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MEDICINE AND LAW

Law, Medicine and the People

THE purpose of law, it is said, is to 'regulate' human activities in a society and the medical world concerns itself with "improvement in physical and mental health of the people and the prevention, diagnosis and treatment of illness". It is, therefore, quite natural that laws relating to the medical world need to be examined and modified/rectified from time to time in relation to their impact on the society and people they aim to regulate.

The Indian legal system and laws, in particular those related to medical practices etc., are borrowed to a great extent from the British system. It is pertinent to compare their impact on the people(s) in terms of their meaningfulness to them. It would be both cumbersome and meaningless to make a comparison of each law (related to medicine) and examine its 'regulatory impact' on the society. Besides, there are laws relating to medical practice that are only remotely concerned with the general public and are, therefore, not of consequence here. In fact it might serve to consider here the different entities and their functions and the laws pertaining to them.

Doctors and Laws

Medical practioners must 'register' before they can practice and collect fees for their advice and registration is subject to minimum standards of qualification. Under the Medical Act these responsibilities are given to respective Medical Councils. These Medical Councils are also empowered by the act to cancel the registration of a medical practitioner from the Medical Register if there is "serious professional misconduct" and there is a Medical Disciplinary Committee set up for this purpose. In UK several registrations have been erased either because it is "necessary for the protection of members of the public or in the best interest of the person suspended." And there is usually a very meaningful debate on the issue in medical journals, which itself acts as a deterrent for others. Such erasure of registration of medical practioner is almost absent so far as the Medical Council of India is concerned. However, the absence of erasure need not be construed to mean that things are above board in India. Adultery, improper association, negligence, and advertising are some of the issues on which registrations can be erased and many of our practitioners violate at least some of these and yet the MCI does not seem to be stirred enough to take action.

To take another example, according to the Act: "Nothing in the act shall extend or be construed to extend to prejudice or in any way affect the lawful occupation, trade or business of chemists and druggist and dentist or the rights, privileges or employment of duly licensed apothecaries so far as they extend to selling, compounding or dispensing medicines". Yet it is almost a universal practice for general practitioners in India to dispense drugs and charge for the same. Neither the MCI not the state have taken any action on this.

Further, "It is the duty of every registered practioner to bring to bear upon all his professional activities that standard of skill and knowledge which is to be expected of a practitioner of his experience and status and of comparable standing to him. It is also his duty to exercise reasonable care in his treatment of a patient. If the failure to exercise the necessary degree of skill or care results in injury to the patient, he will have a right of action for damages. Whether reasonable skill or care has been exercised in a particular case is a matter which has to be considered in relation to the facts of each case." No branch of the law affects the practice of medicine more strongly than the law of tort (civil wrong) under which negligence is perhaps the most talked about.

The glycerol tragedy in the J J Group of Hospitals has highlighted the issue of negligence. There can be no doubt about the fact that there was negligence on the part of everyone including the doctors of the hospital and yet is it not strange that the MCI has chosen to remain silent on the issue? It is in circumstances such as these where the ethics and rules enforcing bodies such as the MCI refrain from acting that the absence of people's participation in such matters become evident. What does one do when professional bodies fail to act?

Yet another example is that of the Bhopal disaster where the gas-affected people were 'denied' the antidote sodium thiosulfate for reasons that are still unclear today. Doctors' obligation, the Council's obligation and the state's obligation are evident by their absence.

Another issue that needs to be discussed here is the one related to informed consent. "A doctor has no right to do anything to a patient without his consent except in the case of emergency when he must exercise his discretion. The securing of a signature to a consent should not be allowed to become an end in itself. The most important aspect of any procedure must always be the duty to explain to the patient or relative the nature and the purpose of the proposed operation and thus to obtain a fully informed consent. In our country this should be even more important (though admittedly also more difficult) since there is so much illiteracy and lack of information. But it is common knowledge (though difficult to prove) that informed consent is reduced to a mere signature-obtaining exercise. The matter becomes even more serious when, to meet the family planning targets, healthy women and men are subjected to sterilisation operations.

Drugs are another entity subject to standards. Our drug laws are very similar to the British ones. An additional regulation in India is the Drug Price Control Order, which sets norms for prices of drugs. Despite

this, unlike in UK, the bulk of 40,000 to 60,000 formulations put into the market by over 9,000 manufacturers, are irrational, useless or even hazardous in some cases. A significant number of them are sub-standard. Doctors' prescriptions are often found to contain superfluous and unnecessary drug formulations, evidently to favour the drug companies' representatives. One report indicates that in Tanzania, there is one drug company representative for every four doctors (see Mukarram Bhagat's *Aspects of Drug Industry in India'*). In India, with 9,000 drug companies, the situation is very much the same. (In UK, the ratio is 1:20). Clearly the Indian patient pays a great deal more for medicine and gets much less value for it. Laws and the legal system need to take cognisance of this and ensure regulatory mechanisms to remedy this situation. What is more, the Bangladesh drug policy has already unequivocally demonstrated that the expenditure on medicine can be reduced and more 'value' made available to the patients and has also proved to be sustainable.

Health Services and Law

If there is similarity in the British and Indian laws in respect of drugs and registrations of doctors, the hospital services policy is different. In UK, under the National Health Services Act 1946, comprehensive health services are made available to the people. This includes a scheme of social insurance, and covers an overwhelming populace of the country. In India there is no comparable legislation and the state health sector incorporates the medical services including CGSS and ESIS. Indeed there are public hospitals and dispensaries which are supposed to deliver medical services free or at very nominal fees but in effect are found wanting. There are no minimal standards clearly specified for commissioning of hospitals or dispensaries and it is not unusual to find Primary Health Centres being reduced to the structure of bricks and mortar. Hence even the Health Policy promises to have at least one PHC for every 30,000 population, this goal is not attained and at times even when there is a PHC existing, it could hardly be functioning. Comically hotels and restaurants of some cities in India are graded according to the services they make available but not the hospitals.

The quality and quantity of health/medical care made available to the people is hopelessly inadequate and with the paucity of resources it is clearly evident that radical and pragmatic legislative and policy approaches are necessary. Strangely it is the countries where health/medical care is of a high standard, which are clamouring for 'radical' changes in their system to be even more effective e g, in March 1987, the British Medical Association recommended that the government introduce a 'no-fault' compensation scheme based on the Swedish model. Diana Brahams (*Lancet*, January 2/9, 1986, p 43) explains "In my view the term 'no fault' is inaccurate; in truth the scheme provides compensation without apportioning blame for unexpected adverse results arising from medical treatment in which error was an important factor. A failure to act, or to act in time, may also be compensable."

It is interesting to compare medical malpractice perspective in US and UK (where consumer awareness is high) before one takes stock of the situation in India. In the United States (as everyone knows) the suits pertaining to medical malpractice are far more frequent than those in United Kingdom. Lois Quam *et al* of the Centre for Socio-Legal Studies, Oxford, have reported in an excellent study in this respect (*BMJ*, vol 294, 1987, pp 1529-1532 and vol 294, 1987 pp 1597-1600) that "the reasons for this are related to American health care and social security systems. "Relative to United Kingdom, there are fewer barriers of access to the courts." "The differences between the National Health Service and American health services are gross and well recognised. The close relation between the cash nexus of private practice and high rates of litigation in the USA is less understood." Patients who are paid directly for their health care, through a mixture of insurance premiums and contributions out of pocket, seem more likely to feel aggrieved when treatment fails. Moreover, litigation is fuelled by the sheer cost of extra care after an iatrogenic injury or treatment.

In principle the National Health Service (UK) seems likely to reduce claims in at least four ways: There is no direct cost to the patient for extra medical care to remedy injury; access to care is guaranteed throughout life; there is no direct financial relation between doctors and patients; and the system of referrals restrains specialists while encouraging loyality between patients and their general practioners."

It is important to note that in both the countries, there is adequate provision (monetary or by services) for medical and nursing care for the remainder of life. In our country medical and health-care is grossly inadequate and despite a number of medical malpractices there is hardly any litigation or effort to redress injustice caused. Even when there is litigation, the odds are heavily pitted against the patient in more ways than one: (i) there is a strong nexus amongst doctors to 'protect' one another in the event of a case in the court; (ii) patient record is not available to the patient (unlike in Sweden) for proper presentation of the case; (iii) and lastly the cases drag on (very often) for such an extraordinary length of time that most people find it beyond their means to 'sustain' litigation. Although the Legal Services Authority Bill has been passed under which free legal services are made a statutory right the bill has grave limitations and is self-defeating. That it does not provide for mass participation and nor does it attempt to provide relief beyond the monetary (see Krishna Iyer's Comment in *From the Lawyer's Collective*, November 1987). Thus, legal provisions cannot be an end in themselves. While legislation provides for the possibility of ensuring justice without prejudice both its content and form are limited to the socio-political context of particular societies. Its extension and implementation is a consequence of people's movements.

Anil Pilgaokar

Medical Malpractices and Law

mihir desai

Although medical negligence claims are an off-shoot of industrial capitalism, given the circumstances, the existing negligence law can serve a useful purpose in imposing a certain accountability on the part of the doctors and providing redressall for injuries. The legislation should thus be seen not just as a reflection of bourgeois ideology but also as a bourgeois democratic right which requires to be extended and expanded.

MEDICAL negligence litigation has in the past too decades risen sharply in England and the US. Especially in the US it has reached such a stage that a strong and active lobby has come up against this. It has also led to the increasing practice of 'defensive medicine' and a rise in doctors' insurance rates. In India, of course, there is no corresponding trend. The Indian law on this aspect, however, slavishly follows the British and the American law. These trends therefore become very relevant in India not only for gauging the potentialities of this type of litigation in India but also to highlight the positive and negative aspects of this system. Though the medical systems in the US and in UK are very different—complete privatisation in the one while state health services in the another—the law is virtually identical. These trends cannot be viewed in a vacuum but only in the context of the socio-economic aspects of medical-malpractice liability and the reasons why its development has been stagnant in India.

Medical negligence litigation is a response to the following types of questions:

What are the rights of patients vis-a-vis the doctors and hospital?

What if the doctor wrongly diagnoses a disease?

What is the level of competence expected of a doctor?

Does a doctor have to take the consent of the patient before an operation?

If many doctors have handled a patient which of them is ultimately liable?

The common issue in all this is the patient's allegation that the doctor has been negligent.

Negligence and Torts

Medical negligence is a branch of the law of negligence which in turn is a branch of the law of Torts. The Tort law is not based on any act of Parliament. It is mainly a judge-made law developing over the years through changing judicial decisions. It is not possible to define Torts but broadly speaking tort is a wrong done by one person to another for which the law provides a remedy. The idea is to monetarily compensate the victim rather than punish the offender—as would be the case in criminal law. It includes disparate events such as a car accident, injuries due to emission of poisonous gas, doctor's negligence causing death of a patient, defamation of a person, compensation for injuries suffered by a wife at the hands of her husband, etc. The motives of the offender are not very relevant. The focus is on the victim...

A person is said to be negligent when s/he acts without due care in regard to the harmful consequences of his/her action. When we say that a person has been negligent we are saying that s/he acted in a way that s/he ought not to have acted. This assumes that we know how s/he ought to have acted. The way in which we consider that s/he ought to have acted is the norm or standard which entitles us to condemn the person for being negligent when s/he fails to comply with the standard.

The tort of negligence is made up of three components:—

(1) A duty or obligation recognised by the law requiring the person to comply with certain standards of conduct for the protection of others against unreasonable risks. Initially charitable hospitals used to claim that they could not be held negligent as they had no duty to take care of patients since they were not charging them. Now of course the courts always disregard such defences.

(2) A failure on the part of the person to conform to the standard required—what is known as a 'breach of duty'.

(3) A reasonably close causal connection between the conduct and the resulting injuries.

(4) Actual loss or damage resulting to the other.

So, negligence ultimately is a matter of risk—that is to say, of recognisable danger or injury. Persons are supposed to meet with certain standards of conduct. This standard is supposedly based on what society demands of its members, rather than upon the actor's personal morality. A failure to conform to the standard is negligence even if it is due to clumsiness, forgetful nature, an excitable temperment or even sheer ignorance. In other words, the state requires of a person not to be awkward or a fool.

In negligence, the actor does not desire to bring about the consequences which follow nor does s/he know that they are certain to occur, or believe that they will. There is merely a risk of such consequences sufficiently great for a 'reasonable person' in his/her position to anticipate them and to guard against them. Risk can be defined as a danger, which is apparent or should be apparent, to one in the position of the actor.

Nearly all human acts, of course, carry some recognisable or remote possibility of harm to another. No person so much rides a horse without some chance of a runaway nor does any surgeon perform an operation without some chance of himself suffering a heart attack and messing up the operation. These are of course, 'unavoidable accidents' for which there is no liability. As the gravity of the possible harm increases, the apparent likelihood of its occurrence needs be correspondingly less to generate a duty of precaution. Thus the standard of conduct which is the basis of the law of negligence is normally determined upon a risk-benefit form of analysis by balancing the risk in the light of the 'social value' of the interest threatened, and the probability and the extent of the harm, against the value of the interest which the actor is seeking to protect and the expedience of the course pursued.

Professional Negligence

Uptil now what we have talked about is the minimum standard below which the individual is not permitted to fall. But if a person in fact has knowledge, skill or even intelligence superior to that of the ordinary person, the law will demand of that person's conduct be consistent with it. Professional persons are not only required to exercise reasonable care in what they do, but also a standard minimum of special knowledge and ability.

Let us look at how in practical situations the law applies to doctors. A doctor may, of course, contract to cure a patient, or to accomplish a particular result, in which case he may be liable for breach of contract. This is not, however, what generally happens. In the absence of such an express agreement, the doctor does not warrant or insure a correct diagnosis or a successful course of treatment and a doctor will not be liable for an honest mistake of judgment where the proper course is open to reasonable doubt. But by undertaking to render medical services, even though gratuitously, a doctor will evidently be understood to hold himself out as having standard professional skill and knowledge. The formula which is used is that the doctor must have and use the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing, and a doctor will be liable if harm results because he does not have them. Sometimes this is called the skill of the 'average' member of the profession, but this is clearly misleading. Since only those in good professional standing are to be considered; and of this it is not the middle but the minimum common skill which is to be looked to. If the doctor claims to have greater skill than this, as when the doctor holds himself out as a specialist, the standard has to be modified accordingly.

Of course, there are areas in which even experts differ. Where there are different schools of medical thought and alternative methods of acceptable treatment, it is held that the dispute cannot be settled by the law and the doctor is entitled to be judged according to the facts of the school the doctor prefers to follow. This does not mean that any quack or a crackpot can let himself be known as a 'school' and so apply his individual ideas without liability. A 'school' must be a recognised one within definite principles and it must be the line of thought of a respectable minority of the profession. In addition there are minimum requirements of skill and knowledge, which any one who holds himself out as competent to treat human ailments is required to have, regardless of his personal views on medical subjects.

Since judges/juries are essentially lay people, they are held to be normally incompetent to pass judgment on questions of medical science or technique and so only in certain types of cases findings of negligence are given in the absence of expert medical evidence. Normal reluctance of doctors to testify against co-professionals came in the way in US and UK and is likely to be a big hurdle even in India. Now of course, in US and UK more and more doctors came forward to give evidence on behalf of patients. Also, where the matter is regarded as within common knowledge of the lay people, as when the surgeon saws off the wrong leg or where injury is caused to a part of the body not within the operative field, the judges often infer negligence without expert evidence.

The cumulative effect of all this is that the standard of conduct becomes one of 'good medical practice' i e, what is customary and usual in the profession.

This, of course, gives medical profession a privilege denied to others, of setting their own legal standards of conduct, merely by adopting their own practices, except in certain cases like in the cases of sponges left in the patient's abdomen after an operation where the task of keeping track of them has been delegated by the surgeon to a nurse. Though this was and is still a routine practice, the doctor was found to be negligent.

Some Specific Trends

In one of the earliest decided cases, in 1767, an English court felt that the surgeon was liable as he had acted contrary to the known rule and usage of surgeons. What happens if the patient is injured because of the omission to carry out an available test, which is not generally conducted by doctors for such patients? In 1974 an American Appeal Court was faced with this issue. Barbara Helling suffered from primary open angle glaucoma. This is a condition of eye where there is an interference in which normal fluids flow out of the eye. There can be a resultant loss of vision. The disease has few symptoms and in the absence of 'pressure test', is often undetected till irreversible damage is done.

Helling contacted two opthamologists—Carey and Laughlin—at that time believing that she was suffering from myopia (shortsightedness). From 1959 to 1968 she consulted these doctors, who fitted contact lenses and believed that irritation caused in her eyes was because of complications associated with the lenses. For the first time in 1968 they tested the patient's eye pressure and field of vision. This indicated that she had glaucoma. By that time the patient, who was 32, had essentially lost her peripheral vision and her central vision was reduced. She filed a case for damages.

The doctors argued and proved that the standard of the profession did not require the giving of routine pressure test to persons under the age of 40 as the incidence of glaucoma is 1 out 25,000 persons under the age of 40. They argued that since they had acted in accordance with the standard practice of the profession they had acted with reasonable prudence. The court, however disregarded this defence. The judges held: "In most cases reasonable prudence is in fact common prudence, but strictly it is never its measure. A whole calling may have unduly lagged in the adoption of new and available devices. Courts must in the end say what is required: there are precautions so imperative that even their universal disregard will not excuse their omission."

The court felt that despite the fact that a pressure test was not used generally by opthalmologists, the doctors ought to have used it. Barbara received compensation.

The importance of the case lies in the fact that the standard of care required of the doctors is widened. Normally, of course the standard adopted in the profession would be acceptable as the standard required of each doctor. But this case for the first time obliged doctors to conduct certain known tests even if they were not being conducted in the profession generally.

This case created a storm in the USA. Attempts were made through courts and legislature to change the law laid down by the case, but ultimately they have proved to be futile. However, the application of this case is only confined to a

narrow field of possibilities and that of 'general practice' within profession is still widely applied.

Hospital Liability

A question of immense significance is whether a hospital can be made to pay for negligence of doctors, nurses and other staff. This is an issue of great importance in India. Many times it is not possible to point out the person whose negligence led to injury. Take the example of a patient who is given saline by a number of doctors and nurses from time to time. A particular needle may not be sterilised causing gangrene. It is not possible to know who exactly was negligent. Can one then sue the hospital? Or many times it may so happen that the negligent staff member does not have means to pay. Can one sue the hospital and recover?

The most important American case on this point was Darling vs Charleston Community Memorial Hospital decided in 1966. In November 1960, Darling, 18 years old, broke his l[illegible] while playing college football. He was taken to emergency ward of Charleston Hospital and treated by Dr. Meroander, who applied traction and placed the leg in a plaster cast. Soon after, Darling was in great pain and his toes which protruded from the cast, became swollen and dark in colour. His condition kept on worsening and ultimately the leg had to be amputated.

As to the question whether there was negligence or not, the court held that the nurses had not checked sufficiently, and as frequently as necessary, the blood circulation in the leg. Skilled nurses would have promptly recognised the condition, and would have known that they would have become irreversible in a matter of hours.

The question was whether the hospital was liable. The judges held: "The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and patients, but undertakes instead simply to procure them upon their own responsibility, no longer reflects the fact. The present day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment. They regularly employ on a salary basis a large staff of physicians, nurses and interns, as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action. Certainly the person who avails himself of hospital facilities expects that the hospital will attempt to cure him not that the nurses and other employees will act on their own responsibility". The hospital was made to pay damages.

The Darling case became a landmark decision in medical malpractice claims as it places a direct responsibility on the hospital for the maintenance of an acceptable standard of care for patients. Subseqently, the scope of even this decision has been widened and charitable hospitals have also been held to be responsible.

Is the hospital liable if the patient's infection is traced to blood products supplied during his operation? In a 1970 Illinois state case, the hospital was held to be strictly liable for supplying contaminated blood. A hospital will also be liable for negligence of any honorary doctors or specialists it calls but not for private doctors called by the patients themselves. Hospitals, in same case have been held guilty even when its employees have acted in direct contradiction of the hospitals' instructions or prohibitions causing injury.

Strict Locality Rule

The standard of care expected of doctors is generally speaking that prevalent in the profession. They are not only required to perform tests generally performed, but also to be informed sufficiently about the new developments in the field.

One of the most debated issues in the US and UK arose out of a presumption that the rural and small time practitioners would be less adequately informed and equipped than their big city colleagues. To adjust to this the courts came out with a theory that there could not be any national standard of care but the standard varies from locality to locality. They applied the strict locality rule which meant that the standard of care expected of doctors depended on the general standard of that particular locality. However, in recent times this rule has been given up and national standard applied on the basis that "new techniques and discoveries are available to all doctors within a short period of time through medical journals, closed circuit television, special radio networks for doctors, tape recorded digests of medical literature and current correspondence course".

This situation is prevalent only in developed capitalist countries. In backward countries like India with uneven development, it is very likely that when cases come up, the strict locality rule will be applied.

Res Ipsa-Loquitor

Ultimately it is for the patient to prove that it was negligence which caused her/his injuries. It many times becomes difficult to do so for varied reasons like information hiding by the doctors, etc. What happens in some cases, however, is that after presenting all evidence, though directly negligence is not proved, it is still pretty obvious that the patient could not have suffered injuries except through negligence. In such cases the legal doctrine of *'Res Ipsa Loquitor'* or 'the thing speaks for itself' is applied. Negligence is presumed to have been proved and the doctors held liable.

In a case decided in an American court in 1975, a patient Anderson was admitted to hospital for a back operation. During the operation, the tip or cup of a forcep like instrument (angulated rongekur) broke off while it was being manipulated in the patient's spinal chord. It could not be recovered and the patient suffered permanent injury. Anderson sued the doctor, the hospital, the manufacturer and the distributor. Each tried to push the blame on the other and it could not be proved as to whose negligence had led to this complication. It was not established whether the rongekur broke because of manufacturing defect, certain problems during transit or due to the doctor's negligence. If it was merely a case of determining negligence from amongst the hospital staff and doctors then even without establishing who exactly was negligent, the hospital could have been saddled with damages. Here of course, the hospital was saying that it was not the neglect of staff or doctors which caused the rongekur to break but that of the manufacturer or dealer.

It was just not possible to establish what caused the breakage. The court, however, came to the rescue of the patient and observed, "In the type of case we consider here, where an unconscious or helpless patient suffers an admitted mishap not reasonably foreseeable and unrelated to the

scope of surgery (such as cases in which foreign objects are left in the body of the patient), those who had custody of the patient, and who owe him a duty of care as to medical treatment, or not to furnish a defective instrument for use in such treatment can be called to account for their default. They must prove their unculpability or else risk liabilities for injuries suffered". All of them were held jointly liable.

The doctrine of *Res Ipsa Loquitor* has been extensively used in 'swab cases' where after the operation, an instrument is left inside the patient's body. It has also been used for other types of cases—for instance in the Canadian case of MacDonald vs York County Hospital Corporation, the patient was admitted for treatment of fractured ankle and left with an amputated leg. Heavy damages were awarded to MacDonald despite there being no direct proof of negligence.

Misdiagnosis

A liability will be imposed when the doctor fails to conduct tests which a competent practitioner would have considered appropriate or when the doctor fails to diagnose a condition which would have been spotted by a competent practitioner. In Langley's case the patient had returned from East Africa shortly before the development of symptoms. The general practitioner failed to diagnose malaria and this was considered as negligence. Similarly in Tuffil's case the patient had spent many years in a tropical climate, the doctor failed to diagnose amoebic dysentry which proved fatal. This failure to diagnose was held to be negligence.

A question which arises is whether a new doctor would have the same responsibility as a seasoned doctor? The law makes no distinction in this regard. In Wilsher vs Essex Area Health Authority, the patient had been born prematurely and had been admitted to a special unit where extra oxygen was administered to him over a long period. His sight was badly affected as a result of a junior doctor's failure to monitor properly the supply of oxygen. The hospital was held to be liable.

In many cases it is a part of the duty of the doctors and nurses to predict that the patients may damage themselves as a result of their medical condition. For instance in one case the patient had been admitted to hospital after a drug overdose. Although he had known suicidal tendencies he was not kept under constant observation and he climbed on the hospital roof and fell incurring injuries, while the two nurses on duty were out of the ward. He was awarded damages of £ 19,000.

Informed Consent

One of the most rapidly growing medical malpractice litigation is in the areas of 'informed consent'. This concerns the duty of physician or surgeon to inform the patients of the risk involved in treatment or surgery.

The principle behind this is the classical bourgeois democratic ideal of individual autonomy, i e, that every person has a right to determine what will be done to her own body and the right to have bodily integrity protected against invasion by others. Only in certain narrowly defined circumstances can this integrity be compromised without the individual's consent.

Surgeons and other doctors have to provide their patients sufficient information to permit the patient to make an informed and intelligent decision on whether to submit to a proposed course of treatment or surgery. So, even if a procedure is skillfully performed, the doctor may nevertheless be liable for an adverse consequence about which the patient was not adequately informed. Of course, the patient has to show a causal link between the non-disclosure and her injury by proving that she would not have undergone the treatment if she had known the risk of harm that in fact occurred. The courts believe that all patients in retrospect would say this and so even here they have evolved the criteria of 'reasonable patient', i e, whether this hypothetical patient in the actual patient's place would have withheld consent to the treatment had the material risks been disclosed. This, of course, is problematic because the individual patient's characteristics are totally ignored. Slowly, the courts in US are trying to incorporate even this subjective factor.

What risks have to be disclosed? All the material risks, i e, the nature of pertinent ailment, the risks of proposed treatment, including the risks of failing to undergo treatment, have to be disclosed. Even if the risk is a remote possibility it should be disclosed. However, unexpected risks may not be communicated. For instance, in an American case a patient suffered cardiac arrest during amniocentesis. There were no prior documented cases like this. The doctor was not held to be negligent.

Even otherwise there are cases where the risk disclosure may be precluded by an emergency situation or the patient's incapacity. In fact in the US all states have passed what are called 'Good Samaritan Laws' aimed at protecting doctors giving emergency roadside treatment.

The disputed issue is whether for the benefit of the patient, the doctor can withhold information from them. This happens many times when doctors feel that the patient will suffer mental shock or nervous breakdown if the risk is communicated. Such withholding is called 'theraupeutic privileges'. But there is another school which believes that all information should be disclosed so that the patient can make up her/his mind in the light of all the circumstances. The courts are divided in this point.

A problem which has not arisen in the western countries but which can arise in India is if the patient is conscious and does not consent to a treatment which is necessary to save her/his life. Can forcible treatment be justified? In most of the western countries suicide is no longer a crime and so doctors cannot forcibly treat anyone. In India, of course, this question is likely to cause some problems.

The case of minors also raises a perplexing problem. Since minors are considered by law incapable of giving consent the parents' consent has to be obtained. But what happens if a minor who is of understanding age gives instruction contrary to that of the parents? In one English case, a school girl aged 15 wanted an abortion but the parents refused to grant permission. The court held that the girl was entitled to abortion as she was capable of understanding its implications.

Nowadays, at least before surgery, a patient is normally required to sign a consent form. But the patient can still prove

that no consent or informed consent was taken and the doctor will then be liable to pay damages.

Indian Cases

In spite of making a detailed survey, the writer could find only three reported cases on medical negligence in India.

(1) The first case was decided by the Lahore High Court in 1935. R N Rao, a lawyer, suffered from high fever and sores on his face. Dr Whitamore, the Civil Surgeon, treated him. He diagnosed the disease as syphillis and gave injection of Sulphatab. Later Dr Rao suffered from gangrene and had to have his fingers amputated. His eyesight was affected and he lost his strength. He never had any syphyllis and he was informed that he had contacted peripheral nueritis because of a mistaken injection of arsenic.

The court, however, did not find the doctor guilty. The reason given was that though the diagnosis was wrong specific carelessness was not proved. The court adopted a reasoning which would be totally unacceptable today. It did not go into the question as to whether the doctor had performed the required tests before concluding that there was syphllis. Neither did it try to a answer the question as to what caused the gangrene.

(2) The second case was one decided by the Supreme Court in 1969. Anand met with an accident on the beach at Palshet in Maharashtra which resulted in the fracture of the femur of his left leg. The only treatment the local physician gave was to tie wooden planks on his legs for immobilisation. The follwing day he advised removing Anand to Poona for treatment. He also substituted splints for the planks. After that, in a taxi, Anand was shifted to Poona. Dr Joshi got him screened and found that he needed pin traction. He was then taken to Dr Joshi's hospital. Dr Joshi asked his assistant to give Anand two injections of morphia and hyoscine HB at ½ hour interval. Dr Irani gave only one injection. Anand was then taken to the X-ray room, and after taking two X-rays removed to the operation room. After about ½ hour when the treatment was over, he was shifted to the room he was allotted. On an assurance given by Dr Joshi that Anand would be out of the effect of morphia in 1½ hours, Anand's father went back to his village. Anand's mother remained with him. After about an hour she found that Anand was having difficulty in breathing and was coughing. The doctors were called, Dr Irani, Dr Joshi's assistant gave emergency treatment upto 9.00 pm when the boy died. Dr Joshi issued a certificate saying that Anand had died of fat embolism.

Dr Joshi was sued. Anand's father contended that Dr Joshi did not perform the essential preliminary examination of the boy before starting his treatment and injecting morphia. It was also alleged that while putting the leg in plaster manual traction was used, using excessive force with the help of three men though such traction is never done under morphia alone, but under proper general anaesthesia. Dr Joshi in his reply denied the allegations by saying th. no general ahaesthesia was given considering the exhausted condition of patient. It was decided to immobilise the fractured femur by plaster of Paris bandage, and no excessive force was used. However, on evidence the court felt that Dr Joshi was negligent. It came to the conclusion that it was due to shock resulting from reduction of fracture attempted without taking the elementary precaution of giving anaesthetic to the patient.

Speaking about the duties of doctors the court repeated the British and American law saying, "The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz, a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of these duties gives a right of action for negligence to the patient".

(3) The third case was decided by the Bombay High Court in 1975. This case reads like a doctor's apology. Philips India had appointed a doctor to give treatment to the employees. One employee contacted smallpox and died. The doctor had treated him for veneral disease. The court felt that there was a genuine error of judgment and since the particular variety of smallpox was fatal, the doctor anyway could not have done much. The problem with the case is not that it exonerated the doctor, especially considering the peculiar facts of the case, but the extent to which it sought to protect doctors. The court expressed the view that negligence for doctors should be interpreted much more narrowly than negligence of others, i e, the doctor has to be placed on a high pedestal and held to be negligent only if it is totally unavoidable.

Of course, this case is not likely to have any impact on subsequent cases, but still it shows the attitude of the judges. The important point decided by this case, however, was in holding that if the doctor had been proved to be negligent, the company which employed him would also automatically be negligent.

All the three cases relied only on English law books—by of course picking and choosing what suited the court's conveniance.

Politics of Torts

A proper understanding of the rise of 'negligence law' requires an analysis of the development and rise of the Tort Law. An extensive application of tort law is found only in developed capitalist countries. Developments at similar scale cannot be expected in third world countries. Let us therefore look at the causes which gave rise to tort law in developed capitalist countries.

In the earlier period, law was largely preoccupied with personal status, control over resources (primarily land) and the development of contractual relations (mercantile capitalism). Industrial capitalism transformed the entire social structure, engendering urbanisation which enormously increased the frequency of interaction among strangers. Important, because unlike aquaintances or intimates strangers would have less incentive to exercise care not to injure one another inadvertently and would find it more difficult to resolve the differences when injury occurred. At the same time interaction between friends and intimates became progressively limited—ultimately confined to the nuclear family. Intimates commit most intentional torts. But within the nuclear family they are rarely resolved by the legal system, (a) because they would destroy the relationship (b) the persons committing torts are sufficiently powerful.

Industrialisation gave capitalists the power to effect extensive damages first through domination of unprecedented

amount of physical force (factories, railways, etc) and now through toxic chemicals. Concentration of capital and mass production increased the number of workers, consumers and others who might be harmed by capitalists' indifference or miscalculation.

Capitalism also shapes the experience of injury. It must create a proletariat which must sell its labour for wages to live. It simultaneously destroys the obligation of mutual support outside the nuclear family and pays those within it who are gainfully employed at a level of wages too low to support non-production members. As inability to work becomes tantamount to destitution or dependence upon charity, the core of damages is compensation for loss of earning capacity.

Second, capitalists, middle classes and even industrial workers acquire consumer goods which require protection against inadevertent destruction.

Third, family is no longer able to care for injury or illness, partly as members must seek employment outside and partly because care itself is commodified and monopolised by the emergent medical profession. As the monopoly allows professionals to command high fees, injuries 'cost' a great deal more.

Finally, commodity form is progressively extended to non-productive experience.

Capitalist tort law exploits and alienates the victims in ways parallel to exploitation and alienation of labour. In pre-capitalist society, injury like work creates use value, it elicits cure from intimates who are motivated by concern and promotes demand for apology backed by threat of retribution. The capitalist state which asserts its monopoly of force to obstruct the latter response also creates a market for injuries in torts and legal system. It separates through the legal proffession tort victims from means of redressing their wrongs and medical profession disabled victims and intimates from caring for the ill. In each instance, a faction of the ruling class mobilises the power of the state in its own interests to protect the monopoly of expertise of lawyers and physicians. The lawyer then combines legal expertise with the victim's injury (as the capitalist combines capital with the workers' labour) to produce a tort (a commodity) that has exchange value both in the state-created market (the court) and in the dependent markets (negotiated settlements).

As capitalists have to maximise profit in a competitive market, they must sacrifice health and safety of others. Another reason why capitalism fosters injury is that it must expand its market and increase consumption; torts contribute to it just like planned obsolescence and warfare.

Tort law, following legal liberalism, eliminated formal legal discrimination. So, with its development discrimination between patients who are victims of charitable hospitals and those of non-charitable hospitals, etc, were eliminated. But it could not and cannot remove certain deeper inequalities.

First, of course, the inequality in the incidence of injury and illness: capitalists and professionals are subjected to totally different hazards than those suffered by workers at the work place or women at home. The rich can avail of the best medical facilities, equipment and medicines, not so the poor.

Secondly, the class and gender will affect the extent to which and the way in which the experience of injury is transformed into a claim for legal redress, the sense of entitlement to physical, mental and emotional well-being (women only recently began to legally resist abuse by their husbands, workers are only now coming to view hazards at work place as a negotiable demand), the feeling of competence to assess a claim, the capacity to mobilise legal process, ability to overcome delay, etc.

Third, the law also discriminates in the availability and generosity of the remedies it offers, the biggest difference being between tort damages and other compensation systems. An industrial worker is far more likely to be injured at work than a person from another occupational category: such injuries are relegated to workmen's compensation, which pays only a fraction of tort damages and rejects altogether certain tort categories. Other oppressed categories—women, children, dalits, religious minorities—are also excluded from tort recovery. They are most frequently the victims of violent crimes and other social crimes whose assailants are either unidentifiable, unavailable, financially irresponsible or simply too powerful. Women and children injured by relatives are left without any remedy.

Another type of discrimination is internal to the tort system. Pecuniary damages are paid on the basis of income of the person. Even the damages for pain and suffering are often expressed as multiples of pecuniary damages. So a poor person will get much less damages than a rich person. Women will get much less than men.

Production of Illness

Capitalist tort law systematically encourages unsafety. The dynamic of capitalism—the pursuit of profit impels the enterprise to endanger the workers, its employees and those who inhabit the environment it pollutes. As the cost of safety reduces profits a capitalist must be as unsafe as he can get away with being.

Apparently the Tort law curbs these destructive tendencies through the threats of damages. But this is not what actually happens.

First, compensation is paid on the basis of the status of the victim not of the offender—the doctor for instance.

Second, the insurance mechanism goes a long way in virtually nullifying the burden on the offender.

Third, as seen above, due to the discriminatory aspect of Tort law many injuries and victims are excluded from its purview.

In fact Tort law motivates the entreprenuers and the professionals to seek to evade the consequences of carelessness not to enhance safety. Their response to the threat to tort liability is to strive to externalise accident costs by concealing information. For instance, the market deterrence, by mandating the payment of money damages, subverts collective efforts to exert control over safety—damages are paid only for an injury caused by the offender's act. This means that unsafe conduct causing no injury is not deterred and that the legal attention is focussed on the temporarily delineated act of an individual rather than on the ongoing activity of a collectivity. Capitalist Tort law, like capitalist medicine, is obsessed with individual care at the expense of collective prevention because capitalism creates a market only for the former.

In fact the medical profession is not even interested in curing patients, only in 'treating' as many as possible. Also the costs of damages are externalised by increased professional

fees and insurance. In England, various Medical Defence Societies have been established. It there is a successful claim involving negligence of a hospital employee, the amount will be shared by the authority and society. As regards nurses, the Royal College of Nursing holds an insurance policy, idemnifying every member. So, ultimately the costs are passed on to citizens.

The Tort law is significant for the reproduction of bourgeois ideology. The fault concept upon which the law was built reinforces a central element of bourgeois ideology, individualism. Predicating liability upon the offender's fault and denying recovery because of the victim's fault perfectly express the bourgeois belief that each person controls his or her own fate.

Tort law offers symbolic support for inequality—by compensating owners for property damage it upholds the notion of private property and its concomitant, i e, the person's weight as a tort plaintiff is proportional to the value of the property he owns.

Also, by relegating injured employees to worker's compensation, which is limited to a fraction of the lost wages, the law treats workers like pure labour value, implicitly denying that they undergo the pain and suffering for which tort victims are given compensation.

Finally, Tort law assumes that for every pain suffered there is some equivalent pain which will erase it, a pleasure that can be bought with money and, therefore, the judges must simulate a market in sadomasochism by asking themselves what they would charge to undergo the victim's misfortune.

Also the Tort law treats all relationships as forms of prostitution—the semblance of love exchanged for money: Tort law thus generalises the feminist critique of marriage. Just as society pays 'pain and suffering' damages to the injured victim who is shunned (so s/he can purchase the commodified care and companionship that will no longer be volunteered out of love and obligation), so it pays damages to those who loved him, compensating them for their lost 'investment' in the relationship (so that they can invest in other human capital).

The Socialist Approach

The primary concern of a socialist alternative should be to ensure that those at risk regain control over the threat of injury and illness: compensation must be subordinated to safety, although the former goal remains important.

Even if all defects in the capitalist compensation system are removed—100 per cent damages, etc—two defects are irremediable.

First, it would mean spreading the costs across society through a social welfare scheme but does not mean spreading the risk of accidents more equally.

Secondly, valuation of injury and illness is still done by the state and not by people who suffer it. These are the problems in New Zealand where since 1974, in place of negligence they have what is called a 'no fault' compensation system.

A just system should be based on substantive equality. It should respond to all victims. Equality amongst victims would mean response to their needs whether or not their misfortunes were caused by fault or by human actions. The second is that the qualities of wealth and income should not be reproduced in the level of compensation.

It is obvious that tort law can develop extensively only in developed capitalist societies—only where there is a strong dominant ideology of bourgeois individualism, extensive and all-pervading commodity production (where everything is measured in term of money) and certain minimum standard of living where victims have the 'staying power' in courts, and offenders have sufficient means of payment. This, of course, is not the case with India, where we have a backward capitalist economy. Even then with the growth of capitalism more and more actions in torts are likely to arise.

Conclusion

Medical malpractice is already a well entrenched litigation sphere in western countries. Though in India uptil now there has been precious little happening on this front, it seems that more and more medical malpractice claims are being filed since the past five years, and over the next decade or so this branch will acquire at least some significance.

One cannot deny the fact that medical negligence claims are an offshoot of industrial capitalism and premises on the bourgeois ideology. Accountability of doctors coupled with redress for the victim can be much better tackled through and for a greater extent solved in societies not based on competition, treating injuries as commodities. The existing negligence law is not a panacea. But given the circumstances, it serves a useful purpose at least to an extent to mitigate the victims and bring accountability to doctors. In fact it should be seen not just as a reflection of bourgeois ideology but also as a bourgeois democratic right which requires to be extended and expanded. Also, in a country like India, where especially the poor receive extremely negligent medical treatment, extensive application of medical negligence law by people and by progressive groups can be very helpful to people and at least some way of improving health services. Also, surveys in US indicate that medical practice litigation provokes greater care at least in diagnosis.

One can only end by saying that despite its limitations, the law of medical negligence should be as widely used in India as possible.

Notes

[For many of the ideas expressed in this article I am deeply obliged to the following works:]

1 Article by Richard Able in *Politics of Law—A Progressive Critique.*
2 Hugh Collins: *Marxism and Law.*
3 Fire: *Democracy and the Rule of Law.*
4 Ronald Dwarking: *Taking Rights Seriously.*
5 Paul Philips: *Marx and Engels on Law and Laws.*
6 Pashukanis: *Marxism and Law.*
7 Curran Shopiro: *Law, Medicine and Forensic Science*
8 Mason and McCall Smith: *Law and Medical Ethics*
9 Keetortn: *Torts.*
10 Christie: *Cases and Materials on Law of Torts.*
11 Charlesworth: *Negligence.*
12 James: *General Principles as the Law of Torts.*
13 K. Bingham: *Modern Cases on the Law of Negligence.*

Banning Pre-Natal Sex Determination-1

Issues and Debates

by teesta setalvad

Five years of extensive campaigning by women and health activists has resulted in a legislation banning the selective abortion of female fetuses through the misuse of amniocentesis and other technologies. What have been the major issues which have emerged in the course of the nation-wide debate?

FIVE YEARS of extensive compaigning by women and health activists have earned us the assurance of proposed legislation banning the selective abortion of female foetuses through the misuse of amniocentesis and other technologies.

The legislation will be restricted to Maharashtra despite the centre's assurances of a countrywide law. This limitation could prove fatal to the effective implementation of the aims. The lack of a ban in neighbouring states, where the practice of selective abortion of female foetuses has grown in alarming proportions since 1983, could prompt a largescale burgeoning of clinics offering this facility indiscriminately, just across the Maharashtra border.

Though the central government has given all possible indications of passing an all India law banning the selective use of amniocentesis and other technologies, and a special committee to recommend the terms of this legislation had been appointed in March 1987 which has submitted these to the government around September last year, New Delhi seems to have chickened out of the issue. Laudable though the decision of the Maharashtra government must seem, it must be remembered that in Gujarat, Punjab, Haryana, and even New Delhi, the country's capital with these clinics blatantly offer these facilities.

Debate among activists demanding such legislation centred around two points, whether such a ban should be total or selective and if the latter, which clinics should be exempted: in the interests of the benefits of some of these tests that are vital in detecting the genetic abnormalities of a foetus. Many activists, though genuinely fearing the growing trend of such selective abortions, expressed grave reservations that such legislation would only push these tests underground. Legislation cannot and should not be the aim of such a campaign. Such legislation that precedes the change in social mores and attitudes so drastically must be backed up by certain schemes that create conditions for the aims of the law to be implemented. The debate among activists on the question of a ban, selective or complete, focussed around two main issues: the overall status of women in the country that can lead to such largescale abortion of female foetuses and the grave question of the misuse of advanced technologies, ignoring its impact on the health of women. Several democratic and liberal forces ranged against the discussion and strove through their stand to defend that ultimate test of freedom—choice.

Are choices exercised in a vacuum? The scores of women interviewed and questioned by journalists and activists clearly enunciated the rationale behind their exertion of the supreme choice—to abort after the result of a sex determination test showed the foetus to be female—to save their skin from torture or battering, to maintain their status within the marital home, to save a marriage on the rocks. All this because of the *woman's* supposed inability to bear a son.

Even more infructuos arguments were used. These included the defence of amniocentesis and other tests as a tool to reach family planning targets. Another devious counter to the increasingly vociferous protests from women's groups was the postulate that the status of women would naturally improve in societies where the sex ratio has declined. Both arguments, it needs to be stressed, have been effectively countered.

Sex determination tests do not guarantee a male child. They merely ensure multiple abortions (that is an abortion for every second foetus tested for its sex) which can do immense, if not irreparable harm to a woman's health. Women are being increasingly used and singled out as target groups (and as a result, victims) for family planning and amniocentesis is part of this trend. Lack of food, clean drinking water and a total denial of economic securities and safe clinical facilities have led to a situation where one woman has to have 6.2 children to ensure one surviving male child. The argument therefore, that successive abortions followed by amniocentesis act as family planning tools is untenable.

Research studies on societies having adverse female sex ratios, reveals that customs like polyandry, sharing a wife (outside wedlock) abduction and purchase of women are widely prevalent in such societies. Besides, it is strongly felt that adverse sex ratios may in fact lead to an increase in incidence of rape, prostitution and grave controls over women.

Female mortality was 60 per cent higher than that of males in the age group upto five years. Today, in a situation where the sex ratio is declining, this 60 per cent higher mortality exists upto 8-9 years among girl children.

Faced with these social circumstances, and now assured of legislation completely banning the use of these tests for sex determination of the foetus, activists belonging to the Forum Against Sex Determination and Sex-Preselection (FASDSP), the umbrella organisation of several groups, have forwarded their demands to the government that would give more teeth to the proposed law. Greater powers, like the one to seize and examine documents must be given to voluntary organisations that make up the Vigilance Committees to ensure that the proposed law is effectively implemented. Moreover, the FASDSP is also demanding that these Vigilance Committees consist of adequate representation from voluntary organisations, doctors and government officials who have powers under the Criminal Procedure Code to ensure concrete results.

The Forum is also asking for the inclusion of all internationally accepted indications and 'exposure to potentially teratogenic chemicals and/or radiations' in the eligibility criteria for prenatal diagnosis. The creation of an all-India supervisory body, like a Technical Expert Committee to issue,

renew and cancel licenses and ensure uniform standards at the places approved for prenatal diagnosis, has also been demanded. Periodic inspection visits by this committee to those centres granted licenses to carry out these tests could act as a monitor.

Since the entire campaign, spanning over five years had exposed the blatant ambivalence of the medical profession on an essential question of medical ethics. the FASDSP is also asking for suitable amendments to the Indian Medical Council Act to enable cancellation of the registration of those doctors found violating this proposed legislation. The Forum argues that the two processes of collection of samples and the testing should be de-linked. The former, that involves a collection of the amniotic fluid in safe and hygenic conditions could be carried out at the medical college level after careful screening of applications. Thereafter the testing must be carried out at genetic counselling laboratories where the testing, with sophisticated machinery need be done. Misuse of ultrasonography for sex determination should also be an offence though ultrasonography itself must be excluded from the purview of the ban due to its varied application. The government is considering imprisonment and fine to the offenders and the Forum is stressing that women who undergo these tests must not be punished.

It can be clearly seen that the emphasis, at every stage, in the recommendations put by the FASDSP, for the legislation to have any use, is on vigilance. Vigilance that involves a high level of commitment from both volunteers and officials who participate in the process. The limitations of just resting with this legislation cannot be underemphasised. The greatest problem being the blind preference for a male child, in a patriarchial society where male attitudes and values dominate.

Maharashtra and Gujarat, have over the last few years implemented schemes aimed directly at promoting the girl child/children family norm. Felicitation from the state to a family with only girl children, a special green card that procures extra rations, concessions in education apart from an all out publicity campaign have already begun. Moreover, one of the promotion schemes started in Maharashtra depcit not merely the single girl child family but portray the woman at the helm, making all relevant decisions concerning health and family. Apart from enthusisastic vigilance from voluntary agencies, commitments of this kind in the state's health policy could make the social impact of this legislation more effective. The aim is to give the woman, from girlhood her rightful place and share in society.

Pathetic Attitude of Doctors

More than anything else, the public debate that preceded the legislation reflected as never before the pathetic 'neutrality' of the medical profession on the ethics of the issue. Whereas more 'glamorous' questions like euthanasia draw the most eminent into the pros and cons of the debate, the selective abortion of female foetuses left the top medicos unmoved.

On the contrary, until pushed into a corner on the blatantly embarassing statistics provided through studies conducted by several organisations, medical practioners openly said that 'amniocentesis and appendicitis were their bread and butter.' At as much as Rs. 500 per sample taken, even in remote rural areas, amniocentesis for sex determination has become a lucrative commercial proposition. The number of such centres, with not even minimum standards has proliferated. In Bombay, the capital of Maharashtra the number has gone up from three to at least 20 in the period between 1983 and 1986. The larger of these sex determination clinics perform a minimum of 1,500 amniocentesis tests a year.

The Voluntary Health Association of India (VHAI) has pointed out through a study that the chances of a premature delivery in a woman having undergone amniocentesis are as high as four per cent, and the risk of abortion as high as 1.5 per cent. With these tests normally being conducted in the fourteenth and fifteenth weeks of pregnancy, abortions that follow in the second trimester are inherently dangerous. It need not be mentioned that these risks were either not revealed at all by the doctors performing these tests or, were grossly underplayed. Unless the culpability of the medical profession is assured through the proposed legislation, loopholes that already exist through provisions of the Medical Termination of Pregnancy (MTP) Act that enable a woman to have an abortion, could be exploited while this abhorrent practice continues unabated.

If effective vigilance is not maintained and these tests continue to be available at different centres for sex determination underground, there is no way in which the offence could be detected at the stage at which a woman comes for the medical termination of her pregnancy, that is, abortion. Under the MTP Act, a section provides that a woman can undergo an abortion for 'failure of contraception'. It is being argued that this section could be misused by unscrupulous medical practitioners in league with family members of the woman who have managed a test that reveals the sex of the foetus.

Apart from this, another lacunae exists that can be blatantly used by practitioners to escape the law. This was brought out through a case filed by the Mahila Dakhsata Samiti in the Bombay High Court after 21-year old Sunita Chaturvedi, mother of two girls, died as a result of an abortion that followed a sex determination test. The case which came up before the High Court in October 1986 but has lain in cold storage since, cited the victim's husband, Girdhari Chaturvedi and two doctors Dr. Meenaxi Merchant and Dr. Rajani Arya as respondents. Apart from making out a strong case against the misuse of amniocentesis, this pattern that has failed to move legal brains, reveals how section 8 of the MTP Act can be misused by unscrupulous doctors to shield themselves from the consequences of heinous acts.

This section, provides that no suit or other legal proceedings can lie against registered medical practitoners for any damage caused by any action committed 'in good faith.' Abortion followed by amniocentesis, dangerous and fatal though it might be in the second trimester of pregnancy for the woman, can leave a doctor untouched if this section remains. Such lacunae in the law can be misused against whatever limited benefits that the proposed legislation selectively banning these tests might achieve. Social attitude apart, it must be remembered, medical practitioners though now somewhat hedged in with the threat of legislation, are likely to be the main contenders of the law.

Unless an internal code of medical ethics or specific provision in general criminal law hold them accountable, the

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become stronger. In order to promote a particular brand of a drug company, doctors prescribe medicines to their patients, which are either of no use or are patently harmful. The tremendous hold of the drug industry over the health care system in our country, was recently brought to light by the Lentin Commission. Another example of the proliferation of useless and spurious drugs in the fact that more than 20,000 kinds of non-prescription drugs are on sale in the Indian market, most of which are non-essential and about 25 per cent of them spurious. As against this, the WHO has prepared a check list of only 200 essential drugs. Though the medical council is fully aware of the unethical practices of doctors prescribing drugs known to be harmful and useless, why has the council not prosecuted the doctors and more importantly should not the medical council have powers to initiate proceedings against drug companies?

The research establishment, both private and government, also collaborate with drug multinationals in conducting human trials. Human experimentation by the medical community is justified on the ground that such trials are for the benefit of humanity. For example, experimentation by administering injectable contraceptive Net-pen, which has not been proved as a safe drug is being conducted on several thousands of Indian women, who are being used as guinea pigs without their informed consent. These trials are being initiated by the government's family planning programme. The Helsinki Declaration clearly states that no tests should be conducted on human beings unless they are proven to be safe and without obtaining the informed consent of the person on whom the experimentation is to be done. The Net-ten tests are in clear violation of this declaration. The governmental institutions are the most consistent violators of medical ethics and yet the medical council and courts have been hesitant and unwilling to take any action.

In the Bhopal case, the government and its research institutions have effectively suppressed all medical information pertaining to the after-effects of MIC, and the treatment to be given to the victims. For example, though the Indian Council of Medical Research (ICMR) prescribed mass detoxification to the victims, by injecting sodium thiosulphate, the medical community in Bhopal ignored this recommendation.

The recent scientific advances in the field of reproduction like amniocentesis, chorion villi biopsy (CVB) are calling into question the philosophy and values of medical ethics. Those techniques which were meant to detect genetic deformities are now being widely used for sex-determination. Not a single doctor has been prosecuted by the medical council.

These are just few of the examples where not only doctors but government institutions have flagrantly violated the various international and national codes. And yet nothing has been done and the medical system continues to devour and maim a large number of people.

The extent to which the medical profession will conform to proper standards of medical care will depend to a large degree on the development of the public's awareness of the issue. The basic rules of social conduct can be ensured only if the public maintains a constant and vigilant eye on the doctors in particular and the functioning of the health care system in general. It is only then that the doctors will be forced to abide by the highest standards of medical practice.

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selective abortion of female foetuses could continue unabated. The callous and blatant attitude of the medical profession towards this question can be illustrated through a front-page advertisement appearing in one of the city's eveningers barely five days after the Maharashtra government's triumphant declaration of intent on January 1. This advertisement read in bold type, "Boy or Girl? Contact clinic." A proposed legislation that will, in all likelihood ban such blatant advertising did not deter the doctor couple offering sex determining facilities. It must not be forgotten that, though pushed into a corner on several occasions, the medical profession refused to take an ethical stand before the government's declaration of bringing in such legislation. Apart from the high level of vigilance, a commitment from an ambivalent medical profession, faced with the loss of quick commercial gains, is a must.

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the groups should utilise the avenues available to participate in the implementation process, in order to expose the hollowness of the bill.

The medical establishment had earlier argued that a law would force female foeticide underground. Now they have, in collaboration with the government, brought a law which can partially keep female foeticide above ground, within the purview of law. There is no alternative but to continue struggle against the medical practice of female foeticide.

This Bill has been passed in the Maharashtra Assembly without any significant amendment in April 1988].

Banning Pre-Natal Sex Determination-II

Scope and Limits of Maharashtra Legislation

amar jesani

The Maharashtra government's bill regulating the use of prenatal diagnostic techniques is a concession to the demands of the five-year long campaign. It is also an indictment of the Medical Council for its open disregard of its own code of professional ethics. On the other hand, it carefully avoids touching the private sector, makes a mockery of people's participation and offers many concessions to the medical lobby.

THE Government of Maharashtra has recently introduced a much awaited and talked about bill in the state assembly, "Maharashtra Regulation of Use of Prenatal Diagnostic Techniques Act, 1988". The bill has come in response to a concerted campaign mounted mainly by the Bombay based Forum Against Sex-determination and Sex-preselection and supported by organisations of women, doctors, health activists, democratic rights activists and even a research institution. These groups organised demonstrations, marches, *dharanas*, exhibitions, seminars and workshops. They also used all available media to draw people's attention to the rampant misuse of medical techniques like amniocentesis, chorion villi biopsy, sonography leading to female foeticide. Many sensitive journalists and other media people helped focus the campaign not only on the issue of misuse of medical techniques but also on the status of women in our society. Several members of these organisations also accepted the government's invitation to participate in a committee which did some necessary groundwork to identify the technical and legal issues involved in stopping this misuse. The bill presented in the Assembly was, however, drafted by the government on its own.

Medical Council Indicted

Although the statement of 'Objects and Reasons' given by the minister of state in the bill, does not explicitly criticise the Medical Council, states that "In breach of professional ethics, unscrupulous medical practitioners do not hesitate to perform abortions even when the sole or one of the reasons for doing so is female foeticide". It also laments that "there seems to be a misconception about the objectives of the existing laws in the minds of many medical practitioners". It seems naive to enact a full-fledged legislation if the issue involved was only a simple misconcept about the existing laws. But to expect the government to be forthright in its assessment of the medical profession is asking for the moon.

Nevertheless, this statement brings out that sex-determination practices involved in breach of medical ethics. Therefore, it squarely indicts the Medical Council. The MC in our country has scarely made any attempt to regulate the medical profession according to the code of medical ethics formulated by it. It has not only allowed the violation of ethics to go unpunished but also at times attempted to provide justificaion and legal cover to such violation. This attitude was very glaring in the specific case of sex determination where it refused to shed its lethargy despite a very hot debate in the media for last seven years. Not only that, in a private conversation, the president of Maharashtra MC defended sex-determination practices of the doctors saying that the medical profession must grant full autonomy to the patients. It was also argued that it is difficult to prove in individual cases that sex-determination was done to get female foetuses aborted.

There are enough provisions in the code of medical ethics of the MC to take stringent action against the profession on this issue. Some individual cases also came to notice but the MC did not move. For instance, Dr. Datta Pai, who runs an abortion clinic (Pearl Centre) in Dadar, Bombay and who was a member of the government's committee on this issue, has publicly admitted that his abortion centre had provided facilities for amniocentesis till he was invited to join the government committee, though he never admitted that amniocentesis was used for female foeticide in his centre. Yet this was a fit case for the MC to seize his records of amniocentesis and the MTPs in this period and scrutinise whether in the same centre women who underwent amniocentesis were offered MTP when the foetus was found to be female. And if it were found to be so, the MC could have used two clauses of its code, namely, first, no discrimination in medical practice and second, the social responsibility of doctors, in addition to the violation of the MTP act, to punish the guilty persons.

Thus, though this bill is a concession to the Forum's demand, it is also an indictment of the Medical Council for its open disregard of its own code of professional ethics.

In our country only drugs and pharmaceuticals are regulated under a full-fledged law (albeit, a very ineffective law). The rest of what constitutes medical technology and techniques are not regulated under any comprehensive law. This bill restricts itself to the regulation of pre-natal technologies and techniques. Again, it does not regulate the introduction of new technologies and techniques even in pre-natal diagnosis. In fact it regulates only their use. Nevertheless, it is an admission of the fact that medical technologies are being misused in pre-natal diagnosis to such an extent that an independent law is needed to deal with them. By logical extension, it could be said that it gives room for health activists to push the idea that all medical technologies and techniques could be widely misused, and they are being misused, therefore stringent regulation on all medical technologies in general and new technologies in particular is urgently needed.

Secondly, it explicitly bans the use of medical techniques and technologies for the purpose of pre-natal sex determination leading to female foeticide. Thirdly, it declares illegal the giving of any advertisement in any manner regarding

facilities available for the pre-natal prediction of sex at the centre, laboratory or clinic. Thirdly, it makes illegal the seeking of such facility by the woman or by any other person for her for the pre-natal determination of sex. Fourthly, it prohibits the indication of "the sex of a foetus with or without the possible object of female foeticide". And lastly, it prescribes rigorous punishment to those who indulge in pre-natal sex determination activities.

Thus, the pressure generated by the Forum's and other individuals and organisations' efforts has helped make some breakthroughs in the present situation. But the gains are quite inadequate in many respect and this bill is a big compromise solution worked out by the government and the medical authorities—both private and public. These inadequacies make the bill, if not weaker, than at least as weak as the present Drugs and Cosmetics Act. In many ways it is a defeat in the victory for the Forum.

Sacrosanct Private Sector

The Forum has, from the very beginning, demanded the abolition of pre-natal sex determination techniques in the private medical sector. For it is the private medical sector which is primarily guilty of their misuse and not the public sector. In government institutions the government has issued a directive almost a decade back to stop their usage for sex determination.

However, the government with talks of inefficiency and corruption in the public sector is building a case for privatisation (which is already underway). It has failed to even pay lip-service to the nationalisation of the private medical sector despite such revelation of gross malpractices. It even fails to acknowledge that the 'liberalisation' that is prevailing in the private medical sector, has brought only ills for the people and for the women in particular.

Instead of abolishing all genetic laboratories and genetic clinics in the private sector the bill only wants to regulate them. As we know that such a regulation of the pharmaceutical industry under the Drugs and Cosmetics Act has not radically changed the drug scene and its misuse continues in *legal* as well as illegal manner. The regulation of genetic laboratories, genetic centres, genetic clinics, gynaecologists, medical geneticists and so on will ultimately entail the creation of an administrative set-up which will look like a mini-FDA. The expenditure that government will incur and what people will pay for these services in these centres, in the name of registration fees will far off-set in a few years the total expenditure the government would have made as a compensation in taking over all genetic laboratories in the state. As a bonus, this would have made the implementation of the ban easier and effective without depriving those women who medically need pre-natal diagnosis.

The story of regulation does not end here. The body (called Appropriate Authority (AA) in the bill) which will grant licenses and enforce the law is full of those health bureaucrats who are already overloaded and proven to be inefficient in regulating their own departments. The Director and the Joint Director of Health Services, who will become ex-office chairman and secretary of the Appropriate Authority respectively, have never made any serious attempt to curb private practice by the doctors in our rural health services. Further they are in charge of an ever-expanding rural health infrastructure which includes over 1500 primary health centres and about 200 rural hospitals. In addition they also manage cottage hospitals, district hospitals etc. They are hardly able to efficiently regulate these establishments. One can only imagine with what efficiency they will be able to regulate private medical profession and its ever increasing number of laboratories.

The composition of the Appropriate Authority (AA) is: Two ex-officio government bureaucrats from the public health department, one bureaucrat from the medical education department, one bureaucrat from the Indian Council of Medical Research, two doctors: one gynaecologist and one geneticist (no other qualification mentioned) and two representatives of voluntary organisations (in the field of health, women and human rights). Except ex-officio members, the rest in the eight member team will be nominated by the government. Thus, the participation of voluntary organisation will be as per the needs of the governments and since the AA will take decisions on simple majority, the voluntary organisations will not have much decisive say in most matters.

Mockery of People's Participation

This bill is a classical example of what the government means by people's participation. As stated above, the selection of the voluntary agency to be represented in the AA will be made by the government and not the people. Further, there will be another agency called the state Vigilance Committee (SVC) to oversee the implementation of the act. Here also, in the seven member committee, two representatives of voluntary organisations will be appointed by the government. In its supervisory functions, the SVC will pay periodic visits to the recognised centres, but it will not have authority to take action against those violating the act. For this the SVC will have to approach the AA.

Further, on the one hand representation to the voluntary agencies in the implementing bodies is given under the guise of people's participation on the other common citizens are forbidden to directly prosecute erring doctors, centres and laboratories. Such citizens will have to first approach the SVC and the AA with their complaints. There is, however, a provision for such citizens to go to court after giving two months' notice to the AA about their complaint. But to counterweigh such action, the AA and SVC, which will be in possession of all information needed to prosecute doctors, centres and laboratories, are given the power to refuse to make information available to such citizens if the same is, in its opinion, against the public interest. Thus, in the last analysis, while talking aloud about people's participation and extending an olive branch to the voluntary organisations, the government has made clever provisions in the bill to see that even those people who want to participate to stop the misuse of pre-natal diagnostic techniques cannot do so or are effectively frustrated in their efforts.

Concessions to Medical Lobby

The pressure exerted by the medical lobby while the bill was being drafted is clearly visible at several places. This is not surprising. The medical bureaucracy has time and again, on various issues (recently on the issue of charging for services) expressed its sympathy for the values of the private

sector. Further, people like the president of Maharashtra MC and Dr. Datta Pai are close advisers of the government health department.

In the defining indications and conditions for which pre-natal diagnostic techniques should be used, they have seen to it that the Forum's proposal of getting written opinion of three concerned specialists has been completely excluded in the bill. In the absence of such a provision, the private gynaecologist will be the sole decision-maker whether to offer pre-natal diagnostic facility to the woman or not. However, vague indication like the history of two or more abortions or foetal loss could be misused in the same way as the failure of contraception as an indication is used for the MTP. Just as the failure of contraception as indication for the MTP has *rightly* made abortion facilities legally available to women, the indications like foetal loss will *wrongly* make available sex-test to women who want to go for female foeticide.

The medical lobby has scored the most in the chapter on 'Offences and Penalties'. This chapter identifies three types of offenders. Type one: Doctors, centres and laboratories. Type two: The woman who seeks the test, her husband and in-laws. Type three: All those who contravene any of the provisions of the act.

The penalty prescribed for type one offenders is rigorous punishment upto three years and fine upto Rs 5000. To demonstrate that the government is going to be very strict with offending doctors, centres and laboratories, the bill has a clause here saying that the minimum penalty to these people should be at least one year imprisonment and fine of Rs.1000. But the hollowness of this provision becomes evident as we read the last clause of this chapter. This clause empowers the court, if it so desires and after giving reasons, to award less punishment than the minimum stipulated under the act. That is, a rich doctor who has misused the techniques leading to female foeticide, can, with the help of powerful lawyers, persuade the court to award minor punishment.

The second type of offenders include the woman, her husband and her in-laws. The bill says that the woman should be assumed to be innocent and thus charged only Rs 50 as a token fine and no imprisonment. The bill also says that it should be assumed that she was compelled by the husband or in-laws to undergo the sex-test. The husband or her in-laws will be punished for abettment of the offence, with rigorous imprisonment upto three years and with fine upto Rs.3000. The bill says, "The court shall always assume, unless otherwise proved, that a woman who seeks such aid of pre-natal diagnostic procedures on herself has been compelled to do so by her husband or members of his family". Here the catch is provided with the addition of words "unless otherwise proved". It is easy to prove that the victim woman will be caught and not the husband or in-laws. Who will prove it otherwise? If the husband is arrested, he will simply say that he did not force his wife to undergo the test. Now, in our society, what is the wife going to say? Of course, she herself will come forward to prove that she was not under compulsion. Feminists and their supporters were fighting against the government to save the woman who is a victim of the patriarchal system. This bill makes the victim a criminal who will have to serve upto three years in prison. This is an outright anti-woman provision. The earlier everybody starts raising their voice against it the better.

We all know that there is inequality in our society. But our constitution says that everybody is equal before the law. We all call it formal equality. But not so in this bill. There is no equality between the doctors, centres and laboratories on one hand, and the victim woman and her husband or in-law on the other hand. The bill says that the offence committed by type two and type three offenders "shall be cognisable, non-bailable and non-compoundable". This means, when a complaint is made to the police against the victim woman, her husband or her in-laws, the police has to act to arrest them. Once arrested, only the court can give bail. The non-compoundablity makes it difficult to get any compromise settlement.

But the type one offenders (doctors, centres and laboratories) are excluded from the above provisions by making their offences, non-cognisable (the police is not required to act when the complaint is filed), bailable (if arrested at all, can get out immediately on personal bond, i.e., the police itself can grant bail) and compoundable (can have out an out-of-court settlement).

This shows that our government considers the offences committed by the doctors less criminal than those committed by the victims (who paid that doctor exhorbitant amounts). In our society the person who actually commits female foeticide by doing a sex-test and selective abortion is less of a criminal than victims of patriarchal ideology and physical and socio-economic compulsions.

Some Lessons and Future Plan

This bill has once again emphasised that only good intentions of some individuals, groups and the 'goodness' of some bureaucrats do not add upto desired change. This is not to question intentions, but the methodology of affecting change and the ultimate gains. The system does not like to have gross irregularities in its functioning. The current system permits irregularities outside its rules only upto the time it needs them. Thus, the government will also be found responding to certain demands for establishing the rules of game in the fields where such irregularities are rampant. Only such an approach can keep up the credible face of the system before the masses.

But these rules of game, under the pressure of small groups and media, are not framed while punishing the guilty. The Environment Act came without punishing Union Carbide. The industry was not punished before bringing the Consumer Protection Act. In the same way the builders are not going to be disciplined before the housing act is brought in. And no doctor is so far penalised for committing female foeticide. This shows the light-mindedness of the government and the feebleness of the efforts made by the groups concerned. As a result, all laws are passed but they are toothless laws.

Therefore, the groups who campaigned against female foeticide cannot remain complacent. They must continue their campaign raising their original demands like abolishing pre-natal diagnosis in the private sector, absolute protection to the victim woman and so on. They must, while going to the masses with those demands, also demand amendments in the bill. If the bill is made a law without demanded changes, the campaign must be continued. At the same time,

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become stronger. In order to promote a particular brand of a drug company, doctors prescribe medicines to their patients, which are either of no use or are patently harmful. The tremendous hold of the drug industry over the health care system in our country, was recently brought to light by the Lentin Commission. Another example of the proliferation of useless and spurious drugs in the fact that more than 20,000 kinds of non-prescription drugs are on sale in the Indian market, most of which are non-essential and about 25 per cent of them spurious. As against this, the WHO has prepared a check list of only 200 essential drugs. Though the medical council is fully aware of the unethical practices of doctors prescribing drugs known to be harmful and useless, why has the council not prosecuted the doctors and more importantly should not the medical council have powers to initiate proceedings against drug companies?

The research establishment, both private and government, also collaborate with drug multinationals in conducting human trials. Human experimentation by the medical community is justified on the ground that such trials are for the benefit of humanity. For example, experimentation by administering injectable contraceptive Net-pen, which has not been proved as a safe drug is being conducted on several thousands of Indian women, who are being used as guinea pigs without their informed consent. These trials are being initiated by the government's family planning programme. The Helsinki Declaration clearly states that no tests should be conducted on human beings unless they are proven to be safe and without obtaining the informed consent of the person on whom the experimentation is to be done. The Net-ten tests are in clear violation of this declaration. The governmental institutions are the most consistent violators of medical ethics and yet the medical council and courts have been hesitant and unwilling to take any action.

In the Bhopal case, the government and its research institutions have effectively suppressed all medical information pertaining to the after-effects of MIC, and the treatment to be given to the victims. For example, though the Indian Council of Medical Research (ICMR) prescribed mass detoxification to the victims, by injecting sodium thiosulphate, the medical community in Bhopal ignored this recommendation.

The recent scientific advances in the field of reproduction like amniocentesis, chorion villi biopsy (CVB) are calling into question the philosophy and values of medical ethics. Those techniques which were meant to detect genetic deformities are now being widely used for sex-determination. Not a single doctor has been prosecuted by the medical council.

These are just few of the examples where not only doctors but government institutions have flagrantly violated the various international and national codes. And yet nothing has been done and the medical system continues to devour and maim a large number of people.

The extent to which the medical profession will conform to proper standards of medical care will depend to a large degree on the development of the public's awareness of the issue. The basic rules of social conduct can be ensured only if the public maintains a constant and vigilant eye on the doctors in particular and the functioning of the health care system in general. It is only then that the doctors will be forced to abide by the highest standards of medical practice.

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selective abortion of female foetuses could continue unabated. The callous and blatant attitude of the medical profession towards this question can be illustrated through a front-page advertisement appearing in one of the city's eveningers barely five days after the Maharashtra government's triumphant declaration of intent on January 1. This advertisement read in bold type, "Boy or Girl? Contact clinic." A proposed legislation that will, in all likelihood ban such blatant advertising did not deter the doctor couple offering sex determining facilities. It must not be forgotten that, though pushed into a corner on several occasions, the medical profession refused to take an ethical stand before the government's declaration of bringing in such legislation. Apart from the high level of vigilance, a commitment from an ambivalent medical profession, faced with the loss of quick commercial gains, is a must.

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the groups should utilise the avenues available to participate in the implementation process, in order to expose the hollowness of the bill.

The medical establishment had earlier argued that a law would force female foeticide underground. Now they have, in collaboration with the government, brought a law which can partially keep female foeticide above ground, within the purview of law. There is no alternative but to continue struggle against the medical practice of female foeticide.

This Bill has been passed in the Maharashtra Assembly without any significant amendment in April 1988].

Good Manufacturing Practices

How Serious is the Government

amitava guha

Through a notification the government has introduced a draft amendment to the Drugs and Cosmetics Rules, 1945 which are aimed at introducing Good Manufacturing Practices (GMP) in the pharmaceutical industry. But clearly, the government is not at all serious about implementing these measures as becomes obvious if the draft GMP is scrutinised.

THE DRUGS and Cosmetics Act, 1942 and Drugs and Cosmetics Rules, 1945 are both ancient laws. They have to render minimum check and control on production, distribution and marketing of modern pharmaceuticals. It is also proved that this Act and its rules although amended in 1979, 1980 and 1982, cannot provide the government adequate power even to ban a harmful drug. The Government of India, through a notification of June 22, 1987 had introduced a draft amendment to Drugs and Cosmetics Rules, 1945. The amendments are aimed at introducing Good Manufacturing Practices (GMP) and it is stated in the notification that:

> Any objection or suggestions which may be received from any person with respect to the said draft rules before the expiry of the period (thirty days from the date on which the copies of the official gazette in which this notification is published are made available to the public) so specified will be taken into consideration by the Central government.

What is GMP

In USA in the early 70s a large pharmaceutical company was convicted when due to faulty manufacturing practices, a drug manufactured by them caused a large number of deaths. The same company, aiming to refurbish its image and goodwill proposed to other manufacturers a self regulatory code for manufacturing of pharmaceuticals. Later, the World Health Organisation took the initiative to prepare a norm of Good Manufacturing Practice. At the 28th World Health Assembly in 1975 the revised text of 'Good Practices in the Manufacture and Quality Control of Drugs' was adopted. It was recommended that all member states (which includes India) should apply the requirements of good manufacturing practice.

The practices laid down in GMP are designed to ensure that the drugs received by the consumers have been subject to stringent control from the beginning to the end of the manufacturing cycle to ensure that they are of high quality. The expression 'manufacturing' for this purpose refers to all operations involved in the production of a drug including processing, compounding, formulating, filling, packaging and labelling.

WHO has grouped GMP in mainly the following sections—personnel, premises, equipment, sanitation, starting materials, manufacturing operations, labelling and packaging, quality control system, self inspection, distribution records, complaints and report of adverse reaction. It has provided very broad guidelines of GMP for its adoption in a suitable form by the member countries. It took India about a decade to think of implementing the decision of the World Health Assembly on GMP.

Without a high standard of ethics it is impossible to maintain GMP. In developed countries drug manufacturers had, on several occasions, faced strong criticisms, litigations resulting in heavy compensation and stringent government regulations. The GMP is self-regulatory and not a compulsion under law in the developed countries. It was found that the same international company which maintains GMP at their establishments in parent countries, does not care to do so at their establishments in the underdeveloped third world countries. In some countries statutory actions have to some extent forced the multinationals to follow some kind of ethics. The Indian experience is different. The Committee on Drugs and Pharmaceuticals (Hathi) expressed its concern on the rampant violation of laws by the drug multinationals in India. Despite this, the Government of India had decided to enforce GMP only by changing the statute. It is, therefore, necessary to analyse the nature of the amendment the government intends to introduce and the consequences of the statute if it is truly implemented.

Some Problems Relating to GMP

WHO had suggested Good Manufacturing Practice for the manufacture of formulations only. There is as yet no code/guideline for manufacturing basic bulk drugs. This is particularly disturbing when now-a-days multipurpose pharma plants are capable of producing more than one drug in the same process plants.

A company may produce a combination of two or more drugs of high technical quality and bioavailability but the combination itself may be irrational and not needed by the population of the country where it is marketed. GMP should also cover these drugs. WHO had defined GMP as 'pre-marketing quality assessment' the essential factors of which are:

"A notification procedure: is the the least resource-intensive ways of obtaining information on drugs offered sale in a country. The amount of information required for notification may vary. It may be initially restricted to the name of the drug and manufacturer, and may then be expanded to include the nonproprietary names for active substances, the composition, including inactive ingredients, and pharmacological classification". This will eliminate all irrational formulations which have no place in any standard books of pharmacology.

"An authorisation procedure: can be developed in which either all drugs or specified ones only require an authorisation before they are marketed in the country. This may vary

in its stringency but it almost always incorporates the element of inspection of the manufacturer and the verification of product quality by analysis.

"A registration procedure: comprises the evaluation of data intended to prove the safety and efficacy of the drug and to determine the indication for its use. The registration may include an assessment both of the drug and of the manufacturing procedures".

Pre-marketing quality assessment therefore should form an integral part of GMP. This is missing from GMPs adopted in most of the countries.

The other thing which is missing in these GMPs adopted in the other countries is a complete set of guidelines for post manufacturing surveillance which should include the marketing code also. This we need to discuss more in the context to our country.

It took a decade for the Government of India to formulate GMP after they participated in 28th World Health Assembly where the resolution on GMP adopted. It is clear why the government suddenly became so conscious of the need to introduce an amendment and pass it in a short 30 days' time. This of course, follow the recent pattern of the government taking snap executive decisions bypassing even the Parliament. Causal, non specific and absurd rules have been suggested that too without determining any logistics for their implementation.

We have three major laws and regulations which govern production and sale of drugs: Drugs and Cosmetics Act 1942; Drugs and Cosmetics Rules 1945; Magic Remedies Act. In UK the main law is the Medicines Act, 1971. There were 34 regulations set out by British government (upto 1981) to govern the production and sale of drugs many of which are directly and indirectly connected to GMP.

There are major inadequacies in the government's draft GMP as far as the premises and equipment are concerned. In the draft only eight points are mentioned while in British GMP there are twenty-two specific directives. The draft says: "They (the building) should conform to the conditions laid down in the Factories Act, 1948 (63 of 1948)'. It is well known that because the age-old Factories Act has been of no use in regulating the conditions of the technologically developed modern factories the government has brought forth a further amendment to the Factories Act. What type of control then can one except from this Act on the 'high tech' pharmaceutical factories?

The draft also had not cared to look into the effect of factories on environment inside and outside the premises. There are international standards on the limit of toxic materials and suspended particles in the air. The draft GMP has totally ignored it. Not only this, the draft has not dealt with the disposal of containers of bulk drugs and other materials which may not loose potency by simple washing with soap water. Nor does it mentioned how and where to dispose toxic effluents. The British GMP, in contrast to our draft, says:

> Waste materials should not be allowed to accumulate. It should be collected in suitable receptacles for removal to collection points outside the buildings, and disposed of at regular and frequent intervals. Special care is necessary over the disposal of waste containing dangerous, highly toxic or sensitising materials (eg hormones, cyto toxic agents, sensitising antibiotics). Disposal of raw materials, printed packing materials and rejected products should be carefully controlled and documented.

The draft is extremely casual in this area. It is very vague and non specific when they state that the manufacturing area for sterile drugs "shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply through bacteria retaining filters (HEPA filters)". While British GMP has a separate chapter containing 126 sub clauses for 'Manufacture and control of Sterile Medicinal Products', our legislators had to be satisfied with only two tiny paragraphs.

Various HEPA filters are used to create sterile conditions of air for different purposes. Therefore, a standard is needed to be fixed for production area of sterile materials. Not only this, there should be standardisation of specific final filter efficacy with recommended minimum air changes per hours and the equivalent classification of HEPA filters available in India. Absence of such standardisation will lead to the controversies in application of strictures and the manufacturers will take recourse to some other laws to evade this vague stipulation.

Another classic example of casual approach can be found in the draft under the peculiar heading 'All Medical Services' that "Medical inspection of workers at the time of employment and periodic check up thereafter once in a year, with particular attention being devoted to freedom from infection conditions and records thereof shall be maintained".

It is beyond the scope of anyone's understanding as to how check up once in a year will ensure that the workers had no infection in the remaining days of the year. We are yet to imagine a worker who is suffering from infective cold voluntarily informing the management of his ailment. When there are a large number of contract labourers working in both big and small companies reporting of such minor but contaminous disease may mean loss of wages for the entire week. British GMP is somewhat more specific in this respect: "There should be preemployment medical checks, and steps should be taken to see that no person with a disease in a communicable form, or with open lesions on the exposed surface of the body, is engaged in the manufacture of medicinal products."

The staff should be required to report infections and skin lesions and a defined procedure followed when they are reported. Supervisory staff should look for the signs and symptoms of these conditions".

In the industrial policy declaration of 1984-85, the government announced broad banding in the pharmaceutical industry. Astoundingly the government under the scheme mentioned that equipment each as mass mixers, cone blenders, drying ovens can be used under broad banding. The British GMP has elaborately dealt with how to avoid cross contamination and mix-up. The draft Indian GMP has only mentioned the term mix-up in a subheading but nothing has been specified as to how to prevent it. Nothing has also been specified regarding the use of masks, gloves, etc, in different manufacturing area.

There should be certain codes for pharmaceutical machinery manufacturers also. For example in most of the hot air driers the lining used is asbestos. The inner walls of such driers, particularly for drying pastes, are usually coated with heat resistant paints. There is every possible chances that such paints may be dislodged from the inner surface and get mixed up with the paste or powders kept in the trays.

It is also necessary that the GMP defines clearly the maximum permissible operations per punches of the tablet compressors after which they should be discarded. Similarly it specifies limits per use of filter bags of the fluidised bed driers, etc.

Experts who had drafted the GMP are so confident of their work that they feel that their work will remain unaltered for eternity. The draft has not suggested a periodical review of the conditions recommended. The first edition of 'Guide to Good Pharmaceutical Manufacturing Practices' was published in UK in 1971. Thereafter it was amended in 1977, and in 1985. It clearly states—"Time has shown that it would be helpful to rearrange and in places, clarify and enlarge the text and to give on further topics." Due to advancement in technology and scientific concepts GMP cannot remain static. In future GMP will need to include norms for electronic data processing and retrival systems.

Quality Control Laboratory

The section on laboratory practice is the most important and sensitive part of GMP. In fact a separate set of law/guideline is needed for this. In the 28th World Health Assembly it was decided that a comprehensive review of approaches to quality assurance system would be made (WHA 28.66). A document accordingly was prepared by the Experts Committee and its report was published in the twenty-seventh report of the committee. Thereafter, the committee has produced three more reports elaborating the quality assurance systems. The thirtieth report had reviewed and added more recommendations to the earlier reports. The draft Indian GMP has ignored these facts. In the 28th World Health Assembly a small guideline was prepared on quality control system giving some objectives. The draft GMP has simply reproduced these guidelines but has not elaborated on either the methodology or the stipulations which are needed for good laboratory practice.

A major decision which is needed to be taken is whether there should be any commercial establishments for certifying quality assurance. After the facts revealed in Justice Lentin's Commission chart how political power and profit dictates the reports of the private laboratories, it is high time we decided whether any private commercial laboratories be allowed to test drugs. On the other hand the government has only five test laboratories in the country to cater to 9000 drug firms registered under DGTD.

Further the government has not considered the prevailing set up in India while preparing a new edition of the Indian Pharmacopea which is a 90 per cent replica of the British Pharmacopea. Any unit, big or small wanting to establish its own quality control laboratory will definitely need microbiology testing system spectrophotometry system for both ultraviolet and visual range, etc. While the former needs a large of space and special furniture the latter costs a large amount of money. The minimum necessary equipment for such a laboratory needs an investment of Rs 3 lakh. The definition of a small scale industry till date is a company having turn over of Rs 50 lakh. How can such a company invest Rs 3 lakh for a quality control laboratory?

Moreover, considering that all companies would have their own quality control system where maintainence of a spectrophotometer would be a must would our government laboratories be in a position to supply International Chemical Reference Substances of all drugs (both active and inactive substances) for regular calibration of their instruments. Our experience is that even the government laboratories do not maintain all reference substances to calibrate their own spectrophotometers. The draft amendment only says: "Every manufacturing establishments shall have a quality control department supervised by approved expert staff. . ." It does not say anywhere what should be the minimum equipment to be maintained in this section.

It is also necessary to clearly describe the premises of the quality control laboratory—how they should be arranged; what are the hygenie conditions, temperature, humidity, sterility conditions etc to be maintained inside. How the instruments are to be calibrated and how often their sensitivity be checked under what standard. Similarly, the reagents need to confirm to a standard guideline. Guidelines for maintaining concentration, standardisation factors, shelf life and storage factors, should also be specified and how often the prepared reagents should be checked to find out their suitability, etc.

There should be clear guidelines as to the stage of collection of samples for quality testing and for identifying, preserving and recording the samples before and after testing. Documentation of the analysis is also of great importance as well as a good documentation system.

The draft GMP had not considered many other substances which are used for curative purposes. No GMP had been suggested for the manufacture of medical gases, or of radio pharmaceuticals. A large number of verterinary medicines are also used in ur country. The draft GMP says nothing about these not even that the GMP for other pharmaceuticals should be followed in producing veterinary medicines as well. Interestingly the British GMP says: "Some veterinary products such as those used for mass external treatment of animals (e g, sheep dips), have no direct equivalent among products for human use and the recommendations on manufacturing premises and equipment given elsewhere in the guide may not be appropriate."

Post manufacturing GMP

Two most important points not given any consideration at all by the draft GMP are post marketing surveillance and distribution. The responsibility of a drug company does not end with the manufacturing of a drug. The manufacturer needs to take care that the drug is stored under prescribed appropriate storing conditions in the factory warehouse and the same has to be followed by the middle men engaged in wholesale and by the retailers in the chemist shop also. Clear guidelines are needed to be specified for transport conditions particularly for a vast country like India. Where products in transit may be subject to conditions such as unacceptable degrees of heat, cold, light, moisture or other adverse influence including attack by micro-organisms and pests.

There should be certain specified norms regarding maintenance of stocks which are rejected due to damages for spillage or breakage. These are to be kept separated from the stocks of expired drugs. Proper recording, labelling and disposal is also to be specified. Therefore GMP should include 'Good pharmaceutical storage, distribution and/or wholesale practice' also.

There is virtually no system in our country to supply package inserts along with each sales pack of drugs giving important side effects, precautions, adverse reactions, interaction with other drugs, etc. Lack of proper norms of labelling has led to situations where sometimes it is very difficult to decipher the constituents of the active ingredients of the drugs from the labels. Brand names are printed in bold while the generics are printed in or in very small type.

In 1968, the 21st World Health Assembly adopted a resolution (WHA 21.41) urging member countries to enforce control on advertisements. The resolution stated the ethical and scientific criteria for pharmaceutical advertising and covered advertising to the medical and related profession as well as to the public. From the perspective of consumer protection, it is important that the consumer should be alerted to all side effects, contraindications, warnings, hazards, and precautions. It has been observed that a fair balance can be considered to be lacking if:

a) Information is included in an advertisement that has not been approved for inclusion in the promotional material at the time of registration.
b) Advantages are claimed for the drug without simultaneous disclosure of disadvantage.
c) Obsolete information is used.
d) Claims are exaggerated.
e) Animal or laboratory data are cited as clinical experience.
f) A statement by a recognised authority is quoted without also citing any unfavourable opinions of that authority.
g) Statements are used out of context.
h) Statistics are used in a misleading way.
i) A headline or pictorial presentation is misleading (*Guidelines for the Development of a National Drug Control Programme*; Pan American Health Organisation; pp 79-80)

The draft GMP shall include all these conditions for the dissemination of correct and unbiased information.

Monitoring of a drug, new or old is continuous work. It has international impact also. Since 1960, the World Health Organisation had been insisting that all member countries should develop centres for monitoring adverse drug reactions. In the 1963 World Health Assembly it was resolved that the member countries would co-operate with each other in the dissemination of adverse drug reaction so that the best possible protection can be offerred to consumers.

In our country, no system of monitoring adverse drug reactions had been set up. Although a few such centres are in existence but they are often found to defend the hazardous drugs instead of monitoring their adverse reaction. A centre under the University College of Medicine, Calcutta was found, a few years ago, to be conducting a study financed by an industry house on the need of a combination drug—chloramphenicol and streptomycin. The head of the centre later published their study in support of this irrational and hazardous combination in the *Journal of Indian Medical Association*.

The draft GMP, under the subhead 'Records of Complaints and Adverse Reaction' only says that—"Reports of serious adverse reactions resulting from the use of drug along with comments shall be informed to the concerned licensing authority". This is the only thinking expressed in the draft regarding adverse drug reaction. The total responsibility has been left to the manufacturers who have no mechanism to keep track of adverse drug reactions. Their tendency is to suppress such information however rare it may be. Even accepting the fact that a manufacturer may report some incidents of adverse drug reaction, what would the government do? The draft GMP suggests nothing. In the event of such incidents, the British GMP elaborates on how to recall the product. The system of recall inflicts a red alert. It not only stop the sale of the product but also directs stoppage of the production operation till the reasons for adverse reaction are explored after investigation by the government authorities.

From the above, it can be concluded that while preparing the draft GMP, the government had not been in the least serious. Incomplete measures, casualness and pro-manufacturers bias to more or less maintain existing frivolous attitude to the safety of the consumers has been reflected in the clauses of this draft. Moreover it will be impossible for the small scale industries to follow this GMP, if the ammendment is converted to law. It will be impossible for them to establish full fledged in-house quality control laboratories. It will also be impossible for the old industries particularly those which are situated in the densely populated area or housed inside old industrial estates to expand the manufacturing area as required by the GMP. Therefore, the incoming GMP will have to compromise with the industry irrespective of their size and capability in the areas of quality of products and will in no way bring minimum safety and security to the consumers and workers of the pharmaceutical industry.

A Note

THIS note is to inform the readers of *RJH* that from June, 1988. I shall be moving from the category of Working Editors of RJH to that of the Editorial Collective. The reason for this shift is that for the past one year I have moved out of Bombay to a small village in Pune district of Maharashtra for a period of five to six years. I have thus hardly been a 'working' editor during this period.

It is only due to my persistent request that the other Working Editors have finally, and reluctantly, agreed to let me shift out. Moving out creates in me a feeling of deep personal loss because all the three Working Editors, as well as some of the comrades in the Editorial Collective of *RJH* are my closest friends. During the next five years I shall greatly miss the warmth and the intellectual stimulation that the RJH collective has always offered to me.

I shall certainly continue to stay within the Editorial Collective of *RJH* because I fully believe in the ideological perspective of the Journal and have no differences either political or personal with the form and content of RJH. I am sorry that I am not able to undertake more responsibility on behalf of *RJH*, much as I want to. And, I am aware that the loss is mine.

In solidarity

Manisha Gupte

Medical Ethics

An Introductory Essay

gayatri singh

With the rapid advance in medicine and its increasing privatisation, the highest standards of ethical conduct are called for from doctors. It is for this reason that the medical profession is governed by certain fundamental ethical principles. By setting certain ethical principles a doctor's expertise is attempted to be harnessed for the needs of society. What are the issues which confront doctors when interacting with patients?

WITH the medical profession becoming increasingly specialised, the acquisition of higher medical education and knowledge has become the prerogative of the upper middle class, resulting in fundamentally altering the age-long close-knit 'family relationship' that existed between a doctor and a patient. Not only has the doctor become increasingly isolated from the needs of the patient, but the medical profession as a whole has miserably failed to extend its knowledge and facilities for the benefit of the public.

Overawed by the doctor's grasp of medical knowledge, and unable to comprehend the complexities of the medical world, the patient is placed in a hopelessly unequal bargaining position. The surrendering of the patient to the doctor has become complete to such an extent that treatment, even if unsafe, is not questioned. Being thus placed in a position where the doctor has virtual control over the well being of the patient it is not surprising that the doctor can, wittingly or unwittingly, abuse his/her superiority. As a consequence of this strained relationship the nagging question that a doctor is constantly faced with and which he has to ultimately is: whether the health and well-being of a patient should be given priority or whether private profit and fame should be the driving motive which ought to define the doctor's relationship with his/her patients. Doctors must perforce decide which interests out of the two should prevail and the taking of such a decision depends to a large extent on the personal inclinations of a doctor. Since a patient is not divorced from the rest of society, the doctor's personal views with regard to the mode of treatment of patients has raised important ethical questions like: Should drugs, known to be positively harmful be prescribed to patients without explaining to them their harmful effects? Should technology and research be promoted for purpose other than for remedying the health of patients? Should doctors aid police officials in issuing false certificate certifying the death of a person to be 'natural' when in fact the death is known to be the direct consequence of tortue inflicted by the police? Should doctors refuse to give emergency treatment to a person solely because it is a medico-legal case?

These are just a few of the many troubling issues, which doctors are invariably confronted with in their day to day practice while interrelating with patients. A doctor may choose not to answer these questions and wriggle out of a delicate ethical dilemma by arguing that the manner in which a doctor relates to his/her patient is basically a private matter. It has been argued that the setting of standards for medical practice, directly impinge upon a doctor's right to practice and hence no such standards should be artificially imposed. A doctor should be allowed to freely relate with his/her patients in the manner which he/she thinks is most appropriate. If a doctor uses the medical profession to maximise his/her profits that is the personal choice of the doctor which ought not to be interfered with.

Yet, though doctors may relate to their patients at a private level, the fact is that doctors play a vital role in preserving and maintaining the health of a society and the medical profession cannot be left to regulate itself for important life and death issues are involved. Since doctors do not operate in a vaccum the decisions that they take vis-a-vis their patients have a bearing upon how they see their role within the medical profession. A doctor does not relate only with the patient but assumes various roles which require him/her to take important decisions which may adversely affect others. Thus, when a doctor decides to perform an abortion, despite laws to the contrary, s/he is not only expressing his/her personal views on abortion but is in fact making a public statement as to whether persons have a basic right to choose whether to bear a child or not; conversely, by refusing to perform an abortion because of one's religious or personal views, one is clearly taking a public stand by *refusing* to extend one's services for performing abortions.

Considering the complex social issues that one is confronted with, it may be extremely difficult to distinguish between what constitutes medical morals and medical ethics. For instance, when does one's personal views become the concern of the public so that public intervention becomes necessary for setting standards with regard to a doctor's practice? With the rapid advance in medicine and its increasing privatisation, the highest standards of ethical conduct are called for from doctors. It is for this reason that the medical profession is governed by certain fundamental ethical principles however outmoded they may be today. By setting certain ethical principles a doctor's expertise is attempted to be harnessed for the needs of society. It attempts to lay down certain guidelines though vague, with regard to what ought to be 'acceptable social conduct' of a doctor.

Evolution of Medical Ethics

If we look at the history of the growth and evolution of medical ethics we find that it was the doctors who initially played a vital role in establishing and setting standards for their profession. It is for this reason that the personal views of the doctors got reflected in the constitution of medical ethics. As the public became increasingly aware of its rights within the health care system, higher standards of practice were sought to be imposed upon doctors, though the code of ethics followed by the medical community has remained virtually stagment and the changes have been far from

satisfactory.

The earliest and the first known medical code was the *Code of Hammurabi* (c. 1900 B.C.), which set out, amongst other guidelines for doctors, the mode of receiving payments from their patients. According to this code, payments should inter alia, take into consideration: (a) the results of the treatment; (b) the patient's ability to pay, and (c) the status of the patient. Though the concept of payment for professional services has undergone certain changes, the basic concept of "no cure, no payment" has been deprecated, in modern day medical ethics.

As medicine developed and became more complex, it became apparent that certain standards for the practice of doctors would have to be specifically outlined with a view to prevent malpractices. Thus, a code of ethics evolved, which is today commonly known as the Hippocratic Oath. This oath forms the basis, upon which all subsequent international and national medical ethics have evolved. It is interesting to note that this oath was not a product of any public outcry against malpractices, but received inspiration and support from within the medical community. The oath lays down the following ethics to be followed by doctors:

1. The medical profession is to be harnessed for the benefit of the public and the doctor must, to the best of his ability, do good to the patient.
2. Abortion and euthanasia are to be condemned.
3. The nature of doctor/patient relationship is outlined and to take advantage of the superior position of a doctor is disapproved.
4. Strict medical confidentiality is to be maintained.

A modernised version of the oath was introduced by the World Medical Association as the Declaration of Geneva, which was amended at Sydney in 1968. Certain general guidelines for doctors were outlined (which stressed the importance of the health of the patient and the belief that the doctor should not only practice his profession with conscience and dignity, but should devote his life to the service of humanity. Great stress was laid on confidentiality which should be maintained even after the death of the patient. Competition within the medical community was also strongly condemned. "Utmost respect for human life from the time of conception" was the advise given to doctors. The strong views of the medical community against abortion is clearly reflected in this declaration even as late as 1968.

This declaration provided the basis for a more comprehensive International Code of Medical Ethics which lays down the duties of doctors in general, namely that a doctor must maintain the highest standards of professional conduct and must practice his profession uninfluenced by the profit motives. The doctor must not do anything unethical like self advertising, collaborating in any form of medical service in which the doctor loses his professional independence or receive any money in connection with services rendered to a patient other than a proper professional fee. As far as the duties of doctors to the sick are concerned the International Code states, *inter alia*, that a doctor must preserve absolute secrecy and must give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care. As far as duties of doctors to each other are concerned doctors are prohibited from enticing patients from their colleagues and a doctor in advised to treat his colleagues as "he would have them behave to him". Though all the three codes, the Hippocratic oath, the Declaration of Geneva and the International Code of Medical Ethics are vague and general in nature, the basic principle underlying all these three codes is the subservience of profit to the motives of the health and well-being of the patient.

An international attempt at setting medical ethics with regard to torture and other cruel, degrading and inhuman treatment, has also been made. This statement is embodied in the Declaration of Tokyo, 1975. Since a medical doctor practices medicine in the "service of humanity" having the utmost respect for human life, he is expected not to "countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures, whatever the offence of which the victim of such procedures is suspected, accused or guilty". Nor shall the doctor provide any premises, instruments, instances or knoweldge to "facilitate the practice of torture or other forms of cruel, inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment." The doctor must also have complete "clinical independence in deciding upon the care of a person for whom he or she is medically responsible. This code for the first time lays international standards and calls upon doctors to take an unabiguous stand against torture, and inhuman treatment of persons. It is obvious, that this declaration is applicable not only to countries under dictatorial rule but equally to countries which operate under the facade of 'democracy'. For it is here that the services of doctors have a greater chance of being misused. Fear of losing their jobs in government hospitals or fear of being deprived of certain benefits and privileges may force doctors to give false evidence or wrongly diagnose the injury of a patient or issue false certificates upon instructions from government officials. To fall a prey to such practices is clearly unethical and the concerned doctor can be hauled up by the national medical bodies for 'misconduct'.

With the increasing growth of medical technology, new inroads are being made in bio-medical research which involve human beings as research subjects, and hence the need was felt by international medical bodies to set guidelines in this regard. The Helsinki Decleration sets guidelines for conducting medical research which are essentially diagnostic and therapeutic in nature as well as for those whose essential object is purely scientific. It declares that concern for the interests of the subject must always prevail over the interest of science and society, and "in any research on human beings each potential subject must be adquately informed of the aims, methods, anticipated benefits and potential hazards of the study and the doctor should obtain the subject's freely given informed consent, preferably in writing". Unfortunately, the Helsinki Declaration bases its recommendations on the premise that if medical progress is to take place at all it must rest, in part, on experimentation which basically involve human subjects. At any rate, the positive aspects of this declaration are being implemented more by their breach.

The Indian code of medical ethics is based upon principles and standards set out under various international codes mentioned above. It incorporate the basic principles with regard to: (a) Service to humanity, (b) Misuse of medical knowledge contrary to the laws of humanity. (c) utmost respect for life from the time of conception; (d) respect for the secrets which

are confided in the doctor; (e) upholding the noble traditions of medicine; (f) treating colleagues as 'brothers'.

The general principles under the code outline the character of the physician and his/her relationship to society. Advertising or solicitation of patients is specifically prohibited. Income from professional activities is to be limited to services rendered to the patient and remuneration to be received for such services should be specifically announced to the patient. A physican is prohibited from prescribing or dispensing secret medicine or other secret remedial agents of which he/she does not know the composition. Duties of doctors to their patients deal with emergency treatment, maintenance of strict confidentiality and provision of proper medical care. The code also deals with duties of the physician to the profession at large, to each other, in consultation and to the public.

The national as well as state codes provide for initiating disciplinary action against a doctor for breach of any of the specified medical ethics. The action may be brought before the appropriate medical council (national or state). The medical council may consider and deal with any form of unethical practice which may be brought before it although it may not appear to come within the scope of the precise wording of any of the categories mentioned in either the national or state codes. It is obvious that if an unethical practice is specifically prohibited by any of the international codes of which India is a signatory, the national or state medical council can take as action against the erring doctor. The appropriate medical council may award such punishment as may be deemed necessary or may direct removal permanently or for a specified period from the register.

At the national level there are various laws which govern medical ethics of the medical profession.

The Indian Medical Degrees Act, 1916 prohibits all persons, save certain specified authorities, from issuing or alleging that they are entitled to issue any degree or diploma in western medicine or surgery. The act is restricted to the western methods of allopathic medicine and surgeons, homeopathic, ayurvedic and unani practitioners being excluded.

The Pharmacy Act, 1948 allows for only those who have attained a minimum standard of professional education to practice the profession of pharmacy. The Central Council of Pharmacy set up under the act is empowered to prescribe minimum standards of education and approved courses of study of examination of pharmacists. Section 36 of the Act lays down conditions under which the name of a registered pharmacist can be removed from the register for e.g. if the name has been entered by error or on account of misrepresentation or if the pharmacist has been guilty of any 'infamous conduct' which includes breach of professional ethics.

The Dentist Act, 1948, contains provisions for the constitution of an Indian Dental Council which is empoowered to lay down minimum standards of training and Provincial Councils which are empowered to maintain registers of persons entitled to practice dentistry. Section 17A of the act empowers the Dental Council of India as well as the State Dental Councils to prescribe standards of professional conduct and etiquette or a code of ethics for dentists. Such regulations may specify which violations thereof shall constitute 'infamous conduct' or in other words professional misconduct. Since the State Dental Councils have powers to adopt rules of professional ethics, they vary from state to state.

The Indian Medical Council Act, 1956, gives representation to licentiate members of the medical profession and provides for the maintenance of an all-India register by the Medical Council of India which will contain the names of all the medical practitioners possessing recognised medical qualifications. Section 20A empowers the medical council (state or central) to prescribe standards of professional conduct and etiquette, and the regulations so framed may specify which violations thereof shall constitute 'infamous conduct' or professional misconduct. Under the act, the name of the medical practitioner can be removed from the register either on his/her own volition or if a misconduct has been indulged in. 'Misconduct' is defined as:

(a) Conviction of a registered practitioner by a criminal court for an offence which involves moral turpitude.

(b) Conviction under the Army Act, 1950

(c) Any conduct which in the opinion of the council, is infamous, in relation to the medical profession particularly under any code of ethics, prescribed by the council or by the Medical Council of India constiuted under the Medical Council Act.

For any of the misconducts an inquiry has to be conducted by the appropriate medical council, before any action against the doctor can be initiated.

Role of the Medical Council

Since the Medical Council is the governing body of the medical profession, its main function has been the protection of a doctor's interest, and moves into action only if the conduct of a doctor brings disrepute to the medical profession. Take for example the highy unethical practices indulged in by the Federation of Obstetric and Gynaecological Societies of India (FOGSI) which took upon itself the task of representing and promoting a particular contraceptive. The Federation had circulated letters to the medical community urging them to promote the use of *Today*, a contraceptive manufactured by Bliss Chemicals. (Report by Rupa Chinai, *Indian Express*, 5.4.1988). The Maharashtra Medical Council because of the publicity, was forced to act against Dr. Daftary chairman of the Medical Termination of Pregnancy Committee. Clause 30 of the Maharashtra Code of Medical Ethics clearly states that medical practitioners would be guilty of 'misconduct' if they associate with "medical agents or manufacturers in the advertisement of products of particular manufacturers." This is not the first time that a medical body like the FOGSI has been closely associated with drug manufacturers. In the public hearing on high dose EP drugs held at Bombay, FOGSI filed affidavits supporting the use of this drug despite the existence of voluminous evidence to show that the drug was harmful. High dose EP drugs are being promoted by various pharmaceutical companies and it is evident, by going through the affidavits alone, that the FOGSI in collaboration with certain drug manufacturers was promoting the drug realising fully well that the drug had been banned in certain western countries because of its proven harmful side effects. The medical council has not taken any action against the FOGSI.

With the growth and poliferation of pharmaceutical companies, the bond between doctors and drug companies has

become stronger. In order to promote a particular brand of a drug company, doctors prescribe medicines to their patients, which are either of no use or are patently harmful. The tremendous hold of the drug industry over the health care system in our country, was recently brought to light by the Lentin Commission. Another example of the proliferation of useless and spurious drugs in the fact that more than 20,000 kinds of non-prescription drugs are on sale in the Indian market, most of which are non-essential and about 25 per cent of them spurious. As against this, the WHO has prepared a check list of only 200 essential drugs. Though the medical council is fully aware of the unethical practices of doctors prescribing drugs known to be harmful and useless, why has the council not prosecuted the doctors and more importantly should not the medical council have powers to initiate proceedings against drug companies?

The research establishment, both private and government, also collaborate with drug multinationals in conducting human trials. Human experimentation by the medical community is justified on the ground that such trials are for the benefit of humanity. For example, experimentation by administering injectable contraceptive Net-pen, which has not been proved as a safe drug is being conducted on several thousands of Indian women, who are being used as guinea pigs without their informed consent. These trials are being initiated by the government's family planning programme. The Helsinki Declaration clearly states that no tests should be conducted on human beings unless they are proven to be safe and without obtaining the informed consent of the person on whom the experimentation is to be done. The Net-ten tests are in clear violation of this declaration. The governmental institutions are the most consistent violators of medical ethics and yet the medical council and courts have been hesitant and unwilling to take any action.

In the Bhopal case, the government and its research institutions have effectively suppressed all medical information pertaining to the after-effects of MIC, and the treatment to be given to the victims. For example, though the Indian Council of Medical Research (ICMR) prescribed mass detoxification to the victims, by injecting sodium thiosulphate, the medical community in Bhopal ignored this recommendation.

The recent scientific advances in the field of reproduction like amniocentesis, chorion villi biopsy (CVB) are calling into question the philosophy and values of medical ethics. Those techniques which were meant to detect genetic deformities are now being widely used for sex-determination. Not a single doctor has been prosecuted by the medical council.

These are just few of the examples where not only doctors but government institutions have flagrantly violated the various international and national codes. And yet nothing has been done and the medical system continues to devour and maim a large number of people.

The extent to which the medical profession will conform to proper standards of medical care will depend to a large degree on the development of the public's awareness of the issue. The basic rules of social conduct can be ensured only if the public maintains a constant and vigilant eye on the doctors in particular and the functioning of the health care system in general. It is only then that the doctors will be forced to abide by the highest standards of medical practice.

(Contd from page 87)

selective abortion of female foetuses could continue unabated. The callous and blatant attitude of the medical profession towards this question can be illustrated through a front-page advertisement appearing in one of the city's eveningers barely five days after the Maharashtra government's triumphant declaration of intent on January 1. This advertisement read in bold type, "Boy or Girl? Contact clinic." A proposed legislation that will, in all likelihood ban such blatant advertising did not deter the doctor couple offering sex determining facilities. It must not be forgotten that, though pushed into a corner on several occasions, the medical profession refused to take an ethical stand before the government's declaration of bringing in such legislation. Apart from the high level of vigilance, a commitment from an ambivalent medical profession, faced with the loss of quick commercial gains, is a must.

(Contd from page 90)

the groups should utilise the avenues available to participate in the implementation process, in order to expose the hollowness of the bill.

The medical establishment had earlier argued that a law would force female foeticide underground. Now they have, in collaboration with the government, brought a law which can partially keep female foeticide above ground, within the purview of law. There is no alternative but to continue struggle against the medical practice of female foeticide.

This Bill has been passed in the Maharashtra Assembly without any significant amendment in April 1988].

UPDATE

News and Notes

Fee for Service in Maharashtra Hospitals

It is not surprising that the Government of Maharashtra has been the first to introduce fee-for-service medical care in all district and Government medical College hospitals from February 9 this year. The trend had started long back: the Municipal Corporation dispensaries and hospitals hiked the OPD case paper charges over a year ago with no significant resistance from any corner. But now the fee-for-service will be and is being charged at a higher rate not only for the OPD and indoor case papers, also for each component of the service availed of by the patient. The outdoor case paper now costs Rs.2 instead of 10 paise for seven days' treatment, and for indoor patients the charge is Rs.5 per day (in addition Rs. 3 per day are charged for diet). For laboratory investigations the charges are: Rs.5 for routine blood, Rs.10 for urine, stool, sputum, ESR, malaria and filaria, Rs.5 for MMR and screening, Rs.20 for standard X-ray. For operations, the charges are: Rs.120 for major operations, Rs.50 for minor operations done in minor OT., Rs.10 for minor operations done in the OPD without anaesthesia. For deliveries in these hospitals, family planning disincentives are applied: Rs.20 for third and subsequent deliveries.

The virtues of fee-for-service have been rigorously propagated in Maharashtra for the last one and a half decades. The political and economic crisis of the Indian rulers, which began to manifest itself from the late 1960s, was reflected acutely in the health-care sector. The experimentation primarily with the support of foreign funding agencies which led later to the formulation of international and national strategies for the primary health-care and the health for all had begun as early as the late 1960s and the early 1970s. All these experiments were meant to develop a strategy without radically changing the health-care structure and so also the social structure and without demanding any extra resources from the state to provide some basic health care to the people.

As these experiments grew under the 'care' of NGOs and voluntary agencies all over India, particularly in Maharashtra, they exerted a strong influence on government policy-making. Many of them attributed their success in people's participation to their policy of charging for services, albeit charging at low price. While attacking government policy of providing free services, it was argued that people do not appreciate services when provided free and there is a wastage of resources, as people misuse and overuse government services. They did not stop here. They even carried out some studies showing that the community is ready to pay for the services from the village health worker level to the hospital level. Thus evolved a strong case for the 'community financing' of health-care.

In this context, two points should be noted. Firstly, the majority of the NGO experiments were and are being carried out noy in the developed districts but in the underdeveloped areas (Jesani, Duggal, Gupte, 19). Therefore, in these areas the penetration of commodity relations is very pronounced. The NGOs' policy only took it further. Secondly, corruption and malpractices in the government sector are so rampant that they have already become institutionalised. The PHCs are no longer exclusive free service institutions nor were the district and the medical college hospitals before the February 1988 order. In a very significant number of them private practice by doctors both inside as well as outside the institution is the norm rather than the exception. In fact, about 25 per cent of PHCs and all rural hospitals and district hospitals officially allow doctors to do private practice, although not within the institution. Therefore, a fee-for-service atmosphere and value system has existed for long in the government sector. The health bureaucracy too believes in and encourages this state of affairs.

However, despite corruption and malpractice, poor were able to avail of some services, though it was second grade as doctors used to be more concerned about those patients who were either VIPs or used to fill their pockets. Now with the government becoming a 'private practitioner', even this second grade service is no longer available to the poor. The provision of providing free treatment to 40 per cent of patients is an eyewash, as it is at the discretion of the civil surgeon and the superintendent, who neither have inclination nor time to indentify such needy patients. Undoubtedly the government has in one stroke thrown overboard the fundamental recommendation of the Bhore Committee (1946) that health care should be available to people irrespective of their ability to pay.

Ironically enough privatisation of health

financing has take place in the context of the much lauded primary health-care and health for all. Certainly, privatisation does not necessarily and logically flow from the basic principles of primary health care. But when the PHC approach is articulated within backward capitalism which has historically, in our country, encouraged private sector through public sector resources, and at a time when the private health sector is attempting to expand its sphere of operation, it could generate a dynamic towards privatisation unless the PHC approach is combined with a vociferous demand for complete nationalisation of health-care services and allied drug and instruments industry.

Moreover the demand for low cost health-care must be made secondary to the demand for a National Health Service. In a climate where the private sector is allowed and given concessions to establish hi-tech medical care and the government hospitals in the urban areas—especially those also catering to the VVIPs—following the same line, people's expectation and aspiration to be treated with the best of medical tools will naturally increase. This is irrespective of whether the so-called best is really the best or not, rational or not and even appropriate or not. This climate decisively undermines the basis of primary health-care approach and it will be regarded as a second grade service by the people. Thus while one must continue to work for rational medical practice—even show to the government how resources could be saved by having rational medical practices in our hospitals (as against charging for services to meet demands)—unless low-cost medical care is propagated with a demand for an NHS, the PHS approach may well turn out to be self-defeating do late

—ACJ

Norplant: 'The Five-Year Needle'

An Investigation of the Bangladesh Trial

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Norplant, a contraceptive subermal implant was introduced for clinical trials in Bangladesh as early as 1981. However, partly because of resistance from conscious groups the trial was abandoned. Four years later, the Bangladesh Fertility Research Programme with other international organisations and a pharmaceutical company once again initiated the trial. This is a report of investigations conducted by a concerned group in Bangladesh.

NORPLANT is the registered trade mark of the Population Council for contracepive subdermal implants. It consists of flexible, nonbiodegradable tubes filled with levonorgestrel, a synthetic hormone of the progestin family. The implants are placed under the skin on the inside of a woman's upper or lower arm. The hormone is slowly released at an almost constant rate for several years.

Norplant implants come in two form. The first, called simply Norplant consists of six hollow silastic (silicone rubber) capsules, each capsule is 34 mm long, with a diameter of 2.4 mm, and contains 36 mg levonorgestrel. The ends of the capsules are sealed shut with silastic adhesive. This is the most widely used of the two systems. In Bangladesh, this system is being used.

The other system called Norplant-2, consists of two solid silastic rods, each 44 mm long. A total of 70 mg levonorgestrel is dispersed in the matrix of each rod. (PRS, 1987).

The promoters of the system are a coalition of hetrogeneous partners, (1) Population Council, New York, USA working through its International Committee for Contraceptive Research (ICCR) and (2) Leires Pharmaceuticals Company, Finland. In Bangladesh the preintroductory trial is being carried out by Population Council and Family Health International (FHI) through the Bangladesh Fertility Research Programme (BFRP).

Norplant Trial in Bangladesh

In this section we shall provide some information regarding the history of Norplant trial in Bangladesh which began as early as 1981.

The 16th meeting of the National Council for Population Control and Family Planning was held on February 7, 1981 at Bangabhavan and was presided over by the late president Ziaur Rahman. In this meeting, among other matters, it was discussed that, Norplant, a sub-dermal contraceptive which is easier and more effective than sterilisation should be introduced on a trial basis (National Council, 1981). Accordingly, a steering committee was formed on Norplant for introduction and examination of suitability and acceptability in Bangladesh. In August 22, 1981 a meeting of the subvention committee, Population Control and Family Planning Division, was held. The meeting considered the project proposal of BFRP on 'Clinical Study of Norplant Reversible Hormone Implant Contraception'. It was approved in principle and a sum of Tk. 7,43,000 including US 20,000 in foreign exchange was recommended for the project to be paid in phases. On October 4, 1981, BRFP put an advertisement in the *Bangladesh Observer and Holiday*, a daily and weekly newspaper respectively:

> A new birth control method
>
> **NORPLANT**
>
> *A wonderful innovation of modern science*
>
> - This method is for women
> - This can be implanted under the skin of arm
> - This will ensure sterility for 5 years
> - When removed, can have child again.
>
> Get more information:
>
> **Bangladesh Fertility Research Programme**
> 3/7, Asad Avenue, (1st Floor), Mohammadpur, Dhaka.

Immediately, there was resistance from conscious groups who pointed out the unethical aspect of the advertisement. An article was published on October 25, 1981, where several issues were raised. A brief text of the article is presented below:

> ... So far as we know through reliable sources that the Technical Advisory Committee in Bangladesh did not approve its use in Bangladesh. However, the BFRP has successfully bypassed the Technical Advisory Committee and announced and advertised its use.
>
> It should be noted here that the BFRP was also the pioneer in using Depo-provera and Norigest in Bangladesh.
>
> Finally, some comments on the BFRP advertisement for Norplant.
>
> First, the advertisement syas *"Norplant-a wonderful innovation of modern science"* Hard to believe because we do not have any scientific evidence.
>
> Secondly, *the method is for use by women*. As women are politically less dangerous.
>
> Thirdly, *it will be implemented under the skin of the arm*. Will ensure identification for coercion.
>
> Fourthly, *this method will ensure infertility for five years*: A safe method for the population controllers and not the users.
>
> Fifthly, *when removed will ensure fertility again*: Nobody knows (Norplant, 1981).

The trial was then postponed, as it was known through sources in government that the Population Council was not interested in being involved with controversial issues. A group of 151 doctors and pharmacists made a petition to the minister for health and population control to stop such an unethical trial. This part of the information seems to be lost in the present document of BFRP. There is no mention of the attempt of the trial in 1981. The BFRP documents now shows that they have initiated the clinical trial on Norplant in February 1985 under the financial and technical assistance

from Population Council and Family Health International (FHI) (FERP, 1986).

In an article by Dr. Halida Hanum Akhter, the present director of BFRP, it was mentioned that the BFRP has initiated the study after obtaining clearance from the Directorate of Drug Administration "to assess the acceptability and effectiveness of the new method among Bangladeshi women through government controlled hospitals and clinics such as the Institute of Post Graduate Medicine and Research (IPGMR), Dhaka Medical College Hospital (DMCH) and Mohammadpur Fertility services and Training Centre (MFSTC)" (*New Nation, 1987*).

Earlier BFRP had obtained clearance from its 19 member executive council headed by the secretary ministry of health and family planning and consisting of members from various government and non-government research organisations. University departments and obgyn departments of medical colleges.

The advisory committee was constituted by the Bangladesh government in February, 1985 to make major policy decision relating to the clinical trials and use of Norplant as a contraceptive, to decide the mode of Norplant study and monitor the acceptability of the new method of female contraception and to decide on the use of Norplant in large scale in the family planning programme cleared the use of Norplant in Bangladesh. . . The BFRP initiated the pre-introduction clinical trials only after the World Health Organisation decided at its Special Technical Review in November, 1984 that the Norplant was an effective and reversible, long-term birth control method which has proved to be superior to all other reversible methods.

It has been found by researchers that contraceptive pills containing progestin and more commonly used other reversible methods necessitate continuous motivational involvement by the user. In a country like Bangladesh this fact is more true than in the developed world. It is, therefore, necessary to introduce methods in Bangladesh which can continue to be effective for long periods without continuous motivation by Family Planning Workers. Norplant is perhaps the most effective method which is likely to prove successful here.

The articles does not say anything about the study on the safety aspects of the research. Again, when BFRP is quoting the WHO special Technical Review decision (which also says nothing about safety) it only emphasises the effectivity and the superiority over other methods.

The BFRP protocol of research does not have the objective of looking into the safety aspects of the method. An effective method means that the method can ensure birth control; but it does not necessarily mean that by being effective it is safe for user's health. The safety aspects are directly relavant for women's health, while the effectivity only deals with population control programme aspects.

It is interesting to note that even before BFRP undertook the trial in February 1985; the Third Five Year Plan had incorporated the use of Norplant. It says:

This long lasting method has the potential advantage of not requiring day-to-day use and therefore may be particularly suitable for our *semi-literate* population. It is proposed to introduce this method initially on trial basis, and the programme for its wider use can be decided according to the experience of the trial (TFUR, 1985). Here again, the effectivity question is mentioned and is specially targetted towards the semi-literature population, in other words, the poorer section of the population, so that population control can be ensured.

The BFRP had started promoting Norplant even before the trial was completed. While the trial began in 1985, the BFRP started making the following claims:

The Norplant contraceptive system is suitable for most women of reproductive age. (BFRP, 1986).

Norplant is a contraceptive system which is still under scientific investigation or trial. Because of the known and unknown health hazards of administering long acting hormonal implants scientists and women's groups all over the world as well as concerned individuals are resisting even the trial of this system. The trial was attempted secretly in Brazil. Later when it became a public scandal and had started facing resistance the experimentation was stopped.

It is important to briefly state the scientific status of Norplant. Here's a critique of the Facts About an Implantable Contraceptive' published in the *Bulletin of the World Health Organisation* 63(3): 485-494 (1985).

A. *Insufficient Animal Experiment*:

1. Levonorgestrol and the half as actived, l norgestrol isomer are used interchangeably. Only the investigations referring to levonorgestrol are relevant. The interchangeable use of the two substances is confusing, and it is not known how far results for one substance are valid for the other substance.

2. The comparison of the doses given to animals and humans is misleading because there are big differences in the bioavailability and terminal half lives of the drug between different species.

Table 1: Bioavailability and Terminal Half Life of Drug between Species

Species	Bioavailability	Terminal Half Life
Rat	9	0.5
Dog (Beagle)	22-6	1.2-0.3
Rhesus Monkey	9-4	4.4-0.5
Women	100	26.4-72

3. Although it is accepted that the beagle bitch is an unsuitable model for studying progestagins, experiments with this animal are included and no replacement experiments were carried out.

4. In the majority of experiments d, l/levonorgestrol was given by the oral route. The comparison with implanted doeses is misleading because there is a difference in bioavailability.

5. Experiments are included which were carried out for approval as an oral contraceptive.

6. Although the rat appears to be a poor model for the testing of implants (local sarcomas) it is nevertheless used in animal experiments.

B. *Insufficient Clinical Research*:

1. The effect of Norplant on lipid metabolism—the experiments carried out to date are contradictory. Fat metabolism is associated with the development of cardiac problems.

2. The relationship between Norplant use and an abnormal glucose tolerance test. (This was only examined in six women according to WHO report.)

3. The safety of long term use of Norplant.

4. The effect of Norplant on blood coagulation.

5. The use of Norplant during lactation. Its effect on the growth and development of the child.

6. The use of Norplant during pregnancy.

7. The effect of Norplant on the levels of testosterone and rostenedione. The experiments carried out to date are contradictory.

8. The effect of Norplant on systolic and diastolic blood pressure in the fourth and fifth year of use.

C. Inadequacy of Relevant Area of Investigation:

1. In general, investigations were carried out with young, healthy, non-smokers. By 'healthy' is understood: without cardiovascular disease, without diabetes (also preferably not in the family), not overweight, without liver disease. Common causes of this are alcohol and poor nutrition. Women who had used injectable contraceptives were eliminated from some experimental series. Thus, not a good cross section of the population.

2. Frequently results are compared with those of women who use oral contraceptives, instead of comparison with women who use no hormonal contraception.

3. Some side effects (although not frequent ones) were not included in the WHO report. More implants were removed as a result of 'other medical reasons' than because of menstrual problems (6.5 per cent of 5.6 per cent), while menstrual problems occur more frequently. Some of these side effects are depression (1 per cent), more then 10 kg wei[illegible] loss (2 per cent in Thailand); and epilepsy. (study in fam[illegible]lanning).

Therefore, the claim of suitability for most women of reproductive age is not based on facts and is misleading.

UBINIG's Involvement in Study

Since 1981 UBINIG has raised the question of ethics of the research which is conducted on human beings. There are specified guidelines for bio-medical research, which must be followed. But it has been observed that the research ethics was violated in several ways. UBINIG's main concern is the health of women and that women, specially the poorer women, because of their vulnerable condition, should not become the victims of such research. From this commitment UBINIG has always pointed out the lapses found in the research in order to improve the situation.

In 1985, UBINIG was informed of the trial on Norplant by a development worker working with women in the slum areas of Dhaka city. She wrote a brief account of her experience with the trial:

> One of our group members (Jahanara) had four children. She became pregnant again and was worried. She went to several family planning centres for abortion (MR), but failed. Finally she told me everything and sought my help.
>
> On 15th December, 1985 I took her to Mohammadpur Fertility Clinic for MR services. We were told that abortion cannot be done because it is already 11 weeks of pregnancy. But soon they said that MR can only be done if she takes ligation operation simultaneously. Jahanara did not want to take ligation. So she was refused by the centre.
>
> I, then, took her to the medical college and met with the counsellor. Jahanara told the counsellor that she would prefer to take an IUD (plastic coil) after the MR. She said that she would not be able to take rest at least for three days after the ligation operation. She has to work. So it is better not to do it now. Then the counsellor told her about an injection. I remembered the side-effects about injectables so I said injections have possible side-effects. The counsellor said: "You are talking about injectables with 2/3 months duration. But here is another injectable which is of 5 years duration. It does not have any side-effects.
>
> I was confused, because earlier I heard of Norplant which is of 5 years duration, but the counsellor did not say that it was Norplant. During our conversation, the counsellor opened up a form and asked Jahanara to put her fingerprint on the paper. I could read what was written in it, although the counsellor did not make any effort to read the text to Jahanara which was meant for her. It said: I am completely aware of the method of menstrual regulation. I know about the problem such as infection, bleeding and peforation of uterus and yet I have requested for the MR.
>
> Jahanara put her fingerprint on the paper without knowing what was written on it.
>
> Then we came downstairs. I saw that several clients were sitting, while two motivators were trying to motivate the clients. A doctor came out of the room and asked. "Did you find a client." The motivators said, "No". The doctor said, "Try to motivate them".
>
> I asked the motivators about the 5-year injectables. They said that it was called Norplant. They also informed me that it is given in the PG hospital, the medical college and Mohammadpur Fertility Clinic and through Dr. Firoza Begum. They also mentioned that Norplant was being given through some private clinics. I became very worried and went to the room where Jahanara had her MR. I told her not to take Norplant. The I went to the doctor and requested her to let us go on that day. We would come back later. In this way Jahanara was saved from Norplant.

After this, we tried to find out more about Norplant. UBINIG research team found that most of the clients in the PG hospital were being motivated for accepting Norplant. However, they were found to have been asked questions such as, whether the woman was a lactating mother or not. One Aya thought that the research team was there as client. She suggested that if they take Norplant, then they could be given Tk 30.00 [app. Rs 60] and some medicine during the first visit. The client could come back in case of any problem and would receive Tk. 30 and medicine. In the PG hospital, we collected a leaflet which was distributed to the clients. The leaflet said:

Facts About Norplant

1. Norplant is a new temporary family family planning method. It is effective for 5 years.
2. Its use is relatively easier.
3. It is given under the skin of the arm with an injection needle.
4. Generally the side-effects of this method are less than that of the pill.
5. It is 100 per cent effective as sterilisation.
6. The user can take out the norplant whenever she wants.
7. The return of fertility after taking out Norplant is after one year.
8. It is possible to carry out normal movement and works when it is in the body.
9. There is no need of taking any other method when the method is in use.
10. The doctor will examine the client before the method is given.

To know more about Norplant, contact the doctor

(Collected From IPGMR on December 24, 1985.)

If we evaluate the points mentioned in the leaflet, we find that it actually violates the ethics by providing false information to the clients. A few examples of the falsity of the information are given below:

Point 1: The claim of effectiveness is not completely true, because according to BFRP newsletter the rate of accidental pregnancies during the first year was 0.4 pregnancies per 1000 users. The WHO records indicate a gross cumulative pregnancy rate at 5 years of 2.6 per 100 women years. The annual pregnancy rate during the first 5 years ranged from 0.2 to 1.3. ('Facts about an Implantable Contraceptive', *WHO Bulletin* 63(3) p. 485-494 (1985).)

Point 2: Its use is not easier because it needs surgical approach to put the capsules under the skin. The WHO recommends that to minimise the risk of infection, both insertion and removal should be performed in a clinical setting. It is of utmost importance that sterile techniques be maintained throughout both procedures.

The above two examples also indicate the violation of ethics by trying to motivate women with false information.

We have tried to collect more information but were not

successful because of the non-cooperation from the research organisations. In November 1986, a conference was organised by BFRP on "Contraceptive Technology Update", among other issues. Norplant research was discussed. A preliminary report was presented by S. Firoza Begum. According to her report 600 clients were admitted under the study within the period February 1985 to April 1986, but the total number that remained in the period Jan-April 1986 was 187 i.e. 31 per cent of all those admitted. She listed a number of reasons for removal. (Table 2).

From the users' satisfaction point of view Firoza Begum had pointed out that 40 per cent have liked the method because it lasts for 5 years, while 30.7 per cent liked it for easiness. About 56 per cent disliked it because of its effects on the change in menstrual pattern. 82 per cent have said that they have received 'enough' information about the method, while 17.8 per cent have not. One wonders what 'enough' means. If the above leaflet is the only source of information it cannot reach all the users because many of them are illiterate.

UBINIG Study on Norplant-Clients

We found out the clients of Norplant during our study on the injectables in urban slum areas. In the area of Mohammadpur, Tikkapara slum we identified women who have taken injectables. We also went to Basila village which is a semi-urban village and found a number of injectable clients. During the interview we discovered one injectable client with Norplant. The client told us that she has taken a 'five-year needle'. Then she showed her arm having the capsules. Gradually we found more women in the same village who have taken the 'Five-Year Needle'. We have interviewed 10 women who have taken Norplant.

Three centres were visted by the UBINIG research team in order to get information about the trial. These centres are: (1) Mohammadpur Fertility Services and Training Centre, commonly known as Mohammadpur Model Clinic or the Mohammadpur Fertility Centre; (2) Dhaka Medical College Hospital, DMCH; (3) Institute of Post Graduate Medicine and Research, IPGMR.

Table 2: Reasons for Removal

Reasons	(N=32) No	Per Cent
1. Pregnancy Related:		
Luteals Phase*	2	6.2
Planned Pregnancy	1	3.1
2. Change in Menstrual Pattern:		
Amenorrhoea	4	12.5
Polymenorrhoea	6	18.8
Menorrhagia	2	6.2
Irregular Bleeding/Spotting	5	15.6
3. Medical Reasons:		
Body Pain	1	3.1
Headache/Nausea/Burning Sensation	3	9.4
Loss of Libido	2	6.2
Weight Gain	1	3.1
Serum Hepatitis	1	3.1
Infection at Insertion Site	1	3.1
Jaundice	1	3.1
4. Personal Reasons:		
Husband Eent Abroad	2	6.2

* In these two cases women were pregnant at the time of admission.
Source: Report of Firoza Begaum (1986).

The information obtained from (1) Dr. Hosna Ara Ali, deputy director and Ms. Pervin (a family planning worker) in the Mohammadpur Model Clinic, (2) Dr. Kohinoor, gynaec specialist and directly working with the Norplant study in Dhaka Medical College Hospital and Ms. Nadira Begum, a family planning counseller in IPGMR.

It was known that about 616 women were given Norplant in three centres. Except in IPGMR the other two centres had 200 clients each, while in IPGMR it was 216. The counsellor reported that another 14 clients will be given Norplant within one month of the interview (i.e. January 1988).

Information received from Mohammadpur Model Clinic shows that the age range of the clients is between 18 and 40 years. The Norplant is given within 1-7 days of menstruation. Women who are not breast feeding their babies are given the method. All medical check-up is done for the clients so that no disease such as jaundice, hypertension, diabetes is found in her. If the clients fall sick after the use of the method then it is taken out and she is admitted to the hospital.

The follow-up is done within 1.3 and 6 months of insertion. Those who have taken Norplant have come from Dhaka mostly, although a few have gone to Chittagong and Comilla after the insertion. However, they have stopped inserting any further Norplant since last one year.

In the Dhaka Medical College, the criteria of the Norplant receipients in terms of age was same as the other two centres i.e. between 18 and 40 years. In addition to that, the gynaec specialist said that one should use Norplant after one child is born. The breastfeeding mothers should not use it, because according to Dr. Kohinoor, "the hormone which is in Norplant may pass from mother to the child through breastmilk and can cause harmful affects on the baby." In response to the question, how do they get the clients Dr. Kohinoor said, "When women come here for taking a contraceptive method we give them a leaflet where the good and bad effects of Norplant use are written. But the women must get the consent of their husband". About follow-up she said that each and every client has a card. If the women do not turn up for follow-up care then workers go and visit them at their homes.

No insertion is made without complete medical checkups. Those who have hypertension should not be given, nor those having jaundice and diabetes.

As for side-effects, the most common side-effect is amenorrhoea. "However, this is not a serious side-effect", she said. "It is better for the health to have amenorrhoea. Because it saves the blood which would have gone through menstruation every month. Therefore there is no chance of having anaemia. You know these women are already malnutritioned Norplant is better for their health." she added. According to her 95 per cent of the clients belong to very poor class. "They are responsible for giving 4 to 5 births each. Since they cannot remember to take birth control method; like pills, every day, long acting methods are better for them. On the other hand, women in the upper class are intelligent and can take any other method".

Finally she said, "In order to get a good thing there is a trade off. If 2/3 women die what's the problem? The population will reduce and 70 per cent of our research has been successful. In every birth control method there are good and bad sides. This has, too."

The doctor in the PG hospital has only joined recently, so she could not give much information.

Every centre we visited referred us to BFRP. But BFRP refused to give information on the ground that we will 'misinterpret them'. We have requested the director in writing.

Profile of Norplant Users

Below we shall provide a brief picture of the users of Norplant in the village Basila, in Dhaka city. There were 10 women, who were found to take Norplant from Mohammadpur Fertility Centre.

(i) *Economic Condition*: According to the information available about occupation of the husbands of users, and by direct observation of their household conditions, the economic status of the users is poor (6) and lower middle (4). Those who are poor are working as boatmen, fish sellers, day labour and small business. The average daily income is Tk. 40.00 to Tk. 50.00. They have no land and have to depend on selling labour for earing their livelihood. The lower middle families are mainly engaged in small business such as tea and groceries. The families are also found to be involved in brick business.

(ii) *Education*: Eight out of 10 users are illiterate; one has read upto primary level, and another has got secondary education.

(iii) *Age*: Two users are in the age range of 15-20 years, three are in 26-30 years, one is in 31-34 years and four users over 35 years of age. The highest age was found to be 45 years, while the lowest age is 18 years.

The age was determined by our investigators by asking the user about her age; about the age at marriage; about her menstrual situation at the time of marriage and about the age of her first child.

All this information together helped the investigators to come to a figure for age of the user. This age information is more or less accurate. In the centres where Norplant is given, the age limit is said to be 18 to 40 years and is noted only by asking the user about her age. In our sample, we find that a woman over 40 years has been given the method.

It is interesting to note that the draft protocol of the Norplant study does not say anything about age of the users. Moreover, the preliminary report submitted by Firoza Begum does not mention anything about the age level of the 600 users of Norplant. The question is whether the researchers are not taking the issue of "age of the user" as an important criterion of the research, whereas Norplant as a "long-acting contraceptive" method must have a limit for age for the method to be effective.

(iv) *Marriage and Child Birth Information*: (a) Duration of married life: Six women had a long married life of 20 to 30 years, while others had between 10 and 20 years. Only 2 young women were married in 1981. It is somewhat related to the age of the user. Most of the users (8) were married at an age of 13 to 16 years, and only 2 were married at the age of 18 years.

(b) Number of living children and children ever born: The average number of children for all the users (N=10) is 43, while maximum number is 8 and minimum is one child. As is known from national statistics, the number of child births is higher than the number of living children. The average number of child births is 4.7 (the maximum is 9).

c) Age at first child birth: Three women have got children before they reached 15 years, while 7 had children between 16 and 20 years of age.

(d) Time gap of first child birth and marriage: Five women got children only after a year of marriage, 4 had between 2 and 3 years and one had 5 years of time gap after marriage before the first child birth.

(e) Average gaps between child birth: The average gap between child births were found to be 2.1 years, with 4 years as the maximum gap.

(v) *Information on Contraceptive Acceptance*: Except 3, seven users have accepted other methods before taking Norplant. These other methods are pill and injection. Norplant has been used as a method of switch from other methods or other methods were taken after Norplant use. This is shown in Table 3.

Table 3: Use of Norplant and Other Methods

Category	No of Users
I Norplant as the first method and no switch	3
II Norplant as the first method but switched to other methods	1
III Norplant after using other methods	6

That is most of the users have switched to Norplant as a change of contraceptive method from other methods. One woman in the category II has already changed from Norplant to other method such as pill. In category I, one woman has taken off Norplant and has not taken any other method. In category III, one women has taken off Norplant. Out of 10, the drop out of Norplant is 3.

Those who used other methods have started using the methods since 1976. The Norplant was given in 1985. Only one woman has taken Norplant in 1986.

(vi) *Present Health Condition of User*: We have taken weight, height, blood pressure, pulse, anaemia etc. as minimum indications of health condition of the user. We shall provide the information in terms of average and maximum and minimum figures.

Height:	Average	4.11	
	Maximum	5.1	N=10
	Minimum	4.9	
Weight:	Average	42.3 kg	
	Maximum	48.0 kg	N=10
	Minimum	38.0 kg	
Blood pressure:		90/60	N=10
	Minimum Normal Level		
Plus rate:	65-80 per minute	5	N=10
	More than 80 per minute	5	
Anaemics:	Normal	2	
	Mild anaemic	2	
	Moderate anaemic	4	N=10
	Severe anaemic	2	

(vii) *Health Condition before Use of Norplant*: We have asked questions whether they had any specific health problems before the use of Norplant, we got the following response.

There was no problem	8	
Irregular Menstruation	2	N=10

That is, women having amenorrhoea and irregular menstruation were given Norplant, which aggravated their problem

even further. We could not however get information on health conditions for which Norplant is contraindicated such as jaundice, diabetes etc. So we abstain from making any analysis of it.

(viii) *Health Conditions after Use of Norplant*: All the 10 Norplant users were facing problems since they have taken Norplant. These were as they have expressed:

"No menstruation since 1 to 1½ years."

"Once menstruation is started continues for 15 to 20 days."

"Irregular bleeding, spotting", etc.

In addition to this the other problems are loss of apetite, vertigo, burning feeling in hand and feet, body ache, weakness, leucorrhoea, etc. If we order the health complaints in terms of the frequency of reporting, then the following pattern emerges:

	N=10
1. Amenorrhoea*	10
2. Irregular menstruation	4
3. Burning sensation	3
4. Excessive Bleeding, White Discharge, Body ache	2
5. Tiredness	1

* Almost all the clients suffered from amenorrhoea for different periods of time and most of them developed irregular or excessive bleeding in between.

Here by amenorrhoea is meant long period without menstruation, even more than 45 days. According to some clients they had no menstruation for one year or more.

A few examples of the users' complaints:

(a) "After I have taken the "Six" (the needle), I felt aches in my body after six months. I cannot look up, I do not have any apetite, I am going to die. The menstruation is very irregular, and during last Shabe-Barat (a religious occasion) I had menstruation for 2 months at a stretch", Anwara Khatun (30 years).

b. "I did not get menstruation for 2 year since I have taken this 5 year needle. Now I have aches in my hands, legs; I feel weak, I cannot explain; it is a terrible feeling", Fulbanu (35 years).

c. "Since I have taken the needle, I get menstruation which continues for 12 + 13 days together. When I took the 3 month needle, I had regular menstruation but now I had bleeding; clots of bloods going at the time of menstruation. I feel pain in the body. I put kerosene oil on my body; when I go near the stove to cook; I see things double. I cannot go near the fire". Nawab Banu (38 years).

Three women who could not tolerate the problems insisted on taking the Norplant off, and finally could succeed in convincing the centre to take it off.

For health problems, the users have gone to the centre to express the problems, but they were given only 30 vitamin tablets and in some cases a prescription to buy medicine from outside. No other treatment was done from the centre. But they had to go to some doctor. For example 2 have gone to a qualified allopath doctor, 3 have gone to traditional healers, called the kabiraj, and one to a quack allopath doctor. Five women did not go to any doctor because they did not have the money to spend.

(ix) *How was Norplant Taken by Users?*: The users first heard of injectables, the 3 month dose, from the family planning workers but later they heard from the neighbours that there is a needle for 5 years. They heard that it was better than the 3 month injection so it would be better for them to take the 5 year needle instead of the 3 month one. From their village, it is difficult to go to the centre frequently, so it was better if they could have a method of 5-year duration. One woman said that every woman goes to take Norplant is asked to talk about the benefits of Norplant to their neighbour, and that they should send their neighbours to take the method. None of the user has mentioned that they were using the method as a trial. The only information which was given to the clients was that Norplant was a 'needle for 5 years'.

(x) *State of Lactation, Pregnancy and Affects by other Contraceptives*: We have received information which is vital before a contraceptive like Norplant is taken by women. Table 4 is the representaton of the situation.

Table 4: Status of Women before Taking Norplant

State of Client's Condition at the Time of Norplant Acceptance	Number of Clients
Breastfeeding	3
Pregnant	1
Already had problems due to use of other contraceptive methods	1
Both breastfeeding and affected by other methods	3
None	3

Six out of 10 women were breastfeeding out of which two women had a child below one year of age. One of these clients had her last baby with the age of 1½ months only. Four women were still breastfeeding their child even though the child was over 1 year of age. In Bangladesh, the average length of breastfeeding is about 18 months.

Table 5 shows that there is no sign of using Norplant as a trial, it is used as a contraceptive method, like the injectables, IUD etc. The clients are not included under the trial with their informed consent nor any proper care is being taken for the health problems of the clients. However, the centres are selectively doing urine tests for some clients and not all of them. It is assumed that they want to eliminate the cases where the women are not coming within 1-7 days of menstruation. By urine tests they want to be sure about pregnancy.

Here again, the evidence suggest that the rules for trial were not followed although the workers are found to be aware of certain rules. Violations are particularly made in taking informed consent, in the selection of clients for the method and in the follow-up care. Information on the monetary incentives for follow-up monitoring was received from IPGMR Hospital. The doctor told us that they give Tk. 20.00 to each client for motivating the clients for visiting the centre for follow-up monitoring. They also reported that the clients are given Tk. 50.00 at the time of first insertion of the method. While the centres try to motivate the clients to come for follow-up visits the clients reported the contrary. According to the clients, there was rather discouragement for reporting health problems. The centre workers are friendly in their attitude before insertion of the method, but afterwards 'they do not even want to talk'. The family planning workers at the centre do not appreciate the clients' health problems at all and they also do not want to take it off. Since the method is clinical, and the clients cannot take it off by themselves, they feel helpless and therefore have to go to the centre and plead for taking off the method. It is upto the decision of the workers whether it would be taken off or not. This is

a helpless situation for the clients.

The clients also become discouraged to go to the centre for follow-up care because they are not given any treatment. They are given 'slip' only i e, prescription. The centre workers says that there is no medicine for treatment of the clients.

Discussion

If the trial is for acceptability and effectivity, the methodology is inadequate to prove either. The research methodology is directed more towards getting women so that the method can be inserted. Women are not considered as a human and social being. Therefore, no information is being shared with her except the information which will only lead to the insertion.

Women who are motivated to take Norplant are supposed to be motivated with full knowledge of the method as a trial. This is not happening. This can be proved not only by the

Ta : An Examination of Rules to be Followed for Trials

Rules	Whether It Was Followed by the Trial
a. Informing the clients about the method and that it is on trial	None of the sample clients know that the method was on trial. The information which was given to the clients was that: 'It is one of the contraceptive methods and it is of 5 years' duration'.
b. Informing the clients about the side-effects	Two clients were told that "there will be some disturbances in the menstruation cycle, either it will stop or may be there will be more bleeding. There will be no other problem". Two clients were asked to come "if there is any problem". One client was told that "if you take this needle, there will be no problem, but if you get sick, we will check". One client was asked to take milk, banana and other good food. Four clients were not given any information.
c. Taking consent of the clients after providing all the information	No information was found which will reveal that an informed consent was taken. The clients were not even told of the name of the method. Only one client knew that the method was called "Norplant" and the rest knew that it was a 5 year injection.
d. Pre-medical examination of the client	Urine test and blood pressure checking was done for 2 clients, weight and blood pressure was taken for 8 clients.
e. Medical support to clients having side-effects after taking the method	Six clients reported that when they went to the centre to report about their health problem, the centre gave them prescription on plain white paper and asked them to buy medicine from outside. According to a client, "I have gone to the centre 2-3 times, they gave us slips only and asked me to buy from outside. I asked them, why should I buy medicine from outside when I have taken the needle from here. I want my treatment to be done here. The big doctor told me that the govt. did not give medicine for us. If I talk about my health problems more, they suggest I go for ligation operation". One client was given 30 vitamin tablets, another client got pain killer tablets once.

Table 6: Discrepancy and Similarities Found in Information Given by Centre and Information Received from Clients

Centre	Clients
a. Norplant is given within 1-7 days of menstruation	All the clients reported of same time period after menstruation.
b. Women who are breast-feeding are not given the method	Six out of 10 users were breastfeeding at the time of taking Norplant.
c. Norplant is taken out as soon as any side-effect is noticed.	Three clients have taken out Norplant. But their experience is that the centre did not want to take it off for first 2-3 times. Then when they insisted further, then it was taken off. In the words of a client, "when I had problems, and could not bear it anymore, then I went to the centre, but they refused to take if off. They said why did you take it?" Next time I went and made a lie by saying that my two children are drowned in the river and my husband wants another child. This time they took it off. The rest seven clients are having side effects but the method is not taken off.
d. All pre-medical tests are done. These include checking of disease like hypertension, jaundice, asthma, etc.	The clients have reported only urine test, blood pressure checking, irregular p/v exam and weight as the premedical test done for them. But these were also not done for all the clients.
e. Norplant is given to women between 18 and 40 years of age.	One client was 16 years and one client was 45 years. The rest were within 18 to 40 years of age.
f. The follow-up procedure is the following: 1st follow-up after one month of insertion, 2nd and 3rd follow-up after three months of insertion. Fourth onwards follow-up in after six months of insertion. Dates of follow-up visits are written on the card. If they do not come then the centre workers go to the clients' houses to see how they are.	The clients reported that they are asked to go to the centre after every 2-3 months. They know that the date is written on the card, but they have not seen any worker coming to their houses for follow-up care.
g. A leaflet is made with the information of good and bad effects of Norplant. This is read out to the clients; and then if they decide to take it then the method is given.	No client has reported of such information
h. Women having post-partum amenohrroea, are not given Norplant.	All the 10 women who have received Norplant during normal menstruation cycle.
i. The clients must have at least one child at the time of taking Norplant.	The clients reported that they were asked about the number of children they have.
j. Those women who have taken pills, must wait six months before they take Norplant.	Two clients were taking pill before taking Norplant. One of them has taken Norplant only after 2 months of stopping pills.
k. Clients must get consent of their husbands before taking Norplant.	Only six clients have taken consent and four did not.

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