Regulation in Health Care in Tamil Nadu (India):

A study of the implementation of Transplantation of Human Organs Act (THOA) 1994, and Consumer Protection Act (CPA) 1986.

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GLOSSARY OF ABBREVIATIONS USED

AA	Appropriate Authority
AC	Authorisation Committee
AIR	All India Report
CGHS	Central Government Health Service
CPA	Consumer Protection Act, 1986
CPR	Consumer Protection Reporter
CWF	Consumer Welfare Fund
DCIC	District Consumer Information Centre
DME	Director of Medical Education
DMS	Director of Medical and Rural Services
ESRD	End Stage Renal Disease
NGO	Non-governmental Organisation
TC	Transaction Costs
THOA	The Transplantation of Human Organs Act, 1994
TN	Tamil Nadu
VCO	Voluntary Consuer Organisation

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Abstract

The functioning of healthcare sector could be substantially influenced by the design and implementation of regulatory policies that govern the behaviour of various stakeholders. The empirical challenge is to assess whether and how far have regulations brought about "desirable and intended" changes in the functioning of the healthcare delivery system. In this study, we assess the experience of the Consumer Protection Act (1986) and the Transplantation of Human Organs Act (1995). In particular, we address the following questions:

1. Have CPA and THOA been able to achieve their stated goals?
2. What factors have influenced their effective implementation? and
3. How have various stakeholders responded to these regulatory mechanisms?

Our empirical analysis shows that both CPA and THOA have not been effective in bringing about desirable changes. Commercialization of human kidneys is as common as before the introduction of THOA. Also, CPA has become more complex, long-drawn and expensive over the years, while it was meant to be a simple, quick and inexpensive legal mechanism. The present study highlights several underlying causes, including administrative, procedural, institutional and transactional costs that have influenced the effective implementation of these regulatory measures in the context of Tamil Nadu (India).

We have used a variety of primary and secondary sources in recording our observations. Official records, in-depth personal interviews and workshops were used as part of our methodology. The study is confined to the experience in the state of Tamil Nadu, but we believe that our observations will hold good to a large extent to other parts of the country as well.

Chapter 1: Introduction

During the past decade, a number of regulatory measures have been introduced by the Government of India (GoI) to improve the overall functioning of the health care delivery system in India. Some of the notable ones in this context are: The Medical Termination of Pregnancy Act 1971, The Consumer Protection Act 1986, The Prenatal Diagnostic Techniques (Regulation of Misuse) Act 1994, The Transplantation of Human Organs Act 1994, The Biomedical Waste Disposal Management Act, 1992.

Although, healthcare is largely a State subject[1], the Government of India continues to exert substantial influence on the overall performance of state health care system through both funding and regulatory measures. Such funding and regulatory policies expect a change in the functioning and structure of health care delivery systems in the long run.

In very broad terms, the purpose of this study is examine how far such regulatory measures have brought about expected changes in the functioning of the healthcare system in the country. As part of the analysis, we shall attempt to throw light on various factors that hinder or promote effective enforcement of such regulatory policies.

With this broad objective, we propose to analyze the experience and effectiveness of two specific regulatory measures, namely the Consumer Protection Act (CPA) 1986 with specific reference to healthcare professionals and The Transplantation of Human Organs Act (THOA) 1994. Both these regulatory measures were introduced by the Government of India and were later adopted by several state governments.[2] Although, our empirical analysis is confined to the experience in Tamil Nadu, many of our observations may hold good for several other states as well. At present, there are very few empirical studies on the effects of regulatory policies in health sector. Our present study is an attempt to filling this gap in the literature on the regulation of the healthcare market in India.

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[1] Constitution of India classifies healthcare in concurrent list.

[2] Although CPA was introduced in 1986, medical services were brought under its purview only in 1995. This is discussed in chapter 2.

The report is organized as follows: In Chapter 2 we describe the salient features of CPA and THOA. In Chapter 3, we present the methodology of this study. In Chapter 4 we present our analysis of the factors that have influenced the implementation of CPA and THOA. In Chapter 5 we conclude with observations on the state's capacity to regulate healthcare sector in general and the limits to which regulations can play a role in influencing the functioning of healthcare market in India in the future.

Chapter 2: Objectives and Features of CPA and THOA

Part I of this chapter describes the basic objectives and features of the Consumer Protection Act. Part II deals with the objectives and features of the Transplantation of Human Organs Act.

Part I

2.1. CONSUMER PROTECTION ACT (CPA), 1986

In 1995, the United Nations provided certain guidelines for governments to frame laws for better protection of the interests of the consumers. This was made with the intent to protect the consumers and provide relief, which was simple, less expensive and speedy, in the event of any hardship.

The existing civil and criminal laws in India, which were meant to protect the consumers, have suffered high costs of litigation, delay in the delivery of justice, limited access to the courts and procedural intricacies. Similarly, most of them were punitive in nature and not compensatory.

These problems raised the necessity for providing an alternative, separate and comprehensive consumer protection legislation, which could provide for speedy, simple and inexpensive relief or compensation to the consumers. This led to the passing of Consumer Protection Act (CPA) by GoI in the year 1986. At the time of introduction of this Act, it was considered the most comprehensive piece of legislation enacted for the protection of the consumers. CPA has undergone several amendments in its provisions in 1991, 1993, 1996, 2001 and 2002.

2.2. Structure of CPA

CPA is broadly divided into six chapters containing 31 sections[3]. Chapter I provides the applicability of the Act along with certain definitions. Chapter II provides for the establishment, constitution, powers and functions of the Consumer Councils. Chapter III deals with the three-tier consumer redressal machinery at the district, state and central (federal) levels and the procedures to be adopted, awards passed by the machinery, appeals

[3] Refer to Appendix I for the Act

by the aggrieved to higher authority, limitation of filing complaints and appeals, dismissal and penalties of frivolous complaints. Chapter IV deals with other miscellaneous provisions. Consumer Protection Rules (CPR) were by the Central Government to supplement the provisions of the Act. Respective State Governments have passed their rules (e.g. Tamil Nadu Consumer Protection Rules[4]) on the functioning of the redressal machinery.

2.3. Objectives and salient features of the Act

The primary objective of CPA is to provide "*for better protection of the interests of consumers and for that purpose to make provision for the establishment of consumer councils and other authorities for the settlement of consumer's disputes and for matters connected therewith*".

Thus it intends to provide "*simple, inexpensive and speedy redressal of the grievances of the consumers*[5] *with complaints against defective goods, deficient services and unfair and restrictive trade practices*".

2.4. CPA and negligence in healthcare services

In India, a patient who suffered injury due to an negligent act of the doctor had to approach a civil court for compensation prior to inclusion of medical services under the purview of CPA in 1995. This used to be an elaborate, cumbersome, expensive and time-consuming process. A classic example was the case before the Andhra Pradesh High Court[6], where the patient got a compensation of Rs.50,000 after 21 years of legal battle. In another case before the Tamil Nadu High Court, a leading national table tennis player had to wait 10 years to get his claim[7].

Medical services were brought under the ambit of CPA in 1995, when the landmark judgment was delivered by the Supreme Court, in *Indian Medical Association v V.P.Shantha Nair*[8]. The

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[4] Refer to Appendix II for the Tamil Nadu Consumer Protection Rules.
[5] Policy Note 2002-2003, Co-operation, Food and Consumer Protection Department, Government of Tamil Nadu.
[6] Dr P Narasimha Rao Vs G Jayaprakasu, AIR 1990 (AP) page 207
[7] Venugopal Chandraskar Vs. Apollo Hospitals Ltd. Case filed in 1984. Verdict given in 1993. Appeal was preferred but finally the matter was compromised.
[8] 1996 Consumer Protection Reporter (CPR), page 1

judgment has made it explicit that doctors can be brought under the purview of the Act. The Supreme Court in its judgment in 1995 held that:

> *"……It would thus appear that medical practitioners though belonging to the medical profession, are not immune from a claim for damages on the ground of negligence. The fact that they are governed by the Indian Medical Council Act and are subject to disciplinary control of Medical Council of India and/ or State Medical Councils is no solace to the person who has suffered due to their negligence and the right of such person to seek redress is not affected." (Para 17)*

According to the Supreme Court, the medical practitioners, Government hospitals/ nursing homes and private hospitals/nursing homes broadly fall in three categories:-

I. Where services are rendered free of charge to everybody availing the said services;

II. Where charges are required to be paid by everybody availing the service; and

III. Where charges are required to be paid by persons availing services but certain categories of persons who cannot afford to pay are rendered service free of charges.

The Supreme Court thus made it clear that healthcare providers offering services free of charge are not covered under the scope of CPA[9]. It further clarified the fact that the services rendered by healthcare providers are in not the nature of "master and servant" (*contract of personal services)* but are in the nature of "principal and agent" (*contract for personal services)*. Under contract for personal services, the patient has no control on the decisions made by the doctor and hence the care given by the doctor falls under the definition of *"service"***.** Thus, the Supreme Court argued, that any person, who is aggrieved by the services of the healthcare provider (hospital, doctor) can seek redressal under CPA.

2.5. Institutional Mechanism under CPA

2.5.1.Consumer Courts:

[9] The Consumer Courts have thus held that Central Government Health Scheme (CGHS) or Employees State Insurance Act (ESI) does not fall under the purview of Consumer Protection Act even though a token amount is paid. The Additional Director CGHS, Pune v Dr. R.L Bhutani, 1996 (1) CPR page 136

CPA provides for a three-tier system of quasi-judicial bodies at the district, state and national levels to resolve consumer disputes. These bodies are commonly known as ***"consumer courts"***. In India (till the end of December 2002) there are 570 District Fora, 35 State Commissions and one National Commission. Tamil Nadu has 30 District Fora, of which 18 have an independent forum each and 6 have combined district fora with a common presiding officer for two adjoining districts. Tamil Nadu has 29 districts, many of which were bifurcated from larger districts for administrative purposes. Chennai district has two consumer fora.

2.5.2. Constitution of redressal machinery:

Each District Forum and State Commission consists of three members, whereas the National Commission consists of four members, one of whom should be a woman. The President of the Forum/Commission shall be a judicial person. The tenure of the members is for a period of five years or upto the age of 65 years in case District Forum, or 67 years in case of State Commission, or 70 years in case of National Commission.

A consumer forum becomes non-functional or defunct when it has no quorum (i.e. at least two members are required to form a quorum to hear the complaints). It is the responsibility of the respective State Governments to fill in the vacancies as far as district and state consumer courts are concerned and that of the Central Government to fill in the vacancy in the National Commission. In the year 2002, 49 district consumer fora throughout India remained non-functional due to the delay in filling up of the posts of President/Members[10].

2.5.3. Procedure under CPA to obtain relief:

Any aggrieved person (patient or his representative) can file a complaint against the healthcare provider for negligence or deficiency in services before the district or state or national commission, depending on the compensation claimed.

[10] Report of the Standing Committee on Food, Civil Supplies and Public Distribution (2003), Government of India.

The District Forum can entertain claims upto Rs.5 lakhs. The State Commission is empowered to entertain claims from Rs.5 lakhs to Rs.20 lakhs and the National Commission entertains claims above Rs.20 lakhs (1 lakh = Rs.1,00,000). The quantum of amount claimed decides the forum before which the complaint is to be filed.

The patient either can appear in person or authorize any other person (not necessarily an advocate) to represent his case. The procedures of consumer courts are meant to be simple unlike the ones followed in other civil and criminal courts in India. There is no Court Fee or Process Fee payable by the consumer for the compensation he claims in the complaint. The complainant has to file the complaint before the appropriate forum/commission, within two years from the date of cause of action[11].

The claim for compensation in the cases of medical negligence is made under different heads such as compensation for medical expenses and future expenses (in cases of permanent damage), physical and mental agony undergone by the complainant or the legal representative in cases of death of the patient, future mental agony, compensation with some percentage per annum etc. However, there is no specific guideline for the courts to arrive at the compensation. It depends on the discretion of the courts granting compensation.

The accused (the physician or hospital) is served with the notice from the consumer court. The provider can either defend his case by himself or through an authorized agent (a lawyer in most cases). The accused has to submit his version (defense statement) within 30 days or such extended period[12]. If he fails to appear or submit his version, the court shall decide the case *ex parte* (in the absence of one party).

[11] Refer to Section 24A (Appendix I).
[12] Refer to Section13(2) (Appendix I)

The forum/commission shall follow the principles of "natural justice" in giving due opportunity for both the parties to set out their case. The courts are normally expected to dispose of the complaints within a period of 90 to150 days[13] from the date of admission.

If the forum/commission decides that there was negligence or deficiency on the part of the healthcare provider, based on the expert opinion and evidence given by the patient, it shall make the provider pay compensation to the patient. However, the onus of proving that the provider was negligent is entirely on the complainant.

In most medical negligence cases, the hospitals where the patient was treated are also held vicariously liable[14] for the wrong done by the doctor. The hospital is also made a party to pay the compensation to the patient.

If the redressal machinery decides that there was no negligence, it shall dismiss the complaint. The consumer courts shall order the complainant to pay costs to the healthcare provider if it is of the opinion that it was a frivolous complaint[15]. Further, the forum/commission can award a penalty against the person who has failed to comply with the order[16].

Either party, the complainant or the provider, if aggrieved by the order of the Forum/Commission can file an appeal against the order. An appeal against the order of the District Forum lies before its State Commission and against the order of the State Commission lies before the National Commission. The time limit prescribed for filing

[13] Refer to Rule 14(4) (Appendix II)

[14] Vicarious liability arises when there is employer-employee relationship. An employer is considered vicariously liable for the negligence and deficiency in providing service by the employee. The liability of the hospital authorities extends to the wrongs of the doctors and the other staff whether permanent, temporary or casual staff, whether paid or honorary, full time or part-time (this is in the case of physicians and surgeons) the hospital is held liable (G.C.Kothandan 2001)

[15] Refer to Section 26 (Appendix I)

[16] Refer to Section 27 (Appendix I)

appeals is 30 days from the date of communication of the order. Similarly, appeals are expected to be disposed of within 90 days[17] by the commissions.

2.5.4. Staff strength & budget allocation for Redressal Machinery:

In Tamil Nadu, each District Forum has 5 staff members and the State Commission has 16 administrative staff members, to assist the members of the forum/commission. In the year 2001-02, the state government of Tamil Nadu incurred an expenditure of Rs.176.44 lakhs towards the administrative expenses for the functioning of the District Fora[18]. The expenditure for the Tamil Nadu State Commission for the year 2001-02 was Rs.40.06 lakhs.

In the year 2001-2002, the Government of India had spent Rs.4.46 crores for meeting the recurring expenditure of the National Commission. For the year 2002-2003, it has allocated a budget of Rs.50 lakhs for constructing a building for the National Commission at New Delhi[19].

2.6. Consumer Protection Councils:

CPA provides for establishing Consumer Protection Councils at the State and Central levels to "*safeguard the interests and the rights of the consumers such as (i) right to safety (ii) right to information (iii) right to choose (iv) right to represent (v) right to redressal and (vi) right to education"*. The Councils consist of representatives of voluntary consumer organisations, trade and industry, farmers, bureaucrats and ministers[20].

The Tamil Nadu Consumer Protection Council, which is a part of Department of Civil Supplies and Consumer Protection, conducts quarterly meetings with Voluntary Consumer

[17] Refer to Rule 8(9) of Tamil Nadu Consumer Protection Rules (Appendix II).

[18] The Tamil Nadu Government has released a sum of Rs.20 lakh during the year 2001-02 for providing furniture and infrastructure for the newly formed six district fora of Thiruvallur, Thiruvarur, Karur, Namakkal, Theni and Perambalur.

[19] Notes on Demand for Grants, 2002-2003, Ministry of Consumer Affairs, Food and Public Distribution, Government of India.

[20] Refer to Sections 4 to 8 (Appendix I)

Organisations (VCOs). These meetings are conducted to redress the grievances of the VCO (who represent public grievances) with various departments and public undertakings in the State[21]. In the year 2001-2002, Tamil Nadu Consumer Protection Council had budgeted Rs.15 lakhs (1.5 million) for consumer education. Every year, March 15 is celebrated as *"World Consumer Rights Day"*. Tamil Nadu Consumer Council takes up one district every year and spends Rs.1.50 lakhs to celebrate the World Consumer Rights Day[22]. It conducts seminars, meetings and awareness programmes on that day throughout the district.

The Central Exercise and Salt Act, 1944 was amended in 1991 to enable the GoI to create the Consumer Welfare Fund. The fund is operated by the Ministry of Consumer Affairs, Food and Public Distribution, Department of Consumer Affairs. The objective of the Consumer Welfare Fund (CWF*)* is "*to provide financial assistance to promote an to protect the welfare of the consumers, develop consumer awareness and strengthen the consumer movement in the country"*, particularly in the rural areas with special emphasis on women's participation. Any agency, organisation, co-operative, industry or state, which is engaged in the consumer welfare activity for a period of three years is eligible to seek financial assistance from the fund. The procedure for applying for financial assistance and the eligibility criteria of the voluntary consumer organisation seeking assistance are specified in the Consumer Welfare Fund Rules. The Standing Committee on Consumer Welfare Fund has approved 527 proposals involving an assistance of Rs. 4.82 crore as on March, 2002 for promoting welfare of consumers and to strengthen the consumer movement in the country[23]. The maximum limit of a grant is Rs.5 lakh. In Tamil Nadu, 67 organisations[24] including government departments have so far availed the grant ranging between Rs.22,500 and Rs.5 lakh[25]. The amount sanctioned is for creating consumer awareness and allied activities.

In addition to CWF, the Central Government in 1996 came up with an idea of setting up District Consumer Information Centre (DCIC) at the District level to disseminate information

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[21] Policy Note 2002-2003, Co-operation, Food and Consumer Protection Department, Government of Tamil Nadu.
[22] In the year 2003, Theni District was taken up for celebrations
[23] Milestones 2002, Press release by Department of Consumer Affairs, Press Information Bureau, Government of India.
[24] Refer to Appendix XII
[25] Website of Indian Embassy <www.indianembassy.org/indiainfo/india_2000/chapters/chp18>

of all aspects of consumer protection. The Central Government had provided a grant of Rs. 5 lakh for setting up District Consumer Information Centre (DCIC) in each district of the country over a period of 5 years. Under this scheme 44 DCIC proposals had been sanctioned for 18 States and Union Territories on the recommendations received from State Governments[26]. In Tamil Nadu only Cuddalore and Erode District have DCIC's established.

2.7. Current situation relating to cases against healthcare providers in Tamil Nadu:

As on December 31, 2001, 15,74,042 (1.57 million) consumer complaints have been filed in the 570 District Fora all over India since the date of establishment of consumer protection fora in 1986. Of which 1.32 million have been disposed, with a disposal rate of 84.44%. Similarly, 2,63,150 cases (original complaints and appeals) were filed in 35 State Commissions and the National Commission since their inception; of which 99,300 were disposed, with a disposal rate of 62.26%. In 1999 alone 29,944 cases were filed against doctors in comparison to less than 10,000 in 1995[27] It is estimated that medical negligence cases account for not more than 5% of the total cases at all levels[28]. For example, *Table 1* shows the number of medical negligence cases that were filed in 2001 before the five district fora, chosen for the study in Tamil Nadu.

Table1. Number of cases filed in 5 District Fora in Tamil Nadu in 2001

S.No.	District Forum	No. of cases filed
01	Madurai	07
02	Tirunelveli	03
03	Tuticorin	01
04	Chennai (South)	11
05	Chennai (North)	09

Source: Registers maintained in the District Forum

[26] Deccan Herald Newspaper, 17 July 2003

[27] "Doctor Vs Patient, Growing Distrust" *India Today,* September 2000

[28] There are no exact figures available on the number of medical negligence cases filed at different levels. But the estimates reported here are widely shared by various government officials dealing with CPA. This is however corroborated by the figures we have collected from various district fora.

It is evident that very few cases have been filed by patients at District Fora. The appeals relating to medical negligence that were filed in the State Consumer Disputes Redressal Commission for three years are also small compared to total number of appeals made. (Refer to *Table 2*):

Table 2. Number of appeals filed relating to medical negligence in Tamil Nadu State Consumer Disputes Redressal Commission (during the years 1998, 1999 and 2000)

S.No.	Year	Total no. of appeals filed	No. of appeals relating to medical negligence
01	1998	870	30
02	1999	1037	32
03	2000	734	34

Source: Appeal Register maintained at the State Commission

PART II

2.7. THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994:

Before India passed the ***Transplantation of Human Organs Act (THOA)*** in 1994, it had achieved considerable notoriety internationally for its organ trade, especially of kidneys bought from poor people by the wealthy from around the world[29]. A residential colony of largely poor people in Villivakkam, Chennai, became infamous as 'Kidneyvakkam' because almost every house had a resident who had sold his or her kidney for money[30]. Several factors led to the regulation of the human organs market through THOA. The primary reasons were:

- To curb the commercial purchase of organs from live donors.
- To protect the donors who are usually from the low socio-economic status from being exploited by the middlemen.
- To restrain the removal of organs from patients without their knowledge.
- To recognize the concept of brain death in order to encourage cadaveric donation.

[29] Website of Eye Bank Association of India (a voluntary organization) <www.ebai.org>
[30] Cohen L , 1989,"Where it Hurts: Indian Material for an Ethics of Organ Transplantation", Daedalus

2.7.1. Salient Features of THOA:

THOA, which is an all-India Act came into force on 11 July 1994. The Tamil Nadu Government adopted it on the 5th May 1995. As of 2003, 14 States have not adopted this Act[31]. The Act[32] is broadly divided into seven chapters consisting of 25 Sections. Chapter I deals with objectives along with certain definitions. Chapter II specifies the authority for removal of human organs. Chapter III and V deal with regulation and registration of hospitals. Chapter IV defines Appropriate Authority and lists out the powers and functions of the authority. Chapter VI deals with offences and penalties for contravention of any of the provisions of the Act. Chapter VII spells out miscellaneous provisions. Following the promulgation of the Act, the State Government established the Transplantation of Human Organ Rules[33]. These rules came into force in 1995.

2.7.2. Preamble of the Act:

The THOA was enacted to *"provide for the regulation of removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs"*.

The Act is applicable only for transplantation of *human organs*[34] for *therapeutic purposes*[35]. There are two regulatory bodies established under this Act: One, the Appropriate Authority (AA) for licensing hospitals to conduct transplant operations, and the other Authorization Committee (AC) to "prevent" commercial transactions between donors and recipients[36].

2.7.3. Pre-requisites for donating organs:

Any person intending to donate an organ during his/her lifetime may do so in the manner prescribed under the Rules *(Form 1)*[37]. People intending to donate their organs after their death may do so by giving their written consent, attested by two witnesses (at lease one of

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[31] Pushpa Singh, 2002, "What ails cadaveric transplant programs in India: Perspectives of a Transplant Coordinator, Prog Transplant 12 (1):49-51, 2002.
[32] Refer to Appendix III for Transplantation of Human Organs Act
[33] Refer to Appendix IV for the Transplantation of Human Organ Rules
[34] Refer to Sec.2(h) (Appendix III)
[35] Refer to Sec. 11 (Appendix III)
[36] Later in this chapter, we provide details of these two regulatory bodies.
[37] Refer Sec. 3(1) (Appendix III)

whom is a near relative)[38]. Similarly, person in lawful possession of the dead body may also give authority for removal of human organs. The persons in lawful possession are near relatives, authorities such as hospital authorities, prison authorities, etc.[39].

2.7.4. (A) Who can be the Donor?

As per the Act, a donor can be 'a live near relative', 'live unrelated' or 'deceased'

a) ***live near related donor*:**

The *"near relative" means spouse, son, daughter, father, mother, brother or sister"*[40] It should be noted that spouse has been included in the list of near relatives in THOA. The law that the donor should be a relative or spouse was also circumvented through certain dubious means such as "kidney marriage" by rich Gulf countrymen, marrying a girl before the operation and divorcing her soon after surgery[41]. In no country, other than India, which has a Act to regulate organ transplant, has the spouse been included as "near relative". In some of the countries, the definition of "near relative" is wide enough to include half brother or half sister, uncle or aunt, niece or nephew, or first cousin, provided there is a direct blood link, but the spouse is not considered as a near relative.

b) live unrelated donor:

The Act permits, an unrelated donor to donate his/her organs if he/she could establish before the AC an "affection or attachment" towards the recipient[42]. This live unrelated donor is not present in many countries.

c) cadaver donor:

The organs of deceased person, who consent to the removal of organs after death, can also be transplanted to the recipient[43]. In fact, THOA has recognized the concept of Brain Death in

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[38] Refer Sec. 3(2) (Appendix III)
[39] Refer to Sec. 3 (3), Sec. 5(1) and Sec.6 (Appendix III)
[40] Refer Sec.2(I) (Appendix III)
[41] Tharien AK, (1996) "Ethical Issues in Organ Transplantation in India", *Eubios Journal of Asian and International Bioethics* 6 (1996), 168-9.
[42] Refer to Sec. 9(3) (Appendix III)
[43] Refer to Sec. 9(2) (Appendix III)

India. *Brain stem death* indicates that the brain stem has permanently and irreversibly stopped to function, and this needs to be certified by a medical board comprising the head of the hospital in which the death has taken place, an independent doctor, a neurologist or neuro-surgeon, and the patient's doctor.

The Act specifically excludes minors from being live donors[44]. This is a very important provision as it keeps check on the minors being exploited. However, the parents of the minor can authorise the removal of organs from the minor in case of a brain stem death[45].

(B) Clinical conditions:

As a precursor to a transplant, a registered medical practitioner is required to examine the body of the deceased donor to confirm that life is really extinct by reasons of cardio-pulmonary failure[46] or brain-stem death[47].

In case of live related donor, the doctors have to certify that the donor is in proper state of health and is medically fit for removal of organ[48]. However, similar certification is absent under the rules for live unrelated donor. There are also certain guidelines prescribed under the rules for ascertaining the relationship between the recipient and related donors[49].

The Act does not insist that these medical tests be conducted by an independent physician or a medical team for ensuring objectivity and preventing "conflict of interests". On the contrary, such tests are typically carried by the transplant team/hospital that conducts the operation. In various other countries that have transplant laws, this is not permitted.

(C) Surgical risks:

It is mandatory for the medical practitioner who performs the transplant to explain all possible effects, complications and hazards connected with the removal to the donor and

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[44] Refer to Sec. 2(f) (Appendix III)
[45] Refer to Sec. 3(7) (Appendix III)
[46] Refer to Sec.3(5) (Appendix III)
[47] Refer to Sec. 3(6) (Appendix III)
[48] Refer Rule 4 (1) (b) (Appendix IV)
[49] Refer Rule 4 (1)(c) (Appendix IV)

recipients[50]. However, the donor gives the declaration that the physician has explained to him of all possible risks. Similarly, the Authorisation Committee also specifically questions the unrelated donors whether they are aware of the surgical complications of undergoing transplantation.

2.8. Regulatory Bodies:

To regulate hospitals involved in the transplantation of human organs and to prevent commercialization, two authorities have been formed under the Act. They are Appropriate Authority and the Authorization Committee. Their functions and roles are discussed below.

2.8.1.Appropriate Authority (AA):

The Appropriate Authority constituted by the State governments, is vested with power to:

- grant registration to the hospitals
- enforce standards for hospitals
- inspect hospitals for examining the quality of transplantation and follow-up medical care of donors and recipients.
- suspend or cancel the registrations
- investigate into complaints for breach of any provisions of the Act

Therefore, the removal, storage and transplantation of human organs should be undertaken only at hospitals licensed by the Appropriate Authority. However, the removal of eyes and ears from the dead body of a donor can be made at other places[51].

The Director of Medical and Rural Services (DMS) is the Appropriate Authority (AA) in Tamil Nadu[52]. AA can issue a license to a hospital only for a period of 5 years at a time. It can renew the license once every five years. The AA is also expected to obtain and maintain monthly reports on the volume of transplants performed in licensed hospitals.

As on June 2002, 44 hospitals including government hospitals were approved by AA to perform organ transplantation in Tamil Nadu. These are situated in Chennai (28), Coimbatore

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[50] Refer Section12 (Appendix III)

[51] Refer Section10 (1) (Appendix III)

[52] G.O.Ms.No.286, dated 5.5.1995 issued by the Health and Family Welfare Department, Government of Tamil Nadu.

(6), Madurai (4), Erode (1), Salem (1), Trichy (1), Dindigul (1), Tirunelveli (1) and Vellore (1). (The numbers in the brackets represent the licensed hospitals in these cities).

The Appropriate Authority is vested with the power to cancel or suspend the registration of the hospital. Any hospital aggrieved by the order of cancellation or suspension of registration by the Appropriate Authority can appeal within 30 days from the date of receipt of the order either to the Central Government or the State Government as the case may be[53].

The Appropriate Authority is vested with the power of taking action against any hospital, doctor, donor, recipient or anybody who contravenes the provisions of the Act[54]. Others who wish to file a complaint against any licensed hospital should inform the Appropriate Authority about their intention and if they receive no reply from the AA, then they can proceed with filing a complaint.

2.8.2. Authorisation Committee (AC):

The ACs are constituted by respective States or Union Territories to "approve" transplants between the recipient and unrelated donors[55]. The primary duty of the AC is to establish that the unrelated donors are not under any coercion or undue influence by monetary consideration to donate their organs. In Tamil Nadu, the Director of Medical Education (DME) has been appointed the chairman of the Committee with Director of Medical and Rural Services (DMS) and Dean, Madras Medical College as its members[56].

The joint applications from live unrelated donors and recipients are forwarded to DME by the hospitals (where the transplant is proposed to be performed, after conducting all medical tests[57]).

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[53] Refer Section 17 (Appendix III)

[54] Refer Section 22 (Appendix III)

[55] Refer Section (4) (a) (Appendix III)

[56] G.O.Ms.No.287 dated 5.5.1995 issued by Health and Family Welfare Department, Government of Tamil Nadu.

[57] Discussed in Chapter III

The AC periodically meets to scrutinize applications and to examine the motives of the donors and whether any monetary transactions were present between recipients and donors. The AC invites both the donors and recipients for personal interviews and to confirm that the donors and recipients have complied with the provisions of the Act[58]. On an average, every week about 20 applications are disposed of by the AC in Tamil Nadu. Approved ones are intimated through post to the concerned hospitals.

It is estimated that so far about 5,000 cases have come up to the Authorisation Committee in Tamil Nadu since 1995[59]. The rejection rate so far has been less than 5%. Between January 2000 to May 2002, the Tamil Nadu AC has approved 1559 unrelated transplants, out of 1868 applications received[60].

Any person aggrieved with the order of the AC can make an appeal to the State government, but this should be made within 30 days of the issue of the order[61].

In, B L Nagaraj & others Vs. Kantha & others[62], the prospective recipient, filed a writ petition before the High Court of Karnataka against the order of the AC which rejected the application for organ donation by the sister-in-law of the recipient on the grounds that near relatives were not considered donors. The High Court while allowing the writ petition held:

> *"There is no provision in the Act which prohibits the person who is not a 'near relative' by definition, from donating his kidney merely because the 'near relative' have not been considered as donors by the family for kidney transplantation. The Committee has misdirected itself in this regard while refusing permission to the petitioners."*
>
> *" The Committee would ascertain from the second petitioner whether she would be donating the kidney out of 'affection and attachment'. The donors relationship with the recipient, period of acquaintance and the degree of association, reciprocity of feelings, gratitude and other human bonds are perhaps some of the factors which would sustain 'affection and attachment' between two individuals. The committee has to ensure that the human organ does not become an article of commerce. The main thrust of the act is against commercial dealings in human organs."*

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[58] Refer Section9(5) (Appendix III)
[59] Frontline, 13 September 2002
[60] As per DMS office, Chennai
[61] Refer Section 17
[62] AIR 1996, Kant, p.82

2.8.3. Offences & Penalties:

Any person or hospital that carries out removal or transplantation without authority is punishable with jail for up to five years and a fine up to Rs 10,000[63]. Similarly, the offending registered medical practitioner is liable to be removed from his respective state medical council rolls for two years for the first offence and permanently for any subsequent offence[64].

2.8.4. Commercialization & Compensation:

Commercial dealings, like indulging in monetary transaction for trading in human organs, brokering human organ trade deals, and advertising to solicit clients, are punishable with imprisonment ranging from two to seven years, and a fine of Rs 10,000 to Rs. 20,000[65].

However, payment towards defraying expenses and compensating the donor on his loss of wages, which is directly attributable for his supplying of organs, is permissible under the Act and is therefore not illegal[66]. However, the Act does not specify who has to reimburse these expenses and the future earnings to the donor. These are discussed later in Chapter 4.

Present scenario of kidney market in India:

In India, every year one lakh fresh cases of kidney failure are reported and the cumulative number or cases amount to over 4.5 lakh in any given year. Twenty to thirty per cent of the cases are due to the complications from diabetes and high blood pressure[67]. More than two lakh kidney patients die every year in the country due to lack of adequate kidney donors and non-affordability of the treatment cost[68]. In Tamil Nadu alone, 7,000 persons develop renal complications every year[69]. However, the number of nephrologists in the State is hardly 200[70]. According to guesstimates fewer than 5% of the End Stage Renal Disease (ESRD)

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[63] Refer Section18 (1) (Appendix III).
[64] Refer Section 18(2) (Appendix III)
[65] Refer Section 19 (Appendix III)
[66] Refer Section 2(k) (Appendix III).
[67] www.medisourceasia.com/biomedsociety/publication/nov-dec2001/industrynews.htm
[68] ibid
[69] Need for more nephrologists, says Semmalai, The Hindu, Dec 09, 2002
[70] ibid

patients actually receive some form of renal replacement therapy, and of these an even fewer number have renal transplants[71].

Transplantation from cadavers (dead persons) was considered illegal in almost all states, except for two, before passing of this Act. The Act allows cadaver transplants, which includes harvesting of organs from brain-dead persons. Between 1995-1999, 10,977 kidneys were transplanted from live-donors, whereas only 491 from cadavers[72]. The donor ratio from cadavers in Spain is 31.2 per million and 21 per million in the US. But in India, only an average of fewer than 100 cadaver kidneys per year is available in a population of more than 1 billion people[73]. However, Tamil Nadu tops the chart with 53% of kidney transplants from cadavers performed in the country. The reasons for the fewer number of cadaver transplants in India include various factors such as social and cultural; religious; infrastructure; policy and procedures.

In the next chapter, we present the methodology used to understand the effectiveness of these regulations.

[71] Against the organ trade*, Frontline magazine, 24 May 2002.*
[72] Pushpa Singh, *What ails cadaveric transplant programs in India: Perspectives of a transplant coordinator,* Programme Transplant 12(1) :49-51, 2002.
[73] ibid

Chapter 3: Study Methodology

In the light of the questions raised in the Introduction, we adopted the following methodology to evaluate the effectiveness of the two regulations: THOA and CPA. We had concluded our period of study at the end of April 2003.

3.1. Methodology used for evaluating the effectiveness of THOA:

3.1.1. Interviews with various stakeholders:

We interviewed a total of 16 recipients and 13 donors (10 unrelated and 3 related donors) of kidney (mostly from the Chennai city) in-depth to understand their life experience and encounters with AC and other stakeholders[74]. Through these personal interviews, we also obtained substantial information on the role of middlemen (brokers) in the organ market. Besides, we also conducted detailed interviews with representatives of hospitals that have been authorized by the government to conduct organ (kidney) transplantation, in order to understand the various factors that have influenced effective implementation of THOA. We also had detailed discussions with a number of medical professionals (including nephrologists, urologists, surgeons associated with organ transplantation)[75] to understand their views on strengths and weaknesses of THOA. All the present members and two formers members of the AA and AC were also interviewed to get their views on the various features of THOA and the "constraints" under which they perform as regulatory authorities.

3.1.2. Workshop:

As part of the study, we also conducted a half-a-day workshop[76] that brought together (for the first time in Tamil Nadu) members of regulatory bodies and several stakeholders to discuss the current status of THOA, ways to improve its effectiveness and examine possible policy options for better organ sharing mechanisms in the state[77].

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[74] Refer to Appendix XV for the list of individuals contacted for this study.
[75] Refer to Appendix XVI for the list of participants to the workshop.
[76] Workshop on "Implementation of THOA 1994: Challenges and Policy Options" held at Indian Institute of Technology (Madras) on March 8, 2003.
[77] An empirical analysis of these questions poses several methodological challenges. In studies such as this, we are almost entirely guided by the willingness of respondents to share with us their experience. In particular,

3.2. Methodology used for evaluating effectiveness of CPA:

3.2.1. Case study:

As primary data, we selected 12 medical negligence cases that were disposed of district and state fora during 1997-2002[78]. Of these 12 cases, 7 cases were from District Forum Chennai; 3 were from the District Forum Madurai; and 2 were from the State Commission. The original records of these cases are available in the respective district or state forum. We selected 5 district fora of Chennai South, Chennai North, Madurai, Tirunelveli and Srivilliputhur as sample districts. Sample selection was based on convenience.

3.2.2. Interviews with various stakeholders:

After familiarizing ourselves with details of these cases, we identified the names and location of patients and the accused (the physicians/hospitals), and had detailed interviews with them to gain insights into institutional and procedural factors and transactional costs that have influenced effective implementation of CPA.

The study methodology consisted of in-depth discussions with staff and members of various consumer fora (including presidents of Districts Fora and State Commission). We interviewed nine advocates who had either represented the patient or physicians in the consumer courts or who had knowledge on the functioning of the consumer courts. We further interviewed representatives of four active voluntary consumer organizations functioning in Tamil Nadu[79].

In addition to this, we also conducted a postal survey of 500 medical professionals in Tamil Nadu to gain a better understanding of their responses to CPA and how they cope with newer

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while evaluating the role of middlemen (brokers) in organ markets, it is extremely difficult to identify them and interact, as they are illegal agents as per THOA. So we cannot get even a few middlemen as sample for in-depth interviews. Tracking donors from official (AC) records or from hospital records was very frustrating, as most donors had given false addresses. This issue is discussed later in this chapter. The situation was more or less the same in tracing recipients also, for reasons discussed later in this chapter.

[78] Appendix V contains summary of these medical negligence cases.

[79] Appendix X contains list of individuals interviewed (CPA).

regulatory mechanisms in place. Out of these 500 professionals, 300 were from Chennai, and the remaining were from Madurai, Coimbatore, Trichy, Tirunelvelli and Villupuram towns. Eighty (16%) responded to our questionnaire. The results are discussed in this chapter.

3.2.3. Workshop:

In addition to these, we also conducted a half-a-day workshop[80] on CPA to understand the various issues that affect the overall performance of CPA in the state. The participants of the workshop included advocates, physicians, medico-legal experts and representatives of VCOs.

[80] Workshop on "Regulation of Healthcare market in Tamil Nadu: a study of implementation of the Consumer Protection Act 1986 and its effectiveness", September 21, 2002.

Chapter 4: Empirical findings

In this chapter, we attempt to answer three related questions:

4. Have CPA and THOA been able to achieve their stated goals?
5. What factors have influenced their effective implementation? and
6. How have various stakeholders responded to these regulatory mechanisms?

Our empirical analysis has shown that shown that:

1. Commercialization of human kidneys is as common now as it was before the introduction of THOA. This study seeks to throw light on many institutional factors that have led to this situation; and

2. CPA has become more complex, long-drawn and expensive over the years, while it was meant to be a simple, quick and inexpensive legal mechanism. The present study highlights several underlying causes, including administrative, procedural, institutional and transactional costs that have influenced the effective implementation of CPA.

We now turn to a presentation of our observations and analysis of factors that have influenced the implementation of THOA and CPA.

4.1. THOA: An analysis of its implementation

Why has THOA failed to control commercialization of human organs? It is essential to observe that no one either from regulatory bodies, or from the medical community, ever disputed that commercialization of human organs has increased over the years, particularly after the introduction of THOA. Also, none of the unrelated donors we interviewed ever denied that they had received money for donating their kidneys. How does this phenomenon – commercial dealing in human organs -- continue despite the fact that THOA was instituted primarily to prevent it? How is the regulatory mechanism structured and how does it function? How does it regulate the market? Are there inherent defects in the structure and functioning of the mechanism in place? Are there larger forces beyond the power of the regulators that affect their effectiveness? These are discussed in this section.

4.1.1. Functioning of THOA:

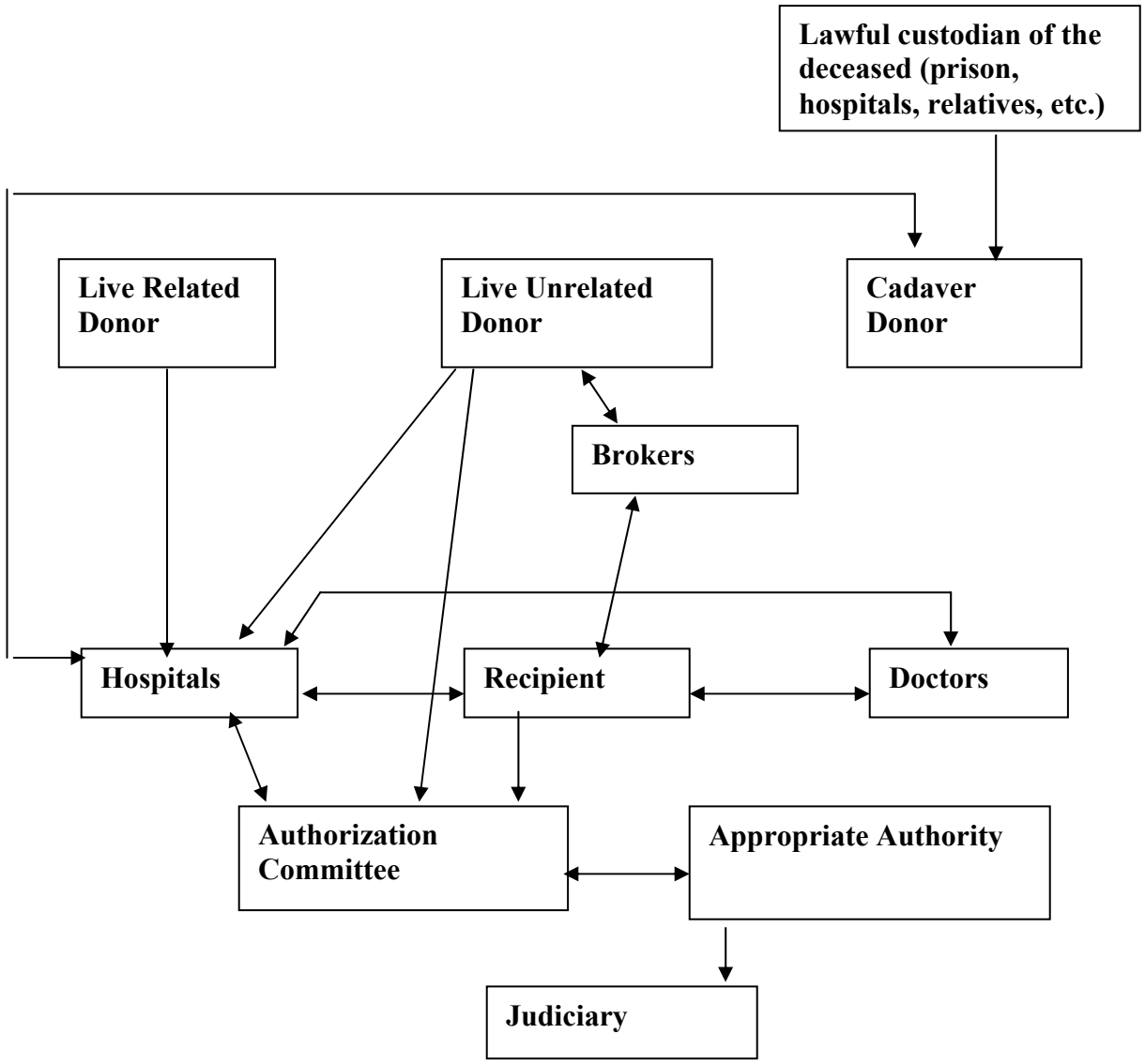

Figure 1 shows the various stakeholders in organ (kidney) market.

In order to understand the key regulatory issues and the role of various stakeholders in Figure 1, we first describe the sequence of events that lead to transplantation of human organs.

In India, the transactions between recipients and donors of kidney are very direct, in that it is up to the recipients to find suitable donors (related or unrelated). Typically the sequence of events leading to kidney transplantation goes like this:

> *The patient with kidney failure is advised by his/her medical team to undergo kidney transplantation. He/she is then asked to find a donor (related or unrelated). At this point of time, if the patient has a related donor, then the donor is made to undergo some medical tests to ensure proper tissue matching with recipient's requirements. In case the patient is unable to find any related donor, he/she begins his/her search for an unrelated donor. At this stage, the patient gets in touch with a "middleman" – a broker – in the market. At times, "contact persons" within hospital premises may also help potential recipients in locating potential donors through middlemen. After negotiating a price for donor's kidney, the middlemen will introduce the donor to the potential recipient and the medical team. The medical team after conducting a series of medical tests on donors and recipients sends them to AC to get its approval to conduct transplantation.*[81]
>
> *The AC invites the unrelated donor and the prospective recipient for a personal interview. Both are interviewed separately. The primary purpose of this meeting is to ensure that the donors were not coerced or influenced by monetary considerations to donate. Typically, the committee members ask donors the following questions: "What motivates you to donate your kidney? How are you related to the recipient?*[82] *Has the recipient assured you that he/she will take care of your health after donation? Has the doctor fully explained to you the possible after-effects of donating your kidney?"*
>
> *Typical, donors' answers to these questions would be: "I donate my kidney out of affection or attachment, not for any financial reasons. The recipient is related to me*[83]*. I am confident that the recipient will take care of my*

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[81] Even though the AC may approve unrelated donors for transplantation (under the provision 9(3) of THOA), it is not mandatory for hospitals to accept unrelated donors. The hospitals may choose not to consider unrelated cases, as a policy. For example, there is a network of private hospitals in Tamil Nadu, which have decided in principle not to conduct any unrelated transplantation even if there were no established monetary deals between donors and recipients. Also, it should be noted that public hospitals that have been authorized to conduct transplantation do not entertain unrelated cases. But a large number of licensed private hospitals do conduct unrelated transplantation, approved by the AC.

[82] As noted in the last chapter, according to THOA, "near relatives" include only "spouses, brothers, sisters, and parents".

[83] In most cases, the donor would claim that he/she was recipient's "first or second cousin, or nephew/niece, or uncle/aunt". Although none of these can be easily disputed, in some instances they are strongly seen purely to be unrelated.

needs in future. I am fully aware of the possible consequences of donating my kidney."

As mentioned earlier, the AC is the regulatory authority to prevent commercialization of human organs. The AC consists of three members, all of whom practically depute their subordinate staff to the weekly meetings held for this purpose[84]. In any case, the presence of AC members, instead of the deputed members, cannot avoid ensuring prevention of commercialization.

How well can the above-mentioned procedure and regulatory mechanism help prevent commercial dealings in organ (kidney) market? We argue that the present regulatory system and the procedure followed are *least capable* of preventing "commercial dealings". We now discuss the reasons in support of our argument.

4.1.2. A. The regulatees:

I. *Donors/Recipients:*

(1) The middleman/broker is usually very knowledgeable of how the AC functions. They know the questions that the AC frequently poses to donors and recipients. They are therefore able to "tutor" the donors and recipients with key responses that cannot be easily disputed by the AC. For example, a donor may claim to be an aunt of the recipient. Yet, there is no proof (other than oral evidence) that the AC can insist upon to establish this relationship. Only the so-called "not near relatives" are required to appear before the AC and orally assure the AC that they did not receive any money for donating their kidney. Many such donors said, "We were asked by the middlemen to talk confidently to the AC and deny that we ever received money for donating our kidney". This is not to say that the AC members cannot at all sense the nature of dealings between donors and recipients. In fact, the members of AC often would be able to rightly guess where there was any commercialization but end up approving such cases either for lack of definitive proof or for other reasons discussed below. After

[84] The members of the AC being extremely busy in their day to day management of their respective departments/institutions, often resort to deputing their subordinate officials to perform the regulatory function, although it is nor clear whether they are allowed by law to delegate this authority to their subordinates. Therefore, such a delegation may be a very practical step to manage their workload, but it needs to be clarified whether the law allows them to do so.

independent inquiry with donors and recipients, the AC may approve the transplantation to take place and informs the concerned hospitals and the parties to carry out the operation.

Evidently, donors escape through the loophole in the law (clause 9(3)) that allows donation "out of affection and attachment" to recipients. Most donors and recipients misuse the provision in the law and there is no means to test the extent of love and affection present between the transacting parties.

Interestingly, some of the donors who have donated kidneys for money have themselves turned into middlemen. A lady at Foreshore Estate in Chennai, sold her kidney in 1993 for Rs.20000, found this to be a potential market to make money. She developed the link with a hospital in Chennai, and has helped others in her locality, who were in debts, to sell their kidneys for money. She was happy getting her commission from both the donor and the recipient[85].

(2) Commercialization takes place through another route. As we noted earlier, the law also defines "spouse" as a near relative. This clause is highly misused. We have come across several cases where a male recipient produces a photograph that shows him as being wedded to a female donor. The female donor is given some money (often as low as Rs.500) to act as his spouse during the interview with AC. In addition, false certificates in connivance with officials, if necessary, are also produced as proof of their relationship. Once the transplantation is over and the payment is complete, the two parties perhaps never meet again except when it is required again! This leads us to another unhealthy phenomenon that takes place in organ market[86].

[85] Interview with donor no.9 (Appendix XIII)

[86] There has also been instance where the near relative (sister) had claimed Rs. 1 lakh for donating her kidney. The Act does not provide any regulatory mechanism to check commercialization between relative donor and the recipient. Probably the law makers never envisaged that there could be such commercial transactions between the relatives.

(3) Most unrelated donors and recipients (that receive kidney from unrelated donors) also misinform the AC with false address of their place of residence. The unrelated donors and recipients resort to such tactics in order to avoid being caught later by police for having engaged in organ trading. In fact, the AC is very much aware of this practice but has not developed any formal mechanism to have this checked. A related phenomenon is that most unrelated donors do not know the whereabouts of the recipients either. The recipients often keep the unrelated donors in the dark in order to avoid being contacted with in future because of the illegal nature of the transactions between them.

(4) Several professionals have said that on many occasions recipients who had appeared before the AC for approval were not the real recipients[87]. Proxy recipients and donors often seem to appear before the AC for approval and these are used as cover by some of these hospitals to perform operations on others; many of the recipients are foreign nationals who for obvious reasons do not prefer to appear before the AC.

(5) There is yet another factor that supports non-compliance of the regulators themselves in enforcing the law to prevent commercial dealing. The members of AC themselves support the reasons to recipients receiving kidneys from unrelated donors. A former member of AC justifies his position thus:

> *"Imagine you in need of a kidney waiting for a year or so. This is a life and death situation. What can you do if you don't find a related donor? Is it correct to stop a donor from giving his/her organ, even though he/she may receive some money in return for his organ? Is it correct to stop a patient receiving an unrelated kidney from a donor?"*

Many policymakers share such a view, as echoed in the following words of a former official in the government:

> *"We too are human beings and we cannot easily say 'no' to applicants seeking our approval for receiving unrelated kidneys, even when we strongly suspect monetary transactions between them. It is very difficult to disapprove them especially when they are in tears crying for our help and have been suffering from want of a kidney for*

[87] Workshop on "Implementation of THOA 1994: Challenges and Policy Options" held at Indian Institute of Technology (Madras) on 8 March 2003.

several months. We tend to give in especially when patients undergo transplant surgery for the second time, which is not uncommon".

In his article 'The Law is an Ass', Dr. Mani recounts the responses from two members of the Authorisation Committee in Tamil Nadu when he asked them how they could bring themselves to sanction patently commercial transactions in kidneys: "One of them denied there was any commercial transaction at all. 'He tells me he loves the recipient. Who am I to say he does not?'" The other member's response was different. Dr. Mani quotes him as saying: "I sanction the transplant on purely humanitarian grounds. Some of the patients actually cry and beg that permission be given." However, Dr. Mani points out, "nowhere in the Act is there a clause which permits the sale of organs for humanitarian purposes."[88] Such "humane" considerations in fact make regulators themselves culpable of not complying with the law, although ethically they may be able to defend their actions.

(6) Political influences on the AC to approve unrelated cases are also not uncommon. In a sense such influences pose the AC members an ethical dilemma: if some unrelated cases could be approved for political reasons, why not several other unrelated cases, which may be as genuinely required to be performed as any other. The only difference between these two types of cases is that one gets through the AC because of political pressure, while the other gets through the AC with its own blessings. It is also not uncommon to hear donors and recipients accusing the AC members as receiving money in return for their approval of unrelated cases. We have not come across any hard evidence in this regard but many donors and recipients have hinted very strongly about the prevalence of this phenomenon. The overall impression of the AC is that it is a very *lenient body* and it is easy to get its approval. The overall rejection rate among unrelated donation is less than 5%, while most of these evidently were directly influenced by monetary considerations, which is rarely disputed by any, as mentioned earlier[89]. All of the unrelated donors/recipients that we have studied *accepted* having received/ paid money. The ten-minute personal interview that the AC

[88] Kidneys still for sale, *Frontline Magazine,* 9 August 2002.

[89] The Tamil Nadu Authorisation Committee, between January 2000 and May 2002, had received 1868 applications from live unrelated donors for approval; 1559 were approved. In Punjab, between 1997 and 2002, 2,384 applications from unrelated donors; of these 1,972 have been approved by Amristar AC. In Karnataka, the AC had cleared 1,012 out of 1,017 applications that came before it from 1996 to 2001.

conducts with donor-recipient is not sufficient to rule out or establish monetary transactions between them. The AC does not necessarily record the proceedings of the weekly meetings with full details. They are required to record their reasons only for rejected cases. The reasons for approval are not recorded.

II. *The providers/hospitals:*

(1) The Approprite Authority (AA) is the regulating authority that checks hospitals performing transplants. Hospitals that claim to have the capacity to perform transplant operations should first apply to the AA for license to carry out such operations in their premises. As per THOA, AA is vested with powers to cancel or suspend the licenses in case of any contravention of the provisions of the Act. Similarly, the authority renews the license of the hospitals every five years. So far in Tamil Nadu, 44 hospitals including 4 government hospitals have been licensed to perform transplants. So far (until April 2003), the Appropriate Committee in Tamil Nadu has not filed even a single complaint against any licensed hospital for non-compliance despite several reported cases of violation of the law in recent years.

(2) As per the law, the hospitals are supposed to submit a monthly report on the volume of transplants performed[90]. Though the authority has structured quite an exhaustive monthly return sheet, which provides adequate data from hospitals, most hospitals have not complied with this requirement. What is important to note is that the AA has not followed up with these hospitals for non-compliance Even the little data that it receives is not collated and analyzed. As a result, the AA is totally in the complete dark as to the volume of related or unrelated transplants that take place in licensed hospitals.

(3) The power to file complaints against hospitals, doctors, donors, recipients and middlemen, lies only with the Appropriate Authority. Several media reports that have appeared in the recent past in India have clearly established the link between hospitals and the presence of the middlemen between them and unrelated donors[91]. Most of these

[90] Mentioned specifically on the reverse of the License Certificate.
[91] Vinay R, *Organized Racket,* India Today, 27 January 2003; Govt throws damper on kidney racket probe, *Deccan Herald, 8 May 2002;* Kidneys still for sale*, Frontline magazine,* 9 August 2002; Against the organ trade*, Frontline magazine, 24 May 2002.*

middlemen (brokers) literally live in the premises of these hospitals that have promoted their survival and growth. Some of the middlemen are even regular employees of these hospitals. Many recipients have literally been forced to pay the middlemen's share (of money) in cash as they were being carried into the operating theatre. Hospitals that allow such transactions to take place are evidently not complying with the law. But such practices are extremely difficult to detect and monitor, which further weakens the effective implementation of THOA.

(4) There is yet another factor that promotes the commercialization of human organs. This is borne out of our discussions with several medical professionals (urologists and nephrologists in particular) during the course of this study. At present, "tissue matching" and other tests that need to be conducted prior to transplant surgery are being carried out either in laboratories attached to hospitals where transplant operations take place, or in laboratories referred to by providers. These tests usually take 4 to 7 days. The law in its present form does not specify any medical norm/parameters to be satisfied for unrelated transplantation to take place. It is left entirely to the concerned physician to make his or her own judgment on the suitability of donor's kidney. "At this stage", many nephrologists have opined, "it is possible for us to cut corners and lower the norms required for performing transplantation". Such practices take place for two reasons: one there are no standards insisted upon by the regulatory authority; two, it is very difficult to monitor non-compliance of acceptable standards followed by peers in the profession. Fudging medical records is not uncommon, particularly in organ market in India. The media in the recent past has exposed several scandals with direct involvement of doctors. From the point of view of regulation, it is perhaps the most difficult aspect to be monitored, even if there were accepted standards.

4.1.2. B. Policy weaknesses:

Most factors discussed so far arise from procedural difficulties in monitoring compliance and in enforcing the provisions of the law. But there are certain policy issues which are either not

well articulated, or ignored in the existing provisions of the law, which contribute to the present condition of the organ-market. These are discussed in this section.

(1) In India, most of the living unrelated donors are economically poor. Most donors (unrelated in particular) have sold their kidneys to overcome immediate financial crisis[92]. A fundamental weakness with the existing law is that it has no mechanism to ensure follow-up care for donors. The poor that come forward to donate their kidneys for money by definition are likely to be in a poor state of health. On account of poor health, they should not have been allowed to donate their kidney at all in the first instance. This is a direct evidence to support our earlier observation on how providers "cut corners and lower standards" to perform transplants. The existing law has no guideline on the simple policy question: What help would a donor (who has donated his/her kidney out of "love or attachment") get for himself/herself when he/she requires a kidney few years later? Can he/she have any legitimate expectation for protection from the State? As a former DMS in Tamil Nadu puts it "though follow up of donors (in cases of live-unrelated donation) is mandatory, many hospitals do not bother either because the donors produce false addresses or because there is no money"[93]. Also the recipient is not legally bound to protect donor's health in future. In most cases, there is no moral binding force between the recipients and donors either, which is why the transactions were often in monetary terms. The prevailing market may be characterized thus: "The kidney has been bought and the donor has been paid. So the donor has no more claims over the purchaser." The policy challenge is to set right this kind of situation by instituting a mechanism to protect health of the donors. The AC routinely asks donors whether recipients would take care of donor's health in future and donors invariably answer in the affirmative. In practice, however, the AC does not/cannot monitor whether the recipient does take care of the donor's health. Very often, the recipient does not take care of the donor's health. The table below illustrates the state of health of the unrelated donors (coming from a very economically weaker section of the society) post donation.

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[92] Goyal M et al (2002), Economic and Health Consequences of Selling a Kidney in India, *Journal of American Medical Association,* 2 October 2002, Vol.288, No.13, page. 1589-1593

[93] Hospitals under scrutiny in Chennai for trading in organs, *Indian Trasnplant Newsletter*, Vol;VI, Issue: 14, Feb-June 2003.

Table 3. **Summary of amounts received for selling kidneys and their present state of health of unrelated donors interviewed**

Name of the donor	Gender/Age	Year of Donation	Amount Received	Present Health Complication
A.Susi Mary	Female 52	1993	Rs.20000	Difficulty in breathing, TB, diabetes
R.Vijaya	Female 25	2000	Rs 40000	Pain at nephrectomy, palpitation
Noorjehan	Female 38	2000	Rs.45000	Pain at nephrectomy, breathlessness.
Anasr Beevi	Female 47	2001	Rs.50000	Pain at nephrectomy, chest pain
Shanthi	Female 55	1994	Rs.20000	Pain at nephrectomy, knee pain
Rajan	Male 27	2001	Rs.30000	Back pain
Shanthi S	Female 30	2003	Refused to reveal	Pain at nephrectomy, less sleep
K.Samandum	Male 42	2000	Rs.45000	Pain at nephrectomy, breathlessness, severe headaches frequently.
Vijaya M	Female 27	2002	Rs.40000	Frequent cold, fever, sore throat.
Selvam K	Male 35	2000	Rs.50000	Panting for breath.

(Source: Interviews conducted in collaboration with MOHAN Foundation)

These donors (all from a slum area) have not received any follow up care after donation.

(2) The current Act does not require "related" donors to appear before the AC, because it assumes that there would be no coercion or monetary influence on related donors. This indeed is a very unrealistic assumption. We have come across many cases of coercion from within family members on donors. We have also come across instances where related donors have demanded money in return for his/her kidney. The law does not recognize these cases as requiring any monitoring. A recent study[94] conducted among the live-related donors, observed that the majority of live-related donors was females (62% - mothers, sisters and wives) and financial dependence appeared to be one of the influencing factors in the

[94] "*What role does gender and financial status play in a person agreeing to be a live-related kidney donor?",* Postgraduate Institute of Medical Education and Research, Chandigarh reported in *Indian Transplant Newsletter,* Oct 2002 - Feb 2003, Vol.IV, Issue No.13.

motivation to donate an organ. The study also reflects the presence of coercion or undue influence of the recipient over the live-related donor. Inclusion of "*spouse"* in the definition of near relative has also a bearing on this. Another study[95] had also clearly indicated that in the spousal era (post-1994 after including wife to be a related donor) the donation from parent donor had significantly decreased.

(3) The law allows "compensation for loss of earnings, expenses incurred by the donor directly attributable to his supplying of organ"[96]. But this provision is practically not useful to donors because they do not have any means to trace the recipients after transplantation. The Act is silent on who should compensate donors for the losses incurred. The regulatory body is not in any position to help donors either.

(4) The counseling mechanism for both donors and recipients also requires strengthening. Several physicians involved in the organ transplantation have uniformly opined "we are far from providing adequate psychological counseling to donors in particular".

(5) At present, there is no systematic awareness campaign/programme for organ donation in India. As of now, potential donors are educated about organ donation just at the time of donation. The donors, therefore, are likely to be concerned of adverse consequences of organ donation.

(6) The existing policy also suffers from lack of coordination between the two regulatory authorities, the AC and AA. For example, even if the AC rejects an application of live unrelated donor suspecting commercial transaction, it does not have power to file a complaint against the donor/recipient/broker. The AC has to intimate the AA about the alleged offence. The Director of Medical and Rural Services (DMS) being a member of both the bodies is expected to provide this vital link, but this has not had much positive effect so far, either in enforcing regulation or maintenance of records.

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[95] *Trends in Kidney donation among blood relatives,* Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, reported in *Indian Transplant Newsletter,* , Vol.IV, Issue No.13, Oct 2002 - Feb 2003

[96] Section 2k (ii)

(7) The current law recognizes Brain Stem death to enable recovery of organs for transplant purpose. The law requires that certificate of brain dead should be issued only by neurosurgeons or neurophysicians authorized by the state government. But, as per the governing rules, only a few neurosurgeons/neurophysicians *in government services* in the entire state have been authorized to issues certificate of brain death. The government has not authorized neuro-physicians/neurosurgeons even in the private hospitals licensed to perform transplants to certify brain stem death. The current policy has one additional defect in this respect, which is that it authorizes only "senior" neuro-physicians/neurosurgeons from government institutions, which is an "unnecessary condition" according to several physicians. As one physician put it "*You don't need to be a senior person to issue such certificates*"[97].

(8) In India, at present, there is no central or state organ registry having the list of patients waiting for a transplant, which is present in most of the countries. Hence, there is no exact data available on the patients awaiting a transplant. During January 1995 and June 2001, 165 organs from cadavers were wasted due to lack of waiting list information[98]. The Organ Registry in Tamil Nadu which was formed in 1999 at MGR Medical University did not take off and has practically become defunct. Its original objectives and implementation mechanism are not well known. Former Chancellor of MGR Medical University [99] says that: "*after I took over as the Vice-Chancellor in January 1999, I convened several meetings between the surgeons, government agencies and NGOs to ensure that public awareness was increased and the people educated about the systems and methodologies involved in the programme (cadaver transplant)*".

(9) One important reason why cadaveric transplants have not taken off in India is due to nonexistence of trained transplant coordinators, who are the backbone of any successful

[97] The government is now in the process of relaxing this condition, thereby authorizing a larger pool of neurosurgeons/neuro-physicians available in public hospitals.
[98] *Indian Transplant News Letter*, Vol.IV, Issue No.13, Oct.2000-Feb.2003
[99] Rasheeda Bhagat , *Why cadaver transplants are still few* , Business Line, August 02, 2001

transplant program. As of 1998, 28 kidney and 6 liver and heart transplant centers existed in India and only 5 centres have trained transplant coordinators[100].

(10) The other weakness is that there is no policy in place for providing drugs for economically poor recipients' either free of cost or at subsidized rates. Recipients spend a large sum of money for drugs after transplantation. On average they may spend between Rs.4000 to 6000 per month for drugs[101]. The recipients who undergo transplantation from government hospitals receive drugs free of cost for a period of two years irrespective of their economic status. But drugs are not given for poor recipients, who undergo transplantation in private hospitals. However, these patients may receive financial assistance from Chief Minister or Prime Minister's fund[102] for undergoing transplantation.

4.1.3. Concluding remarks of THOA:

THOA in its present form has failed to keep a check on the commercialization of organs thereby resulting in increased exploitation of the poor. We observed apart from Villiwakkam which became infamous as Kidneywakkam, that people living in slums in Foreshore Estate, which is situated in the heart of city of Chennai, have sold their organs for money. There are several weaknesses in the provisions of the THOA, procedures and enforcing mechanisms followed in the implementation of the Act. Most stakeholders have ways and means of not complying with the provisions of the law. As a result, the overall effectiveness of this regulation is considerably weak and has not had the desired effect, namely in preventing commercialization of human organs in the State.

The dynamics of the organ market is a reflection of the weak system of regulations prevailing with regard to the private health sector in India. To some extent, the poor functioning of the regulatory system in place can be attributed to the lack of resources and staff at the disposal

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[100] Singh P (2002) , What ails cadaveric transplant programs in India: Perspectives of a Transplant Coordinator, *Prog. Transplant,* 12(1): 49-51, 2002

[101] From our interviews with various recipients.

[102] Financial assistance is provided for poor patients undergoing kidney transplants from *Chief Minister's Relief Fund (maximum Rs.25,000) and Prime Minister's Relief Fund (maximum Rs.30,000)*. In Tamil Nadu, 23 private hospitals are empanelled to receive the financial assistance from CM's fund for its patients. The *government is spending Rs.30 crores a year for providing such financial help.*

of AA and the AC. For example, decentralization of AC's workload may enable a more thorough investigation into the nature of transactions between donors and recipients. But such reasoning can go only up to a point. Decentralization will have to go along with other initiatives to prevent non-compliance and weaknesses discussed above. Some of these possible policy changes that could help better prevent commercialization of human organs in the state are discussed later in this chapter.

4.2. CPA: An analysis of its implementation

CPA is *compensatory* in nature, whereas THOA is *preventive* in nature. The latter requires compliance of stakeholders with various provisions of the law for it to be effective in achieving the stated objectives, whereas the former is meant to provide a "simple, quick and inexpensive" legal redressal mechanism to protect the interests of patients in the event of any perceived negligence or deficiency in medical services received by them. Through such retrospective compensatory means, CPA intends to regulate potential negligence in professional services in future. In response to CPA, health providers have also adopted several professional means and methods to protect their interests. Our study shows that CPA has brought about visible changes in the behaviour of patients, advocates and voluntary agencies representing their interests.

How effective has CPA been in fulfilling its intended objectives? What factors have influenced effective implementation of CPA? How have various stakeholders (medical professionals in particular) responded to the provisions of CPA? These are discussed in this section.

CPA was meant to be a simple, quick and inexpensive legal redressal system to protect the interests of the aggrieved patients/physicians. In order to evaluate its effectiveness against these three yardsticks: we conducted a detailed study of 12 medical negligence cases that had appeared in district and state consumer dispute redressal fora in Tamil Nadu. These case studies have been useful in understanding several factors that have influenced effectiveness of CPA and also the confidence of stakeholders in CPA per se. To understand the response of

physicians to CPA, we conducted a questionnaire based survey of medical professionals in Tamil Nadu. The results of these surveys are discussed here.

4.2.1. Analysis:

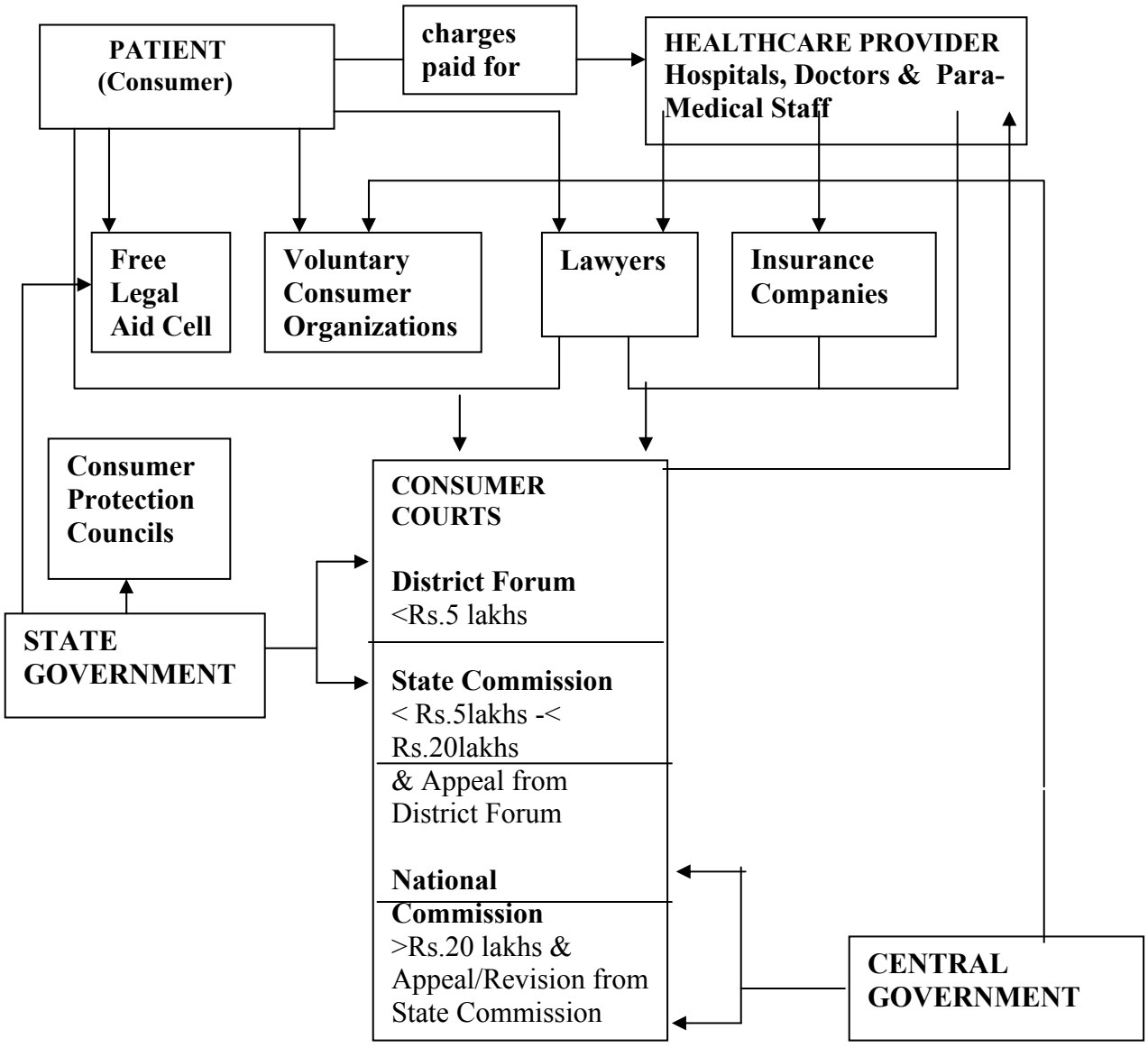

Figure 2 shows the various stakeholders involved in the process of litigation, as conceived by CPA.

In what follows, we first describe the possible sequence of events leading up to the judgment in consumer courts[103]. Using specific case studies, we will estimate transactions costs from the perspectives of various stakeholders. We shall then discuss the various ways in which providers have responded to CPA. This section will conclude with a discussion on the various procedural and institutional factors that have influenced the effective implementation of CPA with reference to medical negligence.

> *Typically, an aggrieved patient suffering from medical negligence or deficiency in care, files a case with the district or state or national consumer dispute redressal forum for compensation from his/her physician or the medical institution where he/she obtained medical care. He/she may file a case with or without help from an advocate or any voluntary organization. The court on receiving the complaint from the patient, sends out a notice to the opposite party (the physician or the hospital as the case may be) and allows a period of 30 days for the accused party to respond. In the original complaint, the patient would narrate (preferably with exact dates, location of care, details of diagnostics made, copies of original bills of payments made, prescriptions made by his/her physicians, etc.) the sequence of events and claim an amount in compensation for the adverse consequences he/she has suffered due to the alleged negligence or deficiency in the medical care received. The compensation amount claimed will determine whether the patient should approach the district or state or national forum. Typically, the compensation amount claimed would cover the cost of medical treatment received so far, the loss of past earning, loss of possible future earnings, monetary value that reflects the mental agony and pain suffered by him/her and his/her family members, advocate fees if any, and costs of prosecuting his/her case. In response to the court's notice, the accused (physician or hospital) may either choose not to challenge the patient or may send his defense with the help of his/her advocate. If he chooses to defend himself/herself, he/she is expected to give his/her version of the course of events (with dates, location and details of diagnostics) leading to the current state of health of the patient. The court then intimates both the parties to appear for further investigation. In order to establish the case one way or another, the court may invite opinions of another medical expert, whose expense will have to be borne by respective stakeholders. Often the proceedings in the court do get adjourned either for*

[103] It is useful to repeat some of details already mentioned in Chapter 2, because they help us keep the context in mind before analyzing the various factors.

lack of a quorum or on request for time by the accused to prepare his/her defense. In the end, if the court awarded any compensation to the patient, the accused will be required to pay the amount within a period of 30 days from the date of judgment. The court will order a penalty amount if the accused fails to pay the compensation within specified time. The accused is allowed to challenge the judgment given by the lower court. Even the judgment of the National Commission can be challenged in the Supreme Court of India. At each level, the judgment is supposed to be given within the stipulated time (of 90 days in cases where there is no need for expert opinion or within 150 days where such expert opinion is needed). If the complaint is found frivolous, the court may order the complainant to pay a penalty. In some instances, the court may ask both the physician and the hospital to share the compensation amount declared.

Studies in the past have shown that CPA has become a complex and long drawn affair. However, there is very little empirical work on how expensive or inexpensive consumer courts have become in protecting the interests of the complainants or the accused. The present study makes a pioneering effort in estimating the transactions costs involved among various stakeholders. In what follows, we first present the cost of various items from the perspective of patients, physicians, and consumer courts.

4.2.2. Transactions costs (TC):

Transaction costs are the costs of arranging a contract *ex ante* and monitoring it *ex post* i.e. costs of acquiring information, establishing contracts, designing, negotiating, monitoring and enforcing contracts, avoiding and resolving a conflict, etc. The costs of running the economic system are transaction costs, for example the governance of the whole system, the establishment of various departments.

In regulating healthcare through CPA, various stakeholders like the government, health providers, patients, voluntary consumer organizations, etc., incur much costs, otherwise called transaction costs. We have tried to identify these transaction costs from the point of view of various stakeholders.

First, we need to conceptually identify several factors that could enter into for calculation of TC. These are shown in Table 4 below. Although the list is not exhaustive, it provides an idea of the nature of data we require for calculating TC.

Table 4. **Various items that determine Transactions Costs:**

Transaction costs incurred by the Consumer

1. Cost of time spent on treatment (in certain cases) subsequent to the alleged negligent act of the previous health provider.
2. Cost of time spent with the advocate in briefing him about the case.
3. Cost of litigation, which includes sending notice, time spent on drafting the complaint, stationary expenses, photocopying charges, filing charges, etc.
4. Advocate's fee
5. Travel costs (for subsequent treatment, to court and advocate's office)
6. Cost of obtaining an expert opinion (travel, waiting time)
7. Cost of collecting relevant material to establish his case.
8. Loss of wages/salary due to appearing before the Court.
9. Cost of time and travel spent on negotiating with the health-provider.

Transaction costs incurred by the provider (physicians/hospital)

1. Cost of time spent with the advocate in briefing him about the case.
2. Cost of litigation, which includes sending reply notice, time spent on drafting the defense, stationary expenses, photocopying charges, etc.
3. Advocate's fee.
4. Cost of time spent of hearings before the Court.
5. Travel costs (to the court, advocate's office, etc.)
6. Cost of collecting relevant material to establish his case.
7. Malpractice insurance premiums.
8. Cost of time and travel spent on negotiating with the patients.

Transaction costs incurred by the voluntary consumer organizations

1. Cost of time spent with the complainant in understanding the case.
2. Cost of time and travel spent on negotiating between the parties.
3. Cost of litigation, which includes sending notice, time spent on drafting the complaint, stationary expenses, photocopying charges, filing charges, etc.
4. Cost of obtaining an expert opinion (travel, waiting time)
5. Cost of collecting relevant material to establish complainant's case.

Transaction costs incurred by the Government

1. Cost of maintaining registers of voluntary consumer organizations
2. Cost of time spent by various government authorities like Commissioner of Civil Supplies, Joint. Commissioner, Assistant. Commissioner, etc., in conducting Consumer Protection Council meetings once every three months.
3. Cost of running the redressal machinery, which includes non-recurring and recurring expenses, i.e. the administrative expenses like the salaries, infrastructure, etc.
4. Cost of time spent on hearing medical negligence cases by the consumer courts.
5. Cost of administration (including time cost of supporting staff in particular)

Though there is no court-fee or process-fee charged to consumers or the accused, the financial burden on them in going through the regulatory machinery, is likely to be considerable. Table 5 shows an estimate of transactions costs for various stakeholders for all

12 primary cases we have studied. In each case, we identified the names and addresses of the complainants, the accused, the advocates and the voluntary consumer organizations wherever they were present. We had detailed open-ended discussions with several of them to understand their versions of the case and obtained an estimate of the expenses they had incurred in defense. Appendix VI & VII contains the questions that guided our discussions with stakeholders. Appendix VIII illustrates the methodology used to arrive at TC for government (the consumer courts).

Table 5. **Transaction costs incurred by patient, health provider and consumer courts in individual litigation**[104, 105]

Sample	Patient	Provider	Consumer Courts	Time taken for disposal (in months)	Judgement in favour of	Compensation claimed.
01	10,000	40,000	623 (DF) + 1033 (SC)	14 (DF) + 35 (SC)	Provider	Rs.4,36.077
02	5,800	NA[106]	1615	39	Provider	Rs.2,11,000
03	5648	36,250	623	11	Provider	Rs.1,61,000
04[107]	NA	NA	1051+1711	16 (DF) + 41 (SC)	Provider	Rs.5,00,000
05	NA[108]	40,000	1380	29	Provider	Rs.4,75,000
06	NA[109]	20,000	879	12	Provider	Rs.2,19,000
07	3,500	6,000[110]	2790	62	Provider	Rs.2,18,000
08	NA[111]	7,000	1991	43	Provider	Rs.2,13,500
09	49,000	NA[112]	675	06 (exparte)	Patient	Rs.4,50,000 (Rs.4.50 lakhs

[104] For some stakeholders, we could not calculate TC. The reasons are given below.
[105] Appendix V contains details of all 12 medical negligence cases. The reader is urged to go through these cases to get an appreciation of the nature of medical cases being handled in consumer courts.
[106] The healthcare provider, naturopathy doctor, had sold his clinic to somebody else and his whereabouts are not known.
[107] The doctor informed us that he had not spent any amount on litigation, as the lawyer was his friend. He had spent only for telephone charges, which he does not remember. The patient was not present at the time of our visit.
[108] The patient had shifted his residence. We were not able to meet him at his new residence.
[109] The patient had shifted her residence. Thus, we were unable to locate his new residence.
[110] The second opposite party, nursing home, appeared party-in-person. The director of the nursing home was bedridden and hence refused to meet us.
[111] The patient's address provided is situated outside the state of Tamil Nadu.
[112] There are two opposite parties, the doctor and the hospital. The doctor who was a visiting consultant had stopped visiting the hospital. The hospital and doctor failed to represent themselves in the litigation.

						granted as compensation)
10	3,600	NA[113]	722	07 (Madurai)	Patient	Rs.1,00,000 (Rs.27,000 granted as compensation)
11	12,300	NA[114]	863	10 (Madurai)	Provider	Rs.98,120
12	4,600	NA[115]	1709	44	Provider	Rs.61,806

(DF- District Forum; SC- State Commission; NA- Not Applicable)

Among the 12 sample cases examined, 10 were in favour of the accused. The remaining two cases (samples 9 and 10) were judged in favour of the complainants (patients). *11 out of 12 complainants (except case 12) had used advocates to defend their cases. Increasing reliance on the services of advocates indicates that CPA is perhaps no longer a simple and inexpensive legal mechanism that it was meant to be.*

Among the three major stakeholders, the transactions costs to the consumer courts are the least in all cases considered. The transactions costs to patients have varied from Rs.3600 to Rs.49,000.00. The transactions costs for providers have varied from Rs.6000.00 to Rs.40, 000.00.

There are possible two reasons for the high transaction costs: One is the long duration that consumer courts take to resolve the disputes; the other is the advocate's fee, which forms a significant portion of patient's transaction costs. More often, advocates' fees form a fixed portion of the compensation received by complainants. This could vary from 2 to 10% depending upon the nature of the case, amount claimed, etc. For example, in sample Case 9, TC for patient was Rs.49, 000.00 because the lawyers' fee alone accounted for Rs.45, 000.00, which was 10% of the compensation amount the patient received. In Case 1, the patient appealed to the State Commission against the judgment of the district court. As a result, the total duration of the court proceedings, cost of frequent visits to State capital to appear before

[113] We were unable to meet the healthcare provider. The doctor remained *ex parte* in the litigation.
[114] We were unable to meet the healthcare provider.
[115] The doctor was has been accused had left his service from ESI hospital and has gone abroad for higher studies.

the State Commission and other incidental expenses also increased. The consequence is reflected in the high TC for the patient.

We now turn to other factors that have influenced the effective implementation of CPA and functioning of consumer courts.

4.2.3. Infrastructure and other constraints:

The effective implementation of CPA depends on two critical aspects: One relates to the inherent capacity of consumer courts to handle medical cases. The other relates to the availability of human and physical resources for the courts to function. The first issue – on the capacity of consumer courts – cannot be questioned by any stakeholder at this stage of development as the Supreme Court of India has already given its judgment that any medical service received in the nature of "contract for service" will come under the purview of the CPA[116]. But the second question remains: Do consumer courts have adequate physical and human resources to function effectively? The proof of the pudding is in the eating. One way to measure the adequacy or inadequacy of infrastructure is to look at the number of pending cases over time and the staff in position to handle cases. As on February 2003, about 6000 cases were pending before the 30 consumer disputes redressal fora in the State. The district forum Chennai (south) tops the list with about 1400 cases pending followed by Chennai (north) with 1100. About 550 complaints are pending adjudication before the Madurai Forum, 350 each in Trichy and Vellore, and 300 in Salem. As far as the State Commission is concerned, by early 2003 there were about 3000 appeal petitions and 900 original petitions to be disposed off[117]. Table 6 presents the number of pending cases before the six district courts in Tamil Nadu.

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[116] Recent literature illustrates clearly the persistence of strong arguments against capacity of lawyers and consumer courts in deciding medical negligence and deficiency in services. The arguments on this issue are not yet over. We will not go into these arguments as they are out of the purview of this study.

[117] Pendency of cases dogs consumer fora, *The Hindu, dated 10 March 2003.*

Table 6. **Details of pending cases over time (as of December 2002)**

District Forum	Total pending cases.	Pending for less than 90 days	Pending for more than 90 days	Pending for more than 180 days	Pending for more than 1 year	Pending for more than 2 years
Chennai (North)	1059	98	160	166	287	384
Chennai (South)	1666	186	140	256	556	528
Madurai	546			85	129	160
Srivilliputhur	185			104	52	16
Tirunelveli	167		40	107	-	-
Tuticorin	16	16	-	-	-	-

Source: From respective District Forum

In the Chennai-North District Consumer Redressal Forum, out of a total of 1059 pending cases (as of December 2002), 278 were filed before 1998. Similarly, in Chennai-South District Consumer Redressal Forum, out of a total of 1666 that were pending, 211 were filed before 1998.

Similarly in all 12 primary cases we have studied, none was disposed of within the stipulated time frame. Except two cases (Cases 9 and 10) all other cases took 10 or more months, some of them more than 30 months.

Clearly, the number of pending cases has been increasing over the years, reflecting inadequate resources and/or complexity of medical negligence cases.

The following have emerged as primary reasons for the long delays caused in court proceedings. These factors have a direct bearing on the overall effectiveness of CPA.

- ✓ *Vacancies and overwork of existing staff*: This is one of the major reasons for the delay. The judges and the members are appointed by the respective state governments. The state government has been very slow in making appointment in various consumer courts. Often Presidents of consumer courts have not been able to proceed and pass judgments due to lack of quorum to decide the matter. In many district courts, the posts of the President have been vacant for months together. As a result, many district Presidents have joint responsibilities. For example, at the time of this study, the President of Srivilliputhur

district forum was assigned with additional charge of Madurai district forum too. Similarly, the district fora at Tirunelveli, Tuticorin and Nagercoil all functioned under the same President simultaneously. He would sit in Tirunelveli on Tuesdays, Wednesdays and Fridays. At Tuticorin, he would sit on Thursdays and at Nagercoil on Mondays. The President and member of the State Commission retired at the end of March 2003 and hence the Commission became defunct since then.

- ✓ *Absenteeism by the president and members of the consumer courts*: From some of the cases, we found that the president has been on long leave for months together. Similarly pronouncing of judgments has been adjourned for several hearings together because of lack of quorum (absenteeism by members). In Srivilliputhur District Forum, the lady member, whose services were actually till October 2002, resigned from service in May 2002. Though her resignation had not been accepted, she absented herself from coming to the Court.

- ✓ *Legal loopholes in the proceedings:* There have been instances where parties have remained *ex parte* (failed to appear before the court) and later moved applications to set aside the order and continue the proceedings and once again remained *ex parte*.

- ✓ *Understanding between the advocates in dragging on the proceeding:* Many advocates we have discussed with have confirmed adoption of this method among them for causing delay in the proceedings. Non-cooperation of parties (complainants and opposite parties) is another reason for accumulation of cases[118].

- ✓ *Inadequate infrastructure and financial resources*: In Srivilliputhur (Virudhunagar district), the forum was supposed to have 6 staff members (2 clerks, 1 steno, 1 junior assistant and 2 office assistants) but it was functioning with only 4 staff members. Similar situation prevailed at Tirunelveli District Forum. As one official put it:

> *"There are more empty chairs than the number of staff. Similarly, the photocopiers are not in working condition. The government neither funds the*

[118] Refer to footnote 104

maintenance of these machines nor does it enter into service contract for maintenance. Similarly, the annual limit on telephone bills is restricted to Rs.3000, which means the monthly bill should not exceed Rs.250. We are forced to restrict making calls to State Commission at Chennai even in cases of emergency and send records by ordinary mail, which causes further delay in conducting the court proceedings. Similarly, the process fee, which is being borne by the consumer courts in sending summons to the opposite parties, is restricted to Rs.2000 per year. Once, this fund is over, we have to apply for release of further funds. Hence, we ask the complainants to provide covers and affix postal stamp (which costs nearly Rs.23 per opposite party)."

- ✓ *Increasing complexities*: Many judges and lawyers with long experience have opined that several of the medical negligence cases by their very nature are quite complex and therefore demand much more time and examination than the time allowed under CPA. In our interview with the former President of the State Commission, he said: "I*t is very difficult to establish that there has been negligence on the part of the doctors. The burden solely lies on the complainant and in most cases, they fail to prove the same. There arises a necessity to engage advocates in medical negligence cases as the patient (mostly) is not equipped to put forth his case. Even the judges of lower courts (district consumer court) are not well equipped in appreciating the merits of such case and arriving at the quantum of compensation that is to be granted*". During our visits to advocates' offices, we found them reading through huge volumes of medical text books for preparing their case/defense. While it is true that not all medical negligence cases may be complex, it is very much plausible that several of the court cases are complex enough to require more than the stipulated time under the law. Our own intuition on many of the cases we have studied lends support to this view expressed by several stakeholders. Increase in time taken for disposal of medical negligence complaints in comparison with the other consumer complaints, indicates that procedure under CPA is not quite simple. The representatives of various VCOs[119] have expressed that the consumer courts were excessively following regular court procedures (followed in civil courts) and hence led to complexity and backlog of cases.

4.3. How have physicians' responded to CPA?

[119] Refer to Appendix X for the list of VCOs contacted

CPA was expected also to bring about a number of changes in the behaviour of physicians to protect their own interests in the long run. Some of the behaviour changes could be viewed as positive, while some others as negative. To understand these changes empirically, we conducted a postal survey of 500 medical professionals in Tamil Nadu. This survey elicited information on their overall experience with and responses to CPA[120]. Through this survey, we have also supplemented our earlier observations on TC from physicians' perspective. In the rest of this chapter, we shall first summarize the findings of this survey.

4.3.1. Survey methodology:

We selected a sample of 500 doctors (consisting both general physicians and specialists from diverse disciplines) in Tamil Nadu. Of these 500, 350 were from Chennai city and the remaining 150 from various other cities (namely, Madurai, Coimbatore, Trichy, Tirunelveli, Thanjavur and Villipuram) in TN. The names and addresses of these professionals were obtained from the telephone directories of respective towns. A detailed questionnaire[121] was sent to these medical professionals to collect information on their awareness on CPA, personal experiences, if any (such as where the case was filed, the forum, outcome of the case, duration, amount spent on defending the case on going through the redressal machinery of CPA, whether they had given expert opinion in any other case), insurance against malpractice litigation, opinion on practice of defensive medicine, changes in practices adopted by them such as referral rate, follow-up, diagnosis, prescription of drugs, documentation, time spent with patients and in-house medical audit. Finally, they also asked to provide ideas on improving the redressal machinery and make suggestions on alternative mechanism to deal with doctor-patient cases.[122]

Out of 500 questionnaires sent, 80 (16%) doctors replied. 59 were returned with different postal endorsements as "no such person", "left the place", etc. 89% (n=71) were male respondents. The years of practice ranged ranged from 3 to 44 years. 58 respondents were

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[120] Refer to Appendix IX for the questionnaire sent to the doctors.
[121] Refer to Appendix III for details of this questionnaire.
[122] The questionnaires were mailed in early January 2003. We allowed five weeks to receive responses.

from Chennai, 10 from Tirunelveli, 7 from Coimbatore, 2 from Trichy and one each from Thanjavur, Ulundurpet and Villipuram towns.

4.3.2. Awareness of CPA:

96% (n=77) of the respondents were aware of CPA. 34% (n=27) of them did not know that they need not engage an advocate before the consumer court. This question was specifically posed to the respondents to know their awareness on the functioning of the CPA.

4.3.3. Direct experience with CPA:

Out of 80 respondents, only 13 (16%) were involved in a litigation before the consumer courts. 8 respondents were before the district forum, 4 were before the State Commission (except 1 which was at another state, namely the Karnataka State Commission) and 1 was before the National Commission.

Of these 13 respondents, 10 got judgments in their favour[123]. Of these 10 cases, in 3 cases negligence was not proved, 3 cases were dismissed for default (which means the complainant or his representative (advocate) did not pursue the case). The remaining two cases were still pending. Only one respondent had lost his case and had to pay a compensation of 75,000.

4.3.4. Transactions Costs:

The cases against 10 respondents took between 2 to 96 months for disposal. Except for one case, all others took more than the stipulated 150 days (5 months). 9 of 13 respondents had spent between Rs.500 and Rs.50, 000 towards advocate fee, which directly adds to their transactions costs.

Many physicians pointed out loss of clinical hours (and loss of earnings) as a major component of opportunity cost of defending their case. 6 of 13 respondents estimated their

[123] This again is in line with the overall trend for medical cases for all-India (Bhat 1997)

loss of time (in terms of visiting advocates office, consumer courts, etc) to be between Rs.2000 and Rs.2, 00,000.00. Such expenses should also add to TC.

The travel cost (in visiting advocate's office, consumer courts, etc.) incurred by 5 respondents varied between Rs.500 to Rs.2, 00,000. Similarly, 6 respondents have spent between Rs.100 and Rs.10, 000 towards documentation charges, such as photocopying of the relevant defense material, purchasing medico-legal books, etc. Only one respondent had spent Rs.2000 for obtaining expert opinion in defending his case.

4.3.5. Professional Malpractice Insurance:

48 (60%) respondents have insured themselves against malpractice litigation with various insurance companies. The respondents have insured themselves between Rs.100,000 and Rs.500,000 with an annual premium ranging from Rs.160 to Rs.10, 000.

Of these 48 respondents, 18 (37.5%) have joined the Professional Protection Linked Social Security Scheme (PPLSSS)[124] started by Indian Medical Association. Under this scheme, providers pay a premium up to Rs.5500 that covers them up to Rs.5 lakh for 5 years.

4.3.6. Changes in practice style:

It is widely believed that physicians have adopted newer clinical practice, in response to CPA. Table 7 shows their views on ways in which they have responded to CPA. We briefly state our main observations.

Table 7. *Responses to the practices adopted by individual physicians*

Practice	**No Change**	**Moderate Change**	**Substantial Change**
Referal Rate	35% (n=28)	35% (n=28)	22.5% (n=18)

[124] Professional Protection Linked Social Security Scheme (PPLSSS) was started by Indian Medical Association (IMA) in 2001 to protect the doctors and hospitals in case of litigation arising during the process of their professional practice. It provides financial as well as guidance in defending their case.

Follow Up	39% (n=31)	34% (n=27)	15% (n=12)
Diagnosis	49% (n=39)	21% (n=17)	20% (n=16)
Prescription of drugs	46% (n=37)	32.5% (n=26)	12.5% (n=10)
Documentation	21% (n=17)	39% (n=31)	34% (n=27)
Time spent with patients	31% (n=25)	46% (n=37)	13% (n=11)
In-house medical audit	12% (n=10)	11% (n=9)	6% (n=5)

4.3.6.i. Increase in defensive medicine:

84% [n=66] of the respondents have opined that there has been a moderate to substantial increase in defensive medicine as a result of CPA. [n=13] 15% have mentioned there was no change in defensive medicine, overall.

Several of them justified defensive medicine, as one doctor who fought a 4 year long battle before the district and state consumer court stated:

> *"...if a patient has malaria he had to spend just Rs.50, which includes my consultation charges of Rs.20 and cost of medicines which is Rs.30. Now, I shall not take any chances. I would ask the patient to undergo blood and urine tests, a scan of the abdomen, an x-ray of the abdomen, in order to rule out any other ailment as the patient should not say in Court that he had complained that he had pain in the abdomen to the doctor in the first instance itself. All these including medicines would cost Rs.1500 for treating malaria. There is nearly 300% increase in cost of treatment in this instance".*

4.3.6.ii. Referral rate:

57.5% of the respondents agreed that there was a moderate (n=28) to substantial (n=18) change in their referral rate of the patients. 35% responded that they had not changed their referral behaviour subsequent to being brought under CPA.

4.3.6.iii. Follow-up:

49% of the respondents have shown a moderate (n=27) to substantial (n=12) increase in the follow-up of patients. However, 39% have felt that there was no change in the follow-up of patients.

4.3.6.iv. Diagnosis:

49% of the respondents mentioned that there was "no change" in their medical practice relating to diagnosis. However, 41% of the respondents noted that there was moderate (n=17) to substantial (n=16) change, which means they made the patients undergo more diagnostic tests.

4.3.6.v. Prescription of drugs:

46% of the respondents have mentioned that there was "no change" in their medical practice relating to prescription of drugs. 32% of the respondents felt that there was a moderate increase in their practice in prescribing drugs. 12.5% respondents have agreed that there was a substantial increase in their prescription practice in response to CPA.

4.3.6.vi. Documentation:

72.5% of the respondents mentioned that there was moderate (n=31) to substantial (n=27) increase in documentation. 21% mentioned that there was no change in their documentation. The Medical Superintendent of a Corporate Hospital in Chennai (which has faced cases in the consumer courts) feels that "*it is only the documentation costs, which are very high. We are maintaining records to safeguard ourselves*".

4.3.6.vii. Time spent with patients:

60% of the respondents have moderately or substantially increased their time spent with patients. 31% have reported no-change in their clinical practice in spending time with the patients. A leading Ophthalmologist and former Chancellor of Dr MGR Medical University states:

"I have started taking little more time in spending with the patients. This helps the patient in gaining confidence in the doctor. I give priority to the patient whose problem has aggravated subsequent to my treatment, as this would help me in two ways: the patient would not be irritated if I don't make him wait and he would not spread negatives to the other patients".

4.3.6.viii. In-house medical audit:

17.5% respondents agreed that there was moderate to substantial increase in their in-house medical audit. 12.5% mentioned that there was no-change. However, 66% of the respondents mentioned that it was "not applicable" for them.

4.4. How have Voluntary Consumer Organizations (VCOs) played their role?

Consumer organizations have been in existence in India since the 1960s. There were several small organizations (registered under the Societies Act) in the country working for the cause of consumers against food adulteration, unfair trade practices, rising prices of commodities, hazardous drugs, faulty weights etc. In 1986 when the CPA was drafted, the voluntary consumer organizations were called upon to raise their views on the issue.

There has been a substantial increase in the number of VCOs in Tamil Nadu after the enactment of the CPA. As of 2002, there were 147 VCOs recognized by the State Government in Tamil Nadu[125]. Many VCOs in Tamil Nadu have contributed to consumer awareness generated through seminars, meetings and training programmes. They provide legal advice to consumers who come to them with their grievances. Some of the organizations also file complaints on behalf of the consumers. A VCO[126] in Cuddalore had filed 700 complaints in consumer courts, out of which 8 were against doctors. Similarly another VCO[127] at Salem had filed totally 150 complaints in consumer courts, of which 4 related to medical negligence.

[125] Policy Notes 2002-03, Department of Co-operation, Food and Consumer Protection, Govt. of Tamil Nadu.
[126] District Consumer Protection Organization, Cuddalore
[127] Consumer Welfare Council, Salem

Many VCOs have also formed regional networks amongst themselves which give them more credibility in representing consumer interests and welfare. The Federation of Consumer Organisations in Tamil Nadu (FEDCOT), formed in 1990, is one such network with more than 350 member VCOs. FEDCOT also takes up activities like training, education, awareness and advocacy campaigns at grass root level. Most of these VCOs offer legal advice to the consumers. As an instance, in a medical negligence case before the District Consumer Dispute Redressal Forum, Cuddalore, a VCO filed a case on behalf of the consumer and got a compensation of Rs.76,000[128].

In April 2002, the State Commission in Tamil Nadu, in a case filed by a VCO on behalf of the widow against a premier hospital held that a VCO does not have the right to audience (they have only the right to appear and not argue on behalf of the consumer)[129]. This decision of the State Commission challenged the very role of VCOs. The decision of the State Commission was challenged before the National Commission. The National Commission while over-ruling the order of the State Commission held that consumer associations and organizations have the right to represent and argue for consumers before consumer courts[130].

The VCOs have also provided manpower and infrastructure facilities for the functioning of the consumer courts[131]. The VCOs have also been quite effective in arriving at out-of-court settlements. We found that there had been instances where the matters have been settled through mediation. For example, a VCO[132] successfully negotiated with the doctor, and obtained Rs.8000 for the patient as compensation for wrongfully administering an outdated anti-rabies injection. This was done without going to the consumer court.

Concluding remarks on effectiveness of CPA:

Evidently, CPA has not only brought about some potentially negative practices such as increased diagnostics and other forms of defensive medicine that would increase the costs of

[128] Doctor ordered to pay compensation, *The Hindu,* 24 June 2000.
[129] Mrs. Madhavi & others Vs. Apollo Hospitals, O.P.No.104/2000, order dated 10 April 2002
[130] NGOs can represent consumers on fora, *The Hindu, 13 April 2003*
[131] For example, Trichy District Consumer Forum received a computer from a VCO.
[132] SMN Consumer Protection Council, Chennai

care, but also certain positive changes in the attitude and practices of physicians such as increased documentation of patients' health status, increase in in-house medical audit in private medical institutions, and an increase in time spent with patients to improve patients' trust in them.

The costs of positive changes in the behaviour of providers are likely to get passed on to patients to some extent but they definitely reflect the effect that CPA has made among the professionals over the years. In this sense, the CPA certainly has had some amount of preventive regulatory effects on the regulatees namely the physicians and medical institutions. To the extent increased diagnostics were essential, they should also be considered as signs of positive effects on the behaviour of regulatees, the physicians. However, we have very little empirical basis to support this line of thinking; on the contrary we have opinions of several experts supporting the view that the increased diagnostics should be seen more as being an unhealthy trend (because it is a sign of defensive medicine) than as any positive welcome phenomenon.

Our evidence strongly suggests that consumer courts have become an expensive legal redressal mechanism to both the patients and the physicians. As a result, it has become inaccessible to the poor in general. In almost all the court cases that we have studied and examined, both physicians and patients have used the services of advocates. This means, the court proceedings have become complex, instead of being simple as envisaged in the objectives of CPA. Because medical negligence cases often involve complex analyses, the courts also tend to take much more time than given.

Chapter 4: Concluding Remarks

The two regulations, namely CPA and THOA that we have considered for this study illustrate a number of policy challenges and organizational constraints prevailing in health care sector in Tamil Nadu in particular and in India in general. They throw much light on the limits to regulations in healthcare and also possible alternatives available to bring about intended changed in health sector. In this concluding chapter, we shall elaborate our reflections on these issues.

Both regulations, CPA and THOA, were motivated by larger social concerns. CPA was introduced by the Central Government in 1986 as part of larger concern for protecting the rights of consumers' in India. THOA was introduced primarily to curb "commercialization" in human organs in India.

CPA was also a response to the decline in trust and confidence of patients in medical professionals driven by commercialization of healthcare market in India. They have another common factor, in that THOA was introduced in 1994 (in 1995 in Tamil Nadu) whereas medical services were brought under CPA in the year 1995. They have had the same years of experience and thus qualify for some comparative observations as well.

What can be said of the capacity of these two regulations in bringing about the desired changes? Can they be more effective? Are there other ways of achieving the intended objectives? We have the following observations to make in this context:

1. In regard to THOA, there is very little evidence to support that it has brought down commercialization in human organs. On the contrary, commercialization seems to have increased since its introduction.

2. With regard to CPA, two related observations can be made. (a) It has become complex, long-drawn and expensive for aggrieved patients to seek legal remedies. These are clearly

different from the intended objectives of CPA. (b) But CPA has brought about much positive change in raising patients' awareness of their rights. This is evident from the increasing number of court cases against medical negligence, though this could also be seen as driven by a number of other factors. Every single judgment made in favour of patients can be seen as a step towards strengthening patients' rights, thus contributing to better functioning of healthcare system in place. To this extent, CPA can be seen as contributing to the notion of equity in patients' access to redressal machinery. But financial access to such redressal mechanisms has not been so favourable to the poor as intended.

3. Several "adaptive" mechanisms and "unintended" consequences have also surfaced to counter the effects of these regulations. These are not *per se* undesirable. In the case of CPA, several physicians in Tamil Nadu have come together under the leadership of the Indian Medical Association and initiated a Professional Protection Linked Social Security Scheme (PPLSSS) to protect themselves against malpractice suits (refer PPLSSS mentioned in chapter 3). There are about 12500 members in IMA and 4000 members are part of this PPLSSS. By becoming a member of this scheme, the physician/hospital gets indemnified against malpractice litigation up to the amount secured. Increasingly, physicians have begun to maintain records of patients they treat in the event of facing any legal suit in consumer courts. This is a positive consequence of CPA, though the costs of this may get passed on to patients to some extent. The case of THOA illustrates another kind of positive "unintended" behaviour among providers. In Chennai, a network of providers, who on principle do not perform unrelated transplants, have developed a mechanism for sharing human organs harvested from diseased and from brain-dead persons. The case of MOHAN foundation is an illustration (Refer to Chapter 3). But such initiatives are less likely to attract many more providers as they have a direct bearing on their financial turn over. But such initiatives point to potential (though limited) alternatives available to counter commercialization in human organs, which the law has tried but failed to curb.

4. Both CPA and THOA have helped understand better the dynamics of private health sector in India. The unbridled growth of private sector have led to several unhealthy/unethical practices among medical professionals and other stakeholders. The fact that very few medical professional come forward to provide expert opinion against their colleagues illustrates a kind of "protective role" they perform towards each other. To the extent this takes place, the law loses its effectiveness. Several providers and institutions have unabashedly allowed middlemen/brokers to operate in their own premises, and thus have allowed commercialization to boom under their very nose. Such unhealthy consequences motivated by financial considerations have also led to dilution of medical norms for matching compatibility between donors and recipients. Since the AC has not imposed any specific set of medical standards that donors and recipients should satisfy for transplantation to take place, several professionals have taken cover under this and allowed poor unrelated donors not-in-good health to donate organs. Part of the reason for relaxing these norms is due to availability of better immuno-suppressant drugs in the market. The poor by definition are in poor health. Therefore, most if not all of them, should not have been allowed to donate at all in the first instance. Therefore, resorting to lower norms in matching donors' and recipients' will compromise the health of both donors and recipients. The law has weakened its capacity to regulate commercialization by not imposing such norms.

5. Overall, THOA in its present form and content seemed to have imposed much more costs than benefits it has conferred on the society. The social and economic institutions that promote illegal markets have been the main cause for the poor performance of the regulatory bodies. Better infrastructure and human resources for regulatory bodies could help but only to a limited extent in improving the effectiveness of regulatory bodies. On the contrary, the effectiveness of the machinery that implements CPA has suffered more from poor infrastructure support and its own procedural codes. The social cost of CPA arising from defensive medicine (adding to the financial burden on the patients) is a worrisome phenomenon but the outcome seen in terms of increasing awareness of patients' rights cannot be underplayed.

6. Public policy should allocate substantial resources for public campaign on organ donation, which will go a long way in promoting alternative organ transfer policies in the state.

7. Increasingly, civil societies (voluntary consumer organizations) have shown some capacity to bring about "out of court" settlement among disputing parties. Such "informal" arrangements could become a viable and even desirable alternative to formal institutional arrangements established through CPA, which has proved costly, long drawn, and complex. There is also considerable scope for voluntary non-governmental organizations to collaborate with regulatory bodies under THOA. This could come in the form of providing counseling and follow up provided to potential donors and recipients, and increasing people's awareness of organ donations through educational and campaigns.

8. If preventing commercialization in human organs were a desirable social policy to pursue, then THOA in its present form and the regulatory structure it has in place would be of little use. One feasible and desirable alternative policy option to curb commercialization in human organs seems to lie in promoting cadaver transplants. So far, there have been very little efforts from policymakers in this direction despite the enormous pool of cadaver organs that is already available from public hospitals. Cadaver policy also requires substantial financial and human resources (such as trained transplant coordinators) and changes in current policy practices (such as empanelling larger number of professionals to certify brain dead and resources to harvest organs from deceased person in public hospitals). The consequent social benefits arising from this alternative would outweigh the additional financial burden falling on the state.

9. Another alternative would be to distinguish organ purchasing from organ distribution mechanisms. Organ purchasing could be done through a centralized agency, which might either purchase or receive organs through voluntary donations. Distribution of organs among competing recipients would require an elaborate set of principles. India is far from

developing such a system. In any case, such an alternative requires a "good" regulatory mechanism in place, which does not exist now in India.

10. Arbitration and conciliatory mechanisms appear to be an alternative to the present adversarial system (consumer courts) under the CPA. In fact they can function as a complementary/supplementary system to, instead of replacing, consumer courts. At present, the Department of Health and Family Welfare in Tamil Nadu devotes little resources to protect and promote patients' rights conferred under the CPA. Public hospitals in the recent past have faced many criticisms for deficiencies in services they offer. These complaints are mostly heard in civil courts, but rarely brought under the purview of CPA.

11. Our overall impression is that the experience of CPA and THOA indicates a fall in society's confidence and trust in medical profession's ability to represent patients' interests without being influenced by monetary considerations. The fact that close to 15% of cases filed in District Fora has gone for appeal before the State Commission illustrates the lack of confidence of patients in both the professional judgment and also in the ability of redressal mechanism in delivering justice to them. This requires a much deeper study and reflection from public policy makers and other alike.

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Appendix I

Consumer Protection Act, 1986
[68 of 1986]

An Act to provide for the better protection of the interest of consumers and for that purpose to make provision for the establishment of consumer councils and other authorities for the settlement of consumers' disputes and for matters connected therewith.

Be it enacted by Parliament in the Thirty-seventh year of the Republic of India as follows :—

Chapter I

Preliminary

Short title, extent, commencement and application.

1. (1) This Act may be called the Consumer Protection Act, 1986.

(2) It extends to the whole of India except the State of Jammu and Kashmir.

(3) It shall come into force on such date as the Central Government may, by notification[133], appoint and different dates may be appointed for different States and for different provisions of this Act.

(4) Save as otherwise expressly provided by the Central Government by notification, this Act shall apply to all goods and services.

Definitions.

2. (1) In this Act, unless the context otherwise requires,—

[134] [(*a*) "appropriate laboratory" means a laboratory or organisation—

(*i*) recognised by the Central Government;

(*ii*) recognised by a State Government, subject to such guidelines as may be prescribed by the Central Government in this behalf; or

(*iii*) any such laboratory or organisation established by or under any law for the time being in force, which is maintained, financed or aided by the Central Government or a State Government for carrying out analysis or test of any goods with a view to determining whether such goods suffer from any defect;]

[135] [(*aa*) "branch office" means—

(*i*) any establishment described as a branch by the opposite party; or

(*ii*) any establishment carrying on either the same or substantially the same activity as that carried on by the head office of the establishment;]

(*b*) "complainant" means—

(*i*) a consumer; or

(*ii*) any voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or under any other law for the time being in force; or

(*iii*) the Central Government or any State Government;

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[133] 15-4-1987 (Chapters I, II & IV).

[134] Substituted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

[135] Inserted, *ibid*

[136][(*iv*) one or more consumers, where there are numerous consumers having the same interest;]
who or which makes a complaint;
(*c*) "complaint" means any allegation in writing made by a complainant that—
[137][(*i*) an unfair trade practice or a restrictive trade practice has been adopted by any trader;]
(*ii*) [138][the goods bought by him or agreed to be bought by him] suffer from one or more defects;
(*iii*) [139][the services hired or availed of or agreed to be hired or availed of by him] suffer from deficiency in any respects;
(*iv*) a trader has charged for the goods mentioned in the complaint a price in excess of the price fixed by or under any law for the time being in force or displayed on the goods or any package containing such goods;
[140][(*v*) goods which will be hazardous to life and safety when used, are being offered for sale to the public in contravention of the provisions of any law for the time being in force requiring traders to display information in regard to the contents, manner and effect of use of such goods,]
with a view to obtaining any relief provided by or under this Act;
(*d*) "consumer" means any person who,—
(*i*) buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods other than the person who buys such goods for consideration paid or promised or partly paid or partly promised, or under any system of deferred payment when such use is made with the approval of such person, but does not include a person who obtains such goods for resale or for any commercial purpose; or
(*ii*) hires [141][or avails of] any services for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any beneficiary of such services other than the person who hires [1][or avails of] the services for consideration paid or promised, or partly paid and partly promised, or under any system of deferred payment, when such services are availed of with the approval of the first mentioned person.
[142][*Explanation.*—For the purposes of sub-clause (*i*), "commercial purpose" does not include use by a consumer of goods bought and used by him exclusively for the purpose of earning his livelihood, by means of self-employment;]
(*e*) "consumer dispute" means a dispute where the person against whom a complaint has been made, denies or disputes the allegations contained in the complaint;
(*f*) "defect" means any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or [143][under any contract, express or implied, or] as is claimed by the trader in any manner whatsoever in relation to any goods;

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[136] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[137] Substituted, *ibid*
[138] Substituted for "the goods mentioned in the complaint", *ibid*
[139] Substituted for "the services mentioned in the complaint", *ibid*
[140] Inserted, *ibid*
[141] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[142] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[143] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

(*g*) "deficiency" means any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service;
(*h*) "District Forum" means a Consumer Dispute Redressal Forum-established under clause (*a*) of section 9;
(*i*) "goods" means goods as defined in the Sale of Goods Act, 1930 (3 of 1930);
(*j*) "manufacturer" means a person who—
(*i*) makes or manufactures any goods or parts thereof; or
(*ii*) does not make or manufacture any goods but assembles parts thereof made or manufactured by others and claims the end pro-duct to be goods manufactured by himself; or
(*iii*) puts or causes to be put his own mark on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself.
Explanation.—Where a manufacturer despatches any goods or part thereof to any branch office maintained by him, such branch office shall not be deemed to be the manufacturer even though the parts so despatched to it are assembled at such branch office and are sold or distributed from such branch office;
[144][(*jj*) "member" includes the President and a member of the National Commission or a State Commission or a District Forum, as the case may be;]
(*k*) "National Commission" means the National Consumer Disputes Redressal Commission established under clause (*c*) of section 9;
(*l*) "notification" means a notification published in the Official Gazette;
(*m*) "person" includes,—
(*i*) a firm whether registered or not;
(*ii*) a Hindu undivided family;
(*iii*) a co-operative society;
(*iv*) every other association of persons whether registered under the Societies Registration Act, 1860 (21 of 1860) or not;
(*n*) "prescribed" means prescribed by rules made by the State Government, or as the case may be, by the Central Government under this Act;
[145][(*nn*)"restrictive trade practice" means any trade practice which requires a consumer to buy, hire or avail of any goods or, as the case may be, services as a condition precedent for buying, hiring or availing of other goods or services;]
(*o*) "service" means service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, [1][housing construction,] entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service;
(*p*) "State Commission" means a Consumer Disputes Redressal Commission established in a State under clause (*b*) of section 9;

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[144] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[145] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

(*q*) "trader" in relation to any goods means a person who sells or distributes any goods for sale and includes the manufacturer thereof, and where such goods are sold or distributed in package form, includes the packer thereof;

[146][(*r*) "unfair trade practice" means a trade practice which, for the purpose of promoting the sale, use or supply of any goods or for the provision of any service, adopts any unfair method or unfair or deceptive practice including any of the following practices, namely :—

(*1*) the practice of making any statement, whether orally or in writing or by visible representation which,—

(*i*) falsely represents that the goods are of a particular standard quality, quantity, grade, composition, style or model;

(*ii*) falsely represents that the services are of a particular standard, quality or grade;

(*iii*) falsely represents any re-built, second-hand, renovated, reconditioned or old goods as new goods;

(*iv*) represents that the goods or services have sponsorship, approval, performance, characteristics, accessories, uses or benefits which such goods or services do not have;

(*v*) represents that the seller or the supplier has a sponsorship or approval or affiliation which such seller or supplier does not have;

(*vi*) makes a false or misleading representation concerning the need for, or the usefulness of, any goods or services;

(*vii*) gives to the public any warranty or guarantee of the performance, efficacy or length of life of a product or of any goods that is not based on an adequate or proper test thereof :

Provided that where a defence is raised to the effect that such warranty or guarantee is based on adequate or proper test, the burden of proof of such defence shall lie on the person raising such defence;

(*viii*) makes to the public a representation in a form that purports to be—

(*i*) a warranty or guarantee of a product or of any goods or services; or

(*ii*) a promise to replace, maintain or repair an article or any part thereof or to repeat or continue a service until it has achieved a specified result,

if such purported warranty or guarantee or promise is materially misleading or if there is no reasonable prospect that such warranty, guarantee or promise will be carried out;

(*ix*) materially misleads the public concerning the price at which a product or like products or goods or services, have been or are, ordinarily sold or provided, and, for this purpose, a representation as to price shall be deemed to refer to the price at which the product or goods or services has or have been sold by sellers or provided by suppliers generally in the relevant market unless it is clearly specified to be the price at which the product has been sold or services have been provided by the person by whom or on whose behalf the representation is made;

(*x*) gives false or misleading facts disparaging the goods, services or trade of another person.

Explanation.—For the purposes of clause (*1*), a statement that is—

(*a*) expressed on an article offered or displayed for sale, or on its wrapper or container; or

(*b*) expressed on anything attached to, inserted in, or accompanying, an article offered or displayed for sale, or on anything on which the article is mounted for display or sale; or

(*c*) contained in or on anything that is sold, sent, delivered, transmitted or in any other manner whatsoever made available to a member of the public, shall be deemed to be a

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[146] Substituted, *ibid*

statement made to the public by, and only by, the person who had caused the statement to be so expressed, made or contained;
(*2*) permits the publication of any advertisement whether in any newspaper or otherwise, for the sale or supply at a bargain price, of goods or services that are not intended to be offered for sale or supply at the bargain price, or for a period that is, and in quantities that are, reasonable, having regard to the nature of the market in which the business is carried on, the nature and size of business, and the nature of the advertisement.
Explanation.—For the purposes of clause (*2*), "bargaining price" means—
(*a*) a price that is stated in any advertisement to be a bargain price, by reference to an ordinary price or otherwise, or
(*b*) a price that a person who reads, hears or sees the advertisement, would reasonably understand to be a bargain price having regard to the prices at which the product advertised or like products are ordinarily sold;
(*3*) permits—
(*a*) the offering of gifts, prizes or other items with the intention of not providing them as offered or creating impression that something is being given or offered free of charge when it is fully or partly covered by the amount charged in the transac-tion as a whole;
(*b*) the conduct of any contest, lottery, game of chance or skill, for the purpose of promoting, directly or indirectly, the sale, use or supply of any product or any business interest;
(4) permits the sale or supply of goods intended to be used, or are of a kind likely to be used, by consumers, knowing or having reason to believe that the goods do not comply with the standards prescribed by competent authority relating to performance, composition, contents, design, constructions, finishing or packaging as are necessary to prevent or reduce the risk of injury to the person using the goods;
(5) permits the hoarding or destruction of goods, or refuses to sell the goods or to make them available for sale or to provide any service, if such hoarding or destruction or refusal raises or tends to raise or is intended to raise, the cost of those or other similar goods or services.]
(2) Any reference in this Act to any other Act or provision thereof which is not in force in any area to which this Act applies shall be construed to have a reference to the correspond-ing Act or provision thereof in force in such area.

Act not in derogation of any other law.
3. The provisions of this Act shall be in addition to and not in derogation of the provisions of any other law for the time being in force.

Chapter II

Consumer Protection Council

The Consumer Protection Council.

4. (1) The Central Government may, by notification, establish with effect from such date as it may specify in such notification, a Council to be known as the Central Consumer Protection Council (hereinafter referred to as the Central Council).
(2) The Central Council shall consist of the following members, namely :—
(*a*) the Minister incharge of [147][consumer affairs] in the Central Government, who shall be its Chairman, and
(*b*) such number of other official or non-official members representing such interests as may be prescribed.

Procedure for meetings of the Central Council.
5. (1) The Central Council shall meet as and when necessary, but [148][at least one meeting] of the Council shall be held every year.
(2) The Central Council shall meet at such time and place as the Chairman may think fit and shall observe such procedure in regard to the transaction of its business as may be prescribed.

Objects of the Central Council.
6. The objects of the Central Council shall be to promote and protect the rights of the consumer such as,—
(*a*) the right to be protected against the marketing of goods [149][and services] which are hazardous to life and property;
(*b*) the right to be informed about the quality, quantity, potency, purity, standard and price of goods [150][or services, as the case may be,] so as to protect the consumer against unfair trade practices;
(*c*) the right to be assured, wherever possible, access to a variety of goods [151][and services] at competitive prices;
(*d*) the right to be heard and to be assured that consumers' interests will receive due consideration at appropriate forums;
(*e*) the right to seek redressal against unfair trade prac-tices [152][or restrictive trade practices] or unscrupulous exploita-tion of consumers; and
(*f*) the right to consumer education.

The State Consumer Protection Councils.
7. (1) The State Government may, by notification, establish with effect from such date as it may specify in such notification, a Council to be known as the Consumer Protection Council for.....(hereinafter referred to as State Council).
[153][(2) The State Council shall consist of the following members, namely :—

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[147] Substituted for "the Department of Food and Civil Supplies" by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[148] Substituted for "not less than three meetings", *ibid.*
[149] Inserted, *ibid*
[150] Inserted, *ibid*
[151] Inserted, *ibid*
[152] Inserted, *ibid*
[153] Substituted for sub-section (2) by the Consumer Protec-tion (Amendment) Act, 1993, w.e.f. 18-6-1993.

(*a*) the Minister in-charge of consumer affairs in the State Government who shall be its Chairman;
(*b*) such number of other official or non-official members representing such interests as may be prescribed by the State Government.
(3) The State Council shall meet as and when necessary but not less than two meetings shall be held every year.
(4) The State Council shall meet at such time and place as the Chairman may think fit and shall observe such procedure in regard to the transaction of its business as may be prescribed by the State Government.]

Objects of the State Council.
8. The objects of every State Council shall be to promote and protect within the State the rights of the consumers laid down in clauses (*a*) to (*f*) of section 6.

Chapter III[154]

Consumer Disputes Redressal Agencies

Establishment of Consumer Disputes Redressal Agencies.
9. There shall be established for the purposes of this Act, the following agencies, namely :—
(*a*) a Consumer Disputes Redressal Forum to be known as the "District Forum" established by the State Government [155][* * *] in each district of the State by notification :
[156][**Provided** that the State Government may, if it deems fit, establish more than one District Forum in a district;]
(*b*) a Consumer Disputes Redressal Commission to be known as the "State Commission" established by the State Government [157][* * *] in the State by notification; and
(*c*) a National Consumer Disputes Redressal Commission established by the State Government by notification.

Composition of the District Forum.
10. [158][(1) Each District Forum shall consist of—
(*a*) a person who is, or has been, or is qualified to be a District Judge, who shall be its President;
(*b*) two other members, who shall be persons of ability, integrity and standing, and have adequate knowledge or experience of, or have shown capacity in dealing with, problems relating to economics, law, commerce, accountancy, industry, public affairs or administration, one of whom shall be a woman.]
[159][(1A) Every appointment under sub-section (1) shall be made by the State Government on the recommendation of a selection committee consisting of the following, namely :—
(*i*) President of the State Commission—Chairman,

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[154] 1-7-1987
[155] Words "with the prior approval of the Central Government" omitted, *ibid.*
[156] Inserted, *ibid*
[157] Words "with the prior approval of the Central Government" omitted, *ibid*
[158] Substituted by the Consumer Protection (Amendment) Act, 2002, w.e.f. 15-03-2003
[159] Inserted, *ibid*

(*ii*) Secretary, Law Department of the State—Member,
(*iii*) Secretary, incharge of the Department dealing with consumer affairs in the State—Member.]
(2) Every member of the District Forum shall hold office for a term of five years or up to the age of 65 years, whichever is earlier, and shall not be eligible for re-appointment :
Provided that a member may resign his office in writing under his hand addressed to the State Government and on such resignation being accepted, his office shall become vacant and may be filled by the appointment of a person possessing any of the qualifications mentioned in sub-section (1) in relation to the category of the member who has resigned.
(3) The salary or honorarium and other allowance payable to, and the other terms and conditions of service of the members of the District Forum shall be such as may be prescribed by the State Government.

Jurisdiction of the District Forum.
11. (1) Subject to the other provisions of this Act, the District Forum shall have jurisdiction to entertain complaints where the value of the goods or services and the compensation, if any, claimed [160][does not exceed rupees twenty lakhs.]
(2) A complaint shall be instituted in a District Forum within the local limits of whose jurisdiction,—
(*a*) the opposite party or each of the opposite parties, where there are more than one, at the time of the institution of the complaint, actually and voluntarily resides or carries on business, or [161][has a branch office or] personally works for gain; or
(*b*) any of the opposite parties, where there are more than one, at the time of the institution of the complaint, actually and voluntarily resides, or carries on business [162][or has a branch office], or personally works for gain, provided that in such case either the permission of the District Forum is given, or the opposite parties who do not reside, or carry on business [163][or have a branch office], or personally work for gain, as the case may be, acquiesce in such institution; or
(*c*) the cause of action, wholly or in part, arises.

[164][**Manner in which complaint shall be made.**
12. A complaint in relation to any goods sold or delivered or agreed to be sold or delivered or any service provided or agreed to be provided may be filed with a District Forum by—
(*a*) the consumer to whom such goods are sold or delivered or agreed to be sold or delivered or such services provided or agreed to be provided;
(*b*) any recognised consumer association whether the consumer to whom the goods sold or delivered or agreed to be sold or delivered or services provided or agreed to be provided is a member of such association or not;

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[160] Substituted for "is less than rupees one lakh", *ibid*
[161] Inserted, *ibid.*
[162] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[163] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[164] Substituted, *ibid*

(*c*) one or more consumers, where there are numerous consumers having the same interest, with the permission of the District Forum, on behalf of, or for the benefit of, all consumers so interested; or
(*d*) the Central or the State Government.
Explanation.—For the purposes of this section, "recognised consumer association" means any voluntary consumer association registered under the Companies Act, 1956 (1 of 1956), or any other law for the time being in force.]

Procedure on receipt of complaint.
13. (1) The District Forum shall, on receipt of a complaint, if it relates to any goods,—
(*a*) refer a copy of the complaint to the opposite party mentioned in the complaint directing him to give his version of the case within a period of thirty days or such extended period not exceeding fifteen days as may be granted by the District Forum;
(*b*) where the opposite party on receipt of a complaint referred to him under clause (*a*) denies or disputes the allegations contained in the complaint, or omits or fails to take any action to represent his case within the time given by the District Forum, the District Forum shall proceed to settle the consumer dispute in the manner specified in clauses (*c*) to (*g*);
(*c*) where the complaint alleges a defect in the goods which cannot be determined without proper analysis or test of the goods, the District Forum shall obtain a sample of the goods from the complainant, seal it and authenticate it in the manner prescribed and refer the sample so sealed to the appropriate laboratory along with a direction that such laboratory make an analysis or test, whichever may be necessary, with a view to finding out whether such goods suffer from any defect alleged in the complaint or from any other defect and to report its findings thereon to the District Forum within a period of forty-five days of the receipt of the reference or within such extended period as may be granted by the District Forum;
(*d*) before any sample of the goods is referred to any appropriate laboratory under clause (*c*), the District Forum may require the complainant to deposit to the credit of the Forum such fees as may be specified, for payment to the appropriate laboratory for carrying out the necessary analysis or test in relation to the goods in question;
(*e*) the District Forum shall remit the amount deposited to its credit under clause (*d*) to the appropriate laboratory to enable it to carry out the analysis or test mentioned in clause (*c*) and on receipt of the report from the appropriate laboratory, the District Forum shall forward a copy of the report along with such remarks as the District Forum may feel appropriate to the opposite party;
(*f*) if any of the parties disputes the correctness of the findings of the appropriate laboratory, or disputes the correctness of the methods of analysis or test adopted by the appropriate laboratory, the District Forum shall require the opposite party or the complainant to submit in writing his objections in regard to the report made by the appropriate laboratory;
(*g*) the District Forum shall thereafter give a reasonable opportunity to the complainant as well as the opposite party of being heard as to the correctness or otherwise of the report made by the appropriate laboratory and also as to the objection made in relation thereto under clause (*f*) and issue an appropriate order under section 14.

(2) The District Forum shall, if the complaint received by it under section 12 relates to goods in respect of which the procedure specified in sub-section (1) cannot be followed, or if the complaint relates to any services,—

(*a*) refer a copy of such complaint to the opposite party directing him to give his version of the case within a period of thirty days or such extended period not exceeding fifteen days as may be granted by the District Forum;

(*b*) where the opposite party, on receipt of a copy of the complaint, referred to him under clause (*a*) denies or disputes the allegations contained in the complaint, or omits or fails to take any action to represent his case within the time given by the District Forum, the District Forum shall proceed to settle the consumer dispute,—

(*i*) on the basis of evidence brought to its notice by the complainant and the opposite party, where the opposite party denies or disputes the allegations contained in the complaint, or

(*ii*) on the basis of evidence brought to its notice by the complainant where the opposite party omits or fails to take any action to represent his case within the time given by the Forum.

(3) No proceedings complying with the procedure laid down in sub-sections (1) and (2) shall be called in question in any court on the ground that the principles of natural justice have not been complied with.

(4) For the purposes of this section, the District Forum shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908 (5 of 1908) while trying a suit in respect of the following matters, namely:—

(*i*) the summoning and enforcing the attendance of any defendant or witness and examining the witness on oath;

(*ii*) the discovery and production of any document or other material object producible as evidence;

(*iii*) the reception of evidence on affidavits;

(*iv*) the requisitioning of the report of the concerned analysis or test from the appropriate laboratory or from any other relevant source;

(*v*) issuing of any commission for the examination of any witness; and

(*vi*) any other matter which may be prescribed.

(5) Every proceeding before the District Forum shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228 of the Indian Penal Code (45 of 1860), and the District Forum shall be deemed to be a civil court for the purposes of section 195, and Chapter XXVI of the Code of Criminal Procedure, 1973 (2 of 1974).

[165][(6) Where the complainant is a consumer referred to in sub-clause (*iv*) of clause (*b*) of sub-section (1) of section 2, the provisions of rule 8 of Order I of the First Schedule to the Code of Civil Procedure, 1908 (5 of 1908) shall apply subject to the modification that every reference therein to a suit or decree shall be construed as a reference to a complaint or the order of the District Forum thereon.]

Findings of the District Forum.

14. (1) If, after the proceeding conducted under section 13, the District Forum is satisfied that the goods complained against suffer from any of the defects specified in the complaint or that any of the allegations contained in the complaint about the services are proved, it shall issue

[165] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

an order to the opposite party directing him to [166][do] one or more of the following things, namely:—
(*a*) to remove the defect pointed out by the appropriate laboratory from the goods in question;
(*b*) to replace the goods with new goods of similar description which shall be free from any defect;
(*c*) to return to the complainant the price, or, as the case may be, the charges paid by the complainant;
(*d*) to pay such amount as may be awarded by it as compensation to the consumer for any loss or injury suffered by the consumer, due to the negligence of the opposite party;
[167][(*e*) to remove the effects or deficiencies in the services in question;
(*f*) to discontinue the unfair trade practice or the restrict trade practice or not to repeat them;
(*g*) not to offer the hazardous goods for sale;
(*h*) to withdraw the hazardous goods from being offered for sale;
(*i*) to provide for adequate costs to parties.]
[168][(2) Every proceeding referred to in sub-section (1) shall be conducted by the President of the District Forum and at least one member thereof sitting together:
Provided that where the member, for any reason, is unable to conduct the proceeding till it is completed, the President and the other member shall conduct such proceeding *de novo*.
(2A) Every order made by the District Forum under sub-section (1) shall be signed by its President and the member or members who conducted the proceeding:
Provided that where the proceeding is conducted by the President and one member and they differ on any point or points, they shall state the point or points on which they differ and refer the same to the other member for hearing on such point or points and the opinion of the majority shall be the order of the District Forum.]
(3) Subject to the foregoing provisions, the procedure relating to the conduct of the meetings of the District Forum, its sittings and other matter shall be such as may be prescribed by the State Government.

Appeal.
15. Any person aggrieved by an order made by the District Forum may prefer an appeal against such order to the State Commission within a period of thirty days from the date of the order, in such form and manner as may be prescribed:
Provided that the State Commission may entertain an appeal after the expiry of the said period thirty days if it is satisfied that there was sufficient cause for not filing it within that period.

Composition of the State Commission.
16. (1) Each State Commission shall consist of—
(*a*) a person who is or has been a Judge of a High Court, appointed by the State Government, who shall be its President:
[169][**Provided** that no appointment under this clause shall be made except after consultation with the Chief Justice of the High Court;]

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[166] Substituted for "take", *ibid*
[167] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.
[168] Substituted for sub-section (2), by the Consumer Protection (Amendment) Act, 1991, w.e.f. 15-6-1991
[169] Inserted by the Consumer Protection (Amendment) Act, 2002, w.e.f. 15-03-2003

(*b*) two other members, who shall be persons of ability, integrity and standing and have adequate knowledge or experience of, or have shown capacity in dealing with, problems relating to economics, law, commerce, accountancy, industry, public affairs or administration, one of whom shall be a woman:

[170][**Provided** that every appointment under this clause shall be made by the State Government on the recommendation of a selection committee consisting of the following, namely:—

(*i*) President of the State Commission—Chairman,

(*ii*) Secretary of the Law Department of the State—Member,

(*iii*) Secretary, incharge of the Department dealing with consumer affairs in the State—Member.]

(2) The salary or honorarium and other allowances payable to, and the other terms and conditions of service [171][* * *] of, the members of the State Commission shall be such as may be prescribed by the State Government.

[172][(3)] Every member of the State Commission shall hold office for a term of five years or up to the age of sixty-seven years, whichever is earlier and shall not be eligible for re-appointment.

(4) Notwithstanding anything contained in sub-section (3), a person appointed as a President or as a member before the commencement of the Consumer Protection (Amendment) Act, 1993, shall continue to hold such office as President or member, as the case may be, till the completion of his term.]

Jurisdiction of the State Commission.

17. Subject to the other provisions of this Act, the State Commission shall have jurisdiction—

(*a*) to entertain—

(*i*) complaints where the value of the goods or services and compensation, if any, claimed exceeds rupees [173][twenty lakhs but does not exceed rupees one crore]; and

(*ii*) appeals against the orders of any District Forums within the State; and

(*b*) to call for the records and pass appropriate orders in any consumer dispute which is pending before or has been decided by any District Forum within the State, where it appears to the State Commission that such District Forum has exercised a jurisdiction not vested in it by law, or has failed to exercise a jurisdiction so vested or has acted in exercise of its jurisdiction illegally or with material irregularity.

Procedure applicable to State Commissions.

18. [174][The provisions of sections 12, 13 and 14 and the rules made thereunder] for the disposal of complaints by the District Forum shall, with such modifications as may be necessary, be applicable to the disposal of disputes by the State Commission.

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[170] Substituted, *ibid*.

[171] Words "(including tenure of office)" omitted, *ibid*.

[172] Inserted, *ibid*

[173] Substituted for "one lakh but does not exceed rupees ten lakhs", *ibid*

[174] Substituted for "The procedure specified in sections 12, 13 and 14 and under the rules made thereunder" by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

[175][**Vacancy in the Office of the President.**

18A. When the Office of the President of the District Forum or of the State Commission, as the case may be, is vacant or when any such President is, by reason of absence or otherwise, unable to perform the duties of his office, the duties of the office shall be performed by such person, who is qualified to be appointed as President of the District Forum or, as the case may be, of the State Commission, as the State Government may appoint for the purpose.]

Appeals.

19. Any person aggrieved by an order made by the State Commission in exercise of its powers conferred by sub-clause (*i*) of clause (*a*) of section 17 may prefer an appeal against such order to the National Commission within a period of thirty days from the date of the order in such form and manner as may be prescribed:

Provided that the National Commission may entertain an appeal after the expiry of the said period of thirty days if it is satisfied that there was sufficient cause for not filing it within that period.

Composition of the National Commission.

20. (1) The National Commission shall consist of—

(*a*) a person who is or has been a Judge of the Supreme Court, to be appointed by the Central Government, who shall be its President:

[176][**Provided** that no appointment under this clause shall be made except after consultation with the Chief Justice of India;]

(*b*) four other members who shall be persons of ability, integrity and standing and have adequate knowledge or experience of, or have shown capacity in dealing with, problems relating to economics, law, commerce, accountancy, industry, public affairs or administration, one of whom shall be a woman:

[177][**Provided** that every appointment under this clause shall be made by the Central Government on the recommendation of a selection committee consisting of the following, namely:—

(*a*) a person who is a Judge of the Supreme Court, to be nominated by the Chief Justice of India—Chairman,

(*b*) the Secretary in the Department of Legal Affairs in the Government of India—Member,

(*c*) Secretary of the Department dealing with consumer affairs in the Government of India—Member.]

(2) The salary or honorarium and other allowances payable to and the other terms and conditions of service [178][***] of the members of the National Commission shall be such as may be prescribed by the Central Government.

[179][(3) Every member of the National Commission shall hold office for a term of five years or up to the age of seventy years, whichever is earlier and shall not be eligible for reappointment.

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[175] Inserted by the Consumer Protection (Amendment) Act, 1991, w.e.f. 15-6-1991

[176] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

[177] Substituted, *ibid*

[178] Words "(including tenure of office)" omitted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993.

(4) Notwithstanding anything contained in sub-section (3), a person appointed as a president or as a member before the commencement of the Consumer Protection (Amendment) Act, 1993, shall continue to hold such office as President or member, as the case may be, till the completion of his term.]

Jurisdiction of the National Commission.

21. Subject to the other provisions of this Act, the National Commission shall have jurisdiction—

(*a*) to entertain—

(*i*) complaints where the value of the goods or services and compensation, if any, claimed exceeds rupees one crore; and

(*ii*) appeals against the orders of any State Commission; and

(*b*) to call for the records and pass appropriate orders in any consumer dispute which is pending before or has been decided by any State Commission where it appears to the National Commission that such State Commission has exercised a jurisdiction not vested in it by law, or has failed to exercise a jurisdiction so vested, or has acted in the exercise of its jurisdiction illegally or with material irregularity.

[180] [**Power of and procedure applicable to the National Commission.**

22. The National Commission shall, in the disposal of any complaints or any proceedings before it, have—

(*a*) the powers of a civil court as specified in sub-sections (4), (5) and (6) of section 13;

(*b*) the power to issue an order to the opposite party directing him to do any one or more of the things referred to in clauses (*a*) to (*i*) of sub-section (1) of section 14,

and follow such procedure as may be prescribed by the Central Government.]

Appeal.

23. Any person, aggrieved by an order made by the National Commission in exercise of its power conferred by sub-clause (*i*) of clause (*a*) of section 21, may prefer an appeal against such order to the Supreme Court within a period of thirty days from the date of the order:

Provided that the Supreme Court may entertain an appeal after the expiry of the said period of thirty days if it is satisfied that there was sufficient cause for not filing it within that period.

Finality of orders.

24. Every order of a District Forum, the State Commission or the National Commission shall, if no appeal has been preferred against such order under the provisions of this Act, be final.

[181][**Limitation period.**

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[179] Inserted, *ibid.*

[180] Substituted, *ibid.*

[181] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993

24A. (1) The District Forum, the State Commission or the National Commission shall not admit a complaint unless it is filed within two years from the date on which the cause of action has arisen.
(2) Notwithstanding anything contained in sub-section (1), a complaint may be entertained after the period specified in sub-section (1), if the complainant satisfies the District Forum, the State Commission or the National Commission, as the case may be, that he had sufficient cause for not filing the complaint within such period:
Provided that no such complaint shall be entertained unless the National Commission, the State Commission or the District Forum, as the case may be, records its reasons for condoning such delay.

Administrative control.
24B. (1) The National Commission shall have administrative control over all the State Commission in the following matters, namely:—
(*i*) calling for periodical returns regarding the institution, disposal, pendency of cases;
(*ii*) issuance of instructions regarding adoption of uniform procedure in the hearing of matters, prior service of copies of documents produced by one party to the opposite parties, furnishing of English translation of judgments written in any language, speedy grant of copies of documents;
(*iii*) generally overseeing the functioning of the State Commissions or the District Fora to ensure that the objects and purposes of the Act are best served without in any way interfering with their quasi-judicial freedom.
(2) The State Commission shall have administrative control over all the District Fora within its jurisdiction in all matters referred to in sub-section (1).]

Enforcement of orders by the Forum, the State Commission or the National Commission.
25. Every order made by the District Forum, the State Commission or the National Commission may be enforced by the District Forum, the State Commission or the National Commission, as the case may be, in the same manner as if it were a decree or order made by a court in a suit pending therein and it shall be lawful for the District Forum, the State Commission or the National Commission to send, in the event of its inability to execute it, such order to the court within the local limits of whose jurisdiction,—
(*a*) in the case of an order against a company, the registered office of the company is situated, or
(*b*) in the case of an order against any other person, the place where the person concerned voluntarily resides or carries on business or personally works for gain, is situated,
and thereupon, the court to which the order is so sent, shall execute the orders as if it were a decree or order sent to it for execution.

[182][**Dismissal of frivolous or vexatious complaints.**
26. Where a complaint instituted before the District Forum, the State Commission or, as the case may be, the National Commission is found to be frivolous or vexatious, it shall, for

[182] Substituted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993

reasons to be recorded in writing, dismiss the complaint and make an order that the complainant shall pay to the opposite party such cost, not exceeding ten thousand rupees, as may be specified in the order.]

Penalties.

27. Where a trade or a person against whom a complaint is made [183][or the complainant] fails or omits to comply with any order made by the District Forum, the State Commission or the National Commission, as the case may be, such trader or person [184][or complainant] shall be punishable with imprisonment for a term which shall not be less than one month but which may extend to three years, or with fine which shall not be less than two thousand rupees but which may extend to ten thousand rupees, or with both:

Provided that the District Forum, the State Commission or the National Commission, as the case may be, may, if it is satisfied that the circumstances of any case so require, impose a sentence of imprisonment or fine, or both, for a term lesser than the minimum term and the amount lesser than the minimum amount, specified in this section.

Chapter IV

Miscellaneous

Protection of action taken in good faith.

28. No suit, prosecution or other legal proceedings shall lie against the members of the District Forum, the State Commission or the National Commission or any officer or person acting under the direction of the District Forum, the State Commission or the National Commission for executing any order made by it or in respect of anything which is in a good faith done or intended to be done by such member, officer or person under this Act or under any rule or order made thereunder.

Power to remove difficulties.

29. (1) If any difficulty arises in giving effect to the provision of this Act, the Central Government may, by order in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the commencement of this Act.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

[185][**Vacancies or defects in appointment not to invalidate orders.**

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[183] Inserted, *ibid*

[184] Inserted, *ibid*

[185] Inserted by the Consumer Protection (Amendment) Act, 1991, w.e.f. 15-6-1991

29A. No act or proceeding of the District Forum, the State Commission or the National Commission shall be invalid by reason only of the existence of any vacancy amongst its members or any defect in the constitution thereof.]

Power to make rules.

30. (1) The Central Government may, by notification, make rules for carrying out the provisions contained in [2][clause (*a*) of sub-section (1) of section 2], clause (*b*) of sub-section (2) of section 4, sub-section (2) of section 2, clause (*vi*) of sub-section (4) of section 13, section 19, sub-section (2) of section 20 and section 22 of this Act.

(2) The State Government may, by notification, make rules for carrying out the provisions contained in [186][clause (*b*) of sub-section (2) and sub-section (4) of section 7], sub-section (3) of section 10, clause (*c*) of sub-section (1) of section 13, sub-section (3) of section 14, section 15 and sub-section (2) of section 16.

Laying of rules.

31. (1) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or that successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity or anything previously done under that rule.

(2) Every rule made by a State Government under this Act shall be laid as soon as may be after it is made, before the State Legislature.

Appendix II

Tamil Nadu Consumer Protection Rules, 1988
No. S.R.O.A-158/88, dated 30-6-1988

In exercise of the powers conferred by sub-section (2) of section 30 of the Consumer Protection Act, 1986 (Central Act 68 of 1986), read with S.O. No. 390(E), published in Part II - Section 3, sub-section (*ii*) of the Gazette of India, Extraordinary, dated 15th April, 1987 and S.O. No. 568(E), published in Part II - Section 3, sub-section (*ii*) of the Gazette of India Extraordinary, dated 10th June, 1987, the Governor of Tamil Nadu hereby makes the following rules: —

Short title and commencement.

1. (1) These rules may be called the Tamil Nadu Consumer Protection Rules, 1988.
(2) They shall come into force at once.

Definitions.

2. In these rules, unless, the context otherwise requires—
(*a*) "Act" means the Consumer Protection Act, 1986 (Central Act 68 of 1986);

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[186] Inserted by the Consumer Protection (Amendment) Act, 1993, w.e.f. 18-6-1993

(*b*) "agent" means a person duly authorised by a party to present any complaint or appeal or reply on its behalf before the State Commission or the District Forum;
(*c*) "appellant" means a party which makes an appeal against the order of the District Forum;
(*d*) "memorandum" means memorandum of appeal filed by the appellant;
(*e*) "Opposite party" means a person who answers complaint or claim;
(*f*) "President" means the President of the State Commission or District Forum as the case may be;
(*g*) "respondent" means the person who answers any memorandum of appeal;
(*h*) "section" means section of the Act;
(*i*) "State" means the State of Tamil Nadu;
(*j*) words and expression used in the rules and not defined, but defined in the Act shall have the meaning respectively assigned to them in the Act.

Salaries and other allowances and terms and conditions of the President and members of the District Forum.

3. (1) [187][The President of the District Forum shall receive the salary of the Judge of a District Court, if appointed on whole time basis or an honorarium of Rs. 150 (Rupees one hundred and fifty) per day subject to a maximum of [188][Rs. 2,100 (Rupees two thousand one hundred only)] per month, if appointed on part-time basis. [189][The President of a District Forum shall receive the transfer travelling allowance if he joins such District Forum from out-side the District]. [190][Other members if sitting on whole time basis, shall receive a consolidated honorarium of Rs. 2,000 (Rupees two thousand) per month and if sitting on part-time basis, a consolidated honorarium of Rs. 750 (Rupees Seven hundred and fifty) per month in addition to Rs. 100 (Rupees one hundred) per day for the sitting.] [191][The members residing away from the headquarters shall also receive the conveyance allowance of Rs. 150 (Rupees one hundred and fifty only) per month.]
(2) The President and the members of the District Forum shall be entitled for such travelling allowance and daily allowance on official tour as are admissible to Grade I Officer of the Government of Tamil Nadu.
(3) The salary or honorarium as the case may be and other allowances shall be defrayed out of the consolidated fund of the Government of Tamil Nadu.
(4) Before appointment, the president and members of the District Forum shall have to take an undertaking that he does not and will not have any financial or such other interests as is likely to affect prejudicially his functions as a member.
(5) In addition to provision of sub-section (2) of section 10 Government of Tamil Nadu may remove from office, the president and members of a District Forum who—
(*a*) has been adjudged as an insolvent, or
(*b*) has been convicted of an offence which in the opinion of the Government of Tamil Nadu involves moral turpitude, or
(*c*) has become physically or mentally incapable of acting as the president or member, or

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[187] Substituted by G.O. Ms. No. 414, Co-operation, Food and Consumer Protection, dated 7th November, 1991.
[188] Substituted by G.O. Ms. No. 344, Co-operation, Food and Consumer Protection, dated 7th November, 1993.
[189] Substituted by G.O. Ms. No. 414, Co-operation, Food and Consumer Protection, dated 7th November, 1991.
[190] Substituted by No. SRO A-178/90, dated 29th November, 1990.
[191] Added by G.O. Ms. No. 204, Co-operation, Food and Consumer Protection, dated 30th August, 1994.

(*d*) has acquired financial or other interests likely to affect prejudicially his functions as the president or a member, or
(*e*) has so abused his position as to render his continuance in office prejudicial to the public interest :
Provided that the president or member shall not be removed from his office on the ground specified in clauses (*d*) and (*e*) of the sub-rule (5) except on an inquiry held by Government of Tamil Nadu in accordance with such procedure as it may specify in this behalf and founds the President or a member to be guilty on such ground.
[192] [(5A) The Government of Tamil Nadu may, after giving a reasonable opportunity of being heard, remove from office, a member of a District Forum who has not attended two consecutive sittings of the District Forum without sufficient causes.]
(6) The terms and conditions of the service of the president and the members of the District Forum shall not be varied to their disadvantage during their tenure of office.
(7) Where any vacancy occurs in the office of the president of the District Forum, the senior most (in order of appointment) member of District Forum, holding office for the time being, shall discharge the functions of the president until a person appointed to fill such vacancy assumes the office of the president of the District Forum.
(8) When the president of the District Forum is unable to discharge the functions owing to absence, illness or any other cause, the senior most (in order of the appointment) member of the District Forum shall discharge the functions of the president until the day on which the president resumes the charge of his functions.
(9) The president or any member ceasing to hold office as such shall not hold any appointment in or be connected with the management or administration of an organisation which has been the subject of any proceeding under the Act during his tenure for a period of 5 years from the date on which he ceases to hold such office.
(10) In case of difference of opinion among the members of the District Forum, the opinion of the majority shall prevail and the opinions or orders of the forum shall be expressed in terms of the views of the majority.
(11) (*i*) The president and the members shall hold office for a term of five years or upto the age of 65 years whichever is earlier, and shall not be eligible for reappointment;
(*ii*) Notwithstanding anything contained in sub-rule (*i*) the president or the member may—
(*a*) by writing under his hand and addressed to the Government of Tamil Nadu resign his office at any time and on such resignation being accepted, his office shall become vacant.
(*b*) be removed from his office in accordance with sub-rule (5) of rule 3.

Place of sitting and other matters relating to District Forum.
4. (1) The office of District Forum shall be located at the headquarters of the District. Where State Government decides to establish a single District Forum having jurisdiction over more than one district, it shall notify the place and jurisdiction of the District Forum so established.
(2) The working days and the office hours of the District Forum shall be the same as that of the Government of Tamil Nadu.
(3) The official seal of the District Forum shall be as follows :—

[192] Inserted by G.O. Ms. No. 121, Co-operation, Food and Consumer Protection, dated 24th June, 1996.

Seal.—The seal shall have two concentric arcs bearing the inscriptions, namely "District Consumer Disputes Redressal Forum" and name of the District at the Centre.
(4) Sitting of the District Forum, as and when necessary, shall be convened by the president.
(5) No act or proceedings of the District Forum shall be invalid by reason only of the existence of any vacancy among its president or members or any defect in its constitution.
(6) State Government shall appoint such staff, as may be necessary to assist the District Forum in its day-to-day work and to perform such other functions as are provided under the Act and these rules or assigned to it by the president. The salary payable to such staff shall be defrayed out of the Consolidated Fund of the State Government.
(7) Where the opposite party admits the allegation made by the complainant, the District Forum shall decide the complaint on the basis of the merit of the case and documents present before it.
(8) If during the proceedings conducted under section 13, the District Forum fixes a date for hearing of the parties, it shall be obligatory on the complaint and opposite party or its authorised agent to appear before the District Forum on such date of hearing or any other date to which hearing could be adjourned. Where the complainant or his authorised agent fails to appear before the District Forum on such day, the District Forum may in its discretion either dismiss the complaint for default or decide it on merit. Where the opposite party or its authorised agent fails to appear on the day of hearing the District Forum may decide the complaint *ex-parte.*
(9) While proceeding under sub-rule (8) the District Forum may, on such terms as it may think fit and at any stage, adjourn the hearing of the complaint but not more than one adjournment shall ordinarily be given and the complaint should be decided within 90 days from the date of notice received by the opposite party where complaint does not require analysis or testing of the goods and within 150 days if it requires analysis or testing of the goods.
(10) Orders of the District Forum shall be signed and dated by the members of the District Forum constituting the Bench and shall be communicated to the parties free of charges.

Procedure to be followed for making complaints before the District Forum/State Commission.
5. A complaint containing the following particulars, shall be presented by the complaintant in person or by his authorised agent to the District Forum/State Commission, or be sent by registered post addressed to the District Forum/State Commission :—
(*a*) the name, description and address of the complainant;
(*b*) the name, description and address of the opposite party as the case may be, so far as they can be ascertained;
(*c*) the facts relating to complaint and when and where it arose;
(*d*) document in support of the allegations contained in the complaint;
(*e*) the relief which complainant claims.

Procedure to be adopted by the District Forum for analysis and testing of the goods.
6. Under clause (*c*) of sub-section (1) of section 13 if considered necessary, the District Forum may direct the complainant to provide two separate samples of the goods packed in clean dry bottles or jars or other suitable containers which shall be sufficiently tight to prevent leakage, evaporation, or in the case of dry substance entrance of moisture, with a

paper slip wrapped and pasted on the container in which the signature or thumb-impression of the person, trader or manufacturer, from whom the goods are purchased shall be affixed :
Provided that in case the person or trader or manufacturer from whom the goods are purchased, refuses to affix his signature or thumb-impression, the signature or thumb-impression of a witness shall be taken in the same manner.
(2) On receiving the samples of such goods, the District Forum shall fix labels on the containers carrying the following information :—
(*i*) Name and address of the appropriate laboratory to whom the sample will be sent for analysis and test;
(*ii*) Name and address of the District Forum;
(*iii*) Case Number;
(*iv*) Nature of articles sent for analysis and test;
(*v*) Seal of the District Forum.
(3) The container of sample shall be completely wrapped in fairly strong thick paper, the ends of the paper shall be neatly folded in and affixed by means of gum or adhesive. The paper cover shall be further secured by means of strong twine or thread both above and across the container and the twine of thread shall then be fastened on the paper cover by means of sealing wax on which there shall be at least four distinct and clear impressions of the seal of which one shall be at the top of the packet, one at the bottom of the packet and the other two on the body of the packet. The knots of the twine or thread shall be covered by means of sealing wax bearing the impressions of the seal of the District Forum.
(4) One of the sealed containers will be retained by the District Forum for future reference and another will be sent to the appropriate laboratory by the District Forum for sending report within 45 days or within such extended time as may be granted by the District Forum, after specifying the nature of the defect alleged and date of submission of the report.
(5) The quantity of sample, in case of food samples, for analysis shall be as specified under rule 22 of the Prevention of Food Adulteration Rules, 1955.
(6) A specimen impression of the seal used to seal the container of the sample packet will be sent to the appropriate laboratory separately by the District Forum.
(7) The amount of fees for carrying out the analysis of samples shall be decided in consultation with the concerned appropriate laboratory.

Salary and other allowances and terms and conditions of the president and members of the State Commission.
7. (1) [193][The President of the State Commission shall receive the salary, allowances and other perquisites as are applicable to a judge of the High Court, if appointed on whole-time basis] or a consolidated honorarium of Rs. 200 (Rupees two hundred only) per day for the sitting if appointed on part time basis. Other members if sitting on whole-time basis, shall receive a consolidated honorarium of Rs. 3,000 (Rupees three thousand only) per month and if sitting on part-time basis, a consolidated honorarium of Rs. 150 (Rupees one hundred and fifty only) per day for the sitting. [194][The members shall also receive the conveyance allowance of Rs. 1,000 (Rupees one thousand only) per month.]

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[193] Substituted by G.O. Ms. No. 408, Co-operation, Food and Consumer Protection, dated 2nd September, 1992.
[194] Added by G.O. Ms. No. 408, Co-operation, Food and Consumer Protection, dated 2nd September, 1992.

(2) The president and the members of the State Commission shall be eligible for such travelling allowance and daily allowance an official tour as are admissible to Grade I Officer of the Tamil Nadu Government.
(3) The salary, honorarium, other allowances shall be defrayed out of the Consolidated Fund of the Government of Tamil Nadu.
(4) The president and the members of the State Commission shall hold office for a term of five years or upto the age of [195][75 years] whichever is earlier and shall not be eligible for renomination :
Provided that president and members may :—
(*a*) by writing under his hand and addressed to the State Government resign his office any time;
(*b*) be removed from his office in accordance with provisions of sub-rule (5).
(5) The Government of Tamil Nadu may remove from office president or member of the State Commission who,—
(*a*) has been adjusted as an insolvent, or
(*b*) has been convicted of an offence which in the opinion of the Government of Tamil Nadu involves moral turpitude, or
(*c*) has become physically or mentally incapable of acting as president or a member, or
(*d*) has acquired such financial or other interest as is likely to affect prejudicially his functions as president or a member, or
(*e*) has so abused his position as to render his continuance in office prejudicial to public interest :
Provided that the president or a member shall not be removed from his office on the ground specified in clauses (*d*) and (*e*) and sub-rule (5) except on an inquiry held by the Government of Tamil Nadu in accordance with such procedure as it may specify in this behalf and finds the president or a member to be guilty on such ground.
[196] [(5A) The Government of Tamil Nadu may, after giving reasonable opportunity of being heard, remove from office a member of the State Commission who has not attended two consecutive sittings of the State Commission without sufficient causes.]
(6) Before appointment, the president and members of the State Commission shall have to take an undertaking that he does not and will not have any such financial or other interests as is likely to affect prejudicially his functions as president or a member.
(7) The terms and conditions of the service of the president and the members of the State Commission shall not be varied to their disadvantage during their tenure of office.
(8) Every vacancy caused by resignation and removal of the president or any other member of the State Commission under sub-rule (4) or otherwise shall be filled by fresh appointment.
(9) Where any such vacancy occurs in the office of the president of the State Commission, the senior most member (in order of appointment) holding office for the time being, shall discharge the functions of the president until a person appointed to fill such vacancy assumes the office of the president of the State Commission.
(10) When the president of the State Commission is unable to discharge the functions owing to absence, illness or any other cause, the senior most member (in order of appointment) of the State Commission shall discharge the functions of the president until the day on which the president resumes the charge of his functions.

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[195] Substituted for the words "70 years" by No. S.R.O.A.-79/90, dated 30th May, 1990.
[196] Inserted by G.O. Ms. No. 121, Co-operation, Food and Consumer Protection, dated 24th June, 1996.

(11) The President, or any member ceasing to hold office, as such shall not hold any appointment in or be connected with the management or administration of an organisation which have been the subject of any proceeding under the Act, during his tenure for a period of five years from the date on which he ceases to hold such office.
(12) In case of difference of opinion among the members of the State Commission, the opinion of the majority shall prevail and the opinion or orders of the commission shall be expressed in terms of the views of the majority.

Places of sitting and other matters relating to State Commission.
8. (1) The office of the State Commission shall be located at Madras.
(2) The working days and the office hours of the State Commission shall be the same as that of the Government of Tamil Nadu.
(3) The emblem and official seal of the State Government shall be as follows :—
Emblem.—The State Commission as Head of the Department shall use the State Emblem in their official letter heads, namely "single colour black Emblem in full with designation within two concentric arcs of two-thirds of a circle."
Seal.—The seal shall have two concentric arcs of two-thirds of a circle with the inscriptions, namely, "State Consumer Disputes Redressal Commission" and with the State Emblem at the Centre.
(4) Sitting of the State Commission, as and when necessary, shall be convened by the president.
(5) No act or proceedings of the State Commission shall be invalid by reasons only of the existence of any vacancy among its president or members or any defect in its constitution thereof.
(6) The government of Tamil Nadu shall appoint such staff, as may be necessary to assist the State Commission in its work and to perform such other functions as are provided under the Act and these rules or assigned to it by the President. The salary payable to such staff shall be defrayed out of the consolidated fund of the Government of Tamil Nadu.
(7) Where the opposite party admits the allegation made by the complainant, the State Commission shall decide the complaint on the basis of the merit of the case and documents presented before it.
(8) If during the proceedings conducted under section 13, State Commission fixes a date for hearing of the parties, it shall be obligatory on the complainant and opposite party or his authorised agent to appear before the State Commission on such date of hearing or any other date to which hearing could be adjourned. Where the complainant or his authorised agent fails to appear before the State Commission on such day, the State Commission may in its discretion either dismiss the complaint for default or decide it on merits. Where the opposite party or its authorised agent fails to appear on the day of hearing, the State Commission may decide the complaint *ex-parte.*
(9) While proceeding under sub-rule (8) the State Commission may, on such terms as it may think fit and at any stage, of the proceedings adjourn the hearing of the complaint but not more than one adjournment shall ordinarily be given and the complaint shall be decided within 90 days from the date of notice received by the opposite party where the complaint does not require analysis or testing of the goods and within 150 days if it requires analysis or testing of the goods.

(10) Orders of the State Commission shall be signed and dated by the members of the State Commission constituting the Bench and shall be communicated to the parties free of charge.

Procedure for hearing appeal.

9. (1) Memorandum shall be presented by the appellant or his authorised agent to the State Commission in person or sent by registered post addressed to the Commission.

(2) Every memorandum filed under sub-rule (1) shall be legible handwriting preferably typed and shall set-forth concisely under distinct heads, the grounds of appeal without any argument or narrative and such ground shall be numbered consecutively.

(3) Each memorandum shall be accompanied by the certified copy of the order of the District Forum appealed against and such of the documents as may be required to support grounds of objection mentioned in the memorandum.

(4) When the appeal is presented after the expiry of period of limitation as specified in the Act, Memorandum shall be accompanied by an application supported by an affidavit setting forth the fact on which appellant relies to satisfy the State Commission that he has sufficient cause for not preferring the appeal within the period of limitation.

(5) The appellant shall submit four copies of the memorandum to the State Commission for official purposes.

(6) On the date of hearing or any other day to which hearing may be adjourned, it shall be obligatory for the parties or their authorised agents to appear before the State Commission. If appellant or his authorised agent fails to appear on such date, the State Commission may, in its discretion, either dismiss the appeal or decide in on the merit of the case. If respondent or his authorised agent fails to appear on such date, the State Commission shall proceed *ex-parte* and shall decide the appeal *ex-parte* on merits of the case.

(7) The appellant shall not, except by leave of the State Commission, urge or be heard in support of any ground of objections not set forth in the memorandum but the State Commission, in deciding the appeal, shall not confine to the grounds of objection set forth in the memorandum or taken by leave of the State Commission under this rule :

Provided that the Commission shall not rest its decision on any other grounds other than those specified unless the party who may be affected thereby, has been given at least one opportunity of being heard by the State Commission.

(8) State Commission may, on such terms as it may think fit and at any stage, adjourn the hearing of appeal, but not more than one adjournment shall ordinarily be given and the appeal should be decided within 90 days from the first date of hearing.

(9) Order of the State Commission on appeal shall be signed and dated by the members of the State Commission constituting the Bench and shall be communicated to the parties free of charge.

Appendix III

Transplantation of Human Organs Act, 1994

An Act to provide for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs and for matters connected therewith of incidental thereto.

WHEREAS it is expedient to provide for the regulation removal storage and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs;

AND WHEREAS Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

AND WHEREAS in pursuance of clause (1) of articles 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Goa, Himachal Pradesh and Maharashtra to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

BE it enacted by Parliament in the Forty-fifth year of the Republic of India as follows: -

CHAPTER I: PRELIMINARY

1. Short title, applications and commencement

(1) This Act may be called the Transplantation of Human Organs Act, 1994.
(2) It applies, in the first instance, to the whole of the States of Goa, Himachal Pradesh and Maharashtra and to all the Union territories and it shall also apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.
(3) It shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories on such date[1] as the Central Government may, by notification appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, means the date on which this Act comes into force in such State or Union territory.

2. Definitions

In this Act, unless the context otherwise requires,--
(a) "advertisement" includes any form of advertising whether to the public generally or to any section of the public or individually to selected persons;
(b) "Appropriate Authority" means the Appropriate Authority appointed under section 13;

(c) "Authorisation Committee" means the committee constituted under clause (a) or clause (b) of sub-section (4) of section 9;

(d) "brain-stem death" means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3;
(e) "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;
(f) "donor" means any person, not less than eighteen years of age, who voluntarily authorises the removal of any of his human organs for therapeutic purposes under sub-section (1) or sub-section (2) of section 3;
(g) "hospital" includes a nursing home, clinic, medical centre, medical or teaching institution for therapeutic purposes and other like institution;
(h) "human organ" means any part of a human body consisting of a structured arrangement of tissues which, if wholly, removed, cannot be replicated by the body;
(i) "near relative" means spouse, son, daughter, father, mother brother or sister;
(j) "notification" means a notification published in the Official Gazette;
(k) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing-

(i) the cost of removing, transporting or preserving the human organ to be supplied; or
(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ from his body.

(l) "prescribed" means prescribed by rules made under this Act;
(m) " recipient" means a person into whom any human organ is, or is proposed to be, transplanted;
(n) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956, and who is enrolled on a State Medical Register as defined in clause (k) of that section;
(o) "therapeutic purpose" means systematic treatment of any disease or the measures to improve health according to any particular method or modality; and
(p) "transplantation" means the grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes.

CHAPTER II : AUTHORITY FOR THE REMOVAL OF HUMAN ORGANS

3. Authority for removal of human organs

(1) Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organs of his body for therapeutic purposes.
(2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ from the dead body of the donor.

(3) Where no such authority as is referred to in sub-section (2), was made by any person before his death but no objection was also expressed by such person to any of his human

organs being used after his death for therapeutic purposes, the person lawfully in possession of the dead body of such person may, unless he has reason to believe that any near relative of the deceased person has objection to any of the deceased person's human organs being used for therapeutic purposes, authorise the removal of any human organ of the deceased person for its use for therapeutic purposes.

(4) The authority given under sub-section (1) or sub-section (2) or, as the case may be, sub-section (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ; but no such removal shall be made by any person other than the registered medical practitioner.

(5) Where any human organ is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself, before such removal, by a personal examination of the body from which any human organ is to be removed, that life is extinct in such body or, where it appears to be a case of brain-stem death, that such death has been certified under sub-section (6).

(6) Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following, namely:-

(i) the registered medical practitioner in charge of the hospital in which brain-stem death has occurred;

(ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approval by the Appropriate Authority;

(iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority ; and

(iv) the registered medical practitioner treating the person whose brain-stem death has occurred .

(7) Notwithstanding anything contained in sub-section (3), where brain-stem death of any person, less than eighteen years of age, occurs and is certified under sub-section (6) , any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the removal of any human organ from the body of the deceased person.

4. Removal of human organs not to be authorised in certain cases

(1) No facilities shall be granted under sub-section (2) of section 3 and no authority shall be given under sub-section (3) of that section for the removal of any human organ from the body of a deceased person, if the person required to grant such facilities, or empowered to give such authority, has reason to believe that an inquest may be required to be held in relation to such body in pursuance of the provisions of any law for the time being in force.

(2) No authority for the removal of any human organ from the body of a deceased person shall be given by a person to whom such body has been entrusted solely for the purpose of interment, cremation or other disposal.

5. Authority for removal of human organs in case of unclaimed bodies in hospital or prison

(1) In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(2) No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even though such near relative has not come forward to claim the body of the deceased person within the time specified in sub-section (1).

6. Authority for removal of human organs from bodies sent for postmortem examination for medicolegal or pathological purposes

Where the body of a person has been sent for post-mortem examination-

(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; or

(b) for pathological purposes,

the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorise the removal, for therapeutic purpose,of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

7. Preservation of human organs

After the removal of any human organ from he body of any person, the registered medical practitioner shall take such steps for the preservation of the human organ so removed as may be prescribed.

8. Savings

(1) Nothing in the foregoing provisions of this Act shall be construed as rendering unlawful any dealing with the body or with any part of the body of a deceased person if such dealing would have been lawful if this Act had not been passed.

(2) Neither the grant of any facility or authority for the removal of any human organ from the body of a deceased person in accordance with the provisions of this Act nor the removal of any human organ from the body of a deceased person in pursuance of such authority shall be deemed to be an offence punishable under section 297 of the Indian Penal Code.

9. Restrictions on removal and transplantation of human organs

(1) Save as otherwise provided in sub-section (3), no human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.

(2) Where any donor authorises the removal of any of his human organs after his death under sub-section (2) of section 3 or any person competent or empowered to give authority for the removal of any human organ from the body of any deceased person authorises such removal, the human organ may be removed and transplanted into the body of any recipient who may be in need of such human organ.
(3) If any donor authorises the removal of any of his human organs before his death under sub-section (1) of section 3 for transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organ shall not be removed and transplanted without the prior approval of the Authorisation Committee.
(4) (a) The Central Government shall constitute, by notification, one or more Authorisation Committees consisting of such members as may be nominated by the Central Government on such terms and conditions as may be specified in the notification for each of the Union territories for the purposes of the section.
(5) On an application, jointly made, in such form and in such manner as may be prescribed, by the donor and the recipient, the Authorisation Committee shall, after holding an inquiry and after satisfying itself that the applicants have complied with all the requirements of this Act and the rules made thereunder, grant to the applicants approval for the removal and transplantation of the human organ.
(6) If, after the inquiry and after giving an opportunity to the applicants of being heard, the Authorisation Committee is satisfied that the applicants have not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for approval.

CHAPTER III : REGULATION OF HOSPITALS

10. Regulation of hospitals conducting the removal, storage or transplantation of human organs

(1) On and from the commencement of this Act,-

(a) no hospital, unless registered under this Act, shall conduct, or associate with, or help in, the removal, storage, or transplantation of any human organ;

(b) no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ at a place other than a place registered under this Act; and

(c) no place including a hospital registered under sub-section (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ except for therapeutic purposes.

(2) Notwithstanding anything contained in sub-section (1), the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purposes, by a registered medical practitioner.
Explanation -For the purposes of this sub-section, "ears" includes ear drums and ear bones.

11. Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purposes

No donor and no person empowered to give authority for the removal of any human organ shall authorise the removal of any human organ for any purpose other than therapeutic purposes.

12. Explaining effects, etc., to donor and recipient

No registered medical practitioner shall undertake the removal or transplantation of any human organ unless he has explained, in such manner as may be prescribed, all possible effects, complications and hazards connected with t he removal and transplantation to the donor and the recipient respectively.

CHAPTER IV : APPROPRIATE AUTHORITY

13. Appropriate Authority

(1) The Central Government shall appoint, by notification, one or more officers as Appropriate Authorities for each of the Union territories for the purposes of this Act.
(2) The State Government shall appoint, by notification, one or more officers as Appropriate Authorities for the purposes of this Act.
(3) The Appropriate Authority shall perform the following functions, namely:-

(i) to grant registration under sub-section (1) of section 15 or renew registration under sub-section (3) of that section;
(ii) to suspend or cancel registration under sub-section (2) of section 16;
(iii) to enforce such standards, as may be prescribed, for hospitals engaged in the removal, storage or transplantation of any human organ ;
(iv) to investigate any complaint of breach of any of the provisions of this Act or any of the rules made thereunder and take appropriate action;
(v) to inspect hospitals periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and the persons from whom organs are removed; and
(vi) to undertake such other measures may be prescribed.

CHAPTER V : REGISTRATION OF HOSPITALS

14. Registration of hospitals engaged in removal, storage or transplantation of human organs

(1) No hospital shall commence any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes after the commencement of this Act unless such hospital is duly registered under this Act:
Provided that every hospital engaged, either partly or exclusively, in any activity relating to the removal, storage or transplantation of any human organ for therapeutic purposes immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement:

Provided further that every hospital engaged in any activity relating to the removal, storage or transplantation of any human organ shall cease to engage in any such activity on the expiry of three months from the date of commencement of this Act unless such hospital has appeared for registration and is so registered or till such application is disposed or, whenever is earner.

(2) Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) No hospital shall be registered under this Act unless the Appropriate Authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed.

15. Certificate of registration

(1) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant to the hospital a certificate of registration in such form, for such period and subject to such conditions as may be prescribed.

(2) If, after the inquiry and after giving an opportunity to the applicant of being heard, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act and the rules made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and on payment of such fees as may be prescribed.

16. Suspension or cancellation of registration

(1) The Appropriate Authority may, *suo moto* or on complaint, issue a notice to any hospital to show cause why its registration under this Act should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If, after giving a reasonable opportunity of being heard to the hospital, the Appropriate Authority is satisfied that there has been, a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any criminal action that it may take against such hospital, suspend its registration for such period as it may think fit or cancel its registration:

Provided that where the Appropriate Authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any hospital without issuing any notice.

17. Appeals

Any person aggrieved by an order of the Authorisation Committee rejecting an application for approval under sub-section (6) of section 9, or any hospital aggrieved by an order of the Appropriate Authority rejecting an application for registration under sub-section (2) of section 15 or an order of suspension or cancellation of registration under sub-section (2) sub-section 16, may, within thirty day from the date of the receipt of the order, prefer an appeal, in such manner as may be prescribed, against such order to-

(i) the Central Government where the appeal is against the order of the Authorisation Committee constituted under clause (a) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (1) of section 13; or
(ii) the State Government, where the appeal is against the order of the Authorisation Committee constituted under clause (b) of sub-section (4) of section 9 or against the order of the Appropriate Authority appointed under sub-section (2) of section 13.

CHAPTER VI : OFFENCES AND PENALTIES

18. Punishment for removal of human organ without authority

(1) 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.
(2) Where any person convicted under sub-section (1) is a registered medical practitioner, his name shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

19. Punishment for commercial dealings in human organs

Whoever -
(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;
(b) seeks to find a person willing to supply for payment any human organ;
(c) offers to supply any human organ for payment;
(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ;
(e) takes part in the management or control of a body of persons, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or
(f) publishes or distributes or causes to be published or distributed any advertisement, -
(a) inviting persons to supply for payment of any human organ;
(b) offering to supply any human organ for payment; or
(c) indicating that the advertiser in willing to initiate or negotiate any arrangement referred to in clause (d),

shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to seven years and shall be liable to fine which shall not be less than ten thousand rupees but may extend to twenty thousand rupees.

Provided that the court may, for any adequate and special reason to be mentioned in the judgement, impose a sentences of imprisonment for a term of less than two years and a fine less than ten thousand rupees.

20. Punishment for contravention of any other provision of this Act

Whoever contravenes any provision of this Act or any rule made, of any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punishable with imprisonment for a term which may extend to three years or with fine which may extend to five thousand rupees.

21. Offences by companies

(1) Where any offence punishable under this Act has been committed by a company, every person who, at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation - For the purposes of this section , -

(a) "company" means any body corporate and includes a firm or other association of individuals; and

(b) "director" in relation to a firm, means a partner in the firm.

22. Cognizance of offence

(1) No court shall take cognizance of an offence under this Act except on a complaint made by-

(a) the Appropriate Authority concerned, or any officer authorised in this behalf by the Central Government or the State Government or, as the case may be, the Appropriate Authority; or

(b) a person who has given notice of not less than sixty days, in such manner as may be prescribed, to the Appropriate Authority concerned, of the alleged offence and of the intention to make a complaint to the court.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(3) Where a complaint has been made under clause (b) or sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

CHAPTER VII : MISCELLANEOUS

23. Protection of action taken in good faith

(1) No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.
(2) No suit or other legal proceeding shall lie against the Central Government or the State Government for any damage caused or likely to be caused for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

24. Power to make rules

(1) The Central Government may, by notification, make rules for carrying out the purposes of this Act.
(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-
(a) the manner in which and the conditions subject to which any donor may authorise removal, before his death, of any human organ of his body under sub-section (1) of section 3;
(b) the form and the manner in which a brain-stem death is to be certified and the conditions and requirements which are to be satisfied for that purpose under sub-section (6) of section 3;
(c) the form and the manner in which any of the parents may give authority, in the case of brain-stem death of a minor, for the removal of any human organ under sub-section (7) of section 3;
(d) the form in which authority for the removal of any human organ from an unclaimed dead body may be given by the person incharge of the management or control of the hospital or prison under sub-section (1) of section 5;
(e) the steps to be taken for the preservation of the human organ removed from the body of any person under section 7;
(f) the form and the manner in which an application may be jointly made by the donor and the recipient under sub-section (5) of section 9;
(g) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under section 12;
(h) the standards as are to be enforced by the Appropriate Authority for hospitals engaged in the removal, storage or transplantation of any human organ under clause (iii) of sub-section (3) of section 13;
(i) the other measures as the Appropriate Authority shall undertake in performing its functions under clause (vi) of sub-section (3) of section 13;
(j) the form and the manner in which an application for registration shall be made and the fee which shall be accompanied, under sub-section (2) of section 14;
(k) the specialised services and the facilities to be provided, skilled manpower and the equipments to be possessed and the standards to be maintained by a hospital for registration, under sub-section (3) of section 14;
(l) the form in which, the period for which and the conditions subject to which certificate of registration is to be granted to a hospital, under sub-section (1) of section 15;
(m) the manner in which and the fee on payment of which certificate of registration is to be renewed under sub-section (3) of section 15;
(n) the manner in which an appeal may be preferred under section 17;

(o) the manner in which a person is required to give notice to the Appropriate Authority of the alleged offence and of his intention to make a complaint to the court, under clause (b) of sub-section (1) of section 22; and
(p) any other matter which is required to be, or may be, prescribed.

(3) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

25. Repeal and saving

(1) The Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 and the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982 are hereby repealed.
(2) The repeal shall, however, not affect the previous operation of the Acts so repealed or anything duly done or suffered thereunder.

Foot Notes

1. The Act came into force from 4th. February, 1995 in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union Territories vide Notifications No. S.O. 80 (E) dated 4th. February, 1995.

Appendix IV

The Transplantation of Human Organs Rules, 1995

In exercise of the powers conferred by sub-section (1) of Section 24 of the Transplantation or Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely :-

1. Short title and commencement.--(1) These rules may be called the Transplantation of Human Organs Rules. 1995.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions.--
(a) "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);
(b) "Form" means a form annexed to these Rules;
(c) "Section" means a section of the Act;
(d) words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. Authority for Removal of Human Organ.--Any donor may authorise the removal. before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in Form 1.

4. Duties of the Medical Practitioner.--(1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death satisfy himself--
(a) that the donor has given his authorisation in Form 1;
(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate as specified in Form 2.
(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form 3 after carrying out the following tests on the donor and the recipient. namely :-

(i) tests for the antigenic products of the Human Major Histocompatibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;

(ii) tests to establish HLA-DR beta and HLA-DQ beta gene restriction fragment length polymorphism;

(iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;

(iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphysms using at least five single locus polymorphic probes.

(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that are so related and shall sign a certificate in Form 4.
(2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself--

(a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;
(b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 6 or Form 7.
(3) A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself--
(a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of Section 3 of the Act;
(b) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of Section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

5. Preservation of Organs.--The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10.

7. Registration of Hospital.-(1) An application for registration shall be made to the Appropriate Authority as specified in Form 11.The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.
(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration and specified in From 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.

8. Renewal of Registration.-- (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Approriate Authority by means of a bank draft to postal order.
(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years .
(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and the Rules made thereunder and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

9. Conditions for Grant of Certificate of Registration.--No hospital shall be granted a certificate of registration under this Act unless it fulfills the following requirement of manpower, equipment, speciaiised services and facilities us laid down below :-

General Requirement

1. Surgical Staff
2. Cardiology Staff
3. NursingStaff
4. Communication System
5. Intensivist
6. Medical Social Worker
7. Perfusionist

Various Departments

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G.I.Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology.

Non-Transplantation Programme Team

1. Neruologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff'

Basic Equipment

Operating Room facilities for routine open heart surgery which include heart lung machine and accessories.

Additional Equipment Required For Transplantation Programme

- CellSaver.
- Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric operated.
- Mobile C-arm, image intensifier for routine biopsies in the sterile operating room.
- Bact/Alert System of early detection of any infection.
- Radioimmunoassy for measuring Cyclosporin levels.
- Routine Laboratory facilities for detection of HIV, Australia antigen,
- CMV, Toxoplasnosis and other Mycology Tests.

Experts

(A) Kidney Transplantation

M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B)Transplantation of Liver & Other Abdominal Organs

M.S. (Gen.) Surgery or equivalent qualification with adequate post M.S. training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation

M. Ch. Cardio-thorasic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by- pass surgery and Heart-value surgery.

10. Appeal.--(1)Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of Section 9, or by an order of the Appropriate Authority under sub-section (2) of Section 15 and Section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

FORMS
THE TRANSPLANTATION OF HUMAN ORGANS ACT, 1994
(Central Act 42 0f 1994)

FORM - 1
(See rule 3)

I, ..., aged ..... S/o, D/o, W/o, Mr. ..... resident of .... hereby authorise to remove for therapeutic purposes / consent to donate my organ, namely ....……
(1) Mr. / Mrs. .....
S/o, D/o, W/o, Mr. .....…….
aged ..... resident of ....
happens to be my near relative as defined in clause (2) of section 2 of the Act.
(Or)
(2) Mr./Mrs. .....
S/o, D/o, W/o, Mr. .....…
aged ..... resident of .....
.....towards when I possess special affection, attachments, or for any special reason (to be specified).
I certify that the above authority/consent has been given by me out my own free will without pressure, inducement, influence or allurement and that the purposes of the above authority/ donation and of all possible complications, side-effects, consequences and options have been explained to me giving this authority or consent or both.

Signature of the Donor

FORM - 2
[(See rule 4(1) (b)]

I, Dr……....., possessing the qualification of .....…… registered as medical practitioner at serial No. .....…… by the ..... Medical as Medical Council, certify that I have examined Shri / Smt / Kum. ..... S/o, D/o, W/o ..... aged ..... who is free and is near elative of the donor and that the said donor is in proper state of health and is ..... medically fit to be subjected to the procedure of organ removal.

Place: ..... Signature **Date: .....…**

FORM -3

[(See rule 4(1) (c)]

I, Dr. ..... possessing the qualification of …….. registered as med. practitioner at Serial No. .... by the .... Medical council, certify that Mr. /Mrs. …… ..... S/o, D/o, W/o …… …… …… aged ..…….....the donor, an Mr./Mrs. …… …… S/o, D/o, W/o …… …… aged ....., the recipient of the organ donated by the said donor are related to each other as brother/sister/mother/father/son/ daughter as per their statement and the fact of this relationship has been established by the results of the tests for Antigenic Products of the Human Major Hysto-compability System, namely .... by the Authorisation Committee as per the information contained in their letter of approval No. ..... dated .....

Place..... Signature

Date.....

FORM -4

[(See rule 4(1) (d)]

I, Dr. ..... possessing qualification of …… registered as medical practitioner at Serial No. ..... by the ....., Medical council, certify that :-

(i) Mr. …….. S/o …….. aged ……. resident of …….. and Mrs. …… D/o, W/o ……. …….. aged ..... resident .... are related to each other as spouse a according to the statement given by them and their statement has been confirmed by means of following evidence before effecting the organ removal from body of the said Shri / Smt / Km.....…… …… ……

(Applicable only in the cases where considered necessary).

(Or)

(ii) The Clinical condition of Shri/Smt..... ..... mentioned above is such that recording of his/her statement is not practicable

Signature of Regd. medical practitioner

Place.....

Date.....

FORM -5

[(See rule 4(2) (a)]

I ..... S/o, D/o, W/o .... aged ..... resident of ..... in the presence of persons mentioned below hereby unequivocally authorise the removal of my organ/organs, namely, ... from my body after my death for therapeutic purposes.

Dated.....

Signature of the Donor

1. Shri/Smt./Km.....
S/o, D/o, W/o .....
……aged .... resident of .... ……

(Signature)

2. Shri/Smt./Km.....
.....aged ..... resident of .....……is a near relative to the donor as.....

Dated.....

FORM -6
[(See rule 4(2) (b)]

I.....s/o,d/o,w/o.....aged.....
resident of.....having lawful possession of the dead body Sri/Smt/km.....s/o,d/o,w/o.....aged.....
of.....having} known that the deceased has not expressed any objection to his/her organ/organs being removed for therapeutic purposes after his/her death and also having reasons to believe that no near relative of the said deceased person has objection to any of his/her organs being used for therapeutic purposes authorize removal of his/her body organs, namely.....

Dated..... Signature
Place …….... Person in lawful possession of the dead body
Address.....
.....

FORM -7
[(See rule 4(2) (b)]

I, Mr/ Mrs./Miss.....having lawful possession of the dead body of Mr/ Mrs./Miss.....son of/ daughter of / wife of .... aged ..... resident of .....after having known that the objection was expressed by the deceased to any of his human organs being used after is death for therapeutic purposes and having reason to believe of deceased person has objection to any of the deceased person's organs being used for therapeutic purposes, hereby authorize the removal of the deceased's organ, namely, ……. for therapeutic purposes.
Signature.....
Name.....
Address.....
.....
Time and Date …….....……...

FORM - 8
[(See rule 4(3) (a) and (b)]

We the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt/Km.....aged about.....son of/wife of/ daughter of.....resident of .....is dead on account of permanent and irreversible cessation of all function of the brain stem. The test carried out by us and the findings therein are recorded in the brain stem death Certificates annexed hereto.

Dated..... Signature.....

1. R.M.P Incharge of the Hospital in which brain-stem death has occurred.
2. R.M.P. nominated from the panel of names approved by the Appropriate Authority
3. Neurologist / Neuro Surgeon nominated from the panel of names approved by Appropriate Authority.
4. R.M.P. treating the aforesaid deceased person BRAIN STEM DEATH CERTIFICATE

(A) PATIENT DETAILS :
1. Name of the Patient Mr/Ms. .....…….... S.O./D.O./W.O. Mr. .... Sex..... Age .....
2. Home Address .....
.....

3. Hospital Number ....
.....

4. Name and Address of next of kin or .....
person responsible for the patient (if none .....
exists, this must be specified) ……
.....
.....
5. Has the patient or next of kin agreed .....
to any transplant ? .....
6. In this a police Case ? Yes.....No.....

(A) PRE-CONDITIONS:
1. Diagnosis : Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details .....
.....
Date and time of accident/onset of illness .....
Date and onset of no-responsible coma ….....
2. Finding of Board of Medical Experts : (i) The following reversible causes of coma have been excluded:

Intoxication (Alcohol)
Depressant Drugs
Relaxants (Neuromuscular blocking agents)

First Medical Examination Second Medical Examination

1st	2nd	1st	2nd
Primary hypothermia			
Hypovolemic shock			
Metabolic or endocrine disorders			
Tests for absent of brain stem functions			

2) Coma
3) Cessation of spontaneous breathing.
4) Pupillary Size
5) Pupillary light reflexes
6) Doll's head eyes movement
7) Corneal reflexes (Both Sizes)
8) Motor response in any cranial nerve distribution, any responses to simulation of face limb

of trunk
9) Gag reflex,
10) Cough (Tracheal)
11) Eye movements on caloric testing bilaterally
12) Apnoea tests as specified
13) Were any respiratory movements seen?

Date and Time of first testing .....
Date and Time of second testing .....

This to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above,
Mr/Mrs..... is declared brain-stem dead.
1. Medical Administrator Incharge of the hospital
2. Authorised Specialist
3. Neurologist/ Neuro Surgeon
4. Medical officer treating patient.
NB. I. The minimum time interval between the first testing and second testing will be six hours.
II. No.2 and No.3 will bo co-opted by the administrator incharge of the hospital from the panel of experts approved by the appropriate authority.

FORM 9
(See rule 4(3) (b))

I, Mr/Mrs.....son of / wife of.....resident of..... hereby authorise removal of the organ/organs namely.....for therapeutic purposes from the dead body of my son/daughter . Mr/Ms.....aged.....whose brain stem death has been duly certified in accordance with the law
Signature.....
Name.....
Place.....
Date.....

FORM -10

APPLICATION FOR APPROVAL FOR TRANSPLANTATION LIVE DONOR OTHER THAN NEAR RELATIVE

Whereas I .....S/O, D/O, W/O, L/O.....aged residing.....have been informed by my doctor that I am suffering from.....and may be benefited by transplantation ..... into my body.
and whereas I .....…….. S.O. D.O. W.O..... aged ..... residing at.....by reason of affection and attachment because :
.....
.....
(reason to be filled in) would like to donate my.....to.....we.....
(donor)
and.....hereby apply to authorization committee for permission
(Recipient) for such transplantation to be carried out.
We solemnly affirm that the above decision has been taken without any undue pressure, inducement, influence or allurement and that all-possible consequences and options of organ transplantation have been explained to us.
.....
.....

Signature and address of prospective donor

Signature and address of prospective recipient

FORM 11

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN TRANSPLANTATION

To
The Appropriate Authority for organ transplantation ..... (State of Union Territory) We hereby apply to be recognised as an institution to carry out organs transplantation. The required data about the facilities available in the hospital are as follows:-

(A) HOSPITAL
1. Name .....
2. Location .....
3. Govt./Pvt. .....
4. Teaching/Non Teaching .....
5.Approached by:
Road: Yes No
Rail : Yes No
Air : Yes No
6. Total bed strength : .....
7.Name of the disciplines in the hospital : ....
8. Annual budget : .....
9. Patient turn-over/year : .....

(B) SURGICAL TEAM : 1. No. of beds .....
2. No. of permanent staff members with their designations ....
3. No. of temporary staff with their designations ....
4. No. of operations done per year .....
5. Trained persons available for .....
transplantation (Please specify organ for transplantation)
(C) MEDICAL TEAM:
1. No. of beds .....
2. No. of permanent staff members with their designation ....
3. No. of temporary staff members with their designation .....
4. Patient turnover per year .....
5. No. of potential transplant candidates admitted per year ....
(D) ANAESTHESIOLOGY
1. No. of permanent staff members with their designation .....
2. No. of temporary staff members with their designations .....
3. Name and No. of operations performed .....
4. Name and No. of equipments available .....
5. Total No. of operation theatres in the Hospital .... 6.
No. of emergency operation theatres ....
7. No. of separate transplant operation theatres ....
(E) I.C.U. / H.D.U. FACILITIES :
1. ICU/HDU facilities : Present.....Not Present.....
2. No. of I.C.U beds .....
3.Trained Nurses .....
Technicians .....
4. Name and number of equipments in ICU
(F) OTHER SUPPORTIVE FACILITIES
Data about facilities available in hospital.
(G) LABORATORY FACILITIES :

1. No. of permanent staff with their designations
2. No. of temporary staff with their designations
3. Names of the investigations carried out in the Dept
4. Name and number of equipments available

(H) IMAGING SERVICES
1. No. of permanent staff with their designations
2. No. of temporary staff with their designations
3. Names of the investigations carried out in the Dept
4. Name and number of equipments available
(I) HAEMATOLOGY SERVICES
1. No. of permanent staff with their designations
2. No. of temporary staff with their designations
3. Names of the investigations carried out in the Dept
4. Name and number of equipments available
(J) BLOOD BANK FACILITIES: Yes..... No.....
(K) DIALYSIS FACILITIES Yes..... No.....…
(L) OTHER PERSONNEL

1. Nephorlogist Yes/No
2. Neurologist Yes/No
3. Neuro-Surgeon Yes/No
4. Urologist Yes/No
5. G.I. Surgeon Yes/No
6. Paediatrician Yes/No
7. Physiotherapist Yes/No
8. Social Worker Yes/No
9. Immunologists Yes/No
10. Cardiologist Yes/No

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/Cheque of Rs. 1,000/- is being enclosed.

sd/-
HEAD OF THE INSTITUTION

FORM-12

CERTIFICATE OF REGISTRATION

This is to certify that.....Hospital located at.....…... has been inspected by the Appropriate Authority and certificate of registration is granted for performing the organ transplantation of the following organs

1. .....
2. .....
3. .....
4. .....

This certificate of registration is valid for a period of five years from the date of issue.

Signature..... Signature.....

FORM-13

(See sub-rule 8(2))

OFFICE OF THE APPROPRIATE AUTHORITY This is with reference to the application, dated.....from..... (Name of the hospital) for renewal of certificate of registration for performing organ transplantation under the Act.

After having considered the facilities and standards of the above said hospital the Appropriate Authority hereby renews the certificate of registration of the said hospital for the purpose of performing organ transplantation for a period of five years.

Appropriate Authority.....

Place.....

Date.....

Appendix V
Summary of cases taken up for study:

Case 1:

Case No.: 443 of 1997 : District Forum, Chennai.

Case of the complainant:

The child Rahima Begum had fever and cough and was taken to the opposite party on 21st February 1997. The doctor prescribed tablets, one of which was "Pyrolfin", for two days and also advised the child to conduct blood and urine test. The results of the blood and urine tests proved negative for clinical malaria. Though the temperature came down, the child developed deep ulceration and fleshy lumps under tongue, puffy eyelids, extensive reddish skin, loss of sensation of both upper and lower limbs, falling hair and loss of appetite. She was under the treatment of the doctor till 3 March and then was rushed to Kalyani General Hospital. From there she was advised to get admit herself in Child Trust Hospital. The child got herself admitted in Child Trust Hospital on 6 March and was there for nearly 25 days. The complainant reliably understood that the child had developed Stevens-Johnson syndrome, which was due to administering "Pyrolfin" tablets which contained sulpha drug which was allergic to the child. The allegation of the complainant is that the doctor was negligent in not conducting the test to see whether the sulpha drug was allergic to the child or not. The complainant also alleged that child lost one year of schooling and had to be under treatment. The vision of the child is impaired and requires treatment by ophthalmologist and the child was left with ugly scars. The complainant claimed Rs.26,077.75 towards medical expenses, Rs.10,000 towards future medical expenses and Rs.4 lakh towards psychic and physical trauma.

Version of the opposite party:

The doctor's defence was that the child came with fever, cough and chillness. He suspected it may be "clinical malaria" and had advised the child to conduct blood and urine test. He had by way of caution prescribed citamycin 250 mg (3); malidens (2) and Pyrolfin (2) to the child. The doctor's contention is that he has been practicing medicine for 18 years. The Pyrolfin is a universally accepted drug and also approved by WHO. Since, the child developed Stevens-Johnson's syndrome, the doctor advised the complainant to take the child to Child Trust Hospital, which is well equipped to treat the disease. But the complainant had taken the child to Kalyani General Hospital and from there she was taken to Child Trust when it was felt by the doctor's of Kalyani General Hospital that they did not have the expertise to treat the child. In fact, there was breach of contract. The other contention of the doctor is that the complainant is that the doctor was not kept abreast of the developments and he was kept at dark and the contention of the complainant that the child was under the treatment of the doctor till 3 March was denied. The doctor denied that there is no test that can be conducted for such sulpha drugs and it is for the patient to disclose if they are allergic to such drug. The doctor denied of any negligence on his part and had claimed Rs.10,000 as exemplary costs against the complainant.

Finding of the Forum:

The forum after giving opportunity to both the sides and after looking into the documents produced by both the parties came to the conclusion that there was no negligence or deficiency on the part of the doctor while administering treatment to the child. It held that the doctor had prescribed the medicine by way of caution and from the literature submitted by the doctor it is seen that the drug is universally accepted drug for curing clinical malaria. Hence, the Forum dismissed the complaint without costs.

Case 2:
Case No. : OP 1004 of 1998 : District Forum, Chennai

Case of the complainant:

Lured by the advertisement in Vijay TV about curing of back pain, the complainant went to the opposite party, as he is a naturopathy expert and had assured to cure the complainant within 15 days. On advise the complainant got him admitted on 16.5.1998 and paid Rs.100 as consultation charges, Rs.2000 for admission charges and Rs.500 for petty expenses. On 18.5.1998, three persons came and asked the complainant to do an exercise called "Suthavajnasanam". As the complainant was not able to do the same, the opposite party asked his subordinates, who have pulled down the body back and put on flat position over the legs and the opposite party himself sat on the complainant's thighs and due to brutal and uncivilized method of treatment the complainant developed pain and could not raise his leg. He developed bi-lateral foot drop and not able to walk. Within short moment there was numbness below the waist and the complainant could not raise his lower limbs. The opposite party started giving Neurobion Forte and Voverion injection with some ayurvedic injection. The complainant was advised to use Iodex spray to control the pain. He was carried by attendants and used bed pans for nature calls. The opposite party advised X-ray and doctor who took x-ray advised correction by means of clinical treatment.

He was injected with osteosclerosis due to brutal method used by the opposite party. On 26.5.1998 and 13.6.1998 the opposite party collected Rs.2000 thus totaling to Rs.10,000. The complainant was forced to undergo some surgical operation and after discharge the complainant reached MIOT hospital for special treatment and is still under constant physiotherapy. The opposite party is using allopathic medicine though he is not authorised to do so.

The complainant is 29 years old and was made immobile and was not able to join his job where he was getting a monthly salary of Rs.10,000. Hence, the complainant claimed for refund of Rs.10,000, Rs.50,000 towards medical expenses, Rs.50,000 towards travel expenses, Rs.1 lakh as compensation and Rs.1000 towards costs.

Version of the opposite party:

The opposite party is a qualified doctor in the field of naturopathy. The complainant stayed in the opposite party's hospital between 16.5.1998 to 13.6.1998. On 13.6.1998 he voluntarily got himself discharged on 13.6.1998. The opposite party never promised of any cure within 15 days. The opposite party never administered any injection. The complainant was referred to M.R.Hospital for x-ray to see the progress after treatment and not as alleged by the complainant. As the progress was slow he was advised to continue the treatment at home. He was walking briskly when he was discharged. Hence there was no negligence or deficiency on the part of the opposite party.

Finding of the Forum:

After considering the arguments of both the parties the Forum held that no expert opinion or evidence was let in by the complainant that the treatment given by the opposite party was the cause for the disease called osteosclerosis or numbness. Similarly, no evidence was given to show that the opposite party had made any promise to cure the illness within 15 days. The complainant has not produced contra-evidence to show that he having taught "Suthavarjasanam". He did not file any rejoinder to deny that he walked briskly when he was discharged. The Forum further held that "perhaps the slow development had made the complainant to file this case. Therefore, the complaint is liable to be dismissed. The complaint is dismissed."

Case 3:

Case No : 241 of 2001: District Forum, Chennai.

Case of the complainant:

The complainant, Dilshad Fathima, filed a complaint against N.R. Medical Home and Dr.(Mrs) Nasreen Ahmed (gynecologist). The case of the complainant is that she had delivered a third girl baby on 7th April 1999 and thereafter underwent a sterilization operation. On 21st June 2001 she met Dr Nasreen as she was having nausea and vomiting. The doctor informed her that she was pregnant again. The complainant was shocked to know this. Later in October 2001 the complainant filed a case against the hospital and the doctor claiming Rs.6000 towards reimbursement of expenses of delivery of the third child; Rs.50,000 towards deficiency of service by the opposite parties in failing to perform proper sterilization; Rs.1 lakh compensation for mental agony and Rs.5000 as costs of the complaint, thus totaling to Rs.1.61 lakh.

Version of the opposite party:

The version of the opposite parties was that the complainant was performed sterilization adopting "Pomeroy's" technique. And according to this practice there is a 0.2% to 1% failure. The parties also contended that the failure was not an immediate one but the complainant had become pregnant after a lapse of nearly 2 years. Hence, no negligence can be attributed to the doctor. It was also contended that the complainant was offered an option

of terminating the pregnancy and re-sterilization free of cost when she came on 21st June 2001. But she opted to continue the pregnancy saying that the fourth child may turn out to be a male child.

Finding of the Forum:

The Forum after hearing the arguments of both the counsels appearing on behalf of the complainant and the opposite parties and after going through the documents filed by both the parties and taking into consideration the judgements already passed by various State and National Commission on similar facts came to the conclusion that there was no negligence on the part of the doctor and the hospital and had dismissed the complaint.

Case 4:
Appeal Nos. : 61 of 1999 and 171 of 2002: State Commission, Chennai.

Complainant's case:
Mrs Thulasimani had some gynecological disorders. She was advised removal of her uterus by surgery. On 30.4.1996 the surgery was performed. On 7.5.1996, the complainant's wife passed away at Coimbatore Kidney Centre. The death certificate issued mentioned that the death was due to acute reneal failure and septicemia. Septicemia is a condition when bacteria or fungi actually multipyling in the blood usually with the production of severe symptoms such as fever and hypertension. It develops from unclean and septic gadgets, theatre, catheters such as intravenous peritoneal, urinary wound infection and deep infection may also bring septicemia. Since operation the complainant's wife had discomfort and uneasiness. This was informed to the opposite party.

The complaint alleged negligence on the part of the opposite party for the following reasons: the opposite party failed to keep the gadgets in an aseptic condition, contradictions in nurses notes and doctor's case sheet, administration of steriod (decadron) even after diagnosing septicemia, failure of information to the deceased's relatives about the patient's condition, failure to exercise due care and caution by permitting inappropriate experts to deal with the case and failed to exercise due care and caution through surgery and thereafter.

On 17.5.1996, the complainant's counsel called for the case records from the opposite party's hospital. The opposite party gave the case sheet and nurses notes through their counsel after a delay of 26 days. In the reply notice dated 10.6.1996, the opposite party conceded that the patient developed complications while still under treatment. The complainant claimed Rs.5 lakh as compensation for the deficiency in service by the opposite party.

Opposite Party's version:
The complainant had already filed OP 143 of 1996 and was dismissed for default. On 12.3.1997, the complainant filed a restoration application and the same was dismissed on merits. Hence the principle of *res judicata* (the court shall not entertain a case which has already been decided on the same issue between the same parties arising on same cause of action) would apply.

Before coming to the opposite party's hospital, the lady was examined by Dr Shyamala, leading gynecologist for excessive discharge during menstrual periods and Dr Shyamala advised removal of uterus and was referred to the opposite party. Previously the lady's sister Saraswathi was successfully operated by the opposite party for a similar problem. The complainant's wife got admitted and was operated upon on 30.4.1996. The opposite party had used all well sterilized and bacteria-free materials. Almost two operations are performed daily and no complaints have been reported so far. It may be due to very low immunity of the patient that even a small infection could have caused septicemia.

On 30.4.1996 and 1.5.1996, she was on intravenous alimentation. On 2nd and 3rd May, she was on oral food and on 4th on solid food. Since she complained vomiting and giddiness on 5th, she was attended by Dr Elango M.D. on 5th, 6th and 7th and the patient was discharged. Dr Elango suspected septicemia and gave all antibiotics. On 6th, Dr Elango called Dr P N Shanmugam, urologist, to rule out the problems in the kidney. Dr Shanmugam examined her and found urinal output was normal and advised continuation of the same treatment. On 7th the opposite party contacted Dr K S Ramalingam of Coimbatore Kidney Centre over phone and on his advice the complainant's wife was sent to Coimbatore after discharging her. She was sent in a well-equipped ambulance. A qualified nurse also accompanied her. Hence, there was no negligence on the part of the opposite party.

District Forum's Finding: (Erode)
Exhibits 20 to 22 and B7 would go to show that the complainant filed a memo in the district forum on 27.4.1998 stating that he has filed an appeal before the State Commission to set aside the order of dismissal for default in OP 148/96. On 21.11.1998, the complainant had sent a letter to withdraw the appeal as trial in this case has been taken up. On 25.1.1999, the appeal was withdrawn in the State Commission. Hence, principle of *res judicata* would not apply.

After considering the facts of the case and arguments put forth by both the parties and from the fact that the nurses have administered some other medicines which were not prescribed by the doctors, the President of the district forum came to the conclusion that the complainant is entitled to Rs.4.50 lakh as compensation for loss of his wife.

On the contrary, the members of the district forum held that there was no negligence on the part of the opposite party and dismissed the complaint with compensatory costs of Rs.5000 to be paid by the complainant to the opposite party.

State Commission's finding:
Hence, two appeals arose from the judgments passed in the district forum. AP 61 of 1999 was filed by the complainant against the majority order passed by the non-judicial members and AP 171 of 2002 was filed by the opposite party against the order of the judicial member (president) of the forum.

Mr R Gandhi, senior advocate, advanced arguments on behalf the complainant and Mr K Duraiswamy, senior advocate, argued for the opposite party.

The State Commission held that the principle of *res judicata* shall not apply as the original case (OP 148/96) was not decided on merits. It also held that the majority order of the forum below is not sustainable in law and hence, the order of the President was upheld. In substance, AP 61 of 1999 was allowed upholding the President's order and AP 171 of 2002 was dismissed setting aside the order of the majority members of the district forum.

Case 5:
Case No. : OP 105 of 2000 : District Forum, Chennai.

Complainant's case:

Complainant married Ms. Anupriya on 10.9.1998. In the year 1999, she developed some gynecological problems and hence consulted Dr Hemaltha, gynecologist. After various tests and ultrasound scan certain medicines were prescribed. She did not get any relief. Again the complainant's wife met Dr Hemalatha in the last week of August 1999. The doctor advised diagnostic laprascopy. Ms Anupriya got herself admitted as in-patient in Dr Mu Va's Hospital on 8.10.1999. After laparascopy, Anupriya developed breathlessness and became hyposensive and she had to be ventilated immediately. Since the hospital had no ventilator facility, it was brought from outside. She was ventilated and incubated at 03:00 a.m. on 9.10.1999. Later, she was shifted to Soorya Hospital. There without regaining consciousness, Anupriya died at 09:40 p.m. on 9.10.1999. The complainant alleged spending Rs.10,000 for various tests between February - September 1999; Rs.1500 towards medicines and Rs.50,000 as medical expenses on 8th October 1999; Rs.10,000 towards the hospital expenses, laboratory tests, doctors fee, medicines, etc. to the third opposite party.

The complainant further alleged that first opposite party refused to give case sheet, discharge report, bills for various amounts collected and to furnish the name of the anesthetist or the exact cause for the sudden breathlessness of the complainant's wife. The complainant termed the death certificate issued by the third opposite party as ridiculous and fallacious.

Hence, the complainant claimed Rs.4 lakh as compensation for the death of his wife and Rs.75,000 towards reimbursement of medical expenses from the first and second opposite parties. There was no claim against the third opposite party.

Version of 1st Opposite Party:

The first opposite party denied running Dr Mu Va's Hospital. The first opposite party said that she was just a consultant in that hospital. The complainant's wife also consulted for her inability to conceive and infertility. The case of the complainant's wife was a case of primary infertility. Hence diagnostic laparascopy was suggested and referred to Dr Viswanathan Pai, eminent laparascopic surgeon and he performed the same on 8.10.1999 at 8:00 a.m. He was assisted by Dr.Bushanam, senior anesthetist, residing at Anna Nagar, Chennai. She was

ventilated with oxygen from Boyles apparatus followed by ventilator. Monitored every 5 minutes till 11:05 p.m. and thereafter every 15 minutes till about 7:30 a.m. As she failed to recover from anesthesia, Dr Geetha Lakshmipathy, M.D., professor of neurology, Kilpauk Medical College, was called. She came early in the morning on 9.10.1999 and saw the patient. Then she suggested shifting the patient to Soorya Hospital. The patient was shifted by ambulance with portable ventilator and pulse oxymeter. At last, the patient died on 9.10.1999 about 10:40 p.m. due to hypoxic encephelopathy and brain stem dysfunction resulting in cardio respiratory arrest.

The opposite party denied having received any fee and performed the laparascopy free of cost. The opposite party also denied the allegations of negligence on their part.

Version of 3rd Opposite Party:

The third opposite party against whom there was no claim, contended that the patient was seen by the neurologist and neurosurgeon and other doctors. The cause of the death was recorded at the time as "cardio respitatory arrest".

Finding of the Forum:

The forum after considering the documents filed and arguments advanced held that complainant has not proved that opposite parties have committed deficiency in service and negligence in their duties and hence is not entitled for compensation. It also held that reasonable care has been taken by the first opposite party.

Case 6:
Case No: O.P.No. 95 of 1992 : District Forum, Chennai

Case of the complainant:

K. Vasantha, the complainant a 30 year old woman wanted to have a second child 7 years after her first child. Dr. Lakshmi Dandayudapani prescribed certain costly medicines for improving chances of pregnancy. On 18.02.91, the doctor confirmed that she was pregnant. On 02.03.91, she developed fever and was taken to the opposite party hospital for treatment. She was examined and on 03.03.91, D&C was performed. She continued to have pain and so some medicines were prescribed. There was no improvement and a scan of the pelvis was taken. It was detected to be a case of "missed abortion". The complainant was taken to CMC Vellore for further treatment and a dead foetus was removed from the tube.

The complainants argued that the opposite parties had wrongly done the D&C due to which the foetus was pushed to the tubes. They argued that it was a case of normal pregnancy and due to the wrongly done D&C she had lost her second baby. They had claimed compensation of Rs.2,19,000 for the loss of child and the medical expenses.

Version of the opposite party:

The opposite party doctor argued with a lot of literature on tubal pregnancy and proved that there was no negligence.

Finding of the Court:

The court held that there was no negligence ordeficiency of service on part of the doctors and the case was dismissed.

Case 7:

Case No.: OP 512 of 1996 : District Forum, Chennai

Complainant's case:

Complainant underwent sterilization on 3.9.1994 at the 2nd Opposite party's nursing home. Dr C Meenal performed the operation. On check-up on 17.10.1996 it was found that she had conceived. The complainant works as senior accountant in Director of Postal Accounts and was entitled for increment of Rs.50 form the date of operation.

The allegations of the complainant were that she was put to much shame in the eyes of the neighbours and officials and loss of income and mental agony. On 17.10.1996, she underwent a MTP due to failure in the sterilization.

Hence, she claimed Rs.2 lakh as compensation, Rs.8000 towards medical expenses and Rs.10,000 towards mental agony and costs.

Version of 1st Opposite Party:

The first opposite party contended that no assurance was given to the complainant that she would not conceive again on performance of the sterilization. She was informed about the possibility of conceiving and that the complainant had consented to the same. The opposite party also took the stand that the complaint is barred by limitation.

Version of the 2nd Opposite Party:

The second opposite party orally mentioned that the first opposite party was just a consultant and that the operation was performed in the nursing home. They did not even file a written version. Hence, the second opposite party was set exparte.

Finding:

After considering the arguments put forth by the complainant and the opposite party the Forum held that there was no evidence or expert opinion let in by the complainant to show that there was a negligent act in performing the operation. Hence, the Forum dismissed the complaint.

Case 8:

Case No.: OP 1054 of 1998 : District Forum, Chennai

Complainant's case:
The complainant had fixed up a cataract operation with opposite party to be performed on 4.8.1997 and paid a consideration of Rs.4998. On 23.7.1997, she consulted a physician for general fitness. On 4.8.1997, cataract operation was performed. On 5.8.1997 she was discharged and was directed to come for review after a week after applying the medicines prescribed. The doctor was satisfied on general condition and prescribed medicines for a period of one month.

On 12.8.1997 when she came for consultation she reported irritation. The opposite party said it would gradually decrease and instructed to continue the medicines. She followed and it increased irritation in the left eye and had difficulty in opening her eye in the mornings. Again she met the opposite party on 23.8.1997 and narrated the intensity of pain, decrease in vision and disturbing symptoms. The opposite party advised her to continue the medicines and report for review after three weeks.

On 15.9.1997, the general physician reported her general bodily condition was normal and that she could go back to her native. Suspecting something went wrong, she went to Arvind Eye Hospital, Madurai and they diagnosed that the complainant was suffering from a condition known as Pseudophalic Bullous Kerotopathy. The complainant understands that the cornea of her left eye had been injured during the cataract operation. Since the oedema had been neglected and allowed to persist for too long a period without treatment the cornea had been infected and resulted damage. The complainant has only an alternative to go for corneal grafting.

Hence, the complainant claimed Rs.50,000 for pain and suffering; Rs.50,000 for mental pain and suffering; Rs.1 lakh for permanent disability and Rs.9000 towards refund of costs of treatment at Arvind Eye Hospital and Rs.4500 for post operative care.

Version of the Opposite Party:
The opposite party was a professor of Opthalmology in Madras Medical College and Superintendent in Government Opthalmic Hospital and at present the Vice Chancellor of MGR Medical University.

The complainant was having a history of minor heart block and was found to have 6/2 and CF 2mts in both the eyes and presence of dryness in both the eyes and cataract in the left eye.

As surgery for cataract under this condition cannot be guaranteed for restoration of full normal vision, the complainant was informed of the prognosis being guarded.

On 15.9.1997, there was a suspicion of non-compliance of the eye drops. She was prescribed temporary glasses and advised to continue the drops.

The opposite party submitted that there was no negligence either at the time of operation or subsequently. The complainant did not follow the instructions of the opposite party.

Findings of the Court:
"Though the complainant had filed 26 documents, she had no document to substantiate her claims. Documents from Arvind Eye Hospital do not establish her case or even support her case. On the other hand it only vindicates the contention of the opposite party. Exhibits A16 and A17 demonstrate that there was no negligence.

Had there been negligence, she would have lost her sight. Instead it has improved to 6/18. Similarly striate keratopathy is a temporary post-operative phenomena which needs no treatment and will heal by itself. The complainant had not followed the instructions of the opposite party and that she had consultations before coming to opposite party and was having Lacryl Eye drops for a longer time. No contra evidence to disprove the same was let in. She never came for review after 15.9.1997."

There is no expert opinion to establish the complainant's case that there was negligence on the part of the opposite party. Hence the complaint is dismissed.

Case 9:

Case No.: OP 128 of 2000 : District Forum, Chennai.

Case of the complainant:
The complainant sustained injuries in a road traffic accident on 2.8.1998 at Chennai. He was treated as in-patient by second opposite party from 2.8.1998 to 26.8.1998 and as out-patient continuously till the month of May 1999.

The complainant had sustained Gr III A Compound # fracture both bone right leg with Gr III A compound injury, right knee with fracture shaft of femur, right with patellar retinacular. The first opposite party performed surgery on 14.8.1998 of open reduction and internal fixation with IM nailing done for fracture shaft of femur under G.A. at the second opposite party hospital.

The complainant has not sustained fracture neck of femur in right leg at the time of accident and the same has occurred only due to the surgery done by first opposite party which fracture was seen immediately subsequent to the said operation.

Since his condition got deteriorated, complainant opted for another ortho doctor's treatment in the month of May 1999, whohas done long stem total hip replacement surgery. He had spent a sum of Rs.1.10 lakh towards medical expenses of opposite parties and Rs.1.60 lakh for subsequent surgery.

The complainant alleges due to improper surgery and inadequate care, the complainant was crippled and bed ridden and has totally ruined the complainant's life in all ways, physically, mentally and monetarily. Hence, the complainant claimed a compensation of Rs.4.50 lakh.

Version of the opposite parties:
The opposite parties remained ex parte.

Findings of the Forum:
The first opposite party filed CMP (application) 190/2000 for setting aside the ex parte order. Hence it was set aside and was given time to file version from 18.4.2000 to 3.5.2000 and again till 17.5.2000 and further time was granted for filing version till 1.6.2000 and again finally to 17.7.2000. There was no representation on behalf of the first opposite party and failed to file version. Hence the first opposite party was set exparte. The matter was pending from 17.7.2000 to 28.7.2000 for enquiry. No steps were taken by the opposite parties for setting aside the ex parte order.

"Despite legal notice, the parties have not responded to the same. A perusal of the documents also establishes the case of the complainant. Despite such serious allegations have been made and notices have been served, the opposite party's silence only shows that they admit the allegations. Therefore the complainant is entitled tot he relief as prayed for. The opposite parties are directed to pay a compensation of Rs.4.50 lakh with costs of Rs.1000. Time for payment one month."

Case 10:

Case No.: OP 88 of 2000 : District Forum, Madurai

Complainant's case:

The complainant is a secondary grade teacher working at Government Girls High School, Y. Othakkadai, Madurai District. In December 1999 she approached the opposite party for performing D&C and Family Planning Operation. The opposite party agreed to perform and demanded Rs.5000. The complainant paid the said amount. On 16.12.1999 after confirming pregnancy (45 days) got herself admitted in Madurai City Poly Clinic as directed by the opposite party. The opposite party performed D&C and Family Planning Operation (MTP Sterilization) on the same day and complainant remained there till 18.12.1999. Even though the complainant took prescribed medicines, she developed pain the stomach within a week. She reported the same to the opposite party. She visited the opposite party more than 10 times and every visit. On 5.2.2000 the complainant's husband contacted the opposite party.

The opposite party directed the complainant to take a scan. On 7.2.2000, the complainant after paying Rs.300 took scan. The scan report has showed some product still remained in uterine cavity. After seeing the scan, the opposite party once again directed the complainant to undergo D&C. On 8.2.2000 the complainant paid Rs.1000 got herself D&C performed once again. Hence, the complaint attributed negligence on the part of the opposite party. She also suffered untold pain for around two months and took leave during the period 13.12.1999 to 22.12.1999; 5.1.2000 to 12.1.2000 and 27.1.2000 to 15.2.2000. This has led to unnecessary financial hardship and expenditure on medicines. The complainant caused legal notice dated 21.2.2000 for which there was no reply from the opposite party. Hence the complainant preferred to file a complaint claiming Rs.25,000 towards deficiency in service by the opposite party, Rs.50,000 towards pain and suffering and Rs.25,000 towards mental agony.

Version of the opposite party:

The opposite party remained ex parte.

Findings of the DCF (Madurai):

The Forum held that this is a case of non-rebuttal by the opposite party. "The opposite party was not prepared to tell what really happened would prove she was trying to hide something which would be against her." Therefore, the court held that there is deficiency in service on part of the opposite party and therefore opposite party was directed to pay Rs.15,000 for deficiency in service, Rs.10,000 towards physical pain, sufferings and mental agony and Rs.2000 towards costs.

Case 11:

Case No.: 222 of 2000 : District Forum, Madurai

Case of the complainant:
On 3.3.2000, the complainant went to the opposite party for confirmation of her pregnancy. She was referred to Sri Ragha Clinical laboratory, attached to opposite party's hospital, for urine test. The bio-chemist gave a report that her gravindex is "negative". The opposite party prescribed certain medicines. If she had taken the medicines the pregnancy would have been terminated. Her husband had his doubt and tested at Avani Clinial lab. There the result was positive. Dr R.Mahalakshmi after examination informed she would deliver a child on 15.10.2000. The complainant had sent a legal notice to the opposite party for which she did not receive any reply. She contended that her relatives abused her of filthy language and caused her mental agony because of earlier report. Hence, she claimed Rs.98,120 as compensation from the opposite party.

Version of the opposite party:
The contention of the opposite party was that he has not even seen the complainant. But on the evening of 3.3.2000 at 6 p.m. the complainant met Dr R. Indumathi at opposite party's

hospital of complaining of missing periods. She suggested urine pregnancy test (gravindex). She was tested at Sri Ragha Clinical lab. On seeing the report as "negative" she had her doubt it could be either due to the test being done late in the evening or due to dysfunctional utrine bleeding (DUB). Hence she had prescribed softeron capsule and uteromine syrup to take care of both the situations. The opposite party was unaware of the subsequent events. The opposite party contended that there was no negligence on his part and hence the complaint is liable to be dismissed.

Findings of the Forum:
After hearing both the parties and exhibits presented, the Forum held that the complainant did not taken any of the medicines prescribed by the opposite party. No evidence has been brought on record to link that the prescription of tablet and tonic with any of the resultant complications in the case nor has any evidence been let which would go to show that the opposite party hospital or any of its doctors were guilty of negligence or deficiency of service. It further held that no evidence was produced to show that the laboratory belongs to the opposite party hospital. Hence, the forum had dismissed the complaint.

Case 12:

Case No.: 257 of 2000 : District Forum, Chennai.

Case of the complainants:

The second complainant was treated by the duty doctor of the opposite on 16.2.1997 in the advanced stage of pregnancy. She was treated ignoring the fact that she was a bad obstetric history (BOH) patient and prescribed some tablets and advised her to come to the hospital the next day. But on reaching home she developed fits and her condition became serious and rushed to Sundaram Medical Foundation, where an operation was performed and she delivered a baby. The hospital charged Rs.16,141.30. But the opposite party sanctioned only Rs.4,335. Hence this present complaint against the duty doctor in not having gone through the her exact medical history and due to negligence on their part, the complainants were made to spend more and undergo mental agony. Hence, the complainants claimed reimbursement of the balance expenditure of Rs.11,806 with compensation of Rs.50,000.

Version of the opposite party:

On 16,2,1997, the second complainant was brought to the casualty department for mild diarrhea and vomiting and not for sudden development of pain in the abdomen. The record of the opposite party has not shown that the second complainant had undergone a periodic regular antenatal checkup. The duty doctor who had examined the second complainant had found her condition to be normal. She was also found not to have any labor pain warranting admission or any other active clinical intervention. There was no negligence or deficiency of service on the part of the duty doctor. The ESI hospital is not dealing with medical reimbursement and hence the complainant is not entitled to any relief. The opposite party also contended that the claim should have been made to ESI Corporation in ESI court.

Finding of the Forum:

The Forum after considering the arguments of the both the parties held that there was no cause of action to file the present petition in this forum. Under ESI Act 1948, any claim by the petitioners should be made against the ESI and filed before the ESI court. Similarly, it held that there is no document to establish that there was any deficiency in service on the part of the opposite party. The complainant's have not produced contra-evidence to state that the second complainant's condition was not normal. The complainant's have not disputed the fact that the opposite party hospital at K.K.Nagar is not connected with reimbursement of medical expenses. Hence on these grounds, the Forum dismissed the complaint.

Appendix VI

Typical questions put forth to patients in our personal interviews relating to CPA.

1. How is the patient now (in cases of patient's relative had filed the case)?
2. What is your occupation?
3. What was your monthly income then and now in 2002?
4. How many of you are there in your family?
5. From when did you know the doctor?
6. How much have you spent so far towards treatment after the incident?
7. Who told you to file a case? Is it the doctor whom you met later or on your own?
8. Were you aware of Consumer Protection Act before filing the case?
9. How did you choose your advocate?
10. How much did the advocate charge your for conducting the case in both district and state forum?
11. Are you aware that there is no need to engage an advocate in the consumer forum? Why did you choose to have an advocate?
12. How much did you spend towards the litigation by way of travel cost and time spent?
13. What is your opinion of consumer courts? Why do you think you did not get justice?
14. Did you seek any doctor to give their expert opinion in the case?
15. What else did you do apart from filing the case? (alternative recourses, if any)
16. Did you get any response to the same?
17. Has this litigation changed your behaviour? In the sense, have you started asking for the bills when you purchase something?
18. Have you started seeing doctors with a suspicion after the incident?
19. Do you feel that had you approached the doctor before filing the complaint, he would have compensated you to some extent?

Appendix VII

Typical questions put forth to the heathcare providers (involved in litigation) in our personal interviews relating to CPA:

1. Can you brief me about your personal experience relating to the case filed in consumer forum.
2. Were you aware that the complainant shall file a case against you?
3. When did you engage an advocate and how did you choose him?
4. Where you aware that the party can conduct his case in the consumer forum?
5. What was the fee that was paid to the advocates?
6. How many times did you visit the advocate?
7. How much time did you spend with them?
8. Were you aware of CPA before your personal experience?
9. Where did you collect the materials for defending your case?
10. Since you had engaged an advocate, did you go to the court on all the hearings?
11. How much do you think you had spent on the litigation in terms of time spent, travel, etc.?
12. What is your opinion of the Consumer Protection Act?
13. What is your opinion of Consumer Courts?
14. What do you think is the outcome of the litigation?
15. Is there an increase in cost of treatment?
16. Is there a change in your behaviour after your personal experience, like maintaining records, etc.?
17. Would you have compensated the patient if he had approached you without filing a case against you?

Appendix VIII

Samples to illustrate calculation of transaction costs:

Cost of consumer courts in Case 1 of the sample cases:

Cost of time spent on numbering the complaint (Rs.10,000÷30÷7)[197]	: Rs.48
Cost of despatching process to the parties (Rs.3500÷30÷7)[198]	: Rs.17
Cost of time spent by forum in deciding the issue {[(Rs.20,000+4,200+4,200)÷30÷6]÷4}×11 (Salary of the president+members)[199]	: Rs.434
Cost of steno for typing the order (6000÷30÷7)[200]	: Rs.29
Cost of the bench clerk [(6000÷30÷7)÷4]×11[201]	: Rs.78
Cost of despatching the order copy (Rs.3500÷30÷7)[202]	: Rs.17
TOTAL	**: Rs.623**

[197] Head clerk's salary is Rs.10,000. Approx. 1 hour of his time is taken in examining & numbering the complaint.
[198] Process server's salary is Rs.3,500. Approx. 1 hour of his time is taken in preparing and despatching the process.
[199] President's salary is Rs.20,000 (approx.), and Member's salary is Rs.4,200 p.m. Approx. 15 mts. is spent per hearing. Totally 11 hearings took place.
[200] The stenographer's salary is Rs.6000. Approx. 1 hour is taken for taking the dictation and typing the order.
[201] Bench clerk's salary is Rs.6,000. Approx. 15 mts. is spent per hearing. Totally 11 hearings took place.
[202] Process server's salary is Rs.3,500. Approx. 1 hour of his time is taken in preparing and despatching the order copy.

Transaction costs incurred by the complainant so far (a pending complaint) before the State Commission, Chennai:

1. Travel cost to meet the advocate to brief him (five occasions they had been to advocates place)	: 5 x Rs.30 Rs.150
2. Cost of time spending with the advocate[203] (5000÷30÷8)	: 10 hrs x Rs.21 Rs.167
3. Cost of preparing & filing the complaint (stationery charges, photocopying, stamps, covers,etc.)	: Rs. 3,500
4. Loss of wages of the complainant	: 4 months x Rs.5000 Rs.20,000
5. Time spent on collecting the material to strengthen the complainants case (This includes advocate's time and travel cost)	: 25 hrs x Rs.1000 Rs.25,000
6. Fee to the advocate in sending notice	: Rs.1,500
7. Cost for advocate in meeting the doctor for expert opinion (includes time and travel cost)	: 5 hrs x Rs.1000 Rs.5,000
8. Advocates fee per attendance[204] (this includes travel and waiting cost)	: 14 days x Rs.1500 Rs.21,000
TOTAL	**: Rs.76,167**

[203] The complainant works in Office of the Official Liquidator of Companies and earns Rs.5000 per month. Calculating 1 hour cost.

[204] The advocate mentioned that generally, advocates would charge around Rs.1.25 lakh for conducting the entire case of this nature. In fact, in cases of medical negligence and motor accident claims, the advocates would charge up to 25 % of the claim awarded by the court. But still made some estimates on the his costs.

Appendix IX

CONSUMER PROTECTION ACT (CPA), 1986 & MEDICAL PRACTITIONERS: A Survey on views and experiences of Medical Practitioners in Tamil Nadu with reference to CPA, 1986

Questionnaire

Name :

Sex :

Place of practice :
(mention name of town/city)

Years of practice :

Specialty (if applicable) :

1. When did you come to know that doctors/hospitals were brought under the purview of Consumer Protection Act, 1986 (CPA)? (Mention the year)

2. How did you come to know? (from personal experience, through IMA/professional association, media, etc.)

3. Are you aware that according to CPA, you need not engage a lawyer to defend your case before the Consumer Forum?

   ☐ Yes ☐ No

4. Have you ever been accused of medical negligence/deficiency of services?

   ☐ Yes ☐ No

   (If no, you may directly proceed to Q.No.12)

5. If yes, was it before the: [Please tick the relevant box(es)]
   (a) District Consumer Disputes Redressal Forum: ☐
   (b) State Consumer Disputes Redressal Commission: ☐
   (c) National Consumer Disputes Redressal Commission: ☐

6. Please give the following details of the case(s) including appeals:
   (In case of appeals please mention the same in brackets)

S.No	Forum (District/State/ National)	Outcome (for or against you)	Compensation		Reason for the order[205]	Duration of the case	
			Amount Claimed (Rs.)	Amount Paid (Rs.)		From	To

(Please use additional sheet, if necessary)

7. Was the appeal made by you or by the complainant?

   ☐ by me ☐ by complainant ☐ not applicable

8. Did you consider "out-of-court" settlement? If so, what was the outcome?
   (Please also mention the amount paid to the complainant)

9. How much money have you spent on the following items in defending your case? (Give atleast an approximate figure)

S.No [206]	Amount Spent				
	Lawyer's Fee (Rs.)	Time Spent [207] (Rs.)	Travel Expenses [208] (Rs.)	Documentation[209] (Rs.)	Expert Opinion[210] (Rs.)

[205] The reasons may vary as frivolous complaint, negligence not proved, etc., Please specify the same.
[206] Provide details as per the serial number in mentioned in Q.No.5
[207] Quantify (in terms of money) the loss of practice, value of time spent on collecting materials to defend your case, visiting advocate's office, courts, etc.
[208] Travel includes visiting libraries to collect relevant material to defend your case, court visits, lawyer's office, etc.
[209] Documentation includes photocopying the material, purchasing books on medico-legal issues, etc.
[210] This is the cost of obtaining expert opinion from any other doctor to defend your case.

10. Did this incidence (alleged negligence) occur in your own set up or in any hospital/nursing home(NH), where you were a consultant?

☐ My own set up ☐ Other Hospital/NH

If it was in any other Hospital/NH, how did they support you in defending your case? (eg. in engaging an advocate, insurance coverage, etc.)

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11. Have you ever appeared before the Consumer Forum for giving expert opinion in any case?

☐ Yes ☐ No

12. If yes, please give the following details:

Case No.	Forum	Your Opinion (state whether it was in favour of physician or patient)

13. Have you insured yourself against malpractice litigation?

☐ Yes ☐ No

14. If yes, please provide the following details:

Name of the Insurance Co.	Amount Insured	Premium Paid	Period

15. How long have you been under any insurance scheme?

☐ 1 year ☐ 2 years ☐ 3 years or more

16. In your opinion, has the practice of defensive medicine increased as a result of CPA?

☐ No change ☐ Moderate change ☐ Substantial change

17. More specifically, which of the following medical practices *adopted by you* have increased, as a result of CPA? (please tick the appropriate columns)

Practice	No change	Moderate Increase	Substantial Increase
Referral rate			
Follow up			
Diagnosis			
Prescription of drugs			
Documentation			
Time spent with patients			
In-house medical audit (if applicable)			

18. In your opinion, should doctors be brought under CPA?

☐ Yes ☐ No

19. If yes, in what ways the functioning of Consumer Forum could be improved?
(You may suggest specific measures to: i) reduce costs of litigation; ii) simplify court procedures; and iii) expedite disposal of complaints)

20. Can you think of alternative mechanism(s) to CPA to address "medical negligence" and "deficiency of service" by doctors?

Appendix X

List of stakeholders interviewed: CPA

Advocates:

1. Mr V.Ramasubramaniam, Chennai
2. Ms. Radhika Krishnan, Chennai
3. Mr. Rajendran, Chennai
4. Mr. S.Kanagaraj, Madurai
5. Mr. Prabhakar, Tirunelveli
6. Mr.S.Balasubramaniam, Madurai
7. Mr. S.L.Sudarsanam, Chennai
8. Mr. Natarajan, Chennai.
9. Mr.Khan Abdul Ibrahim, Madurai.

Doctors:

1. Dr. B.Suresh, Dentist, Chennai
2. Dr. Mathiharan, Medico-legal consultant, Chennai
3. Dr. R.Jothiramalingam, Dept. of Surgery, Govt.Rajaji College, Madurai.
4. Dr.S.Selvachidambaram, Govt. Rajaji Hospital, Madurai.

Government:

1. Justice Janarthanam, Chairman, Tamil Nadu State Consumer Disputes Redressal Commission, Chennai.
2. Mr. Kengusubbiah, Chairman, Tamil Nadu District Consumer Disputes Redressal Commission, Chennai-North.
3. Mr. Subramaniam, Registrar, Tamil Nadu State Consumer Disputes Redressal Commission, Chennai.
4. Mr.P.Manoharan, Member, Tamil Nadu District Consumer Disputes Redressal Commission, Madurai.
5. Ms. Luciya, Court Officer, Tamil Nadu State Consumer Disputes Redressal Commission, Chennai.
6. Mr. Mathew Reddy, Head Clerk, Tamil Nadu District Consumer Disputes Redressal Commission, Madurai.
7. Mr. Boothalingam, Head Clerk, Tamil Nadu District Consumer Disputes Redressal Commission, Srivilliputhur.
8. Mr.S.Balasubramaniam, Head Clerk, Tamil Nadu District Consumer Disputes Redressal Commission, Tirunelveli.
9. Dr. R. Raman, Director of Medical and Rural Services, Govt. of Tamil Nadu, Chennai.
10. Mr.Gajendran, Section Officer, Dept. of Civil Supplies & Consumer Affairs, Govt. of Tamil Nadu, Chennai.

Voluntary Consumer Organizations:

1. Mr.Loganathan, Indian Consumer Protection Council, Chennai.
2. Mr.K.M.Sundaram, FEDCOT, Chennai.
3. Mr.Desikan, CONCERT, Chennai.
4. Mr.Nizammudin, General Secretary, FEDCOT, Cuddalore.

Doctors involved in litigation:

1. Dr. M.Sheik Mohideen, Chennai
2. Mr J.R.Ahmed, Chennai.
3. Dr.Nasreen Ahmed, Chennai.
4. Dr.Kali Gounder, Erode
5. Dr. Hemalatha Pugalendhi, Chennai
6. Dr Chandra Mohan, Chennai
7. Dr Vijayasarathy,Chennai
8. Dr (Mrs) C.Meenal, Chennai
9. Dr K Anandakannan,Chennai

Patients who had filed cases against doctors:

1. Mr. Mohamad Dayan, Chennai
2. Mr. M.H.Mugilan, Chennai
3. Mr. Syed Sirajuddin, Chennai
4. Mrs. Shanthi Kumaravel, Chennai
5. Mr. Baskara Reddy, Chennai
6. Mrs. Devasena, Madurai
7. Mrs. R.Kayalkanne, Madurai
8. Mrs. Geetha Rajan, Chennai.

Appendix XI

List of participants for the workshop on "Regulation of Healthcare Market in Tamil Nadu: A study on implementation of the Consumer Protection Act (1986) and it's effectiveness" held on 21st September 2002 at IIT(M)

1. Dr Mathiharan
   New No.53, Old No.27
   5th Street, Padmanabha Nagar
   Adyar
   Chennai 600 020.

2. Mrs. Radhika Krishnan
   Advocate
   24 Shriram Nagar, North Street
   Alwarpet
   Chennai 600 018.

3. Dr Manjula Dutta
   Head of Department of Epidemology
   Dr MGR Tamil Nadu Medical University
   Guindy
   Chennai 600 032

4. Dr. Chamundishankari
   Srishti Hsopital
   No: 2 Habibullah Road
   T.Nagar
   Chennai- 600017

5. Mr K.M.Sundaram
   FEDCOT
   Karneeswarar Pakoda Street
   Mylapore
   Chennai 600 004.

6. Mr R. Kaladharan
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   Mylapore
   Chennai 600 004.

7. Dr. Sharada Suresh
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   58 Venkataratnam Nagar
   Adayar
   Chennai 600 020.

8. Prof. S.P.Subramaniam
   IIT (Madras)
   Chennai 600 036.

9. Prof. G.Koteswara Prasad
   Dept. of Public Administration
   University of Madras
   Chennai.

10. Mr Swaminathan
    Advocate
    Chennai.

11. Dr. Stephen Jan
    The Health Policy Unit
    LSHTM
    London, UK

12. Dr. V.R.Muraleedharan
    Professor of Economics
    IIT (M)
    Chennai-36.

13. Ms. A.Kavitha
    Research Associate
    IIT(M)
    Chennai 600 036.

14. Mr. S. Ram Prasad
    Research Associate
    IIT (M)
    Chennai 600 036.

Appendix XII

Voluntary Organizations /Government Departments in Tamil Nadu who have received the grant from Consumer Welfare Fund

S.No.	Name of the Organization	Amount Sanctioned (in Rupees)	Year of Sanction
1	District Consumer Council, 5790, Santhanathapuram, 4th Street, Pudukkottai-622001,	85,500.00	30.05.95
2	District Rural Social Welfare Sangam, Opp. Old ATC Shed SANKARI,	41,400.00	28.07.95
3	Consumer Protection Fourm, 51, Dr. Radhakrishnan Salai, Madras,	24,300.00	15.11.95
4	ST. PAUL Educational and Medical Trust, 21, Vanniar Street, Madras,	109,800.00	07.06.96
5	Gnanaguru Welfare Association, 65-A, Khanpalayam, 1st Street, Maduri,	45,000.00	02.05.97
6	Tamil Nadu Consumer Protection Centre, Navjeevan Mansion, North Gate, SS Colony, Madurai,	36,000.00	25.09.97
7	National Mother & Child Welfare Organisation 56, Old Sandipettai Street, Tiruturaipoondi,	36,000.00	30.10.98
8	Anaimalayanpatti Rural DevelopmentAssociation Trust (ARDA), Anaimalayanpatti,Uthamapalayam Tal,	27,230.00	
9	VIKAS, No. 9, Main Road, Trichirapalli District,	37,800.00	29.10.96
10	DR. (Ms) C.M.E. Mathews Memorial Development Association, 2/95, Kollaimattu Street, Katecherimangalam,	40,500.00	25.09.97
11	Village Progress Welfare Centre, Kuppam Village & PO, Kannamangala, Polur Taluk,	22,500.00	20.11.97
12	Federation of Consumer Organisations, Tamil Nadu, 30, Teachers Colony, Adyar,	500,000.00	08.11.94

13	Gramalya, 31-A/29, Nasavalar, Colony, Salai Raod, Mariur, Tiruchi,	135,000.00	08.11.94
14	Commissioner of Labour, Government of Tamil Nadu, Madras,	362,500.00	08.11.94
15	Consumer Pretection Council, 216-B, Main Road, Mettupalayam,	22,500.00	08.11.94
16	Trichy Distt. Consumers Council, 182, Kannan Buildings, Madurai Road, Tiruchirapalli,	258,300.00	08.11.94
17	Campaign for Rural Poor, 120/7, Pariyar Pathai, Madras-600094,	133,200.00	19.05.95
18	Centre for Social Development, 74/C/12, Ramalinga Nagar, Rasipuram, T.K. Salem-637403,	50,850.00	08.06.95
19	Centre for Social Reconstruction, Eathamozhi Road, Nageocoil-629022,	130,500.00	31.05.95
20	Community Action for Rural Development (CARD), Samthuvapuram, Pulivalam-622507,	151,560.00	31.05.95
21	Council for Health Education and Rural Upliftment, Dindagul, Anna District,	90,000.00	30.05.95
22	Grama Suyaraj, Chithupatty, Keelakurichi, Post Annavasai, Via-Pudukkotai,	100,000.00	31.05.95
23	Human Education and Action for Liberation Movement, Orappanavillai Post, Kanya Kumari Distt.,	67,500.00	08.06.95
24	Socio Cultural Awakening Movement (SCAM), Cantonment, Trichy-620001,	82,350.00	01.06.95
25	Consumer Action Gruop, Adayar, Madras,	180,000.00	28.07.95
26	Consumer Rights Protection Council, Ramaanathapuram Distt.,	37,530.00	26.07.95
27	Society for Community, Organisation and Peoples, Education (SCOPE),	81,000.00	26.07.95
28	Tamil Nadu Banjara (Lambadigal) Munnetra Sangam, 1308/3, M.G.R. Nagar,	26,100.00	26.07.95
29	Tamil Nadu Consumer Protection Council, Madurai-625016	90,000.00	26.07.95

30	Annai Indira Sathiya Samuga Nala Mahlir Mandram (AISSNMM), Keelakandani Post, Sivaganga Taluk,	44,280.00	17.11.95
31	Indian Institute of Women and Child Health Trust, Batlagundu Rd., Sempatti, Dindigul Anna Distt.,	16,020.00	16.11.95
32	Trust for Human Resource, and Unity Development, T. Vadugapatt Thanichiam, Madurai Distt.,	23,850.00	17.11.95
33	Centre for Urban & Rural Development (CUPD), 45, Avaikara Street, Kosapet Vellore,	45,000.00	07.06.96
34	Girama Pengal Munnetra Sangam, B/73-B, Main Road, Thengalpatti, Chekkanurani, Madurai,	50,710.00	07.06.96
35	Integrated Action Trust, 5/40, Kemps Town Goods Sheed Rd., Trichirapalli,	30,150.00	07.06.96
36	Poolawari Agraharam Sangam, Poolvari Agraharam Post, Salem,	72,000.00	07.06.96
37	Society for Community Development Project, 88, Seerangalayan Road, Kumarasamypatty, Salem,	67,500.00	07.06.96
38	Trust for Education and Community Health (TEACH), Post Box 19, 8, North Sannathi,	90,000.00	07.06.96
39	Community Organisation for Rural Development (CORD), 11 Chunnambukkara Street,	63,000.00	27.05.96
40	Health Education Awareness & Liberation of Tribal Community Society, (HEAL), Kariyandal, Maruthuvambadi,	78,300.00	27.09.96
41	Nehru Association for Peoples Awareness and Development (NAFAD), Thoppanandal, Vill. Kalvasal,	63,000.00	27.09.96
42	Nehru Ilainger Narpani Mandram, 15/A, Balakanniyan Street, Polur, TS District,	70,000.00	27.09.96
43	Rural Community Mutipurpose Development Society, Vill. Sadayanodal,	63,000.00	29.09.96
44	Rural Women Welfare Society, Chinnaovalapuram, Uthampalayam Taluk Madurai Distt.,	27,000.00	27.09.96

45	Society for Community Organisation and Rural Education, Trichy,	31,500.00	29.10.96
46	Citizens Voice Club, Post Box No. 4604,	22,500.00	15.01.97
47	EMPOWER, 405/2, Cheranmahdevi Road, Triunelveli,	24,300.00	15.01.97
48	Federation of Consumer Organisations (FEDCOT), 30 Teacher's Colony, Adyar,	264,384.00	15.01.97
49	OAZOANE-The Society for Development of Human Abilities & Environment, 32-A, Agraharam, Aranthangi,	36,000.00	15.01.97
50	Pulse of Life - India, No.3, II Anenue, Ashok Nagar,	36,000.00	15.01.97
51	Chetana Vikas, Parthibanur, Ramnad Distt.,	63,000.00	10.04.97
52	Gokul Education and Employment Training Society (GEETS), No. 5/D Block, Pensioners Line,	63,000.00	10.04.97
53	S.M.N. Consumer Protection Council, 115/2, Kamaraj Avenue, Adayar, Madras,	300,000.00	
54	Federation of Consumer Organisation (FEDCOT), 115/2, Kamaraj Avenue, 2nd Street, Adyar,	225,000.00	01.05.97
55	S.M.N. Consumer Protection Council, 2/380,I,Main Road,A.G.S,Colony,Cotimakkm,Chennai-600041	235,000.00	01.06.98
56	Bharathi Integrated Rural Development Society, Ammapalayam Vill & PO, Onnupuram, Arni Taluk,	27,000.00	25.09.97
57	Centre for Rural Oppressed People (CROP), No.7, Appu Gounder Street, Chinna All apuram, Vellore,	27,000.00	24.09.97
58	Society for Education and Economic Development (SEED) Melpadur Village & Post Chengam Taluk, Tiruvannamalai,	36,000.00	20.11.97
59	Centre for Integrated Social Action, 23-Old Pappuraja Line, Edamal Street Theni-625531,	45,000.00	18.03.98
60	Centre for Rural Development (CRD), PO Appipatty, Via Chinnamanur,	45,000.00	18.03.98

61	The Commissioner of Labour, Tamil Nadu Welfare Board Building D.M.S. Complex, Anna Salai, Teynampet, Chennai – 50006,	4,50,000.00	
62	Community Action for Village Improvement, 62, East Palayam, Pattukkottai, Tanjore,	36,450.00	13.06.97
63	Nehru Social Education Centre, Ayakkaranpulam-2, Sethi PO, Vedaraniam Taluk,	45,900.00	03.08.2000
64	Nehru Social Education Centre, Ayakkaranpulam-2, Sethi,P.O, Kedaraniam Taluk	45,900/-	
65	Organization for Rural Development, 5/22 Puliyagovandam Patty, Karumathur, P.O. Thirumangalam, T.K. Madurai		
66	Malar Social Society, 82B/9, Ramu Gowder St. Kamay Agoundanpatti – 625 521, Theni District		
67	Nehru Social Education Centre, Ayakkaranpulam 2 post 614 707, Vedaraniyam Taluk, Nagapattinam Distt.		

(Source: Ministry of Consumer Affairs, Food and Distribution)

Appendix XII

Questions asked to the kidney recipients from unrelated donors. (THOA)

Name :
Sex :
Age :
Address :

1. When did you undergo the transplantation?
2. When was it identified that you had a kidney problem?
3. Were you on dialysis till you underwent transplantation? How much did it cost?
4. Where did you undergo transplantation?
5. Who was the donor?
6. How much did you pay him/her?
7. How did you approach him/her?
8. Can you give the background of the donor?
9. Did the doctor mention anything about the tissue matching of kidneys?
10. How much did you spend for the tests for tissue matching?
11. How much did you spend for transplantation?
12. How did you manage for the funds?
13. Did you get CM and PM relief fund?
14. How much you had spent for post-operative care?
15. What was the financial loss due to transplantation?
16. What were the questions asked by the Authorisation Committee?
17. How is your health now?

Appendix XIV

Questions asked to the kidney recipient and donor (related) : (THOA)

Name :
Sex :
Age :
Address :

Questions to the recipient:

1. When did you undergo the transplantation?
2. When was it identified that you had a kidney problem?
3. Where you on dialysis till you underwent transplantation? How much did it cost?
4. Where did you undergo transplantation?
5. Who was the donor?
6. Did the doctor mention anything about the tissue matching of kidneys?
7. How much did you spend for transplantation?
8. How did you manage for the funds?
9. Did you get Chief Minister's or Prime Minister's Relief Fund?
10. How much you had spent for post-operative care?
11. How are you feeling now?

Questions to the donor:

1. What is your age now?
2. Was there any fear in donating your kidneys?
3. How was the extended family support towards the donation?
4. How is your health, now?
5. Did you have to submit any documents as proof to the hospital authorities?

Appendix XV

List of stakeholders interviewed: THOA

Doctors:

1. Dr. T.Dhinakaran, Nephrologist, Madurai
2. Dr. Soundarapandian, Nephrologist, Madurai
3. Dr. S.Suresh, Nephrologist, Chennai
4. Dr. Sunil Shroff, Urologist, Chennai
5. Dr. Subba Rao, Nephrologist, Chennai
6. Dr. George Kurian, Gastro-Entrologist, Vellore.

Government:

1. Mrs. Girija Vaithyanathan, Health Secretary, Chennai
2. Dr.R.Raman, Director of Medical and Rural Services, Chennai
3. Dr. C. Ravindranath, Director of Medical Education, Chennai
4. Dr. Munnuswamy, Director of ESI, Chennai
5. Dr.(Capt.) Kamatchi, former DMS, Coimbatore
6. Dr.(Mrs.) Elizabeth, Jt.Director, DMS, Chennai
7. Mr. A.J.Christy, Admn.Officer, DMS, Chennai.

Recipients:

1. Ms. Bharathy, Chennai
2. Ms. Chitra, Chennai
3. Mr. Dhandapani, Chennai
4. Ms. Gayathri, Chennai
5. Mr. Kumararajah, Chennai
6. Ms. Meenakshi,Chennai
7. Ms. Padma, Chennai
8. Mr. Padmanabhan, Chennai
9. Mr. Parthasarathy,Chennai
10. Mr. Raman, Chennai
11. Ms. Saraswathy, Chennai
12. Ms. Subashini, Chennai
13. Ms. Tamarai, Chennai
14. Mr. Venkatesh, Chennai
15. Ms. Vijaya, Chennai
16. Mr. Vijay Kumar, Chennai

Donors (related and unrelated)

1. Ms. Noorjahan, Chennai
2. Ms. Vijaya, Chennai
3. Ms. M. Vijaya, Chennai
4. Mr. Rajan, Chennai
5. Ms. Ansar Beevi, Chennai
6. Ms. Shanthi, Chenai
7. Ms. S. Shanthi, Chennai
8. Mr. Sambandhan, Chennai
9. Ms. Susai Mary, Chennai.
10. Mr. K.Selvan, Chennai.
11. Ms. Kamatchi, Chennai
12. Mr. Padmanabhan, Chennai
13. Ms. Kamala, Chennai

Appendix XVI

List of participants for the workshop on "Implementation of Transplantation of Human Organs Act 1994: Challenges and Policy Options" held on 8th March 2003 at IIT (M)

1. Mr.S. Tamil Maran
   Transplant Coordinator
   Christian Medical College
   Vellore.

2. Dr.George Kurian
   Professor & HOD GI Sciences
   Christian Medical College
   Vellore

3. Ms. Srividya Srikanth
   Dialysis Technician
   Apollo Hospitals
   Chennai.

4. Ms. S.Lakshmi
   Executive, Nephrology
   Apollo Hospitals
   Chennai.

5. Mr.A.T.Srimuganth
   Junior Technical Officer
   Nephrology Dept.
   Apollo Hospital
   Chennai.

6. Ms.Shreejal Gandhi
   MOHAN Foundation
   Anna Nagar
   Chennai.

7. Ms.Selvi
   MOHAN Foundation
   Anna Nagar
   Chennai.

8. Mrs.Jaya
   MOHAN Foundation
   Anna Nagar
   Chennai.

9. Mrs.Shaila
   MOHAN Foundation
   Anna Nagar
   Chennai.

10. Dr.Sumana Sundaram
    MOHAN Foundation
    Anna Nagar
    Chennai.

11. Dr Sunil Shroff
    Founder
    MOHAN Foundation
    Anna Nagar
    Chennai.

12. Dr Subba Rao
    Nephrologist
    Apollo Hospital
    Chennai.

13. Dr.R.Ravichandran
    Nephrologist
    Vijaya Hospital
    Chennai.

14. Dr.(Capt.) M Kamatchi
    Former DMS, Govt. of Tamil Nadu
    Coimbatore

15. Dr. Padmini Swaminathan
    Professor
    Madras Institute of Development Studies
    Chennai.

16. Mr.G.Ananthakrishnan
    City Editor
    The Hindu
    Chennai.

17. Dr.M.K.Mani
Senior Nephrologist
Apollo Hospital
Chennai.

18. Dr.S.Vijayalakshmi
Dean
Madras Medical College
Chennai.

19. Dr. M.Jayakumar
Madras Medical College
Chennai.

20. Dr.Amolarpavanathan
Madras Medical College
Chennai.

21. Ms.Malathi Venkatesh
MOHAN Foundation
Anna Nagar
Chennai.

22. Ms. Asha Krishnakumar
Frontline Magazine
Chennai

23. Dr. Kishore Phadke
Chairman
FORTE
Bangalore

24. Mr.V.Kesava Rao
National Law School
Bangalore.

25. Dr. R.Balasubramaniam
Nephrologist
K.G.Hospital
Coimbatore.

26. Dr.K.Mathiharan
Institute of Legal Medicine
Chennai.

27. Dr.C.Ravindranath
Director of Medical Education
Govt. of Tamil Nadu
Chennai.

28. Dr R.Gangadharan
DMS Office
Govt. of Tamil Nadu
Chennai.

29. Mr A.J.Christy
Administrative Officer
DMS, Chennai.

30. Ms.Latha A Kumarasami
TANKER Foundation
Chennai

31. Ms.Geetha Raj
TANKER Foundation
Chennai.

32. Ms.Pushpa Narayanan
Reporter
The New Indian Express
Chennai.

33. Dr. Manjula Dutta
Head of Department of Epidemology
Dr MGR TN Medical University
Guindy
Chennai 600 032

34. Dr.R.Vijaykumar
Nephrology Department
Govt. Stanley Medical College
Chennai.

35. Dr. Stephen Jan
The Health Policy Unit
LSHTM, London, UK

36. Dr.Viroj Tangcharoensathien
International Health Policy Program
Thailand.

37. Mr. Rachata Tungsiripat
International Health Policy Program
Thailand.

38. Dr. V.R.Muraleedharan
Professor of Economics
IIT (M), Chennai-36.

39. Mr. S. Ram Prasad
Research Associate
IIT (M), Chennai 600 036