TRANSPLANTATION OF HUMAN ORGANS: A CRITICAL ANALYSIS

Written by **Prateek Gupta**

Solicitor

ABSTRACT

Human trafficking is an antiquity and has possessed almost all civilizations and cultures in various forms and dimensions. It is a trade that exploits the vulnerability of human beings, especially women and children and leads to complete violation of their human rights. It makes living beings an object of monetary transactions through the use of force, duress or deception, for various purposes, chief among them for commercial sexual exploitation and for exploitative labour. India, one of the largest democracies in the world, has constitutionally prohibited traffic in human beings and has enshrined the right to be free from exploitation as a fundamental right of every person and contravention of same is also made punishable. Apart from human trafficking for purposes of sexual exploitation and forced labour, one of such exploitation extends to trafficking of human organs and transplantation of human organs with or without their consent of the person so concerned. Thus, it can be said emphatically that illegal trafficking of human organs is corollary of human trafficking only.

At a stage where a particular organ of a patient becomes dysfunctional, the only cure is replacement of that dysfunctional organ with a healthy organ of some other person and in simple words it can be termed as transplantation of human organ. However, the procurement of organs for transplantation involves the removal of organs from the body of one person and replacement of same by organ of another person. Thus, this transplantation must follow legal requirements, including the definition of death and consent. Accordingly, in light of these legal requirements and formalities, it becomes essential to understand the distinction between "Organ transplantation and Organ trafficking".

In the globalization era, organ trafficking has become quite synonymous with human sacrifice being witnessed by a widespread violation of human rights.ⁱⁱ Witnessing some inherent issues like the right to life of the patient (Donor) and the recipient (Donee) and the question of

ownership upon such organs especially in cases where donors are still breathing received distinct opinions of experts and liberals.

Like in other parts of the world, India also witness shortage of supply over exceeding demand, issue of adequate mechanism with difficulty in categorizing criminal liability in the process of illegal transplantation from donor to recipient lacking adequate data in spite of a enacted legislation like the Organ Transplantation Act, 1994 reflecting thereby the glimpse of an ever expanding illegality of the organ trade.

The core legislation related to organ donation and transplantation in India is Transplantation of Human Organs Act 1994 and is aimed at regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs.

ORGAN TRANSPLANTATION IN GLOBAL SCENARIO

Since after the first successful kidney transplantation at Peter Bent Hospital in Boston in 1954 on identical twins along with the discovery of cyclosporine, rejection and loss of graft, organ transplantation become easier. iii In spite of prominence of various International documents in preventing organ trade, the global community at large can be divided into organ importing and organ exporting countries. The live donors have been brought from Moldova, Nepal, India, and Pakistan to US, UK, Canada and other wealthy Nations regarded as organ importing countries. Asia is still regarded as the hub of organ trade. In 2001 and 2002 in South Africa, the investigating officers found out that there had been international organ trafficking where most recipients came from Israel and donors came from East European countries. The Sindhu Institute of Urology in Pakistan held that 2000 renal transplants were performed in 2005 where 2/3 rd were performed on foreigners. In China, there has been a law named Rules Concerning the utilization of Organs from Corpuses of Executed Prisoners, 1984 where kidney and liver organ trade of the executed soldiers have been legalized.

In USA, the main law relating to organ transplantation is the National Organ Transplantation Act 1984 comprising several provisions to prohibit organ trafficking in between the States for financial gain. In 1968 a Uniform Anatomical Gift Act was adopted to facilitate heart and kidney transplantation. This particular Act had gone several changes in 1987 adopted by 50 states from which year legislative provisions favoring presumed consent had been provided

where a person of 18 years or above have the liberty to choose or not to choose to make anatomical gift to take effect after death. Further, in 2006 this piece of legislation had made several amendments where even a minor can take the decision to donate after death and different states like Nevada, Arizona and California have applied the UAGA in different manner particularly with respect to penalties. The United Network for Organ Sharing (UNOS) long with US Department of Health and Services manages and procures organ for entire US. Very recently, President Bush adopted the Organ Donation and Recovery Improvement Act financially supporting the living donors, the State of Wisconsin provided them with tax reduction of \$10,000 for medical costs and lost salary.

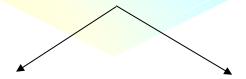
In contemporary world illegal organ trade market is carried out at an alarming rate and the organ importing countries or richer Nations through such trade revived third world exploitation. Organs Watch revealed that still every year 30-50 patients from Canada undergo commercial kidney transplants from donors of third world countries. xiii

The underlying challenge of lack of adequate data and most Nations States differential treatment in handling this sensitive issue made the situation worse.

ORGAN TRAFFICKING IN INDIA

India in past operated in 1967 first successful cadaver kidney transplant in Mumbai following the 1994 first successful heart transplant at AIIMS, Delhi to 1995 first multi organ transplant at Chennai^{xiv}. In India, scenario of the organ trade can be divided into two main phases-

ORGAN TRAFFICKING



Pre-enactment Era

Post enactment Era

(Before existence of any substantive law) (After Transplantation of human organ act 1994)

PRE-ENACTMENT ERA (AFTER ENACTMENT OF TRANSPLANTATION OF HUMAN ORGANS ACT 1994)

Before enactment of Transplantation of human organs act 1994, the systematic regulation of transplantation of human organs was only a myth. The concerned procedure suffered various difficulties as there was no particular law or statute which was especially enacted by the legislature of the state regarding this concept. This difficulty gave rise to illegal trade of human organs and offences like kidnapping, human trafficking, selling of minor children & orphans etc for the purposes of illegal trade of human organs. Shockingly, various hospital and health care authorities were part of such offences in order to satisfy their pecuniary benefits and needs. Cases of Child mafia, Begging mafia, Prostitution etc soon sat on the peak of the society as they showed their interest in selling their subjects for purposes of illegal Trade of Human Organs. In light of such circumstances, legislature felt important to enact a particular law regarding Transplantation of human organs.

POST ENACTMENT ERA (AFTER ENACTMENT OF TRANSPLANTATION OF HUMAN ORGANS ACT 1994)

Reports of large-scale unauthorized kidney transplants in various parts of the country paved the way for this new Act, the main purpose for which was to regulate storage and transplantation of human organs for therapeutic use, preventing any commercial dealings. Also, this Act has been passed only in the States of Maharashtra, Goa and Himachal Pradesh has commercialized the concept of brain death. The other States where the Act is not governed comes under the ambit of Section 326 of Indian Penal Code, 1860.

However, the Act had suffered numerous miscarriages like under Section 3(2) only a near relative (a relative, spouse or a donor out of love and affection) can donate without any monetary transactions indirectly permitting illegal kidney marriages. Further there has been a gross misuse of section 9(3) where a person not being a close and near relative can even donate his organ to the recipient out of mere love and affection; hence it was reasonable to assume that money can change hands between middlemen and lack of adequate stringency since such offence was non cognizable offering very less penalty amount of Rs 10, 000 and of five years punishment.

LAWS AND RULES GOVERNING ORGAN TRANSPLANTATION IN INDIA

The primary legislation related to organ donation and transplantation in India, Transplantation of Human Organs Act, was passed in 1994 and is aimed at regulation of removal, storage and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs.

In India, matters related to health are governed by each state. The Act was initiated at the request of Maharashtra, Himachal Pradesh and Goa (who therefore adopted it by default) and was subsequently adopted by all states except Andhra Pradesh and Jammu &Kashmir. Despite a regulatory framework, cases of commercial dealings in human organs were reported in the media. An amendment to the act was proposed by the states of Goa, Himachal Pradesh and West Bengal in 2009 to address inadequacies in the efficacy, relevance and impact of the Act. The amendment to the Act was passed by the parliament in 2011, and the rules were notified in 2014. The same is adopted by the proposing states and union territories by default and may be adopted by other states by passing a resolution.

The main provisions of the Act (including the amendments and rules of 2014) are as follows:

a. Brain death identified as a form of death. Process and criteria for brain death certification defined (Form 10)

b. Allows transplantation of human organs and tissues from living donors and cadavers (after cardiac or brain death)

c. Regulatory and advisory bodies for monitoring transplantation activity and their constitution defined

 Appropriate Authority (AA): inspects and grants registration to hospitals for transplantation enforces required standards for hospitals, conducts regular inspections to examine the quality of transplantations. It may conduct investigations into complaints regarding breach of provisions of the Act, and has the powers of a civil court to summon any person, request documents and issue search warrants.

- ii. Advisory Committee: consisting of experts in the domain who shall advise the appropriate authority
- iii. Authorization Committee (AC): regulates living donor transplantation by reviewing each case to ensure that the living donor is not exploited for monetary considerations and to prevent commercial dealings in transplantation. Proceedings to be video recorded and decisions notified within 24 hours. Appeals against their decision may be made to the state or central government.
- iv. Medical board (Brain Death Committee): Panel of doctors responsible for brain death certification. In case of non-availability of neurologist or neurosurgeon, any surgeon, physician, anaesthetist or intensivist, nominated by medical administrator in-charge of the hospital may certify brain death.
- d. Living donors are classified as either a near relative or a non-related donor.
 - i. A near-relative (spouse, children, grandchildren, siblings, parents and grandparents) needs permission of the doctor in-charge of the transplant center to donate his organ.
 - ii. A non-related donor needs permission of an Authorization Committee established by the state to donate his organs.
- e. Swap Transplantation: When a near relative living donor is medically incompatible with the recipient, the pair is permitted to do a swap transplant with another related unmatched donor/recipient pair.
- f. Authorization for organ donation after brain death
 - i. May be given before death by the person himself/herself or
 - ii. By the person in legal possession of the body. A doctor shall ask the patient or relative of every person admitted to the ICU whether any prior authorization had been made. If not, the patient or his near relative should be made aware of the option to authorize such donation.
 - iii. Authorization process for organ or tissue donation from unclaimed bodies outlined.

- g. Organ retrieval permitted from any hospital with ICU facility once registered with the appropriate authority. Any hospital having Intensive Care Unit (ICU) facilities along with manpower, infrastructure and equipment as required to diagnose and maintain the brain-stem dead person and to retrieve and transport organs and tissues including the facility for their temporary storage, can register as a retrieval center.
- h. Cost of donor management, retrieval, transportation and preservation to be borne by the recipient, institution, government, NGO or society, and not by the donor family.
- i. Procedure for organ donation in medico-legal cases defined to avoid jeopardizing determination of the cause of death and delay in retrieval of organs.
- j. Manpower and Facilities required for registration of a hospital as a transplant center outlined.
- k. Infrastructure, equipment requirements and guidelines and standard operating procedures for tissue banks outlined.
- 1. Qualifications of transplant surgeons, cornea and tissue retrieval technicians defined.
- m. Appointment of transplant coordinators (with defined qualifications) made mandatory in all transplant centers.
- n. Non-governmental organizations, registered societies and trusts working in the field of organ or tissue removal, storage or transplantation will require registration.
- o. The central government to establish a National Human Organs and Tissues Removal and Storage Network i.e. NOTTO (National Organ & Tissue Transplant Organization), ROTTO (Regional Organ & Tissue Transplant Organization) and SOTTO (State Organ & Tissue Transplant Organization). Website www.notto.nic.in. Manner of establishing National or Regional or State Human Organs and Tissues Removal and Storage Networks and their functions clearly stated.
- p. The central government shall maintain a registry of the donors and recipients of human organs and tissues.

q. Penalties for removal of organ without authority, making or receiving payment for supplying human organs or contravening any other provisions of the Act have been made very stringent in order to serve as a deterrent for such activities.

CHALLENGES IN ORGAN TRANSPLANTATION – INDIA

A. Systemic issues

- a. In spite of periodic amendments to the Organ Transplant Act in the recent past, there has not been a significant change or increase in the overall donation numbers or to the establishment of a donation system within the country (apart from a few states, discussed later).
- b. In the case of living organ donations (from a living donor to a recipient), if the donor is not related to the patient, the transplant needs to be approved by a state-level committee or hospital committee, including government officials. Naturally these requirements lead to delays in the whole process.
- c. In the case of deceased organ donations, few hospitals declare brain deaths and people are not in place to counsel families, both of which lead to a poor conversion rate. Brain death as a form of death is not widely understood or recognized by the public. Also, there is hesitation on the part of the medical fraternity to certify brain death. This has to change if the organ donation rates have to be increased.

B. Infrastructural and skilled Personnel problems

Few hospitals are equipped in terms of the required personnel (qualified doctors and trained transplant coordinators) and equipment to conduct a successful transplant.

a. Ventilators for maintaining brain dead persons are not available everywhere. Limited facilities for transport of donated organs aggravate the situation. Very few specialized private hospitals can boast of standard infrastructure for carrying out a smooth organ transplant process. The situation worsens in case of public hospitals, which account for witnessing majority of such cases.

b. Lack of training for intensive-care unit personnel to maintain brain dead person, is also a constraint according to a number of doctors surveyed in our study.

c. A big percentage of doctors are unaware of the process as a whole a about the idea of brain death since it is not part of their formal education curriculum (as told by a respondent).

C. Lack of awareness, religious and other issues.

Lack of awareness remains one of the leading reasons for such low organ donation rates in India. There are no structured/focused awareness initiatives or drives to help people understand the what, why or how of organ donation. While some NGO's are making efforts, these are at best – drops in the ocean.

It is a usual refrain that people in India do not sign up for organ donation, but in reality, there are hardly any platforms available for 'sign up'. Most people have never been offered this opportunity in their life time. Many don't know where to go even if they are aware and willing.

Religious beliefs also may be a reason why families do not agree to deceased organ donation. The idea of charity and perceptions about donation varies from one community to another. The religious mindset together with the unpleasant experiences in the health sector faced by people is detrimental to the improvement of the organ transplant scenario in India.

An assurance about the system that these organs will be utilized for good and not be a commoditized in the organ market (more so in the black market rackets) may encourage organ pledges.

The idea of a commodity and charity are viewed as distinct and the donor/donors family would not want their charity to be a monetary gain for someone else.

D. Lack of a centralized registry for Organ Donation unlike other countries

India does not have any centralized system in place to enable/assist donors or medical institutions. There is no centralized list of potential recipients being available to different hospitals so that organs could reach the right people in time. Apart from a few states, there

is no sharing protocol in place in the rest of India. This leads to unethical and unhealthy practices. Further, it leads to wastage of organs which is a shame when a family has taken this courageous decision to donate.

E. Expectation of the possibility of organ rejection

Certain studies reveal that technically there is always a possibility that the patient might face a rejection, wherein the body fights off the newly implanted organ even if the surgery goes well. Rejection is harmful to transplant success because the body fights off the new organ as if it were a virus or bacteria akin to any other harmful foreign invader. The immune system makes proteins called anti-bodies that go to the transplanted organ and try to kill it.

In order to hold back the antibodies that threaten the new organ, transplant patients have to take powerful additional immunosuppressant drugs to keep the level of antibodies down, low enough to allow for the organ to integrate into the body.

In India where health services are seemingly expensive for the average person, the ability to afford a transplant operation is beyond the common man's means, especially at a private hospital. The added risk that the organ may not benefit the patient is a negative add-on. Therefore, a majority of patient and patient parties back out due to the uncertainty quotient clubbed with the amount of financial drain out it leads to. This is also in certain ways connected to the fact that health insurance in India still does not have a good enough reach. Most people are not even aware of how they could arrange funds. Cumulatively, it leads to discouragements in a number of ways.

AMENDMENT

The Delhi High Court set up a Committee in 2004 to examine the provisions of 1994 Organ Transplantation Act. Thereafter the new Amendment Bill which passed in Rajya Sabha in 2009, finally came into being in form of fully fledged enactment on February 2011further being extended to West Bengal. ⁵³The Act also permits donations from living persons with inclusion of grandparents and grandchildren. Further, the important notable changes in the new Act are that the Intensive Care Unit (ICU) doctors are now bound to inform the patient or relative about the option of organ donation and ascertain whether they would consent to the donation and in

case of breach of provisions penalty has been extended to 10 years and fine of 5- 20 lakhs.⁵⁴ Furthermore, there are also new provisions of Organ Swapping, Organ Retrieval Agencies⁵⁵. However, it is still not clear that whether increasing penalty provision would curb commercial organ dealing. ^{xv}There have been expert opinions favoring cadaver donations and also granting of financial incentives along with health insurance package for the live donors.

However, still the new Act is not immune from criticisms, like the ever-existing problems are problematic jurisdictions of the Authorization Committee where donor and recipients are from different States.^{xvi}

The role of Advisory Committees^{xvii} under the present Act is not clear so the functions of the Advisory Committee. Still in India the concept of brain stem death is not known to many medical professionals and only very few private hospitals in metropolitan areas have adequate infrastructure.^{xviii}

LANDMARK CASES

Dr. Shyam Sundar Prasad vs State of Bihar (2007 (1) BLJR 382, 2007 CriLJ 1989, 2007 (1) JCR 481 Jhr)

I do find that though the appellant was charged under Section 109 of the Indian Penal Code for abating the offences committed under Sections 326, 327 and 328 of the Indian Penal Code but the appellant was convicted under Section 109 of the Indian Penal Code for making abatement in consequence of which offences under Sections 18, 19, and 20 of the Transplantation of the Human Organs Act has been committed, whereas no charge was framed under Sections 18, 19, and 20 of the Transplantation of the Human Organs Act either against this appellant or the other accused. Therefore, the order of conviction and sentence passed under Section 109 of the Indian Penal Code is quite illegal, Similarly, the order of conviction and sentence passed under Section 201 of the Indian Penal Code is quite erroneous as it has been held by the court that the appellant caused the evidences of commission of the offences under Sections 18, 19, and 20 of the Transplantation of the Human Organs Act disappeared, but no such charge has been framed, rather charge has been framed under Section 201 four causing the evidence of the offences under Section 307, 326, 328 and 420 of the Indian Penal Code disappeared. Moreover, as has been discussed above, I do find that there has been absolutely no evidence to show that documents relating to the Nursing Home were caused to be disappeared intentionally from

screening himself from any illegal Act. In the circumstances, the order of conviction and sentence passed by the court below is hereby set aside: Consequently, the appeal is allowed and the appellant is hereby acquitted of the charges levelled against him and is discharged from the liability of the bail bonds.

Santosh Hospitals Private ... vs State Human Rights Commission

Both the Writ Petitions are disposed of with a liberty to the petitioner-Hospitals to put-forth their case before the State Human Rights Commission, Tamil Nadu as well as the state Appropriate Authority under the Transplantation of Human Organs Act, 1994. It is made clear that both the Authorities are directed to consider the case of the petitioner-hospitals uninfluenced by their observation/conclusion in their letter/Notice for enquiry in accordance with the provisions of the Act and the Rules as well as in compliance with the principles of natural justice. No costs. Consequently, connected Miscellaneous Petitions are closed.

Balbir Singh vs The Authorisation Committee (AIR 2004 Delhi 413)

Based on the date available on the transplantation of organs and the working of the. Authorization Committees, the Committee to examine and make its recommendations on the composition of Authorization Committees and changes, if any, required to ensure timely permissions.

- Whether the jurisdiction of the Authorization Committees should be enlarged by bringing within its ambit the process of certifying a "near relative" or the task be assigned to another Designated authority?
- Review the provisions of the Act and Rules based on the experience of transplantation of organs as carried out and the difficulties arising due to the bottlenecks faced in the said process. The Committee to examine in particular provisions of Section 9 and requirement of carrying out the tests prescribed in Rule 4, certification in Form 3 to review the definition of "near relative" and make its recommendations in the light of the observations made:-
- Examine and specify the organs for transplantation of which the tests prescribed in Rule 4(1)(c) to establish the factum of being "near relative" need not be carried out when other evidence is available.

- Examine the feasibility of establishing and setting up Organ Procurement
 Organizations with data bank to facilitate the dissemination of information on
 availability of organs for transplantation. To encourage organ donation especially
 from cadavers, cases of brain-stem deaths and other deceased persons, who had
 authorized removal of organs upon demise.
- Examine the feasibility of creation of a fund, the corpus to be provided partly come from the Union of India and partly by levying a fixed charge on the total bill of the hospital for transplantation and/or public donations, for providing to a donor social incentives, medical aid and facility of transplantation of organ in future, should the same be required.
- Examine and recommend ways and means to give social incentives, including but not limited, to help and aid and preferred health care, recognition and honour to a donor in the community.
- Examine the causes that lead to exploitation of poor and unaware persons in the
 process of organ donation and suggest methods to reduce, control and ultimately
 eradicate such mal-practices. Recommend programmes for dissemination of correct
 information of ethical, legal and devising procedure concerning organ donation so
 that a conducive atmosphere is generated and disinformation and misgivings are
 dispelled.
- Any other matter relevant to the subject.

The composition of the Committee shall be the following: -

- (i) Secretary, Ministry of Health or his nominee being an officer not less than the rank of Additional Secretary, Ministry of Health, as the Convenor.
- (ii) Director General of Health Services or the Addl. Director General of Health Services as the Member Secretary.
- (iii) The Head of Department of Surgery, AIIMS;
- (iv) Dr. Harsh Johri, Renal Surgeon, Sir Ganga Ram Hospital,
- (v) Secretary of the All India Medical Association; and
- (vi) Mr. Sanjay Jain, Advocate, Chamber No. 488, New Chambers Block, Delhi High Court, New Delhi.

The Committee to give its report and recommendations to the Government within four months. Copy of the same be placed on record.

Shri Hitesh Kishorechand ... vs The State of Maharashtra

Punishment for removal of human organ without authority:

Any person who renders his services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner in, the removal of any human organ without authority, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten thousand rupees."

A plain reading of the above provision would make it manifest that the removal of human organ may be punishable under section 18 in case it is so done for purpose of transplantation and that too without authority. The provisions contained in the Transplantation of Human Organs Act, 1994, basically are aimed at arresting the evil of trading in human organs for transplantation. The Preamble thereof declares the aims and objects of the Act. There is no need of mincing words to ferret out correct meaning of the expressions used in section 18 (1) if the same is considered conjointly with the aims and objects of the Act. It follows, therefore, that removal of human organ during course of medical treatment or the operation without any kind of nexus with misuse of the same for transplantation will not come within ambit of section 18. There is absolutely nothing on record to show that the removal of uterus was done with a view to misuse it commercially for transplantation. It is nobody's case that the petitioners are dealing in any kind of racket of human organs, for misuse to gain monetary benefits.

There is no doubt in my mind that the acts complained of in the FIR do not come within ambit of section 18 of the Transplantation of Human Organs Act, 1994 and, therefore, charge could not have been framed against the petitioners for the said offences, nor the charge could have been framed for offence punishable under section 328 read with section 34 of the I.P.C. The material on record, even if taken as it is, would not crystalize any ingredient of the said offences. The petitioner's request for discharge could have been considered as a request for alteration of the charge. They were not asking for full-fledged discharge from all the offences and in the entirety.

Considering these aspects of the matter, this is a fit case in which a part of the impugned charge must be pruned to the extent of one under section 328 read with section 34 of the I.P. Code and

section 18 of the Transplantation of Human Organs Act, 1994.

In the result, the petition is allowed. The learned Sessions Judge shall delete the charges referred to above by alteration of the same and may add charge for offence under section 279 and/or 337 of the I.P.C. The remaining part of the charge, however, is kept intact and the trial may proceed to the extent of such remaining part of the charge, along with added charges.

CONCLUSION

In India, one can witness that due to lack of substantial evidence regarding the happening of crimes since are wrapped in secrecy and corruption. It is still very difficult to pin point the criminal responsibility and actual perpetrators. The demand ratio will immortally surpass the supply in the organ trade unless the Nation strictly makes a legitimate organ market and endeavours' a sustainable alternative income support for the poor people. The Medical Council of India must also be serious about imposing strict regulations on doctors and hospitals. There is also an urgent need for a binding International treaty on organ trafficking. In India now like other world nations favoring presumed consent system, so the new Amendment act of Transplantation of Human Organs is an applaudable achievement but it will remain only in paper unless the Government takes serious note of other social factors like - poverty, unemployment and legitimizing organ trade in India. For the time being, one can certainly hope that if these actions are taken firmly, the future of organ market in India will be much improved, standing out on a different pedestal in Asian continent.

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- xvi Ibid. In Kuldip Singh & another vs State of Tamil Nadu and others, Appeal (civil) 156 of 2005, March 31, 2005, the Supreme Court on basis of a petition regarding the dispute as to place of Authorization Committee from both donor and recipient belonging to Punjab and concerned transplantation in the hospital in Tamil Nadu the Supreme Court gave the judgment that the Authorization Committee of Punjab will entertain the matter.
- xvii Ibid.Clause 13(A) under the New Act provided for creation of Advisory Committee.
- xviii Supra at note 42.