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STEM CELL THERAPIES IN INDIA

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1. Introduction

The successful completion of the Human Genome Project has helped the medical / pharmaceutical field the most. The knowledge received from the findings of this project has engaged equally researchers, medical professionals, pharmaceutical companies and governments.[1] While many governments allocate huge funds into stem cell research aimed at development of medicines with the hope of finding cures for diseases that have eluded lasting cures through conventional medicines or treatments, pharmaceutical companies invest heavily into the field with the hope of making huge profits.

India is fast becoming an important hub for biotechnology, and especially for stem cell research and therapies. Patients from across the world, even from the developed countries like the U.S. and U.K., flock to India for stem cell therapies which they do not receive in their own countries.[2] While scientists involved in the field still dispute the benevolent nature of stem cells in the long run, especially given the lack of perfection both in technology and administration of the treatment at present, there are many doctors and institutions — hospitals and clinics — seriously engaged in stem cell therapies. They

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[1]See Human Genome Project Information, *Medicine and the New Genetics*, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/medicine.shtml.

[2]For example, see Indo-Asian News Service (IANS), "Americans Flocking to India for Stem Cell Therapy," *IBN Live*, May 28, 2012. Available at http://ibnlive.in.com/news/americans-flocking-to-india-for-stem-cell-therapy/262019-17.html and Times News Network, "Stem Cell Therapy Infuses New Life in Them," *The Times of India*, Nov. 13, 2013, http://timesofindia.indiatimes.com/city/bangalore/Stem-cell-therapy-infuses-new-life-in-them/articleshow/25660947.cms.

also claim to have healed hundreds of patients, both domestic and foreign.[3] Here, in this short paper, my attempt is to investigate into the current practices in stem cell therapies in India and to point out some of the serious ethical issues involved in the practice.

2. The Practice of Stem Cell Therapies in India

The Indian government's Department of Biotechnology (DBT) funds dozens of centres across the country, most of them related / attached to medical colleges and pharmaceutical research centres,[4] to promote stem cell research and develop genetic medicines. According to an announcement in 2010 by the Director-General of the Indian Council of Medical Research (ICMR), Dr V.M. Katoch, from the year 2011 the ICMR would approve and fund three research centres every year in every state at least for five years, so that the maximum capacity of stem cell research is achieved at the state-level. Besides, according to the announcement, ICMR would also fund organizations interested in stem cell research and therapy from January 2012.[5] In fact, the DBT has also started funding private initiatives in the field of genetics and stem cell research.[6] Numerous institutions have come up across the country that are research-intensive conducting basic and applied research, and have clinical trials and pilot treatment capabilities.[7] Although still very controversial across the world with regard to the possibility and benevolent nature of stem cell therapy in the long run,[8] many

[3]See, Times News Network, "Stem Cell Therapy Infuses New Life in Them."

[4]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*, Nov. 22, 2006, http://www.geocities.com/giantfideli/art/CellNEWS_Stem_Cells_India_Upd.html.

[5]See Press Trust of India, "ICMR to Fund Stem Cell Research," *Zee News*, December 27, 2011, http://zeenews.india.com/news/health/health-news/icmr-to-fund-stem-cell-research_15052.html.

[6]For example, see Times News Network (TNN), "Vadodara Doctors, Scientists Get Department of Biotechnology Funds for Stem Cell Research," *The Times of India*, Nov 9, 2013, http://articles.timesofindia.indiatimes.com/2013-11-09/vadodara/43853933_1_stem-cells-shinya-yamanaka-john-gurdon.

[7]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, http://download.cell.com/cell-stem-cell/pdf/PIIS1934590908002944.pdf?intermediate=true.

[8]For instance, see Michael Fumento, "The Greatest Stem-Cell-Research Scam," *New York Times*, July 15, 2009, http://nypost.com/2009/07/15/the-great-stem-cell-

institutions — hospitals and clinics — are engaged in the practice and active promotion of the therapy. Among these institutions are Christian Medical College at Vellore, AIIMS, NuTech Mediworld, and Gangaram Hospital in Delhi, Post Graduate Institute of Medical Education & Research in Chandigarh, Sanjay Gandhi Post Graduate Institute of Medical Sciences in Lucknow, L.V. Prasad Eye Institute in Hyderabad and KEM Hospital and Reliance Life Sciences in Mumbai, Chaitanya Stem Cell Center in Pune.[9]

In the year 2001 the Ministry of Health in India pledged $20 million for medical genomics research to be spent over the next five years. The Indian Council of Medical Research (ICMR) which oversees the fund disbursements announced then that it had already approved 20 research projects and was evaluating another 90 projects "in an attempt to fund broad areas in medical genomics, including microbial genomics, molecular epidemiology, neurogenetics, and pharmacogenetics."[10] The consequent growth in the field of genetic research and the practice of genetic medicines that began soon after have created controversies in the country.[11]

While countries like the USA have strict regulations regarding stem cell research, especially embryonic stem cell research, and clinical trials, India has guidelines that are hardly enforced, if the practices in many research centres and hospitals are of any proof. In countries like the USA,

> effective regulation ensures that medical practices remain ethical and scientific, the use of stem cells in the treatment of diseases such as those of the heart, liver, brain and spinal cord has remained in the experimental stage. Trials in animals have shown unexpected complications — such as

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research-scam/; Gene Tarne and David Prentice, "Playing Politics with Stem Cells," *American Thinker*, August 8, 2010, http://www.americanthinker.com/2010/08/playing_politics_with_stem_cel.html; and "More Stem Cell Therapies to be Lauched in Next Five Years," *Pharmabiz.com*, Jan. 17, 2013, http://www.pharmabiz.com/ArticleDetails.aspx?aid=73322&sid=11.

[9]See Sharma, "Stem Cell Research in India: Developments So Far"; and Indo-Asian News Service (IANS), "Americans Flocking to India for Stem Cell Therapy."

[10]See Ganapati Mudur, "India Invests Heavily in Genomics Research," *British Medical Journal* 322 (March 2001) 576.

[11]For example, soon after this announcement in support of genomic medicine, the government also announced a cut in the funds allocated for the country's malaria and leprosy control programs, making funds scarce for these areas of ordinary people's diseases, creating much controversy. However, the government stuck to its program.

the formation of tumours by the transplanted stem cells — in some cases. Very carefully controlled clinical trials in humans have been permitted in a few instances. The results are being closely monitored by experts not involved in the trials as well as those conducting them.[12]

According to the National Institute of Health, USA, only adult stem cells, such as blood forming stem cells found in bone marrow, are currently used to treat human diseases. This has been done for the last 40 years, since the therapeutic potential of adult stem cells has been sufficiently proved in the treatment of diseases like diabetes and advanced kidney cancer. "However, these newer uses have involved studies with a very limited number of patients."[13]

In India, the scenario is quite different. "Individuals and institutions offer stem cell therapy to all patients. Claims are made on successful use of stem cells in curing diseases of the heart, liver and other organs; spinal cords damaged by injury and even cancer."[14] For example, one of the hospitals in India on the "Current Status of stem Cell Treatment" says the following:

For Heart Disease:

Adult stem cell treatment has been found to be useful for advanced coronary artery disease and heart muscle damage after myocardial infarction (heart attack). The stem cells are injected either into the coronary arteries via a special catheter or directly into the heart muscle. In very high risk cases it can be injected in a peripheral vein. Many studies have shown 20-40% improvement in the pumping capacity (ejection fraction) and circulation status of the heart using Stem cell therapy. The procedure is entirely painless.

For Spinal Cord Injuries:

Stem cells have found use in patients with muscular or bladder paralysis after spinal cord injury. In patients with paraplegia, this therapy is of maximum use in patients 1-2 years after spinal cord injury. It could also be potentially of use for patients with other neurological diseases of the spinal cord. In the future the therapy may be useful for patients with brain damage also. Stem cell injected directly into the Spinal fluid or around the spinal cord, at the site of injury has been found to improve

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

[13]National Institutes of Health resource for stem cell research, "Stem Cell Information," http://stemcells.nih.gov/info/health.asp.

[14]See Pandya, "Stem Cell Transplantation in India," 15; Chaitanya Stem Cell Center, Pune, http://chaitanyastemcell.com/; and Indo-Asian News Service (IANS), "Americans Flocking to India for Stem Cell Therapy."

> nerve function. The injection procedure is done under local anesthesia and is painless.
>
> For Liver Failure...
>
> For Cancer
>
> Natural Killer cells (NK cells) which can be purified from the peripheral blood is found to be beneficial even in late cases of cancers like — melanoma, liver, pancreatic, lung and gastric cancers. This treatment is called "Autologous Immune Enhancement Therapy" (AIET).[15]

It is surprising to note that such advertisements are found also on websites of other hospitals and clinics.[16] Even though these hospitals advertise that they are Joint Commission International (JCI) accredited and International Organization for Certification (ISO) approved, one author points out that the Indian Council of Medical Research (ICMR), the licensing authority in the country, has not recognized any centre for clinical application. According to the Director of the ICMR, Dr Vasantha Muthuswamy, only two institutions are cleared for research on stem cell research and regenerative medicine — *Manipal Acunova* in Bangalore and *Niche* in Chennai.[17]

However, the ground reality is different. "India is rapidly covering ground that the US cannot. Unfettered by ethical and legal constraints that leash the US scientists when it comes to the use of embryonic stem cells, Indian scientists have forged ahead at a blistering pace."[18] Basic and clinical researches are promoted in the country by several science agencies of the government in various institutions and hospitals. Both embryonic and adult stem cells are being used.[19] Even though India has prepared guidelines for stem cell research and therapy, it is clear that hardly anyone follows the guidelines. Even in the presence of central government ministers and state chief ministers, hospitals and clinics publicize and practice stem cell therapies.

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[15]Mediescapes India, "India Stem Cell Research," http://www.mediescapes.com/india-stem-cell-research.html.

[16]For example, see Chaitanya Stem Cell Center, Pune, http://chaitanyastemcell.com/.

[17]See Pandya, "Stem Cell Transplantation in India," 15.

[18]See Seema Kamdar, "In Stem Cells, India Goes Where US Can't," *DNA* News, 23 December 2005, http://www.dnaindia.com/report09.php?NewsID=1003763&CatID=1.

[19]For details regarding the various aspects that are being studied, see Alka Sharma, "Stem Cell Research in India: Developments So Far."

For example, in November 2005, *Nu Tech Mediworld*, a registered in vitro fertilization and genetic centre in Delhi, in the presence of the then Union Health Secretary P.K. Hota and the former Chief Minister of Chattisgarh, Ajit Jogi, and other high ranking dignitaries in the country, claimed that the clinic has "improved medical condition of 100 patients suffering from Alzheimer, paralysis and Parkinson's disease using the technique."[20] The institute was celebrating the completion of the fifth year of its treatment through the technique, which was started in 2000, and the treatment of the 100th patient. The government was very cautious in commenting on the claim made by the director of the institute, Dr Geeta Shroff. The only ambiguous comment made there was by the former Chief Minister, Ajit Jogi, who said, "My presence does not mean I support it... Human life should not be toyed with. We are worried... we will set up a system."[21] Those who understand the Indian political culture will understand that it was clearly a political statement, because Mr. Jogi, who was paralyzed in an accident, was himself treated in the institution later, and he "praised the treatment saying there was a remarkable improvement in his condition. He said that he felt benefits of the therapy immediately after the first shot of stem cells."[22]

Following the claims of this institution, the then Union Health Minister, Anbumani Ramdoss, reportedly had said, "We are conducting an inquiry into the claims of the clinic. Once the inquiry report comes, action will be taken against those responsible for violating the ethical norms and other issues."[23] He had warned of stringent action against the clinic if it was found guilty. Interestingly, the inquiry commission did not seem to have found any violations. The clinic has continued to do its business. According to Laurance Johnston, a researcher in the field, Dr Geeta Shroff has treated over 300 patients so far, many of whom are reportedly in better health

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[20]See "Clinic's Embryonic Stem Cell Therapy Worries Govt.," *Rediff News*, 16 November 2005, http://in.rediff.com/news/2005/nov/16stem.htm.

[21]"Clinic's Embryonic Stem Cell Therapy Worries Govt."

[22]"Clinic's Embryonic Stem Cell Therapy Worries Govt." However it is not clear that even after years of the treatment, to what extent has Jogi recovered, since he still remains disabled. However, there seem to be success stories in cornea reconstruction treatments in the L.V. Prasad Eye Institute in Hyderabad.

[23]See 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.

now.[24] And today she receives patients from all over the world.[25] However, how the clinic has succeeded in avoiding legal action against it is worth exploring. First of all, it did not have the necessary approval from ICMR, or the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). Second, it has not undertaken any of the mandatory clinical trials meant for such novel clinical treatment procedures.

Third, even the committee that was to be set up to inquire into the practices of the clinic, as announced by the then Health Minister, has not come out with any report. We are not even sure if a committee was even set up. Whatever the problems are, the director of the clinic gives the justification that she is right in administering the treatment because she says that the guidelines approve embryonic stem cell therapies if the condition of or disorder in the patient is considered incurable.[26] Since most of her patients are of that category, she feels justified. Besides, she has other justifications too, such as that, following the guidelines prepared by the ICMR, her procedures are evaluated by the institutional ethics committee and the patients are made to sign an informed consent document which clearly states that there is no guarantee of success with regard to the treatment, etc.[27] Since the proceedings of the institutional ethics committee are unavailable to outsiders, there is no way the public can come to know what transpired at these meetings.

> Countering criticism she's using vulnerable and disadvantaged people as guinea pigs, Shroff notes that 30% of her patients are physicians or have family members who are physicians. In other words, highly educated medical professionals who appreciate underlying issues have chosen to avail themselves of the treatment.
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> In addition, a number of senior government officials have been treated and, based on their comments to me, are delighted with the benefits. Documenting interest in her program at the highest levels, Shroff has briefed the Indian President and Prime Minister. Finally, showing that her program is more than just a profit-making venture, many of her indigent patients have been treated without charge.[28]

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[24]For details of the doctor's treatments and some life stories of patients who were treated and the after-effects of the treatment, see Laurance Johnston, "Embryonic Stem-cell Therapy," http://www.healingtherapies.info/hESC.htm#Overview.

[25]See Indo-Asian News Service (IANS), "Americans Flocking to India..."

[26]Johnston, "Embryonic Stem-cell Therapy." However, I have failed to find this clause in the guidelines.

[27]Johnston, "Embryonic Stem-cell Therapy."

[28]Johnston, "Embryonic Stem-cell Therapy."

However, with regard to charges, she agrees that she charges her American patients an average of $25,000.[29] With regard to the effectiveness of the treatment, while she claims more than 90 per cent success rates, many doctors and experts in the field express serious doubts about the success she claims. For example, Dr Wise Young, a leading US neuroscientist, from the Rutgers University in the U. S. says, "There is zero evidence for what she (Shroff) is doing being effective." In a similar vein Dr Sanjay Gupta, the CNN chief medical correspondent says, "Frankly it's the complete wrong way of going about with this sort of science." Dr P.N. Tandon, a leading Indian neurosurgeon, agrees that "there was zero medical evidence of the effectiveness of embryonic stem cell therapy like that provided at NuTech Mediworld."[30] However Dr Shroff disagrees with such criticisms and continues with her practices.

Dr Shroff, in fact, accepts that she does not treat the acutely injured patients because she feels that "critics would dismiss improvements" in such cases "as something that would have occurred anyway during a period in which functional gain is not uncommon."[31]

Nu Tech Mediworld is not the only clinic or hospital that is administering embryonic stem cell based treatments. There are a host of other well established and nationally known institutions in the country providing similar treatments. In 2005 the *All India Institute of Medical Sciences* (AIIMS), New Delhi, a premier health institution in the country "distributed information through newspapers on success in treating cardiac disease in humans by using stem cell transplants."[32] At a press conference, the then Director of AIIMS, Dr P. Venugopal said that stem cell therapy had been tested on 35 patients and all of them had positive results. He said,

> The patients selected for the procedure were all end-stage cases and we used the patients' own healthy cells, introduced them in the diseased area, and then allowed it to adjust to the local micro environment. The therapy worked in all the cases. Good results were noticed within six to 18 months. We now have brought in a robotic stem cell delivery system and will soon be offering the service to patients with muscular dystrophy, neurological disorders, cornea treatment and other ailments. The

[29]Indo-Asian News Service (IANS), "Americans Flocking to India..."

[30]Indo-Asian News Service (IANS), "Americans Flocking to India..."

[31]Johnston,"Embryonic stem-cell therapy."

[32]See Pandya, "Stem Cell Transplantation in India: Tall Claims, Questionable Ethics," 16.

> possibilities are infinite and we are trying to help as many people as possible with the technique, but *we are learning and doing new things each day*... We are now interested in making it available to as many people as we can .[33]

Even though no scientific reports were published or made available on the studies undertaken or on the clinical trials, the then Director General of ICMR, Dr N.K. Ganguly, openly supporting AIIMS, said that he "stood by the authenticity of the work by the Institute." He, in fact, encouraged similar efforts by other institutions, when he continued,

> We have no plan to legislate the guidelines that are in place for carrying out stem cell research. Besides the three other agencies that are doing the therapy in the country, we are not aware of any other company or organisation that is doing it. Carrying out stem cell therapy requires a lot of expertise and technology; standards need to be maintained and it is not possible in a small set-up... we will leave it to the medical profession to maintain a strict code of ethics.[34]

Such statements from an official of the agency that is supposed to be controlling and monitoring the developments in the field has only encouraged institutions that have an interest in the field of stem cell medicine. Leaving "the medical profession to maintain a strict code of ethics" in a country like India is to say that they are left free to do what they want, and that the government does not want to interfere in the undertakings (whether ethical or not) of these institutions. No surprise that today "AIIMS works on a wide spectrum of clinical applications in cardiology, ophthalmology, neurology, and hematology and also carries out basic research on... stem cells and biopolymers aimed at treatments for orthopedic, ocular, and skin diseases."[35]

However, the lack of co-ordination, communication as well as understanding among the officials within ICMR was clear when Dr Vasantha Muthuswamy, senior Deputy Director General and Head of Basic Medical Sciences at the ICMR, said regarding the same treatments began at AIIMS, "We are only a block away from AIIMS and we did not know this was happening there. If the nation's

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[33]Staff Reporter, "ICMR Okays Stem Cell Research by AIIMS," *The Hindu*, 5 April 2005, http://www.thehindu.com/2005/04/06/stories/2005040612771300.htm. Emphasis is added.

[34]Staff Reporter, "ICMR Okays Stem Cell Research by AIIMS."

[35]Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," 12.

premier medical institute did not ask our permission for such therapy, how can we blame private clinics for what they do?"[36]

Hyderabad is another city that started stem cell therapies even before Delhi. The privately owned, nonprofit hospital, *L.V. Prasad Eye Institute* (LVPEI) in Hyderabad pioneered stem cell treatment techniques as early as 2001. According to the institute, it has already used transplanted stem cells in hundreds of patients. By 2008, it had performed the treatment on more than 500 patients with damaged corneas, and had a success rate of over 70%. The treatment through "ocular surface reconstruction method" developed by the institute is considered today as "the best example of a homegrown Indian stem cell treatment that addresses local health needs" in the country.[37] In the city of Hyderabad alone, besides LVPEI, there are other hospitals practicing stem cell therapy. Some of them are reportedly specializing in the treatment of damaged heart muscles, as well as regenerating livers with cases of cirrhosis and pancreas in diabetes patients.[38]

The latest development in the sector of biomedicine is the involvement of huge business firms. Many of them have begun with umbilical cord blood banking and some have already started stem cell based treatments.[39] Indian firms *Life Cell* (in Chennai), *Cryo Stem Cell* (in Bengaluru), *Reliance Life Sciences* (in Mumbai), and *Chaitanya Stem Cell Center* in Pune are some of them. Many of these firms are also tied to international groups based in the United States and other countries.[40]

The government of India considers biotechnology as a "priority area" and expects its Biotechnology industry to generate $10 billion per annum by the year 2015.[41] Therefore, the Department of

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[36]For the full comment, see K.S. Jayaraman, "Indian Regulations Fail to Monitor Growing Stem-Cell Use in Clinics," *Nature* 434, no. 7031 (March 2005) 259. See also Sandhya Srinivasan, "Rogue Research in the Guise of Stem Cell Therapy," *Infochange*, March 2006, http://www.infochangeindia.org/features326.jsp.

[37]See Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," 12. The same page also reports who the beneficiaries are and the nature of their problems.

[38]See Jayaraman, "Indian Regulations Fail to Monitor Growing Stem-Cell Use in Clinics," 259.

[39]Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells for Health Needs in India," 12.

[40]For examples and details, see Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells..."

[41]See Business Standard Reporter, "Indian BioTech Industry to Reach $10 bn Mark by 2015," *Business Standard*, May 5, 2011, http://www.business-standard.com/

Biotechnology has allocated more than Rs. 300 crores (Rs. three Billion) over the last few years towards basic and applied research in stem cell technology.[42]

At present, four government departments are key supporters of stem cell research and development.[43] The pro-embryonic stem cell policy of the US, under President Barack Obama, has encouraged research organization in India even more. Research organizations and pharmaceutical companies are eyeing collaboration with US firms in the field since they can already sense future growth in the field of embryonic stem cell research. They are even "looking at partnering state-run research institutes to develop new drugs. Pfizer, for instance, recently signed an agreement with US-based Wisconsin Alumni Research Foundation for using human embryonic stem cells for development of new drug therapies."[44] Vishwa Mohan Katoch, the director general of Indian Council of Medical Research (ICMR) and Secretary to the Government of India's Department of Health Research, says that even ICMR has "planned to develop and initiate collaborative activities with US institutions for which proposals have been received."[45]

The government supports such initiatives with the argument that India can no longer wait for training more and more people in genetics and that it must plunge into the world of genetic treatments for the benefits of its people and its economy.[46] However, the current practices in many institutions across the country suggests that the country has a long way to go before it can reach anywhere near standards of scientific and ethical excellence enforced in most other countries, especially the developed nations.

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article/companies/indian-biotech-industry-to-reach-10-bn-mark-by-2015-111050500005_1.html.

[42]See Shishir Prasad, "Stem Cell Research: Advantage India" *Forbes India*, Feb. 6, 2010, http://forbesindia.com/article/briefing/stem-cell-research-advantage-india/9892/1.

[43]For details, see Lander, Thorsteinsdóttir et al., "Harnessing Stem Cells...," 13.

[44]Nina Mehta, "Obama Stem Cell Policy Will Boost India R&D," *Business Week*, 14 June 2009, http://www.businessweek.com/globalbiz/content/jun2009/gb20090614_078251.htm.

[45]Nina Mehta, "Obama Stem Cell Policy Will Boost India R&D."

[46]See K. Ghosh and D. Mohanty, "Teaching of Medical Genetics in the Medical Colleges of India — Way Ahead," *Indian Journal of Human Genetics* 8, no. 2 (2002) 43-44.

3. Ethical Challenges in the Context of India

Certain forms of stem cell therapy, like therapy for corneal blindness, bone marrow cancer, etc. have been found beneficial to many patients for whom conventional medicines were found ineffective. Although numerous institutions — hospitals and clinics — promise cure from the use of stem cells for a variety of problems and diseases like spinal cord Injury, Parkinson's disease, stroke and cardiovascular indications, diabetes mellitus, multiple sclerosis, muscular dystrophy, and genetic and hereditary diseases, many scientists and physicians refute such claims, especially as it is practiced today in the country, and they warn of unexpected cancerous formations or teratomas (monster tumors).[47] Also, serious ethical questions are raised with regard to present practices. Some of these questions are with regard to the type and source of the stem cells, the procedures undertaken and their goals, the lack of monitoring authority and clearly enforceable laws, and accessibility. Let us look at them.

3.1. The Source and Use of Stem Cells

The source of stem cells is an issue of controversy. Adult stem cells extracted from human body parts like blood, bone-marrow, etc. do not raise any ethical issues. They are supported and even encouraged. However, stem cells from embryos do raise many ethical issues. While the government of India has not put any objection on extraction of stem cells from left over embryos from IVF clinics, many religious faiths, including the Catholic Church, object to the use of embryos as the source of stem cells. For these faiths human embryo, even at the stage of zygote (one cell stage), has absolute moral value, equal to that of any other human person and, therefore, any embryo research that would harm the embryo is ethically unacceptable. According to the Catholic Church, "Human life must be respected and protected absolutely from the moment of conception" because "From the first moment of its existence, a human being must be recognized as having the rights of a person — among which is the inviolable right of every innocent being to life."[48] The Church also prohibits the production of "human embryos intended for

[47]See Michael Fumento, "The Greatest Stem-Cell-Research Scam," *New York Times*, July 15, 2009. Available at: http://nypost.com/2009/07/15/the-great-stem-cell-research-scam/.

[48]*Catechism of the Catholic Church*, no. 2270.

exploitation as disposable biological material."[49] It is opposed to any research that would harm or destroy human life at any stage and, "As far as the right to life is concerned, every innocent human being is absolutely equal to all others."[50] Therefore, while the use of adult stem cells is approved and appreciated, the use of embryonic stem cells / foetal stem cells is ethically unacceptable.

3.2. The Present Questionable Practices

The present practices in stem cell therapies raise many ethical questions, especially with regard to the safety and security of patients who opt for such therapies. According to the existing Indian Council of Medical Research – Department of Biotechnology (ICMR-DBT) *Guidelines for Stem Cell Research and Therapy* (2012)[51] it is clear that "Safeguards have to be in place to protect research participants receiving stem cell transplants, and patients at large, from receiving unproven stem cell therapies" (No. 1). It admits that there are "several elements of unpredictability in the translation of research in this area" (no. 5.2). Therefore, "the physician / scientist engaged in stem cell research and therapy shall ensure that no hype or unrealistic expectations is created in the minds of subjects or public at large regarding stem cell therapy" (no. 5.7). Besides, there are many requirements with regard to the registration of established human stem lines, compulsory clinical trials, etc. (nos. 6.5 & 6.6).

> As per ICMR-DBT guidelines there is no approved indication for stem cell therapy as a part of routine medical practice, other than bone marrow transplantation and corneal limbal cell treatments. Accordingly, all stem cell therapy other than BMT and corneal epithelial treatment shall be treated experimentally. It should be conducted only as clinical trial after obtaining approval from DCGI. This applies to both autologous & allogeneic clinical trials.[52]

However, these guidelines are clearly violated in practice today. First of all, most institutions that aggressively advertise their facilities and offers of stem cell therapies have never gone through any process of clinical trials. A Bangalore-based company, Stempeutics Research,

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[49] *Donum Vitae*, nos. 1, 5.

[50] *Evangelium Vitae*, no. 57.

[51] Indian Council of Medical Research Department of Health research & Department of Biotechnology (ICMR-DBT) *Guidelines for Stem Cell Research* (*2012*), New Delhi: ICMR, March 2012, http: / / icmr.nic.in / stem_cell_guidelines.pdf.

[52] "More Stem Cell Therapies to be Launched in Next Five Years," Pharmabiz.com, Jan. 17, 2013, http: / / www.pharmabiz.com / ArticleDetails.aspx?aid=73322&sid=11.

a group company of Manipal Education & Medical Group, is the only company in the country which is undertaking the right clinical trials with stem cells.[53] The other institutions have neither applied nor received the necessary permissions for their administration of stem cell therapies. It is very clear from the comments of Dr Vasantha Muthuswamy with regard to what was going on in AIIMS that she was not even aware of them.[54] Yet many advertise boldly the facilities they provide in stem cell therapies and assert that they have already gone beyond the clinical trial stages.[55]

Second, the hype that is created through advertisements makes it seem that these are proven therapies[56] and can mislead many patients into going for such therapies, even though these therapies are actually in clinical trials elsewhere. The reasons why many of these institutions go into therapy directly, without going through the normal procedure of clinical trials, are to make fast money and also to avoid governmental controls. However, as scientists and researchers have already pointed out, unproven stem cell therapies could be dangerous to the patients in the long run. Also, while these institutions make fast money any untoward outcome in the long run, like teratomas, in the patient will destroy their lives, both physically and financially. Already many in the country go for expensive, yet necessary, treatments on borrowed money and they land up in the vicious circle of dependence and poverty. Studies have shown that, on an average, "families in India devoted 58 percent of their total annual household spending to health care when a family member was hospitalized and, as a result, as many as 25 percent of families with a hospitalized member fell into bankruptcy after that

[53]See Biswarup Gooptu, "Startups Do Promising Work in Drug Development, Stem Cell Therapy and Advanced Diagnostics," *Times of India*, Sept. 25, 2013. Available at: http://timesofindia.indiatimes.com/business/india-business/Startups-do-promising-work-in-drug-development-stem-cell-therapy-and-advanced-diagnostics/articleshow/23027927.cms. See also Seema Singh, "Stem Cell Industry: The Battle Within," *Forbes India*, Feb. 12, 2013. Available at: http://forbesindia.com/article/real-issue/stem-cells-industry-the-battle-within/34697/1.

[54]See K.S. Jayaraman, "Indian Regulations Fail to Monitor Growing Stem-Cell Use in Clinics," 259; and Sandhya Srinivasan, "Rogue Research in the Guise of Stem Cell Therapy."

[55]For example, see Seema Singh, "Stem Cell Industry: The Battle Within." They assert that they do not do clinical trials; rather they provide "commercial stem-cell therapy." See also Chaitanya Stem Cell Center, Pune.

[56]For example, see Chaitanya Stem Cell Center, Pune; or IANS, "Americans Flocking to India for Stem Cell Therapy."

hospitalization."[57] High-end medicines like stem cell therapies can only exacerbate this situation, at least in the present circumstances.

Third, it is quite obvious that there is quite a lot of bluff and lies going on in the field. Our analysis of the practices that go on in many institutions like the *NuTech Mediworld* and *AIIMS* in Delhi, *Chaitanya Stem Cell Center* in Pune are all examples of this. The lure of profit or money and fame are clear here. For example, while on the one hand, we hear Dr Shroff saying that her program is more than just a profit-making venture and that many of her indigent patients have been treated without charge,[58] on the other, we also see that she charges her American patients an average of $25,000.[59] Profit is clearly the reason behind most of these institutions foregoing clinical trials and, at the same time, engaging in the practice of therapies. As Dr Alok Srivastava, head, Centre for Stem Cell Research at Christian Medical College in Vellore, rightly says, "The only reason it has not blown up as a major health care problem or come under greater public scrutiny is because in most cases the therapies offered are not harmful in the short term." And he warns that "for a biological 'drug' that isn't metabolised or excreted from the body, long-term monitoring is critical, as cells keep multiplying."[60] Therefore, while genuine stem cell research and clinical trials need to be supported, we need to be wary of unproven therapies for the common good in the long run.

3.3. Lack of Monitoring Authority and Enforceable Laws

As we have already seen, while the developed nations have strict laws regulating stem cell research, especially embryonic stem cell research, and clinical trials, India has only certain guidelines that are hardly enforced. Again, in those countries, strict regulation keeps the medical practices ethical and scientific. This ensures safety and security of the patients. What India needs is effective regulation and strict monitoring of practices underway in numerous institutions. Information given over the practices and facilities should be factual and not with the goal of inducing people for profiteering at all costs.

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[57]Ashok S. Bhattacharjya and Puneet K. Sapra. "Health Insurance in China and India: Segmented Roles for Public and Private Financing." *Health Affairs* 27, no. 4 (July-Aug. 2008): 1006.

[58]Laurance Johnston, "Embryonic stem-cell therapy."

[59]Indo-Asian News Service (IANS), "Americans Flocking to India for Stem Cell Therapy."

[60]Seema Singh, "Stem Cell Industry: The Battle Within."

The regulatory agencies in the country often refuse to act effectively while individuals and institutions flout all guidelines and standards. While political clout often determines regulations, the lives of many could be endangered.[61] Given the socio-political situation in India even if experiments or trials go seriously wrong and lives are lost or risked, the offenders could still escape unnoticed by the public and the offence hushed up by the irresponsible agencies. This is possible because as Shroff says the patients have signed the consent form. However, the public hardly understands how flawed and sloppy the procedures in getting the consent are. Dr Vasantha Muthuswamy makes this point very clear when she says that the quality of informed consent of the participants involved in clinical trials is very suspect. She says that very few centres of clinical trials explain to the participants that they are part of a trial group. Often, gaining consent is as short as the doctor saying, "We are doing this treatment, we are going to use this medicine, we think it will work," and the patient says immediately, "Yes, we agree."[62] Moreover, most of these trials are done in hospitals on patients who have few options and, therefore, are a real vulnerable population, which again is against the guidelines. She agrees that there is no one to oversee or monitor the institutional ethics committees. This naturally is the reason for the wrong people getting into the institutional boards. The sad state of affairs cannot be clearer than when she says 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."[63] This statement alone can give us a picture of what can and is going on in the country. It is clear that the emphasis in the country is misplaced on an inflow of foreign capital or on making profits at the expense of unsuspecting, yet needy or desperate patients. Such a situation demands a proper monitoring authority and enforceable laws. Of course, in a country like India, where the corrupt politician-bureaucrat nexus is very strong, this is a herculean task. Therefore, the involvement of genuine NGOs and individuals of good social standing in the advisory and enforcement agencies needs to be looked into.

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[61]See Pandya, "Stem Cell Transplantation in India: Tall Claims, Questionable Ethics," 17.

[62]See Sandhya Srinivasan, "India Being Projected as a Global Hub for Clinical Trials," *Infochange*, Dec. 2005, http://infochangeindia.org/public-health/features/india-is-being-projected-as-a-global-hub-for-clinical-trials.html.

[63]See Sandhya Srinivasan, "India Being Projected as a Global Hub..."

3.4. Accessibility

It is estimated that the stem cell market today is worth $1.2 billion and it grows at the rate of 30% per annum. It is expected that it would reach around $16 billion by the year 2017. The Indian market is estimated to be $600 million by then. Nearly 4,300 clinical trials are said to be going on in this field worldwide.[64] Since millions are pumped into these experiments and development of these therapies, it is expected that the price of these treatments too will be beyond the reach of the ordinary people who are in most need of them. While the so-called therapy costs of Rs 2-3 lakhs (Rs 0.2-0.3 million) onwards in little known clinics in Pune, clinics like the NuTech Mediworld in Delhi charges an average of $25,000 (Rs 1.5 million), from the overseas patients.[65] Such exorbitant charges are beyond the means of majority of Indians. This is where strict monitoring and regulation together with government funding of beneficent projects in the field can help in making the new medicines accessible to the needy, irrespective of their ability to pay.

4. Conclusion

While stem cell therapies seem to hold much promise to the sick, for whom conventional medicines are found to be ineffective, there is much ground to be covered in order to make them available and affordable to the needy. While safety measures seem to be the biggest challenge to be overcome, issues like victimization or sacrifice of unborn human beings, unethical practices, profiteering, accessibility, etc. too are serious challenges that need to be overcome. Well articulated, enforceable policies and a strict monitoring authority will help in the right practices, and these together with government funding should make them available and accessible to the general public, especially the poor and the disadvantaged who are the ones in most need of them.

[64]Seema Singh, "Stem Cell Industry: The Battle Within."
[65]Seema Singh, "Stem Cell Industry: The Battle Within."