CHAPTER

ONE

Introduction

I. CONTEXTUAL FRAMEWORK

The Indian system of medicine has a long history. It has received worldwide recognition especially in the area of Herbal, *Unani,* and *Ayurvedic* systems. Besides Kautilya's *Arthasastra,* there are a series of ancient authoritative publications, which give a glimpse of the ancient system of medicine. The accountability of the physicians may be traced from the work of Kautilya wherein it is stated that:

> The doctor is mandated to report to the State whenever he is called to a house to treat a severely wounded person and also patients suffering from unwholesome food or drink. This will help him in saving himself from the criminal accusations of not attending to the patient. In case the doctor failed to provide information to the State, he would be charged with the same offence committed by such patient.[1]

According to the *Arthashastra,* the doctor is also subject to punishment and fine for not providing proper information to the patient, for committing a mistake and for negligent treatment.[2] During the British period, the Englishmen brought with them their own physicians and surgeons. However, in the mid-nineteenth century with the advent of change and reorganisation of the British medical system in England, there was a sudden transformation in the Indian medical system.

With the passage of time and the development in the field of science and technology, the liability of doctors has increased. During the last few decades, the confidence and trust reposed by a patient upon doctors has eroded.

1 Rangarajan LN, *Kautilya: The Arthashastra,* Penguin Books, New Delhi, 1992.
2 Kangle RP, *The Kautilya Arthashastra,* Part-II, University of Bombay, 1972.

Commercialisation is on the increase and so are cases of medical negligence and malfeasance. This has given rise to a lot of debate and also concern for the consumer, which in turn has resulted in legislative measures and judicial activism.

A number of committees have been set up by the government to look in to the aspect of public health, and several recommendations have been made to improve the health care system in India. Prominent among them are: Bhore Committee Report,[3] Col Saokhey Committee,[4] Mudaliar Committee,[5] Ajit Prasad Jain Committee,[6] ICMMR/ICSSR

3 Bhore Committee submitted its report during the post war period. The Committee recommended, *inter alia,* for the: (a) establishment of a statutory Central Board of Health; (b) the creation of district health boards; (c) empowerment of the centre to intervene, without delay and effectively, in provincial health administration; (d) control of infectious diseases by taking effective measures; (e) enactment of Public Health Acts at the central and state levels with an objective to: (i) codification of health laws with an aim to bring together existing legal provisions relating to health, which are scattered over various enactments; (ii) make amendments to the various provisions of law to facilitate promotion of efficient administration and implementation of health programmes; (iii) incorporate new provisions under the legislations to meet the needs and expectations of the society; (iv) legalised self-regulatory medical councils and (v) formulation of health care plans including integration of curative and preventive health care (see, Bhore Committee 1946, *Report of the Health Survey and Development Committee,* Vol I, Survey Vol II, Recommendations, Vol III, GOI, Manager of Publication, New Delhi).

4 Col Saokhey Committee popularly known as the 'National Planning Committee Report on National Health', also stressed the need of better public health facilities (see, Sokhey Committee Report 1948, *National Health: Report of the Sub-committee of the National Planning Committee,* Vora & Co, Publishers Ltd, Bombay).

5 Mudaliar Committee, which was constituted after a decade of coming into force of the Constitution, has contributed in bringing out a detailed report on the status of health care in the country. One of the main tasks assigned to the Mudaliar Committee was to follow up the recommendations of the Bhore Committee and make detailed recommendations for further progress. The Mudaliar Committee, like the Bhore Committee has laid more emphasis on the formulation of a comprehensive Public Health Act in the country. In this context, the Mudaliar Committee has also formulated a draft Model Public Health Act. Though the government has taken into consideration many of its recommendations in formulating various health policies, a major portion of its suggestions still need to be implemented (see, Mudaliar Committee Report 1961, *Report of the Health Survey and Planning Committee,* Vol I and II, Ministry of Health, Government of India, New Delhi).

6 Ajit Prasad Jain Committee undertook an indepth study on the hospital conditions in the public sector but it was silent about the setting of standards for the hospitals functioning in the private sector as well as innumerable number of nursing homes, clinics, dispensaries etc (see, Ajit Prasad Jain Committee 1968, *Report of the Study Group on Hospitals,* Government of India, Ministry of Health, Family Planning and Urban Development, New Delhi.

Committee,[7] Varadappan Committee,[8] Committee on Subordinate Legislation.[9]

In India, the participatory management of civil society in health care is of recent origin. For the last decade one can notice a significant shift in this area, and the role being played by various organisations towards public participation. The setting up of consumer protection councils, the appointment of ANM's covering a majority of the villages in India, and the grants being given by the government to NGOs and other agencies for raising awareness about consumer protection etc, are steps in the right direction. In the light of existing circumstances, it may be stated that there is a lack of sensitivity about health care rights among the public, and much needs to be done for bringing about a change in this area. It is time, the government, NGOs and other agencies gave serious thought for taking effective measures, to secure civil society participation in health care in the country.

II. HEALTH CARE AT THE INTERNATIONAL LEVEL

The quality of health services and medical negligence has been a matter of great concern at the international level. The General Assembly of the United

7 ICMMR/ICSSR Committee is a self-constituted Committee set up independently of the government by the Indian Institute of Education, Pune. It has made an attempt to review the health care in India and made recommendations for improvement (see, ICMMR/ICSSR Committee 1981, *Health for All: An Alternative Strategy,* Indian Institute of Education, Pune).

8 Varadappan Committee mainly dealt with the issues related to the nursing profession. The Committee, *inter alia,* highlighted the ineffectiveness of the Nursing Council in streamlining the profession and stressed on the need to streamline the concerned legislations. One of the major lacunae in the Act pointed out by the committee was that, it does not contain provisions either to stop unqualified non-registered nurses in the private nursing homes from practicing or to deregister nurses who violate its code of guidelines (see, Varadappan Committee 1989, *Report of the High Power Committee on Nursing and the Nursing Profession,* Ministry of Health and Family Welfare, New Delhi.

9 Committee on Subordinate Legislation and other bodies are also worth a mention. The Committee on Subordinate Legislation in its various reports has emphasised the need of strengthening the Medical Council Acts for streamlining medical professionals and also making the health services accessible to the public. The Committee recommended, *inter alia,* for the following: (a) the law should be amended to provide for publishing details about the physician (qualification, years of practice, availability and types of services rendered, etc) and the fee charged for each service by them; (b) there should be transparency in the fee charged by doctors and the patient should know in advance the fee for various components of services; (c) the Council should make it compulsory for all the doctors in private practice to notify their fees to the Medical Council (see, Committee on Subordinate Legislation, *Thirteenth Report, Rules and Regulations Framed Under Indian Medical Council Act 1956,* Lok Sabha Secretariat, New Delhi).

Nations, has adopted various resolutions to safeguard the interest of patients. Article 25 of the Universal Declaration of Human Rights states that:

> every one has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, and medical care, and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Article 12 of the International Covenant on Economic, Social, and Cultural Rights 1966, *inter alia,* states that:

> The State parties to the present Convention recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The International Covenant on Civil and Political Rights 1966, the UN Declaration on Elimination of All Forms of Discrimination Against Women 1967, the Convention on the Elimination of All Forms of Discrimination Against Women 1979 and the Convention on the Rights of the Child provide, *inter alia,* for the protection of health care rights of persons including women, children and other disadvantaged sections of society.

The World Health Organisation, has also played a pioneering role for the last fifty years, in guiding health policy development, and action at the global and national levels, with an overall objective of ensuring and attaining the highest standards of health care to all the people around the world. The preamble to the World Health Organisation Constitution,[10] *inter alia,* provides:

> 1. The enjoyment of the highest standards of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic and social condition.
> 2. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and states.
> 3. The achievement of any state in the promotion and protection of health is of value to all.
> 4. Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.
> 5. Healthy development of the child is of basic importance; the ability to live harmoniously in a totally changing environment is essential to such development.

10 The World Health Organisation's Constitution came into force in 1948.

6. The extension to all people of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.
7. Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.
8. Governments have a responsibility for the health of their people, which can be fulfilled only by the provision of adequate health and social measures.

Article 2 of the World Health Organisation Constitution, delineates several functions, which directly and indirectly require the application of legal principles, such as:

1. to act as the directing and coordinating authority on international health work;
2. to propose 'Conventions, Agreements and Regulations', make recommendations with respect to international health matters, and to perform such duties as may be assigned thereby to the Organisation and are consistent with its objective; and
3. to develop, establish and promote international standards with respect to food, biological, pharmaceutical and consumer products.

Apart from the above, a number of international agencies have lent support to public participation in health care. To this end the World Health Organisation Alma Ata Declaration,[11] clearly states that:

> The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

According to the World Development Report,[12] public-private deliberation is not just desirable but in fact critical to the success of reforming the health system. Community participation is the key element of the international action plan, (known as Agenda 21) designed to bring about sustainable development for the 21st century. This plan has been endorsed by over 150 nations at the Earth Summit held at Rio in 1992. Further the fourth International Conference on Health Promotion, held in 1997, in Jakarta reaffirmed the importance of community participation as a key element of health for all.

From the above it is evident that the World Health Organisation has not only given a wider definition to 'health' but also brought the 'vision of health care for all by 2000' articulated by the World Health Assembly and the Alma Ata Declaration. Further, all the resolutions/declarations adopted by the UN and other agencies together constitute the global health policy.

11 Alma Ata Declaration adopted in 1978.
12 See, World Development Report, 1997.

III. PUBLIC PARTICIPATION IN HEALTH CARE IN OTHER COUNTRIES

A survey of the legislations relating to public participation in health care in other countries, reveals that in order to provide for participatory democracy and to improve health planning, a number of countries have enacted legislations for public participation in health care. In the UK, the National Services Reorganisation Act 1973 confers upon community health councils statutory status with a duty, to represent interests in health services of the public in its district.[13] In USA, the National Health Planning and Resource Development Act 1974, creates a network of health planning agencies.

IV. LEGAL FRAMEWORK FOR HEALTHCARE IN INDIA

In India, the right to health care[14] and protection has been recognised since early times. India is a founder member of the United Nations, and has ratified various International Conventions promising to secure health care rights of individuals in society. In this context, art 51 of the Constitution of India provides for promotion of international peace and security.[15] The preamble to the Constitution of India, which strives to provide for a welfare state with socialistic patterns of society under art 21 of the Constitution, guarantees the right to life and personal liberty. It states that:

> No one shall be deprived of his right to life and personal liberty except according to procedure established by law.

Though it does not expressly contain the right to health, it has now been well settled through a series of cases that this includes the right to health. Further, arts 38, 42, 43, and 47 of the Constitution also provide for the promotion of health of individuals in society.

A number of laws have been enacted to protect the health interests of the people. These include: the Indian Penal Code 1860, the Fatal Accidents Act

13 Section 9, National Services Reorganisation Act, 1973.

14 The meaning of health as used in these provisions of the Constitution are defined in the Oxford Dictionary that 'soundness of body or mind, that condition in which its functions are duly and efficiently discharged'. Statutory laws including the Indian Penal Code 1860 and others also ensure the right to be protected against medical negligence.

15 Article 51 states that, 'the State shall endeavour to: (a) promote international peace and security; (b) maintain just and honourable relations between nations; (c) foster respect for international law and treaty obligations in the dealing of organised people with one another; and (d) encourage settlement of international disputes by arbitration'.

1855, the Indian Medical Degrees Act 1916, Dangerous Drugs Act 1930, Drugs and Cosmetics Act 1940, the Dentists Act 1948, Drugs (Control) Act 1950, Pharmacy Council of India Regulations 1952, Prevention of Food Adulteration Act 1954, Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, the Indian Medical Council Rules 1957, the Medical Termination of Pregnancy Act 1975, the Dentists Code of Ethics and Regulations 1976, the Consumer Protection Act 1986, the Consumer Protection Rules 1987, the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act 1994, the Transplantation of Human Organs Act 1994 etc.

Complaints of medical negligence have been made in the past. Of late, such complaints have assumed a wider dimension as the incidents have increased due to the opening of thousands of nursing homes, charitable hospitals, central government health services dispensaries, and employees' state insurance hospitals etc.

Though the Parliament has enacted the Indian Medical Council Act in 1956 and other corresponding legislations governing various branches of medicine such as the Indian System of Medicine, Dentists, Homoeopaths etc, they only provided for the registration and regulation of the conduct of doctors, hospitals and nursing homes, and have failed to protect the interests of persons who have suffered on account of negligence or deficiency on the part of medical professionals.[16] This field left untouched by the Medical Council Acts[s] is covered by the law of tort in general, and now by the Consumer Protection Act 1986. It is worthwhile to remember that the existence on the statute book of the Indian Medical Council Act has not stood in the way of such grievances being agitated before the ordinary civil courts, by the institution of civil suits claiming damages for negligence as against the concerned hospital or medical doctors.

Before the enactment of the Consumer Protection Act 1986, the field of medical negligence was governed only by the law of tort. The base for a liability rested on the concept of negligence. It is not and cannot possibly be the province of this judgement, to enter the tangled thicket of the scope of negligence in tort jurisprudence. It is a field too large to be traversed. It would suffice to point out that prior to the entry of consumer jurisdiction in this field, medical accountability rested primarily on the concept of negligence as understood in the law of torts. That a precise legal definition of negligence is perhaps not possible, and would remain a somewhat

16 Very few states such as Andhra Pradesh, Karnataka, Meghalaya and recently Delhi have enacted state legislations providing for constitution of State Medical Councils. See also Chapter 5.

slippery word. However, the classic attempted judicial definitions of negligence may be noticed from the authoritative treatise of Salmond on the *Law of Torts*[17] as under:

> It is negligence in the objective sense that is referred to in the well-known definition of Alderson B, 'Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.' So also Lord Wright said 'In strict legal analysis, negligence means more that heedless or careless conduct, whether in omission or commission; it properly connotes the complex concept of duty, breach and damage thereby suffered by the person to whom the duty was owing'.

In India it is well settled that the general principle of law of tort is equally relevant and applicable within our country. The development of the law of torts is in line and closely similar, if not identical with its parental concept.[18]

Despite Constitutional and statutory provisions safeguarding the patient against medical negligence, the growing incidence of medical negligence is disturbing. Almost every day one finds newspapers full of gory incidents of medical negligence. Even though reliable official statistics on medical negligence are not available in the country, it has been observed that many a times, the victims of medical negligence are poor persons who do not have adequate resources or finances to avail the services of a private nursing home. They are, therefore, left with no choice but to approach the government run hospitals, dispensaries or charitable hospitals to get medical treatment. However, the government and charitable hospitals have been kept out of the purview of the Consumer Protection Act 1986. This raises doubts about the accountability of these providers.

Health providers in India may be broadly classified into five categories: (i) government run hospitals and dispensaries, clinics, primary health care centres and sub-centres; (ii) private hospitals and nursing homes; (iii) charitable hospitals; (iv) hospitals run by or under the authority of or connected with medical institutes or medical colleges; and (v) hospitals or dispensaries run under the miscellaneous statutes such as the Employees' State Insurance Act 1948, the Plantation Labour Act 1951, and hospitals or dispensaries run by the employer such as CGHS dispensaries, Railways hospitals and health centres; and Army, Navy or Air Force hospitals.

Apart from these recognised categories of health providers, in our country there are private practitioners without any formal qualifications such as

17 19th edn.

18 See also *Dr Ravinder Gupta & ors v Ganga Devi & ors* (1993) 3 CPR 259.

herbalists, *tantriks, hakims, vaidyas* and others. They are very popular in rural sectors, and particularly among the poor and illiterate class of people.

The Courts and Consumer Forums have divided hospitals into three categories, namely, (i) government hospitals and dispensaries; (ii) charitable hospitals; and (iii) private hospitals, nursing homes and dispensaries. No remedy is available to the consumer under the Consumer Protection Act 1986 against the persons/hospitals in the first two categories. However, if they have some paid beds or seats they may be brought under the Consumer Protection Act 1986. However, private hospitals and nursing homes have been brought under the Consumer Protection Act 1986. They are liable for any deficiency in service.

The health providers practice allopathic, homoeopathic and *ayurvedic* or *unani* systems of medicine. Decided cases reveal that sometimes homoeopathic and *ayurvedic* practitioners practice the allopathic system without having the requisite qualifications. Courts have dealt with them firmly under the law. It has also been noticed that many a times midwives or nurses without recognised degrees undertake and run nursing homes, deliveries or other cases. Courts have taken this on a serious note and dealt with them on a firm footing under the law.

Apart from the liability of the health providers under the Consumer Protection Act 1986, all the health providers, irrespective of their employment in government, public or charitable hospitals, may be brought within the purview of the law of torts for medical negligence. Further, they are liable under the Indian Penal Code for rash and negligent acts.

It is unfortunate that despite the lofty ideals contained in the Constitution for securing social justice and health care facilities, the emphasis laid by the Supreme Court and the laudable efforts and contributions made by various committees, much remains on paper. Thus, there is an urgent need to take effective steps to transform the aforesaid ideals into reality. This is also necessary in order to achieve the universalisation of health care services in the country. To this end the Indian Law Institute, the World Bank and the Ministry of Health and Family Welfare, felt the need to review and critically analyse and examine the existing legislations, regulations and other procedures in the light of the judicial decisions, to better understand the role of health providers and other related institutions, in providing health care, and their corresponding accountability.

In view of the serious nature of the legal problems involved in patient care and the difficulties being faced by the consumers for the redress of grievances, the Ministry of Health and Family Welfare, with assistance from the World Bank, have commissioned a study on *The Legal Framework for Health Care in India.* The Indian Law Institute, New Delhi was given the task

of assessing the current status of laws concerning health care to protect the Indian citizen and to suggest measures for improving his conditions.

V. SCOPE OF STUDY

The present work examines the following key research questions:

1. What is the current status of dispute redressal mechanisms to a patient available through the law?
2. What is the current status of redress mechanisms available to a patient at different types of health facilities both in the public and private sectors?
3. What is the current status of adjudication of disputes between consumers and medical service providers under the law of tort, criminal law, consumer protection law, the Indian Medical Council's Act, writ and appellate jurisdiction under the Indian Constitution?
4. What is the role of the Indian judiciary in protecting the interests of patients and the role and responsibilities of health providers?
5. What are the legal and administrative impediments in providing speedy, credible and inexpensive redress to aggrieved patients and what are the options available to improve the situation?

To address the above issues, a reviewof the laws existing in India, as well as a systematic review of the legal system and decisions given by courts and consumer redressal forums on health care has been carried out. Chapters 2 to 7 cover major aspects of the law: Constitutional Law, Law of Torts, Criminal Law, Law for Medical Councils, Consumer Protection Law, and Law of Contracts. Each chapter begins with a description of the law followed by a section on the structure of the law, and the process for accessing and using the law. This is further followed by a summary of the main questions that have been addressed by the law. The emphasis has been laid on the review of the experience of the law and an analysis of the application of the law. Each chapter ends with a section on conclusions and suggestions. Chapter 8 consolidates the recommendations from each chapter. The Appendices include a description of other related health laws under International law and the laws of our country.

The chapters that follow are primarily concerned with making an analysis and review of the current status of the adjudication machinery, procedures and practice followed in redressal of grievances of consumers/ patients or any other aggrieved person under the Constitution, Law of Torts, Criminal Law, Medical Councils Act and other relevant legislations.