CHAPTER 5
DEVELOPMENT OF MEDICAL TECHNOLOGY AND THE MEDICAL EQUIPMENT INDUSTRY

Before we proceed to examine the production, procurement and utilization of medical equipment in India, we take a look at the development, production and use of modern medical technologies at the global level. As discussed in Chapter 4, due to historical reasons the healthcare system in India too is dominated by modern 'western' medicine, and is based on heavy use of all modern medical technologies. Further, the linkages and associations of the Indian healthcare system with the global forces are being re-inforced and reshaped in several ways by the current processes of globalization. In our view tracing medical technologies to their origins can contribute to evolving and enriching a perspective for the study of medical technology and its growth in India. This chapter looks at the development of certain medical innovations and at the medical equipment industry. The second section of the chapter presents data on the structure and activities of the contemporary medical equipment industry, on production, international trade, and arrangements for distribution of technology.
Section I
DEVELOPMENT AND DIFFUSION OF MEDICAL INNOVATIONS

This section examines the development of specific medical equipment. From this review of published work we draw out the considerations and criteria adopted during the development of medical imaging technologies. It sheds light on the development of the medical equipment industry, on the role of industry as a major source of technologies, and on the interaction between high technology and business.

CASE STUDIES OF DEVELOPMENT OF MEDICAL TECHNOLOGIES

5.1.1 Development of Medical Imaging Technologies

We find that imaging technology has been comparatively more studied than other medical technologies.

A. Development of X-ray technology

In January 1896 Wilhelm Roentgen announced his discovery of X-rays (along with an X-ray photograph of his wife's hand showing bones and ring, to demonstrate the remarkable powers of these rays). Roentgen refused many financial incentives to patent his discovery, so that the apparatus could be freely produced. With remarkable speed a thriving and dynamic X-ray industry came into existence in Britain and the USA. In Britain three firms, small but long established makers of scientific instruments and microscopes started manufacturing roentgen tubes (Blume 1992, p 23). In March 1896 GEC (GEC), USA, which was already a very large corporation by then, started design of an X-ray apparatus suitable for commercial sale, and within a month began to place large advertisements in electrical trade journals. Soon its catalogue started listing a range of X-ray products, and there was confidence that, with their existing network of salesmen they would be able to reach their market among doctors, hospitals and scientific laboratories.

Early X-ray instruments were highly unreliable and manufacturers with resources put in efforts into improving their durability, quality and performance. World War I was a watershed for X-ray technology - physicians who had used it in the war were convinced of its value; and industrialists noted the military demand for X-ray equipment. GE had stopped production around 1905. A study by GE in 1914 concluded that the market would be too small to justify manufacture of the new Coolidge's x-ray tubes. The management still insisted that production proceed, noting that 'the tube should be exploited in such a way as to confer a public benefit,
feeling that it is a device which is useful to humanity, and that we cannot afford to take an arbitrary or even perhaps any ordinary commercial position with regard to it' (quoted in Foote 1992, p31). To what extent this was a decision for 'public benefit', and to what extent it was influenced by the large government orders for portable x-ray units for military hospitals during WWI is an open question. GE's innovation and production during the war included portable x-ray machines for use on ships and relatively inaccessible stations such as Pacific island hospitals, and machines that used smaller films; x-ray machines were also used to screen soldiers for tuberculosis (Foote 1992, p52). Government purchasing expanded market size. The company began to make significant profits, and after the war GE took a decision to become a 'full line X-ray equipment supplier'. It bought the Victor x-ray company, and soon came to hold a dominant position in the 'new and increasingly profitable medical equipment supply business' (Foote 1992, p 34). Philips, then the Dutch manufacturer of electric bulbs, initially took to repairing X-ray tubes during the war, and subsequently started producing X-ray tubes. It then went on to establish an X-ray research laboratory, and then took over the Hamburg manufacturer CHF Muller, as part of its move to enter into X-ray equipment manufacturing (Blume 2000 p 176).

There was competition between manufacturers, and in the initial years manufacturers addressed themselves to an ill-defined group of customers. The experiences of users did not form a source of input to the developments/refinements of the technique. According to Blume, the development of x-ray technology at GE was influenced not so much by the medical applications as by the overall interest of the researcher E. Thomson in physics, and who had the physics and electrical engineering communities in mind as the users of this technology. The overall trend in the industry then was toward simplified construction, ease of manipulation, standardised procedures, accompanied by tremendous extension of the credit system in commercial transactions, corresponding expansion of advertising and the development of high-pressure salesmanship to increase volume of sales. All this led to a wide dissemination of the apparatus 'not only in legitimate medical circles, but also among the quacks and outlaws of the borderlands' (Blume 1992 p 34). In the medical profession at that time there was a tendency towards specialisation. Whereas, the constant endeavour of manufacturers was to produce generators that would be simple to operate, so that an increasing number of physicians would be forced to purchase them regardless of lack of the specialised knowledge required to take full advantage of its possibilities. There was little concern for the safety of x-rays – although reports that they could destroy life and damage the skin had started appearing by 1900, and many

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1 It maybe recollected from chapter 2 that GE had many other lines of business, including refrigeration. During the war it also supplied refrigeration and air-conditioning systems for blood and penicillin storage.
investigators and users suffered burns due to inadequate protection, still physicians tended to be dismissive of their harmful effects.

However, gradually the use of X-rays became restricted to the medically qualified radiologist. There was consolidation of the industry in the inter-war period; the innovation process changed, whereby devices were adapted to the demands of specialist practice; within the medical profession specialist radiologists and diagnostic x-ray imaging became established. In fact specialisation itself is viewed as a stimulus to innovation. Manufacturers now began to direct product improvement to meet the needs of this more homogenous group of users. According to some authors these changes led to the creation of an 'inter-organisational field', an area of shared interest in technological advance in which professional customers, who provided the radiological insights, and the manufacturers producing the devices found common cause (Blume 1992).

By the 1950s manufacture of X-ray equipment had become the most important segment of the growing medical equipment industry; it had become highly concentrated as small producers had merged or had been taken over (Blume 2000). It continues to be so - as illustrated by the development of CT-scanning discussed later, and from the structure and activities of the contemporary medical technology industry.

B. Development of ultrasound technology for medical imaging

The experience in World War II of use of sonar and radar technologies for spatial location of objects (based on ultrasound), and of lasers had a significant influence on development of diagnostic ultrasound and of medical lasers respectively. Research on biological effects of ultrasound and possible applications had been going on since the 1920s. Important technical developments in the area took place during WWII; there was much R&D by leading universities and firms in the USA, Britain and Germany. In 1937 an Austrian neurologist Karl Dussik succeeded in generating an image of the skull by passing an ultrasound beam through it. This work was later picked up by Siemens Laboratories, but given up as impossible after few years of work. A medical ultrasound project was also initiated at the MIT Acoustics Laboratory, USA, as there seemed to be clear medical justification for pursuing ultrasound investigations of the brain. There was a clinical need for better techniques for detecting brain damage/abnormalities. This group worked on the transmission of the ultrasound beam through the brain rather than the echo method that was also being investigated by some others (and was used in industry and in radar, etc.). By the mid-1950s the MIT team terminated their line of work on grounds that the images obtained were of poor quality; that transmission imaging of the brain was impossible; that
improvement in instrumentation might lead to better results. However, in 1953 a neurosurgeon Leksell, in Lund, was able to use an industrial flaw detector to detect brain damage in a child and accordingly plan his surgery. After more investigations he concluded that 'the echo method can give valuable diagnostic information with the scalp and skull intact', and could be a safe and rapid method for exploring the brain in case of acute head injury. A clear clinical application in neurology had thus been established for ultrasound and the commercially available industrial flaw detector served this purpose (echoencephalography). An industrial firm Kelvin Hughes, which made industrial flaw detectors, had started working with neurologists and followed up Leksell's work. Around the same time clinical use of the same instrument in cardiology had also been established by a cardiologist working with a physics student on heart structure/motion as a function of time.

Another research program was taken up by a surgeon, John Wild, in collaboration with an aeronautical engineer, on use of ultrasound for distinguishing normal from cancerous tissue. Initial experiments on cerebral tumours seemed promising. Wild chose to study breast tumours in clinical studies. The reason being the limitations of the apparatus due to limited penetration of the ultrasound waves at the frequency he chose; hence the choice of 'accessible tumours', or those on superficial sites of the body. The problem then was to set objective diagnostic criterion. This team also went in for a change in technology. However, this work got discontinued because in the meanwhile the x-ray technique of mammography had been developed and started getting adopted in the mass screening programs for breast cancer. Wild's research funding got terminated and massive litigation ensued between him and the agency managing his research. Moreover his choice of high frequency was considered as mistaken by other workers. Yet another line of work at that time was that of a radiologist Douglass Howry, who along with a university based electrical engineer, explored the possibilities of reflection ultrasound for imaging soft tissue so that it could be an important adjunct to x-rays in diagnosis. Throughout the 1950s Howry and his colleagues worked at improving the design of their instrument to obtain better quality images of the scanned region.

Meanwhile the possibilities of what ultrasound could do in gynaecology and obstetrics was taken up by a gynaecologist, Ian Donald, in Glasgow. Given the concerns with the hazards of ionising radiation posed by obstetric radiography, ultrasound appeared an attractive alternative. It was felt that the clinical practice of gynaecology imposed far greater demands on the flaw detector than did those of cardiology and neurology. By 1956 Donald, along with an engineer Brown from the company Kelvin Hughes, had adapted the industrial flaw detector so that it could be used in gynaecology and obstetrics.
In 1959 an ultrasonics research section had been established in the then Commonwealth Acoustic Laboratory, a set-up of the Australian health ministry. It was intended to be a general centre of technical expertise in the ultrasonics field and from the outset research in cardiography, breast and obstetric studies was pursued through a network of close co-operative relationships with medical practitioners. The physicist in-charge, Kosoff also explored the possibilities in a general way, in terms of obtaining more information from the ultrasonogram. The outcome of this line was the gray scale technique of recording the output, which increased the diagnostic information content and subsequently acquired relevance for all applications of ultrasonic imaging. In USA by the end of 1950s ultrasound diagnosis had been introduced into several medical specialties. The NIH (National Institutes of Health) supported many academic research programmes from which commercial instruments emerged (Foote 1992 p 71). The therapeutic possibilities (especially surgical) of ultrasound were also being investigated in the USA.

We thus find that the usefulness of ultrasound was being investigated in numerous places and for a variety of medical applications, both diagnostic and therapeutic. These different approaches also implied different types of recordings, namely obtaining actual/true images or obtaining signals/wavelike recordings that needed to be interpreted. A striking feature is that individual researchers (some university based) and physician-researchers, with involvement of small manufacturers who supplied equipment to industry, were carrying out all this initial development work. There was also resistance from the obstetricians, not all of whom were convinced of the claims being made for the technique, as also from radiologists, till a consensus was reached.

Notwithstanding such resistance and despite the difficulties of the industrial manufacturers, ultrasound imaging did make its way gradually into hospitals. By the early 1960s commercial diagnostic ultrasound devices were available and were being manufactured largely by manufacturers of industrial flaw detectors, with slight modifications, and were used for neurological, ophthalmological and cardiological use. Further development and improvements on the instrument for gynaecology were carried out by Smiths Industries (that had taken over Kelvin Hughes). The order by the British Ministry of Health for five prototypes reduced the uncertainties associated with production. Nevertheless, due to the industrial rationalisation then taking place and uncertainties in development of electronics, the industry held back on commercial production of the ultrasound equipment for gynaecology. It was only in the early 1970s that it finally reached the market (Blume 1992). Established medical equipment manufacturers like Siemens that had withdrawn from diagnostic ultrasound in early 1950s, entered later when the flaw detection equipment found diagnostic applications; by 1967 it had developed ultrasound equipment mainly for abdominal and gynaecological purposes.
Within each specialty consensus gradually emerged over what exactly the clinical use of ultrasound was to be. In the case of neurology and ophthalmology there was long dispute over the relative roles of A-scan and B-scan instruments; the development of the CT brain scanner led to loss of neurological interest in ultrasound for some time. Over time the professional interests of gynaecology and obstetrics dominated research questions and the 'advantages' of ultrasound technology over x-ray (use of measurements and process as against anatomic details) started getting articulated. In many leading departments in the western countries ultrasound scanning started becoming common practice in prenatal care, with cephalometry becoming the major application. Meanwhile, the fetal heart detector was also developed based on Doppler ultrasound. Its use became widespread through the 1970s, till it became an integral part of prenatal care; and hence the commercial attractiveness of obstetrical ultrasound also increased. Because of the growing markets industrial firms went in for improvement of the current products, and these improvements were largely marginal and not for development of advanced systems. By early 1980s obstetric ultrasound scanning became a routine part of antenatal care in many parts of Europe, and in USA, without evidence of its usefulness and benefits, and adequate information regarding its safety in pregnancy. Even today there is a debate over the necessity of routine ultrasound scanning in low-risk pregnancies and its effectiveness, as well as questions and concerns about the safety of ultrasound. In the course of development of this technology research into its safety was negligible in comparison to the amount of work undertaken on developing the technique for clinical use. Ultrasound has been presumed to be safe, as it does not involve ionising radiations as in x-rays. However, research since the 1980s showing potentially harmful effects of ultrasound have led to debates and serious concerns about the routine use of ultrasound in pregnancies, and safety (discussed later in the chapter).

C. Development of thermal imaging

Infrared thermal imaging also arose as a consequence of redeployment into medicine of technology initially developed for military purposes. However, unlike the case of ultrasound, in this case information was not easily accessible, as in the Cold War period in the 1950s military technology was developed under conditions of extreme secrecy. In the 1950s expertise in advanced infrared technology was situated in military R&D establishments and with industrial defence contractors. It was sought out and deployed in medicine because of a specific need for accurate temperature measurement in case of breast cancer.

In 1955 a Canadian surgeon, Roy Lawson, discovered that breast tumours seemed to be associated with an increase in skin temperature of about two degrees over the affected part. He began investigating the clinical significance of this finding, both as a possible means of diagnosis
and as a means of following progress of therapy. In his view the thermometric criterion for
diagnosis of breast cancer was original and significant, because it was based on conceiving of
tumours in a novel way, different from that of radiology, which relied on morphological
characteristics. His search for good temperature measuring instrumentation led him to infrared
technology. Similarly, in 1959 Lloyd Williams, a surgeon in London also took up investigation
of breast tumours and arrived at similar conclusions. In collaboration with an engineer working
in industry a prototype was developed for heat scanning of the human breast. The results were
encouraging and it seemed that with improvements in scanning speed and detector sensitivity, a
device could be produced for precise measurement of skin temperature that would be useful in
clinical medicine and research. In 1962 Lloyd Williams started working towards producing a
medical thermograph. While Smiths Industries showed interest in the device, it realised the need
for more knowledge and expertise, which was then with the Ministry of Defence. Williams
managed through an influential colleague, to obtain access to this advanced classified knowledge.
Soon prototypes of the Pyroscan, the first medical thermograph, were built. Among the
physicians and the industries with defence expertise that had entered into the field of infrared
thermography, the need was felt to explore the potential of their new device in a variety of
clinical settings. The overall scale of clinical interest was also expanding to other places too,
such as in Japan and other parts of Europe. Since there was no use of external radiation,
questions of safety did not arise.

These results drew the attention of other specialists in the area; such as American radiologist,
Gershon Cohen. By the 1960s screening for breast cancer using x-rays (mammography) was
becoming an important element in radiological practice, especially in the US. According to
Blume, Cohen felt that this development of thermography could become a potential threat to an
important element of radiological practice; that it was essential to incorporate it into radiology.
Cohen too worked with a company, Barnes Engineering in this area at the same time (Blume see
p 131).

While initial results with thermography were promising in rheumatology, in other specialties,
such as gynaecology, it was not well received. In 1965 Cohen argued its utility for obstetrics and
gynaecology, especially for placental localisation, without the risk of exposure of the foetus to
radiation. However, the obstetricians were not impressed and it was felt that 'in its present state
thermography poses more problems than it answers' (Blume p 134). Thermography was
coming to be assessed/dominated by interests in breast cancer, and in effect, by radiologists.
From his study of the development, diffusion and accommodation of thermography into medical
practice, Blume concludes that 'radiologists did succeed in appropriating the technology, though
not in the obvious sense of unique control over its use' (Blume 1992 p 135). Rather, theirs became the dominant assessment and it was their assessment regarding its usefulness that shaped the future of this technique.

In this case we see that attempts to establish clinical utility preceded adoption and any significant commercial activity (unlike the case of other innovations, as discussed later). He goes on to say that so far as the radiologists were concerned the research agenda was clear - they never had any doubts that there could be any possible utility of the technique in breast cancer screening.

From routine thermographic examination through 1967 of nearly 3000 women who were also x-rayed in a radiological breast cancer research programme in a US hospital and analysis of data from 2696 patients examined, the radiologists concluded that 'it appeared that thermography could usefully be deployed in conjunction with mammography' (Blume 1992 p 137). In this case, rather than establishing its general diagnostic possibilities, they sought to establish its utility by comparing the accuracy of the technique with that of other available techniques, such as mammography. Blume points out that the debate over the value of thermography started to take place in a climate marked by frustration and even bitterness, with the protagonists fighting a battle against an emergent consensus within radiology that it had little value. A review of the status of breast cancer detection in 1977 suggested that in the early 1970s thermography seemed to have a clear though modest screening role, particularly given the safety problem with over-use of x-rays. It was hoped that specificity and sensitivity could be improved. Evaluations in the 1970s by a 27-center demonstration study focussed on mammography under the aegis of the American Cancer Society and the National Cancer Institute, and by the British National Health Service ruled out the technique as almost useless in screening. However there have been criticisms of the adequacy of the British study, considered to be a 'strategic publication of statistical studies based upon thermograms of such technical inferiority that a number of experienced thermologists refused to participate in their interpretation', and that there was no critical analysis or open review and that the results were published without the experimental data (Blume 1992 p 142).

We find that despite positive assessments from 'unfashionable specialities' like rheumatology regarding its usefulness, it is the negative assessment of radiologists that carried most weight with the industry and decided their response. At that time with the invention of mammography, breast imaging for cancer was becoming a commitment of health systems, and hence offered an attractive market for firms wanting to move into medical markets. Firms lost interest and most pulled out of thermography.
There have been continued attempts by non-radiologists to establish the value of the technique by various other strategies, such as by redefining the diagnostic criterion. Another one has been to present results to fellow surgeons and not to radiologists (by Dr. Isard), and to persuade the former to ask for a thermogram. However, breast thermography has been used in countries like France, Italy, Japan and the Soviet Union, where the approach to treatment of breast cancer was different. In France, for instance, where radiation therapy is preferred as against mastectomy in the US, thermography was used for monitoring decline in radiation-induced heat.

The history of thermography gives an idea of the range of factors that underlie the 'acceptance' or 'rejection' of a technology as useful or otherwise. Thermography was non-invasive, in relation to x-ray and ultrasound. Yet its development did not get the kind of attention and resources that it should have got. In this case interests had grown around use of x-ray technology, in form of the radiology profession and the x-ray manufacturing industry. Together they had the resources to decide about the usefulness of thermography for diagnosis, and play a role in its establishment within the medical specialties. This also shows that more than one way of examining the body, and getting information about it, was possible and, was being explored. Yet the direction of research and development of technology was set by established professional and business interests.

D. Development and diffusion of CT-scanners

The development of CT-scanning in the 1960s and 1970s can be considered to be a kind of trendsetter and illustrative of several features of the contemporary medical device industry. It is generally thought that CT-scanning represented a major clinical breakthrough. The CT-scanner is well known for its extremely rapid diffusion, which triggered off questions among policy circles about costs of technology. It is the first instance where a lot of planning and organisation went into the introduction and commercialisation of a medical technology. There was planned, organised interaction by the government between the manufacturer and radiologist in the development of the equipment, with the government permitting testing of the prototypes in its hospitals, as also committing funds for initial development and purchase of prototypes. Secondly, a strong commercial dynamic was created among the radiology profession during the development phase itself. Furthermore, the established big names in X-ray manufacturing then, (and currently the major manufacturers of CT-equipment) did not come into the picture in the initial phase of development; they did not want to license CT technology initially; and moved in only when the development was complete and there was a booming market for it. They simply acquired the CT operations of several competitors. It brings out the power of the big players in
the X-ray industry to capitalise on their substantial resources and their established relationship with the radiological profession. It was very expensive by any standards, and yet it was purchased without sufficient information regarding its applications, safety and effectiveness. Lastly, the development of CT-scanning shows a clear interdependence with the development of the computer and the computer industry at the end of the 1960s.

Developments in information processing technology, instrumentation and in radiology made possible the development of CT-scanning, which is based on computer-generated images of X-ray generated information. Godfrey Hounsfield, a radio mechanic in the war who subsequently trained as an electrical engineer, is credited with the invention of the CT scanner in 1971, while he worked at Electric and Musical Industries Ltd. (EMI) in England. Along with Cormack he was awarded the Nobel Prize for the invention in 1979. However, the idea of computed tomography, as well as the theoretical work predates the actual invention. In 1917 an Austrian mathematician, Johann Radon, had worked out the early mathematical basis to show that it was possible to reconstruct two- and three-dimensional objects from a set of their projections. Such theoretical work had applications in numerous fields other than the medical, such as in X-ray crystallography, radio astronomy and electron microscopy. However, actual application was possible only with the development of the computer, since the reconstruction required an enormously large number of calculations to be made from the projections.

Within radiology the limitations of conventional X-rays in localisation of pathologies within the body, of tissues obscured by the bony structure had already been recognised. In the 1920s and 1930s a number of radiologists in Europe had developed the technique of tomography, which entails moving the source of X-rays relative to the body in one direction and simultaneously moving the film (the detector) in a parallel plane in the other direction. In the early 1930s a German radiologist Gustav Grossman developed the first commercial tomographic instrument, which was used to obtain three-dimensional information. In 1961 W.H. Oldendorf, an American neurologist, who wrote about the inadequacies of existing techniques in revealing information about the brain, constructed a working model of a CT scanner for the brain and obtained a patent in 1963. However, nothing came of it - neither the radiologists nor the industry took up his model. Another finding was the work of a physicist A.M. Cormack on measurement of transmission profiles and then using these to calculate linear absorption coefficients. In 1963 he published findings that had implications for determining X-ray absorption coefficients.

EMI, an English firm, was a pioneer in making electric records and other home entertainment equipment, and had made huge profits from sales of the Beatles' records. Following the war the
firm decided to branch into civilian and defence related electronics. When Hounsfield joined EMI in the early 1950s he was assigned to develop a computer for business applications. It was during his work on problems of pattern recognition that he conceived the idea of computed tomographic scanning. The company did take up the idea and Hounsfield was set to work on the task of developing the computer and designing functional equipment. However, the firm refused support for further work. As a result of personal contacts with leading British radiologists and the Department of Health and Social Security (DHSS), England, a group of technologists and radiologists was formed to assess medical applications for the idea. Although not all the members really understood Hounsfield's idea, yet they were convinced that technical problems could be overcome (Berggren 1985). Subsequently DHSS decided to support the experiments. During negotiations with the ministry's technical staff on the purpose the equipment would serve, the firm's idea of one for mass screening of tumours was rejected by the DHSS, on grounds of the anticipated high cost of the equipment. The Department raised the need for a less invasive and risky procedure for the brain, it was felt that any improvement would be useful, and thus emerged the idea of an instrument for scanning the brain.

Impressed by the instrument that Hounsfield constructed then, in 1969 DHSS agreed to contribute to the construction of one or more machines and to arrange for clinical trials. A small London hospital was chosen for the trials; and only the hospital administrator and the collaborating neuro-radiologist, Ambrose, knew about the project. The 'imperative' for secrecy had arisen, as commercial stakes were gradually increasing and 'the curiosity of possible competitors must not be aroused' (Blume 1992 p 165). EMI had to consider once again the implications of going ahead - to maintain its lead it needed to begin constructing more machines even before the assessment of the prototype was complete. At this point DHSS once again stepped in with support - it offered to buy one prototype and committed funds for four more. The next question for EMI was - what if the prototypes were a success, should they go ahead with manufacture and marketing of the product, or licence it? At this stage none of the x-ray equipment companies contacted displayed any interest in buying licenses; they did not believe in the project (Berggren 1985). EMI decided to get into its production and sale. It was immediately clear that the marketing campaign would have to target the US - in view of the commercial nature of health care, the scale of the market and the funds available for equipment in that country. Finally in 1972 the new instrument was announced; a huge and enthusiastic demand arose for it after a demonstration with the prototype, at the annual radiological meeting in the US in 1972. In late 1973 Hounsfield, and then Ambrose, separately published the working principles of the scanner, its use and Ambrose's experiences with it, as also its possible place within radiology.
The installation of two systems in two world-famous hospitals in the US (the Mayo Clinic and the Massachusetts General Hospital) in 1973 resulted in orders for 75 more systems (Berggren 1985). Almost every major department of radiology expressed the need for a CT scanner in order to keep up to date, and many small departments followed, despite the high cost. Radiological journals exclusively devoted to CT scanning were started. According to Blume the enthusiasm of the radiologists and the rapid volume of sales generated two important (and quite opposing kind of) responses, one from the industry, and the other from the governments (Blume 2000 p 180).

The existence of a clear market and the profit potential were features too tempting for the industry to ignore. The potential threat posed by a development like the CT scanner to the existing manufacturers, to the giants of the x-ray industry in their core business by an outside firm forced them to respond. Their determined efforts to gain control of the technology and recapture the radiological market 'gave the development phase of CT scanning a commercial dynamic lacking from either of the other techniques (ultrasound and thermography) at this stage of their careers' (Blume 1992 p 173). They used their vast resources and clinical connections to increase the rate of innovation to far beyond what EMI or other smaller companies could afford. The development period was marked by intense competition and activity, attributable to not just replication of the EMI design, but also of continuous refinement, leading to a tremendous rate of technical change. CT-scanners soon became big business. Scanners were exhibited at radiological conferences. Manufacturers competed on several attributes of the equipment; all offering superior performance to existing scanners. In a commentary on the 'battle for the x-ray scanner market', the author says that several major manufacturers of radiological equipment, including EMI, began chasing the lucrative market in North America. He observes that all were lacking in one attribute essential for medical equipment. Namely - clinical evidence of their capabilities (Kehoe 1976). The situation was such that most of the manufacturers had placed at least one machine in a US hospital, and it was expected that within 12 months they would have some experience to call upon. We find that another aspect was the lack of attention to radiation dosage levels of the machines delivered to the patients. The acceptance of the new technology was so rapid that operating regulations for permissible x-ray levels had not been drawn up; existing ones for the control of use of conventional x-rays were being loosely applied to CT-scanners (discussed in a later section).

By the mid-1970s other companies, including the major X-ray equipment manufacturers entered the CT scanner market. This included Philips, Siemens, General Electric, Hitachi, and Pfizer. EMI had carried out the development work, thereby reducing the risk to them, and now the work was more to do with product refinement. Another big advantage they had, which other
manufacturers lacked was contact with the radiology profession and established marketing organisations in the x-ray sector. All these factors resulted in rapid growth in the number of scanners installed in different countries. The established manufacturers of x-ray equipment began to take over the market.

It was expensive, selling for $310,000 and then $360,000 (around 250,000 pounds, and running costs could be up to 50,000 pounds a year, along with costs of modifying/renovating the building). Despite the high cost, the rate of adoption and diffusion was extremely rapid in the first few years. Firms offered devices for sale before they were even in production. Subsequently the whole body scanner was available. GE entered the market later, initially by marketing the brain scanner of a small California-based company. It acquired the CT operations of several competitors, and its design dominated the market; it became the leading manufacturer by 1981. According to Foote, 'because of GE's reputation and size buyers trusted that it would remain in business and shied away from new, potentially unstable companies' (Foote 1992 p 105). Similarly Pfizer entered the market by marketing a whole-body scanner that was made by R.S. Ledley, a professor of physiology and radiology in Washington DC. The latter had been asked by a hospital to develop a CT scanner for the whole body that would also be cheaper than the EMI one. By the end of 1977 nearly 1000 body scanners and 800 brain scanners had been installed in North America, Europe and Japan (Berggren 1985). There was a major drive to sell scanners in Europe, Japan, Middle East and other countries. An important feature of the sales drive was the mounting of exhibitions of the machines at radiological conferences around the world. EMI went to the extent of loading their body scanner on to a bus to tour major hospitals in several European countries to demonstrate the capabilities of the machine.

The second response to the extremely rapid diffusion was that governments started expressing concern at the cost implications of this promising, but yet far from proven technology. By 1978 governments started imposing restrictions, in terms of needing permission to buy expensive equipment and a patient base of at least 2500 patients for each CT scanner to qualify for compensation from public insurance systems. The slowing down of the market for CT scanners is attributed to these restrictions (Berggren 1985).

The diffusion of the scanner in the UK took an interesting course. Of the eleven body scanners that were installed or on order by April 1977, only one was bought with health service funds, and eight were donated by philanthropists and charities, or were bought by using endowment funds. Simultaneously, new methods of raising money for technologies, which were 'considered essential', were being found. In one case a local newspaper was involved in a
campaign to obtain a scanner for the local hospital. According to Stocking and Morrison, while large expensive pieces of equipment had been donated to the NHS by philanthropists or through fund-raising campaigns, the speed and extent of diffusion of the CT scanner by this route was unusual. While the prime movers for obtaining them were consultant radiologists, the manufacturers also played an important part and took major efforts in ensuring that all radiologists were aware of the development. It also appeared that where interest had been expressed they provided advice on how funds might be raised. The two major problems that such donation to the NHS gave rise to were: firstly, the issue of running costs for the machine - only sometimes the donor agreed to pay for the maintenance contract. Secondly, the NHS had no control over the spread of technology. The majority of the first eleven scanners were in the south of England and in particular in the London area. This was a matter of concern at a time when the NHS was attempting to rectify regional disparities. It was felt that the machine should go to a hospital where a proper evaluation of its use could be conducted. However, the NHS could not exercise such control when there was diffusion by such philanthropic means (Stocking and Morrison 1978).

By 1982 a review of the diagnostic imaging industry felt that the 'major improvements in image quality (of CT) have already been made with the present technology, so that only small, incremental improvements will be made in the future, given the cost restrictions and dose limitations' (p 188).

5.1.2 Development and diffusion of extra-corporeal shock wave lithotripsy (ESWL)

The lithotripter generates high-energy ultrasonic waves that pass through the body and shatter kidney stones into small fragments that can pass out of the urinary tract. The development and diffusion of this technology in Germany has been described by Kirchberger (1988). Research on interaction of shock waves with animal tissue was of interest to the German Ministry of Defence, which commissioned the research to an air-space company Dornier in 1969. Given the interest in ultrasound at that time, universities in Germany were experimenting with the possible use of ultrasound for this purpose. The Ministry for Research and Technology accepted the proposal put forward by Dornier and in the period 1974-1982 supported the development of the lithotripter with funds then totalling up to 8.9 mn DM, and the equipment was developed in 1981. In addition to the therapeutic advantages the equipment offered over surgery, especially multiple surgery for removal of kidney stones, it was also said that it would reduce costs, mainly due to the shorter period of hospitalisation and hence absence from work.
According to Kirchberger this potential for reduced costs explained only partly, the interest of mandatory health insurance agencies in the extremely rapid and widespread distribution of this technology. However, rules did not allow insurance bodies to use their funds to invest in the equipment. (According to a 1972 law all capital expenditure for hospitals in Germany had to be made out of public funds. Furthermore, since 1981 decisions regarding acquisition and use of 'high-level medical technology' were made the responsibility of the concerned governments. Hospitals had to make decisions with regard to the regional requirements and criteria for efficient deployment). So the insurance agencies turned to the Board for Home Dialysis (Kuratorium fur Heimdialyse - KfH), a private non-profit organisation supported by urologists and nephrologists, for financial support. The KfH was an organisation founded in 1969 for the support of patients with kidney disorders. Since 1976 it had been responsible for the construction and organisation of kidney transplant centres in the FRG, and had acquired financial strength. However, the increasing provision of out-patient dialysis treatment by practising doctors was cutting into the activities of KfH, which was therefore looking for other interests. It provided funds for the construction of a lithotripsy centre at the University Hospital of Munich. Subsequently, in cooperation with the Health Insurance Associations, the KfH developed a programme for ESWL treatment throughout Germany, which envisaged a lithotripter for each region of 3 mn population, and estimated that this would for the time being cover the demand. It also declared that it would provide the funds, personnel capacities and infrastructure if necessary. Based on this programme the KfH acquired the option to purchase the first 12 machines from Dornier. In Kirchberger's view, 'although legally it was precarious to use private investment capital for a public service, this offer increased the pressure on the Government for action'. The argument that it (government) lacked the infrastructure, personnel, etc., would not hold in view of the offer of KfH that it would provide these. By end 1986 21 machines were installed in the FRG; in seven cases the KfH took over the expenditures completely or in part, and these costs were to be reimbursed by the insurance agencies.

The author discusses a number of factors that may have led to the rapid diffusion of this technology. As far as therapeutic advantages are concerned, the argument of reduced risk of complications in comparison to surgery did not justify the extensive distribution. To reduce the risk it would have been sufficient to provide few machines to be used/tested in complicated cases. In terms of reduced health care costs, there were limited savings. The argument that this technology may have been used as a test case to control/tackle the issue of distribution and use of high-level medical technology, by assuming that an extensive network of equipment would prevent further distribution, is also not very tenable. The main problem in his view in diffusion of technology lies elsewhere, such as lack of co-ordination between the in-patient and out-patient
sectors. Anyway, these arguments fail in light of the fact that a number of national and foreign companies had begun work on development of cheaper ESWL equipment. There was also the possibility of techniques that could be used in out-patient facilities and would not require hospitalisation. So a slower and selective diffusion would have been more appropriate. *Extensive distribution would only prevent the possibility of acquiring newer, less expensive technology.* Further the KfH almost held a monopoly over this specific type of technology, making negotiations over price considerably difficult. Because of its option to buy the first 12 apparatus, KfH was able to carve a place for itself in the supply system. Apparently, Dornier granted it a quantity discount, and those states that were interested in purchasing the equipment were quoted a price that was 30 per cent higher than that offered to KfH. The company agreed to lower the price only after KfH was drawn into the negotiations.

From his study of the whole process of development and diffusion of this technology Kirchberger argues that *considerations other than those of therapeutic benefits, and control over costs and distribution, may have influenced the decision to effect its rapid distribution.* He contends that interested doctors, the Bavarian Health Insurance Associations and the KfH were the main promoters of the diffusion of the lithotripter. Because of its activities in the area of kidney transplantation, the KfH was in close contact with the people who were working on its development. Some of them were also members of the KfH. In course of the negotiations with the health insurance bodies, a member of the Working Group of the Health Insurance Association became a member of the KfH too. Hence there were intimate associations between those involved in the development of the technology, the KfH and the Health Insurance body. *He concludes that the diffusion of the lithotripter indicates that the market is likely to take precedence over planning needs, and also illustrates the argument that medical technology justifies its application through its very existence.*

**5.1.3 Automated Clinical Chemistry Analyzers**

The changing scale of hospital work and the increasing demand for an increasing number of biochemical tests is considered to be behind development of the autoanalyzer. Biochemical analysis of body fluids for diagnostic purposes, with instruments developed primarily for analytical chemistry, had become standard hospital practice in the initial decades of twentieth century. In the 1940s, faced with an increasing workload and inadequate staff, a hospital biochemist in the US, Dr. Skeggs, set about trying to develop an instrument that could analyse blood on a continuous flow basis. *However, the companies he approached were not ready to manufacture his prototype - the industry was not ready to manufacture expensive instrumentation*
in face of uncertainty regarding readiness of hospitals to purchase them. The situation changed dramatically in a few years - by the 1950s the number of tests and their costs had started rising. The market now seemed attractive for entrepreneurial activity. In 1954 a small company, Technicon, purchased the technology from Skeggs and went on to develop the automated clinical chemistry analyser (ACCA) commercially. Soon, thirty automatic and semi-automatic systems were developed world-wide. Major corporations like Dow Corning and DuPont entered the area; the industry grew and became intensely competitive (Blume 2000 p 177).

ACCAs are said to be cost-effective because they reduce the labour content per test from the fifty per cent (rule of thumb for manual methods) to about five per cent, while reducing the incidence of test errors. They have been widely adopted, despite high prices. Manufacturers of ACCAs usually also specify procedures and sell reagents that can be used with their equipment. Those who wish to perform a test by a method other than that specified/offered by the manufacturer must develop an analyzer compatible method on their own; or find some other method using other equipment or instrument. Test methods for use on one type of analyzers usually cannot be transferred to another type without adaptation. Sometimes they cannot be transferred at all because of differences in equipment operating characteristics. For instance: the Du Pont analyzer is made up of two major components – the equipment itself and single use, disposable, factory-sealed test packs supplied by Du Pont itself. Whereas, Technicon supplied a series of functional modules, which maybe used as system building blocks. While the Du Pont equipment cannot be used for non-standard work, users found the Technicon design suitable for development of non-standard clinical work. Both these companies manufacture ACCAs as well as reagents appropriate for use in their equipment. Over the years the commercial importance of reagent sales to both firms rose relative to that of analyzer equipment sales, because of: (i) the market for such equipment had begun to approach saturation, and (ii) more equipment in the field meant greater reagent sales. While Du Pont had 100 per cent of reagent sales to users of its equipment, Technicon lost 30 per cent of this market to competing reagent manufacturers. This was monetarily significant (considering that Technicon reagent sales in 1977 was $50 million). The reason this was possible was because Du Pont reagents were sold in an elaborate patented package. A prospective competitor would have had to legally contest these claims, or work around these claims, and invest in expensive tooling equipment for packaging, if they wished to produce substitute reagents compatible with the Du Pont analyzer. Technicon reagents were supplied to the user in simple bulk containers, easily obtainable by anyone (Hippel and Finkelstein 1979).
5.1.4 Development and Diffusion of Pacemakers

While the concept of heart stimulation by external means dates back to the 1800s, the development of an implantable device such as the modern-day pacemaker depended on several technological inventions, including the advent of sophisticated batteries and biocompatible materials such as silicone rubber and epoxy resins. World War II had stimulated the development of improved sealed alkaline dry-cell batteries that made it possible to encapsulate the pacemaker in compact resin. The need for convenient pacemakers became evident after the first open heart surgery in the 1950s. A permanently implantable pacemaker developed by a university-based electrical engineer Greatbatch in the 1950s did not evince much interest among cardiologists. However, with the encouragement of a surgeon his first model cardiac pacemaker was implanted in a dog in 1958. Greatbatch used his own finances to develop the device and over the next two years he worked alone and made fifty pacemakers, of which ten were implanted in human beings. Around that period, at the request of a pioneer open-heart surgeon another electrical engineer Bakken, who owned a small company Medtronic that supplied, serviced/repai red, modified and designed equipment on request from hospitals, had developed a wearable external pacemaker. This pacemaker was not free of problems. By 1961 Greatbatch and Bakken had teamed up and the company Medtronic secured exclusive rights to produce and market their implantable pacemaker (Foote 1992 p 107). By early 1970s pacemakers had become a useful tool for cardiac patients, although problems did arise with these early devices. Considerable incremental innovation and developments took place, with improvements in materials technology, in design and battery technology, the latter resulting in part from NASA supported technology on nickel-cadmium batteries that could function for long periods in orbiting spacecrafts. Subsequent lithium batteries had even greater longevity. Continued improvements have resulted in the recent lighter, rate responsive, programmable pacemakers. The pacemaker industry has been highly competitive, and there are numerous cases where smaller entrepreneurial companies were acquired by big manufacturers like Siemens and Telectronics once the market started growing (Foote 1992 p 107).

From her study of the influence of government policies in the USA on distribution of medical devices, Foote has this to say about the pacemaker industry: ‘While innovative and competitive, this industry is hardly a model of corporate responsibility. The structure of the federally subsidised market fostered some of the high-pressure sales tactics that led to significant fraud and abuse……..Companies began rapacious competition on nonprice attributes’ (Foote 1992 p 110). There were roughly 500-550 salespeople for only 1500 physicians who implanted pacemakers. In 1982 it was reported that companies were offering physicians free vacations, stock options at reduced prices, cash kickbacks and consulting jobs with liberal compensation to persuade them
to use the products. Companies instituted sales incentive programs to encourage unnecessary implantations, as well as unnecessary explantations and re-insertions of new products. Several companies were indicted in the subsequent enquiries that were instituted. In 1988 Cordis Corporation, which had introduced the programmable pacemaker, pleaded guilty to multiple charges that it sold pacemakers it knew were faulty. Foote concludes that 'the availability of reimbursement dollars promoted an atmosphere of non-price competition that encouraged less scrupulous companies. ........' (Foote 1992 p 112).

5.1.5 ISSUES IN DEVELOPMENT AND ADOPTION OF MEDICAL TECHNOLOGY

The above case histories of some widely used medical innovations, all of which were being explored and developed at about the same time, provide several insights about the development of medical technologies. Some of the trends that emerge from this are as follows:

1. In modern medicine, by the early 20th century, use of technologies for diagnosis and treatment was considered to be an integral aspect of the practice of 'scientific medicine'. Soon the use of technology (laboratory procedures, mechanical and electronic instruments) increased and, by the 1970s there was the notion of 'technological imperative' in medicine. (See chapter 1 Section II). In the early years innovations had emerged out of the work of researchers who pursued certain areas for investigation due to a general interest in the science aspects, and hence depended upon chance, and chance encounters between individual researchers and entrepreneurs/manufacturers. The process of innovation and development of medical technologies became different in post WW II period. In the period following the two World Wars there was a search for new uses for skills and knowledge acquired during the war; search for clinical / medical applications of technologies, rather than clinical/public health needs and problems became an impetus for development of technologies. At the larger level changes in the larger political and socio-economic sphere, as well as the cultural impact of X-ray technology, were such as to bring about a shift from notion of hygiene and social improvement to 'miracle technologies' as the basis of health (see Chapter 2). Hence there was an overall push in the direction of and a favourable climate for development of technologies, towards 'applying every new discovery in science to health', and so on. There was a search for medical applications of technologies that had been used in the war. Innovations and developments in the immediate post-War period can be looked upon as systematic attempts to redeploy/apply to medicine skills, technologies and knowledge developed during the war. Several groups, in several countries now pursued the possibility of applying several technologies for clinical/medical purposes. The choice of what equipment should be produced or promoted appears to have been largely influenced by the interests and
contacts between physicians, physicists, engineers, and technologists, with industry and with
government. Engineers and physicists, largely university-based as well as from private industry,
provided design skills and ideas to medical practitioners, who provided clinical inputs, and more
importantly had access to patients. Thus, there began the association of medicine and the medical
profession with manufacturing of technology itself.

2. The development of technology (science and technology - 'S&T') now became more
organized. An important development was that now governments started taking interest in
scientific research and development, and started influencing such activities through funding and
other supportive mechanisms. A 'strong' S&T base was considered as an important input for
economic growth and development of a country. Innovations in technology, including medical
technology, became important for the government and for industry. Strengthening and expansion
of the medical technology industry was made a priority in innovation policy in a number of
countries (Blume 1985). For instance: the Japanese Ministry of Trade and Industry introduced a
health-related programme in which technological innovation was a major element; substantial
industrial R&D was underwritten by the government. In France in 1982 special support was
announced for biomedical technology industry. In certain instances, interaction between the
industrial manufacturer and the medical profession was mediated directly by the state. Further,
regulations and policies as well as the mechanisms by which governments provided healthcare
had their impact upon development of technologies and the medical equipment industry. We
also find that in most cases much research developed in defence institutions, and those used
during the II World War, were utilised. In general, for a long time much of the R&D was being
performed in non-industry settings, in hospitals and universities. Many individuals and small
entrepreneurial companies played a significant role in developing much of today’s creative and
glamorous technologies, with or without co-operation from clinicians in hospital settings. The
manufacturing industry, especially big established ones entered the scenario only when they saw
the 'market potential'. By and large, they undertook product refinement, and introduced newer
models, rendering older ones 'obsolete'.

At a conference of several European countries on expensive health technologies, several
country reports observed that government regulatory policies with respect to application and
diffusion were influenced by the interest of national industries (Groot 1988). In Netherlands the
Ministry of Economic Affairs was involved in several projects to encourage production and
marketing of medical devices. In France there was a clear association between government
policies and national industries aimed at bringing equipment into the market. The diffusion of
new technologies in Germany was possibly explained by the existence of a very important
national medical equipment industry. A good example was that of diffusion of lithotripters whose development was aided by government subsidies. A report of a Working Party on Expensive Medical Techniques in UK is more explicit (Council for Science and Society 1982).

According to this report expensive medical techniques 'do not emerge out of the blue and then oblige the National Health Service (NHS) to devote funds to them or reject them. On the contrary encouragement given to technologists and manufacturers by individuals and groups in the NHS influenced what new techniques were developed. NHS policies created more or less favourable conditions for a manufacturer to develop and produce new equipment. The concerned government agencies may give some assistance to produce equipment to meet a known need, especially when there is good prospect of export sales. The manufacturer then promotes it with the interested clinicians or even with charities. The government may provide financial support for manufacture in a number of ways, as also support linking of individual inventors with likely manufacturers. Most new or improved equipment came from manufacturers already in close contact, through various government agencies, with hospitals/universities, and specialist professional associations'.

3. The development and diffusion of the CT scanner sheds light on several considerations guiding the process of medical innovations. While planning and organisation in development of technologies are needed, the problem is with the objectives in this case – they were driven clearly by the industry's questions and concerns - how to support development of the technology, how to manufacture it? How to market it? And so on. Secondly, after the initial work at EMI, government support became critical for the development and testing of prototypes, and further development. We see that the government in UK supported the initial R&D of prototypes, in case of both CT-scanners and ultrasonography. The industry did not take any 'risks', so to say. Thirdly, it raises serious questions about the government being party to the secrecy regarding trials of prototypes of CT-scanners at a London hospital.

Together, these observations on the development of innovations raise questions about the contention of big industry that 'advanced technology'/ high-tech/sophisticated technology needs a lot of R & D input, and therefore will be expensive².

² In the late 19th-early 20th century there were debates (in USA) over the ethics of patenting of products meant for medical care. Universities then resisted patenting innovations for several reasons – such as free flow of scientific knowledge, and how to allocate the profits of the final result because of the interconnectedness of basic scientific research. Often physician-inventors found that commercial organizations exploited remedies based on their work, which went against the traditional professional ethic of profiting from patients (in Foote 1992 p30).
4. There existed a variety of ideas and resources regarding how to get information about the body (investigative mechanisms for process, direct observation of morphology, and measurement of body parameters such as temperature). Of these only some prevailed, and got established into medical practice - x-ray and radiology dominated, while others such as thermography 'failed'. For instance, mammography was promoted over ultrasound and thermal imaging for breast cancer detection. Similarly, despite the possibilities of ultrasound for neurological purposes, it was not taken up. Rather in that period CT-scanning got priority. Several questions arise: How much are these 'failures' attributable to technical limitations? Was enough research conducted before they were shown to be technically not feasible or inappropriate for clinical use? These processes are also entwined with the process of commercialisation and of what the industry wanted to manufacture. What about the role of such professional and commercial interests in the choice of areas to be pursued, in their acceptance as viable or plausible areas for research and development, and in their ultimate 'failure' and 'success' of medical innovations?

It emerges that not just the laws of nature and the limited information of the innovators shape the outcome. The 'success' of a technology, or what will ultimately prevail, appears to depend on numerous factors - such as - the ease with which it can be accommodated in the existing structures, or on the ability of its proponents to mobilise the resources needed for its development or for the restructuring. If they fail in this, the new technology will either be totally blocked or will be marginalised. If the proponents of a new medical technology fail to secure its integration into the appropriate structures of professional practice and industrial production, then it will 'fail'. In case of the 'success' of CT-scanning, it had the backing of an established professional specialty, combined with the powers of the established and resource-rich x-ray manufacturing industry. They give an idea of the conflict among proponents of existing approaches to disease, and the dominance of one over ways of thinking about a disease/abnormalities, and hence of related methodological means of detecting the same. In an article comparing the development and dissemination of CT and ultrasonography, the author raises and discusses this question. Why did a technique such as CT, which was a combination of existing techniques (namely radiography, electronics and computing) have such an enormous impact in such a short space of time (Berggren 1985)? As discussed later on, there was not much information then on efficacy and effectiveness of CT scanning to bring about such rapid adoption. In comparison ultrasonography was a genuinely new technology based on the development of a number of technological innovations, such as those for recording reflected sound. Other important features included the fact that ultrasonographic examinations were more patient-friendly than CT scanning and the former emitted no radiation (although safety of ultrasonic waves had not been established). Moreover, ultrasonographic scanning cost only 5-10 per cent of CT scanning, both
in terms of price and operating costs. It could be readily procured by small hospitals. The author draws attention to several important processes to explain this phenomenon. Firstly: CT scanning was developed by an established company with adequate resources and attracted early support from public agencies. It became very popular after immediate introduction of the prototype and was simultaneously developed and promoted rapidly by the x-ray manufacturers over the next 5-6 years. Ultrasonography (and thermography) was developed in relative obscurity, and for a long time independent researchers played a decisive role, and new companies were then founded to manufacture it. Secondly: CT scanning, being based on x-ray technology, found immediate acceptance in radiology, which by then was well established and occupied a central place in diagnosis. The x-ray industry also had established manufacturing and marketing capabilities, including firm linkages with the radiology profession. Together and independently, the radiology profession and the x-ray industry had well-established channels for disseminating information on developments in CT scanning at all levels, from the local to the international. Thirdly: ultrasonography entails that the examination be carried out and a diagnosis be made at the same time. It requires a certain measure of knowledge and dexterity by the examiner to come up with useful images. This meant that radiologists had to learn to interpret ultrasonographs. They had to acquire new skills and make changes in the existing system. Berggren refers to the backing and resources for CT from an established `socio-technical system of radiology’. In a system as well developed as this and encompassing many common values, the emphasis in technology development and research is on established fields. Fields outside to it tend to get inadequate attention and resources. She concludes that modern technologies are part of an organizational structure that `selects’ (and then promotes) interesting technologies. We mentioned earlier that Blume also considers the role of the inter-organizational field of radiology and x-ray industry crucial to innovations. Subsequently the x-ray manufacturing industry got into manufacture of ultrasonography equipment, and this modality has also now become part of the diagnostic imaging `armamentarium’.

5. What this indicates is also that to understand how and why we now have certain kinds of technologies, we need to look at the history of all innovations/ideas that existed, but `failed’ to become part of modern medicine, or were not as well-accepted as some others were, or were not adequately worked upon or developed.

6. The conflict regarding clinical utility of ultrasound, thermography and mammography in breast cancer reveals existence of double standards in the medical profession over evaluating usefulness of innovations. As elaborated later, several issues regarding mammography were unresolved especially that of safety. Yet, it was advocated and promoted over thermography. Yet another
double standard is that regarding the concept of 'invasive' and 'non-invasive technologies/techniques'. On one hand, sections of the medical profession are always making a case for innovations that are non-invasive or minimally invasive. Much of the development of technology within medicine has been aimed at outlining structures inside the body without having to cut the skin, and therefore without pain (non-invasive or minimally invasive technologies). X-rays were the first of these, followed by the use of CT-scanning, and ultrasound, which was promoted and used in situations where x-rays were likely to be harmful, especially in pregnant women. While promoting CT-scanners it was said that brain scanning had a distinct advantage over the then available pneumoencephalography. However, the fact that these radiations are potentially harmful to the body has been completely negated, and these technologies continue to be perceived as 'non-invasive'. Not only have their safety and safe use not been given attention, their usefulness in relation to their tremendous cost, has still not been sufficiently established. Similarly, the potential of alternative techniques like thermography for breast cancer detection, which involve measurement/observation of physiological parameters as against mammography was not pursued. Instead we have development and promotion of imaging technologies based on subjecting the human body to x-rays, ultrasound and strong magnetic fields, simply on the presumption that no harmful effects have been observed in their use. This is an issue that has significant implications for the concept of safe technologies.

7. With regard to the selection of 'interesting technologies' referred to in 4 above, the 'culture of engineers' needs to be considered, in which the most automated is presumed to be the most 'advanced', the 'best', and in which there is a fascination with computers and the most

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3 A technology can be safe to begin with, or it may be unsafe, but built in a way where it has to be used cautiously to avoid harm. Dyson's description of a project to design and build nuclear reactors for civilian use illuminates this concept of 'engineered safety' and 'inherent safety'. In mid 1950s a group of scientists in USA set upon this project The group comprised of physicists, chemists and engineers, all of whom had been, in some way or other, involved with nuclear energy, including the physicist Freeman Dyson. It became very clear to this group early on that the problem of safety would be decisive for the long-range future of civilian reactors. If reactors were unsafe, nobody in the long run would want to use them. This became the impetus for the notion of 'engineered safety' vs 'inherent safety' of a technology. The aim of the group was to design a reactor so safe that it could be given to a bunch of high school children to play with, without any fear that they would get hurt. At that time the design of nuclear reactors was such that a catastrophic accident was theoretically possible, but was prevented by the way the control system was designed. All large reactors were built with automatic control systems, which made it impossible to pull the rods out suddenly, the occurrence of which leads to a major accident. These reactors possess what the group called 'engineered safety'. For the group this engineered safety was not enough. The group wanted to design a reactor with 'inherent safety' – meaning that its safety was guaranteed by the laws of nature and not merely by the details of its engineering. The group worked on the physics of the safe reactor and the chemistry of its fuel rods, and succeeded in building a safe, working reactor in 1959, which was inaugurated by none other than Niels Bohr. As Dyson describes the moment, 'After the ceremony we went and saw it (the little reactor) sitting quietly at the bottom of its pool of cooling water... It was hard to believe. How could one believe that nature would pay attention to all the theoretical arguments and calculations that we had fought over in the schoolhouse three years earlier? But here was the proof. Warm neutrons really worked.' (Dyson 1979, Disturbing the Universe, p 102).
automated techniques. In this culture human factors (such as in measurement) are construed as sources of error that need to be eliminated. This is a value strongly held by the dominant sections of the professional class of engineers, scientists, doctors, managers, and technocrats in general. To what extent such factors too contributed to the immense 'success' and glamour of CT-scanning, MRI, and other imaging technologies, in general, rather than just their usefulness in diagnosis and management of the disease needs to be considered. The trend in diagnostic equipment is increasingly in favour of imaging systems and scanners that hold information in a computer and come at a tremendous cost (and are being manufactured by a few multinationals and very being strongly promoted and marketed, as we shall see in Section II of this chapter).

8. We also find that different agencies with different interests/motivations (not always commercial) have stepped in and aided and promoted adoption of technologies, in the name of charity and public interest. It is not just the activities of the medical profession, although the endorsement of doctors for a technology is necessary. In absence of resources/funds, or where there are controls/regulations, doctors/health institutions are not easily able to acquire a technology. In such cases other bodies have stepped in - as in the case of charities in UK and other NGOs in case of promotion of the ESWL in Germany.

9. Redundancy and obsoleteness: In the name of product differentiation to boost sales, manufacturers introduce minute technical differences in their products, and also introduce successive generations of products over some time, rendering the previous model 'obsolete'. Some design their machines (say auto-analyzers) in such a manner that the accessories, chemicals, software, etc., have to be obtained only from that company. This illustrates how equipment manufacturers build in differences in functionally similar instruments (differences in design and operating characteristics) to ensure markets and monopoly.

10. It is generally assumed that medical innovations are widely adopted, or become 'standard practice', only after they have been thoroughly tested for their efficacy, effectiveness and safety, based on objective scientific criteria. It would seem self-evident that expensive equipment would be evaluated and tested in detail before huge financial outlays are made on them. That an investment of the magnitude required for CT and MRI equipment would be based on evidence of considerable potential marginal gain. However, we find that there is inadequate evaluation before introduction of a technology: Indications for use of a technology are not sufficiently established before their adoption; the studies made on the effectiveness of technologies such as the imaging technologies, and their safety, had been quite small in number and were extremely uncritical (Creditor and Garrett 1977). Formal evaluation and the usefulness of such high-cost
equipment remain to be established, even though a lot of resources and institutions are committed to them. Despite this there is widespread adoption and many of the users of such equipment are outside teaching hospitals and established clinical research centres, and many are private hospitals and diagnostic centres.

In our view these are important aspects of medical technology and should be given adequate attention in the evaluation and assessment of medical technologies. We therefore discuss this in more detail. The next section gives an account of the debates and unresolved issues regarding the efficacy, effectiveness and safety of the imaging technologies described above.

5.1.6 Efficacy, Effectiveness and Safety Considerations in Development and Diffusion of Medical Technology

A. X-ray technology
Use of mammography as a tool for population screening
Mammography is now widely used for several purposes. Among these are as part of the investigation of breast lesions of unknown nature; for the follow-up of women who have already had one breast cancer; and for periodic screening of the general population. A review of experimental and clinical data on use of mammography as a tool for the screening of asymptomatic women not known to be at elevated risk of having breast cancer was done. The author has analysed the results of a three-way screen (comprising mammography, medical history and clinical examination) with history and examination alone. It came up with several significant conclusions (Bailar 1976). Till then there was no data on long-term effects of mammography; no satisfactory investigations of associated radiation hazards had been published. The possible benefits of mammography were receiving more attention in clinical literature than its defects. The main conclusion was that the overall benefits of mammography in screening of the general populations had not been determined, and that its hazards may be greater than are commonly

4 Clinical efficacy is the benefit expected when a technology is applied to medical practice under the best possible conditions, whereas effectiveness is the benefit when a technology is used in usual medical practice.

5 The review raises and discusses several epidemiological issues pertaining to the benefits of screening programs of the general population. Such as: lead-time bias, length bias, the definition and measurement of the real impact of a screening program – should every lesion discovered by screening be counted as a success of the program, since not every discovery will provide significant benefits to the patient? There are inherent characteristics of the disease (such as slow tumour growth rate) that increase the likelihood of it being detected at screening. In such cases detection and cure cannot be simply taken as benefits of screening resulting from early detection. According to the author there is need to distinguish between the benefits of mammography, and those of physical examination, medical history or other aids. While screening can reduce mortality, it is unclear how much mammography contributes when it is added to standard modalities.
understood. Hence promotion of mammography as a general public health measure was premature.

The second important issue discussed is that of hazards of mammography. There was abundant experimental and clinical evidence that ionizing radiation can cause breast cancer. However, it was not possible to simply extrapolate the available data to radiation doses whose effects had not been measured, or were not directly measurable. There were uncertainties regarding cumulative effects of low radiation doses and existence of threshold levels, which remain unresolved to date. A practical problem of related interest was that in radiation facilities, often radiation doses in diagnostic studies significantly exceeded nominal doses because of poor calibration of machines, departures from recommended methods, or other reasons. Despite such knowledge, effects of radiation used in mammography had not been investigated adequately.

Thirdly, the optimum interval between screens was not known, as also which population subgroups should be screened. More research was needed to ascertain benefits of screening with respect to demographic aspects of women screened, especially age. Young women were at greatest risk from irradiation (because of their longer future lifetime in which to develop induced cancers) and least likely to benefit from the screen (because of lower incidence among them, and certain technical problem with taking good films of young patients). Yet a 35-year age limit was being used, whereas there were recommendations for 50 years. In this author's view the minimum age for screening should have been at least 60-65 years.

The author 'regretfully conclude(s) that there seems to be a possibility that the routine use of mammography in screening asymptomatic women may eventually take almost as many lives as it saves'. The three-way screen for early detection of breast cancer can reduce mortality, but screening by medical history and physical examination alone will probably provide much or most of the same benefit without risk from irradiation, at least in women under some fairly high age limit.

This shows that critical issues pertaining to epidemiology, pathology, and safety remained unresolved at the time that mammography was being advocated and promoted as a population screening measure. The operational modalities and benefits had not been clearly established, and the long-term hazards had not been given enough attention. The subject of radiation dose from mammography remained a topic of interest even after a decade.
Breast cancer screening continued to be an intensely debated issue and consensus had not been reached even by the turn of the century. A review of Breast Cancer Screening in 1999 made the following observations:
- that screening itself may expose breast tissue to unnecessary radiation;
- increased breast cancer observed in women undergoing chest fluoroscopy, surviving the atomic bomb, or receiving radiation therapy;
- risk of inducing breast cancer with radiation appear to be higher in young women and with a genetic pre-disposition.
- There was little data examining the theoretical risk of radiation exposure from mammography among women with a familial or genetic history of cancer.

(Overmoyer 1999)

Effectiveness and safety of CT-scanning
As described earlier on, CT-scanners began with EMI's brain scanner that was launched in 1973. They soon became big business. As mentioned earlier, while there was widespread diffusion, all equipment were lacking in one attribute essential for medical equipment. Namely - clinical evidence of their capabilities (Kehoe 1976). The situation was such that most of the manufacturers had placed at least one machine in a US hospital, and it was expected that within 12 months they would have some experience to call upon.

According to Banta, 'Despite more than five years of experience with CT scanning its usefulness and ultimate place in medical care are largely unknown. The development and diffusion of CT scanners took place without formal and detailed proof of their efficacy. The evidence existing today did not come from well-designed, prospective clinical trials, but from analyses of clinical experience. However, this evidence is restricted almost entirely to assessing diagnostic accuracy and usefulness, and gives little indication of the effects of CT scanning on therapy planning or on patient outcome' (Banta 1980). In an attempt to relate the early diffusion of an expensive innovation like the CT scanner to published evidence of efficacy, Creditor and Garrett raised questions regarding the information base upon which decisions to buy CT scanners (one laden with enormous financial implications) were being made. For instance, they found that there were only 13 clinical papers on whole body scanning in the period when almost 100 units were ordered (Creditor and Garrett 1977). Was there sufficient clinical evidence at that stage to justify the rapid purchase of the machines, at a huge cost of $500,000 each?

Another aspect was the lack of attention to radiation dosage levels of the machines delivered to the patients. The acceptance of the new technology was so rapid that operating regulations for
permissible x-ray levels had not been drawn up; existing ones for the control of use of conventional x-rays were being loosely applied to CT-scanners. According to a doctor in one of the hospitals with an EMI machine, the design of the scanners was such that the dosage given by most machines could vary, even for a single scan. Manufacturers were not able to give firm figures on dosage levels delivered by the machine. The figures that they quoted were often from tests performed on "phantoms" performed in their own laboratories. But doctors wanted evidence from machines operating in hospitals. He said that with some machines it was possible to administer very high doses – upto 50 rads – that normally would be unacceptable to the clinician. This could cause dangers when non-expert medical staff is operating a scanner, which happens when controls are lacking. This was even more a matter of concern, given that in general, the higher the dosage level, the clearer are the pictures obtained. Hence non-medical staff could use high doses to obtain pictures that give more information. Whereas, the aim of doctors was always to obtain maximum information with lowest possible dosage level (Kehoe 1976).

The response of the manufacturers is noteworthy. Two of them (GE and Ohio Nuclear) were reported to have applied for variance from the existing regulations. On the other hand, EMI claimed that its latest machines complied with the rules on the dose of x-ray administered to the patient. However, a large number of units in the field needed to be fitted with a new collimator system (for collimation of the beam) to improve the efficiency of the machines. There were reports (which according to the author may have been misleading) of high dosage level administered by the scanner6. It was expected then that regulation of CT-scanner design to ensure higher safety might slow down their spread initially, but as soon as strong clinical evidence for the advantages became available, then these regulations would be loosened.

CT is an imaging modality that is known to be associated with a relatively high exposure of the patient to ionising x-irradiation (Rehani 2000). The CT -scanning technology has 'advanced' in the 1990s and now there are multi-slice scanning machines (MS-CT). Till 2000 none of the CT manufacturers paid much attention to reducing radiation dosage levels associated with CT equipment. There still are many scanners in clinical use that are not equipped with a provision for dose assessment. The tremendous increase in CT usage has only now led to concerns about the long term consequences of such exposures. Only now dosage reducing programmes have been introduced. In the USA it was seen that among radiologists there was lack of attention to paediatric CT protocols and how to adjust the technical parameters to minimize radiation exposure (Donnelly 2005). This was taking place despite the fact that using non-adjusted adult
protocols on children carried the risk of exposing them to levels that can cause cancer. Another study showed large variations in radiation dose between the same models of multi-slice CT scanner at different hospitals (Koller et al. 2003). A European field survey in 8 countries, of clinical application of CT, with a focus on evaluation of protocols and assessment of patient dose, found that there was little information available on the technical and clinical parameters that are used in routine clinical practice and on associated exposure. This was applicable to scans of adults and even more for paediatric scanning. This survey revealed large differences in CT protocols that were being used in the hospitals surveyed (www.msct.info). In Europe only recently professional groups, governments and manufacturers have initiated measures for radiation protection, for optimization of CT protocols, and have started looking at clinical patient dosimetry. Even now minimum radiation dose necessary to provide adequate diagnostic information has not been established. Many studies indicate that there were opportunities for dose reduction in most of the applications without affecting the diagnostic performance, through collaboration between medical physicists, radiologists and radiographers (Imhof et al. 2003). Physicians and radiologists are now talking of the importance of education to increase awareness of the importance of radiation dose associated with paediatric CT, and of minimizing the dose by reducing or eliminating non-indicated CT scans.

Given the cancer risk associated with CT dosages, medical researchers are not only calling for reducing dosage associated with CT; they are also saying that it is clearly desirable to also reduce CT usage as long as patient care is not compromised (Hall and Brenner 2008). There is a significant proportion of potential situations where CT is not medically justifiable; or where equally effective alternatives exist. One such situation is the promotion of CT for mass screening of asymptomatic individuals, which is being driven partly by increased availability and convenience of CT machines. CT screening is being advocated for lung cancer, cardiac disease, and whole body screening. However, there is no consensus yet about their efficacy, whereas there is significant x-ray exposure involved. There are indications that radiation risk to lung maybe significant. As yet there are no large-scale epidemiological studies reported of the cancer risks associated with CT, one is just beginning. However, given that the dose is associated with significant risk, and given the increased usage, there could be a potential public health issue in the near future.

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6 During a discussion with this researcher (1999) about the medical equipment industry, a cryptic comment was made by an executive of Philips Medical Systems, India about never putting his child through a CT scanner.

7 Carcinogenesis above the baseline cancer rates is a risk associated with doses lower than those previously believed, and such doses can be achieved in children when adult protocols for CT scanning are used. Also tissues of children are upto 10 times more radiosensitive than those of adults.
Given that X-rays have been in use for nearly a century now, and the hazards were well-known, such neglect of safety implies that some issues get set aside as a technique becomes 'routine practice', and associated economic interests develop.

B. Routinization and Safety of Ultrasound

In the 1970s, when ultrasound imaging was being widely adopted in gynaecology and cardiology, the Committee on Bioeffects of the American Institute of Ultrasound in Medicine was given the task of evaluating the bio-effects of ultrasonic energy, especially in the context of defining the conditions for safe medical practice. This Committee made several observations on the subject (Committee Report 1976). Firstly, that there was only scanty information concerning the effects of low intensities of ultrasonic energy with long exposure times, and also repeated short pulses, features which would be most relevant for the diagnostic use of ultrasound. Secondly, statements regarding absence of demonstrated significant biological effects in mammalian tissues at certain low intensities and for certain exposure times were based on data applicable to mammals other than human beings, and it was unclear how this data related to humans. Yet another caveat was that the data available then on intensity levels at which bioeffects occurred were not minimum levels; further research was urgently needed to determine whether significant changes occur at levels lower than those corresponding to the figures quoted in their statement. The Committee felt that it was reasonable to expect that there maybe some lowering of the observed 'threshold' levels for some sensitive biological conditions, and as more critical conditions are identified.

By the 1990s tremendous improvements in diagnostic sensitivity had been made, and research began to be promoted to find newer applications for ultrasonography. The improvements were made possible by substantial increases in the acoustic output levels of ultrasonographic equipment, especially in pulsed Doppler applications.

'Routinisation' Of Obstetric Sonography

Soon after the ultrasonography equipment was introduced in the late 1970s, by early 1980s sonographic screening of all pregnancies became standard practice in several European countries. Routine ultrasound screening during pregnancy was advocated by doctors to detect congenital anomalies, multiple gestation pregnancies, fetal growth disorders, placental abnormalities and errors in estimation of gestational age. In 1984 in the USA an expert panel convened to examine the evidence for screening sonography noted that there was 'no convincing evidence that routine sonographic screening of low-risk pregnant women would improve perinatal morbidity or mortality' (cited in Filly and Crane 2002). This panel asked for a prospective, randomized trial of routine sonography to settle the screening issue, which took place later, in the early 1990s. However, the findings of this expert panel did not impact in any way the 'routine screening' of
pregnant women. According to Filly and Crane, '.....many obstetricians in the United States had already made their own value judgment by this time and had instituted programs of screening in their practices. Indeed, it is fair to state that some practitioners had already concluded that if 1 sonogram during pregnancy was “good”, then 2 sonograms were “better”, and 3, 4, or 5 sonograms were “best” ’ (Filly and Crane 2002). By the time the results of the randomized trial were available, the issue had been 'settled' in favour of routine screening of all pregnant women; and 'had already taken on a major financial impact in American obstetrics. Any result other than an overwhelming endorsement of routine sonography was certain to meet with a backlash’ (Filly and Crane 2002).

The randomized control study (known as the Routine Antenatal Diagnostic Imaging with Ultrasound - RADIUS - study) concluded that screening ultrasound did not improve perinatal outcome as compared with the selective use of ultrasonography on the basis of medical judgment (Ewigman et al 1993). In 1997 the American College of Obstetricians and Gynaecologists commissioned another extensive review of the literature, and noted that the 'evidence was compelling that perinatal morbidity and mortality were not improved by routine sonograms in low-risk women'. Routine sonographic screening also failed to decrease the number of obstetric interventions, maternal hospital days, or cesarean delivery rates. A meta-analysis of randomized studies for the Cochrane Collaboration concluded that '....there is no evidence that ultrasound improves substantive clinical outcomes' (Nielson 1998, cited in Ecker and Frigoletto 1999).

Researchers have continued to argue that the benefits of screening sonography in low-risk pregnancies remain uncertain, and there is need for further studies (Ecker and Frigoletto 1999). What this shows is that in the first place ultrasonography became part of routine antenatal practice without formal evaluation of its benefits or even its need, and continues to remain 'routine' despite evidence of lack of benefit. Some medical researchers point out that (in the context of USA) 'Instead of asking whether routine sonography should be performed, it may be more appropriate to ask whether it can be stopped even if it cannot be justified from a cost-benefit perspective’ (Filly and Crane 2002).

One of the justifications now for routine sonography is that it can detect fetal anomalies, which in turn could decrease neonatal morbidity and mortality. However, the decrease in neonatal mortality as an improved outcome is possible only if the pregnancy is terminated on

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8 This randomized trial involved more than 15,000 pregnant women at low risk for perinatal problems to determine whether ultrasound screening decreased frequency of adverse perinatal outcomes, defined as fetal/neonatal death, neonatal morbidity. One group was randomly assigned 2 ultrasound exams, while another underwent the examination only for medical indications.
detection of severe anomalies. It is argued that nevertheless, fetal anomalies could be indicators of chromosomal abnormalities. However, mere presence of certain markers in low risk women is not easily interpreted and their ‘detection’ is not as beneficial as was hoped (Filly 2000). Moreover, many of these markers can be detected by other serum screening programs (Ecker and Frigoletto 1999). Further, a systematic review of studies of cost and cost effectiveness of routine screening for fetal abnormalities concluded that there is a lack of good quality primary studies on these aspects, and that there is a need for more published data on this issue, and on the longer term consequences of screening (Roberts et al 2002).

Safety of ultrasound in pregnancy

Ultrasound is perceived to be one of the safest diagnostic modalities available, and it is said that up to now there has been no proven harmful biological effect in humans at diagnostic exposures. However, the fact is that there is no verified documented epidemiologic evidence of adverse effects in patients caused by exposure to ultrasound (Ziskin and Petitti 1988), especially since the use of high intensity ultrasonography. The little information that exists is for ultrasound exposure when lower intensity equipment was being used. Researchers writing about biophysical effects of ultrasound warn against such complacency when considering the potential for biological hazards. Laboratory studies have shown that ultrasound is definitely capable of producing serious biological damage if the intensity is sufficiently high (Barnett et al 1994). The damage can result from thermal or non-thermal mechanisms, and is dependent on intensity of the ultrasonic waves and length of exposure. Knowledge of the mechanisms involved is important to extrapolate findings in laboratory conditions to predict effects in human exposures. Researchers working on biological effects of ultrasound believe that the studies that have been carried out are not yet conclusive, and warn against complacency when considering the potential for biological hazards. ‘It is important to realize that the past safety record should not be mistaken for a guarantee that harm can never occur in the future’ (Barnett et al 1994). Statements about the safety of ultrasound are usually based on the assumption that adverse effects have not been observed. According to clinicians, however, “absence of crabs under a few pebbles does not demonstrate an empty beach” (Duck 1999).

9 Thermal – rapid temperature rise, within seconds, localised to the area of the beam. Such a rise would bypass any possible protection mechanism afforded by heat shock proteins. Small elevations have significant biological effects; large ones result in cell death. Embryos and fetuses of all animal species, including humans are susceptible to temperature increases. Effects depend on stage of development, and level and duration of the temperature elevation, and can range from death, to abortion, to developmental effects. Non thermal – Mechanical Effect -Acoustic cavitation - defined as formation and/or activity of gas or vapour filled cavities (bubbles) in a medium exposed to ultrasonic field.
Timing of any embryological experimental study is critical, and there is a paucity of exposure studies covering the full complexity of ultrasound exposure at all stages of embryological development. While gross endpoints such as fetal weight reduction have been studied, subtle effects have not been studied at all. As improvements in resolution continue to occur and new applications continue to be found, the safety issue and risk-benefits need to be constantly assessed.

While it is concluded that the epidemiological findings do not indicate harmful effects, it is important to note that the populations studied were exposed in the 1970s and 1980s, to less intense ultrasound than what is routinely used today. The absence of adverse health effects in humans exposed to diagnostic ultrasound does not necessarily mean that bio-effects do not exist, rather that none has been detected that can be attributed with certainty to ultrasound exposure. There are no studies on human exposures at the high levels that are currently deployed, and used for obstetric examinations. No clinical studies have been performed specifically to assess the long-term impact of postnatal exposure of the central nervous system (Barr 2001). As human oocytes are developed in the foetal period there is a theoretical possibility that ultrasound exposure of the foetal ovaries may harm future generations. This has never been tested in epidemiological studies. Thus, no epidemiological or other evidence was then, or is now, available to support the assertion of safety at these higher exposures (Duck 1999).

We thus see that routine scans in pregnancies are of low benefit, and may actually present a risk for certain foetal examinations, depending on the exposure conditions chosen, and the training, skills and awareness of the ultrasonographer. Despite findings showing potentially adverse effects of ultrasound and uncertainties, it continues to be said that the clinical use is safe. The rider is that its use has a ‘good’ efficacy and safety record only when used in a clinical setting, according to well-laid out standards of medical practice, by skilled and well-trained people. No definite information exists regarding ‘safe levels’. The balance between risk and benefit changes significantly according to the medical reason for undertaking each type of ultrasonographic examination. Yet, obstetric ultrasonography is widely used outside research and clinical settings, by inadequately trained people, and has become ‘routine’ practice.

This situation has been made more difficult by the recent changes in the notion of regulation, whereby automatic safeguards on the output of the machine are not required. It places no responsibility on the manufacturer or any other agency for safety of the machine. Responsibility for safe use has been passed on to the user. Proper education and training become an essential component in this type of regulation, and knowledge and awareness are critical for effective and
safe use. Barnett discusses the implications of display of output by manufacturers. The incorporation of display of output makes the user responsible for risk-benefit assessment. Currently there is lack of awareness and understanding of the existence and relevance of output display indices among the users. So it is unrealistic to believe that low levels would be applied or monitored by the user. In fact the author reports that at an annual congress of the British Medical Ultrasound Society in 2002, the levels of TI (thermal index) often exceeded the allowed upper limit when expert ultrasound technicians were demonstrating the equipment.

C. Efficacy and Effectiveness of MRI scanning

In the mid-1980s MRI was still developing and was expected to be obsolete within ten years. Given its cost then (a few million dollars in capital terms and recurring costs), it entailed a huge cost outlay for any part of the health service. Hence there was need to examine it carefully to ensure that its use gave sufficient improvements for patients to justify the expense. This was needed also because by then everywhere ‘cost-containment’ was a major issue in the health sector.

A similar situation is to be found here as with the diffusion of CT scanners. By the mid-1980s MRI equipment had entered a phase of widespread expansion. Several reviews of the studies of MRI till then pointed to the poor quality of early evaluations of MRI. According to an assessment of MRI of the brain and spine, by the American College of Physicians, ‘the literature on clinical evaluation of MR imaging is not as rigorous as needed in an era of cost-conscious medical practice’ (Health and Public Policy Committee 1988). The general approach to clinical assessment of technology by this professional body included demonstration of technical capacity, diagnostic accuracy, and effects on diagnostic and therapeutic plans, and patient outcomes. It compared the technology in its erstwhile state to established alternatives. It lists out respectively, several demonstrated and potential advantages and disadvantages of the technique. Among the five demonstrated disadvantages were: the high installation and operating costs for the equipment; several categories of patients cannot be evaluated by MRI, especially in out patient diagnostic centers; and occurrence of unexplained image abnormalities and the potential for image artefacts raising the possibility of false-positive interpretation of scans. The potential disadvantage was that the paramagnetic contrast agents used then were still in the investigation stage hence potential for rare but serious toxicity remained undefined. According to this assessment the current clinical literature provided good evidence that MRI produced images of superb quality. However, well-designed studies of its diagnostic accuracy were scarce. Most reports contained methodologic biases that probably ‘inflate estimation of MR imaging’s ability
to detect disease (its sensitivity or true-positive rate). In some situations the high sensitivity of MR imaging to tissue changes results in display of findings that are clinically silent, non-specific or unexplained by present knowledge. Weaknesses in research methods make it difficult to interpret published reports that suggest that MRI's diagnostic performance significantly exceeds that of CT procedures. It offered the following general conclusions: 'Problems of quality control are not addressed by the published literature on MR imaging. As use of the technology becomes commoner in practice settings away from leading research centers, problems with incorrect machine usage, misinterpretation of artefacts, and failure to recognize incidental findings may plague new users. Although the referring physician must carefully choose a radiologist and MR imaging center, no formal guides or data are available' (emphasis added).

In a companion paper the authors point out that at that time published studies on the use of MRI had been undertaken by leading researchers using scanners with extensive technical support from manufacturers. Few studies had been reported by authors from hospitals without major academic affiliations, or from free-standing diagnostic centers. Hence evaluation of clinical effectiveness was not possible at that time. Virtually all the studies were affected by referral bias (where the study was conducted entirely by MR imaging research and development radiologists), because they were done in research centers known for expertise in MRI (emphasis added). It arrived at similar results as those of the study cited above and concluded that published evidence did not show that the clinical efficacy of MRI was generally superior that of existing imaging modalities such as CT (Kent and Larson 1988).

Yet another evaluation of 54 assessments was published in the mid-1980s after introduction of MRI. Both found the assessments to be generally lacking in accepted standards. Specific inadequacies found were lack of controls, presence of common experimental biases, absence of statistical analyses, and no evaluation of the effect of MRI on therapeutic efficacy and patients' outcomes. Most of them were largely descriptive and contained little rigorous efficacy research. Both concluded that the paucity of scientifically rigorous data precludes establishing as meaningful a role for MRI as the articles reviewed contended.
D. Coronary Care Technology – Coronary Care units (CCUs) and Coronary Artery Bypass Graft (CABG)

Intensive care emerged and spread rapidly in the US during the 1960s. Questions arose of proof of any benefit in terms of health outcomes to compensate for the increased cost of ICUs. In the US the 'high-technology' phase in coronary care began in the 1970s, and was characterized by the appearance of several new diagnostic and therapeutic methods based on expensive instrumentation (Braunwald and Antman 1997). Coronary Care Units grew rapidly in the late 1960s-early 1970s despite lack of controlled studies showing effectiveness (Waitzkin 1979). At a conference in 1968, sponsored by government agencies, greater development and support of CCUs were advocated, despite clear statements in the conference that their effectiveness had not been demonstrated. There was increased support from government and private foundations. Serious research on the effectiveness of CCUs did not begin until the 1970s. The studies conducted earlier did not have proper controls, and were descriptive studies of mortality and morbidity on uncontrolled data from patients with myocardial infarction (MI) admitted before and after the introduction of a CCU. One of these was supported by the US Public Health Service, a private foundation and the American Optical Company, which manufactured the tape-loop recall memory system that was used in the CCU. Several studies of effectiveness were undertaken in the 1970s comparing coronary care unit and ward treatment for MI. Patients were 'randomly' admitted to the CCU or regular ward based on the availability of CCU beds. Ward patients were the 'control' group and CCU ones the 'experimental' group. The results of these studies were contradictory, and it was unclear that CCUs improved in-hospital mortality. Three other studies in Great Britain contrasted home vs hospital care for MI. Two of these were prospective, random controlled trials, which indicated that for majority of patients with suspected MI admission to a hospital conferred no clear advantage. The third was a 12-month descriptive epidemiologic study of the incidence of MIs, how they were treated in practice, and the outcomes in terms of mortality. In this case the mortality rates were less for patients treated at home. Thus research indicated that home care was a viable treatment alternative to hospital or CCU care for many

10 The ICU is a predominantly equipment and organisational technology that arose in the US in the late 1950s from the notion of 'progressive care', which in turn conceptualized of hospitals built and organised according to level of intensity of care required – whether intensive, intermediate or minimal. The concept of progressive care had potential for integrating hospital care with ambulatory and long-term care, placing the hospital at the center of a community-wide comprehensive care system. Of this only the ICU really caught on. The ICU according to one author was a largely defensive response to nursing shortage, on one hand, and a shortage of beds on other. ICUs offered a solution to the first of these by concentrating a small number of critically ill patients into a well-equipped, well-staffed area. Once created ICUs gave impetus to the development of special instrumentation for patient monitoring, and by the mid-1960s there were prototypes of automated cardiac intensive care equipment. While the concept of physiological monitoring itself was quite old, now it took a highly specialised and equipment intensive direction. Some of the equipment was modified to a high level of sophistication, with closed loop control of transfusion and infusion of medication (from Flagle 1978).
patients with MI. Early CCU promotion used unsound clinical research. More adequate research has not confirmed CCU effectiveness.

While the issue of CCUs was not quite settled, a study was conducted on costs, productivity and economic efficiency of these facilities (Bloom and Peterson 1973). The purpose of the study was to: determine the true hospital cost and economic efficiency of different types of units (based on bed-size and on teaching function); describe the diseases for which patients were treated in these; and to ascertain mortality in the units. The study demonstrated that about half of the patients treated did not have myocardial infarctions. Most had a variety of cardiac and other diseases; they were a low-risk group for whom such expensive care seemed unnecessary. It also demonstrated important differences in the mean performance of CCUs in university, other teaching and non-teaching hospitals. The differences were shown both by medical and economic measures, including patient selection, case fatality rates, occupancy rates, personnel productivity and treatment cost. It also demonstrated differences that were related to unit size, which was also related to the efficiency of the operation. In general, the units in university hospitals demonstrated the best performance by both medical and economic measures, with the other teaching hospital group in a middle position and the non-teaching hospital group having the poorest record. Economy of services was not a major consideration in the provision of these units. Units had been replicated without attention to nearby facilities, and without consideration for the diseconomies created by the high costs of staffing and running units. The authors argued that in such a situation, where effectiveness was not settled, randomized clinical trials to settle the efficacy of expensive care are not unethical. They raised the question ‘Is it ethical to spend scarce medical dollars on unproved treatment when these funds could be used in other areas where medical care is known to be effective?’

They suggested the need for second-best solutions in a situation where questions of efficacy and effectiveness are unsettled. Services such as radiation therapy, cardiac care and CCUs, should be planned by region, not by individual hospitals, to assure effectiveness and economy. Bodies that are disinterested and have a broader view than that of a single institution must make decisions regarding expensive modalities, such as provision of CCUs. If they are left to individual hospitals, excess capacity and inefficiency will result.

We find that although the results of some randomized trials have suggested that appropriately selected patients with MI maybe adequately cared for at home, most physicians are not convinced of the safety of such an approach and so it has not been adopted into practice (Antman and Kuntz 2000). However, the concern with rising costs of care has resulted in shortened length of hospital
stays after MI. (Initially it was treated with immobilization of the patient and a hospital stay of 4-6 weeks). So the emphasis now is reduced hospital stays, and the debate is on the long-term clinical and economic soundness of this change, of early discharge. Now the argument is like this: practical problems have prevented large-scale trials from being undertaken to prospectively compare early discharge with delayed discharge. When data from such trials are limited or unavailable, cost-effectiveness analyses can be used to synthesize the available information on the costs and benefits of alternative clinical strategies.

A similar picture obtains for surgical measures for coronary heart disease. By the early 1980s this technique had become a "standard" or conventional surgical means of handling heart disease in the US. However, despite all the advantages claimed for it and the large amount of resources invested in it, till then there was only one properly designed and conducted objective evaluation of the measure. An extensive evaluation of 150 different reports on the procedure made the following observations (Mundth and Austen 1975):

• That the medical evidence for CABG consisted entirely of observational reports (such as retrospective studies, case reports, clinical experience and follow-up studies);
• Although not one RCT had been conducted among these reports cited, the superiority of evidence so gathered was recognised;
• Proposals for prospective RCTs were alluded to, with the hope that they could provide answers to the many questions that were still not completely resolved.

The authors concluded that, given this commitment to superiority of RCTs, it would be reasonable to assume that the concerned practice would be influenced by the results of such studies.

Another author made the following observation: "An even more insidious problem is that what might be considered an "industry" is being built around this operation; the creation of the facilities for open-heart operations in community hospitals in which no other cardiac procedures are performed and the enlargement of surgical facilities in teaching hospitals; the proliferation of catheterization and angiography suites as well as facilities for performing screening exercise electrocardiograms; and the expansion and development of training opportunities in clinical cardiology, cardiovascular surgery and cardiovascular radiology. This rapidly growing enterprise is developing a momentum and constituency of its own, and as time passes, it will be
progressively more difficult and costly to curtail it materially, if the results of carefully designed studies prove this step to be necessary’ (emphasis added) (Braunwald 1977).\footnote{11 Similar observations were offered by the Director of an reputed hospital in Delhi, about proliferation of cardiac catheterization labs - about them being ‘money-spinners’ (2004).}

E. The diffusion and adoption of several other technologies such as that of electronic fetal monitoring (EFM) has been seen to follow a similar pattern. EFM was introduced during the mid-1960s and was rapidly and widely accepted in obstetric practice in USA. The purpose of EFM was to detect fetal distress during labour and delivery, enabling intervention that would prevent perinatal morbidity and mortality. An analysis of almost 600 published articles on EFM by Banta and Thacker (1979) indicated little increased benefit from EFM compared to auscultation; and the only four randomized controlled, clinical trials showed no effect on perinatal mortality, and little, if any, benefit in terms of perinatal morbidity. Yet, `public and private policies have largely acted to encourage use of EFM, and none have acted to slow or prevent its spread’.

Problem with (costly) developments in medicine since the mid-twentieth century
We find that studies to determine efficacy and effectiveness, to clarify proper applications, and safety studies lag far behind the development and rapid diffusion of a technology. In the context of use of ultrasound in medicine, it has been stated that there is a huge differential in availability of funds for technological/commercial development and that available for basic scientific and health-related research. As a result development of new techniques is typically ahead of research on relevant bio-effects outcome (Barnett 2003). This carries negative implications for, among other things, safety. The author goes on to say that ‘development of internationally agreed safety standards for safety classification relies on agreement on interpretation of bio-effects data and certain political prejudices and, consequently, lags far behind’.

At the early stages the technology/approach is not fully developed and therefore the evaluation is likely to be negative. Many early studies are usually simply descriptive, and it has been suggested that once the method is established, ways can be developed to produce a statistically acceptable comparison trial. The difficulty with this approach is that once the technology is adopted or machinery is bought (usually at a horrendous cost) and widely distributed, it is extremely difficult to put together trial protocols, which are not biased towards its continued use. It might be actually thought that, even if it was only minimally effective, such expensive machinery cannot be ethically abandoned. At later stages there is a commitment to the
new approach and any evaluation which shows that the method does not work will tend to be ignored. The other difficulty (posed as an ethical one) is that: once a method, whether evaluated or not, is regarded as being part of 'routine diagnostic treatment' by the profession at large, there may be a compulsion on practitioners to use that method, whatever the scientific evidence for its effectiveness on a priori grounds.

As pointed out by some, we find that several levels of double standards exist over clinical trials for evaluating efficacy and effectiveness. On one hand, it is ethical to subject all patients to an innovation, despite the absence of reliable evidence concerning its effectiveness or its potential for harm. On the other, it is unethical to withhold the as yet untested procedure from certain patients in order to ascertain its effectiveness and its potential for harm. Furthermore, the observational studies undertaken in the initial phase are not subjected to as much methodological scrutiny. Whereas, many questions are raised about RCTs and very stringent standards, which are not used in the beginning, are employed to discredit or dismiss them (McKinlay 1981). Yet another anomaly with respect to RCTs exists. Sometimes the results of an RCT do show an innovation to be effective and these are immediately seized upon by its proponents and used to advance it. More often however, RCTs show innovations to be either ineffective, or at best no more effective than existing alternatives, that maybe cheaper. These results tend to be ignored or explained away (as in case of CCU stay for MI, mentioned earlier). McKinlay cites the example of the use of stilbesterol to prevent spontaneous abortion in the 1960s and 1970s. Later it was found to cause problems in young women whose mothers had been given this hormone during pregnancy. At the time of its use there was no known toxicity, however there was no evidence of its efficacy either. There was overwhelming evidence that it had no effect in preventing spontaneous abortion in any group of patients. Its use was banned and this information had become textbook material. Yet, even 15 years after such information was available, several studies of the marketing of stilbesterol revealed that women were receiving it during pregnancy. As pointed out by Chalmers, 'the late-appearing toxicity was irrelevant' (Chalmers 1974, cited in McKinlay 1981). It should not have been prescribed in the first place.

With respect to clinical trials, it needs to be mentioned that in case of certain medical technologies, such as drugs and devices, the industry submits results of trials while making applications for approval and licensing. Often the reports cited by the industry are not published. Moreover, in the name of secrecy many of these submissions or the raw data are not available for evaluation by doctors and researchers. Certain evaluations are made based on manufacturers’ information. For instance: based on a summary of adverse incidents taken from manufacturer's device reports, MR imaging in clinical use has been declared very safe (Gangarosa et al 1987).
Such findings belie the general notion that medical innovations are widely adopted, or become 'standard practice' only after they have been thoroughly tested for their efficacy, effectiveness and safety, based on objective scientific criteria. In the case of costly innovations (of the order of Rs 15-20 lakhs or more for ultrasonography (USG) equipment, Rs 70-75 lakhs or more for CT-scanners and Rs 1 crore for MRI equipment), it would seem self-evident that such equipment would be tested in detail, before large investments are made on them. In reality it is found that new techniques are widely promoted and adopted, even while studies to assess efficacy, safety, and proper applications have not taken place. Innovations become part of medical practice despite the absence or inadequacy of empirical support for their efficacy and usefulness, and information on indications for their use. It indicates that factors other than the results of objective evaluation are involved in the diffusion of a medical technology, in the rate and the extent of its spread. In the context of ultrasonography, it has been pointed out that there is a huge differential in availability of funds for commercial development of technologies and that available for basic scientific and health-related research. As a result, development of new techniques is typically ahead of research on relevant bio-effects outcome (Barnett 2003). This is the case for other technologies too, such as CT-scanning, especially multi-slice CT-scanning. This carries negative implications for, among other things, safety. Thus, we see that there is a disjunction between development and diffusion of medical innovations, on one hand, and research on their efficacy and safety, on the other.

We find that over time the development of medical technology and the process of its diffusion/adoptions have become very closely linked. In case of the imaging technologies technological developments and research on new clinical applications are taking place hand-in-hand (see examples in next section). As manufacturers need data on the equipment, they are teaming up with clinicians and offering incentives to place equipment in hospitals to gather data from patients. The concern has been not so much regarding clinical needs/priorities or safety. We see that without undertaking proper evaluation of their applications, usefulness and safety, based on solely anecdotal or descriptive accounts of doctors using them, medical technologies get promoted and sold widely, even outside research and hospital settings. Once investments are made by industry on development that it considers significant, its influence on adoption of that technology needs to be taken into account. (Marketing has overtaken `science').

What is most striking is that: in a field such as medicine, which claims a scientific basis and is also associated with healing and curing, actual medical care is based upon a belief in efficacy and effectiveness rather than proper evidence based on well designed clinical trials. Further,
safety is a major casualty and does not get the attention that it should in a profession associated with healing and health.

The rapid diffusion of CT in USA and Europe led to formulation of several regulatory measures. Policy analysis showed that these regulatory measures did not have much effect on diffusion of technology. Manufacturers would sometimes join hands with their clinician customer-colleagues in getting around legal measures. According to Blume 'where major economic interests were at stake, ways of circumventing legislation were sought' (Blume 2000 p 182). He cites the example of Philips, one of the largest corporations, having joined with clinicians in avoiding having MRI limited by legislation.

Clearly, adoption and widespread diffusion of medical technology cannot simply be attributed to 'scientific/effective medical practice'. Other factors also play a role.

5.1.7 Dissemination of information about medical technologies
The dominant perception is of medicine as subject to frequent and major changes, and hence of the need for doctors to be up-to-date with these changes. Several features regarding the source and quality of information regarding medical innovations, as to how doctors get to know about the 'developments' in medical knowledge, how decisions to adopt a technique or purchase an equipment are made, all these are relevant to the process of adoption of medical innovations.

Dissemination of new medical information among doctors occurs through a loosely structured process of continuing medical education (CME). This includes reading, attending courses, and engaging in discussions with colleagues. The last of these (endorsements by colleagues) is one of the principal means of exchanging information on innovations (Greer 1988). Post-graduate and in-hospital conferences, symposia, lectures and meetings, and exhibitions are frequent activities. The content of these courses and conferences, as also of medical journals, is usually determined by the editors and planners.

Dissemination of medical information through journals in the field is a complex process and not as objective as one would assume. Several kinds of biases in publication have been reported (de Camargo 2002; Davidoff 1997; Easterbrook et al 1991). A substantial proportion of reports of properly conducted RCTs are never reported or submitted for publication. There is a tendency to

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12 Publication bias – whereby research with statistically significant results is more likely to be submitted and published than work with null or non-significant results. There is evidence for existence of publication bias in several areas of medical research.
publish only reports of 'successful interventions'. There was a bias towards publication of papers with positive evaluations of treatments. There are very few reported unsuccessful interventions. A similar situation was observed with regard to cost-effectiveness studies. There are debates about the extent of publication bias and its importance. Some contend that studies with negative results tend to be poorer in quality. A retrospective survey of 487 research projects shed light on some such perceptions regarding published data (Easterbrook et al 1991). The survey found that studies with statistically significant results were more likely to be published than those finding no difference between study groups. It was also found that positive studies tend to receive more attention, through publication in major medical journals than negative studies. This is of importance, since a highly 'visible' publication may have a profound impact on medical practice, even if the results are subsequently shown to be unreliable. There was no evidence that studies with significant results were superior to those with null results in quality of design.

It has been pointed out that, despite being sceptical about many innovations, many doctors lack the time, knowledge of technical aspects of research, especially epidemiology and statistics, to effectively assess the voluminous information that comes out almost daily. Given the vast amount of literature that gets published or is put on the internet, it is humanly difficult, if not impossible, to meaningfully be in touch with all the information. Not surprisingly, for practising doctors the reading of medical journals is subject to time-constraints and availability of journals, and to the ability to evaluate meaningfully the results of evaluations and studies published in journals. (Camargo 2002; Greer 1988). For many doctors sales representatives of pharmaceutical companies are the first source of information about 'new' medications and drugs. It is now an established fact that the prescription of a drug by a doctor is largely determined by drug industry sources. Much has been written about the 'bribing' of doctors by the drug industry, by subsidizing/funding their trips and stays for conferences and holidays, and more direct methods such as offering gifts, conducting free medical check-ups of doctors at conferences, etc.

At present CME courses, seminars, conferences, live operative workshops, and exhibitions are the major means of acquiring and exchanging information about technologies and procedures. In fact, nowadays these types of activities have become annual events and predate publication of refereed articles or studies. The sponsors use such meetings to introduce new drugs, procedures or other such technologies. Renowned specialists and experts in the field are invited to make presentations. Such venues are covered with posters and signs prominently displaying the company and the drug name. In case of equipment, models of the equipment are exhibited. Much gets written in medical journals about these events, which are held in expensive hotels and/or exotic resorts. Concerns have also been raised by doctors about the implications for
medical practice of the sponsorship and funding of these events by pharmaceutical and equipment industry. Apart from regular contact with doctors and hospitals in name of maintenance, there is organised, continuous interaction of the pharmaceutical and equipment industries with the medical profession. Management professionals are employed for promotion and marketing of 'new' products, as well as by inserting and mailing glossy advertisements in medical journals and medical newspapers.

Regarding exhibition of medical equipment at scientific meetings and conferences, an issue that is currently controversial, yet popular, is the practice of using live models to demonstrate new ultrasonographic equipment at scientific meetings (Barnett 2003). The article gives one example of a meeting of the International Society for Ultrasound in Obstetrics and Gynaecology (ISUOG) in Melbourne, in October 2001, where there was live scanning of pregnant patients on the exhibition floor. Some of the major corporations exhibiting ultrasound equipment made use of private booths or theatrettes associated with their equipment stall. At least one manufacturer arranged after-hours demonstration on live pregnant subjects, when members of the audience were encouraged to try various scanning options. There were no obvious guidelines for duration or type of examination in any of these demonstrations. Patient discomfort after being scanned for more than 30 minutes decided the completion of some examinations. Different organisers and professional associations have taken different positions on this issue, which is attributed to differences in interpretation of the safety issue and their definition of medically relevant use of diagnostic ultrasound. Some have little or no restrictions, while others have policies that are subject to various interpretations. This practice is justified by some on grounds of providing 'educational benefit'. However, as argued by the above author, it is unlikely that any increase in skill levels can be achieved from a single demonstration, where the audience is shown the diagnostic capabilities of the equipment and the technical ability of the expert performing the demonstration. Both are essentially marketing exercises. If the educational benefit is only to the extent of increasing awareness, the same can be achieved by watching a video presentation. Skills can be achieved or improved only by sustained and supervised practice. The author raises the question: why is it important to promote equipment with live scanning when it was acceptable in the past to show high quality images and video presentations? This is like 'test-driving' the equipment before purchase. In this author's opinion the need to allow live scanning is usually driven by economic considerations; the perception is that industry will not otherwise provide sponsorship required for holding increasingly expensive conferences.

Another 'standard' practice, since the 1990s, is the holding of live operative workshops, as part of CMEs. Surgical conferences in India and abroad are dominated by these sessions, where
operative procedures, including endoscopic ones, are beamed 'live' to an audience from the operating room. Surgeons returning from such workshops have been extremely enthused and convinced by what they saw, and were able to convince their hospital administrators of the technology. The necessary equipment was procured and they became 'part of the greatest revolution in surgery' (Ardhanari 2004). Advocates of this practice cite the following reasons: Laparoscopic surgery is still evolving and a large number of surgeons do not have the opportunity to see or practise it during their training. It is difficult for a surgeon in private practice to leave his base for a long period to learn a technique. For many doctors visiting centres of excellence is also financially not possible. Live operative workshops provide an opportunity for such surgeons and postgraduates to see the potential of the technique, and to learn from 'master craftsman at work'. Secondly, dealers and manufacturers cannot take their equipment for demonstration to every centre. Live demonstrations of this new equipment by experts highlight their potential, advantages (and limitations). However, other surgeons who have themselves participated in such workshops have returned highly perturbed, and have expressed serious concerns and reservations about the usefulness and ethics of such practices (Nagral 2004; Ananthakrishnan 2003). One was that the pressure of getting cases for the workshop results in the selection of patients for demonstration who would other be classified as inoperable. Nagral provides an accurate description of one workshop he participated in, from the arrival of the leading foreign surgeon, till the cheers on the completion of the operation. In this author's view it is important to understand the forces driving the 'live demonstration' boom.

"These workshops are essentially a part of a grand marketing strategy for many institutions. Hence the form and content is often designed to promote an institution, procedure, equipment or even an individual, rather than representing a well thought out scientific and educational activity. It is no coincidence that this boom has come at a time when technology has entered surgery in a big way; the best examples being the fields of laparoscopy and endoscopy. A huge and ever-growing medical equipment industry provides the main funds for these workshops as for them it is a ready-made opportunity to display and promote their wares. Often, the unwritten trade-off for such funding is the promise of subtle promotion through the medium of the workshop. The relationship between the industry and profession is really the subject of another debate but the result is that only equipment-intensive (and, in turn, glamorous) procedures form the focus of these workshops. Have you heard of a live workshop on diabetic foot surgery? Or doing proper thyroid operation or an amputation? For that matter, has a workshop ever been organized to show how local innovations can make the practice of surgery cheaper in India? Thus,
the very genesis of these workshops is based on a dominant, market-driven rather than a science- or education-based premise".

The argument that it fulfils an educational need does not hold, as such workshops are a poor alternative to structured teaching and training. They are not part of postgraduate programmes in academic institutions, but usually occur in the private sector outside academic institutions. The setting and the manner in which such procedures are demonstrate rarely allow a discussion on pre and post-operative issues, such as on indications, preparations, investigations, postoperative care and how to handle complications, and so on. In fact, as pointed out by this author, there is a serious danger of some degree of over-simplification of the operative process, as often well-selected patients are operated upon by the best surgeons with the best of equipment and back-up. It is a debatable issue as to how much scientific communication can be achieved amid the glamour and hype of live operative workshops.

Thus it seems that the immediate source of information about medical innovations happens to be the industry itself, and specialists/experts involved in the research and development of the innovation. As others point out, ‘...... it is difficult to ignore the way medical knowledge is communicated in and through the marketing practices of the pharmaceutical, equipment and publishing industries’ (de Camargo 2002).

This kind of information dissemination and creating awareness has implications at two levels:

As Camargo argues, while doctors lack resources to evaluate the ‘new knowledge’ that is being made available, vastly disproportionate forces are available to those who produce such knowledge. The net effect of this situation is the receptivity of the doctors to the selective information presented by the industry side of the medical-industrial complex.

As the next section brings out, nowadays manufacturers offer a variety of services, including maintenance, education of personnel, software support, and even financing for very expensive equipment, and specialized construction/modification of buildings. At the immediate level this leads to a kind of dependence on the part of the purchaser. Under such circumstances, when the systemic nature of the total package makes comparison of alternatives difficult, purchasers tend to play safe and stick to known and trusted suppliers. Furthermore, the more technically complex the product and the less technically sophisticated the buyer the harder it is for the customer to experiment with competing brands. And the less frequently the customer purchases the product the greater is likely to be the tendency to choose a product initially on the basis of the image of
the product or the firm, and to stick with the initial choice. Even if a cost has to be paid in terms of price, they are loyal to their firm, so long as the product is satisfactory. Hospitals are no exception when it comes to such loyalty. It has been observed that individual hospitals, as major consumers of sophisticated imaging equipment, are quite bound to their particular suppliers (Blume 1992 p 67).

The larger point one is attempting to raise is – how well equipped and informed are doctors to take decisions about technologies about which they themselves do not have adequate information and training?

REFERENCES


This section presents information on the global medical equipment industry, such as on market size, manufacturing and trade; and on some major medical technology manufacturers. It also presents information on activities of medical technology industry other than manufacturing, such as in financing, in training, education and research, lobbying and marketing, and the strategies being devised by equipment manufacturers to tap the ‘growing healthcare markets’ in developing countries. The section ends with information on providers of certain kinds of specialised, diagnostic services that require specialised technology, and the mechanisms by which these are being financed.

5. II.1 Characteristics of Medical Equipment and Devices Industry

Although both pharmaceuticals and medical equipment and devices, are deployed in medicine and healthcare, there are some basic differences between pharmaceuticals and therapeutic drugs on one hand, and medical equipment and devices, on the other.

The medical equipment and devices industry (medical technology industry, for convenience) is relatively young, and a very diverse industry. It is made up of a few large companies and a large number of small and medium-sized companies. Research ranging from incremental to radical in many areas such as healthcare, biochemical, biomedical, material and information sciences and engineering disciplines, provides a basis for development of new and innovative products. The development and design of medical devices is per se a complex process. There is continuous innovation and iterative improvements in equipment and devices, based on new science, technology and available materials. Use of medical equipment and devices is often integral to clinical procedures, so user training and education are essential for safe and effective use. Medical technology involves high distribution, and training & education costs, and there is need to provide service and maintenance (more so for the sophisticated electronic equipment). Much of the technical advancements in the medical technology industry is linked to, and increasingly relies on the wider computer technology innovations, in micro-electronics, instrumentation, biotechnology, software development and telecommunication. This applies specifically to the segment of diagnostic, monitoring and therapy equipment. In fact some medical innovations can be looked upon as special applications of computer technology. Such as the application of the digital storage media, such as CD-ROMS – which allow vast amounts of space consuming data to be stored and
retrieved easily. Another major part of the value-addition has been in the design of software which can efficiently manipulate data. A good example of these applications is the integration of radiology with information systems, to give the Picture Archiving and Communications Systems (PACS), which replace traditional film with digital technology that may be stored with a patient's medical history, and doctors have remote access to this information. PACS are also looked upon as cost-saving innovations, since they eliminate the need for film, developing chemicals and processing labour.

The pharmaceutical industry is much older, dating back to the German chemical industry. At present it is comprised primarily of multinationals. The products are based on pharmacology and chemistry, and now also on biotechnology, genetic engineering, etc. Product development in this case proceeds by trial and selection on basis of quality, safety and efficacy. Pharmaceuticals and drugs are biologically active, and hence effective when absorbed into the human body. In this case too there is continuous innovation and some improvements, based on new science and technology. Pharmaceuticals and drugs have low distribution cost, and, in most cases, no service or maintenance. The training required for their use is much less intensive than that required for medical equipment and devices, especially for the high tech equipment and devices, which include the imaging technologies.

Scattered information on the medical equipment industry is available since late 1980s-early 1990s, with the industry growing and generating its own data through market-oriented research. The medical device and equipment industry is considered to be not as large as the pharmaceutical industry. It is thought to be different from other manufacturing industries in certain respects, such as the size of the market, number and size of companies and the nature of the designs. While drugs are developed and manufactured for high volume markets, the medical device industry designs and manufactures many products, ranging from the extremely simple (such as tongue depressors, stethoscope, etc) to products such as catheters, hearing aids and implants, dental products, orthopaedic equipment and prostheses, surgical instruments (including gloves, masks, etc.), hospital furniture, respiratory equipment, rehabilitation equipment, laboratory equipment, dialysis equipment, diagnostic kits, chemicals and other reagents, monitoring equipment, to the extremely complex imaging equipment (X-ray machines, ventilators, pacemakers, CT-scanners, and many others). Thus what is referred to as the medical technology industry, or medical equipment and devices industry, comprises companies that make a large number of low-technology, medium-technology and high-technology products, for small low-volume markets. On the whole it is reported to be a very large, complex and fragmented industry, comprising companies ranging
from large multinationals to small companies that develop and commercialise products for specific niche markets (Clinica Reports 1996).

Medical device manufacturers tend to be small companies - globally, the industry is characterised by small entrepreneurial companies. For instance: in early 2000 approximately 94 per cent of the 7000 individual medical technology and device companies in Europe were small and medium-sized companies, with less than 250 people (Clinica April 29 2002 issue 1005). An outstanding feature of the medical technology industry is that presently the medical imaging industry is completely dominated by multinationals with many other lines of business - General Electric, Philips, Siemens, and Toshiba; for them the medical equipment business is also a profitable and substantial area of activity. These companies provide the full range of diagnostic imaging equipment. They also have the resources, and global sales and distribution networks, which enable them to exploit the opportunities in emerging markets. These MNCs were consolidating their activities through acquisitions in order to establish worldwide presence (discussed later in this chapter).

According to market research while venture capital (VC) investment in pharmaceutical industry has dropped off significantly in recent years, the medical device investment has remained fairly stable, which is considered to be indicative of the increasing interest in this market (Clinica Reports 2004).

5. II.2 Manufacturing, markets and trade

It is the industrialized countries - specifically USA, Germany and Japan - that produce the technologies; they are heavy users themselves and the exports are also very significant for them. The US medical devices industry leads the field in terms of manufacturing capacity, and is considered to hold a competitive advantage in the complementary industries on which the medical industry relies – namely micro-electronics, instrumentation, biotechnology, software development and telecommunication. There are some 10,000+ firms based in the country, ranging from small niche type firms to very large ones (www.ita.doc.gov/td/health/outlook_05_medical.pdf accessed on 10.10.07; Clinica 7 April 1997). In Germany there were roughly 500 companies in the medical devices industry, ranging from small specialist manufacturers to large industrial conglomerates (Anderton and Schultz 1999). Germany has a well-developed medical manufacturing base, and the medical equipment industry is considered to be one of the country's most successful industries, and acknowledged as an important segment of the economy, with a production volume of $ 15.5
bn (DM 28 bn) and an export rate of more than 50 per cent (Anderton and Schultz 1999; Seeger 1998). According to market analysts, despite the large size and the global reach of the medical technology industry, there is still limited information, and market data on all but the largest market sectors is difficult to come by (Clinica Report 2004). Hence the picture is still incomplete.

Available figures show that the industry has grown steadily in the past two decades. For many years the medical equipment industry has been characterized by substantial worldwide growth, although cuts in public health expenditure over the 1980s-90s decade have dampened this growth somewhat in that period (European Commission 1998, cited in Anderton and Schultz 1999). In 1985 it was estimated to be about US $30 bn, about 80 per cent of which was dominated by demand from US and Europe (Banta and Luce 1993 p 262). It grew to about $88.5 bn in 1995 (The World Medical Market Fact File - 1996 Volume 1, Espicom Business Intelligence, UK). Despite cuts in public health expenditure, the global medical equipment market grew by 7 per cent in 1993 (compared to 1.2 per cent for the world economy as a whole) to around 80 bn ECU in 1993, with the EU accounting for 31 per cent of the world market after the USA, the largest purchases with around 40 per cent of the world expenditure. Employment in the EU medical equipment sector grew by around 7 percent between 1990-1994, compared to almost a 14 percent fall in EU manufacturing as a whole (Anderton and Schultz 1999). In 2002 the medical equipment market was valued at $159 bn (Clinica 2002), about $ 180 bn in 2003 (Clinica Reports 2004) and about $ 230 bn in 2005 (in Medical Imaging April 2005). As of January 2007 the global medical device and equipment market was expected to grow steadily by 4.6 per cent per year over the next five years, and was expected to be worth US $ 246 bn by 2011.

Table 5.1: Growth of the world medical equipment market

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<tbody>
<tr>
<td>(US$bn)</td>
<td>30</td>
<td>88.5</td>
<td>159</td>
<td>180</td>
<td>230</td>
<td>246</td>
</tr>
</tbody>
</table>

Although the Asia-Pacific market is the smallest of the three geographic regions, it is an important ancillary market and expected to grow in the coming years. The highest percentage growth was expected in the emerging markets of Latin America and Asia (Medical Market Forecasts to 2011, January 2007, from www.espicom.com/prodcat.nsf/Product_ID.Lookup/00001542?OpenDocument, accessed on 8.10.07).
According to UN statistics exports and imports of electro-medical equipment in 24 countries had increased rapidly during the period 1978-1985, and exports to less developed countries had also grown (Banta and Luce 1993). A study on international trade in healthcare technologies revealed that there is very little statistical data on the trade in health services and health technologies (Baris and McCleod 2000). However, available data showed that developing countries are net importers of healthcare goods and services. According to recent business reports, imports were expected to rise in the Asian medical device market. In five key Asian countries import of medical equipment was expected to rise from US $ 30.43 bn in 2006 to US $ 43.08 bn by 2010 (in 'Asian Medical Device Markets', cited in The Machinist August 2007, accessed on http://www.medicourceasia.com/marketanalysis/9_2007_3.htm). According to this report, Australia, China, India, Japan, and South Korea import diagnostic and imaging equipment heavily, sometimes up to 90 per cent.

According to a study to look at the export success in the UK and German medical equipment industry, due to the circumstances of cuts in public health expenditures in USA and Europe, medical equipment producers have sought to increase their sales by means of increasing exports. Issues of international competitiveness have therefore become more important in this sector (Anderton and Schultz 1999). Similarly, according to the International Trade Association, Department of Commerce, USA, ‘The medical equipment industry was increasingly becoming a global industry, with an ever-increasing number of multinational firms aggressively pursuing the global market, focusing greater attention on international sales and revenues, joint ventures, mergers and acquisitions. In order to facilitate expansion medical device firms are recognizing that they must look increasingly at developing economies for future growth’ (www.ita.doc.gov/td/health/outlook_05_medical.pdf accessed on 10.10.07). Since the mid-1990s the expanding Asian economies were identified as the fastest growing markets for medical technology. With medical markets in the US, Europe and Japan having reached ‘maturity’, the industry started focusing its efforts on the Asia-Pacific and Latin American regions. While the three ‘mature’ markets together accounted for 87 per cent of global sales, however, in these three regions sales slowed down. This was attributed by the industry largely to the cost-containment measures that now dominate healthcare policies in Europe and the US (Clinica 2 January 1996 Issue 686 p 21 and 8 January 1996 issue 687 p 8).
US companies involved in medical equipment and medical devices, telemedicine and e-health are targeting what is seen as a growing market for medical products and services in Asia. In recognition of the opportunities in the Far East, Health Industries Manufacturing Association of the US (HIMA) set up a regional office in Singapore 'to foster better relations with key healthcare and regulatory officials'. China, especially, is being eyed by one and all. A Medical Technology Sub-Group of the US-China Joint Commission of Commerce and Trade was set up in 1995 to facilitate trade between the two countries. Similarly, the US Trade Development Agency also provides trade promotion assistance to high-tech healthcare companies to establish links in Asia and in Latin America. The message of a US Department of Commerce official to the annual conference of the Medical Devices Manufacturers Association (MDMA) in May 1996 was that major emerging markets such as Argentina, Brazil, Malaysia and India 'offer great opportunities for American medical device manufacturers. They were revamping their health systems and US products are highly respected' (Clinica June 10 1996 issue 709). According to business analysis, India's large population, the economic reforms of the 1990s, the increasing purchasing power of the growing middle-class here, all were considered to be significant factors that were leading to increased demand for healthcare, and therefore, for medical technology. Hence, 'India's medical device market is becoming too big to ignore' (Kader and Priestley 1997).

**There is also trade in refurbished equipment.** Trade of hard technologies\(^1\) provides opportunities for middle-income countries to purchase new equipment and to export old equipment to lower income countries.

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\(^1\) Baris and McCleod use a convenient and practical classification of healthcare technologies, as soft and hard technologies. Hard technologies refer to the hardware such as radiology equipment, and so on. Soft technologies refer to computer software, financial models (such as insurance and related actuarial methods- commercial presence of insurance companies or other mechanisms) and delivery models (such health maintenance organisations) and supply of services through tele-medicine.
### World Medical Markets - Some facts and figures*

Table 5.2: Size of World Market for Medical Equipment & devices (by region) (1995) +

<table>
<thead>
<tr>
<th>REGION</th>
<th>US $ bn</th>
<th>% of total market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americas</td>
<td>42.0</td>
<td>47.5</td>
</tr>
<tr>
<td>US</td>
<td>37.7</td>
<td>42.6</td>
</tr>
<tr>
<td>Canada</td>
<td>2.0</td>
<td>2.3</td>
</tr>
<tr>
<td>Central/South</td>
<td>2.3</td>
<td>2.6</td>
</tr>
<tr>
<td>Europe</td>
<td>25.0</td>
<td>28.3</td>
</tr>
<tr>
<td>Western</td>
<td>22.2</td>
<td>25.1</td>
</tr>
<tr>
<td>Eastern</td>
<td>2.8</td>
<td>3.2</td>
</tr>
<tr>
<td>Asia</td>
<td>17.9</td>
<td>20.2</td>
</tr>
<tr>
<td>South-East</td>
<td>16.1</td>
<td>18.2</td>
</tr>
<tr>
<td>China/HongKong</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Other</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Australasia</td>
<td>1.0</td>
<td>1.1</td>
</tr>
<tr>
<td>Middle-East</td>
<td>1.7</td>
<td>1.9</td>
</tr>
<tr>
<td>Africa</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>88.5</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
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(Source: The World Medical Market Fact File - 1996 Volume 1, Espicom Business Intelligence, UK). Following notes from this source:

* The data given in these tables are estimates based upon reported company revenues and national import trends. Views of the medical device industry, trade associations, government agencies and industry analysts have also been taken into account.

+ The review of geographic or product markets is not exact. The figures are arrived at by examining national production and trade, analysis of manufacturers' results and sample surveys of particular market segments. However, this is subject to pitfalls like absence of detailed production figures, and import of devices destined for re-export of local assembly/manufacture and not for local consumption. Examples of the latter are the size of import markets of Hong Kong, Singapore, Belgium and Austria.
Table 5.3: Medical Devices Market & Trade by country (US $ mn)

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>USA</td>
<td>37,700</td>
<td>4958</td>
<td>9000</td>
</tr>
<tr>
<td>Japan</td>
<td>13,600</td>
<td>3171</td>
<td>3253</td>
</tr>
<tr>
<td>Germany</td>
<td>7000</td>
<td>3468</td>
<td>6190 (largely X-ray systems)</td>
</tr>
<tr>
<td>France</td>
<td>3800</td>
<td>2573</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>2520</td>
<td>1656</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>2000</td>
<td>1263</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>2300</td>
<td>1701</td>
<td></td>
</tr>
<tr>
<td>Russian Federation</td>
<td>900</td>
<td>700</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>930</td>
<td>386</td>
<td></td>
</tr>
<tr>
<td>Brazil</td>
<td>765</td>
<td>331</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>430</td>
<td>185</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>520</td>
<td>640</td>
<td></td>
</tr>
<tr>
<td>Singapore</td>
<td>180</td>
<td>474</td>
<td></td>
</tr>
</tbody>
</table>

(Source: The World Medical Market Fact File - 1996 Volume 1, Espicom Business Intelligence, UK)

While US, Japan and Germany are the leading consumers, they also happen to be leading exporters of medical equipment. Other than US and Japan, the other countries have a significant import component. US companies lead the world in medical technology production, and US also is the largest single country consumer of medical and dental equipment and supplies, with a market valued at nearly $ 80bn in 2005. Till recently medical device exports from the US generated a consistent trade surplus: more than $ 50 bn between 1994-2000, and more than $ 3bn in 2001. In 2002 exports and imports began to approach parity, with a small deficit in 2003. However, in 2004 this trend was reversed. (See later in this chapter – Lobbying by the US industry).
Table 5.4: Size of World Medical Markets by Products (1995)

<table>
<thead>
<tr>
<th>Product</th>
<th>US $ bn</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electro-medical/ X-rays</td>
<td>21.7</td>
<td>24.5</td>
</tr>
<tr>
<td>Dental equipment &amp; supplies</td>
<td>5.0</td>
<td>5.6</td>
</tr>
<tr>
<td>Orthopaedic products</td>
<td>6.7</td>
<td>7.6</td>
</tr>
<tr>
<td>Disposables &amp; supplies</td>
<td>23.3</td>
<td>26.3</td>
</tr>
<tr>
<td>Medical/Surgical Instrument &amp; Appliances</td>
<td>31.8</td>
<td>35.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>88.5</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

(Source: The World Medical Market Fact File - 1996 Volume 1, Espicom Business Intelligence, UK).

In 2006 the constituents of the global medical equipment markets were estimated to be as follow (from: Cygnus 2007):

- Ophthalmic equipment: 18%
- Imaging and other equipment: 16%
- Dental equipment: 8%
- Medical disposables: 40%
- IV diagnostics: 12%
- Others: 6%

It is seen that medical equipment comprise about 40-50% of the total medical technology market. Product Area Revenues are the highest in Diagnostic Imaging, followed by that in clinical diagnostics. A look at the world medical imaging market shows that till the mid-1990s X-rays formed the major component of imaging systems.

Table 5.5: Market share of imaging modalities

<table>
<thead>
<tr>
<th>Modality</th>
<th>Market (US $ bn)</th>
<th>Per cent of total market</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray</td>
<td>4.7</td>
<td>38</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>2.0</td>
<td>28</td>
</tr>
<tr>
<td>MRI</td>
<td>1.5</td>
<td>13</td>
</tr>
<tr>
<td>CT</td>
<td>1.3</td>
<td>11</td>
</tr>
<tr>
<td>Gamma cameras</td>
<td>0.7</td>
<td>9</td>
</tr>
<tr>
<td>spectrophotometers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PET</td>
<td>0.1</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>10.3</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

(Source: The World Medical Market Fact File - 1996 Volume 1, Espicom Business Intelligence, UK)
There has been significant growth in imaging markets in the past ten years.

- In the mid-1990s the world market for electro-medical systems and devices was placed at some $20 billion, of which *diagnostic imaging equipment accounted for 55 per cent* (~ $10 bn) (Clinica 647, March 27 1995).

- The global market for medical diagnostic imaging in 2001 was estimated to exceed $14 bn, with growth expected to average 7 per cent annually until 2007 (Clinica Report 2002 – Medical Diagnostic Imaging).

- X-ray imaging continues to be the primary imaging modality, with an increasing trend towards replacement of existing systems by digital systems. Breast-screening is considered to be an increasing multi-billion dollar industry; according to some market estimates there are about 30,000 traditional film-screen mammography systems currently installed worldwide. The estimated conversion to digital systems was expected to reach 1,500 systems per year by 2007 (Clinica Report 2002 – Medical Diagnostic Imaging).

- In the mid-1990s it was believed that the future of imaging was in non-ionising methods such as ultrasound and MRI, and that these areas would show the most market growth (Bromley 1996). MRI enjoyed a boom in market growth in early 1990s, but its growth stagnated between 1992-1995, attributed to healthcare reform and cost-containment measures in the USA and Europe. By 2003 however, MRI, which was thought to be for large, academic healthcare facilities, was available in a variety of facilities of a variety of sizes (Medical Imaging January 2003). China and other emerging markets of S-E Asia were considered to be growing fast and hence providing great opportunities for MRI companies – in 1987 there were an estimated 10 machines in the region, which had increased steadily to 715 by the end of 1995 (Bromley 1996).

- Since 2000 ultrasound imaging was said to be gaining market share (like MRI) at the expense of x-rays, and the ultrasound market climbed steadily in revenues and equipment sales in 2001. The estimated worldwide market then was close to the $ 3 bn mark. In 2000 a single manufacturer GE Medical Systems reported a 30 per cent growth in ultrasound over the previous five years (Medical Imaging June 2000). According to a report by the US-based firm Frost & Sullivan, revenues for the world-wide ultrasound market were projected to reach $ 4.2 bn by 2006, ‘fuelled by developments in new clinical applications and emerging markets in Latin America and Asia’ (Medical Imaging January 2002).

- New brand names also were reported to have entered the imaging industry, with companies like Microsoft, Intel, Dell, IBM, Sun and Oracle joining the world of imaging buyers and budgets. (Medical Imaging May 2002)
Reconditioned imaging systems
There is trade in reconditioned imaging equipment, especially CT-MRI systems. Reconditioned equipment like MRI systems can cost 30-60 per cent less than new technology, and there is demand for reconditioned systems (Bromley 1996). There are companies that deal in reconditioned imaging systems only. Some MRI manufacturers like GE sell their own reconditioned systems. GE has its Gold Seal line of pre-owned equipment. Market experts estimate that, although this demand and selling of reconditioned equipment is likely have an impact on the market, still reconditioned machines do not account for more than 5 per cent of the MRI market. According to a study on international trade in health services and health technologies, trade in refurbished equipment provides opportunities for middle-income countries to purchase new equipment and to export old equipment to lower income countries. This poses a threat of receiving faulty equipment/dumping of obsolete technologies (Baris and McCleod 2000).

5. II.3 Profile of some medical technology companies
This section profiles the major medical imaging manufacturers. We see that they are established multinationals with several other lines of business apart from the high-technology medical manufacturing. Increasingly these multinationals are finding ways to get involved in the 'healthcare industry'. Medical technology industry, imaging industry in particular is emerging as an important segment of the current 'global healthcare market'.

PHILIPS MEDICAL SYSTEMS

Philips Medical Systems (also known as Philips Healthcare) traces its origins to 1917, when during the First World War Dutch doctors could not get replacements for their broken x-ray tubes. They asked Philips - then solely a light bulb manufacturer – to repair them. Subsequently Philips began manufacturing its own x-ray tubes and then began manufacturing x-ray systems. By 1933 the company was manufacturing x-ray equipment in Europe and USA. PMS is part of the Royal Philips Electronics Group, with headquarters in USA and the Netherlands. It is one of the top three suppliers of diagnostic imaging and information technology in the world, and is looked upon as a leader in many of the markets in which it participates. It has development and manufacturing sites at Netherland, Germany & Finland in Europe, at several places in USA, one in Israel, and through a joint venture in China to make CT, MRI, X-ray equipment for global markets. Its sales and service operations are available in 63 countries, with over 6000 service technicians, and it distributes its products in
more than 100 countries globally. It is among the world’s major private research organisations, with research and advanced development activities at 22 Philips sites and 40 medical and technical institutions worldwide (www.medical.philips.com). Philips Medical Systems’ business is reported to have grown from 6 percent of the group’s turnover in 1998 to over 20 percent in 2005 (Industry news from www.hospimedica-india.com, accessed in February 2007). Philips Healthcare is in four businesses:

(i) Imaging Systems - It develops, manufactures and markets diagnostic imaging products such as X-ray, CT, MRI, nuclear medicine, single-photon emission computed tomography (SPECT), positron emission tomography (PET) systems. This is the largest business of PMS, accounting for 40 percent of sales in 2006 (Philips Medical Systems Company Intelligence Report http://www.espicom.com/prodcat.nsf/Product_ID_Lookup/00000179?OpenDocument, 8.10.07).

(ii) Ultrasound and Monitoring Solutions – manufactures patient monitoring, ultrasound systems, defibrillators and other cardiac care technologies.

(iii) Healthcare informatics such as picture archiving and communications systems (PACS); and medical transcription services through MedQuist, a company in which Philips has a majority shareholding. These activities represented 33 percent of PMS’ revenue in 2006 (same reference as above for imaging systems).

(iv) Customer Services: includes consultancy, clinical services, education, equipment financing, asset management and equipment maintenance and repair.

Dunlee, a wholly owned subsidiary of Philips Medical Systems, based in the US, is the world’s leading manufacturer of medical imaging components and replacement tubes for radiographic and CT systems. These tubes are used in imaging systems made by all the major imaging equipment manufacturers – Philips itself, GE, Siemens, Hitachi, Toshiba, Shimadzu and Elscint (www.dunlee.com).

According to the CEO, Asia Pacific, Philips Medical Systems, Philips is moving steadily towards a HLT position – namely Healthcare, Lifestyle and Technology company (The Economic Times December 17 2005). Philips also operates a consumer healthcare business which offers telemetry and other products for use in home care. This business is run by Philips’ Corporate Technologies operations and is not part of PMS.

Acquisitions have played a part in the development of Philips’ medical operations in the past few years. Since 2000 Philips has purchased several large companies in the imaging and healthcare IT field. In 2000 it acquired two companies. One was Healthcare Solutions Group (HSG) of Agilent Technologies (a division of Hewlett-Packard). HSG contained more than 400 healthcare products and services, and was among the world leaders in patient monitoring
products and ultrasound systems, and annual sales of around $1.5 bn. The other company acquired was the nuclear medicine equipment manufacturer ADAC Laboratories, in order to broaden the scope of products and services that Philips offers, particularly in cardiology. It also acquired ATL (a leading manufacturer of ultrasound systems); and Marconi (formerly GEC of UK) (Medical Imaging December 2000). According to Philips with all these acquisitions it had invested more than $4 bn in its Medical Systems business from 1998-2000. In mid-2005 it acquired Stentor Incorporated, a leading PACS (Picture Archiving and Communications Systems) provider. This acquisition was expected to strengthen Philips’ position in healthcare IT by using the ‘very talented people and unique technology’ of Stentor (Medical Imaging August 2005).

Philips Medical Systems (PMS) is reported to be working for the past decade on the most effective imaging methodology.

- A three-way collaboration has been established between PMS-Molecular Imaging group, Washington University School of Medicine and Kereos Incorporated, to develop new molecular imaging agents, and to extend the application of existing one in both pre-clinical and clinical settings, primarily in oncology and cardio-vascular purposes. Under this agreement, the Philips MI group will support the University’s Centre of Applied NanoMedicine, and its MRI and PET imaging systems will be used at this Centre (Medical Imaging June 2005).

- Philips Medical Systems, USA, has also entered into a five-year partnership with a local Technical College, to deliver and facilitate use of advanced imaging technologies, and hold demonstrations and training in these technologies to their students, technologists and regional healthcare facilities. Philips was to offer customized training courses using advanced imaging technologies, such as the company’s X-ray, ultrasound, MR and CT systems. As part of the agreement the company had installed a number of products that are used for medical imaging, radiology, and radiography, as well as two work-stations, one for MR and another for CT. All this is being done to enable students, physicians and other healthcare providers in the region to have interaction with, and hands-on experience in operating, advanced medical imaging systems. The College staff and Philips Medical Systems Educational Staff are working together to develop training programmes that will provide relevant knowledge and experience to radiology and sales professionals nationwide in cutting-edge diagnostic imaging systems. (Medical Imaging March 2005).

- Currently X-ray imaging is undergoing what is termed a 'massive upgrade', namely transitioning to Digital Radiography (DR). So, companies like Philips Medical Systems (in USA) are reported to be making things a little easier by creating several tools to aid
administrators in the transition. Philips Medical now offers "Digital Radiography: An Administrator's Guide," an online guide that covers the basics of DR, how to assess imaging needs, and in-depth case studies—all of which aid in planning, budgeting, and implementation. In addition to this website, the company has released a CD containing an investment justification for DR, a proforma model that determines the financial "break-even" point for leasing and estimates the impact that converting to digital could have on workflow efficiency and cost reduction. Philips Medical also organizes seminars, on "Administrative Essentials of Filmless Radiology," to demystify the process (Medical Imaging October 2005).

- In addition to the above activities in imaging education, Philips Medical Systems also operates an Online Learning Center on imaging technologies, for medical professionals, radiology technologists, nurses, biomedical engineers, Philips employees and new users. It is possible to purchase from this website a credited course, appear for a test and then obtain continuing education credits and a certificate.

- In 2006 Philips opened its first Medical Learning Centre for the Asia Pacific Region. Set up at a cost of $24 million, it is among the three centres set up by Philips for advanced medical equipment training in the world. Located at the Philips Complex in Singapore, it houses millions of dollars worth of sophisticated diagnostic equipment. The centre will provide education and training in skills required to operate technologically-advanced equipment. The advanced equipment includes a MRI machine, where magnets operate at minus 270 degree Celsius to ensure precision scanning of the brain. The walls, floor and ceiling are also embedded with copper to prevent any interference to the machine. According to the CEO, Philips Medical Systems, "..... The upfront investment on technology will help with early diagnosis, which will reduce dramatically the cost of treatment - the stay in hospital. It improves human lives also because we get well sooner with less treatment" (more in later section in this chapter).

- PMS has also instituted awards for research conducted in the use of echo-contrast agents in echocardiography and general ultrasonography. The awards are to be presented in collaboration with the Society of Diagnostic Medical Sonography Educational Foundation (SDMS of USA) (www.sdms.org/foundation/atl.asp. accessed on Sept 15 2005).

- PMS has also launched a new combination X-ray cath lab-MRI system (Philips XMR treatment suite) at the University of California, San Francisco Medical Centre. The configuration combines Philips' 1.5T Intera I/T MRI scanner with its Integris Vascular angiography system in the same room. According to Philips and UCSF the combination will enhance treatment for stroke and cardiovascular disease and help explore other beneficial applications, such as in neuro-vascular areas that might lend themselves to the combination.
While it would be about a year before the XMR came to the market, Philips was looking for other institutions to work with on a research basis (Medical Imaging July 2005).

- PMS also offers healthcare consulting, financial and leasing services and other kinds of customer support, regarding patient throughput, ways to improve productivity and lower cost of ownership of its equipment.

### SIEMENS MEDICAL SOLUTIONS

**Siemens Medical Solutions** is the medical division of Siemens AG, Germany. Siemens Medical Solutions represents over 9 per cent of the parent company's total revenue. Siemens also has a share in Dräger Medical, a leader in the market for electro-medical systems including patient monitoring products and electrophysiological measuring systems. Siemens Medical Solutions is well-known for its medical imaging systems, including X-ray, CT, MRI, PET, mammography, angiography, ultrasound and molecular imaging products, as well as related computer-based workstations, healthcare IT systems, oncology care products and audiology products such as hearing aids. Siemens has a strong global presence. The company has manufacturing facilities throughout North America and Europe, as well as in China and India. It also has joint venture operations in Germany, the US, the UK, China and Japan. Siemens Medical Solutions claims to be the global market leader for hearing systems, and holds a leading or second position in the markets for diagnostic imaging and healthcare IT products, along with Philips and GE Healthcare.

Siemens has built its operations through internal growth, strategic alliances and mergers and acquisitions. For example: it moved into the global *in vitro* diagnostics market by acquiring Bayer's diagnostic division in January 2007 and Diagnostic Products Corporation in July 2006. Siemens is also giving a push to molecular imaging. When Molecular Imaging was a key new area of expansion the company moved into this growth market by acquiring its former subsidiary CTI Molecular Imaging Incorporated (USA), a provider of PET imaging equipment and services, in 2005. It formed a division called Siemens Medical Solutions Molecular Imaging by combining its nuclear medicine operations with CTI Molecular Imaging. This new division was to focus on applications, development and distribution of molecular imaging technologies (Medical Imaging August 2005). In 2007 it acquired a German healthcare IT company GSD to strengthen its position in the healthcare IT sector.

Siemens Medical Solutions maintains R&D centres in Europe, the US and Asia. It has also R&D alliances with companies and academic institutions. It tied up with the University of California in Los Angeles for clinical trials of an imaging agent for identifying Alzheimer's disease; also developed an MRI system in collaboration with the Massachusetts General Hospital. Since 2000 Siemens Medical Solutions, USA, has committed $1.5 mn to a Cancer
Research Foundation in New York, in order to accelerate the use of imaging in cancer diagnosis and treatment. According to the President of the company, the dearth of clinical researchers was a major bottleneck limiting the translation of cancer-related discoveries to patients. Hence the company instituted this award, of a five-year grant of $750,000 towards salaries and research expenses so that young physicians could pursue careers in clinical research and focus on cancer research. The recipients of this award were using or developing imaging technologies for use in cancer diagnosis and therapy (Medical Imaging September 2005).

GE HEALTHCARE

GE Healthcare is a subsidiary of General Electric, one of the largest and most diversified companies in the world. It is headquartered in UK, and is a global leader in products and services for medical imaging, healthcare IT, diagnostic imaging agents, patient monitoring, and drug discovery. GE Healthcare comprises two main entities: GE Healthcare Technologies (formerly GE Medical Systems) and GE Healthcare BioSciences (formerly Amersham plc). GE Healthcare Technologies, headquartered in USA, is a multi-billion dollar business that provides medical imaging and information technologies, patient monitoring systems, and healthcare services. GE Healthcare Biosciences, headquartered in UK, provides diagnostic imaging agents, drug discovery and protein separation systems (GE Healthcare-Company Intelligence Report, accessed on 8.10.2007, http://www.espicom.com/prodcat.nsf/Product_IDLookup/00000171?OpenDocument

GE Healthcare is also committed to molecular imaging. GE Healthcare (USA) has teamed up with the Department of Radiology at Stanford University School of Medicine (Stanford, California) to develop new molecular-imaging technologies. The 5-year partnership, which will be headquartered at Stanford, brings together clinicians, biologists, chemists, and medical physicists from both organizations to create innovative imaging technologies and molecular probes. Together, GE Healthcare and Stanford researchers will work to identify and develop biomarkers of disease states, design targeted molecular-imaging probes, and develop diagnostic imaging and in-vitro diagnostics technologies. "This collaboration embodies our vision of accelerating personalized medicine from discovery to clinic," according to the CEO of GE Healthcare Technologies. "The ability to examine and understand the underlying pathways of the disease in their fundamental stages has the potential to lead to a number of advancements in medicine, including earlier detection of disease, the development of more targeted therapies, and the ability to monitor treatment more effectively." GE Healthcare will provide technology resources for the collaboration, including its PETrace Cyclotron, a suite of PET radiochemistry research equipment and
preclinical imaging technologies. Stanford will expand its radiology department through the construction of a new, modernized laboratory that will house the Cyclotron, high-field MR equipment, and a PET radiochemistry laboratory. It also will continue recruiting faculty, staff, and students (Medical Imaging August 2005).

GE HealthCare offers financing for equipment, real estate, expansion, acquisition operations, etc. GE HealthCare also made donations of imaging equipment and accessories to developing countries. It donated ultrasound equipment to a hospital in Haiti (Medical Imaging February 2005), as well as radiographic contrast media (worth more than $380,000) to Project CURE, an NGO that collects and distributes medical surplus to developing countries.

GE Medical Systems, along with the SDMS and Medison America Inc., has instituted Excellence in Sonography Awards, to promote excellence in sonography (www.sdms.org/foundation/gems.asp).

GE Medical Systems is also capturing new market segments by acquisitions. In 2000 it acquired the private company Critikon Company, maker of non-invasive blood-pressure monitors. The purpose of this purchase was ‘to extend (our) reach into other areas of the hospital, specifically the sub-acute area, where we did not have as large a presence’ (Medical Imaging December 2000). In 1999 the two had a strategic joint development alliance, which allowed GEMS to integrate Critikon’s BP-monitor into pro-patient monitor. This purchase now makes it the largest patient monitoring presence in the world. To boost its position in ultrasound and nuclear medicine, GE also acquired SMV of France. SMV is one of the largest independent dedicated nuclear medicine companies that manufacture nuclear medicine and PET systems and associated products. GE also purchased Parallel Designs on account of its financial growth. Parallel Designs was founded as a technology-consulting firm in 1991. It began producing ultrasound-transducers in 1995. There was a dramatic growth – revenues multiplied 20-fold between 1996 to 2000. As part of this acquisition GEMS was to establish a Global Transducer Technology Centre of Excellence (Medical Imaging, June 2000 and December 2000).

TOSHIBA MEDICAL SYSTEMS

Toshiba Corporation, Tokyo, Japan, is another global company engaged in the production, manufacture and sale of electronic and high-technology energy products. Toshiba is another big player in the imaging industry. Toshiba Medical Systems is a leading global producer of diagnostic medical imaging systems. In addition Toshiba entered the PET market in Japan through a distribution agreement with CPS Innovations, now part of Siemens, in 2003. Under
this agreement Toshiba distributes Siemens’ PET products and a combined CT/PET system in Japan.

In 2004 Toshiba Medical Systems Corporation (TAMS, California) launched Coronary Evaluation on 64 (CorE 64), an international collaboration to investigate the use of multi-slice CT as the primary diagnostic tool for detecting cardiovascular diseases and disorders. CorE 64 is reported to be the industry’s first multi-center clinical study on coronary CT angiography (CTA), using 64-slice CT technology. The participants in this study are Johns Hopkins University School of Medicine (Baltimore, USA), Beth Israel Medical Center (Boston, USA), Leiden University Medical Center (The Netherlands), Humboldt University (Berlin), INCOR Heart Institute of the School of Medicine Hospital, Sao Paulo (Brazil) and Iwate Medical University (Japan). Initial results of the study were to be released in 2006. The patient evaluations will involve noninvasive diagnostic imaging of cardiac patients using the company’s Aquilion CFX line of CT scanners for a period of several months, as well as regular meetings with the study group to measure and discuss the clinical effectiveness of cardiac CT imaging against cardiac catheterizations.

Another industry participant in this Cor E 64 study is Bracco Diagnostics Incorporated, whose contrast agent Isovue will be provided for non-invasive diagnostic imaging in conjunction with TAMS’ CT technologies (Medical Imaging September 2005).

‡ SHIMADZU

Shimadzu Medical Systems & Equipment Division is one of the three divisions of Shimadzu, a Japanese corporation. The other two are Aircraft Equipment and Industrial Machinery, and Scientific & Process Instruments. Shimadzu’s CT systems, MRI scanners and combined CT/PET products are only available in Japan. The medical systems and equipment division represented 19 % of the parent company’s revenue in 2006.

5. 11.4 Market-related activities of the medical technology industry

This part looks at some of the direct market-related activities, as well as promotional activities of the medical technology industry. It gives an idea of the strategies used by medical device companies, and competitive and co-operative practices adopted by them to expand and retain markets, achieve growth in sales and profitability. Although they may appear to be innocuous, activities such as promoting education in new techniques and new uses, and search for new applications and/or uses, etc. influencing policies and lobbying are in reality linked to creating markets and demand for their products, and ensuring profits. The imaging industry, in particular, is involved in all stages of technology, right from introduction
of so-called 'new ideas' to research and development, manufacture, evaluating them, disseminating information on new developments, promoting, sales and marketing them, arranging for finance to buy such equipment, and in organizing the planning, education and training for their use. It gives an idea of the active and intense participation of the multinational corporations in the medical imaging industry (the 'giants' as they are popularly referred to) in advocating and fostering, through several avenues, the adoption and use of imaging technologies, especially for screening/diagnosis of cancer and cardio-vascular purposes.

§ A report in the mid-1990s on the world Magnetic Resonance Imaging (MRI) market gives an idea of the nature of influences that the industry takes into account while assessing markets, and of the prices of medical imaging equipment. The report not only makes an in-depth assessment of market size, growth and product prices; each country chapter also reviews the current healthcare situation, nature of demand, product regulations and clinical trends (Bromley 1996). While the top five MRI markets then were Japan (31 per cent), US (29 per cent), Germany (9 per cent), China and Italy (4 per cent each), China and other emerging markets of South-East Asia were some of the fastest growing and provide the greatest opportunities for MRI companies. The Asian and Oceanian Society of Radiology had plans for establishing a permanent secretariat in Singapore, with the basic purpose of educating Asian radiologists in new technical and clinical advances in order to raise awareness about new techniques. The industry viewed this as an opportunity that would increase the perceived need for new technology and thus increase opportunities for MRI companies in the region.

Price Differentials in MRI equipment - Average market prices in 1996 (US $)

<table>
<thead>
<tr>
<th>strength type</th>
<th>Japan*</th>
<th>US **</th>
<th>Germany***</th>
<th>Italy</th>
<th>France</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.5T</td>
<td>640,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>630,000</td>
</tr>
<tr>
<td>0.5T</td>
<td>790,000</td>
<td>750,000</td>
<td>700,000</td>
<td>632,111</td>
<td>770,000</td>
<td>780,000</td>
</tr>
<tr>
<td>1.0T</td>
<td>1.28mn</td>
<td>1.1mn</td>
<td>1.05mn</td>
<td>913,000</td>
<td>1.19mn</td>
<td>1.02mn</td>
</tr>
<tr>
<td>1.5T</td>
<td>2.46mn</td>
<td>1.5mn</td>
<td>1.83mn</td>
<td>2.1mn</td>
<td>2.04mn</td>
<td>1.41-1.88</td>
</tr>
</tbody>
</table>

T- Tesla is a measure of the magnetic field strength of the equipment.  
(Source: Bromley 1996) Notes from source:
* Domestic ones (low-midfield) were cheapest; foreign manufacturers of high field had managed to keep prices higher.
**Increasing pressure to cut healthcare costs had depressed the prices. Radiologists were considered to play an important role in bargaining for lowered prices and consideration of relative importance of new features.
***Unlike other medical equipment, which tended to command high prices in Germany, MRI equipment prices were relatively low.
Compare these prices with those in a country like China. Here low-mid scanners were manufactured in the country; their prices tended to be much lower than those imported from foreign manufacturers. Therefore there was competition in this range.

<table>
<thead>
<tr>
<th>Strength type</th>
<th>Year</th>
<th>Company</th>
<th>Price (mn $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.35T</td>
<td>1993</td>
<td>Toshiba</td>
<td>1.20</td>
</tr>
<tr>
<td>0.5T</td>
<td>1992</td>
<td>Philips</td>
<td>1.22</td>
</tr>
<tr>
<td></td>
<td>1993</td>
<td>Philips</td>
<td>2.08</td>
</tr>
<tr>
<td></td>
<td>1994</td>
<td>Philips</td>
<td>881,803</td>
</tr>
<tr>
<td>1.0T</td>
<td>1991</td>
<td>Siemens</td>
<td>1.02</td>
</tr>
<tr>
<td></td>
<td>1991</td>
<td>Siemens</td>
<td>1.65</td>
</tr>
<tr>
<td></td>
<td>1993</td>
<td>Shimadzu</td>
<td>1.12</td>
</tr>
<tr>
<td></td>
<td>1993</td>
<td>Shimadzu</td>
<td>1.15</td>
</tr>
<tr>
<td></td>
<td>1993</td>
<td>Shimadzu</td>
<td>2.08</td>
</tr>
<tr>
<td></td>
<td>1993</td>
<td>Unnamed</td>
<td>2.12</td>
</tr>
<tr>
<td></td>
<td>1994</td>
<td>Unnamed</td>
<td>156,404</td>
</tr>
<tr>
<td>1.5T</td>
<td>1993</td>
<td>GE</td>
<td>2.10</td>
</tr>
<tr>
<td></td>
<td>1994</td>
<td>GE</td>
<td>1.85</td>
</tr>
<tr>
<td></td>
<td>1994</td>
<td>Siemens</td>
<td>2.08</td>
</tr>
</tbody>
</table>

(Source: Bromley 1996)

We find substantial difference in prices between countries, ranging between 1.5 mn (UK) to as much as 2.4 mn (Japan) in case of 1.5T equipment. In all cases it is highest in Japan. Similarly, prices are higher in China and even within China there are differences within provinces. For instance: Shimadzu sold 1.0T equipment at three different prices in different provinces, ranging from 1.1mn to 2.1 mn. So did Siemens. This gives an idea of not only the enormous price of this imaging technology. It also indicates that pricing of (expensive) equipment is not simply a matter of high R&D costs, as is commonly believed, but is more to do with markets.

There is intense rivalry between companies for exclusive markets. This is seen to lead to various kinds of adjustments/arrangements, acquisitions/mergers, manipulation of prices and markets, disputes in courts over patent infringement, malpractice, corruption, etc. Companies have also been cutting down operations and shifting production in order to retain or improve competitiveness and/or profits. In most cases such operations have resulted in job-cuts. A
few examples are cited here, which show that the medical technology industry like most others, is driven by profits and markets, and goes to any lengths to protect these two. We also see that there are competitive as well as co-operative practices among the manufacturers, to retain and/create new markets.

§ The medical technology industry in the USA in the mid to late 1990s saw a large number of mergers and acquisitions, and this trend was expected to continue (www.ita.doc.gov/td/health/outlook_05_medical.pdf, accessed on 10.10.07). The reasons for this trend were: (i) small firms found it too expensive to devote resources to provide “proof data” for their new innovations. Therefore, they were merging with larger firms that had the financial resources necessary to bring new products to market. Larger firms received the benefit of the new technology and thus maintained their market shares. (ii) Secondly, large firms had the capacity for exporting products globally, as well as were in a capacity to negotiate favourable deals with HMOs/healthcare companies and hospitals for their products.

§ Original equipment manufacturers (OEMs) of medical devices in North America were reported to be outsourcing production to electronic manufacturing service providers, to cut capital costs. In fact, medical OEMs were considering handing over the complete manufacturing process to electronic manufacturers so that they could focus on core business functions such as new product development and marketing (market research by Frost & Sullivan on www.researchandmarkets.com/reports/c61754, accessed on 26.10.07).

§ European medical device companies, specifically German and British ones, were reported to be facing competition in the low-technology segment from low-cost medical devices manufactured in Asia (Anderton and Schulz 1999; market analysis by Frost & Sullivan reported on www.medicsourceasia.com/marketanalysis/1_2006.htm). They were looking to capitalise on the advantages of low cost, skilled labour, etc., by outsourcing, partnering or relocating manufacturing facilities. They also viewed this as an opportunity ‘to penetrate the massively underserved Asian market’. China and India were seen to be favoured destinations in this respect. Some German and UK companies had outsourced manufacturing of the low-technology segment, namely manufacturing of basic surgical equipment such as simple blades and scalpels, to ‘low-wage countries’ (LWCs) – Malaysia, Indonesia, Pakistan, Eastern European countries, China, Vietnam and Thailand. British companies purchased finished surgical products from these countries and resold them after rigorous checking for quality control and grading, with shorter periods of guarantee than their own products. Some German companies had either acquired or set up new factories in LWCs to economize on the
costly German labour inputs involved; they maintained their high quality through use of state-of-the-art machinery and permanently stationed German foremen and managers in such units (Anderton and Schulz 1999).

§ There was fighting between Nycomed Amersham and DuPont-Merck for the US nuclear imaging contrast agent market, which was estimated to be worth $600 mn annually (Medical Device Business News - MDBN - January 1999, vol 4 issue 35, p 3).

§ In 1996 Boehringer Mannheim initiated an industrial lawsuit against Johnson and Johnson, accusing the latter of illegally obtaining a diabetes monitor prototype, infiltrating private meetings of B-M and stealing confidential documents (Clinica June 24 1996 issue 711 p 1). B-M was then the world-wide leader in the blood glucose monitoring unit, which was worth 1300 $ mn; had a share of 30 per cent, followed by J&J.

§ Between 1999-2000 Gambro, ranked the second largest provider of dialysis equipment and services, cut more than 1000 jobs and halted production at three of its US manufacturing sites in a 'thorough restructuring of its renal care products business'. This arose from relocation of the company's dialysis machine plant from US to Mexico, closure of one plant, merging of marketing and administration departments. The stated aim was 'to consolidate our manufacturing operations to improve our competitiveness'. Whereas, these were undertaken basically to increase the company's profit margins (MDBN January 1999, vol 4 issue 35, p 3). Smith and Nephew of UK also cut jobs 'for an annual savings of pounds 15 mn' in 1999. In 1998 Boston Scientific, an angioplasty products-maker, acquired Schneider WorldWide, a unit of Pfizer. At that time it planned to shut down all of the five manufacturing plants of Schneider's and transfer all the technology and equipment to its plants in US and Ireland, a move resulting in job losses to approximately 2200 employees (Medical Devices Business News February 1999 vol 4 issue 36 p 4). In 1996 Philips Medical Systems planned to cut its workforce in Germany by 30 per cent and in Netherlands too (Clinica March 11 1996 issue 696 p 1). The reason being price reductions and cost-cutting measures in the European and the US health sectors and the weak dollar. It also planned to reduce processing times and contract out parts of production.

§ The German company Boehringer Mannheim was acquired by Hoffman-LaRoche in 1997. Similarly the Bayer Group member Agfa-Gevaert bought over DuPont's imaging division Sterling. The deal was expected to make Agfa one of the world's leading suppliers of
diagnostic imaging film equipment, combining Sterling's presence in US and Agfa's in Europe. There are regular reports of such take-over/acquisitions involving smaller manufacturers (several issues of Medical Imaging Magazine).

§ In the US there are conflicts between large companies and small manufacturers. For instance the Medical Device Manufacturers Association (MDMA) - the industry's small business arm - does not support user fees to the FDA for product reviews or premarket approval applications (Clinica March 11 2002 issue 999 p 9). Competition practices were also a major concern for the MDMA. Group Purchasing Organisations (GPOs) act as 'middlemen' for about half of USA's non-profit making hospitals and negotiate contracts for some $34 bn in supplies. Premier and Novation were two such GPOs. Device companies pay them fees that represent a percentage of hospital purchases. In some cases Premier or its officials have also received stocks or options from companies with which Premier contracts. Device companies have been unable to market superior products to many hospitals because the two GPOs had exclusive contracts with a competitor. Products such as an infant pulse oximeter made by Maximo and a low energy pacemaker, which lasts longer, could not be marketed because of such practices (Clinica March 11 2002 Issue 999 p 11 'Premier and Novation in firing line over competition practices).

§ In Germany in 1994 there were allegations by the health authorities (Krankenkassen) of bribing of doctors by heart valve manufacturers (Clinica June 13 1994 issue 606). At that time heart valves cost about DM1000-1500 to manufacture and distribute. A fair price to clinics might be about DM3000-4000. However, the rate was DM6000-7000. The Kassen claimed that these high prices were deliberately negotiated between heart clinic chiefs and manufacturers so that the companies can make a larger profit. In the return the doctor received 'gifts', such as first class travel to and from and accommodation at medical conferences luxury holidays for the doctor and his/her partner, free cars and computers for the children and cash inducements too. The bribery was thought to be a result of the similarities between different heart valve models. In a 1988 comparison at the Helmhotz Institute in Aachen none of the ten heart valves tested was found to be significantly better than another. The lack of quality or price differences meant that to sell their products manufacturers resorted to offering bribes and incentives. Not surprisingly, the doctors association and the concerned manufacturers (mostly US-based) refuted these reports of corruption and felt that the whole report was politically motivated.
The pacemaker industry has been highly competitive, and there are numerous cases where smaller entrepreneurial companies were acquired by big businesses like Siemens and Teleelectronics once the market started growing. From her study of the influence of government policies in the US on distribution of medical devices, Foote has this to say about the pacemaker industry, 'While innovative and competitive, this industry is hardly a model of corporate responsibility. The structure of the federally subsidised market fostered some of the high-pressure sales tactics that led to significant fraud and abuse.....Companies began rapacious competition on non-price attributes' (Foote 1992 p110-111). There were roughly 500-550 salespeople for only 1500 physicians who implanted pacemakers. In 1982 it was reported that companies were offering physicians free vacations, stock options at reduced prices, cash kickbacks and consulting jobs with liberal compensation to persuade them to use their products. Companies instituted sales incentive programs to encourage unnecessary implantations, as well as unnecessary explantations and re-insertions of new products. Several companies were indicted in the subsequent enquiries that were instituted. In 1988 Cordis Corporation, which had introduced the programmable pacemaker, pleaded guilty to charges that it sold pacemakers it knew were faulty.

In 1999 in US the FDA granted marketing approval to one of the makers of transmyocardial re-vascularization (TMR) equipment makers. This approval boosted the prospects of the manufacturers. Further, the HCFA agreed to re-imburse Medicare patients for treatment of severe angina by TMR. This led to the three main manufacturers to swallow their differences. They settled their patent disputes and one - Eclipse Surgical - took over another (MDBN February 1999 vol 4 issue 36 p 10).

Customer financing has also become an important component of medical equipment sales. In 1992 Picker of US set up a joint venture to provide financing to purchasers of their imaging systems and equipment (Clinica Oct 23 1995 issue 677). Recently, IBM entered the medical technology segment by introducing new financing options for medical technology. According to IBM Global Financing (IGF of USA), 'in the medical industry, it can take as long as 6 months from the time equipment is ordered to when it is completely installed. Equipment manufacturers often require progress payments over this period, tying up a customer's capital on equipment that will not begin to generate revenues for 6 months or longer. In response to this aspect of business it has developed a program that provides a way to acquire equipment without up-front expenses. IBM recognized the need to equip healthcare providers with an innovative way to acquire the high-cost medical technology they
need without the burden of paying for it until installation is complete’ (Medical Imaging Magazine April 2005).

§ Medical Technology companies are creating other kinds of arrangements – such as online purchasing arrangements. The major US companies - Johnson & Johnson, GE Medical Systems, Baxter International Inc., Abbott Laboratories and Medtronic Inc. have all entered into a collaboration on an Internet-based purchasing entity - the Global Healthcare Exchange - to streamline the purchasing process and to raise efficiency and quality at the same time. The founding members of the newest exchange expect to require investments totaling more than $100 million. The group will form its own company with a management team and board of directors of the chief executives from the participating members, as well as three outside directors. They have been joined by Becton Dickinson and Company, Guidant Corporation and Boston Scientific Corporation. Another such arrangement has been created by some other companies too to streamline the purchasing and distribution of pharmaceutical and medical-surgical products, devices and laboratory products and services (Medical Imaging June 2000).

§ Policy Influencing and Lobbying

Lobbying by the US industry and what the US government is doing to assist US medical device industry

Health-care reforms, cost-containment and reimbursement measures and regulations in the existing and future `medical markets' have become as important concerns and issues, for the medical devices industry. The current focus of the medical technology industry is also on developing marketing strategies within medical markets (Fatz 1999). The US industry feels that in an environment where the US healthcare system is changing dramatically, the companies also must re-invent themselves and learn to work with new types of providers. They must realise that in the new environment the FDA is not the only agency to reckon with. They must `forge partnerships with other governmental bodies'; such as the Department of Health and Human Services and the major medical technology purchasers, such as Health Care Financing Administration, Department of Veterans Affairs and Department of Defence (Clinica July 31 1995 Issue 665 p 9).

At a meeting in the US on `medical technology in an era of cost-containment', the industry spoke of the need for government subsidies for innovation and introduction of new
technologies, as it is a public good issue (Southby et al 1987). When queried as to why the US hospital industry, which makes huge profits (~ $2 bn in the 1980s), could not finance new technology, the response was that the issue was to do with 'certainty' in the market as opposed to creating incentives. The President and CEO of Pfizer Hospital Products Group, New York, observed that certainty was more important than incentives. That they 'do not need incentives to develop cost-increasing, quality enhancing technology if (I) have some certainty that it will be adequately reimbursed'. While the incentives are there, industry wants more certainty that their product will get paid for.

The National Medical Device Coalition, comprising ten trade associations including physicians, lobbied for FDA reforms in 1996. Among their demands was the 'unfettered' export of medical devices to countries that have approved their importation (Clinica March 11 1996 issue 696 p 5). The policy agenda of AdvaMed for the year 2002 gives an idea of the importance of lobbying and other such 'non-technical' activity for the industry. It 'will work with leaders in Congress and the Bush administration' to achieve progress on several issues, including the following (Clinica January 21 2002 Issue 992 p 11):

- MediCare reforms regarding coverage and payment;
- Improved access to foreign markets. In this top international priority was to be assigned to 'fending off' foreign reference pricing in Japan; to ensure that Germany's DRG prospective payment system recognises the full value of medical technology; to monitor the work of new agencies established to make coverage and payment decisions in the French private sector, and to ensure that the ongoing health reforms in the UK support the timely adoption of new technologies.

According to the President, AdvaMed, among the important issues facing the US medical technology industry was that of pushing for reforms in Japan, which was USA's second largest trading partner for medical technology. They were working on reforms regarding Japan's system for approving the use of new medical technology as it was the slowest and most costly in the world; secondly Japan's re-imbursement system, which unfairly targeted foreign manufacturers, did not reflect the costs of doing business in Japan. AdvaMed raised this issue aggressively with its own government and administrations, as also with high level government officials in Tokyo (Medical Device and Diagnostic Industry January 2006). The following account substantiates this 'clout' that the US industry and government wield in such critical matters.

The Japanese Ministry of Health, Labour & Welfare proposed introduction of new price-cutting plans for a range of medical devices, with the aim of bringing health care costs under control. It was also prompted by concerns about the disparity in prices for medical
technology locally and overseas. The new prices scale, initially for certain classes of medical devices, including cardiac pacemakers and angioplasty catheters, were to be based on a sample of prices in other countries. Reference pricing was to be set at 1.5 times the price in the sample countries. The devices industry felt that it was not realistic to continue supplying. It argued that pacemaker prices were 1.85 times more expensive in Japan than in the US. The proposal was greeted with considerable nervousness and cries of foul play, not least from overseas devices suppliers, with US suppliers being most vocal. US companies supplied 30 per cent of Japan’s $23-24 bn market. They stood to lose export sales of around half a billion dollars. AdvaMed (Advanced Medical Technology Association) said the new prices did not take account of the high cost of doing business in Japan (Clinica February 25 2002 issue 997 p 1). The US industry worked against and lobbied for several years on this proposal. Not only was it concerned about the potential effects on its industry, but was also ‘smarting from what it sees as Japan’s failure to consult on the issue, which was enshrined in a US-Japan agreement’. The Japanese government’s move violated that provision for consultation. If necessary the US industry was prepared to complain through the WTO (Clinica January 14 2002 issue 991 p 11 ‘US industry vows to keep fighting Japan price move’). The US administration was strongly behind industry efforts to secure changes via bilateral talks. In what was considered a significant development, US Congress members sent a letter to the Japanese Prime Minister expressing concern at the ‘unprecedented discriminatory' foreign reference pricing rules and urged his intervention (Clinica January 7 2002 Issue 990 p 7 ‘Japanese reference pricing plan stirs Senate complaints’). Subsequently the Japanese Ministry backed away from strict use of foreign reference pricing and the planned deep price reductions for foreign devices. According to the US industry, it had ‘succeeded in avoiding double-digit price cuts in Japan. After a series of negotiations Japan has come close to what US companies want’ (Clinica March 11 2002 issue 999 p 13 ‘US industry lobbying gets result on Japanese prices’).

As of April 2002 imports accounted for about 40 per cent of the US medical devices market and were expected to climb up to 50 per cent. However, this was not of great concern to the government. It was believed that US manufacturers ‘exported so aggressively that the nation’s balance of trade in medical devices would still remain positive’ (Clinica April 22 2002 issue 1004 p 10).

US Government Support to its medical device industry
The US private healthcare sector wants to gain access to ‘rapidly expanding healthcare expenditures in many developed countries’ experiencing ‘an increase in their aged population’ (Gould 1999, in Sexton 2003). US companies involved in pharmaceuticals,
medical equipment and devices, telemedicine and e-health are targeting what is considered to be a growing market for medical services and product in Asia. The US Trade Development Agency, as part of its remit to promote private sector participation in middle income and developing countries, also provides trade promotion assistance to high-tech healthcare companies to establish links in Asia, and in Latin America (www.tda.gov accessed on 10.10.07). Thus, as detailed in the Chapter 2 (sec 2.3), the impact of globalization on healthcare services is considerable.

The International Trade Administration of the US government is involved in a variety of programmes to support the domestic medical device industry. Among these are: participating in the medical devices Global Harmonization Task Force; raising industry concerns regarding tariff and non-tariff barriers for medical devices through government-to-government discussion in India, Mexico, Brazil, China, Korea, Taiwan, Russia, Thailand and Singapore; support the Doha round and other trade agreements; organize medical device industry delegations to key markets; write market research reports on priority markets; works in conjunction with the major medical device associations to address regulatory and reimbursement issues in some of the markets that have market potential and significant market access issues, through dialogue with the governments (www.ita.doc.gov/td/health/outlook_05_medical.pdf, accessed on 10.10.07)

In Europe the industry regularly holds global medical device conferences, undertakes intense lobbying and advocacy work with governments as well as the medical profession, and in recent times with patient associations too. Companies like Healthcare and Technology International (HTI) advise healthcare companies on European market entry management and expansion strategies. Device manufacturers are advised to make subtle, incremental changes to products, to provide cost-effectiveness and clinical outcome data; to sell not just 'new technologies', but also to propose/devise new kinds of treatment and new funding requirements to their respective governments (Velde 1998). In evaluating market opportunities companies are advised to consider not just market size and growth, but also to understand and gain familiarity with national healthcare systems – the clinical trends, the regulatory, healthcare purchasing and reimbursement systems. The European medical devices industry is also actively concerned with reimbursement and held a conference in 1998 on 'Reimbursement and Pricing for Medical Devices in Europe'. The objective was to design strategies to turn reimbursement from a control mechanism into an incentive, to overcome the 'hurdles against profitable funding' (Velde 1998). The German medical device industry is very active in lobbying with the government, especially regarding reimbursement of procedures. Every move/proposal by the government regarding healthcare is closely
observed and studied keenly for its advantages or otherwise by the industry. For the manufacturers the annual budget negotiations between each of the 2300 hospitals and sickness funds are absolutely vital and crucial to the funding of products and procedures. Therefore, they are advised to provide their partners in the hospital (namely doctors, nurses, hospital administrators) with good arguments for obtaining funding for their products, and to work with them to utilise new funding opportunities (Seeger 1998). The medical devices industry has been involved in the discussions of the health minister about national health policy since May 2001, and industry associations like BVMed feel that 'it is time to put behind earlier political worries about contacts with the industry' (Schmitt 2002). For instance: BVMed wants a role for industry and business expertise in the Disease Management Programme (DMP) of the health ministry. In its view the DMP should be used as an opportunity to introduce innovative medical technology for treatment of the chronically ill (Clinica April 15 2002 Issue 2003). They are now looking at the entire organisation of health-care, at 'disease management pathways', what goes into outpatient treatment, inpatient treatment, total costs of a treatment, etc, as well as reimbursement mechanisms. The industry is advised to distinguish between formal and informal reimbursement processes and understand the informal process - namely the less defined process consisting of ways to influence allocation of resources and funds to new products or technology. This process consists of identifying the disease management process relevant to their technology; understanding the money flows between all providers and payers involved in this process; identifying and engaging with the key decision makers involved, with special emphasis on non-medical ones and understanding their needs and motivations; establishing the economic justification - clinical and economic outcomes study; and design of sales and service strategies adapted to each decision maker. They are also being advised to engage with patients, to empower patients to play a more direct role in the choice of therapy. The strategic goal in medical device manufacturing is 'to drive utilisation and adoption under the current payment system that is available' (Llana 1998).

There is a move internationally towards harmonisation of product regulation policies. The medical device industry complains that these have begun to limit the range of products marketed in a country (MDBN 1998 vol 3 no 33). Australia, Canada, EU, Japan and US have set up a Global Harmonisation Task Force for this purpose, which has industry representatives and is a public-private initiative.
§ Medical Device Re-processing and Opposition to Re-use of Medical Devices labelled 'single-use'

Re-use of pacemakers and other disposable medical supplies such as cardiac and coronary angioplasty catheters and guide wires, is a standard scientific and carefully monitored practice in hospitals in many parts of the world and in India as well. Many hospitals have long set up critical procedures to salvage equipment, render them safe through various well-documented procedures, tested them for quality and offered them for re-use at a fraction of the cost of new equipment. In the USA hospitals have reprocessed devices safely, and third-party re-processing is a well-regulated $40 mn industry there (Stante 2002).

Early dialysers were re-usable, but as the market increased manufacturers introduced the 'disposable' haemo-dialyser and labeled it 'for single use only'. To cut costs many hospitals cleaned these using the same techniques they had used for the earlier models and found them to be effective. Despite extensive data showing that patients are not put at increased risk from use of re-processed devices, there is resistance from the industry to re-use of single-use devices and pressure to stop it. Requests by medical researchers in the USA to manufacturers for data in this regard were met with only references to possible risks, and manufacturers still label the product 'for single use only'.

However, there is a conflict in the industry over the issue. For instance: in the US the official policy of AdvaMed was to oppose re-use of single-use devices (SUDs), but it took a hands-off position out of deference to one of its members - Steris, a sterilisation company. Frustrated by the advocacy vacuum on what was considered an important, but contentious issue, a handful of manufacturers, including Johnson & Johnson, formed a separate organisation - the Association for Disposable Device Manufacturers (Clinica March 11 2002 Issue 999 p 10). Subsequently many companies joined the ADDM, forcing AdvaMed to take up the re-use issue.

A 7-month study in the USA by government agencies for regulatory purposes, of reprocessing of devices labelled for 'single use', reviewed scientific literature and spoke to officials from the FDA, CDC among others. In its report "Single-use medical devices: Little available evidence of harm from reuse but oversight warranted", the agency concluded, 'the evidence suggests that some kinds of SUDs can be safely reprocessed if appropriate cleaning, testing, and sterilization procedures are carefully followed. However, SUD reprocessing is not invariably safe, and little is known about the practice of SUD reprocessing in healthcare institution. For this reason, FDA has taken steps to increase its oversight of SUD reprocessing', and that 'reprocessed SUDs (single-use devices) do not appear to pose a threat to public health' (Stante 2002). It also states that '.....because the demonstrated health
risks from SUD reprocessing are small, (increased FDA oversight) may have only limited impact on public health. It made several other relevant points. Namely: 'The safety of reprocessing some types of devices, such as some types of (electrophysiology) catheters, is supported by well-developed clinical literature'. That only a very small percentage of the reports (FDA) received through its Medical Device Reporting programme concerned patient adverse outcomes associated with reprocessed SUDs. Many professional organisations expressed qualified support for reuse, and none sought to ban SUD reprocessing.

In the debate over the practice, the Association of Medical Device Reprocessors held that the failure of reprocessed devices should be seen in the context of the failure rate of the original devices, and that it is important to note that there are numerous examples of new medical devices causing patient injury during their first use (from statement of the Association of Medical Device Reprocessors, excerpts on www.emedisourceasia.com/archives/globaltrends/gt12_2005_1.asp, accessed on 30.7.2007). According to the Association over 30 million devices have been reprocessed, and the practice has been found to be every bit as safe, if not safer than the original devices. It feels that it may be that reprocessing makes medical procedures safer because if an original device fails when it is first used, it is not reprocessed. Because every reprocessed device is inspected or tested prior to use, the strong likelihood is that the device will again work properly. The same cannot be said for original devices, which are subject to sample-testing. Reprocessing also eliminates over 900 tons of medical waste per year. According to this Association, hospitals see reconditioned medical devices as a significant cost-cutting measure since they regard the single-use-only label as a manufacturer's ploy to force them buy more devices than they need. According to a government audit report, the 'single-use' label is often little more than a marketing tool of the original equipment manufacturer, who has every incentive to use it in order to sell more devices and avoid the costly validation analysis that the reprocessors have to perform (www.emedisourceasia.com/archives/globaltrends/gt12_2005_1.asp, accessed on 30.7.2007)

The European Confederation of Medical Suppliers Association (EUCOMED) is opposed to re-use of single use devices (SUDs). It has listed out the technical problems that could arise. Such as: inability to achieve effective cleaning; lack of knowledge of compatibility of the cleaning/sterilising/disinfecting process with the concerned device; ignorance of impact of absorption of the agents; absence of indicators to show that the device has not deteriorated (Clinica 4 March 1996 Issue 695 p 6). There have been representations from industry and patient associations for regulation of single-use devices. The industry has been involving the European Parliament in its move to ban reuse of SUDs (Clinica April 29 2002 issue 1005 p 3). Italy and Spain have specific regulations against re-use. UK and France have published
recommendations against it. In Sweden informed patient consent is necessary and the reprocessor has to comply with strict requirements. In Germany standards have been published for reprocessing. Trade Associations believe that it is impossible for hospitals to comply with those requirements. In the US the FDA has issued guidelines placing responsibility for safety and effectiveness on the reprocessor (either an institution or practitioner).

§ Promotion of education in imaging and search for new applications
# As mentioned earlier, in 2006 Philips set up three Global Medical Learning Centres for advanced medical equipment training in the world. The Centre for the Asia Pacific Region is located at the Philips Complex in Singapore, and houses millions of dollars worth of sophisticated diagnostic equipment. The centre will provide education and training in skills required to operate technologically-advanced equipment. In January 2008 Philips announced the International Access to Learning (IAL) program. This program is a collaboration of Philips with the International Society of Radiographers and Radiological Technologists (ISRRT) to simplify access to healthcare education in Europe, Asia and the South Pacific. According to the Company its objective is to improve the quality of radiographic and radiation therapy practice globally through access to education, sharing of best practices and improved collaboration between clinicians.

The first phase of this IAL program is being piloted in three countries: Estonia, Fiji and India. Participants will be able to select from Philips’ catalog of more than 300 accredited, clinical and business courses. Philips will provide these courses at no cost to the members of ISRRT Societies who can access program guidelines and registration via the ISRRT web site. In the future, Philips and ISRRT hope to work together to offer opportunities for member Societies to gain access to educational programs using the Philips Global Training Centers located in the U.S., the Netherlands and Singapore.

The ISRRT represents member associations and societies totaling more than 300,000 radiographic professionals in more than 83 countries. Many of these countries have limited access to any post graduate education opportunities, but in an increasing number, these professionals are required to earn continuing education credits to maintain their certifications and stay up-to-date on current medical technologies. Philips Healthcare's customer services business aims to meet this need by simplifying access to education and training across the globe. Leveraging the Philips Learning Center, the company currently helps train more than 140,000 registered healthcare practitioners in more than 100 countries. With its unique learning management system designed to meet the specific needs of the healthcare industry,
the company supports customers in every season of system ownership with advanced clinical and technical training.

# In 2006 GE and Philips contributed $1 mn each to the American College of Radiology Imaging Network (ACRIN) fund for Innovative Imaging (www.acrin.org).

# Ultrasonic imaging is being promoted in several ways. One of these is the institution of awards by several manufacturers for excellence in use of medical ultrasonography. While we have mentioned those by Philips and GE, there are others. Such as:
- Bracco Diagnostics Incorporated and the Society of Diagnostic Medical Sonography (SDMS) Educational Foundation have established a Research Award to help recipients conduct ultrasound research.
- In order to foster the use of ultrasound contrast agents, Bristol-Myers Squibb Medical Imaging, Incorporated, and SDMS Educational Foundation have announced awards for sonographers who are helping pioneer the use of contrast in ultrasound imaging
- Several ultrasound societies in the USA have joined together to promote public awareness of medical ultrasound and its value in healthcare. This includes societies such as the SDMS, American Institute for Ultrasound in Medicine, American Society of Echocardiography, and Society for Vascular Ultrasound. This is being done through specially planned activities and use of educational materials, as an annual event (http://www.sdms.org/news/release0452004.asp; accessed on 15/09/2005).
- The company Sonosite donated ultrasound systems to an Iraqi hospital (MI February 2005).

# The Society of Nuclear Medicine (in the USA) is offering a competitive grant to researchers in molecular imaging and nuclear medicine, based on a donation from Mallinckrodt, a division of TycoHealthCare. This donation is a demonstration of the company's commitment to advance research in these areas and will be used to fund the first SNM/Mallinckrodt seed grant in molecular imaging and nuclear medicine research.

# Other smaller companies in imaging technology are also entering into research collaborations. Such as that between e2v technologies (London) and Brunel University (London), leading to the creation of the e2v Centre for Electronic Imaging, which will be based at the University's campus. The staff at the campus will concentrate on transforming research and development activity into new electronic imaging technology, and identifying new applications for existing e2v imaging technology. Such as arrangement has been made to secure bright young people with the necessary skills to support continued business growth and retain e2v's leading technology position, which requires world-class technologists. The
CEI will form part of Brunel's School of Engineering and Design. Lecturers, research associates, and doctorate students from Brunel will work on projects that support technology road maps that seek to create a stream of well-qualified imaging engineers and scientists to fill a critical skills gap. The CEI also will create an avenue in which researchers will be able to conduct research and training within a supportive collaborative framework.

5. II.5 Growth of Marketing and Advertising in the healthcare industry

According to market analysts the growing healthcare market worldwide implies increased demand for medical technologies and hence offers great opportunities for manufacturers and traders. Experts forecast an average growth in the international market for medical technologies of 6-7 per cent in the coming years (Medical Imaging 2005). In general healthcare markets worldwide were being treated by all segments of business, including medical technology manufacturers, as a marketing opportunity. There is growing acceptance of marketing and advertising within the healthcare industry. There are several medical business journals/magazines, discussing current market issues in the healthcare industry, considerations to be made in developing marketing plans, advertising, and so on. For instance: the International Journal of Medical Marketing is devoted to 'facilitating excellence in marketing and strategic management in the pharmaceutical, medical device, diagnostic and other markets in which the customer is a clinician or a related professional' (put another way 'these markets are all sub-components of the same pot of money that which society allocates to health'). The journal is primarily addressed to management and marketing professionals.

Medical Imaging is a leading 'healthcare technology' management magazine, that provides technology, and business news and trends for healthcare and industry professionals who are dedicated to cost-effectively selecting, acquiring, integrating, managing, and supporting technology that is used in the medical imaging department of a hospital, freestanding imaging center, or other healthcare facility (www.medicalimagingmag.com). According to this magazine, 'technology is driving healthcare, whether from an IT or clinical perspective, and diagnostic imaging is on the cusp of very exciting developments. Medical Imaging takes you there and gives you the scoop. Each month, we investigate and then report on the technologies available to the industry, the role they play, the benefits that these technologies provide, where and how they're being used, and who the adopters are of these technologies'. The targeted audience of this magazine comprises decision makers - hospital and radiology administrators, technology managers, IT networking managers, medical physicists, PACS managers and consultants, and clinical staff. In addition to those at healthcare facilities, it
caters also to manufacturing companies, original equipment manufacturers (OEMs), dealers, distributors, and resellers.

The Academy for International Health Studies (AIHS), a private healthcare business association was established in 1993 in the US, and is not an academic institution, as the name tends to convey. *The academy treats healthcare worldwide simply as a marketing opportunity.* It arranges trade and/or study missions for senior US healthcare executives to different countries each year, to foster improved understanding of the global healthcare marketplace, to explore business opportunities and to network with peers in the healthcare industry. Each mission consists of academicians, government officials, medical experts and private sector representatives. Such mission destinations include Latin America, China, Japan, Malaysia, Europe and South Africa (www.aihs.com). The academy also organizes an annual trade conference on the global potential for private healthcare. The proceedings of the conference held in December 2000 reveal how multinationals are working with each other, with governments, and with international bodies in a global marketing effort (Buse and Walt 2000). The companies involved in the conference were principally concerned with insurance, and was attended by high-ranking ministers and officials from many countries. There was a keynote address by Jeffrey Sachs, chairperson of the WHO Commission on Macroeconomics and Health, on `HealthCare Globalisation in the 21st century: Issues and Challenges`, and a joint WHO-WB presentation on `State of the World's Healthcare Report`. There were workshops and seminars on such topics as: Private Health Sector Investment – Opportunities and Challenges in........Argentina, Australia, Brazil, Chile, Egypt, Germany, Indonesia, Israel,...........; and `Globalisation of American Managed Care` etc.

Similarly, the Medical Marketing Association in US holds an annual conference in which ‘hundreds of the most inquisitive, creative and influential professionals in medical marketing from big pharmaceutical, biotech, medical device and diagnostic firms, along with advertising agencies, market research firms and publishers come together to listen, learn and exchange ideas’. A Medical Marketer of the Year Award has also been instituted (www.mmanet.org).

5. II.6 Development and Promotion of diagnostic, laboratory and specialized clinical services

As discussed earlier, health-related services now cover not only professional and clinical services (such as hospitals and doctors), but also infrastructure, diagnostic laboratories,
support, nursing, insurance, occupational, community care and pensions services. So companies active in insurance, hospitals, laboratories (clinical laboratory, imaging and therapy such as dialysis), and support services (such as catering and cleaning) all have an interest in, and impact on healthcare services.

In the past few years multinational corporations (MNCs) have also entered public services, and are also increasingly involved in many aspects of healthcare services (Hall 2003 p 77). Regions of special interest are Latin America, Southeast Asia, China and the Pacific Rim, the Middle East, and to some extent south Asia (Notes 10, 11 and 18 in Sexton 2003). Among the reasons given by MNCs to justify their interest in Latin American countries is the reduced possibilities of expansion in the US market, and hence the need for new markets (Iriart et al 2001). During GATS renegotiations US negotiators have made healthcare a special target. `The US is of the view that commercial opportunities exist along the entire spectrum of health and social care facilities, including hospitals, outpatient facilities, clinics, nursing homes, assisted living arrangements, and services provided in the home’ (Kuttner 1999, in Sexton 2003 p 40). The US Coalition of Service Industries is calling for majority foreign ownership of all public health facilities to be allowed:

“We believe we can make such progress in the (GATS) negotiations to allow the opportunity for US businesses to expand into foreign healthcare markets..... Historically, healthcare services in many foreign countries have largely been the responsibility of the public sector. This public ownership of healthcare has made it difficult for US private sector healthcare providers to market in foreign countries” (Sexton 2003 p 40).

Development of diagnostic imaging and laboratory services, based on use of MRI, CT and other high-tech equipment, is becoming widespread. Such equipments require large capital investments and highly trained staff to operate them. In most health systems private companies are providing the equipment and services. For instance: in Canada private for-profit clinics, particularly imaging centers providing MRI and CT, are reported to be opening up and thriving. There is increasing pressure there by the private sector to expand these clinics, ostensibly to take the pressures off the public system. In Eastern and Central Europe MNCs are involved in development of such services. Loans from multi-lateral organizations such as IFC and MIGA are often given for the purchase and establishment of such infrastructure. The International Finance Corporation invests in health care projects and is involved in extensive development of the private health care sector in many countries. For instance: MIGA gave a guarantee loan for a dialysis center in Bosnia, in partnership with
International Dialysis Centers BV; and IFC has made investments in Euromedic to set up centers for renal care in Hungary, Poland and Bosnia (Lethbridge 2003). The following are some American and European multinational companies providing such diagnostic services.

§ Quest Diagnostics

Quest Diagnostics is a leading American corporate provider of diagnostic laboratory testing, which provides diagnostic tests to patients, doctors and health care institutions through a network of laboratories. It not only provides routine tests – blood cholesterol, pap smears, HIV tests, pregnancy, alcohol and other substance-abuse tests. It also provides esoteric less-frequently used tests, which cover tests for endocrinology, genetics, immunology, microbiology, and oncology. It has two other businesses. Through Nichols Institute for Diagnostics it develops, manufactures and markets specialty assay kits and equipment, such as immunoassay diagnostic test kits and systems. Through Quest Diagnostic Clinical Trials, the company also carried out worldwide clinical trials to bring in new treatments. It has two clinical trials testing centres in the US and the UK, as well as partnerships with two centres in Australia and South Africa. Quest Diagnostics also provides sales and marketing support to international clients for specialty diagnostic performed at Nichols Institute, which performs specialized tests for hospitals and laboratories from several countries (www.questdiagnostics.com). For example: it has a link with Lal Pathlabs, New Delhi, India for some esoteric tests (see section 7.1.2). Quest Diagnostics employed 29,000 people in 2001, the majority in the United States. Quest owns one of the largest privately owned clinical laboratories in the UK, which was developed in partnership with an NHS trust/hospital. In Mexico, Quest owns three laboratories and provides testing services throughout Mexico. There is also a centre in Brazil and Quest is aiming to set up additional laboratory services in Brazil. Quest took over SmithKline Beecham Clinical Laboratories, the laboratory business of SmithKline Beecham in 2000. In the past year it has acquired American Medical Laboratories, and Unilabs (of California, USA). It has also recently established an alliance with Roche Diagnostics to develop gene-based medical testing (Lethbridge 2003). It has also set up a centre in Delhi, India, in 2008 (see section 7.1.2).

These acquisitions and alliances point to the shared interests between the laboratory divisions of pharmaceutical companies and diagnostic testing businesses. The invention of esoteric tests, including gene testing, provides opportunities for expansion. These are expensive tests to provide, requiring high technology equipment and staff.
§ Unilabs

Unilabs SA is a specialist provider of clinical laboratory tests prescribed by physicians, public or private hospitals and other clinical testing laboratories, based in Switzerland and operating in France, Spain, Italy, and Russia. Since 2000 Unilabs has acquired several laboratories in France and Spain. In France, it has acquired several regional laboratory-testing companies. In Spain, its laboratories have exclusive contracts with leading Spanish health funds to provide specialised laboratory tests to a large Madrid teaching hospital, the Fundacion Jimenez Diaz. Unilabs recently set up a partnership with the Fundacion Jimenez Diaz. It has also signed contracts for medical analysis services with two Spanish hospital groups, one in Madrid and the other in the south of the country (Lethbridge 2003, www.unilabs.ch).

§ Euromedic

Euromedic Diagnostics BV and International Dialysis Centre BV are both 100 per cent owned Dutch subsidiaries of Euromedic International NV, a holding company of the group (www.euromedic-group.com). Euromedic operates diagnostic imaging centres in Hungary and Poland and haemodialysis centres in Poland and Bosnia. In Hungary, it has 7 private diagnostic imaging centres seeing 20,000 patients per month. 100-150 personnel, mainly doctors, are employed in Hungary. In Poland, Euromedic has 3 diagnostic imaging centres and 3 haemodialysis centre seeing 2,500 patients per month. In Bosnia, it has one haemodialysis centre which sees 230 patients per month (www.ifc.com, cited in Lethbridge 2003). Euromedic also provides distribution and tendering service to hospitals in Hungary

Euromedic received a $13 million loan from the International Finance Corporation to fund a $33 million expansion programme in Central and Eastern Europe. Other shareholders include GE Equity – the private equity arm of GE Capital - Dresdner Kleinwort Benson private equity fund, Global Environment Fund, RPM Partners, a Dutch private investment company and private investors led by Euromedic’s management. The Global Environmental Fund (GEF) has also invested in Euromedic.

§ Renal Health Care

The case of the global renal care industry shows that companies previously involved in equipment and product development have moved into health care provision. Renal care is a growing area of healthcare and part of a very competitive market. There is evidence that companies that manufacture drugs and/or equipment for the treatment of kidney diseases are now also involved in the provision of health care. Multinational companies involved in renal care have combined operations that include:

• healthcare – clinics for treating kidney disease
renal products – products used during dialysis treatment
blood compound technologies and blood bank technology

According to a 2001 profile of the dialysis industry by Merrill Lynch Global Fundamental Equity Research Department, the production of dialysis products was no longer driving the industry because only limited product growth was possible, as synthetic dialyses had become standard equipment (Merrill Lynch Research Department Kidney Machinations The Dialysis Industry could get bloody 11 September 2001, cited in Lethbridge 2003). As a result, major manufacturing companies in this sector will become service providers, for instance, running dialysis clinics, but may expand into other aspects of health care provision. Fresenius, a German manufacturer of dialysis equipment, has already entered into other aspects of patient care. This will have implications for existing health care companies.

Fresenius, Gambro and Baxter RTS are three major multinational companies involved in all three stages of renal health care. All these companies began by manufacturing kidney dialysis equipment and products, but have expanded their activities to include health care provision for kidney patients in the last decade. Providing health care services is a major part of the business of Fresenius in terms of both sales and employment. The two largest companies, Fresenius and Gambro have clinics in the US, Europe and Latin America/ Asia. Four companies, DA Vita, Renal Care Group, Dialysis Clinic Inc, National Nephrology only have clinics in the US. Three companies Kurtorium fur Dialyse, Patienten-Heimversorgung, Braun Eurocare, treat patients only in German speaking countries in Europe. Baxter RTS has clinics in Europe and Latin America/ Asia, but not in the US although it has other production facilities in the US. Baxter RTS treats the majority of its patients outside Europe (Lethbridge 2003). Satellite provides services in the US (operating as Satellite Health) and in Asia as Asia Renal Care.

Fresenius
Fresenius is an integrated kidney care company, which provides kidney dialysis equipment, products and services through four divisions: Fresenius Medical Care, Fresenius Kabi, Fresenius ProServe, and Fresenius HemoCare.

- **Fresenius Medical Care**: products and services for individuals with chronic kidney failure, with some 1,300 dialysis clinics worldwide
- **Fresenius Kabi**: a provider of products for nutrition and infusion therapy and outpatient medical care.
- **Fresenius ProServe**: management services such as project development, consulting, and staff training to hospitals and other health facilities
- **Fresenius HemoCare**: focuses on blood treatment and infusion technology
Fresenius AG has operations in Asia, Europe, Latin America, and North America. North America and Europe are the main focus of sales with 57% and 32% respectively. South America and Asia-Pacific account for 5% and 6% of sales (www.fresenius.de (German version); www.fresenius-ag.com (English version) and Lethbridge 2003). Fresenius Kabi India Private Limited, Pune, is a 100 per cent subsidiary of Fresenius in India.

**Asia Renal Care Ltd (ARC)**

*Asia Renal Care*, based in the Philippines, is one of the main investments in health care made by Fidelity Ventures Far East (FVFE). ARC is a leading provider of kidney dialysis and related services in the Asia Pacific region. It has a network of 20 centres in Asia (in Japan, Philippines, Malaysia, Taiwan, Singapore and Hong Kong), and 12 affiliated centres in the US. Asia Renal Care Ltd is the healthcare subsidiary of Ayala Corporation and ARC, and a joint venture formed between the two in 1998. Ayala Corporation is a leading industrial conglomerate in the Philippines, with significant interests in real estate, tele-communications, healthcare, insurance and food. The other shareholders in Asia Renal Care are: Satellite Group of US, Investor AB – a Swedish investment group, 3i, Walden Group and Equitable Life, of US. Its operating partner, Satellite Dialysis Center, Inc (of Satellite Group), is a non-profit dialysis company, with close links to Stanford University. It conducts quality audits, reviews technical operations and organizes clinical programs on behalf of ARC, as well as regular training programs for ARC staff in both Asia and the United States.

§ **Venture Capital Funding in Healthcare / Diagnostic companies**

The links between private equity investments and health multinational companies are strongest in Latin America and to a lesser extent in Central and Eastern Europe.

*Medicover* is a Swedish healthcare company that offers both medical insurance and a health care delivery system, in Central and Eastern Europe. Medicover employs most of its physicians directly and provides health care through its own facilities. It was sponsored by ORESA Ventures and had obtained an IFC loan of $7 m. *ORESA Ventures is an example of a venture capital company becoming directly involved in health care investment. It was so successful that it ceased to invest in new initiatives and transformed itself into the healthcare company.* In 2001, ORESA Ventures S.A., an investment company whose shares are traded on the Stockholm Exchange, decided to focus its operations exclusively on the Group’s largest holding, the healthcare company Medicover. Other holdings of ORESA Ventures were divested; its name to Medicover, and it became an operating healthcare company.
Salutia is a privately held healthcare connectivity company focused on payer-provider transactions operating in Argentina and Brazil. It is owned by thirty shareholders, which includes Merrill Lynch Global Emerging Market Partners. It also has an IFC equity investment of $2.5m. It aims to make the management of medicine more effective through the use of new technologies, to improve the provision of health care through making information about the patient to be available quickly in the clinic/surgery, to increase the consumer's knowledge/understanding of health by providing confidential information and services (www.salutia.com).

Humana Inc, a US managed health care company has a venture capital arm called Humana Ventures. The Latin Health Fund is a specific fund of Humana Ventures, which has three specific investments in Latin America:
- Consortio International Hospital SA /International Hospital Corporation - a hospital company that operates in Central America. It develops, builds and operates hospitals, and has recently opened hospitals in Mexico and Costa Rica.
- Farmacias Ahumada SA is the largest retail pharmacy in Chile with more than 140 pharmacies and a market share of 30%. The company has expanded into Peru and established itself as the largest chain of retail pharmacies. The company also has the first and largest (1.15 million enrollees) pharmacy benefits management company in Latin America. It was pursuing acquisition opportunities in Brazil.
- Delboni Auriemo Medicina Diagnostica Ltda (Delboni) is the largest clinical laboratory and diagnostic imaging company in Sao Paulo, Brazil in terms of number of tests and second largest in terms of revenues. With 21 outpatient units and a large processing facility, the company has approximately 11% of the Sao Paulo laboratory market. In October 1999, the investor group completed the 100% acquisition of the third largest clinical diagnostic company in Sao Paulo, Bio-Ciencia Lavoisier Analisis Clinicas (Lavoisier).
(www.latinhealthfund.com; www.humanaventures.com)

The Latin Healthcare Fund is a limited partnership, sponsored by Ascendant Health International (AHI) and Global Environmental Fund (GEF). Ascendant Health International is made up of health care managers who founded Advantage Health Corporation, a US health care provider which was sold in 1996 to HealthSouth another US healthcare provider. Ascendant has also worked in the healthcare sector internationally, advising in Latin America and the former Soviet Union, and aims to add value to the Latin Healthcare Fund by applying lessons from US health care market to Latin America. The Latin Health Fund has five strategic partners and the range of these illustrates the linkages between investment funds, health care companies and international development investment agencies:
* HealthSouth-(bought by AdvantageHealth Corporation) – one of the largest providers of health services in the US which also has a network of health services worldwide for American policy holders
* Humana - a supra-regional managed care company
* Interamerican Investment Corporation (IIC) affiliated to International Development Bank and provides support to LHF in the investment process.
* UnitedHealthcare -- an HMO (also investing through Validus venture capital company)
* Chase Capital Partners a global private equity investment company.

5. II.7 Private Sector Planning for the future

Futures research is used by the business sector to generate views about how economic, social, political and environmental trends will interact to shape future societies. Investment companies often seek information on which to base their investments, through private and non-profit research and consultancy centres that specialise in developing visions of the future. Demographic changes, and changes in the financing and demand for the healthcare have implications for the private health care sector and investments will be influenced by the interpretation of these changes. Examples of three global consultancy groups that have contributed to developing “health futures” are outlined below.

(i) The healthcare practice of one of the largest global consultancy groups PriceWaterhouseCoopers (PWC) published in 2000 a report “HealthCast 2010 Smaller World, Bigger Expectations”. It was aimed at PWC health care clients. The report was informed by a survey of policy makers, health system managers, health care employers, doctors, insurers and medical suppliers in US, UK, Finland, Spain, Netherlands, Germany, France, New Zealand, Canada and Australia about future health trends and the implications for the health care industry. The survey results showed that respondents felt that the amount of money spent on health care was growing in most developed countries because societies were getting wealthier. Technical advances were perceived as being able to contribute to cutting the costs of health care but were more than offset by an ageing society, increased health consumerism, biotechnology and medical advances. Survey respondents also felt that increasing costs of health care took away money for spending on other consumable goods. Although health expenditure was considered to contribute to economic growth, decreasing health expenditure was also seen as the key to economic growth. The prospect of an increasingly older population with a decreasing working population is viewed with some concern. One of the major conclusions drawn from this survey was that the customer would play a key role in health care demand in the future. Interestingly, this was seen as potentially
problematic. Quality, efficiency and customer satisfaction will be key to accessing capital. Resources need to be allocated for health workers to be retrained to deal with more consumers. Insurers must stress prevention because early detection and intervention will decrease costs.

This report shows that there are several underlying assumptions about the private sector view of health care futures. More demanding consumers and increased consumer spending on health care are seen as opportunities but also challenges for the future.

(ii) Institute for the Future, a U.S. futures think-tank, together with A.T.Kearney (a management consultancy) organised the Healthcare Future Forces Leadership Roundtable in Venice, Italy, held in June 2001. It was the first of what was to be an annual by-invitation-only gathering of top business leaders representing segments cross the healthcare industry spectrum, as well as top academics in the field. The three themes considered were:

• Assessing the impact of care customisation on the delivery and management of healthcare
• Assessing the impact of consumerism on the management and delivery of healthcare services
• Assessing the impact of information and communication technology on all aspects of the healthcare system.

(iii) Institute of the Americas is another source of futures thinking for the private health care providers and investors. A meeting in July 2000 organised in collaboration with the International Finance Corporation (IFC) looked at ‘Financing Private Health Care in Latin America’. The supporting paper raises a number of issues and challenges about investing in Latin America. These issues provide a useful insight into the type of concerns voiced by the private sector about investing in health care. These relate to:

- What are the best strategies for obtaining reliable data?
- How should investors determine what infrastructure (especially IT) needs to be created or imported and what elements of local health systems be allowed to continue?
- How significant is the training component (to create good management skills) and how can this training be provided?
- Other questions deal with specific barriers to investing in medical equipment/devices, telemedicine and pharmaceuticals. The focus is on the delivery of high technology, curative care and not on locally based primary health care.
5.11.8 Overall Trends In The Medical Equipment Industry

"In general the pharmaceutical industry has not acted differently from other industries operating in similar markets. It conforms to behaviour of large and powerful industries, especially those that operate internationally and wield professional, economic and political power. The significant difference is that - it associates itself with the high standards of the healing arts. That it was especially ethical….." (Liebnau 1987).

Such observations made about the pharmaceutical industry are eminently true for the equipment and devices industry too. While the industry uses the overall societal concern with health, however, it actually has several considerations other than health: markets and profits being of over-riding concern. This industry, like others, is motivated by factors such as saleability, feasibility, profitability, markets, their experience and networks in a particular area, competition, etc. We find that the medical equipment industry too indulges in market manipulation, price fixing, supplying defective/equipment and other kinds of unethical medical and business practices. The industry may not necessarily be developing products of most use to health care. While harmonisation of regulations is high on the agenda, 'harmonisation' of prices is not. On the contrary, there is strong opposition by the industry to moves such as reference pricing. as illustrated by the case of Japan. The basic idea is to maximise profits. The medical device and diagnostic industry plays an influential and even decisive role in policy-making - in product development, selection, pricing and regulation of medical devices. The increasing involvement of financial institutions, financial analysts/stock market observers and advisors, marketing and advertising interests points to the motley range of commercial activities and interests beginning to impinge upon not only development and diffusion of medical technology, but also on delivery of health services and ultimately on medical practice itself. The industry has far more access to policy makers than the common citizen or even the medical profession has. The US industry is also lobbying through international institutions to create/expand markets in other countries, and receives support from its government in such activities.

We also find that the role of big business, of large corporations such as GE and Philips, which are the leading manufacturers of imaging equipment, is not limited to manufacturing. But extends far beyond, into financing, supplying peripherals, customer advice and education, and they are looking for ways to "to get into" health care delivery as well. The implications of these for the kind of technology we have cannot be ignored, and need to be addressed.
REFERENCES


