which is already known as the "pharmacy of the world for cheap medicines"[1] and the "pharmacy of the developing world,"[2] has taken this new field of medicine seriously. India's interest in genetic medicines has the goal not only of the treatment of its own people, but also of earning foreign exchange. Towards this goal, the government has also been actively promoting health tourism in the country.

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[1]Prabodh Malhotra, "The Impact of TRIPS on Innovation and Exports: A Case Study of the Pharmaceutical Industry in India," *Indian Journal of Medical Ethics* 5, 2 (April-June 2008) 64.

[2]See Jeremiah Norris, "How India Used Patents to become Pharmacy of the Developing World," *Science in Public Policy*, May 21, 2012, http://scienceinpolicy.wordpress.com/2012/05/21/how-india-used-patents-to-become-pharmacy-of-the-developing-world/; Ranjit Devraj, "India Affirms Role as Developing World's Pharmacy," *Inter Press Service News Agency*, November 27, 2013, http://www.ipsnews.net/2012/03/india-affirms-role-as-developing-worldrsquos-pharmacy/.

The changing Indian disease scenario has also been promoting genetic medicines in the country. India has been known for its communicable diseases, like malaria, tuberculosis, cholera, diarrhea, acute respiratory infection, etc. and for the numerous deaths due to them. However, surprisingly, the latest studies show that while communicable diseases result in 42.2% of the deaths, non-communicable conditions, like diabetes mellitus, organ disorders, cardiovascular diseases, cancers, etc., together cause 47.9% of deaths.[3] Today India has over 120 million diabetes patients.[4] There are about 850,000 new cases of cancer and about 580,000 cancer related deaths every year in the country.[5] Cardio-vascular diseases have become another serious epidemic in the country, and there are about 30 million people suffering from the disease in India.[6] Such a scenario encourages genetic medicines, since some of these diseases respond better to them, and in some cases they are said to be the only permanent cure for them. Other factors that contribute to India's dive into genetic medicines are India's large scientific and medical community, its technological advancement, a supportive government and a weak law and policy enforcement agency.

While the scenario in the country is very conducive for the production and use of genetic medicines, the field is not free from objections and questions from ethicists specifically on grounds of justice — with regard to accessibility, exploitation of the poor and the illiterate, etc., and the lack of technological perfection. Therefore, although often considered as the futuristic medicine for many diseases on the ground of the promises it makes, genetic medicine or gene therapy is also one of the most challenging fields in the ethics of medicine and health care. Here, after a very brief introduction to gene therapy — what it is and its types — I shall argue for the case of gene therapy in India and explain the challenges it raises. I would argue that the principles of justice should guide any effort in genetic

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[3]J. Kishore, *National Health Programs of India: National Policies and Legislations Related to Health,* New Delhi: Century Publications, 2005, 10.

[4]Juliana C.N. Chan, Vasanti Malik et al., "Diabetes in Asia: Epidemiology, Risk Factors, and Pathophysiology," *Journal of American Medical Association* 301, 20 (May 27, 2009) 2129.

[5]See Cancer Support Society, *Cancer Statistics of India*, http://cancerindia.net/cancerstatistics.aspx. See also P. Marimuthu, "Projection of Cancer Incidence in Five Cities and Cancer Mortality in India," *Indian Journal of Cancer* 45, 1 (Jan–March 2008) 4.

[6]See R. Gupta, "Recent Trends in Coronary Heart Disease Epidemiology in India," *Indian Heart Journal* 60, 2, Suppl. B (March-April 2008) B4.

engineering and in the production of genetic medicines. They should also direct the government in its policies concerning the efforts in the field. Then, after having explained the ethical possibilities of gene therapy in India, especially from the justice point of view, I shall conclude by proposing a few specific requirements of justice in the field in the context of India.

1. Gene Therapy

A gene "is normally a stretch of DNA that codes for a type of protein or for an RNA chain that has a function in the organism... Genes hold the information to build and maintain an organism's cells and pass genetic traits to offspring."[7] Although proteins perform most of the functions and even make up the majority of cellular structures,[8] genes control the production of the proteins. Genes determine which proteins to produce and which not, when to grow and when not. They comprise intricate "written" instructions that control the cells. When the genes are altered, the encoded proteins will no longer be able to carry out their normal functions; and that will result in genetic disorders. Errors in the structure or function of genes are common. While some of them are very slight, others disrupt a vital function of the organism and can even threaten life.[9] The right genes support and improve life.

Gene therapy is a technique for correcting defective genes or genes that are responsible for the development of diseases.[10] In other words, it is an attempt to cure or prevent diseases at the most basic level —

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[7]See Wikipedia, "Gene," at: http://en.wikipedia.org/wiki/Gene. For a more modern working definition of a gene, see Helen Pearson, "Genetics: what is a gene?" *Nature* 441, no. 7092 (May 2006) 401; and Elizabeth Pennisi, "DNA Study Forces Rethink of What It Means to Be a Gene," *Science* 316, 5831 (June 2007) 1556–1557. Even though genes are comprised of DNA, not all DNA makes up genes. For details, see LeRoy Walters and Julie Gage Palmer, *The Ethics of Human Gene Therapy,* New York: Oxford University Press, 1997, 5.

[8]For details, see Human Genome Project Information, "What is Gene Therapy?" at: http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml.

[9]See Walters and Palmer, *The Ethics of Human Gene Therapy*, 4.

[10]To understand what genetic disorders are, their types, causes and their effects, see Walters and Palmer, *The Ethics of Human Gene Therapy*, 13-15; Celia Deane Drummond, *Genetics and Christian Ethics: New Studies in Christian Ethics,* Cambridge: Cambridge University Press, 2006, 79-80; and Human Genome Project Information, "What are genetic disorders?" at: http://www.ornl.gov/sci/techresources/Human_Genome/medicine/assist.shtml.

at the level of DNA. The diseases that are being targeted in gene therapy are not only inherited disorders like hemophilia, cystic fibrosis, Huntington's disease and severe combined immune deficiency (SCID), but also various cancers and AIDS that later develop through various environmental and other causes.

There are several methods or procedures for correcting faulty genes. They are *gene addition, gene replacement*, *gene repair* and *gene-altering* therapies. The only procedure available today is *gene addition* therapy.[11]

1.1. Types of Gene Therapy

Gene therapy can be broadly divided into 'curative gene therapy' and 'enhancement gene therapy / intervention'.[12] Curative gene therapies are for prevention, treatment or cure of diseases and enhancement gene therapies / interventions are for attaining capabilities or characteristics beyond the normal curative purposes. Health-related interventions, such as immunization against infectious diseases or energizing the cells that inhibit growth (growth hormone deficiency) as in the case of turner syndrome (a chromosomal abnormality) can be considered as therapeutic. Gene therapies could be further divided into somatic cell gene therapy or germ-line gene therapy.

1.1.1. Somatic Cell Gene Therapy

Somatic cell therapies include implantation of normally functioning genes into the somatic cells of the affected tissue or area. The term somatic cell therapy refers to the administration to humans of autologous, allogeneic, or xenogeneic living, normal non-germ-line cells, other than transfusable blood products, for therapeutic,

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[11]For more information on these therapies / procedures, see Desmond S.T. Nicholl, *An Introduction to Genetic Engineering,* Cambridge: Cambridge University Press, 2002, 210-211. See also Walters and Palmer, *The Ethics of Human Gene Therapy*, 8-12, 23; and Human Genome Project Information, "Gene Therapy," at: http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml.

[12]The term 'therapy' is used here in a very broad sense. In general, while there is distinction between 'therapy' and 'enhancement', as Kevin FitzGerald points out, this distinction in genetic interventions is blurred because of people's inability to come to an agreement as to what is therapy and what is enhancement. For details and for examples, see Kevin T. FitzGerald, "The Need for a Dynamic and Integrative Vision of the Human for the Ethics of Genetics," in *Genetics, Theology and Ethics: An Interdisciplinary Conversation*, ed. Lisa Sowle Cahill, New York: The Crossroad Publishing Company, 2005, 81-83. It has become common among authors to use the term 'therapy' for both. See also Cahill, *Theological Bioethics*, 238; and Walters and Palmer, *The Ethics of Human Gene Therapy*, 101-102.

diagnostic, or preventive purposes. The genes inserted generally are those which are manipulated or processed *ex vivo* (outside the body).[13] The functional genes, which are also known as transgenes, can be transported to the target cell through inhalation, injection, or through carrier molecules called vectors.[14] The genes that are altered in the process are only in somatic cells and, therefore, the alteration is not passed on to future generations.

1.1.2. Germ-line Gene Therapy

Germ-line stem cell gene therapies are conducted on germ-line cells (gametes). The manipulation and correction of the gene take place in the gametes (sperm or ova) or the zygote (blastomere) cells. Germ-line gene therapy is aimed at correcting the malfunctioning genes not only in the current generation but, also, in future generations. A gene that is added to the gametes or to the zygote in the early stage is passed on to the daughter cells during cell divisions. As a zygote develops to become a child, all of its differentiating cells inherit the added gene, including the somatic and germ-line cells. The newly acquired characteristic is, then, passed on to future generations. This is the clearest advantage of germ-line gene therapy over somatic cell gene therapy.[15]

1.1.3. Genetic Enhancements

Genes provide not only physical structure, but also operational instructions. They even guide many behaviours. This is what is taken into consideration in enhancement therapies.[16] Strictly speaking genetic enhancements are used to raise a person's characteristics or capabilities beyond what is considered normal such as size, intelligence, memory, sleep dependence, behavioural traits, personality characteristics, and aging.[17]

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[13]For details, see the Food and Drug Administration, "Guidance for Industry: Guidance for Somatic Cell therapy and Gene Therapy," at: http://www.fda.gov/cber/gdlns/somgene.pdf.

[14]For more details, see Nicholl, *An Introduction to Genetic Engineering*, 212-213. See also Human Genome Project Information, "Gene Therapy."

[15]See Walters and Palmer, *The Ethics of Human Gene Therapy,* 62-63. See also Council for Responsible Genetics, "Position Paper on Human Germ-line Manipulation," at: http://www.gene-watch.org/programs/cloning/germline-position.html.

[16]For examples and for more details, see James C. Peterson, *Genetic Turning Points: The Ethics of Human Genetic Intervention,* Michigan: William B. Eerdmans Publishing Company, 2001, 39-40.

[17]For a detailed account of the possible enhancements, see Walters and Palmer, *The Ethics of Human Gene Therapy*, 101-107; and Audrey R. Chapman, "The

2. Gene Therapy in India

The Indian government funds over two dozen centres across the country,[18] most of which are related / attached to medical colleges and pharmaceutical research centres, to promote stem cell research and to develop genetic medicines. Most of these institutions are the country's premier medical institutions like the All India Institute of Medical Sciences (AIIMS) in New Delhi, Post Graduate Institute of Medical Education & Research in Chandigarh, Sanjay Gandhi Post Graduate Institute of Medical Sciences in Lucknow, etc., that have much influence in the country in the formulation of policies and programs in the field of public health. Along with these institutions, numerous private institutions, hospitals and clinics have come up across the country with clinical trials and pilot treatment programs in gene therapy.[19] With direct or tacit support of the government and / or of the regulatory authorities, there has been enormous growth in the field of genetic research and the practice of genetic medicine from the year 2001.[20]

The Indian government has been promoting gene therapies with the argument that the country can no longer wait to train more people to plunge into the world of genetic treatments.[21] In a country where the government actively promotes health tourism, it is clear that there is the motive of economic gain hidden in such statements.

Implications of Inheritable Genetic Modifications for Justice," in *Designing Our Descendants: The Promises and Perils of Genetic Modifications*, ed., Audrey R. Chapman and Mark S. Frankel, Baltimore: The John Hopkins University Press, 2003, 144.

[18]For a list of all the centres supported by the Department of Biotechnology (DBT) where stem cell research is going on, see Alka Sharma, "Stem Cell Research in India: Developments So Far," *Cell News*, 22 November 2006, http://www.geocities.com/giantfideli/art/CellNEWS_Stem_Cells_India_Upd.html.

[19]Actually in the name gene therapy, what happens in most of these institutions is stem-cell therapy. For more details on the number of hospitals, clinics and other research institutions that are involved in the field, see Bryn Lander, Halla Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," *Cell Stem Cell* 3, no. 1 (July 2008) 11-15. See also A. Sharma, "Stem Cell Research in India: Developments So Far."

[20]For more details, see "Clinic's embryonic stem cell therapy worries govt.," *Rediff News*, 16 November 2005, http://in.rediff.com/news/2005/nov/16stem.htm; UNI (United News of India), "Government to act against clinic using stem cell therapy," *The Hindu*, 23 January 2006, http://www.hindu.com/2006/01/23/stories/2006012300720900.htm; and Laurance Johnston, "Embryonic stem-cell therapy," http://www.healingtherapies.info/hESC.htm#Overview.

[21]See K. Ghosh and D. Mohanty, "Teaching of Medical Genetics in the Medical Colleges of India - Way Ahead," *Indian Journal of Human Genetics* 8, 2 (2002) 43-44.

However, the current practices in many institutions across the country raise numerous ethical questions, especially because many of these institutions do not follow the guidelines prepared by the government, and they are never enforced. Besides, the latest developments in the sector, of involvement of huge business firms which are already tied up with international groups based in the United States and other developed countries,[22] raise many questions, especially of justice, accessibility, safety and the common good. In the presence of such challenges and, at the same time, with the many promised benefits, should India go ahead with gene therapies?

3. The Case for Gene Therapy in India

I would say that for a country like India with its vast resources, an emphasis on basic health care alone is not sufficient, especially in the context of the changing disease and disability scenario with very high incidence of non-communicable diseases. Since health care has its goal as wholeness, and since every disease — communicable or non-communicable — inhibits persons from attaining that wholeness and harmony, healing to the extent possible of every disease is important.[23] This is one of the contexts in which the question of gene therapies becomes important in India.

It is expected that gene therapy, once it has established itself as a clear, viable treatment for genetic as well as acquired diseases, especially non-communicable diseases, will have many advantages over the present, conventional system of treatment. Somatic-cell gene therapy can function as an alternative to expensive and highly invasive procedures in lung, heart and kidney transplants or other difficult and often hopeless cancer treatments. Besides, in the procedure there are fewer chances of rejection of the added genes by the body's immune system compared to transplanted organs, since the modified cells can be the patient's own cells.[24] In the context of India, the steeply rising number of cases, especially among the younger people who are the main workforce in the country, and the rising percentage of deaths from non-communicable diseases has become a concern for people, health officials as well as the government. Conventional treatment for the non-communicable

[22]For examples and details, see Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," 12.

[23]See Abigail Rian Evans, *Redeeming Marketplace Medicine: A Theology of Health Care,* Cleveland: The Pilgrim Press, 1999, 84.

[24]Walters and Palmer, *The Ethics of Human Gene Therapy*, 36-37.

diseases like heart diseases, kidney failures, diabetes, cancers and so on, are very expensive, repetitive and even lifelong. Treatments for them are often very troublesome and unresponsive. Even though most of these non-communicable diseases are also influenced by environmental factors, many of them have also hereditary causes. Therefore, it might turn out that gene therapy will be the only way to prevent these hereditary diseases and defects. The promise of gene therapy as a one-time, non-invasive treatment can be very beneficial to the people in the long run.

Secondly, germ-line therapy will, probably, be the best way to prevent serious health problems before they occur, rather than attempting to repair the damage after they have occurred. A one time germ-line treatment can possibly save children and future generations from anxiety regarding the disease, and it liberates them from making difficult ethical and practical choices regarding the future treatment. It also saves the parents from parental diagnosis and pre-implantation diagnosis and selective abortion.[25] The possible benefit to all the succeeding generations makes germ-line gene therapy highly desirable.[26] The limited resources that India allocates to health care can be better utilized this way.

Third, gene therapies can treat the immune system in such a way that it can improve the effectiveness of treatments for ailments such as cancer, heart disease and some forms of mental diseases.

Besides these direct health benefits to the people, there are other benefits that gene therapy offers to a country. For a developing country like India with its vast scientific and technological resources, gene therapies can be an added benefit to the already burgeoning health industry in the country which, in turn, can contribute to the economic development of the country. India is already receiving foreign investment in the field and a large number of foreign health tourists. Success in gene therapies will speed up investment and will increase the flow of health tourists to the country, which in turn can boost the economy through investment-returns, employment and so on.

It is true that commercialization and profiteering needs to be checked in the field. However, investment, even by the multinational corporations, in research and development of therapeutic medicines in a country like India has its own advantages. As we have already

[25]Walters and Palmer, *The Ethics of Human Gene Therapy*, 80-82.
[26]Shannon and Walter, *The New Genetic Medicine*, 22.

seen, India is in an advantageous position to go into research and production of such medicines because of the country's fast advancement in science and technology and the presence of a large scientific community. Given these reasons along with the shift in the disease scenario, the promises of the new medicines and the presence of a large medical fraternity, India has the right ambience for the production and use of genetic medicines. India is also in an advantageous position to regulate costs/prices of medical technologies and medicines as it has done in the case of the HIV/AIDS medicines.[27] Such advantages that the country has need to be exploited to regulate pricing and to counter the efforts of multinational biotech corporations to gain unjustified profits.

Finally, with the resources India has in terms of technology and personnel, and the availability of disease samples, the track record India creates will become important to the rest of the world. Therefore, the varied resources and the possibilities India has together with the needs of the country give India an advantageous position to go into genetic research and therapies.

4. Ethical Possibilities of Gene Therapy in India

Genetic medicines are already practiced in various parts of the country. It is clear that in the changed disease scenario, the demand for them will increases, and the practice will also become more known and probably more common. Therefore, prohibiting them altogether will not be easy, given the lack of regulatory and supervisory system in place in the country. At present, while there are clear guidelines in place to regulate gene therapies in the country, hardly anyone follows them. While there is no official sanction for the practice of gene therapies in the country, it is being practiced openly in many clinics, hospitals and other health care institutions, including in the country's premier health care institution, the All India Institute

[27] As we have seen earlier, India has been able to reduce the price of antiretrovirals from USD 15,000 in the US to USD 140 in India in 2003 and to USD 88 per person per year by the year 2008. For details, see Avert, "AIDS, Drug Prices and Generic Drugs," http://www.avert.org/generic.htm; WHO/UNAIDS/UNICEF (2009), *Towards Universal Access: Scaling up Priority HIV/AIDS Interventions in the Health Sector: Progress Report 2009,* Geneva: WHO Press, World Health Organization, 2009, http://www.who.int/hiv/pub/tuapr_2009_en.pdf; and Joint United Nation's Program on HIV/AIDS, "Access to HIV Treatment and Care: Fact Sheet," http://data.unaids.org/Publications/Fact-Sheets04/fs_treatment_en.pdf.

of Medical Sciences (AIIMS).[28] Since the officials responsible for monitoring the practices make statements that are often incongruent or even contradictory with regard to the practices already taking place, institutions that want to practice gene therapies continue with their practices. There is also much ambiguity among the statements of the officials — some openly supporting and others expressing either ignorance of practices or the need for caution. This leads to much ambiguity with regard to the enforceability of the guidelines.[29]

In fact, prohibiting gene therapies altogether is also not desirable because of the benefit people receive from them. Even though there have not been sufficient verification by external agencies, there have been claims made both by therapists as well as patients with regard to benefits received from the therapies.[30] In the face of such benefits, what needs to be done is to have clear enforceable ethical guidelines in the field that can serve the common good. This, of course, is one of the biggest challenges in the field. How can every one be served equitably in a country like India with abysmal disparities in income, health and in every other conceivable area? This is where issues like some being left out, especially the poor, others being used (as in trials) for profits for others, etc., surface. Stringent measures need to be in position to ensure the common good. There needs to be functional regulatory mechanisms in place. This is made difficult in the country by a host of reasons like political interference, corruption, lethargy on the part of regulatory officials, and so on. This needs to be corrected. Public awareness and public action are important for this. It is clear that any serious engagement in the field needs to answer important questions of justice, the common good, accessibility, and so on. Gene therapy in India can be only in the context of a just health care system.

5. A Just Health Care and the Practice of Gene Therapy

The issue of justice is one of the major objections against gene therapies. According to many ethicists, the more important issues in

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[28]See Sunil K. Pandya, "Stem Cell Transplantation in India: Tall Claims, Questionable Ethics," *Indian Journal of Medical Ethics* 5, no. 1 (Jan-Mar. 2008) 15.

[29]See Staff Reporter, "ICMR Okays Stem Cell Research by AIIMS," and K.S. Jayaraman, "Indian Regulations Fail to Monitor Growing Stem-Cell Use in Clinics," *Nature* 434, no. 7031 (March 2005) 259.

[30]For example, see "Clinic's embryonic stem cell therapy worries govt.," *Rediff News*, 16 November 2005, http://in.rediff.com/news/2005/nov/16stem.htm.

health care for a vast majority of people all over the world today are issues of basic health care — of adequate nutrition, potable water, sanitation, basic vaccinations, etc. In a country where basic healthcare facilities are not provided to all, justice demands that the country should not invest disproportionately in the development of expensive gene therapies. The Indian government's allocation to health care in the country has been a mere 0.9% of GDP until recently, of which 70% was spent on paying salaries to the health care personnel.[31] Although officially it is raised to 2.5% for the last one year, with such a low allocation of funds even basic health care facilities are unavailable to huge sections of people, especially the rural and the poorer sections. If expensive procedures, like inheritable genetic modifications (IGM), are to be supported by the government, that will deplete resources meant for primary and basic health care facilities. While basic amenities in health care are unavailable, investment in exorbitant genetic medicines, especially on IGM and enhancement therapies, is a betrayal of these already neglected sections of people. Therefore, the question is to what extent such therapies should be encouraged.

Ethicists like Lisa Cahill say that in addressing the social implications of genetics, our faith urges us to look at the bigger picture and to ask: in whose interests such scientific knowledge is being advanced and who is most likely to profit from them? She is of the opinion that concerns in the field are mostly concerns about those who will be harmed or left out, whether they be embryos, children, the uninsured, or the poor.[32] She, again, rightly points out that much of concentration in the field are not on fair access and distribution of burdens and benefits for all, but on the privacy, choice, and rights of scientists, investors, and clients in the so-called developed countries, where most people already have access to at least minimal medical care.[33] In such a situation, it is true that neither medical nor commercial benefits are going to be shared among all. While the rich would have all the treatments they need, the rest would hardly have access even to essential health care. In such circumstances, she asks, how do we justify such exorbitant genetic treatments for the privileged few? The question here is not that the rich should not be

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[31]See J.P. Gupta and A.K. Sood, ed., *Contemporary Public Health: Policy, Planning, Management,* New Delhi: Apothecaries Foundation, 2005, 2.53; or see K. Satyanarayana, "Towards Equitable Health Care: Drug Prices, and Beyond," *The Indian Journal of Medical Research* 127, no. 4 (April 2008) 301.

[32]See Cahill, *Genetics, Theology and Ethics*, 4.

[33]Cahill, *Genetics, Theology and Ethics*, 117.

treated, but that society has a greater responsibility to treat everyone in an equitable way. What is much easier and less expensive and which, at the same time, benefits a much larger population should have a priority over very expensive treatments that benefit a few individuals. It is a question of just, equitable access to health care.

Private investment in the field is another issue of concern. Private parties will naturally favour the most profitable rather than the most beneficial forms of therapies for the larger public.[34] While there can be more control over government funding, in a capitalist economy or in a country like India there will be very little control over any private sector undertaking — over investment, production and practice of such therapies. These are serious issues that cannot be sorted out easily. As Lisa Cahill rightly points out, in an era of globalization, "biotech corporations do not promote research for its own sake or promote healing as an end in itself."[35] These corporations invest billions into genomics more for their own benefits than for the eradication of illnesses. They foresee possible huge future profits.

The profit motive on the part of the biotech corporations or pharmaceutical companies forces them to produce drugs and treatment therapies that are more lucrative rather than medicines that are needed for more common diseases, such as malaria, flu, pneumonia, etc. This happens even when there is a large shortage of medicines for these ailments.[36] As Keenan points out, support of genetic medicines often stem from self-interests that "overlook the urgent medical questions for all of humanity... where equal access to health care has more rudimentary and less technologically oriented interests."[37] In such endeavours profit considerations often overtake human considerations and human beings are largely considered as means for profit making.

Profiteering and commercialization of technology again can cut short clinical trial procedures in the process of drug development.[38]

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[34]Chapman, "The Implications of Inheritable Genetic Modifications for Justice," 133-134.

[35]Cahill, *Theological Bioethics*, 215.

[36]Cahill, *Theological Bioethics*, 216, taken from Marcia Angell, *The Truth about Drug Companies: How They Deceive Us and What to Do about It?,* New York: Random House, 2004, 91-92.

[37]See Keenan, "What does Virtue Ethics Bring to Genetics?" 109.

[38]For details, see Søren Holm, "The Role of Informed Consent in Genetic Experimentation," in Justine Burley and John Harris, ed., *A Companion to Genethics,* Oxford: Blackwell Publishers, 2002, 87, or Drummond, *Genetics and Christian Ethics*, 135.

Such practices are exploitative of vulnerable human beings and, therefore, unethical and can endanger human lives.

Although gene therapy is meant for those who already have disabilities — physical or mental — commercialization would lead to a complete neglect of those who are really in need of them. Probably such a predicament makes Lisa Cahill assert that genetic interventions offer no hope for the future, because of "the careless drive toward entitlement without responsibility, which has resulted in an extremely unhealthy atmosphere for women and men unable to purchase health care."[39]

Such serious issues and concerns make us reflect over the implication of gene therapies in the context of India.

6. Implications of Justice on Gene Therapies in the Context of India

Acceptance of gene therapies ought to happen only in the context of a just health care system. In India that would involve a number of important issues that protect people and promote the common good. They concern enhancements, safety measures, regulatory system, funding, access and protection of the poor subjects. Let me explain them.

6.1. No Enhancement Therapy

Justice in gene therapies in the context of India would rule out enhancements completely, because technological success of gene therapies will soon switch curing diseases to enhancements. This will lead to numerous social, economic, political and other problems. If enhancement therapy is allowed, the affluent would become more powerful and the poor who cannot afford the therapy would be neglected. A further widening of the gap between the rich and the poor in India will only increase the existing discrimination against the poor and the neglected sections of people, especially the tribals, the dalits and so on. There is already a long and disturbing history of discrimination among people on the basis of class, caste, race and ethnicity. In such a context, the possibility of enhancement will create misplaced priorities in society where only the rich would have chances to compete and progress, and the poor would be completely ignored and may not even receive basic forms of healthcare.

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[39]For details and for examples, see Cahill, *Theological Bioethics*, 222. The quote is from Emilie M. Townes, *Breaking the Fine Rain of Death: African American Health Issues and a Womanist Ethic of Care*, New York: Continuum, 2001, 151.

Discrimination and intolerance toward persons with disabilities may become another major problem with genetic enhancement. In our country where there is already a belief/"superstition" among a considerable number of people that disabilities are the result of his/her previous actions/work (karma in the previous birth) will get reinforced in such situations and the consequences can be worse forms of discrimination.

Many ethicists say that enhancing offspring will take enhancement to a level of no return, and eliminate all chances of competition between the rich and the poor.[40] The disparity this will create will not only be financial but also physical. The possibility of the presence of rich, genetically modified super humans is a situation that, possibly, no one wants to think of because it raises the issue of malevolent use of technology. As Walters and Palmer say, unscrupulous dictators could produce a class of superior human beings or could produce a subservient, servile class, who would willingly perform the least attractive and the most dangerous jobs for society.[41]

Genetic discrimination could also affect eligibility for employment and insurance. Anyone who falls short of technically achievable ideal qualities and characteristics would increasingly be seen as "damaged goods" for discarding,[42] and this in turn will make people turn more to pharmaceutical corporations that promote enhancement applications. Also, as the disparity between the poor and the rich increases within a nation, so also will increase the disparity between the developing and the developed nations. The disparity will be acute between the developed nations and the countries which do not have the technological facilities to conduct complex genetic interventions. In such a situation, the issue of justice raises the question: what is the priority? Should the basic needs of health care be met on a priority basis, or should we encourage enhancement that benefits a few rich which, in turn, would exacerbate already existing disparities among people and dehumanize the poor? We need to opt for the former. Chapman rightly points out, "From a justice perspective, there seems to be only one option: not to go forward with the development and application of IGM" and enhancement.[43]

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[40]See Chapman and Frankel, *Designing Our Descendants*, 11, 14.

[41]See Walters and Palmer, *The Ethics of Human Gene Therapy*, 84.

[42]Chapman, "The Implications of Inheritable Genetic Modifications for Justice," 139.

[43]Chapman, "The Implications of Inheritable Genetic Modifications for Justice," 152.

6.2. Ensure Safety Measures

Since gene therapy is still in its initial stages, scientists point out that there are various possible dangers involved in the therapies such as disease-causing genetic mutations in the body where genes are added, unpredicted gene expressions,[44] suppression of tumour suppressing genes which can lead to the production of *chimeras*,[45] etc. While somatic cell gene therapies are still not fully risk free, germ-line gene therapies are even more dangerous. Given the present state of technological development, scientists still fear negative consequences of gene replacement therapies which are done on germ-line cells. The non-specific integration of an added gene is a real danger to the person. In other words, if a gene inserted into the DNA is integrated into a wrong location in the DNA, it can cause cancer or other diseases. While the integrational mutation of an added gene in a particular somatic cell may lead only to the death of that cell, the integration of an added gene in germ-line therapy can also develop into a cancer leading to the individual's death. Besides, the development of a heterozygous lethal mutation is also transferable to offspring, harming future generations.[46]

6.3. Need a Strong Regulatory System

In the face of the numerous ethical challenges, as we have seen, it is important that proper regulatory measures are in place to promote the health and well-being of people in an equitable way. This is all the more important in a country like ours which has inherent drawbacks with regard to equity and equality in the socio-economic, cultural and religious fields and where exploitation of the underprivileged is common place and social maladies like corruption are rampant, and where lethargy and non-commitment on the part of governments and government officials have become too common. The absence of strictly enforced regulations in a serious field like gene therapies will lead to the exploitation and victimization of the country's numerous poor and the ill.

Since the central government through its Department of Biotechnology (DBT) funds a number of centres across the country, among which are some of the best health care institutions at present

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[44]See Gordon, *The Science and Ethics of Engineering the Human Germ Line*, 180, 121-122.
[45]See Drummond, *Genetics and Christian Ethics*, 67.
[46]Walters and Palmer, *The Ethics of Human Gene Therapy*, 67.

that are involved in stem cell research and genetic medicines, the government can have some control over those centres.[47] The government needs to make sure that the right procedures are followed in gene therapies and trials and that all arbitrary, unapproved procedures are stopped. Since there are many private institutions that are involved in these procedures, both in treatment and trials, there needs to be strict monitoring and stringent measures to regulate them. The regulatory bodies need to have sufficient autonomy and enforcement authority in order to overcome the maladies of unhealthy political interference that cripple almost every public service system in the country. A monitoring body without sufficient autonomy will have no effect on the functioning of a corrupt government.

Given the resources of the country, India needs to make sure that the prices of drugs are kept sufficiently low to provide the much needed drugs for cancers and other serious diseases at cheaper rates as it provides drugs for HIV/AIDS and a host of other diseases that afflict many. Exorbitant prices will have their repercussions on the health of the poor in the country and in many other developing countries that depend on India for their drug needs. While profits are justified, profiteering, especially through patenting that normally lasts for twenty years, needs to be curtailed, so that the poor and the marginalized also will have access to them not too long after the affluent have had access to them. Again, patents should not over-ride urgent needs of people.

6.4. Proportionate Funding

Government funding becomes an important social justice issue because of the prevalence of poverty and the lack of basic health care provisions in the country at present. We have already seen that the central government through its Department of Biotechnology (DBT) funds a number of centres across the country,[48] among which are some of the best health care institutions that at present are involved in stem cell research and genetic medicines. Government funding in research and production of medicines in the context of India has many benefits. First, it can keep the prices of medicines lower,

[47]For more details, see A. Sharma, "Stem Cell Research in India: Developments So Far."

[48]For details, see A. Sharma, "Stem Cell Research in India: Developments So Far."

affordable and accessible to the hundreds of millions of poor in the country. Second, government funding is one of the mechanisms that can be used to control / regulate quality, production and distribution of medicines needed for the country. Third, government funding also helps regulate and control the private sector control over medical market. This is a definite benefit to the general public, especially the poor.

While the country needs to invest in research and production of medicines, including genetic medicines, what is needed is a balanced or proportionate emphasis that is according to the real health care needs of the people. The danger in the country lies in the exaggerated emphasis on the growth of the economy (GDP) that skews government projects and priorities. While growth in GDP is important, that cannot be at the cost of the general health of the people of the country. While the nearly 40% of the people cannot even afford basic health care, the government should not over-emphasize genetic medicines. This is all the more important since the general allocation to health care in the country is very low. An increase in the share allocated to genetic medicines can happen only with an equal decrease in the share allocated to basic health care which is more important for the poor of the country who depend largely on the primary health care system.

6.5. Guaranteed Access to All

Accessibility should be among the primary goals of the government in its policies and programs in health care. Access to adequate / basic health care for all, irrespective of their class-caste differences, especially their ability to purchase care, is an important aspect of just health care in a country. This has been one of the most important recommendations by the first health care committee (The Bhore Committee) in the country. In order to promote just health, it is important not only that medicines and medical facilities are available / present but also that they are accessible to the general public.

Today we see that a number of multinational pharmaceutical companies have begun to invest in the country and a number of Indian firms are tying up with international groups, clearly with goal of making profits.[49] Therefore, there needs to be sufficient

[49]For details, see Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," 12.

mechanisms in place to check overpricing and to facilitate accessibility for all. Adequate government funding and strict regulatory measures, especially regulating prices, are the best ways to ensure accessibility. Government can regulate prices through subsidies, direct funding of projects or through a national insurance system. There needs to be greater commitment in these areas.

6.6. Protection of Poor Subjects

Protection of poor subjects involved in trials and treatments is an enormous task in the country, especially because of the complex situation in the country of wide-spread illiteracy, poverty and ill-health. Such a situation is again worsened by structural and social anomalies, like poor supervisory and regulatory measures, corruption and lethargy on the part of the government officials, and so on. There is need for a strong mechanism that regulates all experiments in gene therapies (often in the name of treatments) that take place both in public and private health care institutions in the country. The vulnerable poor and the needy should not be made guinea pigs through trials and experiments on them in the name of treatments. The situation in India of poor accountability to the poor and the underprivileged is a great danger and a challenge.

In countries like India, research subjects are often not even aware that they are participants in a research project.[50] It is very important that the participants in trials have sufficient knowledge of the procedures, possible risks-benefits and so on before they sign consent forms. Short-cuts in gaining informed consent should be eliminated.[51] There should be sufficient mechanisms in place for compensation for the risks undertaken and for ill-consequences, if they occur. Therefore, only ethically and financially sound organizations or institutions should be allowed to undertake trials. Ethics boards need to have credible and independent organizations or individuals on them. Besides, strict accountability needs to be demanded from all institutions involved, and data from trials and treatments need to be

[50]See also concrete examples of how participants are denied of legitimate benefits in Márcio Fabri dos Anjos, "Power, Ethics, and the Poor in Human Genetics Research," in *The Ethics of Genetic Engineering*, ed., Maureen Junker Kenny and Lisa Sowle Cahill, Maryknoll: SCM and Orbis Books, 1998, 74. See also Lisa Sowle Cahill, "Genetics, Theology and Common Good," 128.

[51]In order to know the malpractice that take place in obtaining consent, see S. Srinivasan, "India Being Projected as a Global Hub for Clinical Trials."

maintained and made available to the public; if not, made available at least to the monitoring authorities.

In the context of India, the participants in the research projects on therapies do not receive the benefits for their effort and the risks they undertake because often, once the testing period is over, the participants are left to themselves without continued treatment for the diseases for which drugs were tested, unless they can pay for them. Depriving participants of their due share in the process and pricing drugs out of reach of the poor are a sacrifice of the common good to financial gain. It is most disappointing when the regulating authorities say that having laws to regulate research will not "guarantee anything," because those who want to flout the law will do so anyway as is seen in cases of "organ transplants and sex selection."[52]

Conclusion

What we have seen here is the applicability and acceptability of gene therapies in the context of India, where both the disease as well as the treatment scenario is undergoing fast changes. While I have supported the new genetic medicines for the new disease scenario dominated by non-communicable diseases, for which genetic medicines are probably more effective and beneficial in the long run, I have recommended the needed precautions to ensure justice to all and to promote the common good. The ethical issues in gene therapy in the context of India concern primarily the issues of justice, profiteering/commercialization, safety, accessibility, funding, protection of the poor subjects, etc. These are issues that need to be taken into consideration for the aforesaid goal.

What I have proposed here is gene therapy for therapeutic reasons. Finding cures to debilitating and serious diseases that defy conventional medicines is an ethical/moral good that needs to be pursued by those in the field. Merely looking at the present challenges alone can inhibit all progress and that is not desirable, especially in a country with advanced facilities and personnel in science and technology. Of course, as clearly said, this should not be at the cost of basic necessities. The goal here is the protection and promotion of human life, human dignity, human rights and common good.

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[52]S. Srinivasan, "India Being Projected as a Global Hub for Clinical Trials."