

Can TV serials violate the law?

Recently, the widely-watched TV serials *Kyunki Saas Bhi Kabhi Bahu Thi* and *Kudrat* had doctors informing parents-to-be of the sex of the foetus. As the largest public service broadcasting unit, Doordarshan has a strict code for programmes and advertisements, with two preview committees to weed out 'objectionable' material in serials before telecast. Interestingly, they didn't find anything objectionable with *Kudrat* serial.

Anuradha Raman Now DD's *Kudrat* in spot over sex test. *Indian Express* May 17, 2002. www.indian-express.com/full_story.php?content_id=2903

Doctor on 'public trial'

In the government hospital at Ernakulam, Kerala, a gynaecologist nearing retirement was forced to undergo a 'public trial' by Yuvajana Vedi activists for demanding bribes from her patients. This turned violent and police intervened and arrested the activists. A few days earlier, angry relatives had locked the doctor up in the hospital when she demanded a bribe from a woman who had come for delivery. The state government suspended Dr Jameela on the basis of a vigilance committee's report investigating the alleged bribery. The hospital staff went on a flash strike protesting against the harassment caused to the doctor.

Vedi activists hold 'public trial' of doctor. *The Hindu*, May 30, 2002.

www.hinduonnet.com/thehindu/2002/05/30/stories/2002053005300400.htm

Rigorous imprisonment for negligence

In a landmark judgement, the Kolkata high court sentenced two leading medical doctors to three years' rigorous imprisonment and a fine of Rs 3,000 for negligence leading to the death of Anuradha Saha, wife of Kunal Saha, a non-resident Indian.

During the Sahas' visit to India in May 1998, Anuradha suffered a skin ailment for which she was reportedly attended to by Drs Mukherjee, Haldar and another physician, Abani Roy Chowdhury. When her condition deteriorated, she was shifted to Mumbai, where she died. Saha filed a case against the three doctors in the city's Alipore Court and the West Bengal Medical Council (WBMC).

The court held Mukherjee and Haldar to be guilty (Roy Chowdhury was let off for lack of evidence) as they did not follow current practice in the administration of a cortico-steroid. They continued the same treatment even when the patient's condition worsened and made no attempt to inquire if the treatment was taking effect. This constitutes not just medical negligence but a reckless and uncaring attitude and a refusal to consider that the doctor's diagnosis may have been incorrect.

Incidentally, the WBMC said it could not act on the complaint because it had not received the papers. However, Saha produced receipts from the courier company proving delivery of the documents in question.

The West Bengal unit of the Indian Medical Association said the court judgement would impair medical practice and that medical councils and associations should have been left to decide the matter. The Kolkata chapter of the IMA has decided to involve itself in the Saha case if it goes to a higher court.

Editorial *EPW*. Medical practice: shirking responsibility. June 8, 2002

Rape in hospital

The alleged rape of a 23-year-old woman patient with 60% burns, by an outsider at Kozhikode Medical College Hospital, has shocked everyone here.

Hospital authorities say the woman's relatives had called in an outsider, Subramanian, to give her a bath though instructions on the patient's case-sheet did not permit a bath.

The victim stated to the investigating officer that she was raped, and medical and laboratory investigations confirm that she was sexually assaulted. The police have arrested the accused and booked him under Sections 376 (rape) and 377 (unnatural sexual offence). Two nurses were placed under suspension. In a curious turn of events, the State Women's Commission chairperson claimed that the victim told her she was not raped.

The Women's Commission, the state human rights commission and the Assembly committee are investigating. The nurses association is protesting that they have been blamed unnecessarily. Opposition parties have demanded a judicial probe, the state youth wing of the Democratic Youth Federation of India is demanding action against hospital authorities, and neighbours from the victim's village are demonstrating for justice.

The Hindu. Rape case: 'test report getting delayed' July 2, 2002. Rape case: Minister promises to take action July 19, 2002. Rape incident: two nurses suspended. July 20. Political colour to a human tragedy. July 27, 2002

The kidney trade in Kerala and Tamil Nadu

Frontline's on-going investigation into the kidney trade has produced two more reports documenting the collaboration between doctors, brokers, patients, the state authorisation committee, and various other commissions and medical associations.

A racket in illegal kidney donations emerged from Kerala, a state hitherto considered free from such types of exploitation, when a Malayalam daily reported that middlemen were buying kidneys from poor tribals in Idukki district to sell to critically ill renal patients in private hospitals in Kozhikode. Two tribal men stated at a press conference that they were duped into selling their kidneys with promises of Rs 3 lakhs each. In Tamil Nadu, the Chennai police arrested a Mr Mahalingam on a complaint made by a Mr Dhileep – the complaint being that Mahalingam had not delivered on his promise of supplying a kidney. Mahalingam turned out to be a broker of kidneys.

The latest investigations also provide clear evidence of a cover-up by state-level authorisation committees set up to prevent trade in human organs.

R Krishnakumar. Kidney racket in Kerala. *Frontline* 2002 July 6; 19(14). A Krishnakumar Kidney commerce in Tamil Nadu *Frontline* 2002 August 31; 19 (18). www.flonnet.com/kidneytrade.htm (check)

Approved drug, unapproved use

Dr P K Rajiv of the Amrita Institute of Medical Sciences, Kochi, Kerala, used the active component of the drug Viagra (sildenafil citrate) to save critically-ill new-borns with pulmonary hypertension. The drug is approved for treatment of male erectile dysfunction.

The infants were on ventilators to assist breathing, with nitric oxide to keep their the blood vessels dilated. Dr Rajiv based his medical treatment on a paper in the journal *Circulation* which suggested that sildenafil citrate could also act as a pulmonary dilator in children. The infants improved rapidly after a small dose of sildenafil citrate was added to the standard treatment.

However, the hospital did not have the Drugs Controller of India's permission to use the drug on sick new-borns. Nor had scientific evidence of its pulmonary vasodilatory actions been established. Dr Rajiv justified his disregard for regulatory requirements saying the infants were "near death", and ventilatory and nitric oxide support

was very costly.

Pallava Bagla, Baby dying so doctor says he 'broke' rules. Viagra: Opens an untested door, *Indian Express*, New Delhi, July 10, 2002.

Doctors help one another...

The National Consumer Disputes Redressal Commission upheld the order of the Maharashtra State Commission holding Dr Janak Kantimathi Nathan and Shushrusha Citizens' Co-operative Hospital Ltd guilty of medical negligence.

In December 1992, Dr Nathan was consulted for a second opinion on 13-year-old Amit, who was suspected of having epilepsy. Dr Nathan changed the medication. Amit developed a rash so the medication was changed once more. However, his condition worsened. On the night of January 4, 1992, he developed severe convulsions but Dr Nathan refused to see him as he did not see patients on weekends. Amit was taken to a nursing home, where Dr Nathan was contacted; he advised continuance of the prescribed treatment. On January 6, 1992, Amit was shifted to Shushrusha Hospital under Dr Nathan, but passed away two days later. The cause of death stated in the death certificate was terminal cardio-respiratory arrest on account of septicemia, preceded by viral encephalitis.

According to the complainant, as soon as the medications prescribed by Dr Nathan were administered, Amit became unconscious and remained so till he died 52 hours later. The hospital's stand is that Amit was walking about on the morning of January 7, 1992. However, the Commission observed that the hospital records indicated otherwise. A Dr Pai, to whom Dr Nathan referred Amit for feverishness, filed an affidavit claiming that he found the boy drowsy but able to speak coherently when aroused. However these findings were not recorded in the hospital case papers. About Dr Pai's affidavit, the Commission observed: "This type of statement of doctors to help one another is not uncommon..."

Jehangir B Gai Consumer Court/City doctor and hospital found guilty of negligence. *Indian Express*, Mumbai, July 11, 2002

Clinical trials to be made easier

Indian law on the conduct of clinical trials (CTs) of new drugs is to be changed, allowing for the first time foreign drug companies and institutions to conduct human trials of new (potential) drugs concurrently with corresponding trials in the country of the drug's origin. India currently doesn't participate in multi-centric global phase I and II CTs; permission is granted only for phase III trials, after submission of trial results from other countries. This means that tests done in elsewhere must be repeated in India – a policy has virtually excluding India from the global drug discovery process, besides delaying the introduction of top-of-the line drugs in the domestic market.

An expert committee is currently fine-tuning proposed changes in the schedule Y of the Drugs & Cosmetics Act, which deals with pre-clinical and clinical trial protocols and procedures, in order to align the CT protocols with those of global regulatory bodies.

Mr Ashwini Kumar, drug controller general of India, states that CTs in India cost one-fifth to one-tenth of the cost of trials in US or Europe. India's participation could save millions of dollars in the expensive drug discovery process. The rich, diverse genetic variations among people and more accurate results with regard to international acceptance levels of trials held in India.

It is an opportune time for multinationals interested in doing CT in India, evident from the spurt in their requests for trial permits with the drugs controller. With the increased focus on R&D, domestic

drug companies too are queuing up to file investigational new drug applications in an unprecedented way.

Times News Network. Curbs on human trials of drugs to go. *The Economic Times*. July 11, 2002

Unethical trial of anti-diabetic drugs

Clinical trials of the anti-diabetic drug ragaglitazar were conducted by the European company Novo Nordisk before animal studies were completed – contrary to ethical and regulatory requirements.

The drug discovered in India by Dr Reddy's Laboratories, and licensed to Nov Nordisk which mounted a multi-centre human trial of this insulin sensitiser even while animal teratogenicity studies were going on. It cancelled the trials only after it was found that the drug caused urinary bladder cancer in animals.

The Drugs Controller of India overlooked this requirement though the new molecule was for a chronic disease for which good medicines exist. Dr P Bhargava of the Centre for Cellular and Molecular Biology emphasises that drug trials with concurrent animal toxicity studies are warranted only for life-threatening conditions like cancer.

The company argues that concurrent studies are acceptable for chronic diseases and that short-term animal studies didn't reveal any toxicity. The trials were approved in the US and Europe.

Ganapati Mudur. Researchers question ethics of diabetes drug trial. *BMJ* August 2002; 325: 353

Strikes in hospitals banned

In a major judgement the Delhi High court banned strikes in all government hospitals in the capital. Functioning of the hospital with its doctors and services is very important to save patients' lives. The reasoning is that banning strikes ensures patients' fundamental right to life when seeking medical care. It is felt that such a judgement will stop health professionals from striking work unmindful of the needs of poor patients using public hospitals.

On the other hand, this does not address the abject and exploitative working conditions that health professionals must put up with in public hospitals. Larger issues of the state of decay of government hospitals, restructuring the health system or instituting a redressal mechanism have not been addressed. Denying the employees the right to protest peacefully may be also counter-productive.

Editorial. Healthy judgment. *The Times of India*. August 31, 2002

http://timesofindia.indiatimes.com/articleshow.asp?art_id=20688105