

On cloning and on the rights of patients¹

At first sight, the bioethics convention which was recently signed at Oviedo, Spain by the health ministers of 20 European countries, seems like a harried attempt at putting the bioethic genie back into the bottle.

Seven years ago, when work on the convention began, the possibility of obtaining copies of humans through cloning seemed remote. By last November, when the European accord was completed, however, the identical ewes, **Megan** and **Morag**, had **been** born from **sheep** embryos followed by the cloning of **Dolly**. Both events set off a series of 'soulquakes' around the world. The convention prohibits the creation of human embryos for research as well as trade in human parts and regulated organ transplants.

Many parts of the developed world already have strict laws on these matters and some countries such as the UK and the Netherlands had outlawed human cloning long before **Dolly** was born.

The Spanish health minister has said that the accord is based on 'the general principle that the interests and rights of individual humans must prevail over the interests of science.' The question is whether a conflict of interest between the two can ever be permitted.

The agreement also 'guarantees the right of patients to provide or withhold consent for medical procedures and to have information regarding their health.' This sounds eminently sensible on paper but policing and implementing the various provisions will be far from easy.

Today, the real threat to an individual's medical and human rights seems to stem not as much from so-called Orwellian science as from privately funded research. Being more 'market-friendly' and demand-driven, the latter is potentially far more opportunistic and can be more easily hijacked by special interests and individuals. **Dolly**, herself, was created by people searching for 'a better glass of milk' containing pharmacologically valuable human proteins.

Not surprisingly, the fallout of this research has been most unforeseen and portentous. Alongside a somewhat muted demand for human cloning, whether for sentimental narcissistic, medical or faddish purposes, has been a divisive debate on its ban. Some experts suggest that the extrapolation of cloning from the sheep to the shepherders

may be hamstrung by 'insurmountable' obstacles. Even if it can be achieved, the prospect of carving, cutting, coring and electrically shocking human cells into clones is fraught with the most profoundly disturbing uncertainties.

Apart from the health or abnormality of individuals born out of such unholy practices, there is an entire minefield of ethical questions regarding the dignity and quality of their life. It will require more than a convention of European health ministers, howsoever well-meaning, to confront these imponderable perplexities.

Yet another regulatory agency...2

In an earlier editorial³ we had referred to the fact that instead of ensuring that existing agencies to monitor and correct medical malpractice do their work efficiently and effectively, the Government of India is setting up newer agencies for the same purpose. A recent report describes 'complaint cells' being set up in New Delhi and each state by the Union Ministry of Health Family Welfare to look into allegations of negligence against doctors.

Health Ministry officials stated that the cells will look into all complaints by patients or relatives made by telephone or in person. 'Strict action will be taken against all those found guilty.'

Fees charged by public hospitals 4

Radhika, wife of a poor coolie, was in the throes of labour pain and was rushed to Dufferin Hospital in Lucknow... Ignoring her critical condition, the hospital officials asked her to pay Rs. 600 as admission fee before she could be attended to. As the miserable relatives could not raise the amount, she was taken to Queen Mary Hospital a few kilometres away. Radhika never reached there. She died en route.

The tragedy of Radhika is not an isolated instance of the poor dying for want of medical attention. There are many instances since the Uttar Pradesh Government raised medical charges in their hospitals.

The State Government, in its bid to raise revenue for the exchequer, seems to be totally oblivious of the basic principles laid down in our constitution which should be the guiding force behind any law making process. The present hike in medical charges is clearly a breach of Article 21 of the Constitution prescribing 'Right to life'.

It is the poor like Radhika who fall an easy prey to the Uttar Pradesh Government's

steep hike of charges for medical care. A normal delivery will now cost Rs. 1200 and one requiring surgery Rs. 1800. An operation on the heart, which hitherto cost Rs. 10,000 will now cost Rs. 1,50,000 - simply out of reach of the poor.

'The Governor, Romesh Bhandari, has helped the private hospitals and nursing homes by such a steep hike in medical charges,' said Ram Kumar, a clerk in a private firm. 'If there is no difference in the charges levied by a private hospital and by the government, people would obviously prefer the former which, at least provides better services.'

It is not as though services have improved at Government hospitals which normally have shortage of funds, medicines and equipment. Despite having increased the charges many fold, grant to the various hospitals remained the same, lamented the chief superintendent of a government hospital in Lucknow.

Legal responsibility for medical error 5

The Bombay High Court has ruled that the medical superintendent of the Tata Memorial Hospital could not be held responsible for mistakes made by a doctor of the hospital in treating a patient.

Mr. D. M. Sanghvi filed a criminal complaint against Sanjay Sharma, a surgeon, for negligence... Based on the complaint, the Metropolitan Magistrate summoned the doctor and the superintendent of the hospital. Aggrieved, the medical superintendent moved the High Court. He contended that in order to hold the hospital responsible, Mr. Sanghvi had held the superintendent of the hospital also responsible. The Court quashed the decision of the lower court and held, 'The complaint has repeatedly pointed to the doctor who performed the surgery. There is no justification to connect the superintendent with the offence.'

Human guinea pigs 6

Lynette Dumbie, senior research fellow in the department of surgery at Royal Melbourne Hospital, University of Melbourne, condemned the manner in which human growth hormone extracted from pituitary glands taken from cadavers in many countries, including India, was used in infertile women and children with short stature, despite warnings that the hormone might be contaminated with the agent producing Creutzfeld-Jacob disease.

A laudable ruling favouring the patient with AIDS ⁷

In a major triumph for those afflicted with AIDS, Justices V.P. Tipnis and D. K. Trivedi of the Bombay High Court have ruled that a public sector organisation must pay Rs. 40,000 as back wages to one of its casual labourers who was dismissed merely because he tested positive for HIV. The presence of infection was noted during a medical checkup he was asked to undergo by the corporation. The report had stated that though he tested positive for HIV, 'he was otherwise medically fit'.

Countering the argument made by the lawyer representing the corporation, the judges cited a Supreme Court ruling to show that the company had wrongfully interpreted the meaning of 'ill-health'. 'The expression has to be construed relatively. The company should have determined whether the illness interferes with the orderly functions of the patient... The question of great contemporary significance is whether it is permissible under our constitution to condemn a person infected by HIV to virtual economic death before he eventually dies of the ailment.'

The judges clarified that there cannot be any generalisation regarding recruitment of patients with AIDS. A patient with AIDS also afflicted with other diseases rendering him disabled and a potential threat to those who come into contact with him may not be fit to perform his duties. Such cases must be decided 'not just on the basis of medical tests but also on the basis of competent medical opinion.'

In another far-sighted move, the Court did not bring on record the name of the patient with AIDS and of the corporation in view of the stigma attached to the disease.

Can patients trust anyone? ⁸

The Delhi High Court was informed on 22 April that former medical superintendent of Safdarjung Hospital has been charged with his alleged involvement in the multi-million rupee intravenous fluid purchase scam.

The fact came to light while the division bench comprising the Acting Chief Justice Mahinder Sharma and Justice S. K. Mahajan were hearing the public interest petition filed by the Peoples Union for Civil Liberties alleging that P. C. Rai, whilst medical superintendent of Safdarjung Hospital had purchased the intravenous fluid through a supermarket at almost twice the market price.

Some of the fluid, which had suspended particles in it, had been administered to patients resulting in at least two deaths in 1993.

The counsel for the petitioner alleged that officials of the health ministry had tried to shield Dr. Rai by not sending the bodies of those who had succumbed for *post mortem* examination.

These bottles of intravenous fluid, which resulted in death, were cleared by the standard testing laboratories at Naraina.

The doctor's dilemma ⁹

'The best doctors in the world, wrote Jonathan Swift three hundred years ago, are Dr. Diet, Dr. Quiet and Dr. Merryman. Such simplistic prescriptions pay their price and few seem inclined ever to give the 'Swift remedy' a try. Ever since then, the cost of living has had to battle it out with the cost of trying to be alive and well.

Science has taken major strides and who knows, even nervous breakdowns might soon be brought within the reach of every one in our lifetime.

Soldiers and government ministers, doctors and members of Parliament - all have to 'take solemn oaths' or pledges that they would discharge their onerous public duties honourably.

Unlike the politician, the modern medical man does not pass the buck. He keeps it.

The world of physicians, surgeons, radiologists and pharmacists is abuzz today because the British Medical Association and its fraternal counterparts in the West are keen to update and modernise the Hippocratic Oath which, simply put, is like the Ten Commandments, which also came, as the Bible says, in the form of tablets. Clearly, what the pioneer physician Hippocrates visualised as the p's and q's which doctors must carefully observe was a perception taken some 2500 years ago.

Since then, *homo sapiens* has remained the same but the ills that flesh is heir to are many and not all are curable. How do you have an authorised version of an oath written two-and-a-half millennia ago when issues of ethics bristle with every advance medical science 'makes, whether it is genetic engineering, cloning, heart and liver transplantation, sex-determination tests, test-tube babies, abortion or euthanasia.

Some medical practitioners regard this as anathema, as if Atlas had shrugged. Others plead that everything else that science touches - including patient confidentiality - has had to be updated and modernised, and it would be invidious for scientific personnel to turn away from demands of the 21st century. As in other things, the new bio-ethics convention of the Council of Europe drew up a brand new oath, based on the 'lowest common denominator in wishes' from people of different religious

and medical persuasions. Dr. Richard Nicholson, editor of the *British Bulletin of Medical Ethics* has opposed the move to make the Hippocratic Oath modern because 'writing something by a committee is often not the best way for sharp results.' The proposed horse ends up as castrated camel and all are unhappy. Truly, a doctor's dilemma!

Breach of trust with HIV patients ¹⁰

Social workers, non-governmental organisations, doctors and lawyers have expressed serious concern over reports that the Director-General of Health Services (DGHS) has disclosed the names of some HIV-positive persons to the press. This disclosure came in the wake of allegations that there was an undue delay in the clearance of customs duty exemptions for life saving drugs needed by such patients. To prove that this was not true, DGHS disclosed that the certificate necessary for importing medicines was issued to HIV/AIDS patients within 10 days of applications. The names of patients were also given along with it.

Many have complained that this is a breach of trust and confidentiality on the part of the DGHS. The reported disclosure will lead to serious problems for patients, already undergoing trauma.

An HIV-positive patient pointed to the landmark judgement by the High Court in Mumbai stating the HIV/AIDS patients have a right to anonymity. He said, 'If such revelations by the officials at DGHS - many of whom are doctors - continues, some patients might even think of suicide as a result of the mental agony.'

Conferences sponsored by drug companies ¹¹

The Union Ministry for Health and Family Welfare has banned the visit of government doctors to international conferences which are sponsored by multinational pharmaceutical companies.

The government move is aimed at ensuring that medical specialists in reputed institutions are not influenced by these companies in their purchase of drugs and medical equipment. Officials in the health ministry say that the move will ensure 'objectivity' in decisions taken by medical experts.

Director of All India Institute of Medical Sciences, Dr. P. K. Dave, said the move was good and would help avoid pressure by the pharmaceutical industry on medical experts.

A few doctors have said that accepting sponsorship by local pharmaceutical companies even within the country can be termed unethical. In fact, a paediatric

conference some time back avoided taking any funds from the local or multinational pharmaceutical companies.

Was an ICMR trial ethically deficient? 12

The study of pre-cancerous lesions on Indian women has triggered a debate on the responsibilities of researchers towards patients volunteering for clinical trials and on the need to have their informed consent.

The *Telegraph* had earlier reported that government doctors had withheld treatment to several women with lesions to monitor their behaviour, as a result of which nine women developed cervical cancer and 62 acquired low-grade cervical malignancies.

Critics of the research, conducted on 1,158 women without their written consent, felt a similar study could not have been carried out in countries with stricter ethical guidelines and higher patient awareness. Nearly 60 per cent of the women who participated in the Indian study were illiterate, according to the Indian Council of Medical Research (ICMR). Medical ethics experts said enrolling illiterate women increased the responsibility of researchers.

The ICMR has conceded that 10 women with severe dysplasia were 'lost' during the follow-up - they did not return or could not be traced. 'If the women were explicitly told that their lesions might be cancerous, they would have come back,' said Mr Amar Jesani, an ethics expert of the journal, *Issues in Medical Ethics*. 'If the women were informed about the cancer-causing potential, how many of them would have agreed to take part in the study?' he asks.

'Such a study is possible only in those cases in which women refuse to be treated or they could not be treated for various health reasons,' said Dr Puneet Bedi, a Delhi-based gynaecologist who was a junior doctor in a government hospital involved in the study.

The British gynaecologist, Dr Joseph Jordan, of the Birmingham Women's Hospital agreed. 'I am quite sure it would have been impossible to do a study that would entail observing severe dysplasias without treatment in Britain, even in the mid-1970s,' said Dr Jordan.

'These issues are relevant today because patients in India are treated badly by medical researchers,' said Dr Samiran Nundy, a surgeon and former editor of the *National Medical Journal of India*.

The patient as customer 13

In the wake of the tidal wave set up by Dr. Prathap Reddy through his chain of Apollo

Hospitals, others have been quick to seize the opportunity of cashing in on patients. Mr. Amit Bagaria, chief executive officer of FDS Gainwell Ltd., focuses on a crucial element in planning his private hospitals.

His hospitals will ensure that there is no callousness on the part of hospital staff, constant availability of life-saving drugs, functioning equipment, clean bed-sheets and other linen and well-appointed patients' rooms. 'We have to visualise and establish a scenario where the patient is treated as a customer and, since customer is king, he supercedes the doctors, nurses and everybody else in importance when he walks into the hospital...'

Bagaria focuses on another important point: 'Prior to our coming into the market, the surgical laser was being sold as a magic tool. But out of some 20 existing in India till late 1995, only three lasers were actually being used. After selling them, the campanics just disappeared...'

Caveat emptor... Ayurvedic drugs 14

If the Supreme Court verdict (banning practice of any form of medicine other than that in which the doctor holds a certificate) needed support, the first episode narrated in this essay provides it.

'A sixty-two-year-old-man was brought into casualty at the K. E. M. Hospital (Mumbai) in an unconscious state. When questioned by doctors, his relatives revealed that he was a diabetic whose hypoglycaemia was well controlled with insulin and glibenclamide. Five days earlier, he had been started on an ayurvedic drug for psoriasis. He developed giddiness following ingestion of the drug but ignored it. Subsequently he became unconscious. He succumbed to hypoglycaemic coma.' Investigation showed that death followed adverse interaction between the ayurvedic drug and those prescribed for diabetes by allopathic doctors.

Dr. Sharadini Dahanukar, head of the department of pharmacology at Seth G. S. Medical College, Mumbai also points out that in many of the ayurvedic products tested by her department, the processes necessary to detoxify and purify them were not carried out properly. 'As a result, some herbal medicines have been found to contain poisonous substances.'

The reason why manufacturers are able to get away with selling such drugs is that ayurvedic drugs are not covered by the Drugs and Cosmetics Act (1940) or by the quaintly termed Magical Remedies Act (1954). Manufacturers are thus under no obligation to prove the clinical efficacy of their preparations or subject them to safety tests.

Dhaniram Baruah (continued)^{15,16}

In a two-part feature subtitled 'Baruah Bungle', we are provided details on the man who shot to notoriety when he implanted a pig's organs into a man in Guwahati with fatal consequences. Baruah is in a financial mess. His unit in the Santa Cruz Electronics Export Promotion Zone (SEEPZ) has been sealed for defaults on export commitments and non-payment of rent. Baruah owes SEEPZ Rs.3,30,000 and the State Bank of India Rs.12,000,000 besides several hundreds of thousands of rupees to others.

It is a measure of his lack of sincerity that whilst he remains at Sonapur, near Guwahati, planning his next two pig-to-man transplants, he continues to insist that his unit at SEEPZ is only 'temporarily closed'. The next two hapless victims Baruah has set his sights on are 26-year-old Anil Kumar from Andhra Pradesh and 22-year-old Eba Moni Baruah from Dewrigaon. 'If the Indian Council of Medical Research turns down my plea to conduct these operations, I'll ask my patients to go to the High Court.'

Baruah's associate, Jonathan Ho from Hong Kong, has in the meanwhile agreed to turn approver and has been permitted to return to his country. Ho was dismissed from a Beijing hospital after he transplanted a buffalo's organs into a human being.

Hoodwinking the medical council? 17

The Tema Medical College in Navi Mumbai 'borrowed' staff from Mahatma Gandhi Mission's Medical College (MGM) in Aurangabad just before an inspection by the Medical Council of India (MCI). The urgent 'hiring' was facilitated largely because both Tema and MGM are owned by former Congress ministers Padamsinh Patil and Kamal Kishore Kadam respectively.

Some of the medical staff at MGM, Aurangabad told *Express Newsline* that just before May 15 and 16, the days that the MCJ team was to visit the unrecognised and under-staffed Tema Medical College at Navi Mumbai, the Tema management requisitioned some junior doctors from MGM, Aurangabad.

The doctors who were to be 'loaned' were asked to collectively resign on May 13 and were told that after the MCI inspection in Navi Mumbai, they would be 'returned' to their posts.

House officers Anju Malani, Jyotsna Patil, Sharmilee Kadam, Himali Gala and Sonali Mandot from the gynaecology department were some of the chosen doctors.

The doctors travelled from Aurangabad to

navi Mumbai and back in a van belonging to the MGM College.

When contacted by *Express Newsline*, authorities at Terna claimed that five to six of these junior doctors 'had been recruited to their staff'. Our investigation proved that these doctors are still doing their postgraduate work at MGM College, Aurangabad.

When contacted MCI authorities refused to comment on the matter.

This is not the first time that such a pre-inspection cover up has taken place. A staff member joined the MGM College, Aurangabad in December 1993. In an appeal to the University Tribunal, Aurangabad, he states, "The appellant was first directed to go to the Mahatma Gandhi Medical College, Navi Mumbai and to be present there for some days as the MCI team was to come for inspection of the said college. After the inspection, the appellant returned to Aurangabad and started work in this college."

Callous doctors¹⁸

Justice Samir Kumar Mukhopadhyay, Chief Justice of Calcutta High Court, has reminded doctors of the need for dedication to their duty. Addressing the annual meeting of South Calcutta branch of the Indian Medical Association, he spoke a home truth that cannot please the medical community but the public at large will surely be happy.

Doctors are sometimes attacked, he said, because some doctors do not attend to their duty, which is a gross understatement, as every Calcuttan will say.

In government hospitals doctors are as distant as the gods. After attending to their chambers, nursing homes and calls, they seem to have little time for the poor hospital cases. The relatives of patients wait in an anxious bunch, like poor peasants waiting to plead with the zamindar... and consider themselves fortunate if given a few minutes' hearing.

Exceptions apart, most doctors act as if they were doing patients a favour and treat their relatives with unconcealed contempt. Nurses and other assistants have the same attitude. Apart from the shortage of beds and medicine, rude behaviour from all quarters makes life miserable for all patients.

The complaint is equally true of most of the big names in private practice. Somehow, bad temper is a common trait among them. Questions often invite a rude snub or are not considered worth an answer. Instructions are cold and laconic. The patient is made to feel that he is simply wasting the great man's time and the

sooner he pays his fees and gets out the better.

Tests are prescribed profusely leaving the patient to wonder whether some of the diagnosis could not be done by the doctor himself, instead of by the expensive laboratories which have mushroomed in Calcutta over the years.

Appointments have to be fixed one to three months in advance in some cases and even after a prior appointment, one may have to wait for hours in the lounge because priority is being given to post-operative and pre-operative cases.

The standard of medical care in Calcutta has deteriorated alarmingly over the years and it is shocking that in Dr. Bidhan Roy's city, doctors who are getting more prosperous every year should choose to be so heartless.

Female fetuses unwanted^{19,20}

Will your child be a boy or 'yet another girl'? Pay Rs. 5,000 and you will soon find out. When asked for a cheaper rate, a doctor from Malad warned, 'You must go in for a reliable test. I aborted several male fetuses because the parents went to an unreliable doctor.'

Nearly a decade after the use of diagnostic tests to determine the sex of a child were banned in the state, several clinics in Mumbai continue to offer them clandestinely. When approached, seeking information on behalf of a prospective client, gynaecologists in several parts of the city admitted to performing sex-determination tests.

The ban in 1988 has had an impact on how the tests are conducted. Tests have now gone underground. Most doctors operate through a network of references and get their clients through general practitioners. The modus operandi is fairly simple. The test is performed in the clinic's operation theatre and the patient is discharged in a few hours. Test results are communicated orally and the patient decides whether to go in for an abortion. 'Since the tests are illegal, we don't maintain records,' said a gynaecologist in Goregaon. She did not mind providing fictitious medical bills to allow the patient to claim reimbursement.

'The tests are continuing because there is no political will to enforce the law. Even if one doctor was convicted for conducting the tests, it would have an impact,' says one gynaecologist.

The state government admits it has not been able to curb the tests. 'Implementing social legislation is difficult since the demand for the tests continues to be high. Patients and doctors collude and perform the tests clandestinely. It is difficult for us

to get information,' says Subhash Salunkhe, the state director of health services.

The medical fraternity is not acting against the tests either. R. P. Soonawala, former president of the Federation of Obstetricians and Gynaecologists, says, 'We are against these tests and tell our members not to encourage them but our role is not that of a police organisation. There are black sheep in every profession.'

Doctors in Bihar reject regulation²¹

The state government's decision to promulgate an ordinance to regulate the establishment of private nursing homes and clinics in Bihar has drawn strong protests from the Indian Medical Association (IMA). The outgoing president, surgeon Narendra Prasad, declared that doctors would prefer going to jail than getting their nursing homes and clinics registered.

Fraudulent autopsies²²

Dismayed that the present format for preparing post-mortem reports in cases of custodial deaths gives scope for 'doubt and manipulation', the National Human Rights Commission (NHRC) has asked all state governments to adopt a 'model autopsy form' prepared by it.

Mr. Justice Venkatachaliah, chairperson of the commission, noted that a number of instances had come to the commission's notice where the post mortem reports appeared to have been doctored owing to influence/pressure exerted by the police or jail officials. In some cases it was found that the post mortem examination was not carried out properly. In others, inordinate delays had occurred in their writing.

In order to prevent such fraud, the commission had earlier recommended that post mortem examinations should be video-filmed and that cassettes should be sent to the commission.

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