

Indian doctor in protest after using Viagra to save “blue babies”

Sanjay Kumar *New Delhi*

A doctor who gave the anti-impotence drug sildenafil (Viagra) to three newborn babies with pulmonary hypertension has caused a controversy over the unauthorised use of the drug.

In what may be the first such case in India, the babies were given Viagra orally at the Amrita Institute of Medical Sciences and Research Centre, a private charitable trust, at Kochi, Kerala, in May and June.

Standard intensive treatment had failed, and Viagra was given in a situation described as “life threatening” by APS Krishnan, vice president and spokesman for the Amrita Institute.

“There were children dying in my presence, and I was expected as a responsible physician to use all available methods to save my patients,” Dr Parapurath Kovummal Rajiv, head of newborn services at the institute, said. “So, I used sildenafil citrate,” he added. All three babies lived.

The doctors were using the drug to dilate the blood vessels supplying the babies’ lungs, in the hope of reducing pulmonary hypertension.

Dr Rajiv was criticised by local non-governmental organisations and the national media for unethical and illegal administration of the drug. Such a use

is not authorised by the drugs controller of India; Viagra is authorised under medical supervision only for male erectile dysfunction. The institute discounts ethical concerns in this case. “The question of ethics arises in the case of clinical trials,” said Mr Krishnan.

“Using the drug on three patients acquires the form of a planned experiment,” said a WHO expert, who did not want to be named. Such persistent unlicensed use cannot be acceptable, he added. If something went wrong, the doctor could be held responsible.

Dr Weerasuriya, regional adviser on essential drugs for WHO’s south east Asia region, said the next step should be to take all the available data and evaluate the new use scientifically. “Maximum benefit can be derived by thoroughly investigating it under controlled

clinical trials,” he said.

Dr Mira Shiva of the Voluntary Health Association of India, a leading non-governmental health organisation, was concerned that other doctors may adopt this treatment.

“India has acquired the potential of becoming a fertile ground for non-transparent or even clandestine drug trials by Indian and foreign companies without accountability, compensation, surety, or safety of patients,” she cautioned.

However, she added: “My sense of ethics allows using sildenafil citrate as a life saving drug for children.”

Faced with hostile reactions in sections of the media, Mr Krishnan would say only that it would depend on the medical condition of the patient and the judgment of the doctor concerned whether they would repeat the treatment. □

Shipman murdered more than 200 patients, inquiry finds

Owen Dyer *London*

The British former GP Harold Shipman murdered at least 215 of his patients, the first phase of the public inquiry into the serial killings concluded last week. There is a “real suspicion” that he claimed the lives of another 45 victims, according to the judge leading the inquiry.

High court judge Dame Janet Smith said Shipman may have been hoping to get caught when he altered the will of his last victim, Kathleen Grundy, 81. The “crude forgery” of the will “made detection inevitable,” she said, concluding: “It is hard to resist the inference that Shipman was driven by a need to draw attention to himself and his crimes.”

The inquiry examined a total of 888 cases in its 2000 page report, *Death Disguised*. Shipman was found not responsible for 604 deaths, and no conclusion was reached in a further 38 cases. The 215 people that the inquiry determined were killed by Shipman comprised 171 women and 44 men.

Asked if Shipman’s motives would ever become clear, Dame Janet said, “The short answer, I think, is no. Only he could

answer that question and at the moment it seems very unlikely he will.” Shipman continues to proclaim his innocence and refuses to submit to psychiatric examination.

“I think it likely that whatever it was that caused Shipman to become addicted to pethidine also led to other forms of addictive behaviour,” said Dame Janet. “It is possible that he was addicted to killing.”

The inquiry, which has already reviewed 3500 witness statements, will enter its second phase this autumn, looking at how Shipman escaped detection for so long and how he produced corroborating signatures from other doctors on cremation certificates.

The former GP has reported the forensic psychiatrist who examined him in custody to the General Medical Council. He accuses Dr Richard Badcock of breaching patient confidentiality by giving a newspaper interview. The GMC is currently investigating the complaint. □

The report can be accessed at www.the-shipman-inquiry.org.uk/reports.asp



Tribespeople win £4.5m damages

More than 200 Masai tribespeople have been awarded a total of £4.5m (\$7.0m; €7.1m) plus costs from the UK Ministry of Defence for the injuries and deaths caused at the British army’s practice ranges in central Kenya. Some of the more seriously injured people will receive as much as £250 000 each.

Twenty five year old Beatrice Lelelong (pictured), who was in London to hear the out of court mediation settlement, lost most of her hands and feet when a bomb exploded in 1981.

Lynn Eaton *BMJ*