FROM THE PRESS

Negligent doctor brought to book after 12 years

Twelve years after a patient died during treatment, the National Consumer Disputes Redressal Commission asked an Ahmedabad-based doctor to pay Rs 2.5 lakh to the deceased's mother in compensation for medical negligence.

Prakash Kushwaha died after being administered medicine in the polyclinic of Dr Arvind Shah. His mother approached the State Consumer Redressal Commission with the complaint that the doctor had failed to record a provisional diagnosis of her son's ailment before prescribing treatment. She was awarded Rs 5 lakh in compensation, but the doctor went to the national commission to challenge the state commission's decision.

The national commission upheld Ms Kushwaha's case though it reduced the compensation awarded to her. It held the doctor "clearly guilty of serious deficiency in service (medical negligence) in not issuing a prescription for the treatment of Prakash on 4.09.1997 and then not recording his diagnosing Prakash's ailment in the prescription(s) of 6.09.1997."

The commission also stated that it was "in the interest of both parties, particularly a reasonably competent doctor to record a prescription mentioning the patient's history of complaints, current symptoms, his vital parameters and other clinical observations and a provisional diagnosis..."

Express News Service. Doc to pay Rs 2.5 lakh compensation for negligence. *Indian Express*, June 4, 2009.

Rs one crore compensation for botched surgery

The Supreme Court ordered the Nizam Medical Institute of Hyderabad to pay a record compensation of Rs one crore to a victim of medical negligence. Bangalore-based engineer Prashanth S Dhananka was operated on for removal of a benign tumour in his chest. A mishap during surgery led to his becoming paralysed waist down.

In 1993, the National Consumer Disputes Redressal Commission ordered the institute to pay Dhananka compensation of Rs 15 lakh. The institute challenged the order, while Dhanaka contended that the compensation was too little. After cross appeals from each party, the Supreme Court ordered a compensation of Rs one crore.

The court stated that the compensation amount was justified "keeping in mind that a brilliant career has been cut short and there is, as of now, no hope of improvement in his physical condition." It awarded Rs 25 lakh for the loss of his prospective earnings, another Rs 25 lakh for his medical care, Rs 10.8 lakh for his physiotherapy, and Rs 14.4 lakh for his nursing and care, among other costs.

IANS. Court orders Rs 10 mn compensation for medical negligence. *Hindustan Times,* May 14, 2009

CCTVs to prevent theft of babies

The Mumbai Municipal Corporation has indicated that it will install closed circuit televisions in maternity wards to prevent the theft of newborns from its hospitals.

The corporation was responding to a petition in the Bombay High Court filed by Mohan and Mohini Nerurkar whose four-day-old baby boy was stolen from the Lokmanya Tilak Municipal General hospital in January this year. The parents allege that the infant was stolen from the hospital ward when the mother had gone to the restroom to wash the boy's clothes.

The court asked for suggestions on how to prevent baby theft.

In response, the hospital dean, Sandhya Kamat, suggested CCTV cameras, employing female security guards in maternity wards, a computerised biometrics entry system to record the fingerprints of every mother and child, LCD screens to display important messages, and restricting new mothers to the ward except for essential tests. The Nerurkars' lawyer suggested matching identification bands for infants and parents, and detailed assessments of babies at birth.

Hetal Vyas. BMC's formula to prevent theft of newborns. *Mumbai Mirror, May 5, 2009*.

Charitable hospitals: no tax exemptions on clinical trial revenue

Public hospitals and speciality healthcare and research institutions operated by charitable trusts may no longer avail of tax exemptions on revenue they earn from performing clinical trials, a profitable and growing business opportunity.

An amendment to section 2(15) of the Income-tax Act that came into force in April stripped such institutions of the tax breaks that they enjoyed even while conducting such research for commercial gains, often for overseas drug companies.

The amendment was made because a number of institutions engaged in commercial clinical trials were claiming tax exemption on the ground that these trials were in the public interest.

C H Unnikrishnan, Khushboo Narayan. Charitable hospitals may face I-T scan. *Mint*, May 4, 2009.

No action against illegal trials at government hospital

On April 2, police registered a complaint against a government doctor in Gujarat, for conducting clinical trials for private companies without ethics committee clearance or supervision.

Dr Amul Bhattacharya and three others at the Guru Govind Singh Hospital in Jamnagar, Gujarat, used hospital equipment and staff services for their business.

According to one account, the authorities learned of the illegal trials after Dr Bhattacharya was transferred to Vadodara. The Mumbai-based Glenmark Pharmaceuticals was running trials at the hospital and a hospital official was approached regarding a replacement.

Bhattacharya has stated that the authorities were aware of the trials. However, members of the institutional ethics committee, including the hospital superintendent and the dean of M P Shah Medical College, say Bhattacharya forged documents to get the contract from Glenmark.

Glenmark has reportedly closed down its clinical trial site at the GG hospital and asked the Drugs Controller General of India to conduct an audit.

Express News Service. Mystery shrouds illegal drug trial at G G Hospital. *Indian Express*, April 5, 2009.
Hiral Dave. Trial trail: No action yet on illegal clinical research in govt hospital. *Indian Express,* May 3, 2009.

Self regulation

On April 19, 2009, doctors, nurses, hospital administrators, patients' groups and NGOs, met at the KEM Hospital in Mumbai to launch a patient safety initiative under the aegis of the World Health Organization's "World Alliance for Patient Safety".

This nationwide patient safety movement would involve a confidential mechanism for hospitals to report errors. The Indian Confederation for Healthcare Accreditation plans to lay down healthcare standards, train employees of hospitals, nursing homes and clinics in spotting medical errors and adverse reactions, and encourage them to report such incidents in order to create an Indian database.

Monitoring frequently occurring errors would enable hospitals to modify practice guidelines and train staff in safe procedures. However, doctors are reluctant to report errors as they fear legal cases. And few victims of error are able to fight legal battles. A voluntary, in-house, confidential error reporting system could reduce error without penalising the person who reports it.

Many questions remain. How will such self-monitoring be carried out in over-crowded public hospitals? How will the unregulated healthcare sector be monitored? What about unregistered services? Still, the patient safety initiative is a bold step forward for accountability in the healthcare system.

Express News Service. Finally, an initiative to encourage hospitals to report medical errors. *Indian Express*, April 20, 2009.

Tata Hospital's 100 crore cancer drug scandal

At least 26 patients admitted to Mumbai's Tata Memorial Hospital during 2007-08 consumed cancer medicines after their death - if one goes by the memos issued by hospital staff. This and other facts came to light after the Central Bureau of Investigation (CBI) began investigating a Rs 100 crore drug scam that it believes has been going on for five years.

One of the medicines illegally sold outside is "Fungizone" which costs Rs 6,000 to Rs 15,000 a dose.

The CBI has filed cases against six hospital staffers after being tipped off by the father of a patient that cancer medicines from the hospital were illegally sold in the open market. These medicines were meant either for free distribution or to be given at discounted rates to patients. They were issued by forging memos in the names of dead patients, or relatives of other patients, without their knowledge. Some prescriptions contained the forged signatures of doctors - at least 45 such prescriptions in 2007-2008.

During inquiries from hospital records and staffers who were raided, the CBI found that the medicines were issued in the names of dead patients up to 145 days after their death. The CBI's figures are only for one year and the scam is believed to be at least four years old.

It will take some time to go through all the memos to see how many were forged. The hospital issues 300-400 every day, or up to 1,46,000 every year.

Times News Network. 100cr scam in Tata cancer hospital. *The Times of India*, May 16, 2009.
M Pachouly. '26 dead patients consumed medicines'. *Hindustan Times*, May 19, 2009

Gujarat cancer institute faces charges of illegal trial

In April 2009, LambDa Therapeutic Research Limited, a contract research organisation, shut down its trial site at the V R Desai Cancer Research Institute in Rajkot following reports that the trials being conducted there were illegal.

This was done following complaints that commercial trials were being conducted at this trust-run hospital. The income tax exemption given to trust-run hospitals can be cancelled if they are found to engage in commercial clinical research.

Kishore Ghia, a hospital trustee, who registered the complaint with the state medical services department, also noted that the hospital research ethics committee did not share basic details on the trials it approved.

In January, A Buch, professor with the Rajkot Medical College, resigned from the post of chairperson of the hospital research ethics committee as the hospital's managing body refused to make public information on the names of the drugs being tested, the drug companies involved, the number of trials conducted and the number of people in these trials.

Hiral Dave. Multinational research company shuts unit at Rajkot hospital. *Indian Express*, May 5, 2009.

Independent US IRB suspended by the FDA

In the US, an independent review board got caught in a government sting operation to see how well such review

committees evaluate the proposals sent to them. Coast Independent Review Board (CIRB) reviewed and approved a sham trial involving a make-believe surgical product with non-existent doctors.

"Independent review boards" get paid by drug and device companies to review proposals and monitor trials. These review boards are meant to ensure the ethical and safe conduct of clinical trials. The worry is that since commercial review boards depend on payments from drug companies, they may be too accommodating of these companies.

Undercover government investigators created a proposal for a sham trial that was to be run by doctors who did not exist. They sent these documents out to a number of commercial boards. CIRB approved the proposal.

CIRB monitors some 300 clinical trials for drug and device manufacturers. The company agreed to temporarily suspend approving new government-regulated medical studies and enrolling new patients in on-going studies.

CIRB's revenue more than doubled, to $9.3 million, between 2004 and 2008. It was revealed that the company reviewed 356 study proposals over a five-year period and rejected only one of them.

Barry Meier. Overseer of medical trials, under FDA pressure, agrees to suspension. *The New York Times*, April 16, 2009.

Developing countries will be worst hit by pandemic flu

The pandemic flu poses a double burden in developing countries: poor people may be more vulnerable to serious infection even as they have less access to effective drugs and vaccines.

Sangeeta Shashikant of the Third World Network fears that agreements between rich countries and drug companies could deprive people in poor countries.

The antiviral drugs Tamiflu (Roche Holding AG) and Relenza (GlaxoSmithKline) have worked against the current strain of pandemic flu. But there are limited stocks and definitely not enough to treat the whole world in a pandemic.

Shares in Roche and Glaxo rose 4% and 5% in European trading on expectations that these companies would benefit as governments and corporations ordered their drugs.

Generics may be the answer, and there are at least five companies in India and China manufacturing generic versions of oseltamivir, or Tamiflu. More generic competition will make the drug even cheaper, increasing the drug's availability in poor countries.

Poor countries may also find it difficult to get vaccines, said Sangeeta Shashikant of Third World Network. "You need production for developing countries and access to technology."

Indonesia created a diplomatic uproar during fears of a bird flu pandemic three years ago; it refused to share virus samples without a guarantee that poor countries would be assured the vaccines developed from these samples, and at affordable prices.

Developing countries are most vulnerable to the pandemic flu, as poor populations are already weakened by malnutrition, chronic conditions like asthma and diabetes, or low immunity due to HIV/AIDS. The problem is compounded by weak health systems.

The United Nations secretary-general Ban Ki-Moon noted that "Poorer nations are especially vulnerable. They have been hit hard by other crises this year: food, energy, the global economy, climate change. We must ensure that they are not also hit disproportionately hard by a potential health crisis."

Reuters. Developing nations could face flu drug shortages. April 28, 2009. Third World Network http://www.twnside.org.sg/title2/intellectual_property/info.service/2009/twn.ipr.info.090403.htm

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