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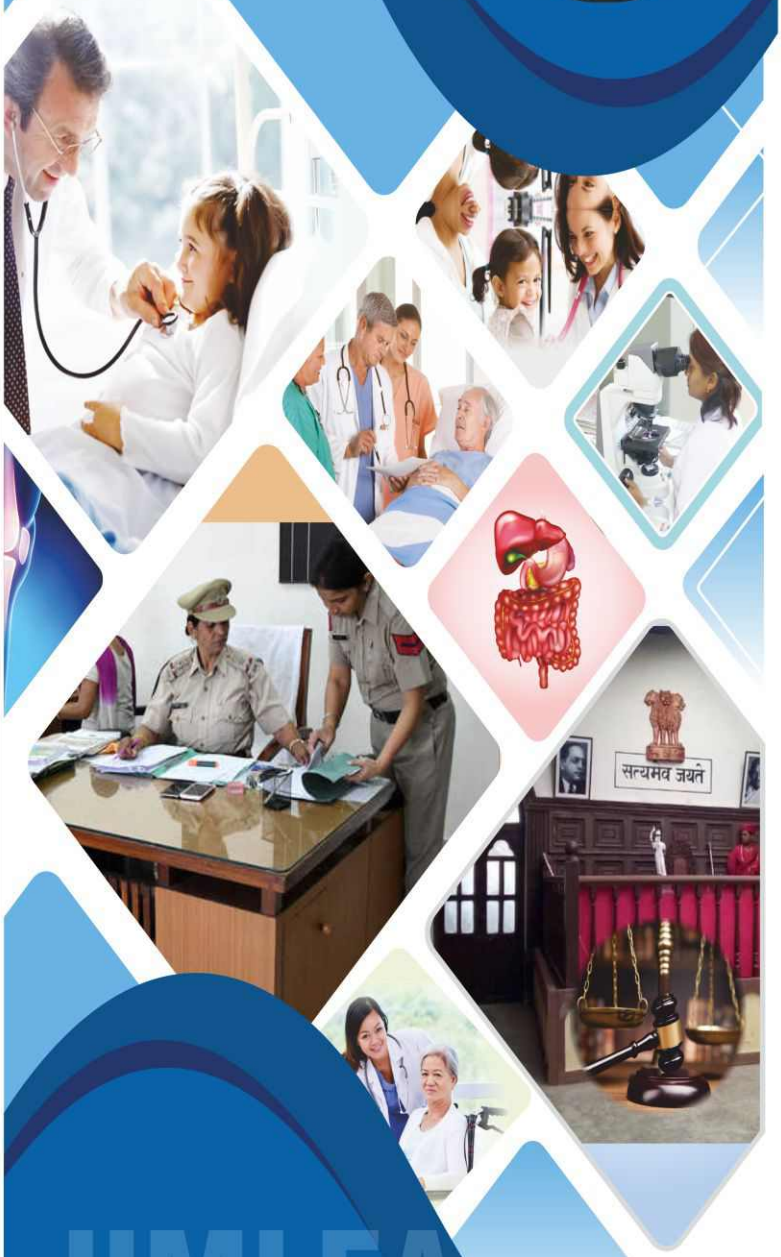

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Editorial :

Be Safe from clutches of law

Dr. Satish Tiwari

Received for publication : 10th Sept. 2022 Peer review : 20th Sept. 2022 Accepted for publication : 05th Oct. 2022

Keywords :-

Zero tolerance, DPR, CPA, Human Rights, Ignorance of law.

The 21st Century has seen many ups and down in the community. **"Zero tolerance"** is being observed in each and every citizen's behavior. In the current scenario, everybody (including Doctors) has the fear about medico-legal problems. As per the information, 1 out of 2000 patients raises a threat of medico-legal problem and every practitioner fears the devil of medico-legal problem. No medico-legal expert will deny the above situation. A medical professional believes that he is practicing since more than 20 years and he faced no problem then why should he bother now! But this is not a thoughtful approach.

During medical education, students are buying degrees and experiences from the corporate hospitals or private medical colleges. They are also borrowing from financing agencies and banks to set up their hospitals and have to pay the loans installments with interest when the education is over and they start the practice. The relatives or patients buy various mediclaim insurances or register for government health schemes and feel that **'money can buy life'.** But they fail to realize that in real life the hospitals can provide care but not cure! The soaring expectations of the patients, lack of communication skills, increasing accountability, unethical practices and judicial activism etc have torn apart the sacred age-old doctor- patient relationship (DPR). It is a universal truth that the laws are required to be changed with the change in the social system and the same is happening here in India. We have to first make ourselves aware about these laws and its requirements and the effects of its non-compliances.

Different Laws and Remedies:-

a) Civil Laws: The citizens of a country have many fundamental rights and for these rights there are legal remedies. The Sec.70 of Indian Contract Act creates a contract (oral, written or implied) between the patients, relatives and the doctors, and all the concerned parties are bound by it. If proper and complete treatment is not given by the physician he may be liable for the deficiency in the services. Similarly, patient should pay the fees of the hospital or the doctors, and if they don't pay the bills, doctors can file a suit in the civil court. Doctors can also ask for advances or deposits before admitting the patients, but can't keep patient in confinement for nonpayment of hospital bills. Filing of cases in civil courts is time-consuming, expensive, and cumbersome.

b) Criminal Law: Criminal Laws are applicable in cases of public wrongs. The state or the government can punish the wrong doer in order to protect the rights of the community. The administrative authorities are usually not involved in cases of medical negligence, deficiency in service or issues related to DPR unless allegations of gross negligence are there resulting either in serious injury or death. At this stage the physicians face the maximum difficulties sometimes resulting in arrest and/or imprisonment. This may happen due to ignorance of law and the decisions to apply the various sections of Indian Penal Code (IPC). The offences registered under Sec 304 or 304-A of IPC exemplify this.

c) Consumer Protection Act (CPA):- This Act was initially enacted and passed in 1986, but different high courts had different opinions till the Supreme Court included medical services under CPA in 1995 in V. P. Shanta vs. IMA case. The Act was modified and passed again in 2019. But, still there are many

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paradoxes and inadequacies and possibilities of misuse of the act remain.

d) Human Rights Commission: In the present era, Human Rights Commission can also be approached if there is violation of basic human rights.

e) Other laws like MTP Act, PCPNDT Act, IT Act, Drug Act, Labor laws etc are also there to keep a watch on medical practitioners. The National Medical Commission (NMC) as a regulatory body has power to punish a physician for his professional misconduct.

It is surprising that about **80 different enactments** are there which govern the medical professionals and hospitals. There is not a single legal practitioner, who can claim expertise in all these enactments, so how a medical practitioner can know and follow the provisions of these rules and regulations? The policy-makers, government and judiciary enact many laws, legislations, ordinances, Acts etc but the same should be implemented without any differentiation and bias as well as avoiding the corruption and malpractices. In the modern and civilized world administration of justice can be a substitute for age-old practices like private vengeance and violent self-help. If policy makers and administration fail in their duties the past era of 'eye for eye', 'hand for hand' or 'life for life' may return. One untoward incidence may lead to another if the administration fails and the ultimate result may only be victimization and retaliation. The authorities should make sure that such situation and incidences do not happen.

With advancement of the society and emergence of Multinational Companies, a new culture of **"Corporate World"** was introduced. While you opt to make your career in the world of Corporate, one must be aware of the consequences of being part of it. No doubt that the laws of the land are becoming more and more stringent and for a slightest mistake, punishment is there. At times, it is seen that for making easy money, several litigations were initiated by some greedy persons. The practitioner is now seen not as ethical professional, but as a trader. The technological advances may have increased physicians' skills and capabilities, but they lose credibility and confidence by becoming technology dependent. This dependency is regulated by market pressures and not by scientific evidence. Technology has become means to make faster money through its misuse. Sex determination and sex selection are well known examples of such unethical use of technology, gadgets and scientific knowledge. Sometimes unethical practice also gets involved in criminal activities as has happened in organ transplantations. Threat can be of any kind.

Can a DPR be terminated?

Healthcare services have drastically changed over past many years and also the trust between a patient and his /her health care provider. The happenings in the health facilities may weaken the bond between the stakeholders. The trust is broken and there is need to take a good hard look at the DPR to determine whether it should continue or not. If the relationship is under strain and mutually non-beneficial, it may be appropriate to terminate the same. This can be done for noncompliance of instructions, nonpayment of bills, communication difficulties or any other genuine reason. But abandoning the patient may be unethical.

Whenever a critical patient is brought for treatment, an open and honest discussion with the relatives or patient may be a practical and good approach. If the treating doctor does not wish to provide his services to the patient brought to him for treatment, he should explain the reasons for the termination and emphasize the importance and need for continued care and treatment. While sending over any case to another hospital for continuing the treatment, give a reasonable transition period for the transport and also help to find out a new healthcare facility. As a rule of thumb, enough time should be given if more specialized care is required or the transport time to seek another facility is more.

Appropriate steps to terminate the patient-physician relationship typically include:

1. Provide relatives and patient with explanation for terminating the DPR. (A valid reason, like non-compliance, failure to follow-up etc.)

2. Continue the management of patient and access to services for a reasonable period till alternative arrangement is made.
3. Guide the patient or relatives to find out another facility of same specialty with equally competent services.
4. Give proper discharge summary or transfer records to a newly referred center.

Disaster versus Risk Management

Both are quite different. *"Risk Management"* is to avert the risk, to curtail it and to take care of all the factors raising a risk by taking timely steps so that it will not prove to be injurious. After the risk has proven to be a disaster of any kind, handling the new situation is a *"disaster management"*.

Crisis management committee:

The deteriorating DPR can be improved or tackled by an appropriate crisis management committee. We can select people from different sections of society, judiciary, policy makers, authorities and government having a positive thinking, attitude and approach in such situations. Many times in such untoward incidence the problems can be handled or tackled tactfully and peacefully. There is need to convince that no sane person will damage his or her own reputation, image and interest by doing wrong or unwanted actions or treatment. Many untoward happenings are unintentional acts, a mere accident and there is no ***"Mens rea".***

Punishment and Disciplinary Action:

The National Medical Commission has been given the power to hold an enquiry on receipt of any complaints of professional misconduct. Any act which violates the code in letter or spirit can be treated as professional misconduct calling for disciplinary action. Every case shall be decided by a peer group as per the guidelines prescribed by the NMC and the facts brought before the commission. The punishment shall be as deemed necessary.

Many practitioners feel that the doctors are *"soft targets"* not only for the people but also for the policy makers and the judiciary. Many State Governments have Ordinances or Acts to prohibit violence against medicare service persons and damage to property in medicare service institutions and for matters connected therewith and incidental thereto. The offender, who acts in contravention to Section 3 of this Act, shall be punished with imprisonment for a period of three years and with fine up to rupees fifty thousand. The offence shall be cognizable and non-bailable. Additionally, the offender shall be liable to a penalty twice the amount of purchase price of medical equipment damaged and loss caused to the property as per the provisions in Section 4 of this Act.

The law cannot let you free on the pretext of your ignorance as it is a settled preposition that ***"Ignorance of law can't be an excuse"***. "Vicarious liability" is there, which holds the person liable for the consequences of any misdeed which happened at the hands of his subordinate. If you are aware of the risk, you can manage to avert it. The medico-legal experts or risk managers for the medical professionals always are on the move at the place of the members for ensuring a smooth and trouble-free practice with peace of mind. The deteriorating DPR is one area where the media has played a negative role most of the times rather than a positive approach, role or outcome. Some of the "law fearing" or "media shy doctors" have started defensive practice in order to minimize such problems in future. There is need to discuss, plan, think and develop effective ways to solve this deteriorating scenario in the community at the earliest. We must have strong medico-legal associations, medico-legal cells, Self-introspection' and ways to find out where and with whom lies the fault in the community. The associations should help the members in formulating the programs which will help in improving the present scenario. The authorities, policy makers, police, media, doctors, and the society should **work as friends and not as foes.** Finally best thing is to avoid the problems by doing right things.

Review Article :

Legal Duties of Doctors in Poisoning Cases

Dr. O. Gambhir Singh,

Received for publication : 24th August 2022 Peer review : 06th Sept. 2022 Accepted for publication : 30th Sept. 2022

Keywords :

Homicidal poisoning, Suicidal poisoning, Accidental poisoning, Medico-legal cases, Indian Penal Code.

Abstract:

The role of doctors in poisoning cases is dual in nature as medical duty and legal duty. The first and foremost duty in a poisoning case is to save the life of the person and then legal responsibilities following the medical treatment. Every case of poisoning must be treated as a medico-legal case and accordingly, the nearest police station must be informed after entering it into the accident register. At least two marks of identification must be noted along with other details such as name, age, sex, marital status, occupation, religion and address. All the relevant information must be documented properly. Samples such as vomitus, feces, stomach wash and blood should be preserved for chemical analysis. In case of death of the person, the doctor shouldn't issue the cause of death certificate instead, the dead body should be sent for a medico-legal autopsy.

Introduction:

Poison may be defined as any substance, solid, liquid, or gaseous form when ingested, inhaled, or introduced into a living body, causes ill health or death by its constitutional or local effects, or both[1,2]. However, the Indian legal system doesn't define poison. The same substance which is useful when administered in smaller doses may become poisonous in larger doses. Poisoning may also occur from the bites and stings of many poisonous animals. Although in an ordinary sense bacterial toxins are not considered a poison, there were many incidents where fatal poisoning occurred due to these toxins. So, the concept of poison is very vague and unsatisfactory. For convenience, any substance when given with a bad intention may be considered poison [3,4].

The incidence of poisoning is comparatively higher in India if we compare it with the western countries because India is mainly an agricultural country with wide use of insecticides and pesticides [5]. During and just after the rainy season, the incidence of snake bites and scorpion stings is higher in India. There are scattered incidences of food poisoning due to the consumption of poisonous foods or adulterated foods. There are few incidents of deaths due to the consumption of adulterated local-made alcohol every year. So, poisoning may occur in various forms. It may be a case of accidental, suicidal, or homicidal poisoning.

Acute poisoning cases are usually emergency and they need immediate treatment. When such a case is brought and admitted to a hospital a doctor may face some problems as it involves not only medical treatment but also other legal formalities and responsibilities such as police intimation, proper documentation, sample collection and arrangement for dying declaration depending on the case. Here in this review article some important medico-legal aspects of such cases are discussed in detail. The medical aspect is out of the scope of this review article.

Legal Provisions & Aspects:

A private doctor or a private hospital has the right to accept or refuse a poisoning case except in emergency cases, but a government doctor or a government hospital has no such right (Medical ethics). The first and foremost duty of a doctor in such a case is the initiation of immediate treatment

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to save the life of the person. This was exemplified by the honorable court judgment in Parmanand Katara vs Union Of India [6]. After that only all the legal formalities should be completed [1,4]. In all cases of poisoning, whether suicidal or accidental or in private or government hospitals, it is mandatory to inform the nearest police station. The case must be registered in the medico-legal register and accordingly, it must be entered into the accident register. If a medico-legal registration number has been allotted by the previous hospital then no need of assigning a new number.

There are no clear legal guidelines that who is a qualified doctor to handle poisoning cases. He must be a registered medical practitioner whose name is enrolled in one of the state medical councils or the National Medical Commission. The honorable court verdict in Dr.P.V.Nair, vs Allettutty Jose, has clearly cited that in an emergency situation an MBBS doctor can give treatment to save a life [7].

All cases of poisoning whether accidental (u/s 284, IPC), suicidal (u/s 309, IPC), or homicidal (u/s 302, IPC) must be informed to the nearest police station even though only homicidal poisoning (u/s 302, IPC) is included in Sec. 39, Cr.P.C. This is because a doctor, unlike the general public, is in a unique position with access to evidentiary material which is related to a crime. It is wrongly mentioned in some standard textbooks of forensic medicine that a private doctor need not inform the police in cases of accidental or suicidal poisoning if the victim survives[8]. The doctor must try to get the police diary number by calling the nearest police station or by dialing number 100. If there is a failure on the part of the doctor to inform the police then he may be sued under Sec. 176, IPC, and the punishment may be imprisonment for 6 months with or without a fine of Rs.1000/-. The doctor may also be sued under Sec. 201, IPC for causing the disappearance of evidence, and the punishment awarded for such an act will be variable according to the type of offence shielded. Further, the doctor may be sued under Sec. 202, IPC for intentional omission to give information of offence by a person bound to inform – imprisonment for 6 months with or without fine [5,7].

If the condition of the patient is serious then an arrangement must be made for the recording of the dying declaration (DD) preferably by an Executive Magistrate. It is an oral or written statement of a dying person regarding the cause of his death, Sec.32 (1), Indian Evidence Act, 1872. If there is no time and the condition of the victim is very serious then the doctor must record the DD by himself in the presence of two independent witnesses. In the end, the victim, the doctor, and the witnesses all must sign the dying declaration. If the DD is recorded by the magistrate then no signature from another person is required. Here, it is worthy to remember that the main duty of the doctor in DD recording is to certify the composed mentis of the victim.

In cases of food poisoning, adulteration of foods, or contamination of drinking water, doctors must notify it immediately to the public health authorities [1,2].

Paper Documentation & Record Maintenance:

All cases of poisoning must be considered medico-legal cases and accordingly, they must be entered into the accident register. At least two marks of identification must be noted on the case sheet for future references. Preliminary particulars such as name, age, sex, marital status, occupation, address, date, brought by whom must be noted as usual. Detail history of the poisoning such as the name of poison, time of consumption, route of consumption or administration, previous history of suicide, drug abuse, and mental illness must be documented properly[1,2]. All this documentation work may be done after rendering life-saving treatment to the patient[5,7]. On the top of the file cover, the word MLC must be written in red ink and it must be preserved safely as per the existing hospital protocol.

Sample Collection:

The first sample of gastric lavage or vomitus must be preserved in a sealed container for chemical analysis. The container may be a wide-mouth transparent glass or plastic bottle with a stainless steel screw cap of about one-liter capacity. Blood, saliva, sweat, urine, and milk. may also be collected in a smaller container for chemical analysis. Clothes soiled with vomit, and feces should be preserved for chemical analysis[1,5,7]. Vacutainer tubes can be used for blood sample (about 10ml) collection and they are very convenient as they already have anticoagulants and preservatives. Otherwise, preservatives containing EDTA and Sod Fluoride must be used. For urine concentrated hydrochloric acid or thymol can be used[1,2]. For the preservation of vomitus or gastric lavage saturated solution of common salt can be used. Otherwise, samples may also be preserved by keeping them in refrigeration at about 40^0C. Soiled clothes must be air dried before packing. If the remnant of consumed poison is brought by the relatives it must be properly documented on the case paper and the sample must be handed over to the police after sealing and labeling. All samples thus collected and preserved must be well labeled and sealed before being handed over to the police investigating officer.

Final Opinion In Poisoning Cases:

Opinions must be given very carefully. The Police Investigating Officer may seek the medico-legal opinion of the treating physician if the victim survives or of the autopsy doctor if the victim dies. The doctor must analyze carefully the history, clinical features, laboratory investigation reports, toxicology reports, and response to the treatment protocol[1,2,9]. In case of death, the final opinion will be given by the autopsy doctor after a thorough post-mortem examination and visceral report examination. Generally, the clinical findings, laboratory reports, post-mortem findings, and viscera chemical analysis reports are enough to opine on the final cause of death. However, the following points must be kept in mind while giving an opinion:-

1. Age, sex and body weight
2. Degree of toxicity
3. Whether it was sufficient to cause death
4. Route of administration
5. Synergistic effect of drugs
6. Post-mortem drug redistribution
7. False positive or negative toxicology results, etc.

Discussion:

When a poisoning or a suspected case of poisoning is brought to the casualty, the treating doctor has two important duties one is to render immediate treatment to save the life of the person and another is to help the legal system by informing the police and collecting and preserving the suspected material for chemical analysis. However, as soon as possible life saving treatment must be initiated first [6].

Sections 284, 299, 300, 304A, 324, 326 and 328 of I.P.C., 1860 deal with various offences relating to handling and administration of poisonous substances. As per Indian law, administration of any substance with the intention of causing hurt or death is punishable[11]. According to Sec.324,(IPC),and Sec.326, (IPC) poisons can also be treated as dangerous weapons and accordingly, they can cause hurt or grievous hurt[8,10]. The possession, sale and control of poisons are governed in India by The Poisons Act, 1919, The Drugs Act, 1940, The Drugs and Magic Remedies Act, 1954, The Narcotic Drugs and Psychotropic Substances Act, 1985, and The Pharmacy Act 1984 [1,2,4].

Palaniswamy Vaiyapuri vs State, this case established the fact that the perpetrator who administered the poison and caused the death of an individual should be punished even when the poison in the body could not be identified after investigation[12].In another similar case of Mahabir Mandal and Others vs State of Bihar,

honourable court has said that the mere non detection of the poison does not mean that the death was natural[13]. In another case supreme court has observed that - In a case of unnatural death inviting Sec 304-B, IPC or Sec 306 IPC, as long as there is evidence of poisoning, identification of the poison may not be absolutely necessary. If the guilt of such administration of poison is discovered by oral or circumstantial evidence that is valid for conviction in the court of law.

Doctors must be aware of chronic poisoning cases also. West Bengal and some adjoining states are prone to chronic arsenic poisoning due to contaminated underground water[14]. Chronic insecticide poisoning can also occur from consumption of contaminated food or water. When such poisoning comes into his knowledge it is his duty to report it to the concerned public authority, so that action can be taken to prevent the damage. It is under privileged communication that doctor can inform the concerned public authority as a duty to protect the interest of the community or the state.

Conclusion:

All cases of poisoning must be made an MLC and accordingly the concerned police station must be informed. A private doctor shouldn't refuse treatment of poisoning cases due to the fear of legal implications. Proper knowledge of law is the only solution for discharging duty.

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Review Article :

Dolo 650: Why the Hue and Cry?

Dr. Yash Paul

Received for publication : 10th August 2022 Peer review : 6th Oct. 2022 Accepted for publication : 15th Oct. 2022

Recently a Public Interest Litigation (PIL) has been put in the Supreme Court of India, by the Federation of Medical and Sales Representatives' Association of India (FMRAI) that Micro Labs, the manufacturer of Dolo 650 Tablets, had spent about Rs. 1000 crores on freebies to the doctors to prescribe Dolo 650 tablets. The PIL has two points:

1. Since the market price of paracetamol up to 500 mg is regulated, the company (Micro Labs) moved to higher dose.
2. In a bid to increase sales, freebies were given to doctors to incentivize them to prescribe Dolo 650 mg.

There have been some critical comments in the newspapers, thus bringing this issue in public domain.

According to the company the amount spent on publicity including the so called freebies is around Rs. 5-6 crore only. Accepting bribe in any from to prescribe a particular drug is wrong. But it seems that PIL has been put for some other reasons. Generally the cost of freebies is passed on to the consumers. The author found that it was not the case. The author checked the MRP(maximum retail price) of Paracetamol 650 tablets and Paracetmol 500 tablets of some reputed manufactures, (the MRP of these products is presented in the Table1).

It can be seen that MRP of 15 tablets of Dolo 650 is quite similar to other brands with minute difference. It seems that sale of these products was high and this is the reason for the hue and cry.

It would be interesting to know the parameters on which different MRPs were permitted by the National Pharmaceutical Pricing Authority for same drug formulations. It is surprising that GSK markets paracetomal as Calpol and Crocin. MRPs of Calpol and Crocin are different as can be seen in the table.

TABLE-1 MRP of 15 Tablets of Paracetmol 650 and 500 tablets in Rupees.

No.	Product	Manufacturer	650	500
1	FENACE	Invision	44.955	15.00
2	DOLO	Micro Labs	30.91	15.29
3	CALPOL	GSK	30.91	15.04
4	CROCIN	GSK	30.24	14.95
5	FEBREX	Indoco (Spade)	30.24	21.42
6	PACIMOL	Ipca (Intime)	30.24	15.29
7	PARACIN	Stadmed	30.22	15.90
8	P-650/P-500	Apex	29.07	14.28
9	MACFAST	Macleods	29.02	14.25
10	FEPANIL	Citadol	28.99	14.11
11	PELCIN	Pax Healthcare	28.50	21.00
12	PRODOL	Redicure	18.00	13.65

Sources for MRP.

1. CIMS Therapeutic Index Jan-March 2022.
2. IDR Drug Compendium 2022 Issue -3.

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Review Article :

What should the Doctors do in case Pharma Industry resorts to malpractices endangering lives of people?

Dr. Yash Paul

Received for publication : 28th Sept. 2022 Peer review : 7th Oct. 2022 Accepted for publication : 15th Oct. 2022

Keywords:

Spurious drugs, substandard drugs, irrational drug formulations harmful drug formulations.

Abstract:

Drug manufacturers are commercial houses and not charitable NGOs. Though pharmaceutical companies make legitimate profit from the sale of drugs these should take necessary steps to ensure the well being and safety of people. The drugs should be safe, effective and rational products. It seems that in a race for 'one–up man ship' the pharma industry has turned a blind eye to the science of pharmacy and safety of people despite the existence of supervising authorities. It is time that doctors take right steps to abide by the Hippocratic Oath or Charak Shapath .

Introduction:

In the year 2012 the author had stated "A doctor prescribes or administers drugs to a patient and is expected to follow the 'cause no harm' principle [1] Primarily the relationship between the Medical profession and the Pharma Industry is based on the common goal namely to provide benefits to the people during illness and to keep good health. There should be no reason for conflicting interests or complaints against each other. The most important point is that drug formulations should be appropriate, safe and uniform. [2] Sadly some pharmaceutical companies have failed on these three points viz. 1 Appropriate, 2. Safe and 3 Uniform drugs. The author would like to take up some issues.

In our country we have three constitutional supervising authorities regarding Pharmaceutical Industry. (i) Authority issuing licenses for manufacture- Drugs Controller General of India (DCGI) and State Drug Controllers. (ii) Authority supervising quality of drugs viz. The Central Drugs Standard Control Organization (CDSCO), (iii) Authority for pricing viz. National Pharmaceutical Pricing Authority (NPPA).

I. Drug Formulations:

All drug formulations should be appropriate regarding ingredient(s) and the quantity of ingredients.

1. **Appropriate and uniform formulations**: Petrol available at all petrol pumps is of same quality but mischief like adulteration may occur at local levels.

   (i) Paracetamol syrup: In children paracetamol dose is 15mg/kg per dose. Conventional wisdom would suggest that 150mg and 300mg of paracetamol per 5ml of suspension form would be most convenient for doctors to calculate the correct dose of drug. Presently Paracetamol syrup with 120 mg, 125mg, 156.25mg, 250mg and 500mg per 5ml are available. One would like to know the science behind formulation having 156.25mg per 5 ml instead of 150mg per 5ml.

   (ii) Anticold Drugs: Anticold drugs available have different combinations in different quantity of each ingredient. Cetirizine is recommended once a day, in children it is recommended in two divided doses.

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Levocetirizine is recommended once a day. Phenylephrine HCl, Chlorpheniramine Maleate and Paracetamol are recommended four times a day.

These are example which pose problems for doctors. In year 2013 the author had stated in an article titled 'Need for safe and doctor friendly drug formulations.'[2].

2. **Unapproved formulations:** Clavulanic Acid is approved in combination with Amoxicillin and Sulbactum for combination with Cefoperazone. Presently many antibiotics in combination with Clavulanic Acid or Sulbactum are available in the market. These formulations add tremendously to the cost of therapy without providing any additional benefit to the patients [3].
3. **Different formulations:** The author cites example of one medicine. Phenytoin liquid preparation for children is available under two brand names: (i) Dilantin Suspension, each ml contains 25mg of active ingredient and (ii) Eptoin Suspension each 5 ml contain 30 mg of active ingredient. Liquids dispensed as drops mention ingredients per ml, suspensions mention ingredients per 5 ml. Though Dilantin is available as suspension, quantity of phenytoin is mentioned per ml and not 5 ml.

   In case Dilantin suspension is given inadvertently instead of Eptoin suspension without specifically mentioning the change in dose of the drug, a child who needed 30 mg of phenytoin being given 5 ml of Eptoin suspension would receive 125 mg of phenytoin as 5 ml of Dilantin suspension. On the other hand a child who needs 50 mg of Phenytoin from 2 ml of Dilantin suspension would get 12 mg phenytoin if administered 2 ml of Eptoin suspension. Interchange of Dilantin and Eptoin bottles can lead to mishap. Both products should have similar amounts of the drug to avoid any mishap.[1] This was published in year 2012 in a Pharma Journal but pharma industry has turned a blind eye to this issue of serious concern.
4. **Problematic Formulations:** Some combination formulations pose problems for doctors. The author cites one example. Combination of Cefexime and Ofloxacin having equal quantities of both salts. Dose of Cefexime for children is 4 mg/ kg BD and dose of Ofloxacin is 7.5 mg/kg BD. In case dose is calculated according to Ofloxacin then the administered dose of Cefexime would be double of the recommended dose and may result in overdose toxicity. On the other hand if dose is calculated according of Cefexime then the administered dose of Ofloxacin would be half of the recommended dose and may results in antibiotic resistance.

It appears that safety of patients has taken a back seat. Question arises: What is the role and necessity of Drug Controller General of India and State Drug Controllers? A patients takes a drug prescribed by a doctor because patient has full faith in the treating doctor knowing that a doctor would abide by the cardinal principle of medical profession "cause no harm." A doctor prescribes a drug believing that any drug which has been licenced must be safe and approved. Is it a misplaced trust?

Amoxicillin and Clavulanic Acid Formulations:

Different manufacturers market this combination where quantities of both molecules are different. Macleods markets Acuclav Tablets having Amoxicillin 250 mg and Clavulanic Acid 125 mg. Aden Healthcare markets Adentin Tablets having Amoxicillin 500 mg and Clavulanic Acid

125 mg. Cipla markets this Combination in three different formulations: Amoxicillin in 200 mg, 400 mg and 875 mg with Clavulanic Acid 28.5 mg, 57 mg and 125 mg respectively.

II. Spurious and Sub-standard Formulations

A. Spurious drug is that which does not have the required molecule(s).

B. Sub-standard medicines are pharmaceutical products that do not meet their quality standards and specification. In case the quantity of any ingredient(s) is less than 90% of the labelled quantity it is called sub-standard drug. Problems with spurious and substandard drugs is that by the time these facts are known thousands of persons have already consumed these drugs.

The Central Drugs Standard Control Organization (CDSCO) is the supervising agency. There is an urgent need that this agency becomes proactive. The Indian Express dated 9th August 2022 had an article by Dinesh Thakur who was the whistle blower in the Ranbaxy pharma case and Prashant Reddy T who is a lawyer active in drug regulation. Article was titled "Chalta hai regulation- New drugs Bill serves interests of pharma industry not public health". Limits for substandard drug is to be reduced from 90% to 70%. This would suggest that medicines manufactured in India are of very high quality that even 70% of the required dose will provide full benefit to the patient. The author, quotes some part of the article: "Last month the Union Ministry for Health & Family Wellfare Published a new Bill to replace the colonial-era Drugs & Cosmetics Act, 1940. This proposed bill was written by a drafting committee of eight bureaucrats headed by the Drug Controller General of India (DCGI) and included a senior bureaucrat who has since been arrested on suspicion of corruption."

III. Criminal negligence.

Permissible level for diethylene glycol (DEG) is .01% to 2% in India. A report by The Indian Express dated February 26,2020 titled 'Under scanner for 11 deaths, 3400 bottles of cough syrup sold.' Stated: "Between December 2019 and January 2020, at least 17 children experienced adverse effects in Ramnagar area of Udhampur district in Jammu region. Eleven of these children died from kidney failure. It happened due to presence of 35 percent of diethylene glycol(DEG). " The author had highlighted this issue in an article titled "Laws to Curb Unethical Practices by Pharmaceutical Industry [4]. Presence of potentially toxic substance in such high quantity cannot be called unethical but it is outright criminal negligence. The author had further stated in the article "It should be presumed that diethylene glycol got mixed with the preparation inadvertently. This raises serious concern regarding check and safety measures followed by the manufacturer. Thus, it is very necessary that the government should enact some laws to control pharmaceutical industry [4].

IV. Pricing of Medicines:

National Pharmaceutical Pricing Authority grants MRP for all the medicines and vaccines. Petrol of different quality is priced differently, but price of same quality of petrol is same in an area whether purchased from Bharat Petroleum, Indian Oil or Hindustan Petroleum.

But some drug formulations marketed by different pharma houses have different MRPs,

(i) MRP of Paracetamol 500 mg tablet varies from Re 0.938 per tablet (AMIL.marketed by Triveni Formulation) to Re. 1.60 (FACIPIK marketed by a Arpik).

(ii) MRP of Ciprofloxacin 500mg tablet varies from Rs. 3.61 (AICIFLOX NOVO by Alkem)

to Rs. 6.60 (BEKACIN by Sanofi Aventis)

(iii) MRP of Ofloxacin 200 mg tablet varies from Rs. 4.80 (INFLOBID by Intra labs) to Rs. 8.05 (OFLOX tablets by Cipla).

(iv) Micro Labs markets paracetamol syrup in three concentrations i. 120 mg/ 5 ml 60 ml MRP Rs. 35.62, ii. 156.25 mg/ 5ml 60 ml MRP Rs. 47.00 and iii. 250 mg/ 5 ml 60 ml MRP Rs. 39.65. It is difficult to guess the rationale for 156.25 mg/ 5ml formulation costing more than 250 mg/ 5 ml formulation by same manufacturer.

What can doctors do?

The author has been taking up issues of unsafe drug formulations since year 2012 by writing articles in pharma and medical journals. Unfortunately these issues have been ignored by the Pharma Industry, Supervising Authorities as well as Medical profession. In past the author had raised some issues with the Medical Representatives. They assured to provide answer after taking up these issues with their respective pharma house seniors. But none came back. The only probable explanation could be that they were told somewhat like: "We manufacture these drugs because these are being sold all over the country. These drugs are being sold because doctor all over the country prescribe these drugs so, you ignore this doctor from Jaipur and carry on with your visits to all the other doctors."

In year 2017 the author had stated in an article titled "Onus of Patients' safety is on the Doctors": Thus the only recourse available to the doctors is not to prescribe such formulations. If all the doctor prescribe rational drugs only the pharmaceutical industry will automatically stop manufacturing irrational drugs despite having valid manufacturing license" [5].

Reference:

1. Paul Y. Drug formulations: safety of patient remains the main concern. Express Pharma 2012, 7:34.
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3. Paul Y. Problems Associated With Some Drug Formulations Indian Pediatr 2019, 56: 513-514.
4. Paul Y. Laws to curb Unethical Practices by Pharmaceutical Industry. *J.Indian Medico Legal and Ethics Asso*. 2020. 105-106.
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Contribution in JIMLEA

All the readers of this issue and the members of IMLEA are invited for contributing articles, original research work / paper, recent court judgements or case laws in the forthcoming issues of JIMLEA. This is a peer-reviewed journal with ISSN registration. Please send your articles to Dr. V. P. Singh, email : singhvp@gmail.com

Medicolegal News

Compiled by : Dr. Santosh Pande

No Medical Negligence In Treating Pneumonia, Consumer Court Exonerates Physician, Hospital

New Delhi: Upholding the order of the State Commission, the National Consumer Disputes Redressal Commission (NCDRC) recently exonerated a physician and a hospital from charges of medical negligence while treating a patient who ultimately died of pneumonia.

The wife of the deceased had brought allegations of medical negligence against the doctor and the hospital and blamed improper diagnosis and improper treatment as the reason for the patient's demise.

However, the top consumer court exonerated the doctor after 21 years after it took note of the report of the expert- Dr SB Aggarwal, Professor & Head (Medicines) at BJ Medical College, Ahmedabad. The history of the case goes back to 20 years ago when the husband of the complainant had approached the treating physician, Dr. Gadhvi, for complaints of cough and cold. After examining the patient, the doctor had advised him X-Ray and sonography. On the basis of the test reports, the physician allegedly advised the complainant to take her husband to the hospital for general check-up without assigning any reasons for the X-ray and sonography.

Two days later, the patient started experiencing stretching in his hand and the mother-in-law of the patient informed the same to the nurse, who administered one injection to the patient and allegedly informed that Dr. Gadhvi was not in the hospital. It has been alleged in the complaint that after giving the injection, the condition of the patient worsened.

On the request of the mother-in-law of the patient, the doctor came to the hospital and after examining the patient, he advised her to shift the patient to Shardaben Hospital.

He, however, did not write any reference note stating that he would accompany them to the Hospital. At that time, deceased was unconscious and water with foam was coming from his mouth. After examining the patient, the doctor at the Sharda W Hospital declared the patient to be dead.

The cause of death in the PM note had been mentioned as septicemic shock due to liver abscess. However,the complainant alleged that the report of Dr. Gadhvi did not mention liver abscess or abdominal pain or jaundice as the cause of death.

It was also alleged that the doctor did not accompany them while shifting the patient and the reports of X-ray and sonography, which had been submitted at the Sharda hospital at the time of admission, had not been returned.

Aggrieved by the improper diagnosis and improper treatment of the deceased done by the doctor and the hospital, the complainant approached the State Commission and prayed for a compensation of Rs .15 lakh towards mental agony at 24% rate of interest per annum.

On the other hand, the doctor denied all the allegations and submitted that the patient had come to his hospital with complaints of cold, bronchitis and respiratory problems. On being examined, it was found that he had pneumonia in his left lung and therefore was advised to get X-Ray Chest and 2D Echo.

It was seen that the heart beats of the deceased were fast and pericardial rub in the heart was also noticed. At that time, the relatives of the patient had allegedly informed the doctors that the patient was alcoholic. In this situation, it was essential to admit the patient and the same was done. The deceased was administered higher and broad spectrum antibiotics and was being continuously monitored. All necessary blood and urine test were also advised but any condition relating to jaundice or liver could not be detected.

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The doctor further claimed that no staff of the hospital had administered any injection to the patient without his knowledge. He further submitted that after the condition of the patient worsened, he had informed the mother-in-law of the patient to shift him to Sharda Hospital. However, ambulance was available after two hours and therefore, the deceased had been sent in rickshaw and Reference Note was also sent along with the staff.

It was also claimed by the doctor that the reason for the patient's death was not liver abscess but it was because of pneumonia and septicemia. Sharda Hospital submitted that when the patient had been brought to their hospital, the on-duty doctor Dr. Solanki had examined the patient. After examining the patient, she had declared him to be dead and told the relatives of the deceased to get a Post Mortem Examination performed in the Civil Hospital. Therefore, the hospital denied any responsibility for negligence or for paying any compensation.

After considering the matter, the State Commission opined that there was no medical negligence and therefore the complainant approached the NCDRC bench. The counsel for the doctor argued that the patient was alcoholic. It was submitted that liver abscess is a slowly progressing disease which complicates to the rupture of liver in the lungs or abdomen. Therefore, the patient becomes critical. The doctor's counsel argued that in the instant case, the death was not due to liver abscess, but due to septicemia because of pneumonia. Referring to the history of the patient, the doctor's counsel submitted that the patient had consumed heavy liquor on 31st December eve.

Taking note of the arguments, the NCDRC bench referred to the expert opinion and submitted, "It is pertinent to note that on the basis of X-ray chest and 2D ECHO report, the patient was immediately admitted. He was not merely suffering from cough and cold, but properly treated for pneumonia. It was confirmed by the opinion of expert - Dr. S. B. Aggarwal, Professor & Head (Medicines) at B.J. Medical College, Ahmedabad. In the opinion, it was stated that the proper treatment for Gram positive and Gram negative anaerobic organisms was given. We further note that the liver enzymes (SGOT & SGPT) were normal, the urinary bile salts and pigments were absent and USG findings were not suggestive of liver abscess. Therefore, the allegation of not giving the treatment for liver abscess is not sustainable."

"We note that the patient was brought in the casualty of the Opposite Party No. 2 Hospital on 04.01.2001 at 8.20 a.m. The doctor on duty – Dr. Ashaben Solanki examined the patient, who was found to be dead. Therefore, the body was sent for Post-Mortem at Civil Hospital, Ahmedabad. As the patient did not bring any medical record, there was no question for the Opposite Party No. 2 to return any documents," it added.

The top consumer court referred to Supreme Court order in the case of Jacob Mathew's case and in the case of Dr. (Mrs.) Chandarani Akhouri & Ors V Dr.M.A.Methusethupathi & Ors. Referring to these judgments, the commission noted, "Based on the discussion above and the precedents of the Hon'ble Supreme Court, we do not find any medical negligence from the treating doctor. Therefore, accordingly, the instant First Appeal is dismissed."

Ref.: *https://medicaldialogues.in/news/ health/ medico-legal/no-medical-negligence-in-treating-pneumonia-consumer-court-exonerates-physician-hospital-96...Accessed on 20/07/2022*

No Bail To Acupressure Practitioner For Treating Gangrene Without Qualification Resulting In Amputation

Chandigarh: The Punjab and Haryana High Court recently denied the plea for anticipatory bail for an acupressure practitioner, whose alleged negligent treatment resulted in the amputation of left leg of the patient.

Denying the plea for bail, the HC bench comprising of Justice Sandip Moudgil noted that the accused petitioner was not competent to

provide treatment to the patient.

"In the present case treatment has been given by the accused petitioner for a disease, which was beyond her knowledge and qualification, for which she was not authorised and none of her educational qualifications brought to the notice of this Court are recognized by the competent authorities like Medical Council of India or any State Medical Board to advance the practicing in alternate medicine for the ailment of gangrene," observed the bench.

Apart from this, the bench also noted that the petitioner failed to serve the patient with reasonable degree of care and skill and noted, "This Court is sanguine of the fact that the accused petitioner, even according to her possessed qualification for Acupressure and Electro Homeopathy Medical System, has a duty to act with a reasonable degree of care and skill has an implied undertaking of not to give a chance for breach of such duty, has given a cause of action for negligence which resulted into huge damage to the father of the complainant, which cannot be compensated in any manner whatsoever."

The concerned acupressure practitioner was providing treatment to the father of the complainant who was suffering from gangrene on the thumb and three fingers of left foot. Besides, the patient had diabetes and he was a heart patient as well. It has been alleged that the accused had displayed a board outside her clinic that read Dr. Mamta Kapoor. She also assured the complainant of curing the disease.

Consequently, the father of the complainant was treated from 28.01.2022 till 06.02.2022. At the time of discharge from the clinic, the accused petitioner did not give any document but promised to give the complete summary of treatment and discharge, later on. Following this, she made home visits till 13.02.2022 at the house of the complainant's sister and charged an amount of Rs 1 lakh in total for the complete treatment.

However, the father of the complainant started having acute pain in the left foot and got him examined at Gupta Hospital, Siddharth Nursing Home, Amritsar. It was diagnosed that the gangrene had infected the entire left leg, which had to be amputated failing which it would endanger his life. The reasons for such severe infection was the wrong and negligent medical treatment given by the accused petitioner.

Consequently, the complainant came to know about other persons whose life had been put at risk by the accused petitioner and for these the accused is already facing complaints. It has been alleged that the accused acupressure practitioner was practicing as a 'doctor' without having any valid license.

After being booked under Sections 338, 406, 420 IPC and Section 15 of Indian Medical Council Act, the accused petitioner filed the plea under Section 438 Cr.P.C seeking anticipatory bail. The counsel for the petitioner-accused claimed that the accused has due qualification to provide Electro Homeopathy/Acupressure treatment and to prove the same, the counsel submitted the Result-cum-Detailed Mark Certificate issued by the Council of Electro-Homeopathy System of Medicine (Punjab), apart from a certificate of M.D.Acu. issued by Acupressure Research, Training & Treatment Institute, Jodhpur, Rajasthan.

Apart from this, the counsel further submitted that the accused petitioner has completed Complimentary Medicine (Medicine Alternative) through correspondence course from an institute registered by the Punjab Govt. under S.R. Act & Govt. of India under T.M. Act, 1999 along-with a Diploma in Community Medical Services & Essential Drugs (CC) granted by the Para Medical Council (Punjab).

It was further stated by the petitioner's counsel that she has been registered as Community Health Worker with the Para Medical Council, Punjab and she is duly equipped with the course of Diploma in Acupuncture. The Counsel for the petitioner denied the fact that she runs a clinic

displaying Doctor before her name Mamta Kapoor, who is running a similar clinic in single storey dwelling unit consisting of three rooms as a small time alternative medicine therapist.

The petitioner further submitted that neither there was any indoor admission arrangement in the clinic nor any such facility to admit the father of the complainant. Therefore, FIR, in question, is absolutely false and having no iota of truth in it.

On the other hand, the Deputy Advocate General of Haryana vehemently opposed the plea seeking anticipatory bail and contended that the accused petitioner had a degree of BEMS (Master Degree Certificate in Acupressure) and she is not qualified for treating the patient suffering from disease like gangrene.

Moreover, he submitted that the accused petitioner was duly made aware of the other medical issues like diabetes and heart ailments of the father of the complainant, still she chose to give false assurance of curing the disease. As a result of medical negligence, the father of the complainant lost left leg which had been amputated below the knee.

At this outset, reference was made to an inquiry conducted by the Medical Board, consisting Dr. Sham Lal, SMO, Civil Hospital, Panipat, Dr. Pardeep, Medical Officer, Civil Hospital, Panipat, Dr. Ravinder Garg, IMA, Representative Panipat, Dr. Vishwajeet Singh, NIMA, Representative Panipat and Civil Surgeon, Panipat, which opined that the petitioner-accused was not a recognized medical practitioner and the treatment of already established disease of gangrene was beyond her acumen and knowledge of medical science. In fact, the Committee had further concluded it to be a case of negligence on the part of the accused petitioner due to which the left leg of the father of the complainant had to be amputated.

The counsel for the State further submitted that prima-facie offences under Sections 338, 406 and 420 IPC and Section 15 of Indian Medical Council Act, 1956 are found to be made out against the accused petitioner. He also pointed out that until now, the accused petitioner could not be traced and the investigation in the FIR cannot be conducted until or unless the accused petitioner is not taken into custody for interrogation.

After considering the submissions made by both the parties, the bench observed that the accused had provided treatment for a disease that was beyond her knowledge. The Court noted, "In the present case treatment has been given by the petitioner accused for a disease, which was beyond her knowledge and qualification, for which she was not authorised and none of her educational qualifications brought to the notice of this Court are recognized by the competent authorities like Medical Council of India or any State Medical Board to advance the practicing in alternate medicine for the ailment of gangrene. It is evident from the record and also not disputed by the counsel for the petitioner-accused that the disease was initially in the thumb and fingers of the left foot only."

Further holding the petitioner guilty of not acting in accordance with a reasonable degree of care and skill, the bench observed, “This Court is sanguine of the fact that the petitioner-accused , even according to her possessed qualification for acupressure and Electro Homeopathy Medical System has a duty to act with a reasonable degree of care and skill has an implied undertaking of not to give a chance for breach of such duty, has given a cause of action for negligence which resulted into huge damage to the father of the complainant, which cannot be compensated in any manner whatsoever.”

Such loss will not only disable a person from routine course of his life but will also keep on pricking in his mind to cause consistent mental cruelty and harassment apart from embarrassment in daily routine in the society at large," it added.

Therefore, denying to provide anticipatory bail, the HC bench mentioned in the order, "In the light of the aforesaid discussions and the facts on record,

this Court does not find any merit in the present petition and is fully convinced that the custodial interrogation of the petitioner is necessary to move the investigation in the case."

Ref.: *https://medicaldialogues.in/news/health/no-bail-to-acupressure-practitioner-for-treating-gangrene-without-qualification-resulting-in-amputation-96231... Accessed on 20/07/2022*

NCDRC Holds No Medical Negligence In Cataract Surgery, Exonerates Kolkata Eye Hospital, Doctors

New Delhi: The National Consumer Disputes Redressal Commission (NCDRC) has exonerated Kolkata based Eye Care Hospital and its two doctors from charges of medical negligence in cataract surgery, which allegedly resulted in vision loss of the patient.

Although the District and State Commission had held the doctors guilty of negligence and awarded compensation, the NCDRC bench recently observed, "in our view, the retinal detachment was properly treated by the OP-3 and further by senior vitireo retinal surgeon Dr. Tamal Kanti Roy Sarkar. We do not find deficiency or negligence on the part of the OP-3. The negligence cannot be attributed to him so long as he performed his duties to the best of his ability."

The patient had approached the District Consumer Court alleging post-cataract negligence causing loss of vision in the right eye of the complainant. As per the medical record, the patient approached the Vasan Eye Hospital and after detecting cataract, the doctors suggested cataract surgery. Before the operation, the patient's vision in the right eye was 6/36 N18(P).

At that time, the patient was explained in detail about the visual outcome and prognosis after the surgery because he also had corneal ailment. Accordingly, the right eye cataract extraction was conducted on 22.11.2012 by Manual phaco/SICS with Acrysof IQ Lens under Viscoat to protect the cornea.

Although the surgery was uneventful, during the follow up checkup it was noted that the vision in the right eye was +3.25 N10 and left eye +3.00 N6. Following this, the patient had been referred to Dr. Prosenjit Mondal for the complaints of floaters in the right eye and examination of retina. After examining the patient, Dr. Mondal noted that the Anterior Segment of Right Eye showed good Pseudo-phakia with well-placed lOL in the bag/No reaction in Anterior and Posterior Segment. The Left Eye showed immature Cataract. Fundus Examination of Right Eye revealed Retinal Detachment & Pale Optic Disc, and accordingly, surgery under Guarded Visual Prognosis was advised. After this, the patient underwent Right Eye Sclera buckle with Pars Plana-Vitrectomy with Perfluoro-cabon liquid injection with Endo-laser with silicon oil. The Retina well attached with silicon oil filled eye. In this case as well, the post-operative period was uneventful. A few months later, the patient underwent right eye silicon removal.

Consequently, the patient had been referred to the senior vitireo retinal surgeon Dr. Tamal Kanti Roy Sarkar who, on 21.03.2013, performed Right Eye IOL Explantation with Endo-laser with silicon oil injection. Examination of the patient revealed that the patient's best corrected visual acuity was 6/12 P in Right eye and 6/12 in left eye.

The record further revealed that since there was corneal pathology, the patient had been advised to use Contact Lens. However, the patient did not follow the advice and insisted for implantation of Secondary Lens which was detrimental to the patient in view of corneal ailment with history of previous retinal detachment. hereafter, on 04.07.2013, the patient underwent right eye silicon oil removal with Endo-laser.

When the patient approached the District Commission, the consumer court held that the third operation was not at all necessary and due to this, the complainant lost his vision in the right eye. Therefore, the Commission had directed the Hospital to pay Rs 50,000 as compensation for the loss of his eye.

When the matter reached the State Commission, the court enhanced the compensation amount and directed the hospitals to pay Rs 1 lakh each for the alleged medical negligence.

Being aggrieved, both the hospital and the doctors filed the revision petitions before the top consumer court. After reiterating the facts and presenting the evidence the counsel for complainant vehemently argued that the complainant lost his vision permanently, therefore, he deserves enhanced compensation as prayed in the complaint. On the other hand, the Counsel for the Hospital and the doctors referred to the medical record and argued that there was no medical negligence on their part.

After taking note of the submissions by both the parties and also perusing the medical record, the NCDRC bench noted, "Thus, in our view, the retinal detachment was properly treated by the OP-3 and further by senior vitireo retinal surgeon Dr. Tamal Kanti Roy Sarkar. We do not find deficiency or negligence on the part of the OP-3. The negligence cannot be attributed to him so long as he performed his duties to the best of his ability."

At this outset, the bench referred to the Supreme Court judgment in the case of Achutrao Haribhao Khodwa & Others V State of Maharashtra & others, where the top court held that "Negligence cannot be attributed to a doctor so long as he is performing his duties to the best of his ability and with due care and caution. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession."

Referring to this, the top consumer court exonerated the hospital and the doctors and mentioned in the order, "Based on the foregoing discussion, both the fora below erred to hold the OPs liable for medical negligence. It was an error that the District Forum awarded compensation of Rs. 50,000/- on humanitarian ground, whereas the State Commission enhanced it to Rs. 1 lakh each. In our view, both the fora have taken sympathetic view and awarded the compensation, however sympathy cannot substitute for conclusive evidence of medical negligence. In the instant case, the medical negligence could not be conclusively attributed against the hospital and the treating doctors."

Ref.: *https://medicaldialogues.in/news/education/ensure-proper-mechanism-for-scholarship-of-medical-dental-students-kerala-hc-directs-state-96185?infini...Accessed on 21/07/2022*

Relief To Anesthetist After 25 Years: NCDRC Holds Death Of Patient Post Surgery Not Conclusive Proof Of Negligence

New Delhi: Holding that simply the death of a patient is not a conclusive proof of medical negligence, the National Consumer Disputes Redressal Commission (NCDRC) bench recently exonerated Rajasthan Hospital and its Anesthetist from charges of negligence after around 25 years.

Although the complainant had claimed that the patient, who had been operated for intestinal obstruction, had suffered cardiac arrest because of the overdose of anesthesia by Dr Gauri Punjabi, the top consumer court clarified, "Simply because the patient died after a surgery is not a conclusive proof of alleged negligence."

"The operative notes clearly show that there was no complication during the surgery. The CPR was performed as per the standard protocol. Therefore, the allegation of medical negligence against the Opposite Parties is not sustainable," it further added.

The matter goes back to 1997 when the patient got admitted to Rajasthan Hospital after suffering from some digestive problems. Various tests including blood test,X-ray, electrocardiograph (ECG) had been conducted and the patient was discharged after a couple of days. However, the patient had to come back again and he had been operated for intestinal obstruction on 05.01.1998.

After the operation, while transferring the

patient suffered a sudden cardiorespiratory arrest at around 4.10 p.m. and he suffered the second arrest at around 7.45 p.m. and around 30 minutes later, the patient had been declared dead.

It was the contention of the complainant that the patient was young, around 32 years old at that time. He had good general condition and had been declared to be fit for surgery as per normal ECG and other reports. Therefore, the complainant alleged that his death during the operation was due to negligence and carelessness or overdose of anesthesia. Being aggrieved, the wife of the patient and other legal heirs filed the Consumer Complaint and prayed for Rs 10 lakh as compensation.

On the other hand, the Hospital and it's doctor denied any negligence during the treatment. They submitted that while the operation was uneventful, the patient had suffered cardiac arrest while being transferred from the operation theatre.

After taking note of the submissions and arguments, the State Consumer Court had dismissed the complaint as it had opined that the complainant had failed to prove negligence.

Therefore, challenging the State Commissioner's order, the complainant approached the NCDRC bench. The counsel for the Complainants argued that the State Commission had dismissed the complaint without considering the evidence on record. He further argued that even though the patient was normal, he had suffered three cardiac arrests due to negligence during surgery and by anesthetist.

It was further claimed that the hospital did not take any precautionary measures and the dead body had been brought out of the operation theatre. With this argument, the Complainants' counsel contended it to be a clear case of "Res Ipsa Loquitor". He also pointed out that post mortem was necessary in the case of unnatural death but it had not been performed.

The counsel for the complainants also argued that the State Commission had grossly erred to consider an expert report of Forensic Medicine Department of B.J. Medical College which speaks about negligence of the hospital. Further, they claimed that the deposition of expert in examination in chief and cross examination was not considered properly by the State Consumer Court.

However, the doctor and the hospital argued that there was no medical negligence during operation. They also submitted that the patient had suffered Cardio-respiratory arrests twice and the same had been treated as per standard resuscitative protocol.

Apart from considering the arguments, the top consumer court bench also perused the medical record and noted that the patient had been admitted in the hospital on 02.01.1998 with the complaint of recurrent pain in the abdomen since 15 days, acute pain for 7 days and vomiting, which was clinically suggestive of obstruction. Following this, the barium meal test confirmed obstruction in small intestine at multiple sites. Therefore, the doctor had carried out the intestinal resection anastomosis operation without any complications. The NCDRC bench also noted that the operation had been carried out with the surgical team work under vital monitors and there was no excess blood loss during the operation. After the patient suffered cardiac arrest, immediately cardiopulmonary resuscitation (CPR) was started and all the necessary treatment had been given to the patient including endotracheal intubation and cardiac massage.

The top consumer court also noted that the patient had been treated by a team of expert doctors belonging to the Hospital including a Senior Anaesthetist Dr. S. T. Multani, Dr. Rupalben and Dr. Punjabi. Although the patient had responded to the treatment initially, he started having a cardiac arrest and ultimately died.

It was further noted by the NCDRC bench that the complainant had filed a criminal complaint u/s 304 A. Consequently, the Investigating officer had referred the case to Forensic Medical Department of B.J. Medical College, Ahmedabad along with the application and the whole treatment

case papers, including the death certificate.

Following this, Assistant Professor Dr. Ganesh Govekar and Dr. V. R. Patil, Tutor in Forensic Medicine B.J. Medical College jointly opined "Death, in this case, is an un-natural death and can be due to surgical operation and/or anesthesia because all analysis report done before operation was normal."

Taking note of this, the NCDRC bench referred to the Supreme Court's order in Jacob Mathew's case, where the Supreme Court had laid down certain guidelines to govern the future prosecution of doctors for medical negligence allegations. Referring to this, the top court bench noted, "Simply because the patient died after a surgery is not a conclusive proof of alleged negligence. In our considered view the Opposite Parties had taken all necessary precautions before performing the surgery. The operative notes clearly show that there was no complication during the surgery. The CPR was performed as per the standard protocol. Therefore, the allegation of medical negligence against the Opposite Parties is not sustainable."

Therefore, exonerating the doctor and the Hospital from the charges of medical negligence, the top consumer court ordered, "Based on the discussion above, we find neither negligence nor deficiency in service of the treating doctors or hospital in the instant case. Accordingly, the First Appeal stands dismissed. There shall be no orders as to costs."

Ref.: *https://medicaldialogues.in/news/health/medico-legal/relief-to-anesthetist-after-25-years-ncdrc-holds-death-of-patient-post-surgery-not-conclusive-pro…Accessed on 21/07/2022*

Mop Left Inside Patient's abdomen During Whipple's Operation: Consumer Court Slaps Rs 5 Lakh Compensation On NIMS

Hyderabad: The State Consumer Disputes Redressal Commission in Telangana recently held the Nizam's Institute of Medical Sciences (NIMS) and it's HOD of Department of Surgical Gastroenterology, guilty of medical negligence for allegedly leaving mop inside a patient's abdomen while conducting Pancreatico - Duodenectomy (Whipple's operation) back in 2009.

Although NIMS denied any negligence, the State Commission opined that there was no other way to explain how the Mop was found inside the patient's abdomen two and half years after the first surgery.

Upholding the District Commission's order, the SCDRC has directed the Hospital and the doctor to pay Rs 5 lakh as compensation alongwith Rs 60,000 for medical expenses and Rs 3000 as costs to the patient within 45 days.

"Time for compliance of the order of District Forum is 45 days, failing which the awarded amounts (Rs.60,000/-+Rs.5 lakhs+Rs.3,000/-) will carry interest @ 7% p.a. till realisation," ordered the State Consumer Court.

The history of the case goes back to 2009 when the complainant was suffering from abdominal pain and for that she consulted doctors at NIMS. After undergoing several tests, she had been diagnosed with a Cystic Lesion of Pancreas (Uncinate). Therefore, the doctors advised her surgery for which she gave her consent. Consequently the doctors operated her and after a few days, she was discharged.

Two years after the surgery, the complainant developed unbearable abdominal pain and body pain and therefore she approached the local clinic at Warangal. After undergoing several tests, she had been informed that there was a tumor like object in the abdomen and another operation was necessary for the removal of the same.

Therefore, she underwent another operation at another hospital and was informed that there was no tumor but there was surgical Mop in the stomach, which allegedly was left behind during the previous surgery.

Following this, the complainant approached the District Forum and submitted that because of the negligent treatment of NIMS and it's

doctors, she had to undergo another life risk operation, suffer a lot of mental agony and sustain physical and monetary loss. Therefore, the complainant prayed for Rs 13,20,000 as compensation.

On the other hand, the NIMS and it's Doctor submitted that the complainant was in need of a complicated operation called Pancreatico - Duodenectomy (Whipple's operation). Submitting that all the major operation in the Department of Surgical Gastroenterology are done under the supervision of a senior consultant, NIMS further mentioned that at the end of any operation all the disposables and non disposables including surgical mops and instruments are accounted for and recorded.

Therefore, the hospital doubted the possibility of a mop being left inside the abdomen. The Hospital also pointed out that the patient did not suffer any permanent disability and submitted that a foreign body accidentally left in the abdomen, once removed will not leave any permanent disability.

NIMS further claimed that there was no negligence on the part of the treating doctors at any stage and reasonable precautions had been taken and the act that was totally accidental perhaps occurred for the first time when more than 25,000 major operations have been conducted. Denying any deficiency in the service, the hospital prayed for the dismissal of the complaint.

After considering the matter and the evidence, the District Forum allowed the complaint partly and directed the NIMS and it's doctors to jointly and severally pay the complainant a sum of Rs 60,000 for medical expenses incurred during the second surgery and another Rs 5 lakh towards compensation.

Aggrieved with the order, NIMS approached the State Commission and claimed that the allegation of finding a mop inside the patient's abdomen three years after the first surgery was without any basis and the complainant failed to submit any evidence to prove that the Mop was found in her abdomen.

It was further contended that the ultrasound did not reveal that there was a foreign body- like a surgical mop in the abdomen. NIMS argued that a CT Scan would have clinched the evidence since all the mops used at NIMS have a radio opaque thread embedded in them.

While considering the matter, the State Consumer Court of Telangana noted that the complainant had undergone her second surgery at Sakhamuri Narayana Memorial Nursing Home for the suggestions of cystic lesion arising from the pelvis leading to a suspicion of ovarian tumor.

The Commission also noted that the operation notes during the second surgery mentioned, "when the cyst was relieved from flimsy adhesion from parieties, it ruptured out along with plenty of pus coming out nearly 300 ml. of pus came out along with mop."

At this outset, the State Consumer Court noted, "It is evident that upon the second surgery, the 'surgical MOP' wad found that was left behind during the first surgery. This is further supported by the evidence submitted by Dr. H. Sandhya Rani" (who conducted the second surgery).

Dr. Rani had mentioned in her statements, "I found a well defined cystic mass completely occupying the pelvic region, few loops of small intestine adherent to the cystic mass, when the cyst was released from flimsy adhesions from parieties, it ruptured out along with plenty of pus coming out nearly 300 ml. of pus came out along with MOP (Cotton)."

Taking note of this, the Commission observed, "Although the Appellant/Opposite parties have urged the plea that MOPS were counted at the end of the surgery and found to be correct, we find this to be challenged in the face of the evidence and operation notes (Ex.B6) submitted by RW.4. There is no scope for the surgical MOP to be found at the site of surgery, unless appellants/opposite parties 1 & 2 had left it behind during the first surgery conducted on 3.11.2009."

The Commission further noted that Dr. Rani had stated in her evidence that the said material was sent to Histopathology Department for Examination. The necrotic material was foul smelling and covered by necrotic slough, but this report has not been filed.

At this outset, the bench referred to the order in the case of Shanti Thallapali & anr. vs. Surana Sethia Hospital & anr. and noted, "There is no evidence in the present complaint that the complainant had undergone any other surgical procedure between the 1st surgery at the appellants / opp.parties hospital and 2nd surgery at Sakhamuri Narayana Memorial Nursing Home on 22.7.2012, where the foreign body mop was detected."

Reference was also made to the top court judgment in the case of Jacob Mathews vs. State of Punjab & anr. and Achuthrao H. Khodwa vs. State of Maharastra, where the court had noted that a medical practitioner must bring to his task a reasonable degree of skill and knowledge and exercise a reasonable degree of care.

Thereafter, the State Commission observed, "the context of the case in hand, the presence of a foreign body left in the system/body during the surgery, clearly indicates that reasonable care was not taken and therefore it amounts to medical negligence."

"In this case the sponge was left negligently in the abdominal cavity of the complainant during the operation by the opposite parties. There was no operation in between 26.12.1997 and 6.4.1998. Apparently, the old retained sponge was that of the opposite parties," further noted the consumer court.

Addressing the contention that the Mop was not seen in any of the visual tests, the Commission observed, "A sponge/mop left for an extended period of time can create serious problems. The complainant underwent CT Scan and other investigative tests but the mop was not visualised . This imaging method is not helpful when these markers are disintegrated or fragmented. CT scan is the method of the choice for detecting gossypibomas and possible complications, but the reported C.T. appearances of gossypibomas are often not pathognomic and most of the times they are non -specific. In the instant case, the DoctorRW.4 has not visualised this owing to lack of clinical suspicions and familiarity with imaging features as stated in her cross examination."

Opining that there was medical negligence during the operation at NIMS, the Commission noted, "In general experience, accident in question does not happen without negligence. Mere allegations will not make out a case of negligence. However, in this case it is proved by reliable evidence and is supported by expert evidence. Doctor and hospital are liable for damages where foreign objects are left in the body after surgery. The principle of Res-ipsa -Loquitor comes into play and the burden is on the Doctor/ opposite parties to explain how the incident could have occurred without negligence."

Therefore, agreeing with the District Forum, the Commission noted, "In view of the afore a said discussion, we see no reason to interfere with the well appreciated order of the Forum below. Hence the order of the District Forum stands confirmed."

"Time for compliance of the order of District Forum is 45 days, failing which the awarded amounts (Rs.60,000/-+Rs.5 lakhs+Rs.3,000/-) will carry interest @ 7% p.a. till realisation," ordered the State Consumer Court.

Ref.: *https://medicaldialogues.in/news/health/medico-legal/mop-left-inside-patient-during-whipples-operation-consumer-court-slaps-rs-5-lakh-compensatio...Accessed on 21/07/2022*

Delay In Shifting Patient Is Medical Negligence: HC Holds Govt Facility Guilty, Directs Rs 5 Lakh Compensation To Patient Who Underwent Forceps Delivery

Chennai: Slamming a Mettupalayam based Government Hospital for failing to shift a patient to Coimbatore W Medical College Hospital, the

Madras High Court recently awarded Rs 5 lakhs compensation to a young mother who had to undergo three surgeries at a private facility after the hospital delayed discharging her to the better facility.

Although the petitioner had developed perineal tear after her forceps delivery, the Government facility did not shift her to Coimbatore immediately even though it could not provide adequate care to the patient.

Holding the hospital guilty, the bench comprising of Justice Mr. N Anand Venkatesh noted, "The 3rd respondent hospital, after having realised that the petitioner cannot be given adequate care in the hospital, should have immediately shifted the petitioner to the Coimbatore Medical College Hospital. In fine, this Court holds that there was a clear negligence on the part of the 3rd respondent hospital for not having taken proper care of the petitioner and for having failed to shift the petitioner to Coimbatore Medical College Hospital when the situation really warranted."

Back in 2005, the petitioner had been admitted to Mettupalayam Government Hospital for the delivery of her child. The Medical Officer of the Hospital, Dr. Tamilselvi had conducted the delivery and due to a last minute complication, the doctor had to use forceps and it required stitches.

It was alleged that from the next day of the delivery, pus was oozing from the surgical scars and the petitioner was experiencing difficulty in urinating and defecating. A few days later, the doctor removed the stiches and redid it once more. Despite this, the situation did not improve and pus continued to ooze out of the scars and in fact it was dribbling down the legs. The patient was experiencing extreme pain and hardship.

Since the patient's condition did not improve, the husband of the petitioner decided to discharge her from the hospital. However, the Medical Officer of the Hospital, Dr. Tamilselvi asked the petitioner to wait for a second surgery that would be performed by Dr. Ilanchezian, who was not readily available at that time. However, the petitioner's husband insisted for the discharge and following this, he took the petitioner to a private hospital immediately.

The private hospital allegedly informed the petitioner that her rectum had been badly injured. The reason for this was mentioned as forceps delivery and the fact that it had not been stitched and treated properly, resulting in infection. Therefore, the doctor at the private hospital informed the petitioner about the need for a three stage surgery required to address the problem.

Consequently, the first surgery was conducted within a few days of the delivery. Following this, the left leg of the petitioner began to swell and therefore, the patient had to be admitted in the vascular care centre for nearly 15 days. After the swelling subsided, the second surgery had been conducted in May 2006 and the third one in July 2006.

For these three surgeries, the petitioner allegedly had to pay Rs 1.5 lakh towards surgery expenses only, excluding the money required for medicine, rent and travel expenses. Apart from this, the petitioner suffered heavily since she could not take care of her new born child for nearly nine months.

Citing these reasons, the petitioner approached the Madras High Court and sought Rs 10 lakh as compensation and sought direction upon the Director of Medical and Rural Health Services to initiate appropriate disciplinary action against the doctor, who was allegedly negligent while performing the operation. However, the court noted that the second prayer was invalid since the doctor had died during the pendency of the plea.

On the other hand, the Director of Medical and Rural Health Services submitted that shifting to the private hospital had been the decision of the petitioner and her husband. Even though they had been advised to wait for a second surgery, they insisted for discharge.

Apart from this, the Director had also referred to the Inquiry report by the Joint Director

of Health Services, Coimbatore at Tiruppur. The concerned report had mentioned, "In my opinion there is a possibility of occurrence of complete perineal tear in the patient Mrs.Banupriya which can be treated and managed at Coimbatore Medical College Hospital, Coimbatore where there were enough facilities available. Under the above enough circumstances and on the basis of the opinion statement submitted by the expert doctors I am to conclude that No negligence is noticed on the part of Doctors who gave treatment to the patient and hence the question of rendering financial remedy to the petitioner does not arise."

The hospital and the doctor had also denied negligence on their part. It had been submitted by the hospital that the petitioner was alright for the first four days and after that she started having problems and it was found that there was a breakdown of muscle and skin layer which is a common complication for any surgical procedure depending upon the health. Following this, the patient had been put on higher antibiotics and the doctor had re-sutured the wound.

"Such repaired wound sometimes breaks down more than once, inspite of efficient and meticulous efforts requiring repeated repairs because of poor resistance power of the patient and proximity of the wound to anus which leads to all infections with known and unknown bacteria, some of which are resistant to all available antibiotics," submitted the hospital.

It was further claimed by the hospital that the petitioner's husband had allegedly insisted for the discharge of the patient even though the hospital had suggested referring the patient to Coimbatore.

After considering the submissions made by both the parties, the High Court bench noted that the Apex court has repeatedly held that a medical practitioner cannot be held to be negligent just because something went wrong while performing the procedure or surgery, inspite of the best efforts put in by the doctor and the doctor had exercised a reasonable degree of care, skill and knowledge as is expected under normal medical standards.

The HC bench noted that the doctor had performed episiotomy, a regular procedure adopted for normal vaginal deliveries. In this procedure, an incision is made on the vagina of the patient to make space at the outlet bigger for the baby to come out comfortably and to make the birth easier and in order to avert a possible brain damage for the baby.

Referring to the relevant medical literature, the bench observed that it is common for the perineum to tear to some extent during childbirth. In fact, tears can also occur inside the vagina or other parts of the vulva, including the labia.

Opining that the decision of forceps delivery was right on the part of the doctor, the bench noted, "It is clear from the above that the 4th respondent was forced to adopt this procedure since the baby's head was at the outlet and was not able to come out and the petitioner was not able to strain any further. That apart, the fetal heart rate was decreasing and in order to save the baby, the 4th respondent applied outlet forceps after giving episiotomy, whereby, the perineum was cut down to create space for the delivery of baby. This procedure adopted by the 4th respondent cannot be held to be negligent and she had taken the decision in the interest of the petitioner and her baby."

In fact, the court held that the doctor could not be blamed for the perineal tear as well. The court noted, "On going through the medical literature, it is seen that a perineal tear is not uncommon after an episiotomy procedure. In fact, there is a possibility of 4 degrees of perineal tear."

Referring to several degrees of the perineal tear, the bench noted, "It is clear from the above that complete perineal tear that resulted from the procedure, cannot be held to be negligence on the part of the 4th respondent doctor."

Therefore, exonerating the doctor from charges of medical negligence, the bench noted, "...this Court does not have the expertise to hold that the procedure performed on the petitioner by the 4th respondent resulting in the complete perineal

tear was as a result of insufficient care taken by the 4th respondent."

However, while considering the negligence on the part of the hospital, the bench noted that even though the hospital claimed that the advise for shifting to Coimbatore had been turned down by the petitioner's husband, nothing of this sort had been mentioned in the discharge summary. The court observed, "Even in the discharge summary, there is absolutely no reference to the effect that the petitioner was referred to the Coimbatore Medical College Hospital. It only states that the patient was discharged at request."

Finding fault with the hospital, the bench noted, "In the considered view of this Court, the 3rd respondent hospital was expected to take effective decisions since the situation faced by the petitioner could not be effectively handled in the 3rd respondent hospital. This became apparent even on 13.11.2005, when the petitioner was diagnosed with a complete perineal tear. At that point of time, immediate steps must have been taken by the 3rd respondent to shift the petitioner to the Coimbatore Medical College Hospital. This decision does not require the consent of the petitioner or her husband. The interest of the patient gains significance and to waste time for 3 more days till 16.11.2005, virtually gave an impression in the mind of the husband of the petitioner that effective steps are not being taken to treat the petitioner and he was a witness to the pain and agony undergone by his wife."

The bench further noted, "This situation could have been averted by the 3rd respondent hospital by immediately shifting the petitioner to the Coimbatore Medical College Hospital atleast on 13.11.2005 and all these procedures could have been done in that hospital. The delay on the part of the 3rd respondent which caused anxiety to the husband of the petitioner, should necessarily be held to be negligence on the part of the 3rd respondent hospital. The 3rd respondent hospital, after having realised that the petitioner cannot be given adequate care in the hospital, should have immediately shifted the petitioner to the Coimbatore Medical College Hospital."

"If this was not done and the 3rd respondent was waiting for the arrival of a doctor who had gone on leave, the petitioner cannot continue to face pain and agony and under the given circumstances, the husband of the petitioner thought it fit to shift the petitioner to a private hospital. In fine, this Court holds that there was a clear negligence on the part of the 3rd respondent hospital for not having taken proper care of the petitioner and for having failed to shift the petitioner to Coimbatore Medical College Hospital when the situation really warranted," it also observed.

Therefore, holding the Government hospital vicariously liable for negligence, the court awarded the petitioner with Rs 5 lakhs compensation and noted,

"The petitioner was admitted four times in the hospital to undergo three surgeries and to recover for her swelling of leg, in a vascular care centre. In this process, the petitioner was forced to spend money towards surgery expenses, medicine expenses, travel expenses and also rental expenses, when they were forced to stay at Sathyamangalam, till all the three surgeries were completed. That apart, the petitioner also faced untold hardship in not being able to take care of her new born baby effectively for nine months. In view of the same, this Court is inclined to fix a lumpsum compensation of Rs. 5 Lakhs payable to the petitioner."

Ref.: *https://medicaldialogues.in/news/health/medico-legal/delay-in-shifting-patient-is-medical-negligence-hc-holds-govt-facility-guilty-directs-rs-5-lakh-compensation-to-patient-who-underwent-forceps-delivery-97532 Accessed on 20/08/2022*

Patient Dies Of Cerebral Hypoxia: NCDRC Directs Ar my Hospital To Pay Rs 25 Lakh

New Delhi: The National Consumer Disputes Redressal Commission (NCDRC) has recently

directed the Army Hospital R&R, Delhi Cantt. to pay Rs 25 lakh compensation to the parents, wife and daughter of an Army Commissioner Officer for their negligence while treating the patient who had been admitted there, after facing a major road accident.

After considering the medical record and the case sheet it was held by the top consumer court that the patient suffered hypoxia due to failure in duty of care in the ICU. It noted, "As discussed supra (para 25) the doctors at AHRR failed in their duty of care towards the accident victim. It was a major accident and patient suffered facio-maxillay injuries. However, there was no evidence of head injury which was confirmed by CT scan and MRI. Thus, the root cause of hypoxia was failure in duty of care in the ICU. As discussed above the medical records are not convincing about reasonable standard of care exercised by the doctors and staff at AHRR. The records at places revealed tampering. The entirety attributes medical negligence of Opposite party No.1. The patient remained under treatment and hospitalisation for long period due to vegetative state."

The history of the case goes back to 2004 when the patient, who was working as a Commissioner Officer in the Air Force Hospital, met with a major road accident and suffered injuries on face and chest. After receiving first-aid treatment at the local hospitals including SMS Hospital, Jaipur, he had been airlifted to AHRR at Delhi Cantt and got admitted in ICU under Dangerously Ill List and was put on ventilator. There, the doctors had instructed for "Care of ET tube (endo trachial tube) connecting ventilator, and Regular Suction of ET (for clearing airways).

The doctors at AHRR noted that the patient had Maxillo Facial Injury, multiple rib fracture and undisplaced fracture C-2. Therefore, a doctor at the hospital had advised to maintain SPO_2 and watch for respiratory distress. On the same night, the patient was found to be in distress and restless and the SPO_2 decreased to 40%.

In the complaint, several allegations had been made against Dr Chaturvedi who allegedly supressed the real facts of the patient and falsely created the theory of "self extubation" for the purpose of eye wash of gross medical negligence committed in the AHRR.

The complaint further alleged that the AHRR case record was tampered at many places to cover up their gross negligence. It also pointed out that the entries of doctors at SMS Hospital and RR Hospital did not match. Referring to the diagnostic notes, the complainants claimed that the false insertion of 'head injury' in the hospital records was made by the Army Hospital.

Besides, the complaint referred to several other instances of negligence on the part of the hospital including administering expired medicine IV Astymin, wrong blood transfusion resulting in allergic reaction, negligence of staff resulting in the fall of patient from the bed and resulting in fracture of right arm and shoulder with severe bruises on back.

Following this, the patient had been prematurely transferred to Army Hospital at Hindon despite the fact that it had no Neurologist, no qualified Physiotherapist or no special attendant. Therefore, the physiotherapy stopped and the patient's body became stiff. Due to lack of physiotherapy patient's right leg became weak and got paralyzed.

Consequently, the patient had been taken to AIIMS but the Orthopaedic doctor in there suggested "No Ortho intervention is required" and referred the patient to PMR, discharged from AIIMS and consequently sent him back to Air Force Hospital. It was alleged that even though the USG done at Army Hospital showed renal stones, no treatment had been prescribed and later the patient had to undergo surgery for stones in PSRI through AHRR, Delhi Cantt.

Alleging negligence against the three hospitals- AHRR, Air Force Hospital and AIIMS, the complainant sought Rs 2,04,05,000 as compensation.

On the other hand, the hospitals denied any

negligence on their part and questioned the maintainability of the complaint as well. The Army Hospital submitted that AHRR was doing one of the soverign functions of the State. It argued that AHRR was not for commercial activity and therefore the complainant was not a consumer.

Air Force Hospital Hindon denied that untrained Physiotherapist had fractured patient's hip bone. It was further submitted that patient's management of kidney stone was done as per standard treatment protocols.

Meanwhile, AIIMS submitted that the complainant was not a consumer under provisions of the Act, 1986 since AIIMS does not levy any charge or receive consideration for the professional services. It was further submitted the allegations made against AIIMS and the treating doctors, are wholly wild, vague, mischievous/ scandalous and unspecified.

Reiterating the events, the father of the patient informed the Consumer Court that they had been informed that the patient pulled out the ET tube and as a result the oxygen supply was cut off and he suffered cardiac arrest. There was a gap of 20 minutes for resuscitation, which was long enough to develop cerebral hypoxia due to damage to the brain cells. Thereafter, the patient's condition started deteriorating, pulse rate and blood pressure were fluctuating and he showed more myoclonic jerks. After prolonged treatment for 2 months his vital parameters were under control but he did not regain consciousness.

He also claimed that the doctors at AHRR simply relied upon the CT scan done at SMS Hospital, Jaipur, but did not do MRI scan for such a long-time. Finally the MRI was done after a lot of persuasion and although it did not indicate any major defect in the brain, it indicated subdural hygroma (Water Accumulation) and ventricular dilation, which could be due to prolonged ventilation. He claimed that the Neurology Department did not take any efforts to rehabilitate the patient but openly told that patient had gone into coma due to brain injury and no chances of revival.

After taking note of the submissions, the NCDRC noted that the crux of the case was that at what time the patient suffered hypoxia. Therefore, the top consumer court perused the entire medical record, clinical notes and case sheet. Thereafter NCDRC noted, "The crucial entries of SPO_2 values on 15.05.2005 and 16.05.2005 are missing. Most of the entries are erroneous...clearly it shows haphazard maintenance of record. Even the daily progress chart was not properly maintained. The daily progress treatment chart dated 16.05.2004 or (Page 134) shows the SPO_2 values from 8.00 a.m. to 1.00 p.m. are not visible. We would like to quote that 'good medical record is good defence, poor medical record is poor defence and no medical record is no defence'. Thus, the poor record maintenance at AHRR becomes poor defence."

Referring to AHRR medical record, the bench further noted, "The dates in the case sheet are not matching with the sequence of treatment e.g. patient was treated in "2004", but most of the records show entry as "2005", [pg 50A – Part – I / Vol – II]. It creates strong doubt about tampering of record and/or prepared as fresh, afterthought."

Opining that there was medical negligence, the top consumer court noted, "Therefore, in our considered view, the patient had suffered hypoxia due to extubation for more than 5-10 minutes and it subsequently progressed into coma and patient became vegetative. It is also evident about number of glaring discrepancies in the recording of vital parameters, SPO_2 level. Improper and haphazard maintenance of medical record suggests about tampering. The patient kept under sedation and on ventilator support with regular suction. They performed trial extubations / intubations several times, resulted into coma. It is also evident that the patient fell down from the bed on 26.02.2005 and sustained fracture of right arm and shoulder, it further prolonged hospitalisation."

While elaborating on the idea of medical negligence, the NCDRC bench referred to Supreme Court's observations and judgments in the case of Kusum Sharma and others v. Batra

Hospital and Medical Research Centre & Others, Dr. Laxman Balakrishna Joshi vs. Dr. Trimbak Bapu Godbole & Anr, and A.S. Mittal vs. State of U.P. that talk about the duty of care expected from the doctors. Referring to these the bench noted,

"Let us examine the case on hand, whether there was any breach of duty by Opposite Party No. 2. The question remains unanswered how and why self extubation occurred in ICU. The expected duty of care in the ICU is highest one especially at AHRR, which is a tertiary care hospital. Admittedly in the ICU, patient suffered cerebral hypoxia which led him to vegetative stage till his death. It reflects the breach/lack of duty of care from the hospital materially contributed to the damage, that is usually sufficient to attribute negligence. As HBOT treatment (75 runs) at Apollo Hospital, there were signs of improvement, but further treatment was stopped due to lack of funds. For the same reason, the patient could not go for higher treatment to USA also. During hospitalisation the patient sustained fracture of right shoulder and further developed large bedsore." "As discussed supra (para 25) the doctors at AHRR failed in their duty of care towards the accident victim. Though it was major accident, patient suffered facio-maxillay injuries but, there was no evidence of head injury which was confirmed by CT scan and MRI. Thus, the root cause of hypoxia is failure in duty of care in the ICU. As discussed above the medical records are not convincing about reasonable standard of care exercised by the doctors and staff at AHRR. The records at places revealed tampering. The entirety attributes medical negligence of Opposite party No.1. The patient remained under treatment and hospitalisation for long period due to vegetative state," it further noted.

While determining the amount of compensation, the NCDRC bench took note of several factors including the fact that the patient had died at the age of 32 years, had earned several certificates for meritorious services, left behind his parents, wife and a daughter etc. Therefore, the bench noted,

"Based on the discussion above and respectfully following the precedents of Hon'ble Supreme Court, in the ends of justice a lump sum compensation of Rs. 25 lakh is just and fair in the instant case. Accordingly, the Complaint is partly allowed. The Opposite Party No. 1 is directed to pay Rs. 25 lakh with interest @ 9 % per annum from the date of filing of this Complaint till its realisation to the Complainants. The amount awarded shall be shared / devolve among the Legal Heirs as per Hindu Succession (Amendment) Act, 2005."

Ref.: *https://medicaldialogues.in/news/health/medico-legal/patient-dies-of-cerebral-hypoxia-ncdrc-directs-army-hospital-to-pay-rs-25-lakh-97534?infinitescroll=1 Accessed on 20/08/2022*

Eye Hospital, Ophthalmologist, Anaesthetist Directed Rs 1 Crore Compensation 22 Years After Patient Died During Squint Eye Correction Surgery

New Delhi: Holding an eye hospital, its operating Ophthalmologist and anaesthetist guilty of medical negligence while conducting squint eye correction surgery, the National Consumer Disputes Redressal Commission (NCDRC) has recently directed them to pay Rs 1 crore compensation to the parents of a patient, who died on the operation table.

The top consumer court held the anesthetist guilty for not warning the operating surgeon about possible reaction from a medication and also held the hospital vicariously liable for the death of the patient 22 years ago.

The son of the Complainants, who was about 6 years of age back in 2000, had been taken to Chennai at Sankar Nethralaya. After examining the patient, Dr. S Agarkar had advised a minor surgery to correct the squint. She had proposed the name of Senior Surgeon - Dr. T. S. Surendran for the operation.

After preoperative investigations, blood and urine tests, a doctor had noticed faint functional systolic 'murmur' and chest wall

abnormality. The same was brought to the notice of Dr. S. Bhaskaran, a Senior Cardiologist, who further examined the child with some exercises and concluded about no murmur and he also ruled out further need for any tests like ECG, ECHO or Chest X-ray etc.

Therefore, the child had been declared to be "Fit for General Anesthesia" and before the operation, the child had been administered three injections at around 3.00 p.m. on 14.06.2000. Around three hours later, the complainants had been informed about the death of the child on the operation table.

Further they alleged that the hospital had issued patient's case summary after two days and the discharge summary was vague without any details of Cardio Pulmonary Resuscitation (CPR) and the happenings in the Operation Theatre. Despite repeated requests, the doctors had failed to provide the complete medical record. Therefore, the Complainants had approached the Prime Minister's Office and finally after six months entire medical record including the Post mortem report had been handed to the Complainants.

Apart from this, it was further alleged by the complainants that there was excessive gap between the last oral intake and commencement of the surgery. Thus, the child was kept on fasting for 9 hours 20 minutes, due to which he became hypoglycemic, which could lead to cardiac arrest. Halothane was used as an anesthetic agent which was known to cause bradycardia (heart rate slows down). Atropine was given as a pre-medication in all the cases to prevent bradycardia.

Therefore, the child was not administered the correct dose at the right time and there was a huge gap between atropinization and actual surgery. The Anesthetist failed to intubate, which was the cause of death. Besides, the Complainants claimed that on that very day, Dr. T. S. Surendran had already completed 16 operations and there was no hurry to operate on the child on the very day itself, wherein high degree of care was needed.

It was argued by the Counsel for the Complainants that the squint surgery was an elective surgery and not an emergency. The Counsel contended that the operating surgeon was unaware about the special warnings for using Scoline in pediatric cases and the anesthetist failed to warn to the surgeon about it. Besides, the Counsel for the complainants referred to the fact that the deceased was the only child and the mother already underwent hysterectomy in 1997, therefore losing her chance of another child.

On the other hand, the doctors and the hospital filed their replies and denied allegations of negligence. However, they expressed their deep sympathies for the death of patient. It was submitted that as per medical guidelines, routine pre-operative ECG, ECHO and X-ray were not necessary for children and persons below the age of 40 years except medically warranted.

The hospital submitted that it was equipped with all the infrastructure and operation theatre (OT) including monitor, centralized Oxygen and all facilities for administering GA or any type of anesthesia for performing squint surgery. Referring to the procedure of operation, the hospital submitted that all the procedures had been followed including CPR, cardiac thump, external cardiac massage and DC shock for reviving the patient. Dr. S. Bhaskaran, Cardiologist joined in the resuscitation efforts. In spite of all resuscitative measures, the patient could not be saved.

The Government of Tamilnadu, in response to the representation made by the Complainants to the Prime Minster and the Railway Minister, appointed four - committees to enquire the matter. After enquiry, the committees did not observe any adverse comment or report on the hospital facilities and on the treatment aspect. The death had occurred due to cardio-respiratory arrest.

The Counsel for the hospital and doctors submitted that the entire treatment had been done as per the standard of practice. Further, the treatment had been reviewed by four independent committees of experts who had not made any adverse comment or report on the treatment aspect

and hospital facilities etc.

After considering the submissions by both the parties, the NCDRC bench perused the entire material on record including the Medical Record for the concerned case.

While considering the role of the cardiologist, the Commission noted that "No doubt, the child was about 8 years and school going, there was less possibility of congenital anomaly. But, we cannot ignore that the child was suffering from bilateral squint and chest deformity, which were congenital anomalies. Therefore, the cardiac anomalies cannot be ruled out in this case. Moreover, if one physician (MD) notices functional murmur, then the expected skill from the Super Specialist i.e. the Cardiologist was more and higher degree of care should be there. It is lacking in the instant case and unfortunately, the child was declared fit for GA."

In this regard, the Commission referred to the opinion by Dr K P Mishra, a senior Cardiologist who had supported the method of diagnosis by the concerned Cardiologist. However, the NCDRC bench noted, "We do not accept the evidence of Dr. Mishra in totality for the reasons stated in para (I). In our view, it was the failure of duty of care and the casual approach of the Cardiologist. Moreover, the entries made in the progress report appear to be an afterthought and added later on."

Further referring to the medical procedure, the Commission observed, "We do not find any significance about fasting state of child. Several studies revealed that there is no uniform fasting practice for children before effective surgery. Fluids in small quantity are acceptable 2-3 hours prior to GA. The complainant No.2 (father) signed the Informed Consent. The child was not administered Atropine in correct dose at proper time. We don't find importance to the pre-medication by Atropine for Antisialagogues to decrease the flow rate of saliva is not routinely used. In the recent days it is not regularly in practice by the Anesthetist."

When the bench considered the process of intubating the child, it noted, "In the instant case, as the vocal cord was anterior, it was not possible to intubate the patient in the first attempt. It is not clear from the record that Scoline was administered before first intubation, as such the possibility cannot be ruled out." "...it is pertinent to note that use of Scoline further precipitated the bradycardia which was already occurred due to Halothane anesthesia," it further observed.

The Commission opined, "In our considered view it was the Oculocardiac Reflex (OCR), also known as the Aschner reflex or trigeminovagal reflex (TVR). It is a reduction in the heart rate secondary to direct pressure placed on the eyeball. It is defined by a decrease in heart rate by greater than 20% following globe pressure or traction of the extraocular muscles. Most commonly, the reflex induces bradycardia. However, OCR also has a reported association with reduced arterial pressure, arrhythmia, asystole, and even cardiac arrest. This reflex has most notably been depicted during ophthalmologic procedures, more specifically during squint / strabismus Ocular Surgery...Therefore, in the instant case the Intra-Operative diagnosis of OCR was missed and the child suffered Cardiac Arrest. The patients who are considered at-risk for the OCR should warrant particular attention."

Further the Commission noted that "all drugs used in anesthesia have adverse minor to major life threatening complications. Anesthetists are aware of such effects and use the drugs depending on the patient, nature and requirements of surgery, disease profile and the situation."

Referring to the medical record, the Commission expressed its confusion regarding giving the patient Atropine and how it was administered. "The failed intubation cannot rule out possibility of wrong intubation (in the esophagus). After failed 1st intubation, Scoline was injected for 2nd intubation and then child suffered hypoxia bradycardia and arrest. In our view it was the effect of Halothane and Scoline. The anesthetist (OP-3) should have alerted/ cautioned the

operating surgeon (OP-2) about the warning signs of Scoline. The surgeon was not aware about any special warnings for the use of Scoline in pediatric cases," further noted the consumer court.

Apart from this, the top consumer court also agreed with the complainant's Counsel that "surgery could have been abandoned." Referring to the busy schedule of the operating surgeon, the Commission noted,

"Therefore, the question arose in our mind why the squint surgery was not deferred to another date. Moreover, it was a planned surgery and there was not an emergency at all or the Complainants have not forced for it. The child was not co-operative. Halothane was used as an anesthetic agent, a known hypotensive. During the procedure, after removal of halothane and nitrous oxide mask, there was difficulty in intubation. The 1st attempt was failed and therefore, the Opposite Party No. 3 intubated by injecting a relaxant- injection Scoline, which also induces bradycardia. Thereafter, there was reduction of oxygen saturation and the child suffered cardiac arrest. The discharge / death Certificate did not mention about intubation for general anesthesia."

At this outset, the Commission referred to the laws laid down by the Supreme Court regarding medical negligence in the case of Kusum Sharma and ors v. Batra Hospital and Medical Research Centre & Ors., Dr. Laxman Balakrishna Joshi vs. Dr. Trimbak Bapu Godbole & Anr, and A.S. Mittal vs. State of U.P.

Thereafter, holding the Hospital vicariously liable for the acts of medical negligence committed by the doctors, the commission observed,

"...when a patient goes to a hospital, he/she goes their on account of the reputation of the hospital and with the hope that due and proper care will be taken by the hospital authorities. If the hospital fails to discharge their duties through their doctors, being employed on job basis or employed on contract basis, it is the hospital which has to justify the acts of commission or omission on behalf of their doctors."

Considering the fact that there was no chance for the mother of the deceased for having another child, and also after taking note of the fact that the litigation was pending for 20 years, the Commission awarded the Complainants with Rs 1 crore compensation and noted, "In the instant case, since, the Cardiologist – Dr. Bhaskaran has not been arrayed as a party, therefore, monitory liability cannot be fixed upon him, and therefore, the OP-1 is held vicariously liable. Accordingly, we direct the Shankara Nethralaya (OP-1) to pay Rs. 85 lakh; the Anesthetist, Dr. R. Kanan (OP-3) shall pay Rs. 10 lakh and the operating Ophthalmologist, Dr. T. S. Surendran (OP-2) shall pay Rs. 5 lakh to the parents of the deceased child (Complainants) within 6 weeks from today. Beyond 6 weeks, the amount shall carry interest at 9% per annum till its realization. The OP-1 shall further pay Rs. 1 lakh towards cost of litigation."

Ref.: *https://medicaldialogues.in/news/health/medico-legal/eye-hospital-ophthalmologist-anaesthetist-directed-rs-1-crore-compensation-22-years-after-patient-died-during-squint-eye-correction-surgery-98544 Accessed on 08/09/2022*

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LIFE MEMBERSHIP FORM

Name of the applicant : _____
(Surname) (First name) (Middle name)

Date of Birth : _____ Sex : _____

Address for Correspondence: _____

_____

Telephone No.s : Resi. : _____ Hosp. : _____ Other : _____

Mobile : _____ Fax : _____ E-mail : _____

Name of the Council (MCI/Dental/Homeopathy/Ayurved /Other) : _____

Registration No.: _____ Date of Reg. : _____

Medical / Legal Qualification	University	Year of Passing

_____ _____

Name, membership No. & signature of proposer Name, membership No. & signature of seconder :

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If, Yes (Give details) _____ (Attach separate sheet if required)

C) Do you have a Professional Indemnity Policy (Yes / No) : _____
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F) Is your relative / friend practicing Law (Yes / No) : _____
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G) Any other information you would like to share (Yes / No) _____ If Yes, please attach the details
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I hereby declare that above information is correct. I shall be responsible for any incorrect / fraudulent declarations.

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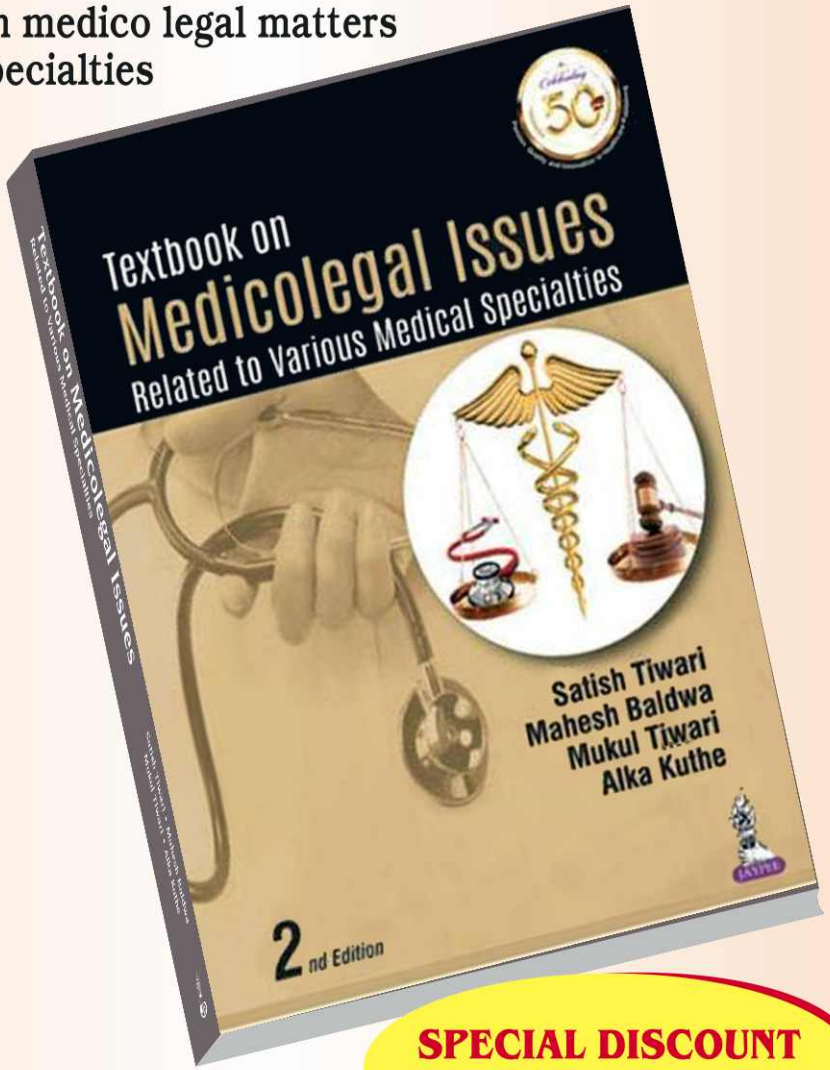

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