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(Accepted 6 April 1988)

Letter from Bombay

An unmitigated tragedy

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Sir Jamsetjee Jejeebhoy Hospital—J J Hospital—was founded in 1845 and was soon acclaimed. Associated with the Grant Medical College, it is the oldest teaching institute in western and central India. The following account would have made the first Indian baronet, Sir Robert Grant, Dr Charles Morehead, and the others who led the institutions to glory hang their heads in shame.

"In January 1986 tragedy struck [patients in] the J J Hospital. . . . It started with Bapu Thombre. He died on 21 January. He was followed by 13 others. The last was Dawood Dholakia on 7 February . . . they all died unnatural and untimely deaths. Their ages ranged from 10 to 76. Two of them were well on their way to recovery . . . they too died. The common drug administered to all 14 was glycerine. . . .

"But this glycerine was not harmless. It was lethal. It was contaminated with diethylene glycol, a deadly poison. As a result, all these patients developed anuria leading to renal cortical necrosis. It was irreversible. Dialysis was of no avail. They did not ask to be born; they did not choose to die. They died. They died as they had lived, quietly and in poverty.

"Little could they know that by their deaths they would arouse an outcry of public indignation which would lay bare lack of probity in public life, malaise and corruption in places high and low indulged in contempt of the laws of God and man.

"All is over bar the shouting. It is time to pause and forage into the murky water of lies, deceit, intrigue, ineptitude and corruption to salvage the truth about what led to this ghastly and tragical episode.

"To that end . . . hereunder . . . the sequence of events."

The 289 page report that follows, again in the words of Justice Lentin, describes "the ugly facets of the human mind and human nature, projecting errors of judgment, misuse of ministerial power and authority, apathy towards human life, corruption, nexus and *quid pro quo* between unscrupulous . . . analytical laboratories, elements . . . controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA and persons holding ministerial rank. None of this will be palatable in the affected quarters. But that cannot be helped."

A rising toll

Four of the fourteen who died had brain tumours. Three were receiving treatment for head injury. One had a cerebral stroke. Three had glaucoma, two cataracts, one iridocyclitis. One had undergone keratoplasty.

Vomiting; diarrhoea; gastrointestinal bleeding; abdominal pain, guarding, rigidity, and distension set in within four to five days of the administration of the

toxic glycerin. Over a further two to three days oliguria, anuria, acidosis, and instability of blood pressure followed.

The infusion of sodium bicarbonate, administration of acetazolamide, mannitol, and frusemide and the use of dialysis (in 12) were of no help. The first patient, Bapu Thombre, had been admitted to the general surgery ward on 15 January 1986 after a head injury. The next day he was transferred to the neurosurgical ward. On 20 January he developed anuria and despite the administration of mannitol and frusemide—on the advice of a nephrologist—died on 22 January. By 24 January seven patients who were developing anuria on neurosurgery, neurology and ophthalmology wards had been referred to the nephrology unit. Two of these seven died. By 27 January the number of patients with such anuria had risen to 11.

There was nothing in the natural course of the diseases afflicting these patients to explain renal failure. The neurosurgeons and nephrologists were thus forced to consider the possibility of drug toxicity. Acetazolamide, mannitol, gentamicin, and glycerol, being the drugs common to the treatment given to all these patients, were withdrawn from use on 25 January.

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On 27 January the professor of pharmacology, Dr R D Kulkarni, first raised the suspicion of the adulteration of glycerol. He knew that glycerol was expensive and in short supply. The irreversible nature of renal damage in these patients led him to postulate the presence of glycols in glycerin, with the possibility that industrial glycerin had been supplied to the hospital instead of glycerin for medicinal use.

At necropsy acute, extensive cortical necrosis was seen in the kidneys. The liver showed centrilobular necrosis. Extensive haemorrhages were seen in the adrenal medullae. Rats and rabbits fed the toxic glycerol also showed extensive renal damage.

Chemical analysis of the toxic drug showed the following composition: diethylene glycol 18.5%, polyglycol 51.0%, water 21.0%, glycerol 9.0%. "To call such a concoction glycerol is a mistake. It can more correctly be described as diethylene glycol with a dash of glycerine."¹

A damning report

Justice Lentin, forming the commission of inquiry appointed by the government of Maharashtra to go into this matter stated unequivocally: "There was no negligence or dereliction of duty on the part of doctors/paramedical/other ancillary staff in identifying or withdrawing the killer drug . . . the Dean, Dr Chandrikapure and the Superintendent Dr Deshmukh are guilty of negligence and dereliction of duty."¹ Neither visited the hospital when informed of the deaths. Neither took steps to withdraw the suspected drugs. "Thus for two vital days . . . the Dean enjoyed his holidays and did nothing. . . . The Superintendent's course of conduct, like the Dean's, borders on the grotesque. He compounds negligence and dereliction of duty by the brutality of his observation that every death that takes place is no signal for him to rush to the hospital, and that there was nothing he could do about the deaths which had already taken place."¹ Justice Lentin concluded that the dean and the superintendent were unfit to hold any post with responsibility.

How did toxic glycerin reach patients?

Jethalal Soni made it for industrial use. Although pure glycerin costs 54 rupees (a little more than £2) a kilogram, Soni sold his product for 30 rupees a kilogram. Trader Mahendra Doshi bought it and through an intermediary firm (Alpana Pharma) sold it to J J Hospital. Doshi's claim, that he warned his customers that this glycerin was not for medicinal use, was disbelieved by the judge who could find nothing to support it except that he himself said it. Alpana Pharma was awarded a rate contract for the supply of glycerin through the active intervention of the then professor of pharmacology, Dr R D Kulkarni, whose "macabre role" is dealt with extensively in the commission's report. Justice Lentin also came down upon the hospital purchase committee, which functioned in a slapdash manner, followed totally unsatisfactory procedures, and purchased medicines, including life saving drugs, indifferently or as guided by corrupt members or interfering ministers.

Of the Food and Drug Administration (FDA) and the health ministers of the government of Maharashtra supervising it, Justice Lentin commented: "The entire structure of FDA, [at one time a prestigious body famous in all Asia] has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a sense of non-accountability all round" Of the health minister the judge concluded: ". . . Bhai Sawant as Health Minister was, for the FDA and the general public, a disaster of the first magnitude. He has not set

an example either of efficiency or rectitude. . . . He is guilty of gross ministerial interference and favouritism for extraneous consideration and misuse of power and authority . . . coupled with dereliction of statutory duties. . . . He is unfit to hold a ministerial post. . . ."

Public inquiry

Well aware of the manner in which some inquiries are conducted here, Justice Lentin decided not to function in camera. "An inquiry of this nature, involving no State or Defence secrets, was better allowed to unfold itself not within the cloistered doors of secrecy but within full public gaze with access to one and all. . . . Secrecy breeds suspicion, and suspicion breeds contempt. . . ." Court room No 37 was packed to capacity throughout the inquiry. The press provided detailed coverage. Strangely, the medical profession was silent as the facts unfolded.

It was a newspaper (*Maharashtra Times*) that had originally broken the story of these deaths and prevented hushing up. The headlines conveyed the chief findings of the commission as they emerged. "FDA still shielding guilty,"² Name of game is favouritism,"³ "Of ministerial incompetence, graft and neglect,"⁴ "Labs hand-in-glove with FDA" (highlighting analytical laboratories that had proved "false, misleading and had provided imaginary and incomplete reports"),⁵ "Sinister gangs of merchants of death,"⁶ "Proxy payment behind glycerol contract" (referring to the 18 000 rupees—£720—paid to Dr R D Kulkarni by Alpana Pharma's guiding hand Mr Karwa),⁷ "Never before such lies"⁸ (by witness after witness).

Waiting for action

Justice Lentin completed his inquiry in 301 days and submitted his report on 30 November 1987. The public eagerly awaited steps to correct the disgraceful state of affairs. On 18 February 1988 an editor commented: "Given the nature of the tragedy, given the fact that adulterated drugs are playing havoc with public health, given the underlying callousness which amounts to nothing less than culpable homicide—one would have imagined that the findings [in the form of Justice Lentin's report] would be made public at once and all the follow-up action taken with utmost despatch. The Maharashtra Government has done neither. In fact, it has done nothing at all."⁹

It was only after a public cause case was filed in court demanding release of the report that the government promised to do so on 30 March 1988. On 10 March 1988 health minister Bhai Sawant resigned from the cabinet. On 30 March, while placing the report of the Lentin commission before the state legislative assembly, the government endorsed virtually all the points made by the judge. It also suspended the dean, R S Chandrikapure, Superintendent V G Deshmukh and two others from the J J Hospital, and three officials of the FDA, including the joint commissioner S M Dolas. The government stated that the suggestions made by Justice Lentin would be implemented.

Strange though it may appear, legislators of the state of Maharashtra defended the indicted health minister. Some, perversely, proposed action against Justice Lentin. The organised bodies of the state and national medical fraternity maintained a studied and damning silence. It was left to eight doctors who had formerly worked at the J J Hospital to speak publicly of the rot in that institute. They pleaded for the appointment of competent and responsible senior staff empowered to run the institute without the need to kowtow to bureaucrats and ministers. Interference by ministers in day to day work and their use of transfer of professorial

staff from Bombay to Poona, Nagpur, or Aurangabad, or vice versa to confer largesse on favourites or punish those not putting up with misdemeanours were condemned.

Lessons

What are the lessons to be learnt from our experience in Bombay?

Firstly, there is much that is rotten in our system of institutional medical care, the monitoring of drugs, and ensuring public health and safety. As a consequence tragedies are inevitable, and when they do occur we tend to hush them up. We need close monitoring of all our public institutions by courageous and incorruptible individuals or groups.

Secondly, when a tragedy is uncovered, a detailed inquiry into it in public by a judge of proved integrity becomes imperative. Justice Lentin has provided an admirable model. Public opinion must be marshalled towards ensuring immediate and total follow up action based on the recommendations that come from such an inquiry.

Thirdly, the organised bodies of the medical

profession have, in this instance, failed to meet their responsibilities. This speaks poorly of their health and vitality. We physicians have to heal ourselves.

Fourthly, in countries such as ours, continued vigilance is essential for preventing recurrent catastrophe. It is a telling commentary that even as Justice Lentin was submitting his report to government, a news item from Bihar startled us. It told of the deaths of five men and two women from renal failure caused by glycerol contaminated with diethylene glycol. These seven were receiving treatment for cataracts at the Patna Medical College and Hospital.

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